Lexington-Fayette Urban County Government

Response: Drug Testing for Community Corrections – RFP# 13-2013

Siemens FEIN: 952802182

200 East Main Street
Lexington, KY 40507
Attention: Todd Slatin

Siemens Healthcare Diagnostics Inc

SIEMENS
medical

LFUCG RFP# 13-2013

Drug Testing for Community Corrections

Siemens Healthcare Diagnostics Inc.

Response

Pricing

Required Documents:

- 510K Documentation
- FDA Warning Ltr.
- Shipping Policy
- WMBE/Small Business Plan

Siemens Healthcare Diagnostics Literature

Lexington-Fayette
Urban County Government

Request For Proposal

The Lexington-Fayette Urban County Government hereby requests proposals for **RFP #13-2013 Drug Testing for Community Corrections** to be provided in accordance with terms, conditions and specifications established herein.

Sealed proposals will be received in the Division of Central Purchasing, Room 338, Government Center, 200 East Main Street, Lexington, KY, 40507, until **2:00 PM**, prevailing local time, on **April 30th, 2013**.

Proposals received after the date and time set for opening proposals will not be considered for award of a contract and will be returned unopened to the Proposer. It is the sole responsibility of the Proposer to assure that his/her proposal is received by the Division of Central Purchasing before the date and time set for opening proposals.

Proposals must be sealed in an envelope and the envelope prominently marked:

RFP #13-2013 Drug Testing for Community Corrections

If mailed, the envelope must be addressed to:

Purchasing Director
Lexington-Fayette Urban County Government
Room 338, Government Center
200 East Main Street
Lexington, KY 40507

Additional copies of this Request For Proposals are available from the Division of Central Purchasing, Room 338 Government Center, 200 East Main Street, Lexington, KY 40507, (859)-258-3320, at no charge.

Proposals, once submitted, may not be withdrawn for a period of sixty (60) calendar days.

The Proposer must submit one (1) master (hardcopy), (1) electronic version in PDF format on a flashdrive or CD and four (4) duplicates (hardcopies) of their proposal for evaluation purposes.

The Lexington-Fayette Urban County Government reserves the right to reject any or all proposals, and to waive technicalities and informalities when such waiver is determined by the Lexington-Fayette Urban County Government to be in its best interest.

Signature of this proposal by the Proposer constitutes acceptance by the Proposer of terms, conditions and requirements set forth herein.

Minor exceptions may not eliminate the proposal. Any exceptions to the specifications established herein shall be listed in detail on a separate sheet and attached hereto. The Lexington-Fayette Urban County Government shall determine whether any exception is minor.

The Lexington-Fayette Urban County Government encourages the participation of minority- and women-owned businesses in Lexington-Fayette Urban County Government contracts. This proposal is subject to Affirmative Action requirements attached hereto.

Please do not contact any City staff member or any other person involved in the selection process other than the designated contact person(s) regarding the project contemplated under this RFP while this RFP is open and a selection has not been finalized. Any attempt to do so may result in disqualification of the firm's submittal for consideration.

Laws and Regulations

All applicable state laws, municipal ordinances and regulations of all authorities having jurisdiction over the project shall apply to the contract, and shall be deemed to be incorporated herein by reference.

Equal Employment Opportunity

The Entity (regardless of whether construction contractor, non-construction contractor or supplier) agrees to provide equal opportunity in employment for all qualified persons, to prohibit discrimination in employment because of race, color, creed, national origin, sex or age, and to promote equal employment through a positive, continuing program from itself and each of its subcontracting agents. This program of equal employment opportunity shall apply to every aspect of its employment policies and practices.

Kentucky Equal Employment Opportunity Act

The Kentucky Equal Employment Opportunity Act of 1978 (KRS 45.560-45.640) requires that any "county, city, town, school district, water district, hospital district,

or other political subdivision of the state shall include in directly or indirectly publicly funded contracts for supplies, materials, services, or equipment hereinafter entered into the following provisions:

"During the performance of this contract, the contractor agrees as follows:

(1) The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, age, or national origin;

(2) The contractor will state in all solicitations or advertisements for employees placed by or on behalf of the contractors that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, age, or national origin;

(3) The contractor will post notices in conspicuous places, available to employees and applicants for employment, setting forth the provision of the nondiscrimination clauses required by this section; and

(4) The contractor will send a notice to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding advising the labor union or workers' representative of the contractor's commitments under the nondiscrimination clauses."

The Act further provides:

"KRS 45.610. Hiring minorities -- Information required

(1) For the length of the contract, each contractor shall hire minorities from other sources within the drawing area, should the union with which he has collective bargaining agreements be unwilling to supply sufficient minorities to satisfy the agreed upon goals and timetables.

(2) Each contractor shall, for the length of the contract, furnish such information as required by KRS 45.560 to KRS 45.640 and by such rules, regulations and orders issued pursuant thereto and will permit access to all books and records pertaining to his employment practices and work sites by the contracting agency and the department for purposes of investigation to ascertain compliance with KRS 45.560 to 45.640 and such rules, regulations and orders issued pursuant thereto.

KRS 45.620. Action against contractor -- Hiring of minority contractor or subcontractor

(1) If any contractor is found by the department to have engaged in an unlawful practice under this chapter during the course of performing under a contract or subcontract covered under KRS 45.560 to 45.640, the department shall so certify to the contracting agency and such certification shall be binding upon the contracting agency unless it is reversed in the course of judicial review.

(2) If the contractor is found to have committed an unlawful practice under KRS 45.560 to 45.640, the contracting agency may cancel or terminate the contract, conditioned upon a program for future compliance approved by the contracting agency and the department. The contracting agency may declare such a contractor ineligible to bid on further contracts with that agency until such time as the contractor complies in full with the requirements of KRS 45.560 to 45.640.

(3) The equal employment provisions of KRS 45.560 to 45.640 may be met in part by a contractor by subcontracting to a minority contractor or subcontractor. For the provisions of KRS 45.560 to 45.640, a minority contractor or subcontractor shall mean a business that is owned and controlled by one or more persons disadvantaged by racial or ethnic circumstances.

KRS 45.630 Termination of existing employee not required, when

Any provision of KRS 45.560 to 45.640 notwithstanding, no contractor shall be required to terminate an existing employee upon proof that employee was employed prior to the date of the contract.

KRS 45.640 Minimum skills

Nothing in KRS 45.560 to 45.640 shall require a contractor to hire anyone who fails to demonstrate the minimum skills required to perform a particular job."

It is recommended that all of the provisions above quoted be included as special conditions in each contract. In the case of a contract exceeding $250,000, the contractor is required to furnish evidence that his workforce in Kentucky is representative of the available work-force in the area from which he draws employees, or to supply an Affirmative Action plan which will achieve such representation during the life of the contract.

Contention Process

Vendors who respond to this invitation have the right to file a notice of contention associated with the RFP process or to file a notice of appeal of the recommendation made by the Director of Central Purchasing resulting from this invitation.

Notice of contention with the RFP process must be filed within 3 business days of the bid/proposal opening by (1) sending a written notice, including sufficient documentation to support contention, to the Director of the Division of Central Purchasing or (2) submitting a written request for a meeting with the Director of Central Purchasing to explain his/her contention with the RFP process. After consulting with the Commissioner of Finance the Chief Administrative Officer and reviewing the documentation and/or hearing the vendor, the Director of Central Purchasing shall promptly respond in writing findings as to the compliance with RFP processes. If, based on this review, a RFP process irregularity is deemed to have occurred the Director of Central Purchasing will consult with the Commissioner of Finance, the Chief Administrative Officer and the Department of Law as to the appropriate remedy.

Notice of appeal of a RFP recommendation must be filed within 3 business days of the RFP recommendation by (1) sending a written notice, including sufficient documentation to support appeal, to the Director, Division of Central Purchasing or (2) submitting a written request for a meeting with the Director of Central Purchasing to explain his appeal. After reviewing the documentation and/or hearing the vendor and consulting with the Commissioner of Finance and the Chief Administrative Officer, the Director of Central Purchasing shall in writing, affirm or withdraw the recommendation.

SELECTION CRITERIA:

A. Technical Equipment and Service (20 points max.) Items evaluated will include system capacity, software capacity, applicability to the proposal, reliability, maintenance and repair, security features, and support.

B. Price (30 points max.) The lowest offered price consistent with the requirements specified in the RFP will be awarded 30 points. Remaining proposals will be awarded a proportionate number of points based in the amount of difference between the two quoted prices.

C. Corporate Stability (15 points max.) Each Vendor will be evaluated in terms if the financial stability of the Vendor based on the audited financial report submitted.

D. Experience (15 points max.) Each Vendor will be evaluated on their prior experience in providing services.

E. Quality of Response (15 points max.) Each response will be evaluated to determine the Vendor's understanding of the project and its ability to perform and meet each technical specification. Each item must have been discussed clearly and succinctly

F. Degree of Local Employment (5 points max.)

Proposals shall contain the appropriate information necessary to evaluate based on these criteria. A committee composed of government employees as well as representatives of relevant user groups will evaluate the proposals.

Questions shall be addressed to:

Todd Slatin
Director
Division of Central Purchasing
tslatin@lexingtonky.gov

Affirmative Action Plan

All vendors must submit as a part of the proposal package the following items to the Urban County Government:

1. Affirmative Action Plan for his/her firm;
2. Current Work Force Analysis Form;

Failure to submit these items as required may result in disqualification of the submitter from award of the contract. All submissions should be directed to:

Director, Division of Central Purchasing
Lexington-Fayette Urban County Government
200 East Main Street, 3rd Floor
Lexington, Kentucky 40507

All questions regarding this proposal must be directed to the Division of Central Purchasing, (859)-258-3320.

AFFIDAVIT

Comes the Affiant, _____, and after being first duly sworn, states under penalty of perjury as follows:

1. His/her name is Kim A. Christensen and he/she is the individual submitting the proposal or is the authorized representative of Siemens Healthcare Diagnostics Inc., the entity submitting the proposal (hereinafter referred to as "Proposer").

2. Proposer will pay all taxes and fees, which are owed to the Lexington-Fayette Urban County Government at the time the proposal is submitted, prior to award of the contract and will maintain a "current" status in regard to those taxes and fees during the life of the contract.

3. Proposer will obtain a Lexington-Fayette Urban County Government business license, if applicable, prior to award of the contract.

4. Proposer has authorized the Division of Central Purchasing to verify the above-mentioned information with the Division of Revenue and to disclose to the Urban County Council that taxes and/or fees are delinquent or that a business license has not been obtained.

5. Proposer has not knowingly violated any provision of the campaign finance laws of the Commonwealth of Kentucky within the past five (5) years and the award of a contract to the Proposer will not violate any provision of the campaign finance laws of the Commonwealth.

6. Proposer has not knowingly violated any provision of Chapter 25 of the Lexington-Fayette Urban County Government Code of Ordinances, known as "Ethics Act."

Continued on next page

7. Proposer acknowledges that "knowingly" for purposes of this Affidavit means, with respect to conduct or to circumstances described by a statute or ordinance defining an offense, that a person is aware or should have been aware that his conduct is of that nature or that the circumstance exists.

Further, Affiant sayeth naught.

Kim A. Christensen

STATE OF _____

COUNTY OF _____

The foregoing instrument was subscribed, sworn to and acknowledged before me by _____ on this the _____ day of _____, 2013.

My Commission expires: _____

_____
NOTARY PUBLIC, STATE AT LARGE

EQUAL OPPORTUNITY AGREEMENT

The Law

- Title VII of the Civil Rights Act of 1964 (amended 1972) states that it is unlawful for an employer to discriminate in employment because of race, color, religion, sex, age (40-70 years) or national origin.

- Executive Order No. 11246 on Nondiscrimination under Federal contract prohibits employment discrimination by contractor and sub-contractor doing business with the Federal Government or recipients of Federal funds. This order was later amended by Executive Order No. 11375 to prohibit discrimination on the basis of sex.

- Section 503 of the Rehabilitation Act of 1973 states:

  The Contractor will not discriminate against any employee or applicant for employment
  because of physical or mental handicap.

- Section 2012 of the Vietnam Era Veterans Readjustment Act of 1973 requires Affirmative Action on behalf of disabled veterans and veterans of the Vietnam Era by contractors having Federal contracts.

- Section 206(A) of Executive Order 12086, Consolidation of Contract Compliance Functions for Equal Employment Opportunity, states:

  The Secretary of Labor may investigate the employment practices of any Government
  contractor or sub-contractor to determine whether or not the contractual provisions specified in Section 202 of this order have been violated.

****

The Lexington-Fayette Urban County Government practices Equal Opportunity in recruiting, hiring and promoting. It is the Government's intent to affirmatively provide employment opportunities for those individuals who have previously not been allowed to enter into the mainstream of society. Because of its importance to the local Government, this policy carries the full endorsement of the Mayor, Commissioners, Directors and all supervisory personnel. In following this commitment to Equal Employment Opportunity and because the Government is the benefactor of the Federal funds, it is both against the Urban County Government policy and illegal for the Government to let contracts to companies which knowingly or unknowingly practice discrimination in their employment practices. Violation of the above mentioned ordinances may cause a contract to be canceled and the contractors may be declared ineligible for future consideration.

Please sign this statement in the appropriate space acknowledging that you have read and understand the provisions contained herein. Return this document as part of your application packet.

Bidders

I/We agree to comply with the Civil Rights Laws listed above that govern employment rights of minorities, women, Vietnam veterans, handicapped and aged persons.

Kim A. Christensen — *Signature*

Siemens Healthcare Diagnostics — *Name of Business*

* see enclosed

WORKFORCE ANALYSIS FORM

Name of Organization: _____

Date:_____/_____/_____

Categories	Total	White		Latino		Black		Other		Total	
		M	F	M	F	M	F	M	F	M	F
Administrators											
Professionals											
Superintendents											
Supervisors											
Foremen											
Technicians											
Protective Service											
Para-Professionals											
Office/Clerical											
Skilled Craft											
Service/Maintenance											
Total:											

Prepared by: Kate Will - HR
Name & Title

CO = D055830
U = T809340

EQUAL EMPLOYMENT OPPORTUNITY
2012 EMPLOYER INFORMATION REPORT EEO-1

UNIT REPORT - TYPE 4

SECTION B - COMPANY IDENTIFICATION

1. SIEMENS CORPORATION
300 NEW JERSEY AVENUE NW

WASHINGTON
DC 20001

2.a. SIEMENS HEALTHCARE DIAGNOSTICS
500 GBC DRIVE
GLASGOW BUS COMM RTE 896
NEWARK NEW CASTLE
DE 19702

c. Y (WAS AN EEO-1 REPORT FILED FOR THIS ESTABLISHMENT LAST YEAR?)

SECTION C - TEST FOR FILING REQUIREMENT

1 - Y 2 - Y 3 - Y DUNS NO: 064608573

SECTION E - ESTABLISHMENT INFORMATION

NAICS: 339112
Surgical and Medical Instrument Manufacturing

SECTION D - EMPLOYMENT DATA

JOB CATEGORIES		HISPANIC OR LATINO		********** MALE **********						********** FEMALE **********						OVERALL TOTALS
		MALE	FEMALE	WHITE	BLACK OR AFRICAN AMER	NATIVE HAWAIIAN OR PAC ISL	ASIAN	AM IND OR AK NATIVE	TWO OR MORE RACES	WHITE	BLACK OR AFRICAN AMER	NATIVE HAWAIIAN OR PAC ISL	ASIAN	AM IND OR AK NATIVE	TWO OR MORE RACES	
EXECUTIVE/ SR OFFICIALS MGRS	(1.1)	0	0	6	0	0	0	0	0	0	0	0	0	0	0	6
FIRST/MID OFFICIALS MGRS	(1.2)	6	6	96	5	0	9	0	0	60	6	0	6	0	0	194
PROFESSIONALS	(2)	9	18	327	14	0	29	0	1	182	18	1	30	0	0	629
TECHNICIANS	(3)	14	6	127	24	0	7	0	1	84	14	0	3	0	0	280
SALES WORKERS	(4)	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
ADMINISTRATIVE SUPPORT	(5)	1	3	11	1	0	0	0	0	56	9	0	0	0	0	81
CRAFT WORKERS (SKILLED)	(6)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OPERATIVES (SEMI-SKILLED)	(7)	18	16	58	24	0	4	2	1	24	26	0	2	0	0	175
LABORERS & HELPERS (UNSKLD)	(8)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SERVICE WORKERS	(9)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	**(10)**	**48**	**49**	**626**	**68**	**0**	**49**	**2**	**3**	**406**	**73**	**1**	**41**	**0**	**0**	**1366**
PREVIOUS REPORT TOTAL	(11)															

071512 THRU 071512 (DATE(S) OF PAYROLL PERIOD USED)

DIRECTOR, DIVISION OF CENTRAL PURCHASING
LEXINGTON-FAYETTE URBAN COUNTY GOVERNMENT
200 EAST MAIN STREET
LEXINGTON, KENTUCKY 40507

NOTICE OF REQUIREMENT FOR AFFIRMATIVE ACTION TO ENSURE EQUAL EMPLOYMENT OPPORTUNITIES AND DBE CONTRACT PARTICIPATION

The Lexington-Fayette Urban County Government has set a goal that not less than ten percent (10%) of the total value of this contract be subcontracted to MBE/WBE's. The goal for the utilization of certified MBE/WBE's as subcontractors are recommended goals. Contractors who fail to meet such goals will be expected to provide written explanations to the Director of the Division of Central Purchasing of efforts they have made to accomplish the recommended goals and the extent to which they are successful in accomplishing the recommended goals will be a consideration in the procurement process.

For assistance in locating MBE/WBE Subcontractors contact Marilyn Clark at 859/258-3320 or by writing the address listed below:

Marilyn Clark, Division of Central Purchasing
Lexington-Fayette Urban County Government
200 East Main Street – Room 338
Lexington, Kentucky 40507

Lexington-Fayette Urban County Government
MBE/WBE Participation Goals

PART 1 - GENERAL

1.1 The LFUCG request all potential contractors to make a concerted effort to include Minority-Owned (MBE) and Woman-Owned (WBE) Business Enterprises as subcontractors or suppliers in their proposals.

1.2 Toward that end, the LFUCG has established 10% of total procurement costs as a Goal for participation of Minority-Owned and Woman-Owned Businesses on this contract.

1.3 **It is therefore a request of each Submitter to include in its proposal, the same goal (10%) or for MBE/WBE participation and other requirements as outlined in this section.**

PART 2 - PROCEDURES

2.1 The successful proposer will be required to report to the LFUCG, the dollar amounts of all purchase orders submitted to Minority-Owned or Woman-Owned subcontractors and suppliers for work done or materials purchased for this contract. (See Subcontractor Monthly Payment Report)

2.2 Replacement of a Minority-Owned or Woman-Owned subcontractor or supplier listed in the original submittal must be requested in writing and must be accompanied by documentation of Good Faith Efforts to replace the subcontractor / supplier with another MBE/WBE Firm; this is subject to approval by the LFUCG. (See LFUCG MBE/WBE Substitution Form)

2.3 For assistance in identifying qualified, certified businesses to solicit for potential contracting opportunities, submitters may contact:

A. The Lexington-Fayette Urban County Government, Division of Central Purchasing (859-258-3320)

2.4 The LFUCG will make every effort to notify interested MBE/WBE subcontractors and suppliers of each RFP, including information on the scope of work, the pre-proposal meeting time and location, the proposal date, and all other pertinent information regarding the project.

PART 3 - DEFINITIONS

3.1 A Minority-Owned Business Enterprise (MBE) is defined as a business which is certified as being at least 51% owned and operated by persons of African American, Hispanic, Asian, Pacific Islander, American Indian or Alaskan Native Heritage.

3.2 A Woman-Owned Business Enterprise (WBE) is defined as a business which is certified as being at least 51% owned and operated by one or more Non-Minority Females.

PART 4 - OBLIGATION OF PROPOSER

4.1 **The bidder shall make a Good Faith Effort to achieve the Participation Goal for MBE/WBE subcontractors/suppliers. The failure to meet the goal shall not necessarily be cause for disqualification of the bidder; however, bidders not meeting the goal are required to furnish with their bids written documentation of their Good Faith Efforts to do so.**

4.2 Award of Contract shall be conditioned upon satisfaction of the requirements set forth herein.

4.3 The Form of Proposal includes a section entitled "MBE/WBE Participation Form". The applicable information must be completed and submitted as outlined below.

4.4 **Failure to submit this information as requested may be cause for rejection of the proposal.**

PART 5 - DOCUMENTATION REQURIED

5.1 Proposers reaching the Goal are required to submit only the "MBE/WBE Participation Form." The form must be fully completed including names and telephone number of participating MBE/WBE firm(s); type of work to be performed; estimated value of the contract and value expressed as a percentage of the total Lump Sum Proposal Price. The form must be signed and dated, and is to be submitted with the proposal.

5.2 Proposers not reaching the Goal must submit the "MBE/WBE Participation Form", the "MBE Quote Summary Form" and a written statement documenting their Good Faith Effort to do so (If proposal includes no MBE/WBE participation, proposer shall enter "None" on the subcontractor / supplier form). In addition, the proposer may submit the following as proof of Good Faith Efforts to meet the Participation Goal:

A. Advertisement by the proposer of MBE/WBE Contracting opportunities associated with this proposal in at least two (2) of the following:

1. A periodical in general circulation throughout the region
2. A Minority-Focused periodical in general circulation throughout the region
3. A Trade periodical aimed at the MBE/WBE community in general circulation throughout the region
4. Proposer shall include copies of dated advertisement with his submittal

B. Evidence of written notice of contracting opportunities to at least five (5) MBE/WBE firms serving the construction industry at least seven (7) days prior to the proposal opening date.

C. Copies of quotations submitted by MBE/WBE firms which were not used due to uncompetitive pricing or other factors and/or copies of responses from

firms that were contacted indicating that they would not be submitting a proposal.

D. Documentation of Proposer's utilization of the agencies identified to help locate potential MBE/WBE firms for inclusion on the contract including responses from agencies.

E. Failure to submit any of the documentation requested in this section may be cause for rejection of the proposal. Proposers may include any other documentation deemed relevant to this requirement. "Record of MBE/WBE Solicitation" and other required documentation of Good Faith Efforts are to be submitted with the proposal, if participation Goal is not met.

MINORITY BUSINESS ENTERPRISE PROGRAM

Marilyn Clark
Minority Business Enterprise Liaison
Division of Central Purchasing
Lexington-Fayette Urban County Government
200 East Main Street
Lexington, KY 40507
mclark@lexingtonky.gov
859-258-3323

OUR MISSION: The mission of the Minority Business Enterprise Program is to facilitate the full participation of minority and women owned businesses in the procurement process and to promote economic inclusion as a business imperative essential to the long term economic viability of Lexington-Fayette Urban County Government.

To that end the city council adopted and implemented resolution 167-91—Disadvantaged Business Enterprise (DBE) 10% Goal Plan in July of 1991. The resolution states in part (a full copy is available in Central Purchasing):

> *"A Resolution supporting adoption of the administrative plan for a ten percent (10%) Minimum goal for disadvantaged business enterprise participation in Lexington-Fayette Urban County Government construction and professional services contracts; Providing that as part of their bids on LFUCG construction contracts, general Contractors shall make a good faith effort to award at least ten percent (10%) of All subcontracts to disadvantaged business enterprises; providing that divisions of LFUCG shall make a good faith effort to award at least ten percent of their Professional services and other contracts to disadvantaged business enterprises..."*

A Disadvantaged Business Enterprise is defined as a business at least 51% owned, operated and managed by a U.S. Citizen of the following groups:

- African-American
- Hispanic-American
- Asian/Pacific Islander
- Native American/Native Alaskan
- Non-Minority Female

We are very happy that you have decided to bid for a contract, request for proposal, submitted a quote or are interested in learning more about how to do business with Lexington-Fayette Urban County Government. We have compiled the list below to help you locate certified minority vendors.

LFUCG—Economic Engine Listings
Marilyn Clark
mclark@lexingtonky.gov
859-258-3323

Commerce Lexington—
Tyrone Tyra, Minority Business Development
ttyra@commercelexington.com
859-226-1625

Tri-State Minority Supplier Diversity Council
Sonya Brown
sbrown@tsmsdc.com
502-625-0137

Small Business Development Council
Dee Dee Harbut /UK SBDC
dharbut@uky.edu

Shawn Rogers, UK SBDC
Shawn.rogers@uky.edu

Shiree Mack
smack@uky.edu

Community Ventures Corporation
James Coles
jcoles@cvcky.org
859-231-0054

Kentucky Department of Transportation
Shella Jarvis
Shella.Jarvis@ky.gov
502-564-3601

KPAP
Debbie McKnight
Debbie.McKnight@ky.gov
800-838-3266 or 502-564-4252

Bobbie Carlton
Bobbie.Carlton@ky.gov

Ohio River Valley Women's Business Council
Rea Waldon
rwaldon@gcul.org
513-487-6534

Kentucky Small Business Connect
Tom Back
800-626-2250 or 502-564-2064
https://secure.kentucky.gov//sbc

National Minority Supplier Development Council, Inc. (NMSDC)
www.nmsdc.org

& See enclosed documentation - tab 4

LFUCG MBE/WBE PARTICIPATION FORM
Bid/RFP/Quote Reference #_____

The MBE/WBE subcontractors listed have agreed to participate on this Bid/RFP/Quote. If any substitution is made or the total value of the work is changed prior to or after the job is in progress, it is understood that those substitutions must be submitted to Central Purchasing for approval immediately.

MBE/WBE Company, Name, Address, Phone, Email	Work to be Performed	Total Dollar Value of the Work	% Value of Total Contract
1.			
2.			
3.			
4.			

The undersigned company representative submits the above list of MBE/WBE firms to be used in accomplishing the work contained in this Bid/RFP/Quote. Any misrepresentation may result in the termination of the contract and/or be subject to applicable Federal and State laws concerning false statements and false claims.

Company **By**

Date **Title**

LFUCG MBE/WBE SUBSTITUTION FORM
Bid/RFP/Quote Reference #_____

The substituted MBE/WBE subcontractors listed below have agreed to participate on this Bid/RFP/Quote. These substitutions were made prior to or after the job was in progress. These substitutions were made for reasons stated below and are now being submitted to Central Purchasing for approval. By the authorized signature of a representative of our company, we understand that this information will be entered into our file for this project.

SUBSTITUTED MBE/WBE Company Name, Address, Phone, Email	MBE/WBE Formally Contracted/ Name, Address, Phone, Email	Work to Be Performed	Reason for the Substitution	Total Dollar Value of the Work	% Value of Total Contract
1.					
2.					
3.					
4.					

The undersigned acknowledges that any misrepresentation may result in termination of the contract and/or be subject to applicable Federal and State laws concerning false statements and false claims.

_____ _____

Company **Date**

_____ _____

Company Representative **Title**

MBE QUOTE SUMMARY FORM

Bid/RFP/Quote Reference #_____

The undersigned acknowledges that the minority subcontractors listed on this form did submit a quote to participate on this project.

Company Name	Contact Person
Address/Phone/Email	RFP Package / RFP Date

MBE/WBE Company Address	Contact Person	Contact Information (work phone, Email, cell)	Date Contacted	Services to be performed	Method of Communicatio (email, phone meeting, ad, event etc)	Total dollars $$ Do Not Leave Blank (Attach Documentation)	MBE * AA HA AS NA Female

(MBE designation / AA=African American / HA= Hispanic American/AS = Asian American/Pacific Islander/ NA= Native American)

The undersigned acknowledges that all information is accurate. Any misrepresentation may result in termination of the contract and/or be subject to applicable Federal and State laws concerning false statements and claims.

_____ _____

Company Company Representative

_____ _____

Date Title

LFUCG SUBCONTRACTOR MONTHLY PAYMENT REPORT

The LFUCG has a 10% goal plan adopted by city council to increase the participation of minority and women owned businesses in the procurement process. In order to measure that goal LFUCG will track spending with MBE/WBE vendors on a monthly basis. By the signature below of an authorized company representative, you certify that the information is correct, and that each of the representations set forth below is true. Any misrepresentation may result in termination of the contract and/or prosecution under applicable Federal and State laws concerning false statements and false claims. Please submit this form monthly to the Division of Central Purchasing/ 200 East Main Street / Room 338 / Lexington, KY 40507.

Bid/RFP/Quote #_____

Total Contract Amount Awarded to Prime Contractor for this Project_____

Project Name/ Contract #	Work Period/ From: To:
Company Name:	Address:
Federal Tax ID:	Contact Person:

Subcontractor Vendor ID (name, address, phone, email	Description of Work	Total Subcontract Amount	% of Total Contract Awarded to Prime for this Project	Total Amount Paid for this Period	Purchase Order number for subcontractor work (please attach PO)	Scheduled Project Start Date	Scheduled Project End Date

By the signature below of an authorized company representative, you certify that the information is correct, and that each of the representations set forth below is true. Any misrepresentations may result in the termination of the contract and/or prosecution under applicable Federal and State laws concerning false statements and false claims.

Company _____ Company Representative _____

Date _____ Title _____

LFUCG STATEMENT OF GOOD FAITH EFFORTS
Bid/RFP/Quote # 13-2013

By the signature below of an authorized company representative, we certify that we have utilized the following methods to obtain the maximum practicable participation by minority and women owned business enterprises on the project. Please indicate which methods you used by placing an X in the appropriate place.

____ Attended LFUCG Central Purchasing Economic Inclusion Outreach Event

____ Sponsored Economic Inclusion event to provide networking opportunities

____ Requested a list of MBE/WBE subcontractors or suppliers from LFUCG Economic Engine

____ Advertised for MBE/WBE subcontractors or suppliers in local or regional newspapers

____ Showed evidence of written notice of contracting and/or supplier opportunities to MBE/WBE firms at least seven days prior to the proposal opening date

____ Provided copies of quotations submitted by MBE/WBE firms which were not used and/or responses from firms indicating they would not be submitting a quote

____ Provided plans, specifications, and requirements to interested MBE/WBE subcontractors

X Other
Please list any other methods utilized that aren't covered above.
See letter Regarding FDA classifies IVD instruments as medical devices. - See Job 4.

The undersigned acknowledges that all information is accurate. Any misrepresentations may result termination of the contract and/or be subject to applicable Federal and State laws concerning false statements and claims.

Siemens Healthcare Diagnostics — Company

Kim A. Christensen — Company Representative

4/29/2013 — Date

SVVA Director — Title

Firm Submitting Proposal: Siemens Healthcare Diagnostics Inc.

Complete Address: 511 Benedict Ave Tarrytown, NY 10591
Street City Zip

Contact Name: Diane Crawford Title: Sylva Analyst

Telephone Number: (302) 631-0417 Fax Number: (302) 631-7997

Email address: diane.d.crawford@siemens.com

GENERAL PROVISIONS

1. Each Respondent shall comply with all Federal, State & Local regulations concerning this type of service or good.

   The Respondent agrees to comply with all statutes, rules, and regulations governing safe and healthful working conditions, including the Occupational Health and Safety Act of 1970, *29 U.S.C. 650 et. seq.*, as amended, and KRS Chapter 338. The Respondent also agrees to notify the LFUCG in writing immediately upon detection of any unsafe and/or unhealthful working conditions at the job site. The Respondent agrees to indemnify, defend and hold the LFUCG harmless from all penalties, fines or other expenses arising out of the alleged violation of said laws.

2. Failure to submit ALL forms and information required in this RFP may be grounds for disqualification.

3. Addenda: All addenda, if any, shall be considered in making the proposal, and such addenda shall be made a part of this RFP. Before submitting a proposal, it is incumbent upon each proposer to be informed as to whether any addenda have been issued, and the failure to cover in the bid any such addenda may result in disqualification of that proposal.

4. Proposal Reservations: LFUCG reserves the right to reject any or all proposals, to award in whole or part, and to waive minor immaterial defects in proposals. LFUCG may consider any alternative proposal that meets its basic needs.

5. Liability: LFUCG is not responsible for any cost incurred by a Respondent in the preparation of proposals.

6. Changes/Alterations: Respondent may change or withdraw a proposal at any time prior to the opening; however, no oral modifications will be allowed. Only letters, or other formal written requests for modifications or corrections of a previously submitted proposal which is addressed in the same manner as the proposal, and received by LFUCG prior to the scheduled closing time for receipt of proposals, will be accepted. The proposal, when opened, will then be corrected in accordance with such written request(s), provided that the written request is contained in a sealed envelope which is plainly marked "modifications of proposal".

7. Clarification of Submittal: LFUCG reserves the right to obtain clarification of any point in a bid or to obtain additional information from a Respondent.

8. Bribery Clause: By his/her signature on the bid, Respondent certifies that no employee of his/hers, any affiliate or Subcontractor, has bribed or

attempted to bribe an officer or employee of the LFUCG.

9. Additional Information: While not necessary, the Respondent may include any product brochures, software documentation, sample reports, or other documentation that may assist LFUCG in better understanding and evaluating the Respondent's response. Additional documentation shall not serve as a substitute for other documentation which is required by this RFP to be submitted with the proposal,

10. Ambiguity, Conflict or other Errors in RFP: If a Respondent discovers any ambiguity, conflict, discrepancy, omission or other error in the RFP, it shall immediately notify LFUCG of such error in writing and request modification or clarification of the document if allowable by the LFUCG.

11. Agreement to Bid Terms: In submitting this proposal, the Respondent agrees that it has carefully examined the specifications and all provisions relating to the work to be done attached hereto and made part of this proposal. By acceptance of a Contract under this RFP, proposer states that it understands the meaning, intent and requirements of the RFP and agrees to the same. The successful Respondent shall warrant that it is familiar with and understands all provisions herein and shall warrant that it can comply with them. No additional compensation to Respondent shall be authorized for services or expenses reasonably covered under these provisions that the proposer omits from its Proposal.

12. Cancellation: If the services to be performed hereunder by the Respondent are not performed in an acceptable manner to the LFUCG, the LFUCG may cancel this contract for cause by providing written notice to the proposer, giving at least thirty (30) days notice of the proposed cancellation and the reasons for same. During that time period, the proposer may seek to bring the performance of services hereunder to a level that is acceptable to the LFUCG, and the LFUCG may rescind the cancellation if such action is in its best interest.

    A. Termination for Cause

    (1) LFUCG may terminate a contract because of the contractor's failure to perform its contractual duties

    (2) If a contractor is determined to be in default, LFUCG shall notify the contractor of the determination in writing, and may include a specified date by which the contractor shall cure the identified deficiencies. LFUCG may proceed with termination if the contractor fails to cure the deficiencies within the specified time.

(3) A default in performance by a contractor for which a contract may be terminated shall include, but shall not necessarily be limited to:

(a) Failure to perform the contract according to its terms, conditions and specifications;

(b) Failure to make delivery within the time specified or according to a delivery schedule fixed by the contract;

(c) Late payment or nonpayment of bills for labor, materials, supplies, or equipment furnished in connection with a contract for construction services as evidenced by mechanics' liens filed pursuant to the provisions of KRS Chapter 376, or letters of indebtedness received from creditors by the purchasing agency;

(d) Failure to diligently advance the work under a contract for construction services;

(e) The filing of a bankruptcy petition by or against the contractor; or

(f) Actions that endanger the health, safely or welfare of the LFUCG or its citizens.

B. At Will Termination

Notwithstanding the above provisions, the LFUCG may terminate this contract at will in accordance with the law upon providing thirty (30) days written notice of that intent, Payment for services or goods received prior to termination shall be made by the LFUCG provided these goods or services were provided in a manner acceptable to the LFUCG. Payment for those goods and services shall not be unreasonably withheld.

13. Assignment of Contract: The contractor shall not assign or subcontract any portion of the Contract without the express written consent of LFUCG. Any purported assignment or subcontract in violation hereof shall be void. It is expressly acknowledged that LFUCG shall never be required or obligated to consent to any request for assignment or subcontract; and further that such refusal to consent can be for any or no reason, fully within the sole discretion of LFUCG.

14. No Waiver: No failure or delay by LFUCG in exercising any right, remedy, power or privilege hereunder, nor any single or partial exercise thereof, nor the exercise of any other right, remedy, power or privilege shall operate as a waiver hereof or thereof. No failure or delay by LFUCG in exercising any right, remedy, power or privilege under or in respect of this Contract shall affect the rights, remedies, powers or privileges of LFUCG hereunder or shall operate as a waiver thereof.

15. Authority to do Business: The Respondent must be a duly organized and authorized to do business under the laws of Kentucky. Respondent must be in good standing and have full legal capacity to provide the services specified under this Contract. The Respondent must have all necessary right and lawful authority to enter into this Contract for the full term hereof and that proper corporate or other action has been duly taken authorizing the Respondent to enter into this Contract. The Respondent will provide LFUCG with a copy of a corporate resolution authorizing this action and a letter from an attorney confirming that the proposer is authorized to do business in the State of Kentucky if requested. All proposals must be signed by a duly authorized officer, agent or employee of the Respondent.

16. Governing Law: This Contract shall be governed by and construed in accordance with the laws of the Commonwealth of Kentucky. In the event of any proceedings regarding this Contract, the Parties agree that the venue shall be the Fayette County Circuit Court or the U.S. District Court for the Eastern District of Kentucky, Lexington Division. All parties expressly consent to personal jurisdiction and venue in such Court for the limited and sole purpose of proceedings relating to this Contract or any rights or obligations arising thereunder. Service of process may be accomplished by following the procedures prescribed by law.

17. Ability to Meet Obligations: Respondent affirmatively states that there are no actions, suits or proceedings of any kind pending against Respondent or, to the knowledge of the Respondent, threatened against the Respondent before or by any court, governmental body or agency or other tribunal or authority which would, if adversely determined, have a materially adverse effect on the authority or ability of Respondent to perform its obligations under this Contract, or which question the legality, validity or enforceability hereof or thereof.

18. Contractor understands and agrees that its employees, agents, or subcontractors are not employees of LFUCG for any purpose whatsoever. Contractor is an independent contractor at all times during the performance of the services specified.

19. If any term or provision of this Contract shall be found to be illegal or unenforceable, the remainder of the contract shall remain in full force and such term or provision shall be deemed stricken.

Kim A. Christensen

Signature

4/29/2013

Date

REQUEST FOR PROPOSAL SPECIFICATIONS

A. SCOPE OF THE PROPOSAL

The Lexington Fayette Urban County Government / Division of Community Corrections is releasing this RFP to acquire items required to perform on-site testing for Drugs of Abuse. The testing will only be for Drugs of Abuse and method of testing utilized is Immunoassay. All items not satisfactorily explained in the proposal may be considered as non-compliance responses. Any exceptions to the specifications must be noted by the Vendor. Performance categories to be rated will include: corporate financial stability; amount of experience in providing equipment and service; equipment performance; current references; and, service and support.

B. GENERAL TERMS AND PROVISIONS

1. Proposals: Must be contained in a SEALED envelope addressed to: Todd Slatin, 200 East Main Street, Lexington, KY 40507. To prevent inadvertent opening, the proposal must be marked as a PROPOSAL DOCUMENT (including the proposal number, proposal date and the time of opening) on the outside of the envelope.

2. If our specifications, when included in our Request for Proposal, are not returned with your proposal, and no specific reference is made to them in your proposal, it will be assumed that all specifications will be met. When material, sketches, cuts, descriptive literature, Vendor's or manufacturer's specifications which accompany the proposal contain information that can be construed or is intended to be a deviation from our specifications, such deviation must be specifically referenced in your proposal response.

3. The responsibility for getting the proposal to the Lexington-Fayette Urban County Government (LFUCG) Division of Purchasing on or before the stated time and date will be solely and strictly the responsibility of the Vendor. LFUCG will in no way be responsible for delays caused by the United States Postal Service or a delay caused by any other occurrence, or any other method of delivery. The Vendor shall be responsible for reading very carefully and understanding completely the requirements in the specifications. Proposals will not be accepted after the time specified for receipt. Such proposals shall be returned to the Vendor unopened with the notation "This Proposal Was Received After the Time Designated For the Receipt and Opening of Proposals."

4. Time for Consideration: Vendor warrants by virtue of proposing the prices quoted in his proposal will be good for a minimum evaluation period of sixty (60) calendar days from the date of proposal opening unless otherwise stated. Vendors will not be allowed to withdraw or modify their proposals after the opening time and date.

5. Prices:

    a. The Vendor's attention is directed to the fact that the tax laws of the Commonwealth of Kentucky apply to this present proposal matter and that all applicable taxes and fees shall be deemed to have been included in Submitter's proposal.
    b. State sales tax and federal excise taxes shall not be included as the Division of the Community Corrections is tax-exempt for materials sold directly to them. Exemption certificates shall be issued to the successful Contractor when requested.
    c. Lease price(s) bid is/are to be F.O.B. Destination.

6. Proposal Errors: When errors are found in the extension of proposals prices, the unit price will be govern. Proposals having erasures or corrections must be initialed in ink by the Vendor.

7. Term of Contract: The Proposal pricing shall remain constant and cover a **three (3) year period.** Upon mutual agreement, The Proposal may be renewed for **two (2) additional one-year (1) extensions** based upon negotiations of service delivery and costs.
    a. Changes in the contractual provisions or services to be furnished under the Proposal may be made only in writing, must be approved by the Division and the agent of the Vendor.
    b. Should a decision be made to increase the scope of the Proposal, the Division and the Vendor shall mutually agree, in writing, to any adjusted Contract pricing.
    c. The Division my execute proportions of the contract with different vendors based on the Scope of the Proposal.

8. Conditions of Materials & Packaging: Unless otherwise indicated, it is understood and agreed that any item offered or shipped on this proposal shall be **NEW** and in **FIRST CLASS CONDITION,** that all containers shall be new and suitable for storage or shipment and that prices include standard commercial packaging for the items shipped.

9. Termination: Either the Division of Community Corrections or the Vendor may terminate any agreement resulting from the Request for Proposal without cause upon giving the other party not less than sixty (60) calendar days written notice of termination.

10. Claims: The successful Vendor will immediately replace missing or damaged items and will be responsible for making any and all claims against carriers.

11. When to Make Delivery: Deliveries resulting from this proposal are to be made during normal working hours of the Division. It is the Vendor's responsibility to obtain this information.

12. Manufacturer's Name: Any manufacturer's names, trade names, brand names information and/or catalog numbers used herein are for purpose of description, reference, and establishing general quality levels. Such references are not intended to be restrictive and products of any manufacturer may be offered if they are approved as equals. The determination as to whether any alternate product or service is or is not equal shall be made by the Division and such determination shall be final and binding upon all Vendors.

13. Information and Descriptive Literature: Vendor must furnish all information requested in the proposal. If specified, each Vendor must submit cuts, sketches, descriptive literature and/or complete specifications covering the products offered. Reference to literature submitted with previous proposals will not satisfy this provision. Proposals which do not comply with these requirements will be subject to rejection.

14. Proposal Submittal Cost: Submittal of a proposal is solely at the cost of the Vendor and the Division is in no way liable or obligates itself for any cost accrued to the Vendor in coming up with the Proposal Submittal.

15. No Proposal: If the receipt of the request for the proposal is not acknowledged, Vendor's name may be removed from the proposal mailing.

16. Compliance with Occupational Safety and Health Act. Vendor certifies that all material, equipment, etc., contained in his proposal meets all O.S.H.A. requirements.

17. Acceptance and Rejection: The Director of the Division of Community Corrections reserves the right to reject any or all proposals, for cause, to waive, irregularities, if any, in proposal, and to accept the proposal or proposals which in the judgment of the Director is in the best interest of the Division of Community of Corrections.

18. Work Site: Before submitting proposals, Vendors must carefully examine the site of the proposed work and make all necessary investigations to inform themselves thoroughly as to all difficulties involved in the completion of all work required pursuant to the mandates and requirements of this proposal package. No pleas of ignorance or conditions of difficulties that may exist prior to the proposal opening time or of conditions of difficulties that me be encountered in the execution of the work pursuant to this package as result of failure to make necessary and reasonable examinations of the Contract Documents, nor will they be accepted as a basis for any claims whatsoever for extra compensation or for any extension of time.

19. Delivery Time/Liquidated Damages: Vendors are hereby advised that if the Contract Documents so indicate, an amount determined for the liquidated damages at the rate specified shall be assessed against the successful Vendor

not complying with a stated delivery time or performance time (or similarly stated information) as found in the Special Provisions, Part B.

20. Assignment of Contract: Vendor may not make any assignment of the resulting contractual agreement between the parties, in whole or in part, without prior written authorizations as may be given at the sole discretion of the Director of the Division of Community Corrections.

C. MINIMUM VENDOR QUALIFICATIONS AND INFO

1. Any portion of this contract that is subcontracted out by the selected vendor shall be disclosed by the vendor within this proposal.

2. The Vendor must have five years in the providing support services for the proposed field equipment, software and hardware.

3. The Vendor must provide a Dunn and Bradstreet credit rating to determine financial stability.

D. GENERAL REQUIRMENTS

1. The equipment offered in the proposal shall be fully supported by the original equipment manufacturer.

2. The equipment and software provided must be the Vendor's most recent version released in the industry and upgraded as new versions become available.

3. The Vendor must supply all necessary tools and supplies to operate the system. Maintenance costs for the equipment shall be included as part of this proposal.

4. The Vendor shall appoint a project manager who will also act as a contact and liaison for the Division.

5. The project manager shall have, at a minimum, three years of work experience in related field.

6. The project manager will schedule minimum of 2 on-site visit annually with the department to review performance and to make any needed changes.

7. The Vendor will provide qualified personnel in the event that expert testimony on functional aspects of the system and equipment is needed in Court for cases involving services and materials provided.

8. The Vendor must be ready to proceed with provision and operation of the equipment within thirty (30) days after receiving a notice to proceed.

9. Identify all products that you do not self-manufacture. Identify the manufacturer and location of the manufacturing facility.

10. Address in detail your ability to guarantee supply. Have you had any product shortages within the last 18 months? If so, identify the product and the case volume affected.

11. Transition: Upon award of the contract, the Vendor shall work with the Division and any other organizations designated by the Division to ensure an orderly transition of services and responsibilities under the contract and to ensure the continuity of those services.

12. The vendor shall pay for all shipping costs and/or fuel charges through the scope of this contract.

E. CUSTOMER SUPPORT, TECHNICAL SERVICES, AND QUALITY CONTROL

1. The Vendor must have a dedicated Customer Support Staff that is trained in every facet of the company, its' field equipment, software and hardware. The Support Staff must understand the proposed software and hardware and must be able to provide real-time help and remote diagnostics for both hardware and software issues.

2. During the past 18 months, have any of your manufacturing facilities received FDA FD 483 observations or FDA warning letters? If so, attach unedited copies of those letters, along with an unedited copy of your response.

3. Have you had any product recalls with the last three years? If so, indicate the name of the product and the reason for the recall, and the class of the recall (I, II, or III).

4. Quality Review: The Vendor shall understand and agree that the accuracy of the reagents proposed are subject to outside laboratory verification at the Divisions discretion.

    a. This will be at cost of the Division.

    b. In the event the Division determines by verification, the contractor's reagents are inaccurate or unreliable, the Vendor may be cancelled without further cost to the Division.

F. TRAINING

1. The Vendor shall provide 5 days of training to selected Division staff and will be responsible for providing the skills and knowledge necessary to

implement and manage the program. The training providing by the Vendor should give a thorough review of the entire operation of the system.

2. What training materials and programs do you have available?

3. The Vendor shall provide training materials for end user on the proper use of testing devices to achieve accurate test results.

4. All designated Division personnel shall be certified by the Vendor in the operation of the system, this number to be determined by the Division. This shall be at no cost to the Division.

    a. The Division will provide appropriate space for training.

G. MAINTENANCE AND REPAIRS-FIELD EQUIPMENT

1. The Vendor shall provide maintenance of the equipment for the length of the contract at no additional cost. The Vendor shall maintain the equipment and spares in good operating condition and arrange for prompt repair or replacement. All maintenance shall be done within manufacture guidelines.

2. Please explain maintenance can be performed on –site by the division and which requires a field engineer/technician to perform.

3. Please explain the ability of the analyzer to be able to perform automated maintenance.

H. ANALYZER

1. The Vendor must have procedures in place for the frequent backup of data generated by the analyzer.

2. Battery backup should be in place onsite should an electrical outage occur to allow for allow equipment to be safely shutdown by the users and no loss of data.

3. All data generated by the system will be the property of the Division and available to the Division in an Open Database Connectivity (ODBC) compliant format upon request.

4. Please provide documentation as a separate attachment to certify the proposed system is FDA approved.

5. Describe the cleaning process for your product.

6. The Division will require a unit that supports non-vendor reagents and should have an open test menu. Please define how many user defined open tests are available.

7. Describe the calibration process and frequency.

8. Describe the Quality Control program.

9. The equipment proposed shall have the ability to perform a minimum of 500 tests per hour.

I. REAGENTS

1. List of Reagents used and volume for 2012.

	Reagent	Volume
a.	Ethyl Alcohol	27,571
b.	Amphetamine	34,367
c.	Barbiturate	25,801
d.	Benzodiazepine	37,203
e.	Buprenorphine	25,792
f.	Cannabinoids	39,831
g.	Cocaine	39,830
h.	Creatinine	39,830
i.	Ethyl glucuronide	12,268
j.	Fentanyl	1,768
k.	Methadone	25,791
l.	Opiate	38,075
m.	Oxycodone	38,075
n.	pH	25,781
o.	Specific Gravity	2,190
p.*	Synthetic Cannabinoids	8
q.	Tramadol	1,768
r.	6-Acetylmorphine	Projected Usage 10,000

* Started testing at end of 2012. Expected usage is unknown.

2. Please provide documentation as a separate attachment to certify which proposed product is FDA approved.

3. Cut-offs for any assays proposed shall by SAMHSA standards if available.

4. All reagents, controls, and calibrators shall have an expiration date clearly marked. Any that are not received with an expiration date of less than 4 months from date of receipt, will be rejected at the vendor's expense.

5. The reagents proposed must be highly accurate and reliable with performance data comparable to gas chromatograph/mass spectrometer (GC/MS) testing.

6. The testing devices shall minimize false positives results caused by over-the-counter medications. Please include a cross reactivity list with each reagent proposed.

J. MISCELLANEOUS

1. All computer equipment and connections needed to provide the Division with 3 internal workstations shall be included in this RFP.

2. Vendor shall provide all necessary hardware and software necessary for communication with the analyzer and web based host.

3. The Vendor will provide the ability to access the results with a web-based platform. The Division should also have the ability to view on-line, e-mail, and fax results as needed.

4. The Vendor's proposed system shall allow for existing data to be transferred to the new database.

K. PRICING

(Please provide pricing in both formats)

1. Reagent Cost (Provide the equipment lease pricing for the reagent to include pricing for all consumables, workstations, controls/calibrators and necessary maintenance.)

2. Reagent Cost (To include calibrator and controls. Not to include equipment, other consumables, and maintenance.)

L. REFERENCES

1. Vendor shall supply a minimum of six (6) references for whom the Vendor has provided comparable contractual services to those specified in this Request for Proposal.

2. Vendor must provide complete addresses and telephone numbers for each of the six references, as well as the name, title and the telephone number of a contact individual. The contact person shall be knowledgeable of the contract and shall be able to answer questions pertaining to the Vendor's proposed equipment and monitoring center services.

EVALUATION CRITERIA

The ability of this Division to effectively operate and manage a successful program is directly related to its ability to acquire reliable equipment. Your response must demonstrate that the equipment being proposed has a history of quality operation and reliability.

Additionally, program budgets need to be stable to help assure program success. In the evaluation of proposals, this Division will ascertain the costs associated with each system submitted. We encourage each Vendor to be as comprehensive and thorough as possible when responding to this request for proposal. Vendors may be called upon to attend an oral interview and equipment demonstration.

The categories will be scored as follows:

A. Technical Equipment and Service (20 points max.) Items evaluated will include system capacity, software capacity, applicability to the proposal, reliability, maintenance and repair, security features, and support.

B. Price (30 points max.) The lowest offered price consistent with the requirements specified in the RFP will be awarded 30 points. Remaining proposals will be awarded a proportionate number of points based in the amount of difference between the two quoted prices.

C. Corporate Stability (15 points max.) Each Vendor will be evaluated in terms if the financial stability of the Vendor based on the audited financial report submitted.

D. Experience (15 points max.) Each Vendor will be evaluated on their prior experience in providing services.

E. Quality of Response (15 points max.) Each response will be evaluated to determine the Vendor's understanding of the project and its ability to perform and meet each technical specification. Each item must have been discussed clearly and succinctly

F. Degree of Local Employment (5 points max.)

Best Possible Score: 100 points

RFP #13-2013 - Drug Testing for Community Corrections					
Consultant/Vendor Name:					
Selection Criteria	Notes	Total Points	Score(1-5)	Weighted Score	Comment
Technical Equipment and Service - Items evaluated will include system capacity, software capacity, applicability to the proposal, reliability, maintenance and repair, security features, and support.		20	0		Weighted Score= (Total Points/5)xScore
Price - The lowest offered price consistent with the requirements specified in the RFP will be awarded 30 points. Remaining proposals will be awarded a proportionate number of points based in the amount of difference between the two quoted prices.		30	0		Weighted Score= (Total Points/5)xScore
Corporate Stability - Each Vendor will be evaluated in terms if the financial stability of the Vendor based on the audited financial report submitted.		15	0		Weighted Score= (Total Points/5)xScore
Experience - Each Vendor will be evaluated on their prior experience in providing services.		15	0		Weighted Score= (Total Points/5)xScore
Quality of Response - Each response will be evaluated to determine the Vendor's understanding of the project and its ability to perform and meet each technical specification. Each item must have been discussed clearly and succinctly		15	0		Weighted Score= (Total Points/5)xScore
Degree of local employment to be provided by the person or firm.		5	0		Weighted Score= (Total Points/5)xScore
Final Technical Score		100	0	0	

DBE Participation(Name) _____ Evaluator: _____

DBE Portion(Percentage) _____

Comments: _____

_____

Description	Adjective	Numeric Rating
Fails to meet minimum requirements; major deficiencies which are not correctable	Unacceptable	1
Fails to meet requirements, significant deficiencies that may be correctable	Poor	2
Meets requirements; only minor deficiencies which can be clarified	Acceptable	3
Meets requirements and exceeds some requirements; no deficiencies	Good	4
Exceeds most, if not all requirements; no deficiencies	Excellent	5

SIEMENS

RFP # 13-2013

Drug Testing for Community Corrections

Due: April 30, 2013 @ 2:00 p.m., CST.

Lexington-Fayette Urban County Government

Room 338, Government Center

200 East Main Street

Lexington, KY 40507

Todd Slatin

Siemens Healthcare Diagnostics, Inc. Inc. would like to thank you for the opportunity to respond to **RFP #13-2013** for **Drug Testing for Community Corrections**. In order to ensure prompt response for any questions or requests pertaining to this bid please note the address and contact information I have listed below for this function of our company.

RFP Mailing Address

Siemens Healthcare Diagnostics

500 GBC Drive, MS: 528

Newark, DE 19702

Attn: Diane D. Crawford

Phone: 302.631.0417

Fax: 302.631.7997

Email: diane.d.crawford@siemens.com

Siemens Corporate Address

Siemens Healthcare Diagnostics

511 Benedict Avenue

Tarrytown, NY 10591

Attn: Diane D. Crawford

Phone: 302.631.0417

We appreciate the opportunity to participate in this process and look forward to answering any and all questions about our proposal. Siemens Healthcare Diagnostics – Syva division wishes to thank Lexington-Fayette Urban County for their time and consideration.

Sincerely,

Siemens Healthcare Diagnostics – Syva Division

James Boosalis, Amy Adkins and Diane Crawford

Siemens Healthcare Diagnostics Inc. (“Siemens”) has provided its standard bid responses in this proposal. We recognize that Lexington-Fayette Urban County (***LFUCG***) may be limited in what terms and conditions will be deemed acceptable, and Siemens is open to negotiation of the terms and conditions to reach a mutually agreeable resolution.

Siemens will retain title to the Equipment. You agree to clearly indicate that the Equipment is the sole property of Siemens. You also agree that to the extent required by law Siemens may file a UCC financing statement, or any other document or instrument required by law, to give public notice of Siemens's interest in the equipment.

Purpose

Siemens Healthcare Diagnostics, Inc. is responding to Lexington-Fayette Urban County RFP #13-2013 dated October 22, 2012, 2011 to provide full instrumentation and supplies for DACC to be able to test for drugs of abuse in inmates.

Siemens Healthcare Diagnostics, Inc. will provide an integrated solution to State of Wisconsin as outlined in the Bid for a term contract for use by DACC – Drug Abuse Correction Center.

The Siemens solution consists of the following **cost effective options**:

Option 1: Reagent Cost #1

Option 2: Reagent Cost #2

The Siemens solution will consist of one (1) Beckman AU680 Clinical Chemistry analyzer, Syva EMIT® Drugs of Abuse (DAT) assays, Millipore Water system, warranty/four (4) years of service on the analyzer and water system, IMS Data Management system and other supplies, which will provide Lexington-Fayette Urban County a cost effective, accurate and labor efficient solution.

Siemens will provide off-site training for (**2**) lab personnel on the AU6Drug Test80 Clinical Chemistry system at the Beckman, Brea, CA training facility. In addition to the training provided, Siemens offers comprehensive technical support through Global Call Centers, Technical Field Personnel, Advanced Global Product Support and Siemens.com on-line. The Syva Technical Solution Support Center is available twenty-four hours per day, seven days a week and provides trained personnel to resolve technical issues in a timely manner.
This contract is for a three (3) year period with two (2) additional one (1) year renewal periods. Pricing is firm for three (3) years of the initial contract term.

C. Minimum Vendor Qualifications and Info

1. No subcontractors will be used with this submission.
2. Siemens acknowledges and agrees with this statement.
3. Siemens Dunn and Bradstreet # 798318598.

Siemens Healthcare Diagnostics Inc has been a market leader in drug testing for more than 45 years with the Syva® product line. Syva® EMIT® assays, the gold standard in the drug testing marketplace, are the most extensively validated in the industry and used by more than 85% of US Substance Abuse and Mental Health Services Administration (SAMHSA) laboratories. Drug Court Programs across the United States use the Syva® Technology, and Siemens Healthcare Diagnostics is a Pioneer Member of NADCP.

Besides the extensive experience that Syva® provides, having started the drug testing business in the 1970's on board US Navy Submarines, the company also supplies a complete solution for the

drug court program, from accurate analysis and data management, to the full Case Management System. By manufacturing and partnering with high quality suppliers, like iMs-Dynetics, Millipore Water Systems, and Beckman Coulter, Siemens Healthcare Diagnostics provides a one source solution to the customer, under the Syva® umbrella. In this way, the company offers the most complete range of instruments, software, case management, and reagent menu for drug of abuse testing, on the market today. The Syva Emit® brand of reagents is legally defensible in court, the combination of Syva drug testing products and GC/MS for confirmation has been acknowledged by the U.S. Supreme Court as highly accurate.

Under the Syva® and Emit® brand names, Siemens Healthcare Diagnostics offers tests that either detect or provide quantitative measures of therapeutic drugs, drugs of abuse, and drugs to be used to prevent rejection of transplanted organs. Drugs of abuse tests are used in a wide range of settings including hospitals, industry and criminal justice labs, workplace and work release programs and nuclear power plants. Considering the diverse markets we serve, at least 60-75% of our customers are state or federally funded.

The Syva® name remains, after four decades, the leading brand in the drug testing market segment. Siemens Healthcare Diagnostics Inc has over 20 dedicated Syva Sales representatives nationwide currently working on a variety of different projects within the criminal justice and drug treatment market that are state or federally funded.

D. General Requirements

1**. Siemens acknowledges this statement.** Siemens Healthcare Diagnostics, Inc is an Authorized Distributor of Beckman Coulter AU Chemistry Analyzers in the Toxicology and Drugs of Abuse market and will be bidding one (1) new AU680 Analyzer.

2. Siemens acknowledges this statement, although some other vendors may offer "*refurbished*' Beckman analyzers, by choosing a **non-authorized distributor** you will **not** be assured of the following:

- Analyzer installed by trained personnel and installed as per manufacturer's documented protocol and validation process.

- Analyzer has the latest software version by the manufacturer. If not using an authorized distributor, you cannot be assured of the latest software version or any future software enhancements or upgrades. You will not receive any software enhancements or upgrades by the manufacturer if not using an authorized distributor. .

- Regarding a specific history for an analyzer, there is no accurate history for the serial number on the analyzer you are getting from a 3rd party provider. You will have no history of that system or the repairs, etc., performed on the system.

Siemens – Syva Division will ensure that the Beckman Coulter – AU680 analyzer installed will meet or exceed the requirements stated herein to accurately and efficiently analyze specimens over the life of this contract.

3. Siemens acknowledges this statement.

4. James Boosalis, Syva Sales Representative will act as the contact and liaison for the Division.

5. James Boosalis is tenured with the Syva organization and is knowledgeable of the Drugs of Abuse product line; he has been with Syva for 11 years.

6. James Boosalis will schedule a minimum of 2 on-site visits annually with the department to review performance and to make any needed changes.

7. Dr. Leo Kadehjian is an independent biomedical consultant in Palo Alto, California, primarily lecturing and writing on the clinical, scientific, regulatory, and legal issues in drugs of abuse testing. He has provided consulting services for a wide variety of both private and public sector drug programs worldwide, and currently serves as a consultant to Siemens (Syva). He has special experience with on-site testing programs and provides oversight of the U.S. Federal Courts' on-site drug testing programs. He also serves on the faculty of the National Judicial Center. An inter-nationally recognized speaker, he has earned Outstanding Speaker recognition from the American Association of Clinical Chemistry and has provided expert testimony in court and labor arbitration.

   Any request for an expert witness must go through your Sales Representative, James Boosalis. James will work with Lexington-Fayette Cty Urban Government location and determine with Dr.Kadhejian what is required for any testimony. Many times telephone consultations are an option and have met the needs of customers

8. Siemens acknowledges this statement and will work with LFUCG to establish mutual timelines regarding the installation of the analyzer upon the bid award.

9. Siemens does not self-manufacture the following products from Immunalysis: these products are for Forensic Use Only

a.	****ETG**	**500, 1000 ng/ml**
b.	****Oxycodone**	**100, 300 ng/ml**
c.	****Tramadol**	**200 ng/ml**
d.	****Bupenorphine**	**5 ng/ml**
e.	****Merpidine**	**200 ng/ml**
f.	****Methadone/EDDP**	**300 ng/ml**
g.	**Fentanyl*****	
h.	**Synthethic Cannabinoids*****	

****Forensic Use Only**

***These products can be purchased directly from Immunalysis Corporation.

10. Siemens – Syva Product Managers closely monitor supply and demand of our Syva Emit reagents. The Product Managers work closely with several groups within Siemens to ensure that there is inventory available for both our US and Global customers. If a back-order situation arises, it is managed closed and product is allocated to ensure that every customer is able to obtain product during this Managed process. Siemens-Syva take these situations seriously and work to ensure on a daily basis that shortages or product allocations to do occur.

11. Siemens Healthcare Diagnostics is the current vendor that LFUCG is using for their Drugs of Abuse testing.

12. *Siemens acknowledges this statement.* Siemens has implemented a new shipping and handling policy that is designed to enable customers to receive no charge Shipping and Handling by partnering with Siemens Healthcare Diagnostics in optimizing the supply

chain. It is based on simple straight-forward requirements: order size, order method (electronic vs. phone/fax), and shipping mode (standard vs. expedited).

The standard shipping and handling charge per order is $80. This charge is easily waived by complying with two objectives**: order on line, and meet the order value.** The Shipping and Handling Policy is included in the bid submission.

All orders will be shipped at no cost as long as they meet the following criteria per our policy:

1. Orders must be placed on-line
2. Orders must have a minimum of $2,000 per order

All reagents and parts shipped including reagents, consumables, calibrators, and controls will have clear storage instructions on package as defined by the manufacturer.

E. Customer Support, Technical Services, and Quality Control

1. Siemens Healthcare Diagnostics has a total team of specialists including the following:

James Boosalis, Syva Sales Representative
Amy Adkins- Syva Specialty Lab Consultant
Chris Zurface – Syva Sr. Technical Applications Specialist
Beckman Coulter, Inc. local Field Service Engineers

In addition, both Siemens Healthcare Diagnostics and Beckman Coulter, Inc. have 24 hour Customer Service and Support, which most small 3rd party companies do not provide. In addition, you will get (2) Preventive Maintenance visits per year by certified Beckman Coulter engineers. Preventive maintenance increases instrument reliability, minimized down time, and assures performance to published specifications.

The Standard Plus Service Agreement (8a – 5p, M-F) includes 2 preventive maintenance visits scheduled during normal business hours, unlimited service visits (labor and travel),and all necessary replacement parts, excluding disposables and customer maintenance and operation supplies, during normal business hours. **Service is provided by the manufacturer, Beckman Coulter with certified engineers and guaranteed parts.**

Beckman Coulter, Inc has a Technical Support hotline available at the following number:

Beckman Coulter **800-854-3633**

Customers are requested to contact the Siemens Healthcare Diagnostics Technical Support Center (TSC) **twenty-four hours per day, seven days per week** for all inquiries; including clinical and technical phone assistance or on-site service requests at this number:

Syva Technical Solutions Center 1.800.227.8994

The TSC is Siemens Healthcare Diagnostics' front line operation to resolve minor issues and get the equipment operational as fast as possible. Our TSC personnel, System Specialists, and Engineers

possess a strong clinical and/or technical background. If our TSC personnel determine that more extensive on-site service is required they will notify the local Technical

Application Specialist (TAS). The TAS will call you to schedule a visit and determine if additional parts or resources may be required.

TSC reps and FSR reps have completed manufacturer-authorized training courses and continue to receive the latest technical documentation. Our FSR reps are equipped with the recommended alignment tools and calibration equipment so instruments are repaired to the manufacturer's specifications.

Although over 90% of the incoming calls can be corrected over the phone, if a Siemens Technical Representative or Beckman Field Service engineer is needed, one will be dispatched within 24 hours to the customer.

Siemens has stated the ability of our Technical Service, and Support group to ensure that the analyzer is operational and properly maintained for the term of the contract.

1. Siemens –Syva division has not received any FDA FD 483 observations or FDA warning letters. However other Siemens manufacturing site received a warning letters**.** The FDA routinely inspects the facilities of Siemens Healthcare Diagnostics and as a result of those inspections has occasionally made Form 483 Observations. In 2012, the Company has received three Warning Letters related to recent inspections of its Tarrytown NY, Walpole MA and Glasgow DE facilities. In each case, the Company has submitted detailed responses and action plans to address the concerns raised by FDA. On January 28, 2013, the FDA issued an official close-out letter to the Company with respect to the Glasgow DE Warning Letter. In the case of the Warning Letter for the Walpole facility, the FDA has informed the Company that it believes the Company's response appears to be adequate.

2. Syva has not had any product recalls in the past three years.

3. Siemens acknowledges this bid specification.

F. Training

- Siemens acknowledges this section and can meet the requirements herein.

  By choosing Siemens Healthcare Diagnostics, you will receive a total of <u>2 training slots</u>, including travel, meals, and lodging.

Siemens and Beckman Coulter have extensive training offerings for customers. The training on the AU680 is done at the Beckman Coulter facility in Brea, CA and is a 4 day Training class. ***All travel, meals, lodging, and training will be at no cost to LFUCG.***

Additional training can be provided at no additional charge in the field, as needed, to recertify operators.

Training is instructor-led and primarily in front of analyzers and software. The program is instructor-led and consists of hands-on exercises, practice runs, and maintenance.

- Basic course objectives are as follows:
- Acquire an understanding of the operation and function of the hardware components.
- Perform the daily Start Up and End Process procedures.
- Perform reagent blanks, calibrations, QC, routine, stat, and repeat sample analysis.
- Interpret the data printout.
- Use basic software menus and perform basic software operations.
- Perform routine operation procedures.
- Explain the different analyzer modes. Recover from Warm Up, Stop, and EM Stop.
- Perform scheduled and as needed maintenance.
- Identify and perform corrective actions for error flags and alarms.
- Apply a logical thought process to troubleshooting problems.

This valuable training is not available by 3rd party vendors. The training by the manufacturer is most important and will ensure for a smooth and easy transition for your lab technicians.

Siemens will provide a tenured Technical Application Specialist (TAS) to provide additional training when the analyzer has been installed. At the completion of this install the Siemens Healthcare Diagnostics Technical Applications Specialist (TAS) will come on-site and install the Syva EMIT drug testing reagents listed in this bid. We will set up all reagents at the requested cut-offs of the LFUCG lab staff and run the proper calibration studies to make sure the Syva EMIT reagents are running and working properly on the proposed instrument. This service will take approximately 2-3 days and will remain on-site until LFUCG is comfortable running live samples.

Both, Siemens and Beckman provide on-line training opportunities for customers. Webinars are also held by Siemens on some of today's hot topics in the world of drugs of abuse.

G. Maintenance, and Repairs-Field Equipment

1. The Standard Plus Service Agreement (8a – 5p, M-F) includes 2 preventive maintenance visits scheduled during normal business hours, unlimited service visits (labor and travel),and all necessary replacement parts, excluding disposables and customer maintenance and operation supplies, during normal business hours. **Service is provided by the manufacturer, Beckman Coulter with certified engineers and guaranteed parts.**

2. The Beckman Coulter AU680 is operated through a new and highly intuitive graphic user interface, including embedded videos to support key maintenance steps. Daily operator maintenance can be performed on the AU680 on average of five (5) minutes. Beckman Coulter offers On Demand training that will help you meet your education needs by offering training solutions 24 hours a day, 7 days a week. AU680 Daily Start-up and System Overview are a few of the titles available. A wide variety of tools and aid to assist you in mastering the AU680 are included in this bid submission. Competency checklists have been provided detailing weekly, bi-weekly and monthly maintenance that will be performed by the lab staff.

3. The AU680 is a fully automated, random-access clinical chemistry system with Stat capability.

H. Analyzer

1. In conjunction with the Data management system that Siemens is providing, data is safely backed up and stored.
2. Siemens will be providing a UPS – this will allow the users to safely shutdown the analyzer and not experience a loss of data.
3. Siemens acknowledges this statement.
4. Enclosed within the bid submissions is the FDA certificate regarding the AU680 as requested.
5. The AU680 provides automated cleaning and system checks. These processes are covered in-depth at the training session in Brea, CA.
6. The AU680 is an open channel chemistry analyzer.
7. Upon Installation the calibrators for each test are programmed into the analyzer by the installer. The calibration process includes a Blue Rack which is the Reagent Blank rack and Yellow Calibration Racks where the calibrators are placed. Once the calibration is requested, the operator can select “Display Cup Set” and they will have a visual representation of what racks to use and where to put the calibrators. On the analyzer, the operator chooses Request calibration and a screen with all the tests appears and the operator selects the tests to calibrate. They will the place the racks on the analyzer and select Start. Calibration data can be viewed “real time” as the calibrations are completed. Calibrations are stable until QC goes out of established QC ranges which are programmed into the analyzer.
8. Upon Installation the Quality Control material positions are defined for each test in the QC Parameter screen by the installer. The Green racks are used for QC. Once positions are assigned, all the QC ranges are programmed into the analyzer by the installer. QC Requisition is the same as Calibration Requisition….Select QC Requisition and choose tests. Display Cup Set will tell the operator where to put the required QC material. When QC is run, if it falls out of the programmed range the analyzer will alarm indicating which QC is out. The QC program provides:

    - QC statistics for Cumulative Data

- The Daily Chart graphs all the data points for each day along with the daily statistics.

- When index is changed (done daily) the daily qc goes to the Day to Day QC where you can view the QC over a period if time. Again with the cumulative statistics.

Daily and Day to Day graphs can be printed for record keeping.

9. The new, Beckman Coulter AU680 analyzer meets or exceeds this bid requirement.

The AU680® is designed for the demanding environments of mid-sized to large laboratories and hospitals. Flexibility of design offers stand-alone operation or connectivity to lab automation systems for direct sampling, with random access throughput of up to 800 photometric tests per hour (up to 1200 with electrolytes), on-board menu of up to 63 tests and user-definable options for many operations such as sample handling and customized testing. The AU680 delivers field proven reliability and efficiency for real world labs today and tomorrow.

I. Reagents

1. Siemens acknowledges and can meet the list of reagents used in this RFP submission.

2. Enclosed is a list of the FDA approved reagents.

3. Siemens has enclosed the cut-off's as requested:

EMIT Reagents

Syva chemists developed the first commercial homogeneous enzyme immunoassay and marketed the assay under the trademark EMIT. EMIT an acronym, stands for Enzyme Multiplied Immunoassay Technique.

All of our assays utilize the EMIT Chemistry. There are 2 reagents in this system. Rgt A & B. Reagent A contains antibodies, substrate (glucose-6-phosphrate) and co-enzyme (NAD) Rgt. B contains the enzyme labeled drug. The EMIT assay has shown excellent correlation with confirmatory **GC/MS >99%.**

Syva EMIT® immunoassays are the most widely used and scientifically documented screening tests available for drugs of abuse. No other drugs of abuse screening tests have a longer or more reliable record. The combination of Syva drug testing products and GC/MS for confirmation has been acknowledged by the U.S. Supreme Court as highly accurate.

The Syva division of Siemens builds reliability into every test it markets. Each EMIT® assay must pass a rigorous testing protocol to show that it can consistently distinguish between negative (drug-free or containing drug levels below the EMIT® assay cutoff) and positive (containing drug levels above the EMIT® assay cutoff) samples. The results of our studies are confirmed by independent laboratories. Overall, thousands of hours of testing are required before a new assay is ready to be marketed.

Once an assay is on the market, each newly manufactured lot must pass additional testing procedures. A production lot is not released unless it meets performance criteria during quality assurance testing.

Each EMIT® assay is repeatedly tested on drug-free urine samples and samples containing know drug concentrations. In addition, EMIT® assays are subjected to multiple tests performed on different instruments by different operators. All results are compared to reference methods, including gas chromatography/mass spectrometry (GC/MS).

As stated above, the EMIT® immunoassays are the most widely used and documented methodology available for screening. The majority of SAMSHA laboratories, over 85%, use the Syva EMIT® immunoassays for screening. In addition, the Syva Division is considered to be the gold standard in drug screening, and have been the gold standard for over 45 years.

Siemens Healthcare Diagnostics is the only Pioneer Member for the National Association of Drug Court Professionals (NADCP), and works closely with this agency as a Pioneer Member providing drug testing solutions and trainings for their national conferences.

Siemens Healthcare Diagnostics has the following reagents available. Note many reagents have multiple cutoff levels available:

Name	Cutoff /Calibrator Concentrations
• Amphetamine/Methamphetamine.	300, 500, 1,000 ng/ml
• Barbiturates	200, 300 ng/ml
• Benzodiazepines	200, 300 ng/ml
• Cocaine	150, 300 ng/ml
• Ecstasy	300, 500 ng/ml
• Cannabinoid	20, 50, 100 ng/ml
• Ethyl Alcohol	Quantitative
• LSD	0.5 ng/mL
• Methadone	150,300 ng/ml
• Methaqualone	300 ng/ml
• Opiate	300, 2,000 ng/ml
• PCP	25 ng/ml
• Propoxphene	300 ng/ml
• 6-Acetylmorphine	10 ng/ml
• ****ETG	**500, 1000 ng/ml**
• ****Oxycodone**	**100, 300 ng/ml**
• ****Tramadol**	**200 ng/ml**
• ****Bupenorphine**	**5 ng/ml**
• ****Merpidine**	**200 ng/ml**
• ****Methadone/EDDP**	**300 ng/ml**

****Forensic Use Only**

Siemens Healthcare Diagnostics Inc. has the following EMIT ® Syva Specimen Validity Tests available:

- *Creatinine*

- *Nitrites*
- *Oxidants*
- *pH*
- *Specific Gravity*

*All EMIT II ® reagents are liquid, ready to use reagents.

*All EMIT II ® calibrators and controls are liquid, ready to use reagents

4. Siemens guarantees 90 day (3 month) dating on reagents, calibrators and controls. Siemens, Syva EMIT® II Plus Reagents are stable once opened or left unopened and stored in accordance with the Information for Use (IFU) until the bottle expiration date. Siemens Healthcare Diagnostics standard reagent shipping policy states that no reagents will be shipped with less than a 3 month shelf life. The average shelf life for reagents range from 6 to 18 months when stored in accordance with the IFU.

- Material Safety Data Sheets (MSDS) and the descriptive literature for each reagent are provided in each container provided by Siemens. The package insert states the procedure for each reagent.

- Any reagents that do not perform according to Siemens' manufacture read statements and protocols will be replaced at no additional cost.

5. Siemens acknowledges this statement.

6. Enclosed on the electronic version of RFP # 13-2013 is a Cross Reactivity guide.

J. Miscellaneous

1 – 4. Siemens agrees and can meet these specifications.

K. Pricing

1. Pricing in Both formats. See pricing spreadsheet for further information.

L. References

1. Siemens acknowledges this statement and has provided a minimum of 6 references per the bid specification.

2. Siemens acknowledges this statement.

(References)

St. Elizabeth Medical Center South
1 Medical Village Drive
Edgewood, KY 41017
Contact: Barbara Baker
Phone: (859) 301-7278

Analyzer: Beckman AU480

County of Jefferson Metro Health Center
400 East Gray Street
Louisville, KY 40202
Contact: Gwen Nixon
Phone: (502) 574-6540
Analyzer: Beckman AU480

Davidson County Community Corrections
408 2'nd Avenue N, Suite 2100
Nashville, TN 37201
Contact: John Holley
Phone: (615) 880-2269
Analyzer: Beckman AU400

South Bend Medical Foundation (SAMHSA Lab)
530 N. Lafayette Blvd.
South Bend, IN 46601
Contact: Dr. Prentiss Jones
Phone: (574) 234-4176
Analyzer: (2) Beckman AU2700

Substance Abuse Screening Lab - Division of Community Corrections
315 Spring Garden Street, Suite 1B
Greensboro, NC 27401
Contact: Steven Worthy
Phone: (919) 716-3189
Analyzer: (2) Beckman AU400

St. Joseph County Adult Probation & Drug Court
125 S. Lafayette Blvd., Suite 200
South Bend, IN 46601
Contact: Jesse Carlton
Phone: (574) 235-9565
Analyzer: Beckman AU680

WARRANTY AND LIMITATION OF LIABILITY

LFUCG acknowledges that Siemens Healthcare Diagnostics, Inc. is not the manufacturer of the Equipment and that Siemens Healthcare Diagnostics, Inc. is arranging for installation of the Equipment at Customer's Premises in return for Customer's commitment to purchase Consumables from Siemens Healthcare Diagnostics, Inc. Siemens Healthcare Diagnostics, Inc. hereby assigns and transfers to Customer any and all warranties relating to the Equipment which Siemens Healthcare Diagnostics, Inc. receives from the Equipment's manufacturer Olympus. Customer may contact Beckman Coulter directly to discuss such warranties.

Siemens Healthcare Diagnostics, Inc. warrants that the Consumables shall be free from defects in material and workmanship and conform to the manufacturer's specifications when delivered. SIEMENS HEALTHCARE DIAGNOSTICS, INC. MAKES NO OTHER WARRANTIES, EXPRESS, STATUTORY OR IMPLIED, IN CONNECTION WITH THE EQUIPMENT OR CONSUMABLES, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY AS TO DESIGN, MERCHANTABILITY, OR FITNESS FOR ANY PURPOSE. Any claim for breach of this warranty, if any, must be made in writing within one (1) year of the delivery of the product by Siemens Healthcare Diagnostics, Inc. Siemens Healthcare Diagnostics, Inc.'s sole obligation for breach of this warranty shall be, at Siemens Healthcare Diagnostics, Inc.'s option, the repair or replacement of the breaching product or an appropriate refund, allowance or credit reflecting depreciation. In no event shall Siemens Healthcare Diagnostics, Inc. be liable for any special, consequential, or indirect damages. Siemens Healthcare Diagnostics, Inc. also promises that the use of the Consumables in the form delivered to Customer and in accordance with the instructions and manufacturer's specifications will not infringe the U.S. patent of any third party. This promise does not cover the use of the Consumables in combination with any other product or equipment not approved by Siemens Healthcare Diagnostics, Inc.

No oral or written promises as to the Equipment or Consumables which conflict with this Warranty and Limitation of Liability will bind Siemens Healthcare Diagnostics, Inc. unless signed by an authorized representative of the party to be bound.

Ordering and Handling:

- Material Safety Data Sheets (MSDS) and the descriptive literature for each reagent are provided in each container provided by Siemens. The package insert states the procedure for each reagent.

- Any reagents that do not perform according to Siemens' manufacture read statements and protocols will be replaced at no additional cost.

On-Site Maintenance/Installation

Upon bid award, Siemens Healthcare Diagnostics will coordinate with a Beckman engineer to visit the account and do a complete Beckman 680 Site Survey Questionnaire. The purpose of the Site Survey is to meet with the customer and ensure all electrical and water requirements are sufficient, as well as space, etc.

The engineer will leave a copy of the Site Survey with the customer. Once the site is prepared and ready, the shipment and delivery of the analyzers will be determined. A Beckman Field Service engineer will meet the truck upon arrival and complete the full installation of the analyzer.

Upon final installation, the Beckman engineer will fill out the 680 Installation Quality Control Check list.

Repair equipment
If the Technical Support Hotline cannot correct the problem, either a field service engineer or technical service representative will be dispatched within 24 hours to repair the system.

Replacement Part
Any replacement parts or repairs needed for the Beckman analyzer will be provided at no charge.

Preventive Maintenance
Two times per year Beckman Field Service Engineers will perform a Preventive Maintenance on the analyzer.

Operations/Maintenance Manual
One Beckman Operations and maintenance manual for the Beckman AU480 Clinical Chemistry system will be shipped with the system. There is daily, weekly, and monthly maintenance on the systems, which will be performed by the technical staff at the laboratory. Any preventive bi-annual maintenance or repairs, etc., will be performed by Beckman engineers.

SUBCONTRACTING:

- No subcontractors will be used for this bid.

Lexington Fayette Urban County Government

Solicitation Number: 13-2013

Beckman Coulter AU680 Drug Testing Analyzer with WinTOX

Catalog Number	Product/Packaging	Price	Test/Kit	Cost/Test
DAT Group N				
9K409UL	Emit® II Plus Alcohol, 1L	$ 2,275.00	6250	$ 0.52
DAT Group Q				
9D129UL	Emit® II Plus Barbiturate 1L	$ 4,628.00	8900	$ 0.52
9F129UL	Emit® II Plus Benzodiazepine, 1L	$ 4,628.00	8900	$ 0.52
9H129UL	Emit® II Plus Cocaine Metabolite, 1LL	$ 5,070.00	9750	$ 0.52
9C329UL	Emit® II Plus Amphetamine, 1L	$ 4,342.00	8350	$ 0.52
9E129UL	Emit® II Plus Methadone, 1L	$ 4,628.00	8900	$ 0.52
9B329UL	Emit® II Plus Opiate, 1L	$ 5,327.40	10,245	$ 0.52
DAT Group R				
9N129UL	Emit® II Plus Cannabinoid, 1L	$ 3,410.68	8430	$ 0.52
DAT Group V	28 mL - 30 mL			
9R039UL	Emit® II Plus 6-AM	$ 147.00	285	$ 0.70
Syva Validity Tests				
3T019UL	Creatinine Reagent Kit - Large	$ 666.00	3840	$ 0.10
3T699UL	Syva Specific Gravity Validity Test R Large	$ 441.00	5355	$ 0.10
3T899UL	Syva Specific Gravity Validity Test R small	$ 49.00	590	$ 0.10
3T289UL	Syva pH Validity Test R Large	$ 472.50	5630	$ 0.10
Forensic Use Only				
10718394	Buprenorphine 100 mL	$566.00	1132	$ 0.50
10718393	Buprenorphine 25 mL	$141.50	283	$ 0.50
10718395	Buprenorphine 500 mL	$2,830.50	5661	$ 0.50
10718401	Oxycodone 100 mL	$566.00	1132	$ 0.50
10718399	Oxycodone 25 mL	$141.50	283	$ 0.50
10718402	Oxycodone 500 mL	$2,830.50	5661	$ 0.50
10718404	Tramadol 100 mL	$ 962.20	1132	$ 0.85
10718403	Tramadol 25 mL	$ 240.55	283	$ 0.85
10718405	Tramadol 500 mL	$ 4,811.85	5661	$ 0.85
10718410	Ethyl Glucuronide 100 mL	$ 650.00	1000	$ 0.65
10718409	Ethyl Glucuronide 25 mL	$ 162.50	250	$ 0.65
10718711	Ethyl Glucuronide 500 mL	$ 3,250.00	5000	$ 0.65
10718407	Methadone/EDDP 100 mL	$ 495.00	900	$ 0.55
10718406	Methadone/EDDP 25 mL	$ 123.75	225	$ 0.55
10718408	Methadone/EDDP 500 mL	$ 2,475.00	4500	$ 0.55
10718397	Meperidine 100 mL	$ 905.60	1132	$ 0.80
10718396	Meperidine 25 mL	$ 226.40	283	$ 0.80
10718398	Meperidine 500 mL	$ 4,528.80	5661	$ 0.80

Emit II Calibrators/Controls

Catalog Number	Product/Packaging	Price
9A509	Emit Calibrator/Control Level 0	Included

9A529	Emit Calibrator/Control Level 1	Included
9A549	Emit Calibrator/Control Level 2	Included
9A569	Emit Calibrator/Control Level 3	Included
9A589	Emit Calibrator/Control Level 4	Included
9A609	Emit Calibrator/Control Level 5	Included
9K029	Calibrator Alcohol Negative	Included
9K049	Control Alcohol, Low	Included
9K059	Calibrator Alcohol 100	Included
9K079	Control Alcohol, High	Included
3T159UL	Creatinine Validity Calibrator 400	Included
3T139UL	Creatinine Validity Calibrator 20	Included
3T149UL	Creatinine Validity Calibrator 100	Included
3T129UL	Validity Negative Calibrator/Control	Included
9M109UL	Cannabinoid 100 ng Calib., 5	Included
9M859UL	Cannabinoid 100 ng Calib., 100 mL	Included
9M209UL	Cannabinoid 20 ng Calib., 5	Included
9M129UL	Cannabinoid 200 ng Calib., 5	Included
9M509UL	Cannabinoid 50 ng Calib., 5	Included
9R529UL	Emit II Plus 6-AM Calibrator/Control Level 1	Included
9R549UL	Emit II Plus 6-AM Calibrator/Control Level 2	Included
9R569UL	Emit II Plus 6-AM Calibrator/Control Level 3	Included
9R589UL	Emit II Plus 6-AM Calibrator/Control Level 4	Included
C341-10-1-1000	Ethyl Glucuronide 1000 ng/mL Calibrator	Included
C341-10-2-500	Ethyl Glucuronide 375 and 625 ng/mL Controls	Included
C341-10-1-500	Ethyl Glucuronide 500 ng/mL Calibrator	Included
C341-10-2-1000	Ethyl Glucuronide 750 and 1250 ng/mL Controls	Included
C302-10-1-100	Oxycodone 100 ng/mL Calibrator	Included
C302-10-1-300	Oxycodone 300 ng/mL Calibrator	Included
C302-10-2-300	Oxycodone 225 and 375 ng/mL Controls	Included
C302-10-2-100	Oxycodone 75 and 125 ng/mL Controls	Included
C302-10-5	Oxycodone Calibrators 0, 100, 300, 500, 1000 ng/mL	Included
C304-10-2	Tramadol 150 and 250 ng/mL controls	Included
C304-10-1	Tramadol 200 ng/mL Calibrator	Included
C304-10-5	Tramadol Calibrators 0, 100, 200, 500 and 1000 ng/mL	Included
C336-10-2	Buprenorphine 3.75 and 6.25 ng/mL controls	Included
C336-10-1	Buprenorphine 5 ng/mL Calibrator	Included
C336-10-5	Buprenorphine Calibrators 0, 5, 10, 20 and 40 ng/mL	Included

Lexington Fayette Urban County Government

Solicitation Number: 13-2013

Onsite AU400 Drug Testing Analyzer sn#5123575 with WinTOX

Catalog Number	Product/Packaging	Price	Test/Kit	Cost/Test
DAT Group N				
9K409UL	Emit® II Plus Alcohol, 1L	$ 2,275.00	6250	$ 0.50
DAT Group Q				
9D129UL	Emit® II Plus Barbiturate 1L	$ 4,450.00	8900	$ 0.50
9F129UL	Emit® II Plus Benzodiazepine, 1L	$ 4,450.00	8900	$ 0.50
9H129UL	Emit® II Plus Cocaine Metabolite, 1LL	$ 4,875.00	9750	$ 0.50
9C329UL	Emit® II Plus Amphetamine, 1L	$ 4,175.00	8350	$ 0.50
9E129UL	Emit® II Plus Methadone, 1L	$ 4,450.00	8900	$ 0.50
9B329UL	Emit® II Plus Opiate, 1L	$ 5,122.50	10,245	$ 0.50
DAT Group R				
9N129UL	Emit® II Plus Cannabinoid, 1L	$ 3,410.68	8430	$ 0.50
DAT Group V	28 ml - 30 mL			
9R039UL	Emit® II Plus 6-AM	$ 147.00	285	$ 0.65
Syva Validity Tests				
3T019UL	Creatinine Reagent Kit - Large	$ 666.00	3840	$ 0.08
3T699UL	Syva Specific Gravity Validity Test R Large	$ 441.00	5355	$ 0.08
3T899UL	Syva Specific Gravity Validity Test R small	$ 49.00	590	$ 0.08
3T289UL	Syva pH Validity Test R Large	$ 472.50	5630	$ 0.08
Forensic Use Only				
10718394	Buprenorphine 100 mL	$566.00	1132	$ 0.50
10718393	Buprenorphine 25 mL	$141.50	283	$ 0.50
10718395	Buprenorphine 500 mL	$2,830.50	5661	$ 0.50
10718401	Oxycodone 100 mL	$566.00	1132	$ 0.50
10718399	Oxycodone 25 mL	$141.50	283	$ 0.50
10718402	Oxycodone 500 mL	$2,830.50	5661	$ 0.50
10718404	Tramadol 100 mL	$ 962.20	1132	$ 0.85
10718403	Tramadol 25 mL	$ 240.55	283	$ 0.85
10718405	Tramadol 500 mL	$ 4,811.85	5661	$ 0.85
10718410	Ethyl Glucuronide 100 mL	$ 650.00	1000	$ 0.65
10718409	Ethyl Glucuronide 25 mL	$ 162.50	250	$ 0.65
10718711	Ethyl Glucuronide 500 mL	$ 3,250.00	5000	$ 0.65
10718407	Methadone/EDDP 100 mL	$ 495.00	900	$ 0.55
10718406	Methadone/EDDP 25 mL	$ 123.75	225	$ 0.55
10718408	Methadone/EDDP 500 mL	$ 2,475.00	4500	$ 0.55
10718397	Meperidine 100 mL	$ 905.60	1132	$ 0.80
10718396	Meperidine 25 mL	$ 226.40	283	$ 0.80
10718398	Meperidine 500 mL	$ 4,528.80	5661	$ 0.80

Emit II Calibrators/Controls

Catalog Number	Product/Packaging	Price
9A509	Emit Calibrator/Control Level 0	Included
9A529	Emit Calibrator/Control Level 1	Included

9A549	Emit Calibrator/Control Level 2	Included
9A569	Emit Calibrator/Control Level 3	Included
9A589	Emit Calibrator/Control Level 4	Included
9A609	Emit Calibrator/Control Level 5	Included
9K029	Calibrator Alcohol Negative	Included
9K049	Control Alcohol, Low	Included
9K059	Calibrator Alcohol 100	Included
9K079	Control Alcohol, High	Included
3T159UL	Creatinine Validity Calibrator 400	Included
3T139UL	Creatinine Validity Calibrator 20	Included
3T149UL	Creatinine Validity Calibrator 100	Included
3T129UL	Validity Negative Calibrator/Control	Included
9M109UL	Cannabinoid 100 ng Calib., 5	Included
9M859UL	Cannabinoid 100 ng Calib., 100 ml	Included
9M209UL	Cannabinoid 20 ng Calib., 5	Included
9M129UL	Cannabinoid 200 ng Calib., 5	Included
9M509UL	Cannabinoid 50 ng Calib., 5	Included
9R529UL	Emit II Plus 6-AM Calibrator/Control Level 1	Included
9R549UL	Emit II Plus 6-AM Calibrator/Control Level 2	Included
9R569UL	Emit II Plus 6-AM Calibrator/Control Level 3	Included
9R589UL	Emit II Plus 6-AM Calibrator/Control Level 4	Included

Explain difference in Kit yield.

Lexington Fayette Urban County Government

Solicitation Number: 13-2013

Beckman Coulter AU680 Drug Testing Analyzer with WinTOX

Catalog Number	Product/Packaging	Price	Test/Kit	Cost/Test
DAT Group N				
9K409UL	Emit® II Plus Alcohol, 1L	$ 2,275.00	6250	$ 0.52
DAT Group Q				
9D129UL	Emit® II Plus Barbiturate 1L	$ 4,628.00	8900	$ 0.52
9F129UL	Emit® II Plus Benzodiazepine, 1L	$ 4,628.00	8900	$ 0.52
9H129UL	Emit® II Plus Cocaine Metabolite, 1LL	$ 5,070.00	9750	$ 0.52
9C329UL	Emit® II Plus Amphetamine, 1L	$ 4,342.00	8350	$ 0.52
9E129UL	Emit® II Plus Methadone, 1L	$ 4,628.00	8900	$ 0.52
9B329UL	Emit® II Plus Opiate, 1L	$ 5,327.40	10,245	$ 0.52
DAT Group R				
9N129UL	Emit® II Plus Cannabinoid, 1L	$ 3,410.68	8430	$ 0.52
DAT Group V	28 ml - 30 mL			
9R039UL	Emit® II Plus 6-AM	$ 147.00	285	$ 0.70
Syva Validity Tests				
3T019UL	Creatinine Reagent Kit - Large	$ 666.00	3840	$ 0.10
3T699UL	Syva Specific Gravity Validity Test R Large	$ 441.00	5355	$ 0.10
3T899UL	Syva Specific Gravity Validity Test R small	$ 49.00	590	$ 0.10
3T289UL	Syva pH Validity Test R Large	$ 472.50	5630	$ 0.10

Emit II Calibrators/Controls

Catalog Number	Product/Packaging	Price
9A509	Emit Calibrator/Control Level 0	Included
9A529	Emit Calibrator/Control Level 1	Included
9A549	Emit Calibrator/Control Level 2	Included
9A569	Emit Calibrator/Control Level 3	Included
9A589	Emit Calibrator/Control Level 4	Included
9A609	Emit Calibrator/Control Level 5	Included
9K029	Calibrator Alcohol Negative	Included
9K049	Control Alcohol, Low	Included
9K059	Calibrator Alcohol 100	Included
9K079	Control Alcohol, High	Included
3T159UL	Creatinine Validity Calibrator 400	Included
3T139UL	Creatinine Validity Calibrator 20	Included
3T149UL	Creatinine Validity Calibrator 100	Included
3T129UL	Validity Negative Calibrator/Control	Included
9M109UL	Cannabinoid 100 ng Calib., 5	Included
9M859UL	Cannabinoid 100 ng Calib., 100 ml	Included
9M209UL	Cannabinoid 20 ng Calib., 5	Included
9M129UL	Cannabinoid 200 ng Calib., 5	Included
9M509UL	Cannabinoid 50 ng Calib., 5	Included
9R529UL	Emit II Plus 6-AM Calibrator/Control Level 1	Included
9R549UL	Emit II Plus 6-AM Calibrator/Control Level 2	Included
9R569UL	Emit II Plus 6-AM Calibrator/Control Level 3	Included
9R589UL	Emit II Plus 6-AM Calibrator/Control Level 4	Included

Lexington Fayette Urban County Government				
Solicitation Number: 13-2013				
Onsite AU400 Drug Testing Analyzer sn#5123575 with WinTOX				
Catalog Number	**Product/Packaging**	**Price**	**Test/Kit**	**Cost/Test**
DAT Group N				
9K409UL	Emit® II Plus Alcohol, 1L	$2,275.00	6250	$ 0.50
DAT Group Q				
9D129UL	Emit® II Plus Barbiturate 1L	$4,450.00	8900	$ 0.50
9F129UL	Emit® II Plus Benzodiazepine, 1L	$4,450.00	8900	$ 0.50
9H129UL	Emit® II Plus Cocaine Metabolite, 1LL	$4,875.00	9750	$ 0.50
9C329UL	Emit® II Plus Amphetamine, 1L	$4,175.00	8350	$ 0.50
9E129UL	Emit® II Plus Methadone, 1L	$4,450.00	8900	$ 0.50
9B329UL	Emit® II Plus Opiate, 1L	$5,122.50	10,245	$ 0.50
DAT Group R				
9N129UL	Emit® II Plus Cannabinoid, 1L	$3,410.68	8430	$ 0.50
DAT Group V	28 ml - 30 mL			
9R039UL	Emit® II Plus 6-AM	$ 147.00	285	$ 0.65
Syva Validity Tests				
3T019UL	Creatinine Reagent Kit - Large	$ 666.00	3840	$ 0.08
3T699UL	Syva Specific Gravity Validity Test R Large	$ 441.00	5355	$ 0.08
3T899UL	Syva Specific Gravity Validity Test R small	$ 49.00	590	$ 0.08
3T289UL	Syva pH Validity Test R Large	$ 472.50	5630	$ 0.08

Emit II Calibrators/Controls

Catalog Number	Product/Packaging	Price
9A509	Emit Calibrator/Control Level 0	Included
9A529	Emit Calibrator/Control Level 1	Included
9A549	Emit Calibrator/Control Level 2	Included
9A569	Emit Calibrator/Control Level 3	Included
9A589	Emit Calibrator/Control Level 4	Included
9A609	Emit Calibrator/Control Level 5	Included
9K029	Calibrator Alcohol Negative	Included
9K049	Control Alcohol, Low	Included
9K059	Calibrator Alcohol 100	Included
9K079	Control Alcohol, High	Included
3T159UL	Creatinine Validity Calibrator 400	Included
3T139UL	Creatinine Validity Calibrator 20	Included
3T149UL	Creatinine Validity Calibrator 100	Included
3T129UL	Validity Negative Calibrator/Control	Included
9M109UL	Cannabinoid 100 ng Calib., 5	Included
9M859UL	Cannabinoid 100 ng Calib., 100 ml	Included
9M209UL	Cannabinoid 20 ng Calib., 5	Included
9M129UL	Cannabinoid 200 ng Calib., 5	Included
9M509UL	Cannabinoid 50 ng Calib., 5	Included
9R529UL	Emit II Plus 6-AM Calibrator/Control Level 1	Included
9R549UL	Emit II Plus 6-AM Calibrator/Control Level 2	Included
9R569UL	Emit II Plus 6-AM Calibrator/Control Level 3	Included
9R589UL	Emit II Plus 6-AM Calibrator/Control Level 4	Included

FDA Approved Reagents for Siemens Healthcare Diagnostics, Inc.

Syva® Emit 2000	Carbamazepine Assay	4F019UL	K913066
Syva® Emit 2000	Carbamazepine Calibrators	4F109UL	K913066
Syva® Emit 2000	Cyclosporine Negative Cal.	6R319UL	P920031
Syva® Emit 2000	Cyclosporine Specific Assay	6R079UL	K053061
Syva® Emit 2000	Cyclosporine Specific Assay	6R079UL	P920031
Syva® Emit 2000	Cyclosporine Specific Cal.	6R119UL	P920031
Syva® Emit 2000	Digoxin Assay	4H019UL	K951755
Syva® Emit 2000	Digoxin Calibrators	4H209UL	K934135
Syva® Emit 2000	Gentamicin Plus Assay	4T039UL	K962519
Syva® Emit 2000	Gentamicin Plus Calibrators	4T209UL	K962519
Syva® Emit 2000	N-Acetylprocainamide Assay	4N019UL	K922915
Syva® Emit 2000	N-Acetylprocainamide Cals	4N109UL	K922915
Syva® Emit 2000	Phenobarbital Assay	4D019UL	K913190
Syva® Emit 2000	Phenobarbital Calibrators	4D109UL	K913190
Syva® Emit 2000	Phenytoin Assay	4A019UL	K913429
Syva® Emit 2000	Phenytoin Calibrators	4A109UL	K913429
Syva® Emit 2000	Procainamide Assay	4K019UL	K922914
Syva® Emit 2000	Procainamide Calibrators	4K109UL	K922914
Syva® Emit 2000	Quinidine Assay	4Q019UL	K922913
Syva® Emit 2000	Quinidine Calibrators	4Q109UL	K922913
Syva® Emit 2000	Siro/Tacro Sample Pretreatment Reagent	8S079UL	K083487
Syva® Emit 2000	Sirolimus Assay	8S019UL	K083487
Syva® Emit 2000	Sirolimus Calibrators	8S109UL	K083487
Syva® Emit 2000	Tacrolimus Assay	8R019UL	K060385
Syva® Emit 2000	Tacrolimus Calibrator	8R109UL	K060371
Syva® Emit 2000	Tacrolimus Sample Pretreatment Reagent	8R079UL	K060385
Syva® Emit 2000	Theophylline Assay	4P019UL	K913123
Syva® Emit 2000	Theophylline Calibrators	4P109UL	K913123

FDA Approved Reagents for Siemens Healthcare Diagnostics, Inc.

Syva® Emit 2000	Tobramycin Assay	4S019UL	K003341
Syva® Emit 2000	Tobramycin Calibrators	4S109UL	K003341
Syva® Emit 2000	Valproic Acid Assay	4G019UL	K002551
Syva® Emit 2000	Valproic Acid Calibrators	4G109UL	K002551
Syva® Emit 2000	Vancomycin Assay	4W019UL	K020692
Syva® Emit 2000	Vancomycin Calibrators	4W109UL	K020845
Syva® Emit 2000 (Convenience Pack)	Cyclosporine Specific Assay (Convenience Pack)	6R019UL	P920031

Syva® Emit II Plus	6-Acetylmorphine Assay (Reagent 1)	9R039UL	K102779
Syva® Emit II Plus	6-Acetylmorphine Assay (Reagent 2)	9R129UL	K102779
Syva® Emit II Plus	6-AM/Ecstasy Calibrators/Controls Level 1 (5 ng/mL)	9R529UL	K102779
Syva® Emit II Plus	6-AM/Ecstasy Calibrators/Controls Level 2 (10 ng/mL)	9R549UL	K102779
Syva® Emit II Plus	6-AM/Ecstasy Calibrators/Controls Level 3 (15 ng/mL)	9R569UL	K102779
Syva® Emit II Plus	6-AM/Ecstasy Calibrators/Controls Level 4 20 ng/mL)	9R589UL	K102779
Syva® Emit II Plus	Amphetamine Assay (115 ml)	9C309UL	K031004
Syva® Emit II Plus	Amphetamine Assay (1L)	9C329UL	K031004
Syva® Emit II Plus	Amphetamine Assay (29 ml/12 ml)	9C039UL	K031004
Syva® Emit II Plus	Barbiturate Assay (115 ml)	9D029UL	K993987
Syva® Emit II Plus	Barbiturate Assay (1L)	9D129UL	K993987
Syva® Emit II Plus	Barbiturate Assay (28 ml/13 ml)	9D039UL	K993987
Syva® Emit II Plus	Benzodiazepine Assay (115 ml)	9F029UL	K993985
Syva® Emit II Plus	Benzodiazepine Assay (1L)	9F129UL	K993985
Syva® Emit II Plus	Benzodiazepine Assay (29 ml/12 ml)	9F039UL	K993985

FDA Approved Reagents for Siemens Healthcare Diagnostics, Inc.

Syva® Emit II Plus	Cannabinoid Assay (115 ml)	9N029UL	K993984
Syva® Emit II Plus	Cannabinoid Assay (1L)	9N129UL	K993984
Syva® Emit II Plus	Cannabinoid Assay (28 ml/12 ml)	9N039UL	K993984
Syva® Emit II Plus	Cocaine Metabolite Assay (115 ml)	9H029UL	K031512
Syva® Emit II Plus	Cocaine Metabolite Assay (1L)	9H129UL	K031512
Syva® Emit II Plus	Cocaine Metabolite Assay (28 ml/12 ml)	9H039UL	K031512
Syva® Emit II Plus	Ecstasy Assay	9X029UL	K043028
Syva® Emit II Plus	Ecstasy Assay (1L)	9X129UL	K043028
Syva® Emit II Plus	Ecstasy Calibrator/Control Level 1	9X529UL	K043028
Syva® Emit II Plus	Ecstasy Calibrator/Control Level 2	9X549UL	K043028
Syva® Emit II Plus	Ecstasy Calibrator/Control Level 3	9X569UL	K043028
Syva® Emit II Plus	Ecstasy Calibrator/Control Level 4	9X589UL	K043028
Syva® Emit II Plus	Ethyl Alcohol Assay (115 ml)	9K309UL	K993980
Syva® Emit II Plus	Ethyl Alcohol Assay (1L)	9K409UL	K993980
Syva® Emit II Plus	Ethyl Alcohol Assay (28 ml/12 ml)	9K039UL	K993980
Syva® Emit II Plus	Methadone Assay (115 ml)	9E029UL	K994005
Syva® Emit II Plus	Methadone Assay (1L)	9E129UL	K994005
Syva® Emit II Plus	Methadone Assay (29 ml/12 ml)	9E039UL	K994005
Syva® Emit II Plus	Methaqualone Assay (115 ml)	9Q029UL	K993986
Syva® Emit II Plus	Methaqualone Assay (1L)	9Q129UL	K993986
Syva® Emit II Plus	Methaqualone Assay (28 ml/12 ml)	9Q039UL	K993986
Syva® Emit II Plus	Opiate Assay (115 ml)	9B309UL	K971596

FDA Approved Reagents for Siemens Healthcare Diagnostics, Inc.

Syva® Emit II Plus	Opiate Assay (1L)	9B329UL	K971596
Syva® Emit II Plus	Opiate Assay (29 mL/11 mL)	9B039UL	K971596
Syva® Emit II Plus	Phencyclidine Assay (115 ml)	9J029UL	K993983
Syva® Emit II Plus	Phencyclidine Assay (1L)	9J129UL	K993983
Syva® Emit II Plus	Phencyclidine Assay (29 ml/12 ml)	9J039UL	K993983
Syva® Emit II Plus	Propoxyphene Assay (115 ml)	9G029UL	K993981
Syva® Emit II Plus	Propoxyphene Assay (1L)	9G129UL	K993981
S4/29/2013yva® Emit II Plus	Propoxyphene Assay (29 ml/12 ml)	9G039UL	K993981
Syva® Emit II Plus	6-AM (1 L)	9R129UL	K102779
Syva® Emit II Plus	6-AM (30 ml)	9R039UL	K102779

Inspections, Compliance, Enforcement, and Criminal Investigations

Siemens Healthcare Diagnostics, Inc. 6/29/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
PHILADELPHIA DISTRICT
900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

WARNING LETTER

12-PHI-18

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 29, 2012

Mr. Edward Leonard
Vice President, Global Logistics/Site Leader
Siemens Healthcare Diagnostics, Inc.
700 GBC Drive
Newark, DE 19702

Dear Mr. Leonard:

During an inspection of your facility located in Newark, Delaware, from December 14, 2011, to February 9, 2012, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures in vitro diagnostic products for human use. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, (21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a response from you dated February 14, 2012, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, which was issued to your firm. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a).

Specifically section **(b)(4)** contains **(b)(4)** considerations used by your firm to determine when a Replace on Complaint Action may be performed and when a Field Correction is required. During the 2010-2011 time period, your firm chose to replace on complaint instead of initiating a field correction on **(b)(4)** occasions. For example:

a. **(b)(4)** dated 5/18/11, was initiated as a result of multiple complaints associated with a high calibration failure rate for Mass CKMB Isoenzyme Calibrator, lot **(b)(4)** when used with certain reagents lots. Your firm's investigation revealed that the incorrect **(b)(4)** was assigned. A **(b)(4)** meeting was held 6/03/11 and the decision was made to scrap remaining inventory of **(b)(4)** and to replace on complaint for product already distributed. Your firm received **(b)(4)** additional complaints for this malfunction. Your firm's **(b)(4)** document specifies that a field correction is warranted if the situation has a significant impact on product usability/functionality or if it results in product not meeting performance specifications. When this failure

occurs, the device is unusable and cannot function as intended. This also results in the device not meeting its performance specifications. Your firm failed to initiate a field correction to control its nonconforming product as required by its documented procedures for addressing nonconforming products.

b. **(b)(4)** dated 9/08/11, was initiated as a result of multiple complaints associated with a low bias on quality control and patient results at the low end of the assay range following calibration with Mass CKMB Isoenzyme Calibrator lot **(b)(4)**. Your firm's investigation determined that **(b)(4)** are not adequate to prevent QC shifts, and a **(b)(4)** meeting was held 9/19/11.The **(b)(4)** meeting resulted in the decision to scrap remaining inventory **(b)(4)** and to replace on complaint for product already distributed. Your firm received **(b)(4)** additional complaints for this for this malfunction after the **(b)(4)** decision. When the bias exceeds the acceptable quality control range, the customer will not be able to use the device. Additionally, when the low bias is seen on patient samples, the device cannot function as intended. Both of these failures result in the device not meeting its performance specifications. Your firm failed to initiate a field correction to control its nonconforming product as required by its documented procedures for addressing nonconforming products.

c. **(b)(4)** dated 4/18/11, was initiated as a result of multiple complaints associated with a high rate of Slope Error calibration failures for Stratus CS nt-ProBNP (CPBNPM), lot **(b)(4)**. Your firm's investigation revealed that the Alkaline Phosphatase in the substrate may **(b)(4).** A **(b)(4)** meeting was held 4/25/11 and resulted in the decision to replace on complaint. Your firm received **(b)(4)** additional complaints for this malfunction after the **(b)(4)** decision. When this failure occurs, the device is unusable and cannot function as intended. This also results in the device not meeting its performance specifications. Your firm failed to initiate a field correction to control its nonconforming product as required by its documented procedures for addressing nonconforming products.

We reviewed your firm's response and conclude it is not adequate. Your firm stated that it will issue a communication to make customers aware of the malfunction in example (a.) above; however, your firm's response did not include the communication. Additionally, since this communication will result in the correction or removal of the nonconforming product, you should also comply with correction and removal regulations. Your firm also stated that it will review all "replace on complaint" actions taken since January 1, 2010, to determine whether any impacted products are not expired and therefore potentially remain on the market. Your firm's response did not include a timeframe for when this would be completed or any documentation of how it would correct any m[illegible]nctioning products that are still on the market. The Procedure **(b)(4)** has been updated to remove the "re[illegible]ace on complaint" option, and this appears to be adequate; however, the training of appropriate personnel on the revised document has not been completed and will have to be reviewed for adequacy after completion. Additionally, your firm did not provide documentation that it has considered a systemic corrective action for this deficiency to include review of other aspects of its quality system to ensure that procedures are implemented as required.

2. Failure to establish and maintain adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework to ensure that the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2). Specifically, your firm did not document reevaluation activities, including a determination of any adverse effect from the rework on its product in the Design History Record, as specified by regulation. For example, no investigation was conducted to determine the cause of the failure of Immulite Substrate, validation lot **(b)(4)** to meet finished product specification prior to the initiation of rework activities. The bulk lot passed the in-process assay and was approved for filling. The finished product was again sampled **(b)(4)** and failed the Immulite Assay. As a result, the finished product was **(b)(4)**. The product was re-tested and passed the Immulite Substrate Assay. However, your firm's personnel stated that the lot was rejected and scrapped due to the post filling failure and the need for rework. Despite this rejection, your firm did not document an investigation into the cause of the failure or its adverse effects from the rework of the nonconforming product.

We reviewed your firm's response and conclude it is not adequate. Your firm stated that, as of July 28, 2009, the rework procedure that was followed in the example above was made obsolete and replaced with an updated rework process. However, your firm did not include any documentation that the appropriate personnel were trained on the new process. Your firm also concluded that this observation was found to be an isolated incident due to **a** specific **(b)(4)** but did not submit any documentation that it has reviewed all **(b)(4)** to ensure that this was the only occurrence of this type of incident. Additionally, your firm did not provide documentation that it has considered a systemic corrective action for this deficiency to include review of rework activities for other products to ensure that ac[illegible]ies were completed as required.

3. Failure to establish and maintain adequate procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.100(a). Specifically, your firm's CAPAs did not adequately document the investigation or confirmation of suspected causes of nonconformities. The CAP As also did not adequately document corrective and/or preventative actions. For example:

a. CAPA **(b)(4)** submitted 4/11/2011, was initiated to investigate the cause of multiple slope error calibration failure complaints associated with Stratus CS nt-ProBNP (CPBNPM), lot **(b)(4)**. Your firm's investigation Phosphatase (ALP) Inhibitor contained in the substrate **(b)(4)** and caused the slope to increase. This slope increase resulted in calibration failures before the product's expiration date. Your firm concluded that the malfunction could be mitigated by **(b)(4)** or reducing the product's expiration dating to 6 months. However, your firm's documented action was to do neither of these and simply accept the customer complaints. The CAPA did not identify why the ALP Inhibitor was failing and the CAP A was closed on 11/30/11 and documented that your firm would not perform any corrective or preventative action.

b. **(b)(4)** CAPA-date submitted 6/28/11, was initiated due to complaints regarding QC and patient shift with the use of LOCI Cardiac Troponin I Calibrator, lot **(b)(4)**. Your firm confirmed a patient shift up to 30% at low troponin concentrations following calibration with the affected lot and issued an Urgent Field Safety Notice to customers in August 2011. CAPA-**(b)(4)** identified differences in the way the distributed calibrators and the calibrators used for value assignment/testing are **(b)(4)** during the manufacturing process as the potential root cause. Preventive actions were implemented based on the potential root cause identified above, but the root cause was never confirmed by testing affected and unaffected lots side by side. Without additional evidence to substantiate the root cause documented, the listed actions may not preclude the recurrence of this nonconformance. At the time of the inspection the CAPA was still open awaiting a final report. Additionally, the preventive actions identified were not implemented until September, 2011, and multiple LOCI Cardiac Troponin I Calibrator lots were manufactured between 6/20/11, when the CAPA was submitted, and September 2011, when the preventative actions were implemented. These lots were manufactured under the same conditions as nonconforming lot **(b)(4)**.

c. CAPA **(b)(4)** submitted 10/06/2011, was initiated as a result of multiple complaints regarding QC and patients shifts with the Dimension Vista Cardiac Troponin I Calibrator lot **(b)(4)**. Your firm issued an Urgent Field Safety Notice in November 2011. The CAPA identified the potential root cause as **(b)(4)** at a **(b)(4)**. The CAPA failed to document evidence to substantiate this claim. The instructions for use for this product claim the product can be stored from -20 to -10 C. Without additional evidence to substantiate the root cause documented, the listed actions may not preclude the recurrence of this nonconformance. At the time of this inspection the CAPA was still open awaiting the final report which will only discuss the actions items identified in the action plan.

We reviewed your firm's response and conclude it is not adequate. Your firm is updating the CAPAs specified above, but at the time of your firm's response, this had not been completed. Your firm is also updating its CAPA procedures and will be providing training to appropriate personnel. These actions are targeted for completion by May 30, 2012. Your firm's response is not adequate because documentation that a corrective action for this deficiency was implemented was not provided and evidence that a systemic corrective action was considered to include review of other CAPAs to ensure that they were completed as required was not provided.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Fi y, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring

the products into compliance.

Your firm's response should be sent to: Kirk D. Sooter, District Director, Room 901 U.S. Customhouse, Philadelphia, Pennsylvania, 19106-2973. If you have any questions about this letter, please contact Compliance Officer Richard C. Cherry at (215) 717-3075 (phone) or (215) 597-8212 (fax).

Sincerely yours,

/s/

Kirk D. Sooter
District Director
Philadelphia District

Page Last Updated: 08/16/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

Siemens Healthcare Diagnostics

NOTE: Siemens will abide by its standard shipping policy at the time of product shipment, and that this policy is subject to change.

Reagent and Consumable Shipping and Handling Policy

Note: number for customer orders, all product lines: 888-588-3916

Siemens Shipping and Handling Information

The Shipping and Handling policy is designed to enable customers to receive no charge Shipping and Handling by partnering with Siemens Healthcare Diagnostics in optimizing the supply chain. It is based on simple straight-forward requirements: order size, order method (electronic vs. phone/fax), and shipping mode (standard vs. expedited).

The standard shipping and handling charge per order is $80. This charge is easily waived by complying with two objectives: order on line, and meet the order value.

Policy Factors:

- *Order size*
- *Order method (electronic vs. non electronic)*
- *Order mode (standard vs. expedited)*

Order Size:

If the order value is equal to or greater than $6,000 ***or*** *the product line value, the order meets the threshold. If there are multiple product lines on an order and the order value is less than $6,000, each product line must meet its Threshold value.*

Table 1. Threshold Requirements

Product Line	Order Threshold
Combination	$6,000
Immuno Assay, Chemistry and Integrated Systems	$5,000
Stratus CS	$3,500
Syva	**$2,000**
Urinalysis	$3,000
Blood Gas	$1,500
Diabetes Care	$1,500
Hematology	$1,000
Coagulation	$1,000
Platelet Function (PFA)	$1,000
Plasma Protein	$1,000
Micro Biology	$1,500
Molecular	$6,000
Automation	$1,000

Product Line	Order Threshold
Informatics	$1,000

If the order meets the threshold, the $40 Order Value Fee is waived.

Order Method:

If the order is placed via electronic means, the $40 Non Electronic Fee is waived. Electronic orders are defined as: GHX, EDI, or On-line. Does not apply to telephone, fax or other non electronic means.

The most a customer can pay for an order using standard transportation modes is $80 ($40 for low value orders and $40 for non electronic orders).

Standard Shipping

Order to delivery lead times

Standard Shipping is the default shipping method. Order placed by 12:00 p.m. in the customer's time zone will be processed the same day (4:00 p.m. Eastern for customers in AK and HI). Refrigerated products (reagents etc.) are shipped for a maximum of two days (air or ground) and non refrigerated products (cuvettes, diluents, etc.) are shipped via ground (1-4 days). Products are shipped with the appropriate packaging to maintain separate shipment for their refrigerated and not refrigerated products that are placed on the same sales order. There is no cost impact to the customer and actual delivery dates are provided for each delivery at time of order entry or via the confirmation documents. Product packaging and shipping requirements are published on the Siemens Healthcare Diagnostics website.

Table 2. Zone 1 Customers

Order Day	*Refrigerated Delivery Day*	*Non Refrigerated Delivery Day*
Mon	Tue	Tue
Tue	Wed	Wed
Wed	Thu	Thu
Thu	Fri	Fri
Fri	Tue*	Tue*

**Following week*

Table 3. Zone 2, 3, 4 Customers

Order Day	*Refrigerated Delivery Day*	*Non Refrigerated Delivery Day*		
		Z2	*Z3*	*Z4*
Mon	Wed	Wed	Thu	Fri
Tue	Thu	Thu	Fri	Mon*
Wed	Fri	Fri	Mon*	Tue*
Thu	Wed*	Wed*	Tue*	Wed*
Fri	Wed*	Wed*	Wed*	Thu*

**Following Week*

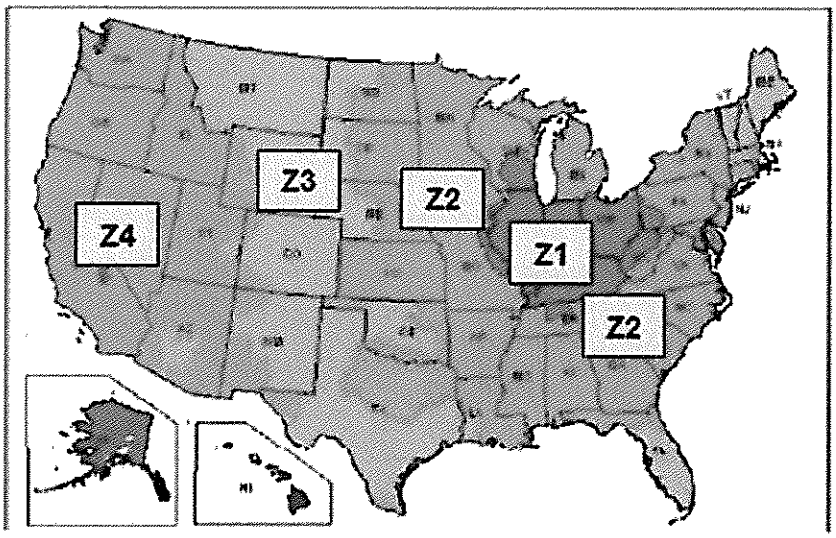


Figure 1. FedEx Ground Transit Days

Expedited Shipping Options

Two day delivery

- *Place order by 2:00 p.m. in your time zone*
- *Delivered by 3:30 p.m. second day in most zip codes***

Next day delivery

- *Place order by 2:00 p.m. in your time zone*
- *Delivered by 3:30 p.m. in most zip codes***

*Next morning delivery**

- *Place order by 2:00 p.m. in your time zone*
- *Delivered by 10:30 a.m. in most zip codes***

*Next morning delivery by 8:00 a.m.**

- *Place order by 2:00 p.m. in your time zone*
- *Delivered by 8:00 a.m.**

*Saturday delivery**

- *Place order by 2:00 p.m. Friday in your time zone*
- *Delivered by 3:30 p.m. in most zip codes***

Same day / Holiday delivery

- *Orders will be shipped on next available commercial flight or delivered by courier depending on location.*
- *Delivery commitment time is provided at time of order and varies by date, time and location.*
- *Additional charges apply for expedited services.*

**Where available*

***For actual commitment times by zip code see fedex.com*

Table 4. Assessorial Fees

Description	*$/lb1*	*Minimum*
Two day	$4.50	$100
Next day	$5.50	$150
Next morning/Saturday[2]	$7.50	$175
First Overnight	$10.00	$250
Same Day	$15.00	$550
LTL Inside delivery[3]	$100 per order	
LTL Lift gate[3]	$100 per order	
No LTL[4]	No Charge	

Cost per pound is based on net weight of product shipped, not packaging and gel ice.

Table 5. Instrument Shipping and Handling

Except as otherwise noted below, if multiple instruments/equipment from the same product line category are included on the same order, then Customer will be charged the full Freight Amount listed below for first instrument (the instrument with the highest Freight Amount) and fifty-percent (50%) of the Freight Amounts for the remaining instruments.

Instrument/Equipment Description	Freight Amount
Dimension	
EXL	$2,500
EXL 200	$2,500
RxL Max Basic	$1,500
RxL Max w/HM	$1,500
RxL Series Recert	$1,500
RMS	$675
RMS Recert	$675
Xpand Plus Basic	$1,500
Xpand Plus w/HM	$1,500
Xpand Series Recert	$1,500
Vista*	
Vista 1500	$2,500
Vista 500	$2,500
***Multiple discount does not apply**	
Hemostasis	
CA-500 Series	$300
CA-500 Series Recert	$300
CA-1500 Series	$750
CA-7000 CCS	$1,500
BCS Recert	$1,500
BCS XP	$1,500
BFT II	$150
PFA-100	$200
PFA-100 Recert	$200
Syva	
Olympus AU 400	$1,500
Olympus AU 640	$1,500

Instrument/Equipment Description	Freight Amount
Plasma Protein	
BN 100	$875
BN 100 Recert	$875
BN II	$1,500
BN II Recert	$1,500
ProSpec	$875
Stratus	
Stratus CS	$675
Stratus CS Recert	$675
MicroScan	
AutoScan 4	$525
AutoScan 4 Recert	$525
Walk-away 40	$1,500
Walk-away 40 Recert	$1,500
Walk-away 96	$1,500
Walk-away 96 Recert	$1,500
LabPro Only	$150
Accessories	
QCC Powerpak	$150
EasyLink	$100
Automation*	
Refrigerated Storage Module	$2,000
Core Module	$1,500
Centrifuge	$500
Track Extension	$500
STM Module	$500

Instrument/Equipment Description	Freight Amount
Olympus AU 680	$1,500
Olympus AU 2700	$1,500
Olympus AU 5420	$1,500
Olympus AU 5421	$1,500
Olympus AU 5430	$1,500
Olympus AU 5431	$1,500
V-Twin	$1,200
Viva E	$750
Viva Jr	$550
Centaur	
XP	$1,500
CP	$1,000
ADVIA Chemistry	$1,500
IMMULITE	
1000	$1,000
2000 and 2500	$2,000
XPi	$2,000

Instrument/Equipment Description	Freight Amount
Tube Sealer	$500
StreamLab	Variable
WorkCell	Variable
*** Multiple discount does not apply**	
Blood Gas	
248,348,340,350,400	$100
1200	$225
Urinalysis	
Atlas	$750
AUW	$1,000
Hematology	$1,000
Molecular	
VERSANT 340	$250
VERSANT 440	$500
Auto LIPA 48	$200
Auto Blot 3000	$200

Systems are shipped FOB Destination, prepaid and added. (if customer is paying for freight) OR

Systems are shipped FOB Destination, prepaid and absorbed by vendor. (if Siemens is paying for freight)

Siemens Healthcare Diagnostics Inc.
EQUAL OPPORTUNITY POLICY STATEMENT

Siemens Healthcare Diagnostics Inc., is firmly committed to Equal Employment Opportunity (EEO) and to compliance with all Federal, State and local laws that prohibit employment discrimination on the basis of age, race, color, gender, national origin, religion, sexual orientation, disability, protected veteran status and any other legally protected classifications. This policy applies to all employment decisions including, but not limited to, recruiting, hiring, training, promotions, pay practices, benefits, disciplinary actions and terminations.

As a government contractor, Siemens Healthcare Diagnostics Inc. is also committed to taking affirmative action to hire and advance minorities and women as well as qualified individuals with disabilities and covered veterans.

We invite employees who are disabled or protected veterans and wish to be included under our Affirmative Action Program to self-identify as such with the EEO Coordinator by contacting your local Human Resource Representative. This self-identification is strictly voluntary and confidential and will not result in retaliation of any sort.

Employees of and applicants to Siemens Healthcare Diagnostics Inc. will not be subject to harassment, intimidation, threats, coercion, or discrimination because they have engaged or may engage in filing a complaint, assisting in a review, investigation, or hearing or have otherwise sought to obtain their legal rights related to any Federal, State, or local law regarding EEO for qualified individuals with disabilities or qualified protected veterans or any other legally protected status.

As CEO of Siemens Healthcare Diagnostics Inc., I am committed to the principles of Affirmative Action and Equal Employment Opportunity. In order to ensure dissemination and implementation of equal employment opportunity and affirmative action throughout all levels of the company, I have selected Michael Bolinger as the EEO Coordinator for Siemens Healthcare Diagnostics Inc.. One of the EEO Coordinator's duties will be to establish and maintain an internal audit and reporting system to allow for effective measurement of the company's programs.

In furtherance of Siemens Healthcare Diagnostics Inc.'s policy regarding Affirmative Action and Equal Employment Opportunity, Siemens Healthcare Diagnostics Inc. has developed a written Affirmative Action Program which sets forth the policies, practices and procedures which the company is committed to applying in order to ensure that its policy of non-discrimination and affirmative action for qualified individuals with disabilities and qualified protected veterans or other legally protected bases as appropriate is accomplished. This Affirmative Action Program for qualified individuals with disabilities and qualified protected veterans is available for inspection by any employee or applicant for employment upon request, between 9:00AM and 4:00pm at the Human Resources department. Any questions should be directed to me, your supervisor, or Michael Bolinger, EEO Coordinator.

Michael Reitermann
CEO

May, 2010

SIEMENS

To Whom it May Concern:

Siemens Healthcare Diagnostics manufactures in-vitro diagnostic (IVD) instruments, and the reagents and consumables used in those instruments.

The U.S. Food and Drug Administration classifies IVD instruments as "medical devices." To ensure the integrity of test results, the manufacturing of instruments, reagents, and consumables entails many complex processes that must be done under strict quality controls, adhering to stringent regulatory requirements.

The vast majority of reagents are manufactured in-house. Instruments are manufactured in-house or by proven suppliers, with oversight by appropriate Siemens personnel. Consumables are manufactured to strict specifications by proven suppliers, with oversight by appropriate Siemens personnel.

Raw materials are bought only from highly qualified, proven suppliers. Every raw material is subjected to lengthy and rigorous testing to ensure that customers obtain consistent results. Raw materials for reagents include chemicals and biologicals (some of which are obtained from the animals on Siemens farms). Materials and subassemblies for instruments include custom-made hardware and software.

When switching suppliers for a particular chemical or biological, scientists must test every reagent that relies on that particular raw material. Testing can take anywhere from weeks to months. Similarly, when switching suppliers for a particular piece of hardware or software, engineers must test every instrument function that could be affected by the change. Due to the extensive testing requirements, switching suppliers is very costly. Consequently, Siemens does not switch suppliers for these goods unless absolutely necessary.

Reagents are provided in sealed containers that must go through similarly rigorous testing to ensure that they remain intact under normal shipping and handling conditions, and do not in any way threaten the integrity of the reagents or diagnostic testing process.

The labels on the containers, the labels on the outside packaging, the outside packaging itself, and the protective foam inserts are all manufactured under contracts with proven suppliers.

Shipping of instruments, reagents, and consumables is handled by various shipping firms under long-term, mostly national contracts.

Field service and technical support are provided by highly trained Siemens employees, not outside contractors.

Siemens has a track record of using suppliers that are minority-owned and woman-owned. However, for all the reasons above, Siemens is unable to subcontract any of the goods or services under this contract.

If you have any questions regarding Siemens' supplier diversity efforts, please call me at the number below or email me at jennifer.l.wright@siemens.com.

Sincerely,

Jennifer L Wright
Supplier Diversity Liaison
Siemens Healthcare Diagnostics

1717 Deerfield Rd.
Deerfield, IL 60015

847-236-7009
www.siemens.com/diagnostics

Rec'd 8/30/12

SMALL BUSINESS SUBCONTRACTING PLAN
(Model Outline*)

SUBCONTRACTING PLAN PERIOD: October 1, 2012 to September 30, 2013

Individual plans should cover the entire period of performance, and commercial plans should coincide with the company's fiscal year. In the event your company's fiscal year is for a period that will end before the contract periods of any federal contracts you hold which include the requirement to have a small business subcontracting plan, you will be required to submit a new subcontracting plan for approval thirty (30) days prior to expiration of the existing subcontracting plan. In the event an acceptable plan cannot be negotiated prior to expiration of the existing subcontracting plan, your contract(s) may be terminated.

DATE SUBMITTED: August 20, 2012

NAME OF PLANHOLDER: Siemens Healthcare Diagnostics

SUBSIDIARIES INCLUDED: None

ADDRESS: 511 Benedict Avenue
Tarrytown, NY 10591
USA

ITEM/SERVICE: Medical Diagnostic instruments, reagents, and assays

1. TYPE OF PLAN

List the total estimated dollar value of all planned subcontracting (to all types of business concerns, both large and small). Select only one of the following:

a) Individual Plan (This Contract Only) Contract #/Solicitation # _____)
Total value of projected subcontracts (both large and small businesses) $ _____

b) Commercial Division-wide Plan
Total projected sales $ 1,955,000,000
Total value of projected subcontracts (both large and small businesses) $ 935,000,000
(Subcontracts Represent 47.8% of Total Annual Sales)

c) Commercial Company-wide Plan
Total projected sales $ _____
Total value of projected subcontracts (both large and small businesses) $ _____
(Subcontracts Represent _____% of Total Annual Sales)

** Federal Acquisition Regulation (FAR), paragraph 19.708(b)(1), prescribes the use of the clause at FAR 52.219-9 entitled "Small Business Subcontracting Plan." The following is a suggested model for use when formulating such subcontracting plan. While this model plan has been designed to be consistent with FAR 52.219-9, other formats of a subcontracting plan may be acceptable. However, failure to include the essential information as exemplified in this model may be cause for either a delay in acceptance or the rejection of an offer where the clause is applicable. Further, the use of this model is not intended to waive other requirements that may be applicable under FAR 52.219-9 or that may appear in the Government's solicitation. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a federal government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.*

2. GOALS

State separate dollar and percentage goals, expressed in terms of percentages of the total available subcontracting dollars listed in the previous section.

a) Total estimated dollar value and percent of planned subcontracting with small businesses (SB) (including ANCs and Indian tribes), veteran-owned small, service-disabled veteran-owned small, HUBZone small, small disadvantaged (including ANCs and Indian tribes), and women-owned small business concerns:

$ 238,425,000 and 25.50%

b) Total estimated dollar value and percent of planned subcontracting with veteran-owned small businesses (VO):

$ 12,155,000 and 1.30%

c) Total estimated dollar value and percent of planned subcontracting with service-disabled veteran-owned small businesses (SDVO) (Note: This is a subset of veteran-owned):

$ 374,000 and 0.04%

d) Total estimated dollar value and percent of planned subcontracting with small disadvantaged businesses (SDB) (including ANCs and Indian tribes):

$ 3,459,500 and 0.37%

e) Total estimated dollar value and percent of planned subcontracting with women-owned small businesses (WO):

$ 13,744,500 and 1.47%

f) Total estimated dollar value and percent of planned subcontracting with HUBZone small businesses (HUB):

$ 1,028,500 and 0.11%

3. PRODUCTS AND/OR SERVICES

The principal types of products and/or services that will be subcontracted under this plan to all types of businesses (both large and small) are as follows: All types of goods and services with relation to medical device manufacturing, especially facilities-related goods and services, IT-related goods and services, consulting and professional services, chemicals, biologicals, printing, packaging, fabricated plastic parts, fabricated metal parts, and electronics.

The types of products and/or services to be subcontracted to SBs and the subcategories are:

SB: Computers, computer peripherals, molded plastics, ceramics, blood products, electronics, electronic assemblies, professional services (contractors, legal, consultants, temporary), mobility logistics, packaging, metal parts, chemicals, chemical gases, medical equipment, optics, R&D technology, distribution channel partners, power supplies/components/subassemblies.

VO: Medical equipment, validation testing, electronics, leasing, optics, packaging, magnetic products, R&D design, rubber/metal/plastic parts, components, fasteners, pest control, bearings, sterilization services, professional services.

SDVO: Bearings, biological chemicals, distributors, optics,

SDB: Chemical gases, professional services (engineering, IT, general consult), blood products, validation testing, fiber optics, optics, machine tooling.

WO: Translation services, packaging, tax accounting services, professional services (IT, engineering, general consult), distributors, flooring, communications, chemicals, biologicals, electronics, graphics/visual arts/marketing, computing, logistics

HUB: Thermo-electric cooling, product integration, graphics, legal, electronics, automation, hardware, bearings

4. GOAL DEVELOPMENT

The following method was used in developing the subcontracting goals:

To develop Siemens Healthcare Diagnostics, three factors were focused upon:
- FY13 business needs which are expected to remain similar to FY12 business needs
- The global marketplace and how the current economy affects opportunities to utilize small businesses
- Siemens AG FY13 Global Procurement strategy, which emphasizes consolidation of spending among fewer vendors, with increased usage of national and global contracts

It was concluded that the overall usage of small businesses is likely to drop, but the percentage for each subcategory may remain the same. Consequently, the goals for each subcategory were adopted for FY13.

5. IDENTIFYING POTENTIAL SOURCES

The following methods were used to identify potential sources for solicitation purposes (See FAR 52.219-9(d)(5) for examples of methods that may be used.

We rely primarily on our own procurement spend database cleansed by D&B to identify SBA suppliers, D&B reports, and state-government sponsored lists, such as, SAM "CCRSBA" small business search, www.wbenc.org, National Minority Supplier Development council (nmdsc.org) including regional councils.

Ensuring that subcontract procurement RFQs (Through internally developed RFQ Toolkit) are designed to permit participation of Small Business, Small Disadvantaged, Woman-Owned Small Business, HUBZone Small Business, Veteran-Owned Small Business and Service Disabled Veteran Small Business concerns.

Through the attendance of Siemens sponsored Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, etc.
In addition, we conduct Internet searches and read the corporate information section of supplier websites to identify those likely to be small businesses.

6. INDIRECT COSTS

Indirect costs ☒ have ☐ have not been included in the dollar and percentage subcontracting goals stated above. (Check one.)

If "have been" is checked (and you are proposing an individual plan), explain the method used in determining the proportionate share of indirect costs to be incurred with small business (including Alaska Native Corporations and Indian tribes), veteran-owned small business, service-disabled veteran-owned small business, small disadvantaged business (including ANCs and Indian tribes), women-owned small business, and HUBZone small business concerns. *Note: Commercial planholders who choose to include indirect costs will not need to provide the aforementioned explanation because the costs will be applied at 100%.*

7. PROGRAM ADMINISTRATOR

The following individual will administer the subcontracting program:

NAME: David Anderson

TITLE: Sr. Manager Procurement

ADDRESS: 511 Benedict Avenue
Tarrytown, NY 10591
USA

TELEPHONE: 914-524-2726

E-MAIL: david.anderson@siemens.com

This individual's specific duties, as they relate to the firm's subcontracting program, are as follows:

- Gather and analyze data, prepare and submit the annual subcontracting plan and annual eSRS report.
- Coordinate the company's activities during compliance review by federal agencies.

8. EQUITABLE OPPORTUNITY

The following good faith efforts (internal and external) will be taken to assure that small business, veteran-owned small business, service-disabled veteran-owned small business, small disadvantaged business, women-owned small business, and HUBZone small business concerns will have an equitable opportunity to compete for subcontracts:

We will continue to use our own database and the SBA's database, as well as other databases and lists to identify small businesses as outlined under section 5 of the plan.
We will continue to educate requestors, buyers and commodity managers on the importance of giving small businesses the opportunity to compete as outlined by Siemens Healthcare USA Policy Stated below:
Ensuring that subcontract procurement RFQs are designed to permit participation of Small Business, Small Disadvantaged, Woman-Owned Small Business, HUBZone Small Business, Veteran-Owned Small Business and Service Disabled Veteran Small Business concerns.

We will continue to use our own database and the SBA's database, as well as other sources (i.e. Small Business Conferences) to identify small businesses for existing and future business.

We will continue to educate our organization including procurement buyers and commodity managers on the importance including small businesses in their supplier selection strategies

We will continue to work with the Siemens companies throughout the U.S. to share best practices and improve our recordkeeping activities with respect to small businesses.

We will continue to work with the SBLO in our parent company and other Siemens companies throughout the U.S. to share best practices and improve our recordkeeping activities with respect to small businesses.
Through Siemens parent company which has membership in the minority supplier development council MSDC; we will participate in the 2013 Procurement Confernce and Trade Show hosted by MSDC to further expand and engage the small business community.

9. FLOW-DOWN CLAUSE

The offeror agrees that the FAR clause of this contract entitled "Utilization of Small Business Concerns" (52.219-8) will be included in all subcontracts which offer further subcontracting opportunities, and all subcontractors (except small business concerns) that receive subcontracts in excess of $650,000 with further subcontracting possibilities will be required to adopt a subcontracting plan that complies with the requirements of this clause.

NOTE: FAR 52.219-9(j) states that "subcontracting plans are not required from subcontractors when the prime contract [i.e. your VA contract] contains the clause at 52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders – Commercial Items". This clause is in all VA FSS and NCS contracts. Therefore, only the first part of the above flow-down language, that is the requirement to flow-down 52.219-8, is applicable.

10. REPORTING & COOPERATION

The offeror agrees to

(i) Cooperate in any studies or surveys as may be required;

(ii) Submit periodic reports so that the Government can determine the extent of compliance by the offeror with the subcontracting plan;

(iii) Submit the Individual Subcontracting Report (ISR) and/or the Summary Subcontract Report (SSR), in accordance with the paragraph (l) of this clause using the Electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov. The reports shall provide information on subcontract awards to small business concerns (including ANCs and Indian tribes that are not small businesses), veteran-owned small business concerns, service-disabled veteran-owned small business concerns, HUBZone small business concerns, small disadvantaged business concerns (including ANCs and Indian tribes that have not been certified by the Small Business Administration as small disadvantaged businesses), women-owned small business concerns, and Historically Black Colleges and Universities and Minority Institutions. Reporting shall be in accordance with this clause, or as provided in agency regulations;

(iv) Ensure that its subcontractors with subcontracting plans agree to submit the ISR and/or the SSR using eSRS;

(v) Provide its prime contract number, its DUNS number, and the e-mail address of the offeror's official responsible for acknowledging receipt of or rejecting the ISRs, to all first-tier subcontractors with subcontracting plans so they can enter this information into the eSRS when submitting their ISRs; and

(vi) Require that each subcontractor with a subcontracting plan provide the prime contract number, its own DUNS number, and the e-mail address of the subcontractor's official responsible for acknowledging receipt of or rejecting the ISRs, to its subcontractors with subcontracting plans.

11. RECORDKEEPING

The following is a description of the types of records that will be maintained concerning procedures that have been adopted to comply with the requirements and goals in the plan, including establishing source lists; and a description of the offeror's efforts to locate small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns and award subcontracts to them. The records shall include at least the following (on a plant-wide or company-wide basis, unless otherwise indicated):

(i) Source lists (*e.g.*, CCR), guides, and other data that identify small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns.

(ii) Organizations contacted in an attempt to locate sources that are small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, or women-owned small business concerns.

(iii) Records on each subcontract solicitation resulting in an award of more than $150,000, indicating --

(A) Whether small business concerns were solicited and if not, why not;

(B) Whether veteran-owned small business concerns were solicited and, if not, why not;

(C) Whether service-disabled veteran-owned small business concerns were solicited and, if not, why not;

(D) Whether HUBZone small business concerns were solicited and, if not, why not;

(E) Whether small disadvantaged business concerns were solicited and if not, why not;

(F) Whether women-owned small business concerns were solicited and if not, why not; and

(G) If applicable, the reason award was not made to a small business concern.

(iv) Records of any outreach efforts to contact --

(A) Trade associations;

(B) Business development organizations;

(C) Conferences and trade fairs to locate small, HUBZone small, small disadvantaged, and women-owned small business sources; and

(D) Veterans service organizations.

(v) Records of internal guidance and encouragement provided to buyers through --

(A) Workshops, seminars, training, etc., and

(B) Monitoring performance to evaluate compliance with the program's requirements.

(vi) On a contract-by-contract basis, records to support award data submitted by the offeror to the Government, including the name, address, and business size of each subcontractor. Contractors having commercial plans need not comply with this requirement.

Signed: _____

Typed Name: David Anderson

Title: Sr. Manager Procurement

Date Signed: 8.28.2012

Plan Approved by (Government official): Lydia L McKay

Typed Name: Lydia L McKay
Contracting Officer

Date Approved: 9/6/2012

	**2012 Goals	**2012 Actuals	2013 Goals
Total Subcontracting Dollars +	€ 1,170,020,443	$ 934,196,038	$ 935,000,000
Small Business Dollars	€ 292,505,111	$ 238,425,935	$ 238,425,000
Small Business Percent	25.00%	25.52%	25.5%
Small Veteran-owned Dollars #	€ 17,550,307	$ 11,769,968	$ 12,155,000
Small Veteran-owned Percent #	1.50%	1.26%	1.3%
Service-Disabled Veteran-Owned Dollars #	€ 5,850,102	$ 346,843	$ 374,000
Service-Disabled Veteran-Owned Percent #	0.05%	0.04%	0.04%
Small Disadvantaged Dollars	€ 7,020,123	$ 3,414,565	$ 3,459,500
Small Disadvantaged Percent	0.60%	0.37%	0.37%
Small Women-owned Dollars	€ 23,400,409	$ 13,746,065	$ 13,744,500
Small Women-owned Percent	2.00%	1.47%	1.47%
HUBZone Small Business Dollars	€ 5,850,102	$ 1,034,877	$ 1,028,500
HUBZone Small Business Percent	0.5%	0.11%	0.11%

**2012 Goals do not correlate to 2012 Actuals as discrepancies between the two reporting periods became apparent. The previous admin submitted the Subcontracting plan 2012 Goals reflecting Siemens Global suppliers spend in EURO; additionally, Global sales figures in EURO were also reported in the Siemens 2012 Small Business Subcontract plan. 2012 Actuals, reported by the new admin, reflect US vendor spend in USD; therefore, 2012 goals and 2012 actuals do not reflect the same data sets or currency and should not be used to compare adherence to 2012 goals stipulated in last year's plan.

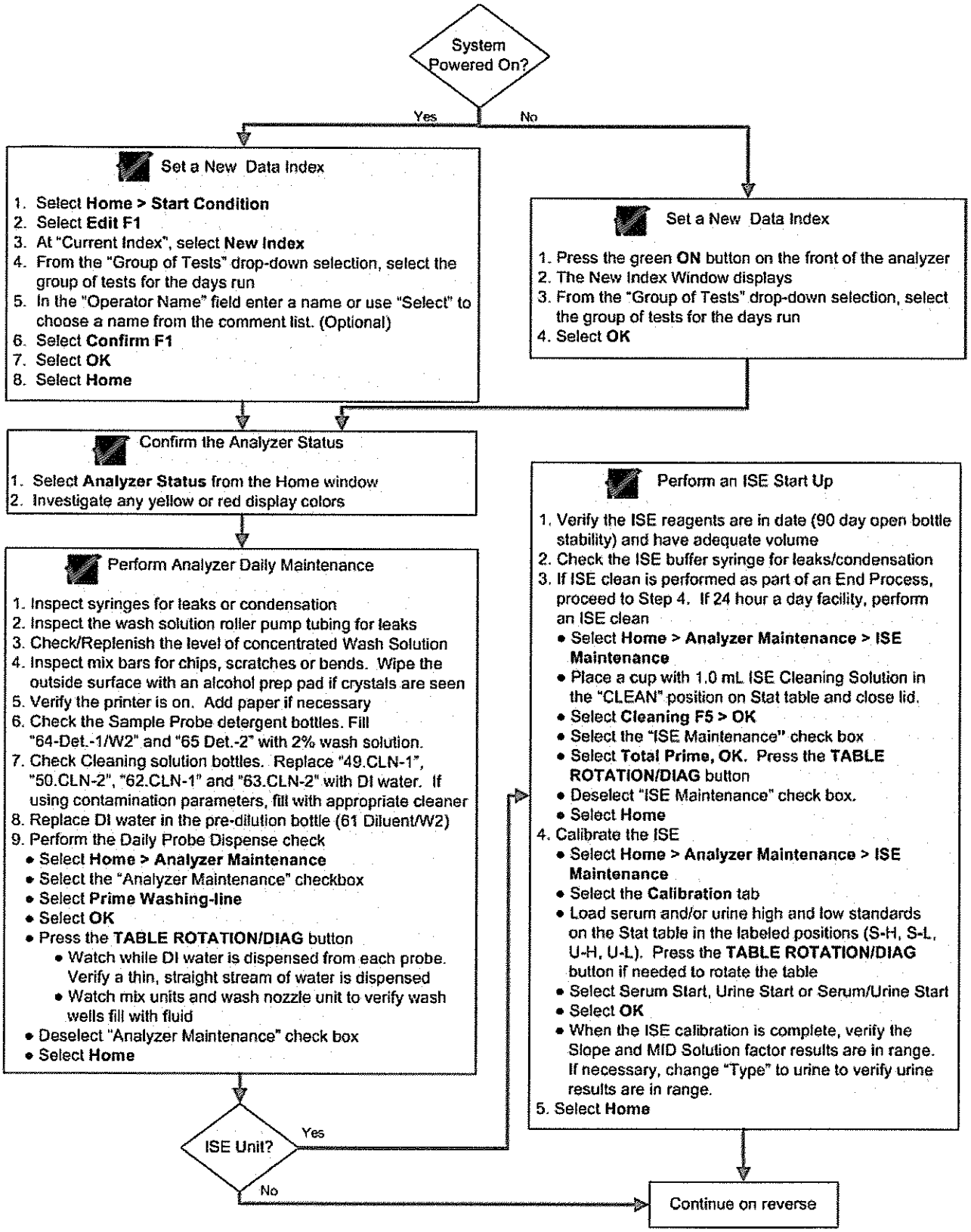
Round percentages to two decimal places and dollar figures to the nearest whole dollar.

* If total prior year contract achievements are not available, use actual figures and estimate/prorate balance.

+ Including subcontracting dollars for small and large businesses

Dollars for Small Vet-owned and Service-Disabled Vet-owned businesses cannot be included in your actual achievements unless the company has been "verified" in the Vendor Information Pages (VIP) database on VetBiz.gov.

AU680® Daily Start Up



AU680® Daily Start Up
Continued

Check Analyzer Status and Reagent

1. Select **Home > Reagent Management**
2. Select **Reagent Check F5 > Check All Positions > Start**
3. View reagent information
   - From the Main Tab, view shots/volume available
   - From the Details Tab, view reagent stability and verify fixed reagents are in correct positions
   - Repeat for each sample type
4. Load new reagents if needed
   - Open the main cover
   - Lift and remove the appropriate refrigerator lid
   - Place the reagent bottles in an empty position. Use an adapter or partition plate as needed
   - Ensure all barcoded reagents are placed in the reagent tray with barcode facing out
   - "Fix" reagents without barcodes
5. Select **Reagent Check F5 > Check All Positions > Start**
6. View reagent information to verify reagents have adequate stability and volume

Perform RB/Calibrations

1. Select **Home > Rack Requisition Sample > Calibration**
2. Select the type of samples requiring calibration from the Type drop-down menu
   Note: the instrument will auto requisition required RB and Calibrations. Select **Start Entry F1** to make changes. Repeat for each sample type. Select **Exit F2**
3. Select **Display Cup Set F5.** Scroll down to view additional racks
4. Pour the solutions identified on the **Display CAL Racks** screen in the appropriate racks
5. Select **Close**
6. Load the racks on the rack supply belt. Always load the blue rack followed by the yellow rack
7. Select **Start**

Perform Quality Control

1. Select **Home > Rack Requisition Sample > QC**
2. Select the type of samples requiring QC from the Type drop-down menu
   Note: the instrument will auto requisition QC based on the default QC profile defined. Select **Start Entry F1** to make changes. Repeat for each sample type. Select **Exit F2**
3. Select **Display QC Set F6.** Scroll down to view additional racks
4. Pour the solutions identified on the **Display QC Racks** screen in the appropriate racks
5. Select **Close**
6. Load the racks on the rack supply belt.
7. Select **Start**

Review the printed reports to verify that all RB/Calibrations/QC meet your laboratory requirements.

Start Up Complete

AU680 Every Other Week and Weekly Maintenance Job Aids

For Training Purposes Only

These job aids are shortened versions of the procedures found in the source below. The procedures are written as standalone procedures to ensure they can be performed in any order. Information in the job aid is correct as of the date published. Verify you have the correct information.

Source: AU680® Chemistry Analyzer User's Guide PN B04779AA (March 2011)

Document Disclaimers

Document Disclaimers	This document is not intended to replace the information in your User's Guides, Quick Response Guide or other product documentation. Information in the User's Guide and Quick Response Guide supersedes information in any other manual.
Warnings and Precautions	Read all product manuals and consult with Beckman Coulter trained personnel before attempting to operate the instrument. Beckman Coulter, Inc. urges its customers and employees to comply with all national health and safety standards such as the use of barrier protection. This may include but is not limited to, protective eyewear, gloves, suitable laboratory attire when operating or maintaining this or any other automated laboratory equipment.
Intention for Use	**This document is not intended to replace the information in your Instrument Instructions for Use Manual (IFU), User's Guide and Quick Response Guide. Information in the User's Guide supersedes information in any other manual.**
Revision Status	Rev. A (Feb. 2013) Software version 3.7
Trademarks	AU680® Chemistry Analyzer

Every Other Week or Every 3,000 Samples ISE Maintenance

Manually Clean the ISE Mix Bar, Liquid Level Sensors, Sample Pot and Sample Pot Tubing

Supplies Required:

- Alcohol prep (70% isopropyl alcohol)
- 1% wash solution (1 part wash solution added to 99 parts DI water)
- Beaker
- Disposable pipette tip
- Sonicator
- Squeeze bottle or syringe
- Clean, dry lint-free cloth

Ensure the system is in ***Standby*** or ***Warmup*** Mode

From the Home screen, select **Analyzer Maintenance** jump button

Select the **ISE Maintenance** tab, place a ✓ in the **ISE Maintenance** check box

Select the **Drain-Flowcell** button, select **OK**

Press the green **TABLE ROTATION/DIAG** button to drain the flowcell

Open the main cover, then open the ISE cover

Disconnect the mixing unit liquid level sensor connector 714 and mixing motor connector 706

Loosen the knob securing the mixing unit and gently lift to unseat it

Use an alcohol prep to wipe the two nozzles, two liquid level sensors, and the mix bar

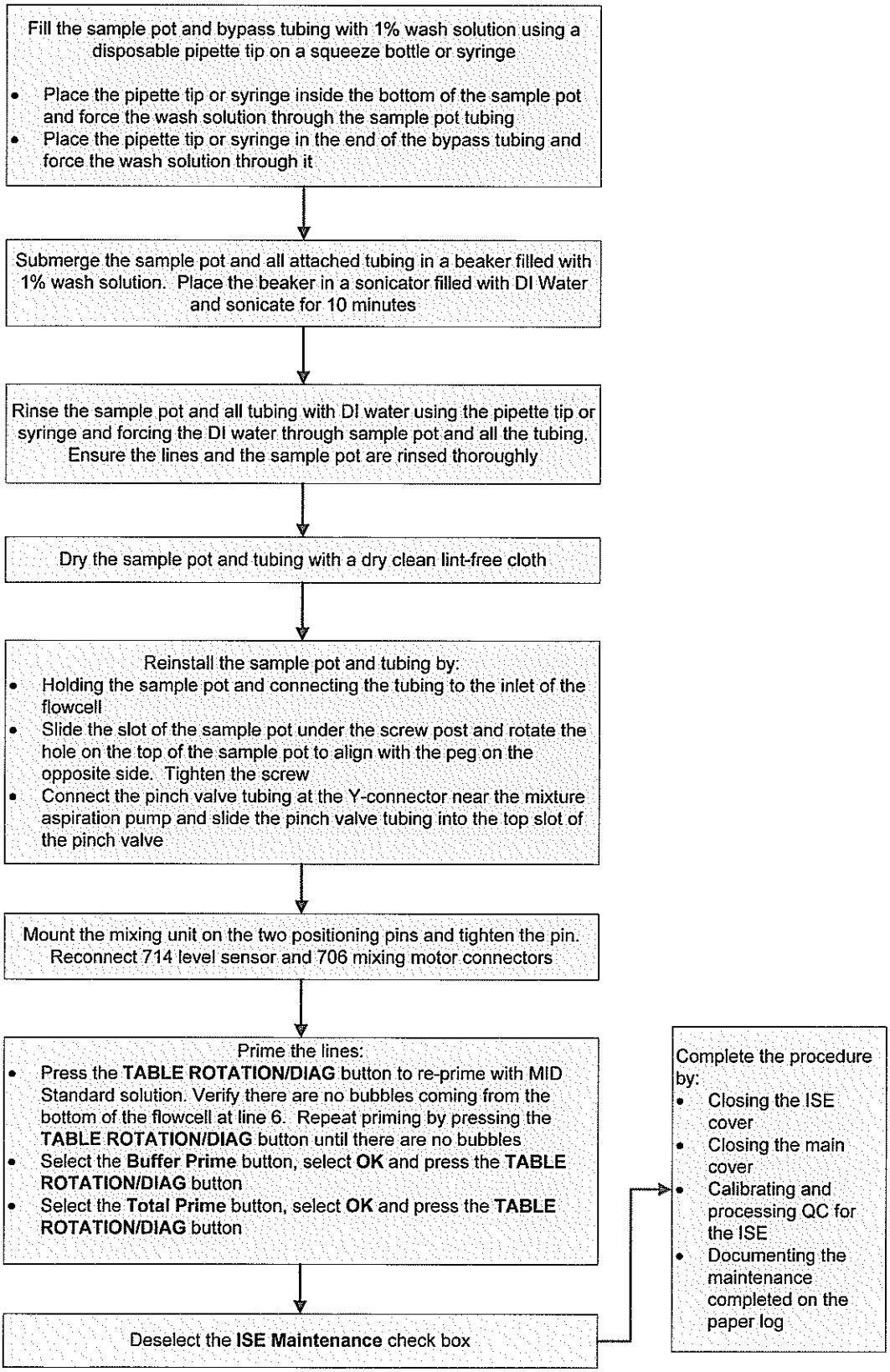
Place the mixing unit on the mixing unit holder

Loosen the retaining knob securing the sample pot and lift the pot off the peg

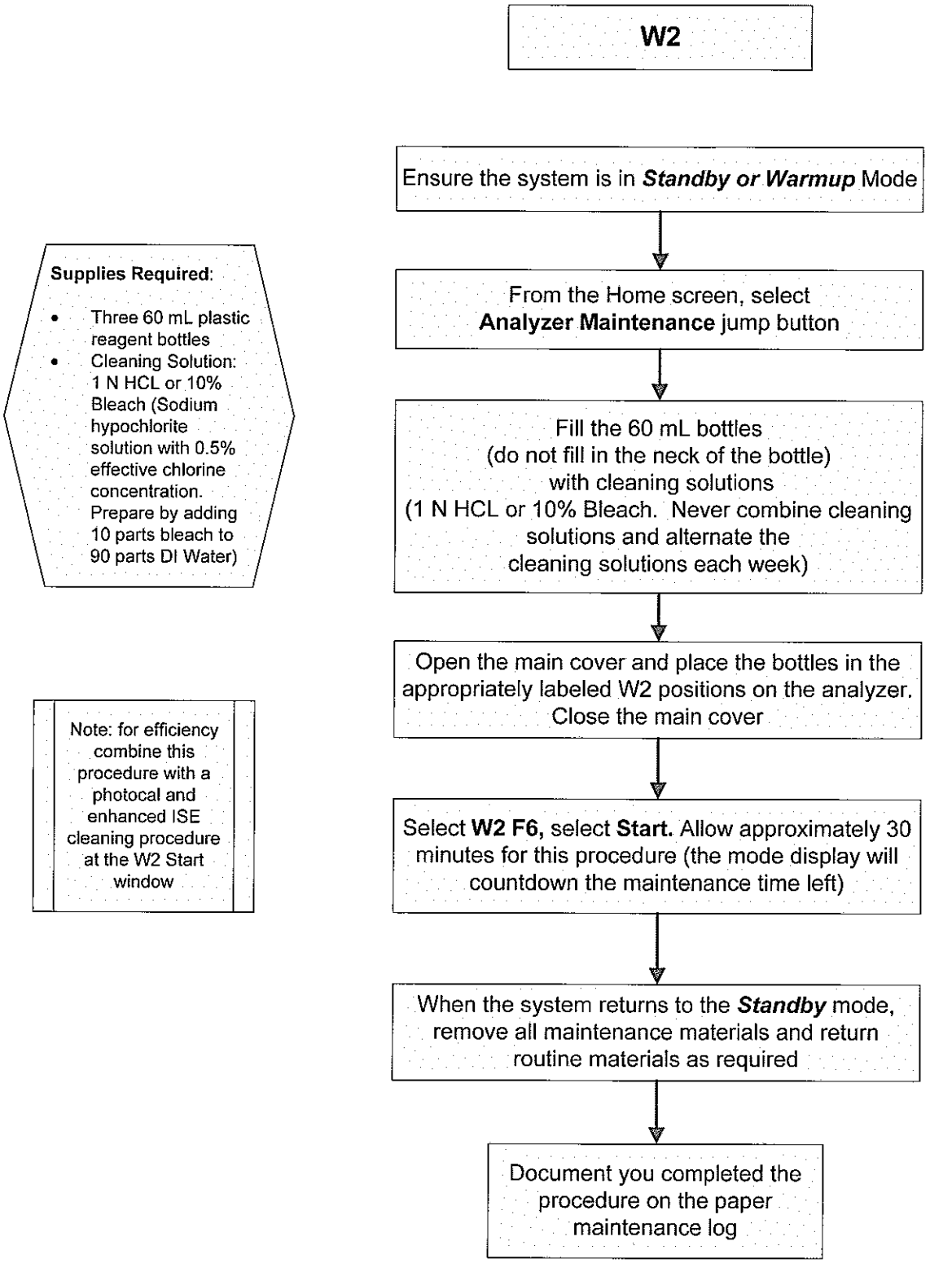
Hold the sample pot in one hand and remove:

- Sample pot tubing from the inlet of the flow cell
- Bypass tubing labeled 5 from the pinch valve
- Bypass tubing labeled 5 at the Y-connector near the mixture aspiration pump

Continue on the next page


Fill the sample pot and bypass tubing with 1% wash solution using a disposable pipette tip on a squeeze bottle or syringe
• Place the pipette tip or syringe inside the bottom of the sample pot and force the wash solution through the sample pot tubing
• Place the pipette tip or syringe in the end of the bypass tubing and force the wash solution through it
Submerge the sample pot and all attached tubing in a beaker filled with 1% wash solution. Place the beaker in a sonicator filled with DI Water and sonicate for 10 minutes
Rinse the sample pot and all tubing with DI water using the pipette tip or syringe and forcing the DI water through sample pot and all the tubing. Ensure the lines and the sample pot are rinsed thoroughly
Dry the sample pot and tubing with a dry clean lint-free cloth
Reinstall the sample pot and tubing by:
• Holding the sample pot and connecting the tubing to the inlet of the flowcell
• Slide the slot of the sample pot under the screw post and rotate the hole on the top of the sample pot to align with the peg on the opposite side. Tighten the screw
• Connect the pinch valve tubing at the Y-connector near the mixture aspiration pump and slide the pinch valve tubing into the top slot of the pinch valve
Mount the mixing unit on the two positioning pins and tighten the pin. Reconnect 714 level sensor and 706 mixing motor connectors
Prime the lines:
• Press the TABLE ROTATION/DIAG button to re-prime with MID Standard solution. Verify there are no bubbles coming from the bottom of the flowcell at line 6. Repeat priming by pressing the TABLE ROTATION/DIAG button until there are no bubbles
• Select the Buffer Prime button, select OK and press the TABLE ROTATION/DIAG button
• Select the Total Prime button, select OK and press the TABLE ROTATION/DIAG button
Deselect the ISE Maintenance check box
Complete the procedure by:
• Closing the ISE cover
• Closing the main cover
• Calibrating and processing QC for the ISE
• Documenting the maintenance completed on the paper log

Weekly Analyzer and ISE Maintenance



Photocal

Ensure the system is in ***Standby*** Mode

From the Home screen, select **Analyzer Maintenance** jump button

Select either:

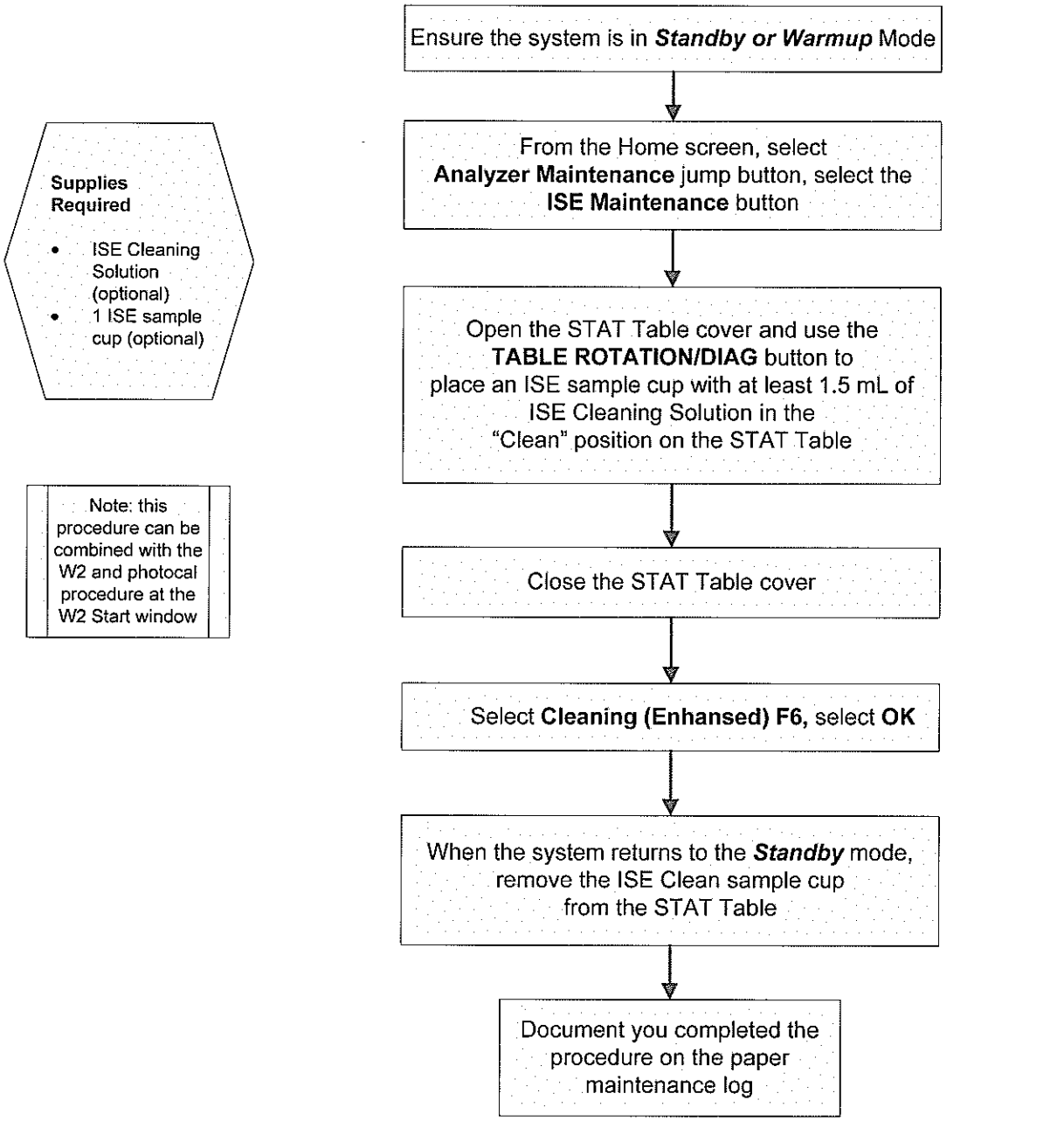
- **ALL Cuvettes** (perform on a weekly basis or when all cuvettes need a photocal, allow approximately 30 minutes)
- **Cuvettes No**. and enter a cuvette number in the No. field (Perform when only one cuvette failed the photocal or was replaced. Only one cuvette number can be entered at a time, allow approximately 7 minutes per cuvette)

Select **Start** (the mode display will countdown the maintenance time left)

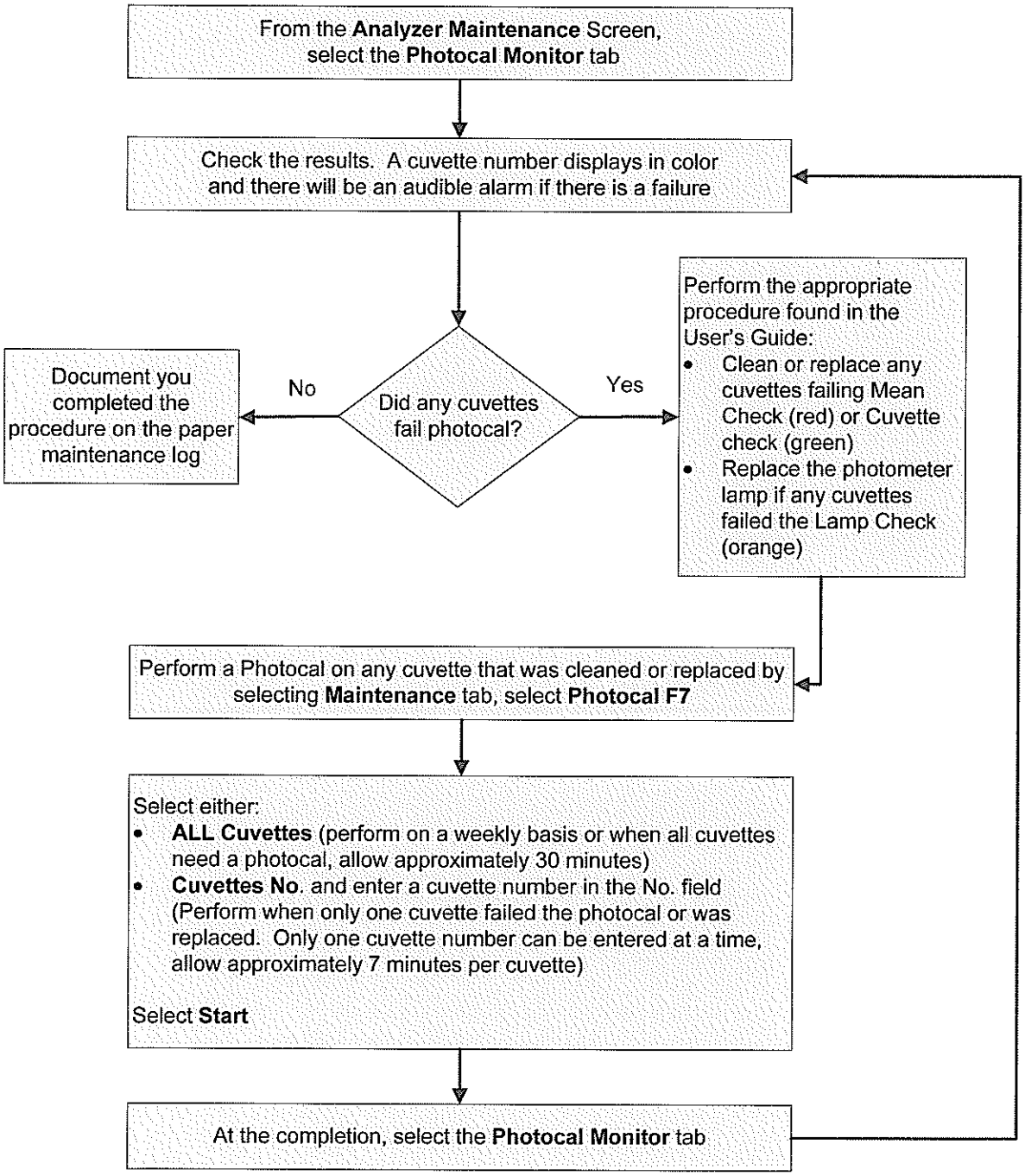
When the system returns to the ***Standby*** mode, continue with the **Check Photocal Results** procedure

Note: this procedure can be combined with W2 and enhanced ISE cleaning procedures at the W2 Start window

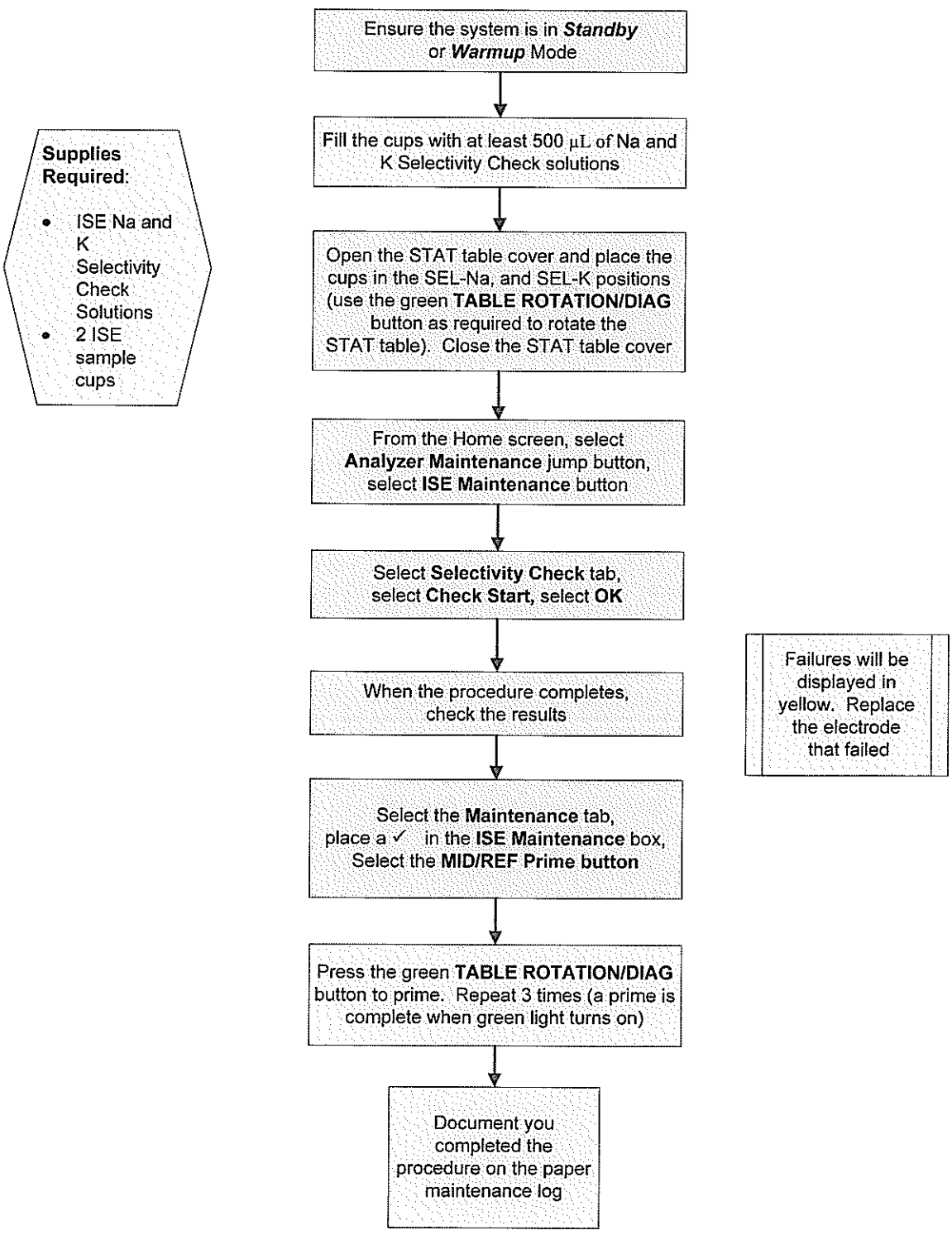
Enhanced Cleaning of the ISE Electrode Line (optional module)

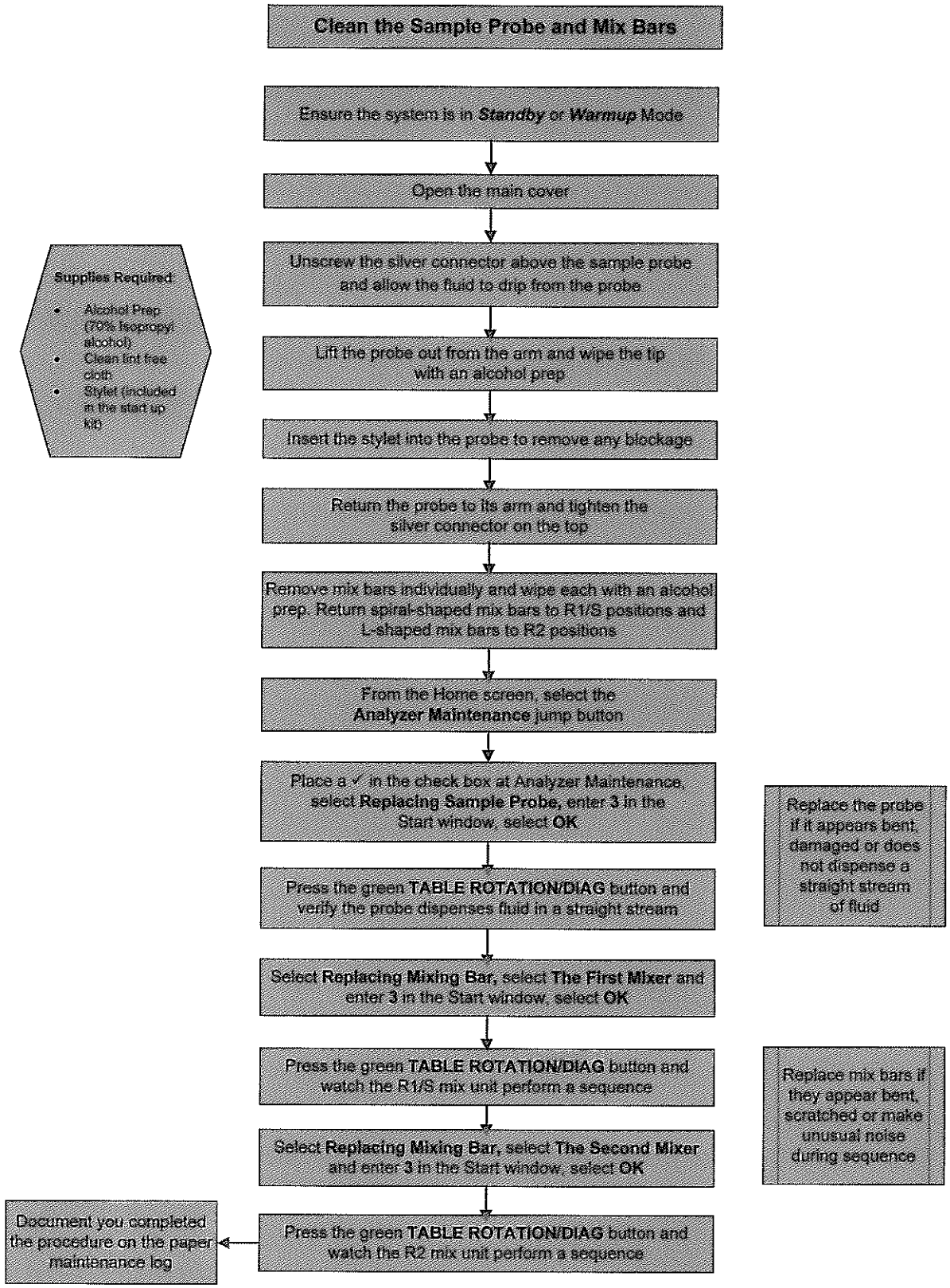


Check the Photocal Results



Check the Selectivity of the Na/K Electrodes

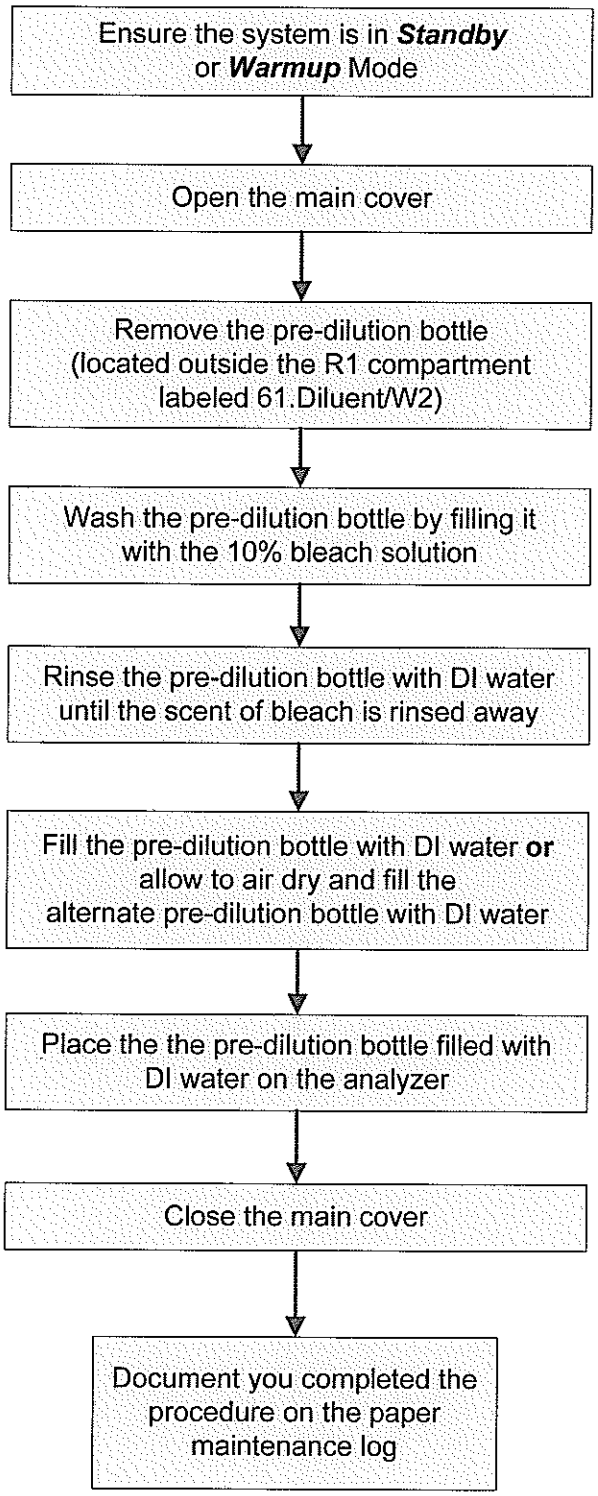



Clean the Sample Probe and Mix Bars
Ensure the system is in Standby or Warmup Mode
Open the main cover
Unscrew the silver connector above the sample probe and allow the fluid to drip from the probe
Lift the probe out from the arm and wipe the tip with an alcohol prep
Insert the stylet into the probe to remove any blockage
Return the probe to its arm and tighten the silver connector on the top
Remove mix bars individually and wipe each with an alcohol prep. Return spiral-shaped mix bars to R1/S positions and L-shaped mix bars to R2 positions
From the Home screen, select the Analyzer Maintenance jump button
Place a ✓ in the check box at Analyzer Maintenance, select Replacing Sample Probe, enter 3 in the Start window, select OK
Press the green TABLE ROTATION/DIAG button and verify the probe dispenses fluid in a straight stream
Select Replacing Mixing Bar, select The First Mixer and enter 3 in the Start window, select OK
Press the green TABLE ROTATION/DIAG button and watch the R1/S mix unit perform a sequence
Select Replacing Mixing Bar, select The Second Mixer and enter 3 in the Start window, select OK
Press the green TABLE ROTATION/DIAG button and watch the R2 mix unit perform a sequence
Document you completed the procedure on the paper maintenance log
Supplies Required
Alcohol Prep (70% Isopropyl alcohol)
Clean lint free cloth
Stylet (included in the start up kit)
Replace the probe if it appears bent, damaged or does not dispense a straight stream of fluid
Replace mix bars if they appear bent, scratched or make unusual noise during sequence

Clean the Pre-dilution Bottle

Supplies Required:

- 60 mL plastic reagent bottle (optional-alternate weekly)
- 10% Bleach (Sodium hypochlorite solution with 0.5% effective chlorine concentration. Prepare by adding 10 parts bleach to 90 parts DI Water)



Explore versatile capabilities and flexibility for your lab

AU680 Clinical Chemistry System

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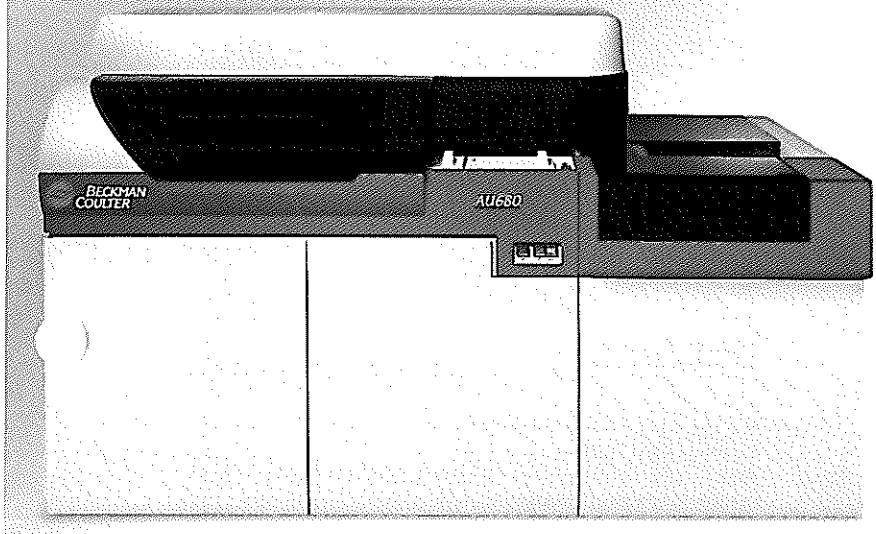

The AU680 is designed for the demanding environments of mid-sized to large laboratories and hospitals to meet ever increasing pressures on time and productivity. Flexibility of design offers stand-alone operation or connectivity to lab automation systems. With random access throughput of up to 800 photometric tests per hour (up to 1200 with electrolytes), and a broad menu of over 125 tests, the AU680 delivers field proven reliability and efficiency.

- Proven reliability and low maintenence
- Refrigerated reagent compartment and STAT module
- High-quality, permanent glass cuvettes
- High-precision microsampling
- Proprietary precision optics
- Long-life ISEs
- 150 samples continuous rack loader
- Priority re-run lane
- Plug and play calibration (2-D bar-code)
- Whole blood sampling capability for HbA1c testing

U.S. Food & Drug Administration

510(k) Premarket Notification

- [1]

FDA Home[3] Medical Devices[4] Databases[5]

[6]

510(k)[7]|Registration & Listing[8]|Adverse Events[9]|Recalls[10]|PMA[11]|Classification[12]|Standards[13]
CFR Title 21[14]|Radiation-Emitting Products[15]|X-Ray Assembler[16]|Medsun Reports[17]|CLIA[18]|TPLC[19]

New Search

Back To Search Results

Device Classification Name	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use[20]
510(K) Number	K961274
Device Name	OLYMPUS AU600 CLINICAL CHEMISTRY ANALYZER
Applicant	OLYMPUS AMERICA, INC. Two Corporate Center Dr. Melville, NY 11747 3157
Contact	Laura Storms-Tyler
Regulation Number	862.2160[21]
Classification Product Code	JJE[22]
Date Received	04/02/1996
Decision Date	07/05/1996
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Clinical Chemistry
Review Advisory Committee	Clinical Chemistry
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No
Combination Product	No

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9. ../cfMAUDE/TextSearch.cfm
10. ../cfRES/res.cfm
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13. ../cfStandards/search.cfm

EMIT Drugs-of-Abuse Urine Assays Cross-Reactivity List

Answers for life.

SIEMENS

EMIT II Plus

Cross-Reactivity Guide

Applicability of Cross-Reactivity Data

The information contained in this Cross-Reactivity List is applicable to any Drugs-of-Abuse Urine Assays that utilize the Siemens Syva® EMIT® II Plus Drugs-of-Abuse Reagents. Siemens analyzers that use these reagents are the ADVIA® 1200/1650/1800/2400, Dimension® RxL/EXL,™ Dimension Vista,® and the Vital Viva®/Viva E®/V-Twin®/Viva Jr® chemistry analyzers. The Siemens Syva EMIT II Plus Drugs-of-Abuse assays can also be run on other, non-Siemens clinical chemistry analyzers using Siemens-validated application parameters. These include, but are not limited to, the Beckman Coulter AU® series analyzers, COBAS MIRA series analyzers, and the HITACHI (Roche) 700 and 900 series analyzers.

Amphetamines

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, Phenmetrazine is listed at 2,300 for the Amphetamines assay at 300 ng/mL cutoff. This means that it takes a concentration of 2,300 ng/mL Phenmetrazine in urine to produce an instrument response equal to the 300 ng/mL d-methamphetamine calibrator. This concentration of drug in urine may be achieved in patients taking Phenmetrazine.

Negative – Structurally Related
Concentration in µg/mL of listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is NOT clinically significant, and is not generally encountered in individuals taking the listed drug.

For example, Bupropion is listed as 250 for the Amphetamines assay at 300 ng/mL cutoff. This means that it takes 250 µg/mL (250,000 ng/mL) of Bupropion to produce an instrument response equal to the 300 ng/mL d-Methamphetamine calibrator. This concentration of drug in urine is higher than normally seen in patients taking this drug.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

Amphetamines

The Amphetamines Assay has three cutoffs: 300 ng/mL, 500 ng/mL, and 1,000 ng/mL d-Methamphetamine.

Positive – The drugs listed are in ng/mL at which they will cross-react equivalent to the d-Methamphetamine cutoff.

	300 Cutoff	500 Cutoff	1,000 Cutoff
d,l-Amphetamine	625	1,050	2,150
l-Amphetamine	3,450	3,750	11,500
Benzphetamine*	400	700	1,000
erythro-Dihydrobupropion	20,000	32,000	(see page 6)
1,3-Dimethylpentylamine	3,400	5,500	14,900
Isometheptene	16,000	29,000	56,000
d,l-Methamphetamine	450	700	2,100
l-Methamphetamine	725	1,325	3,650
MDA (Methylenedioxyamphetamine)	1,100	1,700	(see page 6)
MDEA (Methylenedioxyethamphetamine)	4,400	6,800	(see page 6)
MDMA (Methylenedioxymethamphetamine)	5,200	9,150	(see page 6)
Phenmetrazine	2,300	3,500	13,000
Selegiline	#	#	#

*Benzphetamine metabolizes to amphetamine and methamphetamine.

#Selegiline metabolizes to l-amphetamine and l-methamphetamine. Patients taking Selegiline may test positive by Amphetamine assays.

Amphetamines

Negative – Structurally Related – The drugs listed are in µg/mL at which they will cross-react equivalent to the d-Methamphetamine cutoff.

	300 Cutoff	500 Cutoff	1,000 Cutoff
Bupropion	250	500	2,220
erythro-Dihydrobupropion	(see page 5)	(see page 5)	82
Cathinone	> 100	> 100	> 100
4-Chloramphetamine	2.6	4.5	12.2
Chloroquine	2,100	2,200	4,500
l-Ephedrine	400	800	3,500
Fenfluramine	25	40	150
MDA (Methylenedioxyamphetamine)	(see page 5)	(see page 5)	6.5
MDEA (Methylenedioxyethamphetamine)	(see page 5)	(see page 5)	27.2
MDMA (Methylenedioxymethamphetamine)	(see page 5)	(see page 5)	34.3
Mephentermine	8	15	60
Methcathinone	> 100	> 100	> 100
Methoxyphenamine	90	160	360
Phentermine	5.8	9	25
Phenylpropanolamine	700	1,000	2,000
PMA (p-Methoxyamphetamine)	4	7	34
PMMA (p-Methoxymethamphetamine)	8	14	81
Propranolol	100	125	500
d,l-Pseudoephedrine	1,400	2,600	8,300
nor-Pseudoephedrine	40	70	170
Quinacrine	2,500	3,800	16,500
Tranylcypromine	30	60	200
Tyramine	150	200	600

Negative – The compounds in this table were negative for the Amphetamines 300, 500, and 1,000 cutoffs at the concentrations shown except where noted. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alendronate	1,000
Alprazolam	1,000
5-Aminosalicyclic Acid	1,000
Amitriptyline	1,000
Amlodipine	750
Amoxicillin	1,000
Atenolol	1,000

Atomoxetine	1,000
Atorvastatin	1,000
Azithromycin	1,000
AZT (Zidovudine)	2,000
Benazepril	1,000
Benzoylecgonine	1,000
1-Benzylpiperazine @ 300	300
1-Benzylpiperazine @ 500	460
1-Benzylpiperazine @ 1,000	460
Buprenorphine	1,000

Amphetamines

Butorphanol	1,000
Caffeine	1,000
Carbamazepine	250
Carvedilol	1,000
Carisoprodol	1,000
Celecoxib	1,000
Cephalexin	1,000
Cetirizine	1,000
Chlorpheniramine	1,000
Chlorpromazine	200
Cimetidine	1,000
Ciprofloxacin	1,000
Citalopram	1,000
Clomipramine	2.5
Clonazepam	1,000
Clonidine	1,000
Clopidogrel Hydrogen Sulfate	1,000
Clotrimazole	1,000
Codeine	500
l-Cotinine	100
Cyclobenzaprine	1,000
Desipramine @ 300	300
Desipramine @ 500	500
Desipramine @ 1,000	800
Dextromethorphan	1,000
Dextrorphan	280
Diazepam	1,000
Diclofenac	1,000
Diethylpropion	1,000
Diltiazem	1,000
Diphenhydramine	1,000
Dobutamine	1,000
Doxepin	1,000
Doxycycline	1,000
Doxylamine	1,000
EDDP (2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)	1,000
Enalapril Maleate	1,000
Ephedrine	125
l-Epinephrine	1,000
Escitalopram	1,000
Escomeprazole	1,000
Eszopiclone	1,000
Ezetimibe	1,000
Fenoprofen	150
Fentanyl	75
Fexofenadine	1,000
Fluconazole	1,000
Fluoxetine	500
Fluticasone Proprionate	1,000
Furosemide	1,000
Gabapentin	1,000
Glutethimide	500
Glyburide	1,000
Griseofulvin	1,000
Guaifenesin	1,000
Haloperidol @ 300	500
Haloperidol @ 500	700
Haloperidol @ 1,000	1,000
Hydrochlorothiazide	1,000
Hydrocodone	1,000
Hydromorphone	1,000
Ibuprofen	1,000
Imipramine	750
Isoniazid	1,000
d,l-Isoproterenol	1,000
Isoxsuprine @ 300	300
Isoxsuprine @ 500	500
Isoxsuprine @ 1,000	500
Ketamine	100
Ketoprofen	1,000
Ketorolac Tromethamine	1,000
LAAM (l-α-Acetylmethadol)	25
dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	25
nor-LAAM (l-α-Acetyl-N-normethadol)	25
Labetalol	750
Lamotrigine	1,000
Lansoprazole	1,000
Levetiracetam	1,000
Lidocaine	1,000
Lisinopril	1,000
Lorsartan	1,000
LSD (Lysergic acid diethylamide)	2.5
MEGX (Monoethylglycinexylidide)	1,000
Meloxicam	1,000
Meperidine	1,000
Meprobamate	1,000
Mescaline @ 300	1,000
Mescaline @ 500	1,500
Mescaline @ 1,000	1,500
Metaproterenol	500
Metformin	1,000
Methadone	1,000

Amphetamines

Methaqualone	1,500
d,l-Methyldopa	1,000
l-Methyldopa	1,000
Methylphenidate	1,000
Metoprolol Tartrate	1,000
Metronidazole	1,000
Mirtazapine	1,000
Modafinil	1,000
Morphine	1,000
Nalmefene	20
Naloxone	500
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	1,000
Nicotinic Acid	500
Norsertraline	10
Nortryptyline	750
Nylidrin	750
Ofloxacin	100
Omeprazole	1,000
Oxazepam	300
Oxycodone	1,000
Oxymorphone	1,000
PABA (p-Aminobenzoic Acid)	1,000
Paroxetine	1,000
PCA (1-Phenylcyclohexylamine)	50
PCC (1-Piperidinocyclohexane Carbonitrile)	50
Phenazopyridine	300
PCP (Phencyclidine)	1,000
Phenelzine @ 300	50
Phenelzine @ 500	100
Phenelzine @ 1,000	100
Phenethylamine @ 300	15
Phenethylamine @ 500	20
Phenethylamine @ 1,000	20
Phenylephrine	1,000
Phenytoin (DPH)	1,000
Phthalic Acid	1,000
Pioglitazone	1,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	100
Procainamide	1,000
Promethazine	1,000
Propofol	1,000
Propoxyphene	1,000
Propylhexedrine @ 300	20
Propylhexedrine @ 500	30
Propylhexedrine @ 1,000	50
Quetiapine Fumerate	1,000
Quinapril	1,000
Rabeprazole	1,000
Ramipril	1,000
Ranitidine	1,000
Risedronate	1,000
Rifabutin	125
Rofecoxib	1,000
Ropinirole	500
Scopolamine	500
Secobarbital	1,000
Sertraline	1,000
Sildenafil	1,000
Simvastatin	1,000
+/-Synepherine	1,000
Sulfamethoxazole	1,000
Tapentadol	1,000
11-nor-Δ^9-THC-9-COOH	100
Thioridazine	100
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	2,000
Topiramate	1,000
Tramadol	1,000
Tranylcypromine	16
Trazodone	1,000
Trifluoperazine	1,000
Trihexylphenidyl	1,000
Trimethobenzamide	500
Trimethoprim	1,000
3-OH-Tyramine	300
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100

Barbiturate

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, Butalbital is listed as 304 for the Barbiturate assay at 200 ng/mL cutoff. This means that it takes a concentration of 304 ng/mL Butalbital in urine to produce an instrument response equal to the 200 ng/mL Secobarbital calibrator. This concentration of drug in urine may be achieved in patients taking Butalbital.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

Barbiturate

The Barbiturate Assay has two cutoffs: 200 ng/mL and 300 ng/mL Secobarbital.

Positive – The drugs listed are in ng/mL at which they will cross-react equivalent to the Secobarbital cutoff.

	200 Cutoff	300 Cutoff
Allobarbital	345	744
Alphenal	284	978
Amobarbital	348	923
Aprobarbital	275	478
Barbital	1,278	4,148
5-Ethyl-5-(4-hydroxyphenyl) barbituric acid	927	4,719
Butabarbital	274	523
Butalbital	304	475
Butobarbital	349	875
Cyclopentobarbital	304	527
Pentobarbital	252	447
Phenobarbital	509 – 971	2,386 – 4,624
Talbutal	194	262
Thiopental	16,400	80,400

Barbiturate

Negative – The compounds below were negative for the Barbiturate 200 and 300 cutoffs at the concentrations shown. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alendronate	1,000
Alprazolam	1,000
5-Aminosalicyclic Acid	1,000
Amitriptyline	1,000
Amlodipine	1,000
Amoxicillin	1,000
Atenolol	1,000
Atomoxetine	1,000
Atorvastatin	1,000
Azithromycin	1,000
AZT (Zidovudine)	2,000
Benazepril	1,000
Benzoylecgonine	1,000
Buprenorphine	1,000
Bupropion	1,000
Bupropion, *erythro*-dihydro metabolite	1,000
Butorphanol	1,000
Caffeine	1,000
Carbamazepine	1,000
Carbamazepine 10,11-Epoxide	1,000
Carvedilol	1,000
Celecoxib	1,000
Cephalexin	1,000
Cetirizine	1,000
Chlorpheniramine	1,000
Chlorpromazine	1,000
Cimetidine	1,000
Ciprofloxacin	1,000
Citalopram	1,000
Clomipramine	2.5
Clonazepam	1,000
Clonidine	1,000
Clopidogrel Hydrogen Sulfate	1,000
Clotrimazole	1,000
Codeine	500
Cotinine	100
Cyclobenzaprine	1,000
Desipramine	800
Dextromethorphan	1,000
Dextrorphan	280
Diazepam	1,000
Diclofenac	1,000
Diltiazem	1,000
Diphenhydramine	1,000
Doxepin	1,000
Doxycycline	1,000
Doxylamine	1,000
EDDP (2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)	1,000
Enalapril Maleate	1,000
Ephedrine	1,000
Escitalopram	1,000
Escomeprazole	1,000
Eszopiclone	1,000
Ezetimibe	1,000
Fentanyl	1,000
Fexofenadine	1,000
Fluconazole	1,000
Fluoxetine	1,000
Fluticasone Proprionate	1,000
Furosemide	1,000
Gabapentin	1,000
Glutethimide	300
Glyburide	1,000
Griseofulvin	1,000
Guaifenesin	1,000
Hydrochlorothiazide	1,000
Hydrocodone	1,000
Hydromorphone	1,000
Ibuprofen	1,000
Isoniazid	1,000
d,l-Isoproterenol	1,000
Isoxsuprine	1,000
Ketamine	100
Ketoprofen	1,000
Ketorolac Tromethamine	1,000
LAAM (l-α-Acetylmethadol)	25
dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	25
Lamotrigine	1,000
Lansoprazole	1,000
Levetiracetam	1,000
Levofloxacin	1,000

Barbiturate

Lidocaine	1,000
Lisinopril	1,000
Lorazepam	250
Lormetazepam	1
Lorsartan	1,000
LSD (Lysergic acid diethylamide)	2.5
Meloxicam	1,000
Meperidine	1,000
Meprobamate	1,000
Metaproterenol	1,000
Metformin	1,000
Methadone	100
d-Methamphetamine	35
Methaqualone	1,500
MDA (Methylenedioxyamphetamine)	5
MDMA (Methylenedioxy-methamphetamine)	200
Metoprolol Tartrate	1,000
Metronidazole	1,000
Mirtazapine	1,000
Modafinil	1,000
Morphine	1,000
Myoglobin	287
Nalbuphine	1,000
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	1,000
Norsertraline	10
Nortryptyline	1,000
Nylidrin	1,000
Omeprazole	1,000
Oxazepam	300
Oxycodone	1,000
Oxymorphone	1,000
Paroxetine	1,000
Phenazopyridine	300
PCP (Phencyclidine)	1,000
Phenytoin (DPH)	1,000
Pioglitazone	1,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	100
Promethazine	1,000
Propofol	1,000
Propoxyphene	1,000
Propranolol	1,000
Pseudoephedrine	1,000
Quetiapine Fumerate	1,000
Quinapril	1,000
Rabeprazole	1,000
Ramipril	1,000
Ranitidine	1,000
Rifabutin	1,000
Risedronate	1,000
Risperidone	1,000
Rofecoxib	1,000
Ropinirole	1,000
Scopolamine	500
Sertraline	1,000
Sibutramine HCl	1,000
Sildenafil	1,000
Simvastatin	1,000
Terbutaline	1,000
Sulfamethoxazole	1,000
Tapentadol	1,000
11-nor-Δ^9-THC-9-COOH	100
Thioridazine	100
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	1,000
Topiramate	1,000
Tramadol	1,000
Tranylcypromine	1,000
Trazadone	1,000
Trifluoperazine	1,000
Trihexylphenidyl	1,000
Trimethoprim	1,000
Tyramine	100
Valproic Acid	1,000
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100

Benzodiazepine

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, Alprazolam is listed as 65 for the Benzodiazipine assay at 200 ng/mL cutoff. This means that it takes a concentration of 65 ng/mL Alprazolam in urine to produce an instrument response equal to the 200 ng/mL Lormetazepam calibrator. This concentration of drug in urine may be achieved in patients taking Alprazolam.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

Benzodiazepine

The Benzodiazipine Assay has two cutoffs: 200 ng/mL and 300 ng/mL Lormetazepam.

Positive – The drugs listed are in ng/mL at which they will cross-react equivalent to the Lormetazepam cutoff.

	200 Cutoff	300 Cutoff
Alprazolam	65	79
7-Aminoclonazepam	2,600	(see page 15)
7-Aminoflunitrazepam	590	1,400
7-Aminonitrazepam	365	1,000
Bromazepam	630	1,400
Chlordiazepoxide	3,300	7,800
Clobazam	260	800
Clonazepam	580	1,100
Clorazepate	#	#
Clotiazepam	380	670
Demoxepam	1,600	4,000
N-Desalkylflurazepam	130	160
N-Desmethyldiazepam	110	140
Diazepam	70	120
Estazolam	90	1,100
Flunitrazepam	140	190
Flurazepam	190	250
Halazepam	110	160
α-Hydroxyalprazolam	100	150
α-Hydroxyalprazolam Glucuronide	110	120
1-N-Hydroxyethylflurazepam	150	150
α-Hydroxymidazolam	150	220
α-Hydroxytriazolam	130	190
Ketazolam	100	140
Lorazepam	600	890
Medazepam	150	210
Midazolam	130	160
Nefopam	135 @	280 @
Nitrazepam	320	560
Norchlordiazepoxide	2,600	4,900
Oxaprozin	*	*
Oxazepam	250	350
Prazepam	90	130
Temazepam	140	210
Temazepam glucuronide	6,900	11,000
Tetrazepam	70	100

Clorazepate degrades rapidly in stomach acid to nordiazepam. Nordiazepam hydroxylates to oxazepam.
@ Therapeutic doses of nefopam may produce positive results with this assay.
* Therapeutic doses of oxaprozin may produce positive results with this assay.

Benzodiazepine

Negative – Structurally Related – The drugs listed are in µg/mL at which they will cross-react equivalent to the Lormetazepam cut-off.

	200 Cutoff	300 Cutoff
7-Aminoclonazepam	(see above)	8.6
Lorazepam glucuronide	> 20	> 20
Oxazepam glucuronide	> 20	> 20

Negative – The compounds below were negative for the Benzodiazepine 200 and 300 cutoffs at the concentrations shown except where noted. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alendronate	1,000
5-Aminosalicyclic Acid	1,000
Amitriptyline	1,000
Amlodipine	1,000
Amoxicillin	1,000
d-Amphetamine	1,000
Atomoxetine	1,000
Atorvastatin	1,000
Azathioprine	1,000
Azithromycin	1,000
AZT (Zidovudine)	2,000
Benazepril	1,000
Benzoylecgonine	1,000
Buprenorphine	1,000
Bupropion	1,000
Bupropion, *erythro*-dihydro metabolite	1,000
Butorphanol	1,000
Caffeine	1,000
Carvedilol	1,000
Celecoxib	1,000
Cephalexin	1,000
Cetirizine	1,000
Chlorpheniramine	1,000
Chlorpromazine	1,000
Cimetidine	1,000
Ciprofloxacin	1,000
Citalopram	1,000
Clomipramine	2.5
Clonidine	1,000
Clopidogrel Hydrogen Sulfate	1,000
Clotrimazole	1,000
Clozapine	50
Clozapine N-Oxide	50
Codeine	500
Cotinine	100
Cyclobenzaprine	1,000
Desipramine	800
N-Desmethylsertraline	500
Dextromethorphan	1,000
Diclofenac	1,000
Diltiazem	1,000
Diphenhydramine	1,000
Doxepin	1,000
Doxycycline	1,000
Doxylamine	1,000
EDDP (2-Ethylidene-1,5-dimethyl- 3, 3-diphenylpyrrolidine)	1,000
Enalapril Maleate	1,000
Ephedrine	1,000
Escitalopram	900
Escomeprazole	1,000
Eszopiclone	1,000
Ezetimibe	1,000
Fentanyl	1,000
Fexofenadine	1,000
Fluconazole	1,000
Fluoxetine	1,000
Fluticasone Proprionate	1,000
Fluvoxamine	1,000
Furosemide	1,000
Gabapentin	1,000
Glutethimide	500
Glyburide	1,000
Griseofulvin	1,000
Guaifenesin	1,000
Hydrochlorothiazide	1,000
Hydrocodone	1,000
Hydromorphone	900
Ibuprofen	1,000
Isoniazid	1,000
d,l-Isoproterenol	1,000

Benzodiazepine

Isoxsuprine	1,000
Ketamine	100
Ketoprofen	1,000
Ketorolac Tromethamine	1,000
LAAM (l-α-Acetylmethadol)	25
dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	25
Lamotrigine	1,000
Lansoprazole	1,000
Levetiracetam	1,000
Levofloxacin	1,000
Lidocaine	1,000
Lisinopril	1,000
Loratadine	1,000
Lorsartan	1,000
LSD (Lysergic acid diethylamide)	0.01
MDA (Methylenedioxyamphetamine)	5
MDMA (Methylenedioxy-methamphetamine)	200
Meloxicam	1,000
Meperidine	1,000
Meprobamate	1,000
Metaproterenol	1,000
Metformin	1,000
Methadone	100
d-Methamphetamine	35
Methaqualone	1,500
Metoprolol Tartrate	1,000
Metronidazole	1,000
Mirtazapine	1,000
Modafinil	500
Morphine	1,000
Myoglobin	287
Nabumetone	1,000
Nalbuphine	1,000
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	1,000
Norsertraline	10
Nortriptyline	1,000
Nylidrin	1,000
Olanzapine @ 300	1,000
Omeprazole	1,000
Oxycodone	900
Oxymorphone	1,000
Paroxetine	1,000
Phenazopyridine	300
PCP (Phencyclidine)	1,000
Phenytoin (DPH)	1,000
Pioglitazone	1,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	100
Promethazine	1,000
Propofol	1,000
Propoxyphene	1,000
Propranolol	1,000
Pseudoephedrine	1,000
Quetiapine Fumerate	500
Quinapril	1,000
Rabeprazole	1,000
Raloxifene	1,000
Ramipril	1,000
Ranitidine	1,000
Rifabutin	1,000
Risedronate	1,000
Risperidone	1,000
Rizatriptan Benzate	1,000
Rofecoxib	1,000
Ropinirole	1,000
Scopolamine	500
Secobarbital	1,000
Sibutramine HCL	1,000
Sildenafil	1,000
Simvastatin	1,000
Sulfamethoxazole	1,000
Tapentadol	1,000
11-nor-Δ^9-THC-9-COOH	100
Thioridazine	100
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	1,000
Topiramate	1,000
Tramadol	1,000
Tranylcypromine	1,000
Trazadone	1,000
Trifluoperazine	1,000
Trihexylphenidyl	1,000
Trimethoprim	1,000
Tyramine	100
Valerian Root	10,000
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100
Zopiclone	1,000

Cannabinoid

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, 11-Hydroxy-Δ^8-THC is listed as 67 for the Cannabinoid assay at 50 ng/mL cutoff. This means that it takes a concentration of 67 ng/mL 11-Hydroxy-Δ^8-THC in urine to produce an instrument response equal to the 50 ng/mL 11-nor-Δ^9-THC-9-COOH calibrator. This concentration of drug in urine may be achieved in patients taking THC.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

Cannabinoid

The Cannabinoid Assay has three cutoffs: 20 ng/mL, 50 ng/mL, and 100 ng/mL 11-nor-Δ^9-THC-9-COOH.

Positive – The drugs listed are in ng/mL at which they will cross-react equivalent to the 11-nor-Δ^9-THC-9-COOH cutoff.

	20 Cutoff	50 Cutoff	100 Cutoff
(-)9-Carboxy-11-nor-Δ^9-THC-glucuronide	79	95	328
8-β-11-Dihydroxy-Δ^9-THC	24	58	109
11-Hydroxy-Δ^8-THC	43	67	129
11-Hydroxy-Δ^9-THC	42	77	124
8-β-Hydroxy-Δ^9-THC	26	68	146

Cannabinoid

Negative – The compounds below were negative for the Cannabinoid 20, 50, and 100 cutoffs at the concentrations shown except where noted. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alendronate	1,000
Alprazolam	1,000
5-Aminosalicyclic Acid	1,000
Amitriptyline	1,000
Amlodipine	1,000
Amoxicillin	1,000
d-Amphetamine	1,000
Atomoxetine	1,000
Atorvastatin	1,000
Azathioprine @ 50	1,000
Azathioprine @ 100	1,000
Azithromycin	1,000
AZT (Zidovudine)	2,000
Benazepril	1,000
Benzoylecgonine	1,000
Buprenorphine	1,000
Bupropion	1,000
Bupropion, *erythro*-dihydro metabolite	1,000
Butorphanol	1,000
Caffeine	1,000
Celecoxib	1,000
Cephalexin	1,000
Cetirizine	1,000
Chlorpheniramine	1,000
Chlorpromazine	1,000
Cimetidine	1,000
Ciprofloxacin	1,000
Citalopram	1,000
Clomipramine	2.5
Clonazepam	1,000
Clonidine	1,000
Clopidogrel Hydrogen Sulfate	1,000
Clotrimazole	1,000
Codeine	500
Cotinine	100
Cyclobenzaprine	1,000
Desipramine	800
Dextromethorphan	1,000
Diazepam	1,000
Diclofenac	1,000
Diltiazem	1,000
Diphenhydramine	1,000
Doxepin	1,000
Doxycycline	1,000
Doxylamine	1,000
EDDP (2-Ethylidene-1,5-dimethyl- 3, 3-diphenylpyrrolidine)	1,000
Efavirenz	1,000
Enalapril Maleate	1,000
Ephedrine	1,000
Escitalopram	1,000
Escomeprazole	1,000
Eszopiclone	1,000
Ezetimibe	1,000
Fentanyl	1,000
Fexofenadine	1,000
Fluconazole	1,000
Fluoxetine	1,000
Fluticasone Proprionate	1,000
Furosemide	1,000
Gabapentin	1,000
Glutethimide	500
Glyburide	1,000
Griseofulvin	1,000
Guaifenesin	1,000
Hydrochlorothiazide	1,000
Hydrocodone	1,000
Hydromorphone	1,000
Ibuprofen	1,000
Isoniazid	1,000
d,l-Isoproterenol	1,000
Isoxsuprine	1,000
Ketamine	100
Ketoprofen	1,000
Ketorolac Tromethamine	1,000
LAAM (l-α-Acetylmethadol)	25
dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	25
Lamotrigine	1,000

Cannabinoid

Lansoprazole	1,000
Levetiracetam	1,000
Levofloxacin	1,000
Lidocaine	1,000
Lisinopril	1,000
Lormetazepam	1
Lorsartan	1,000
LSD (Lysergic acid diethylamide)	0.01
MDA (Methylenedioxyamphetamine)	5
MDMA (Methylenedioxy-methamphetamine)	200
Meloxicam	1,000
Meperidine	1,000
Meprobamate	1,000
Metaproterenol	1,000
Metformin	1,000
Methadone	100
d-Methamphetamine	35
Methaqualone	1,500
Metoprolol Tartrate	1,000
Metronidazole	1,000
Mirtazapine	1,000
Modafinil	1,000
Morphine	1,000
Myoglobin @ 50	287
Myoglobin @ 100	287
Nalbuphine	1,000
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	1,000
Norsertraline	10
Nortriptyline	1,000
Nylidrin	1,000
Omeprazole	1,000
Oxazepam	300
Oxycodone	1,000
Oxymorphone	1,000
Pantoprazole	1,000
Paroxetine	1,000
Phenazopyridine	300
PCP (Phencyclidine)	1,000
Phenytoin (DPH)	1,000
Pioglitazone	1,000
Potassium Nitrite @ 50	5,000
Potassium Nitrite @ 100	5,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	1,000
Promethazine	1,000
Propofol	1,000
Propoxyphene	1,000
Propranolol	1,000
Pseudoephedrine	1,000
4-Pyridoxic Acid @ 100	1,000
Quetiapine Fumerate	1,000
Quinapril	1,000
Rabeprazole	1,000
Ramipril	1,000
Ranitidine	1,000
Rifabutin	1,000
Risedronate	1,000
Risperidone	1,000
Rofecoxib	1,000
Ropinirole	1,000
Scopolamine	500
Secobarbital	1,000
Sertraline	1,000
Sibutramine HCL @ 100	1,000
Sildenafil	1,000
Simvastatin	1,000
Sulfamethoxazole	1,000
Thioridazine	100
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	1,000
Topiramate	1,000
Tramadol	1,000
Tranylcypromine	1,000
Trazadone	1,000
Trifluoperazine	1,000
Trihexylphenidyl	1,000
Trimethoprim	1,000
Tyramine	100
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100

Cocaine Metabolite

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, Cocaine is listed as 40 – 119 for the Cocaine Metabolite assay at 300 ng/mL cutoff. This means that it takes a concentration of 40 – 119 µg/mL Cocaine in urine to produce an instrument response equal to the 300 ng/mL benzoylecgonine calibrator. This concentration of drug in urine may be achieved in patients taking Cocaine.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

Cocaine Metabolite

The Cocaine Metabolite Assay has two cutoffs: 150 ng/mL and 300 ng/mL benzoylecgonine.

Positive – The drugs listed are in µg/mL at which they will cross-react equivalent to the benzoylecgonine cutoff.

	150 Cutoff	300 Cutoff
Cocaine	18 – 53	40 – 119
Ecgonine	2 – 6	7 – 20

Negative – The compounds below were negative for the Cocaine Metabolite 150 and 300 cutoffs at the concentrations shown except where noted. Concentrations listed are in µg/mL.

Acetaminophen	1,000	Clotrimazole	1,000
Acetylsalicylic Acid	1,000	Codeine	500
Albuterol	1,000	Cotinine	100
Alendronate	1,000	Cyclobenzaprine	1,000
Alprazolam	1,000	Desipramine	800
5-Aminosalicyclic Acid	1,000	Dextromethorphan	1,000
Amitriptyline	1,000	Diazepam	1,000
Amlodipine	1,000	Diclofenac	1,000
Amoxicillin	1,000	Diltiazem	1,000
d-Amphetamine	100	Diphenhydramine	1,000
Atomoxetine	1,000	Doxepin	1,000
Atorvastatin	1,000	Doxycycline	1,000
Azathioprine	1,000	Doxylamine	1,000
Azithromycin	1,000	EDDP (2-Ethylidene-1,5-dimethyl- 3,	
AZT (Zidovudine)	2,000	3-diphenylpyrrolidine)	1,000
Benazepril	1,000	Enalapril Maleate	1,000
Benztropine	1,000	Ephedrine	1,000
Bupivicaine	1,000	Escitalopram	1,000
Buprenorphine	1,000	Escomeprazole	1,000
Bupropion	1,000	Eszopiclone	1,000
Bupropion, *erythro*-dihydro metabolite	1,000	Ezetimibe	1,000
Butorphanol	1,000	Fentanyl	1,000
Caffeine	1,000	Fexofenadine	1,000
Carvedilol	1,000	Fluconazole	1,000
Celecoxib	1,000	Fluoxetine	1,000
Cephalexin	1,000	Fluticasone Proprionate	1,000
Cetirizine	1,000	Furosemide	1,000
Chlorpheniramine	1,000	Gabapentin	1,000
Chlorpromazine	1,000	Glutethimide	500
Cimetidine	1,000	Glyburide	1,000
Ciprofloxacin	1,000	Griseofulvin	1,000
Citalopram	1,000	Guaifenesin	1,000
Clomipramine	2.5	Hydrochlorothiazide	1,000
Clonazepam	1,000	Hydrocodone	1,000
Clonidine	1,000	Hydromorphone	1,000
Clopidogrel Hydrogen Sulfate	1,000	Ibuprofen	1,000

Cocaine Metabolite

Isoniazid	1,000
d,l-Isoproterenol	1,000
Isoxsuprine	1,000
Ketamine	100
Ketoprofen	1,000
Ketorolac Tromethamine	1,000
LAAM (l-α-Acetylmethadol)	25
dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	25
Lamotrigine	1,000
Lansoprazole	1,000
Levetiracetam	1,000
Levofloxacin	1,000
Lidocaine	1,000
Lisinopril	1,000
Lormetazepam	1
Lorsartan	1,000
LSD (Lysergic acid diethylamide)	0.01
MDA (Methylenedioxyamphetamine)	5
MDMA (Methylenedioxy-methamphetamine)	200
Meloxicam	1,000
Meperidine	1,000
Meprobamate	1,000
Metaproterenol	1,000
Metformin	1,000
Methadone	1,000
d-Methamphetamine	35
Methaqualone	1,500
Metoclopramide	1,000
Metoprolol Tartrate	1,000
Metronidazole	1,000
Mirtazapine	1,000
Modafinil	1,000
Morphine	1,000
Myoglobin	287
Nalbuphine	1,000
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	1,000
Norsertraline	10
Nortriptyline	1,000
Nylidrin	1,000
Omeprazole	1,000
Oxazepam	300
Oxycodone	1,000
Oxymorphone	1,000
Paroxetine	1,000
Phenazopyridine	300
PCP (Phencyclidine)	1,000
Phenytoin (DPH)	1,000
Pioglitazone	1,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	1,000
Promethazine	1,000
Propofol	1,000
Propoxyphene	1,000
Propranolol	1,000
Pseudoephedrine	1,000
Quetiapine Fumerate	1,000
Quinapril	1,000
Rabeprazole	1,000
Ramipril	1,000
Ranitidine	1,000
Rifabutin	1,000
Risedronate	1,000
Risperidone	1,000
Rofecoxib	1,000
Ropinirole	1,000
Scopolamine	500
Secobarbital	1,000
Sertraline	1,000
Sibutramine HCl	1,000
Sildenafil	1,000
Simvastatin	1,000
Tetracaine	1,000
Sulfamethoxazole	1,000
Tapentadol	1,000
11-nor-Δ^9-THC-9-COOH	100
Thioridazine	100
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	1,000
Topiramate	1,000
Tramadol	1,000
Tranylcypromine	1,000
Trazadone	1,000
Trifluoperazine	1,000
Trihexylphenidyl	1,000
Trimethoprim	1,000
Tyramine	100
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100

Ecstasy

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, BDB is listed as 220 for the Ecstasy assay at 300 ng/mL cutoff. This means that it takes a concentration of 220 ng/mL BDB in urine to produce an instrument response equal to the 300 ng/mL MDMA calibrator. This concentration of drug in urine may be achieved in patients taking BDB.

Negative – Structurally Related
Concentration in µg/mL of listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is NOT clinically significant, and is not generally encountered in individuals taking the listed drug.

For example, Bupropion is listed as 2,000 for the Ecstasy assay at 300 ng/mL cutoff. This means that it takes 2,000 µg/mL (2,000,000 ng/mL) of Bupropion to produce an instrument response equal to the 300 ng/mL MDMA calibrator. This concentration of drug in urine is higher than normally seen in patients taking this drug.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

Ecstasy

The Ecstasy Assay has two cutoffs: 300 ng/mL and 500 ng/mL MDMA.

Positive – The drugs listed are in ng/mL at which they will cross-react equivalent to the MDMA cutoff.

	300 Cutoff	500 Cutoff
BDB (3,4-(Methylenedioxyphenyl)-2-butanamine)	220	780
HMMA (4-Hydroxy-3-methoxy-methamphetamine)	50,000	50,000
MBDB (N-Methyl-1-(1,3-Dimethylpentylamine)-2-Butanamine)	200	430
MDA (Methylenedioxyamphetamine)	280	578
MDEA (Methylenedioxyethamphetamine)	290	528
PMA (p-Methoxyamphetamine)	13,000	22,000
PMMA (p-Methoxymethamphetamine)	1,900	3,600
Haloperidol	8,000	(see page 26)
Trazodone	7,000	(see page 26)
Tetrazepam	70	100

Ecstasy

Negative – Structurally Related – The drugs listed are in µg/mL at which they will cross-react equivalent to the MDMA cutoff.

	300 Cutoff	500 Cutoff
d-Amphetamine	160	430
l-Amphetamine	220	685
d,l-Amphetamine	32	83
Benzphetamine	36	88
Bupropion	2,000	4,400
Bupropion, *erythro* dihydro-metabolite	25	–
4-Chloramphetamine	9	60
Chloroquine	2,000	2,000
Dobutamine	37	130
l-Ephedrine	230	2,200
Fenfluramine	5	22
Haloperidol	(see page 25)	85
Isoxsuprine	22	165
Labelatol	35	80
Mephentermine	180	380
d-Methamphetamine	37	130
l-Methamphetamine	30	87
d,l-Methamphetamine	200	430
Methoxyphenamine	6,900	13,400
Nylidrin	24	70
Phenmetrazine	3,400	7,400
Phentermine	700	1,700
PPA (Phenylpropanolamine)	700	2,200
Propanolol	440	1,500
d-Pseudoephedrine	450	1,600
nor-Pseudoephedrine	830	7,600
Quinacrine	4,000	4,000
+/-Synepherine	650	1,500
Tranylcypromine	420	2,800
Trazodone	(see page 25)	24
Tyramine	3,200	7,000

Ecstasy

Negative – The compounds below were negative for the Ecstasy at the 300 and 500 cutoffs at the concentrations shown except where noted. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alendronate	1,000
Alprazolam	1,000
5-Aminosalicyclic Acid	1,000
Amitriptyline	10
Amlodipine	1,000
Amoxicillin	1,000
Atenolol	1,000
Atomoxetine	1,000
Atorvastatin	1,000
Azithromycin	1,000
AZT (Zidovudine)	2,000
Benazepril	1,000
Benzoylecgonine	1,000
Buprenorphine	1,000
Bupropion	1,000
Butorphanol	1,000
Caffeine	1,000
Carbamazepine	250
Carisoprodol	1,000
Celecoxib	1,000
Cephalexin	1,000
Cetirizine	1,000
Chlorpheniramine	500
Chlorpromazine	500
Cimetidine	1,000
Ciprofloxacin	1,000
Citalopram	1,000
Clomipramine	2.5
Clonazepam	1,000
Clonidine	1,000
Clopidogrel Hydrogen Sulfate	1,000
Clotrimazole	1,000
Codeine	500
l-Cotinine	100
Cyclobenzaprine	125
Desipramine	800
Dextromethorphan	1,000
Dextrorphan	280
Diazepam	1,000
Diclofenac	1,000
Diethylpropion HCl	1,000
Diltiazem	1,000
Diphenhydramine	1,000
Doxepin	250
Doxycycline	1,000
Doxylamine	1,000
EDDP (2-Ethylidene-1,5-dimethyl-3, 3-diphenylpyrrolidine)	1,000
Enalapril Maleate	1,000
Ephedrine	62.5
l-Epinephrine	1,000
Escitalopram	1,000
Escomeprazole	1,000
Eszopiclone	1,000
Ezetimibe	1,000
Fenoprofen	1,000
Fentanyl	75
Fexofenadine	1,000
Fluconazole	1,000
Fluoxetine	125
Fluticasone Proprionate	1,000
Furosemide	1,000
Gabapentin	1,000
Glutethimide	500
Glyburide	1,000
Griseofulvin	1,000
Guaifenesin	1,000
Hydrochlorothiazide	1,000
Hydrocodone	1,000
Hydromorphone	1,000
Ibuprofen	1,000
Imipramine	750
Isoniazid	1,000
d,l-Isoproterenol	1,000
Ketorolac Tromethamine	350
Ketamine	100
Ketoprofen	1,000
LAAM (l-α-Acetylmethadol)	25
dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	25
Lamotrigine	1,000
Lansoprazole	1,000
Levetiracetam	1,000
Levofloxacin	1,000
Lidocaine	1,000

Ecstasy

Lisinopril	1,000
Lorsartan	1,000
LSD (Lysergic acid diethylamide)	0.15
MEGX (Monoethyl-glycinexylidide)	1,000
Meloxicam	1,000
Meperidine HCl	1,000
Meprobamate	1,000
Mescaline	1,500
Metaclopramide	1,000
Metaproterenol	250
Metformin	1,000
Methadone	1,000
Methaqualone	1,500
l-Methyldopa	1,000
d,l-Methyldopa	1,000
Methylphenidate	1,000
Metoprolol Tartrate	1,000
Metronidazole	1,000
Mirtazapine	1,000
Modafinil	1,000
Morphine	1,000
Nalmefene	20
Naloxone	500
Nalbuphine	1,000
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	16
Nicotinic Acid	500
Nitroglycerin	1,000
Noracetylmethadol	25
Norsertraline	10
Nortriptyline	1,000
Ofloxacin	100
Omeprazole	1,000
Oxazepam	300
Oxycodone	1,000
Oxymorphone	1,000
PABA (p-Aminobenzoic Acid)	1,000
Paroxetine	5
Phenazopyridine	300
PCA (1-Phenylcyclohexylamine)	50
PCC (1-Piperidinocyclohexane Carbonitrile)	50
PCP (Phencyclidine)	1,000
Phendimetrazine	400
Phenelzine	100
Phenethylamine	20
Phenylephrine	20
Phenytoin (DPH)	1,000
Phthalic Acid	1,000
Pioglitazone	1,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	100
Procainamide	1,000
Promethazine	1,000
Propofol	1,000
Propoxyphene	1,000
Propranolol	250
Propylhexedrine	125
Quetiapine Fumerate	1,000
Quinapril	1,000
Rabeprazole	1,000
Ramipril	1,000
Ranitidine	1,000
Rifabutin	1,000
Risedronate	1,000
Risperidone	16
Rofecoxib	1,000
Ropinirole	1,000
Scopolamine	500
Secobarbital	1,000
Sertraline	125
Sildenafil	1,000
Simvastatin	1,000
Sulfamethoxazole	1,000
Tapentadol	1,000
11-nor-Δ^9-THC-9-COOH	100
Thioridazine	100
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	2,000
Topiramate	1,000
Tramadol	1,000
Tranylcypromine	125
Trifluoperazine	1,000
Trihexylphenidyl	1,000
Trimethobenzamide	500
Trimethoprim	1,000
3-OH-Tyramine	300
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100

LSD

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, Fentanyl is listed as 3 for the LSD assay at 0.5 ng/mL cutoff. This means that it takes a concentration of 3 ng/mL Fentanyl in urine to produce an instrument response equal to the 0.5 ng/mL LSD calibrator. This concentration of drug in urine may be achieved in patients taking Fentanyl.

Positive, Not Clinically Significant
Concentration in µg/mL of listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is NOT clinically significant, and is not generally encountered in individuals taking the listed drug.

For example, d-Amphetamine is listed as 500 for the LSD assay. This means that it takes 500 µg/mL (500,000 ng/mL) of d-Amphetamine to produce an instrument response equal to the 0.5 ng/mL LSD calibrator. This concentration of drug in urine is higher than normally seen in patients taking this drug.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

LSD

The LSD Assay has one cutoff at 0.5 ng/mL

Positive – The drugs listed are in ng/mL at which they will cross-react equivalent to the LSD cutoff.

	0.5 Cutoff
Ambroxol	60
Amitriptyline	7,800
Chlorpromazine	1,410
Clomipramine	2,560
Dicyclomine	22,300
Diltiazem	390
Doxepin	7,800
Ergonovine	1,000
Fentanyl	3
Fluoxetine	3,800
Flurazepam	130
Haloperidol	240
Lysergol	10,300
Maprotiline	25,100
Methysergide	3,000
Metoclopramide	350
Nortriptyline	15,600
Norverapamil	13,300
Nylidrin	15,600
2-oxo-3-hydroxy-LSD	21
Risperidone	1,950
Sertraline	390
Thioridazine	7,100
Thiothixene	14,500
Verapamil	7,800

Positive, Not Clinically Significant – The drugs listed are in ug/mL at which they will cross-react equivalent to the LSD cutoff.

	0.5 Cutoff
d-Amphetamine	500
Cyclobenzaprine	29
Diphenhydramine	71
Dothiepin	17
d,l-Ephedrine	272
Fenfluramine	46
MDMA (Methylenedioxy-methamphetamine)	80
Mephentermine	57
Methadone	400
d-Methamphetamine	100
Nicotine	500
Norfluoxetine	50
Paroxetine	100
PCP (Phencyclidine)	30
Perphenazine	5
Prochlorperazine	11
Trazodone	24

LSD

Negative – The compounds below were negative for the LSD 0.5 cutoff at the concentrations shown. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alprazolam	100
5-Aminosalicyclic Acid	1,000
Amlodipine	1,000
Amobarbital	100
Amoxetine	62.5
Amoxicillin	100
d,l-Amphetamine	100
Aprobarbital	100
Atenolol	100
Atorvastatin	1,000
Barbituric Acid	100
Benazepril	1,000
Benzoylecgonine	1,000
Bromazepam	100
Buprenorphine	1,000
Bupropion	15.6
Bupropion, *erythro*-dihydro metabolite	15.6
Butalbital	100
Butorphanol	1,000
Caffeine	100
Captopril	500
Carbamazepine	250
Carbamazepine 10,11 Epoxide	500
Celecoxib	1,000
Cetirizine	62.5
Chlordiazepoxide	100
Chlorpheniramine	1,000
Cimetidine	100
Ciprofloxacin	1,000
Citalopram	125
Clonazepam	100
Clorazepate	100
Clotrimazole	1,000
Codeine	100
Cotinine	100
Desmethyldiazepam	100
Dextromethorphan	125
5,5'-Diallylbarbituric Acid	100
Diazepam	20
Diclofenac	1,000
Dihydrocodeine	100
Dihydroergotamine	100
Doxylamine	500
Ecgonine	100
Ecgonine Methyl Ester	100
Ephedrine	250
l-Epinephrine	20
α-Ergocryptine	20
Ergotamine	100
Ethylmorphine	100
Ezetimibe	1,000
Fenprofen	100
Fluconazole	1,000
Glyburide	1,000
Griseofulvin	1,000
Guaifenesin	1,000
Hexobarbital	100
o-Hydroxyhippuric acid	500
Ibuprofen	100
Ipratropium bromide	100
Isoniazid	1,000
d,l-Isoproterenol	1,000
Isoxsuprine	31
Ketamine	100
Ketoprofen	1,000

LSD

Lamotrigine	1,000
Levetiracetam	1,000
Levofloxacin	1,000
Lidocaine	500
Lysergic Acid	100
Medazepam	100
Mefenamic Acid	100
Mephobarbital	100
Meprobamate	1,000
Metaproterenol	1,000
Methaqualone	1,000
Metoprolol	1,000
Metronidazole	1,000
Mirtazapine	7.8
Modafinil	1,000
Morphine	1,000
Morphine-3-Glucuronide	100
Morphine-6-Glucuronide	100
Nalbuphine	100
Naproxen	100
Nefazodone	15.6
Nifedipine	500
Nitrazepam	100
Nornicotine	100
d-Norpropoxyphene	100
Norsertraline	5
Omeprazole	1,000
Oxazepam	250
Oxycodone	100
Penicillin	1,000
Pentobarbital	100
Phenazopyridine	150
Phenothiazine	100
Phentermine	100
Phenylpropanolamine	1,000
Phenytoin	1,000
Prazepam	100
Pioglitazone	1,000
Pregabalin	100
Promethazine	6.8
Propofol	1,000
Propoxyphene	1,000
Propranolol	7.8
Pseudoephedrine	100
Psilocin	100
Psilocybin	100
Quinapril	1,000
Rabeprazole	7.8
Ramipril	1,000
Ranitidine	500
Risedronate	1,000
Rofecoxib	1,000
Ropinirole	7
Secobarbital	1,000
Serotonin	1,000
Sibutramine HCL	250
Sildenafil	1,000
Sulfamethoxazole	1,000
Tapentadol	62.5
Temazepam	100
11-nor-Δ^9-THC-9-COOH	150
Tizanidine	7.8
Tolmetin Sodium	1,000
Tramadol	500
Tranylcypromine	125
Trifluoperazine	16
Trihexylphenidyl	62.5
Trimethoprim	1,000
Tryptamine	100
l-Tryptophan	100
Tyramine	1,000
Zaleplon	500
Zolpidem	100

Methadone

Definitions of Categories

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is NOT clinically significant, and is not generally encountered in individuals taking the listed drug.

User Notes:

Methadone

The Methadone Assay has two cutoffs: 150 ng/mL and 300 ng/mL methadone.

Positive – For Methadone only.

Negative – The compounds below were negative for the Methadone 150 and 300 cutoffs at the concentrations shown. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alendronate	1,000
Alprazolam	1,000
5-Aminosalicyclic Acid	1,000
Amitriptyline @ 150	25
Amitriptyline @ 300	50
Amlodipine	1,000
Amoxicillin	1,000
d-Amphetamine	1,000
Atomoxetine	500
Atorvastatin	1,000
Azithromycin	1,000
AZT (Zidovudine)	2,000
Benazepril	1,000
Benzoylecgonine	1,000
Bromphenirmaine	1,929
Buprenorphine @ 150	100
Buprenorphine @ 300	1,000
Bupropion	1,000
Bupropion, *erythro*-dihydro metabolite	1,000
Butorphanol	1,000
Caffeine	1,000
Celecoxib	1,000
Cephalexin	1,000
Cetirizine	1,000
Chlorpheniramine	500
Chlorpromazine	125
Cimetidine	1,000
Ciprofloxacin	1,000
Citalopram	125
Clomipramine	2.5
Clonazepam	1,000
Clonidine	1,000
Clopidogrel Hydrogen Sulfate	1,000
Clotrimazole	1,000
Codeine	500
Cotinine	100
Cyclobenzaprine @ 150	28
Cyclobenzaprine @ 300	62.5
Desipramine	800
Dextromethorphan	1,000
Diazepam	1,000
Diclofenac	1,000
Diltiazem	1,000
Diphenhydramine @ 150	250
Diphenhydramine @ 300	500
Doxepin @ 150	10
Doxepin @ 300	125
Doxycycline	1,000
Doxylamine @ 150	100
Doxylamine @ 300	250
EDDP (2-Ethylidene-1,5-dimethyl- 3, 3-diphenylpyrrolidine)	1,000
Enalapril Maleate	1,000
Ephedrine	1,000
Escitalopram	125
Escomeprazole	1,000
Eszopiclone	1,000
Ezetimibe	1,000
Fentanyl	1,000
Fexofenadine	1,000
Fluconazole	1,000
Fluoxetine	500
Fluticasone Proprionate	1,000
Furosemide	1,000
Gabapentin	1,000
Glutethimide	500
Glyburide	1,000
Griseofulvin	1,000
Guaifenesin	1,000
Hydrochlorothiazide	1,000
Hydrocodone	1,000
Hydromorphone	1,000
Ibuprofen	1,000
Isoniazid	1,000
d,l-Isoproterenol	1,000
Isoxsuprine	1,000
Ketamine	100
Ketoprofen	1,000
Ketorolac Tromethamine	1,000
LAAM (l-α-Acetylmethadol) @ 150	2
LAAM (l-α-Acetylmethadol) @ 300	5

Methadone

dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	25
Lamotrigine	1,000
Lansoprazole	1,000
Levetiracetam	1,000
Levofloxacin	1,000
Lidocaine	1,000
Lisinopril	1,000
Lormetazepam	1
Lorsartan	1,000
LSD (Lysergic acid diethylamide)	0.01
L-α-Methadol	2
MDA (Methylenedioxyamphetamine)	5
MDMA (Methylenedioxy-methamphetamine)	200
Meloxicam	1,000
Meperidine @ 150	250
Meperidine @ 300	500
Meprobamate	1,000
Metaproterenol	1,000
Metformin	1,000
d-Methamphetamine @ 150	2
d-Methamphetamine @ 300	35
Methaqualone	1,500
Metoprolol Tartrate	1,000
Metronidazole	1,000
Myoglobin	287
Mirtazapine	1,000
Modafinil	1,000
Morphine	1,000
Nalbuphine	1,000
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	1,000
Norsertraline	10
Nortriptyline	750
Nylidrin	1,000
Omeprazole	1,000
Oxazepam	300
Oxycodone	1,000
Oxymorphone	1,000
Paroxetine	750
Phenazopyridine	300
PCP (Phencyclidine)	1,000
PPA (Phenylpropanolamine)	100
Phenytoin (DPH)	1,000
Pioglitazone	1,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	100
Promethazine @ 150	37
Promethazine @ 300	75
Propofol	1,000
Propoxyphene	1,000
Propranolol	1,000
Pseudoephedrine	1,000
Quetiapine Fumerate	1,000
Quinapril	1,000
Rabeprazole	1,000
Ramipril	1,000
Ranitidine @ 150	900
Ranitidine @ 300	1,000
Rifabutin	1,000
Risedronate	1,000
Risperidone	1,000
Rofecoxib	1,000
Scopolamine	500
Secobarbital	1,000
Sertraline	500
Sibutramine HCL	1,000
Sildenafil	1,000
Simvastatin	1,000
Sulfamethoxazole	1,000
Tapentadol	250
11-nor-Δ^9-THC-9-COOH	100
Thioridazine	100
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	1,000
Topiramate	1,000
Tramadol @ 150	100
Tramadol @ 300	1,000
Tranylcypromine	1,000
Trazadone	1,000
Trifluoperazine	250
Trihexylphenidyl	1,000
Trimethoprim	1,000
Tyramine	100
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100

Methaqualone

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, 3'-Hydroxy-methaqualone is listed as 438 for the Methaqualone assay. This means that it takes a concentration of 438 ng/mL 3'-Hydroxy-methaqualone in urine to produce an instrument response equal to the 300 ng/mL Methaqualone calibrator. This concentration of drug in urine may be achieved in patients taking Methaqualone.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

Methaqualone

The Methaqualone Assay has one cutoff: 300 ng/mL methaqualone.

Positive – The drugs listed are in ng/mL at which they will cross-react equivalent to the methaqualone cutoff.

	300 Cutoff
3'-Hydroxy-methaqualone	438
4'-Hydroxy-methaqualone	233
2'-Hydroxymethyl-methaqualone	1,670
Mecloqualone	290

Methaqualone

Negative – The compounds below were negative for the Methaqualone 300 cutoff at the concentrations shown. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alendronate	1,000
Alprazolam	1,000
Amitriptyline	1,000
Amlodipine	1,000
Amoxicillin	1,000
d-Amphetamine	1,000
Atomoxetine	1,000
Atorvastatin	1,000
Azithromycin	1,000
AZT (Zidovudine)	2,000
Benazepril	1,000
Benzoylecgonine	1,000
Buprenorphine	1,000
Bupropion	1,000
Bupropion, *erythro*-dihydro metabolite	1,000
Butorphanol	1,000
Caffeine	1,000
Celecoxib	1,000
Cephalexin	1,000
Cetirizine	1,000
Chlorpromazine	1,000
Cimetidine	1,000
Ciprofloxacin	1,000
Citalopram	1,000
Clomipramine	2.5
Clonazepam	1,000
Clonidine	1,000
Clopidogrel Hydrogen Sulfate	1,000
Clotrimazole	1,000
Codeine	500
Cotinine	100
Cyclobenzaprine	1,000
Desipramine	800
Dextromethorphan	1,000
Diazepam	1,000
Diclofenac	1,000
Diltiazem	1,000
Diphenhydramine	1,000
Doxepin	1,000
Doxycycline	1,000
Doxylamine	1,000
Enalapril Maleate	1,000
Ephedrine	1,000
Escitalopram	1,000
Escomeprazole	1,000
Eszopiclone	1,000
Ezetimibe	1,000
Fentanyl	1,000
Fexofenadine	1,000
Fluconazole	1,000
Fluoxetine	1,000
Fluticasone Proprionate	1,000
Furosemide	1,000
Gabapentin	1,000
Glutethimide	500
Glyburide	1,000
Griseofulvin	1,000
Guaifenesin	1,000
Hydrochlorothiazide	1,000
Hydrocodone	1,000
Hydromorphone	1,000
Ibuprofen	1,000
Isoniazid	1,000
d,l-Isoproterenol	1,000
Isoxsuprine	1,000
Ketamine	100
Ketoprofen	1,000
Ketorolac Tromethamine	1,000
LAAM (l-α-Acetylmethadol)	25
dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	25
Lamotrigine	1,000
Lansoprazole	1,000
Levetiracetam	1,000
Levofloxacin	1,000
Lidocaine	1,000
Lisinopril	1,000
Lormetazepam	1
Lorsartan	1,000
LSD (Lysergic acid diethylamide)	0.01
MDA (Methylenedioxyamphetamine)	5
MDMA (Methylenedioxymethamphetamine)	200
Meloxicam	1,000
Meperidine	1,000
Meprobamate	1,000
Metaproterenol	1,000

Methaqualone

Metformin	1,000
Methadone	1,000
d-Methamphetamine	35
Metoprolol Tartrate	1,000
Metronidazole	1,000
Mirtazapine	1,000
Modafinil	1,000
Morphine	1,000
Nalbuphine	1,000
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	1,000
Norsertraline	100
Nortriptyline	1,000
Nylidrin	1,000
Omeprazole	1,000
Oxazepam	300
Oxycodone	1,000
Oxymorphone	1,000
Paroxetine	1,000
Phenazopyridine	300
PCP (Phencyclidine)	1,000
Phenytoin (DPH)	1,000
Pioglitazone	1,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	100
Promethazine	1,000
Propofol	1,000
Propoxyphene	1,000
Propranolol	1,000
Pseudoephedrine	1,000
Quetiapine Fumerate	1,000
Quinapril	1,000

Rabeprazole	1,000
Ramipril	1,000
Ranitidine	1,000
Rifabutin	1,000
Risedronate	1,000
Risperidone	1,000
Rofecoxib	1,000
Ropinirole	1,000
Scopolamine	500
Secobarbital	1,000
Sertraline	1,000
Sibutramine HCl	1,000
Sildenafil	1,000
Simvastatin	1,000
Sulfamethoxazole	1,000
Tapentadol	1,000
11-nor-Δ^9-THC-9-COOH	100
Thioridazine	100
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	1,000
Topiramate	1,000
Tramadol	1,000
Tranylcypromine	1,000
Trazadone	1,000
Trifluoperazine	1,000
Trihexylphenidyl	1,000
Trimethoprim	1,000
Tyramine	100
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100

Opiate

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, 6-Acetylmorphine is listed as 435 for the Opiate assay at 300 ng/mL cutoff. This means that it takes a concentration of 435 ng/mL 6-Acetylmorphine in urine to produce an instrument response equal to the 300 ng/mL morphine calibrator. This concentration of drug in urine may be achieved in patients taking Heroin.

Negative – Structurally Related
Concentration in µg/mL of listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is NOT clinically significant, and is not generally encountered in individuals taking the listed drug.

For example, Oxymorphone is listed as 9.3 for the Opiate assay at 300 ng/mL cutoff. This means that it takes 9.3 µg/mL (9,300 ng/mL) of Oxymorphone to produce an instrument response equal to the 300 ng/mL morphine calibrator. This concentration of drug in urine is higher than normally seen in patients taking this drug.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

Opiate

The Opiate Assay has two cutoffs: 300 ng/mL and 2,000 ng/mL morphine.

Positive – The drugs listed are in ng/mL at which they will cross-react equivalent to the morphine cutoff.

	300 Cutoff	2,000 Cutoff
6-Acetylmorphine	435	2,100
Codeine	102 – 306	660 – 1,980
Dihydrocodeine	291	1,872
Hydrocodone	247	1,545
Hydromorphone	498	5,349
Levofloxacin	360,000	(see below)
Levorphanol	1,048	7,680
Morphine-3-Glucuronide	626	6,167
Nalorphine	5,540	(see below)
Naloxone	11,000	(see below)
Normorphine	1,200	–
Ofloxacin	400,000	(see below)
Oxycodone	1,500	(see below)
Pholcodine	320	1,400

Negative – Structurally Related – The drugs listed are in µg/mL at which they will cross-react equivalent to the morphine cutoff.

	300 Cutoff	2,000 Cutoff
Levallorphan	> 5	> 120
Levofloxacin	(see above)	5,200
Meperidine	> 15	> 400
Nalorphine	(see above)	> 100
Naloxone	360	> 350
Ofloxacin	(see above)	4,600
Oxycodone	(see above)	23
Oxymorphone	9.3	> 100
Tapentadol	250	> 250

Opiate

Negative – The compounds below were negative for the Opiate 300 and 2,000 cutoffs at the concentrations shown except where noted. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alendronate	1,000
Alprazolam	1,000
5-Aminosalicyclic Acid	1,000
Amitriptyline @ 300	500
Amitriptyline @ 2,000	1,000
Amlodipine	1,000
Amoxicillin	1,000
d-Amphetamine	1,000
Atomoxetine	1,000
Atorvastatin	1,000
Azithromycin	1,000
AZT (Zidovudine)	2,000
Benazepril	1,000
Benzoylecgonine	1,000
Buprenorphine	1,000
Bupropion	1,000
Bupropion, *erythro*-dihydro metabolite	1,000
Butorphanol	1,000
Caffeine	1,000
Carisoprodol	1,000
Celecoxib	1,000
Cephalexin	1,000
Cetirizine	1,000
Chlorpheniramine	1,000
Chlorpromazine	125
Cimetidine	1,000
Ciprofloxacin	1,000
Citalopram	1,000
Clomipramine	2.5
Clonazepam	1,000
Clonidine	1,000
Clopidogrel Hydrogen Sulfate	1,000
Clotrimazole	1,000
Cotinine	100
Cyclobenzaprine	63
Desipramine	800
Dextromethorphan	63
Dezocine	1,000
Diazepam	1,000
Diclofenac	1,000
Dihydroergotamine	1,000
Diltiazem	1,000
Diphenhydramine	1,000
Dothiepin	100
Doxepin	10
Doxycycline	1,000
Doxylamine	500
Droperidol	1,000
EDDP 2-Ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	1,000
EMDP	100
Enalapril Maleate	1,000
Ephedrine	1,000
Escitalopram	1,000
Escomeprazole	1,000
Eszopiclone	1,000
Ezetimibe	1,000
Fentanyl	1,000
Fexofenadine	1,000
Fluconazole	1,000
Fluoxetine	900
Fluticasone Proprionate	1,000
Furosemide	1,000
Gabapentin	1,000
Glutethimide	500
Glyburide	1,000
Goldenseal	Tea solution
Griseofulvin	1,000
Guaifenesin	1,000
Hydrochlorothiazide	1,000
Ibuprofen	1,000
Isoniazid	1,000
d,l-Isoproterenol	1,000
Isoxsuprine	1,000
Ketamine	100
Ketoprofen	1,000
Ketorolac Tromethamine	1,000
LAAM (l-α-Acetylmethadol)	25
dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	25
Lamotrigine	1,000
Lansoprazole	1,000
Lidocaine	1,000
Lisinopril	1,000
Loperamide	1,000
Lormetazepam	1
Lorsartan	1,000

Opiate

LSD (Lysergic acid diethylamide)	0.01
MDA (Methylenedioxyamphetamine)	5
MDMA (Methylenedioxymethamphetamine)	200
Meloxicam	1,000
Meprobamate	1,000
Metaproterenol	1,000
Metformin	1,000
Methadone	100
d-Methamphetamine	35
Methaqualone	1,500
Metoprolol Tartrate	1,000
Metronidazole	1,000
Mirtazapine	1,000
Modafinil	1,000
Myoglobin	287
Naltrexone	1,000
Nalbuphine	1,000
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	1,000
Norsertraline	10
Nortriptyline	250
Nylidrin	1,000
Omeprazole	1,000
Oxazepam	300
Paroxetine	1,000
Phenazopyridine	300
PCP (Phencyclidine)	1,000
Phenytoin (DPH)	1,000
Pioglitazone	1,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	100
Promethazine @ 300	143
Promethazine @ 2,000	1,000
Propofol	1,000
Propoxyphene	1,000
Propranolol	1,000
Pseudoephedrine	1,000
Quetiapine Fumerate	1,000
Quinapril	1,000
Rabeprazole	1,000
Ramipril	1,000
Ranitidine	900
Rifabutin	1,000
Risedronate	1,000
Risperidone	1,000
Rofecoxib	1,000
Ropinirole	1,000
Scopolamine	500
Secobarbital	1,000
Sertraline	250
Sibutramine HCL	1,000
Sildenafil	1,000
Simvastatin	1,000
Sulfamethoxazole	1,000
11-nor-Δ^9-THC-9-COOH	100
Thioridazine	100
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	1,000
Topiramate	1,000
Tramadol	1,000
Tranylcypromine	1,000
Trazadone	1,000
Trifluoperazine	500
Trihexylphenidyl	1,000
Trimethoprim	1,000
Tyramine	100
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100

Phencyclidine

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, PCM is listed as 41 for the Phencyclidine assay. This means that it takes a concentration of 41 ng/mL PCM in urine to produce an instrument response equal to the 25 ng/mL Phencyclidine calibrator. This concentration of drug in urine may be achieved in patients taking PCM.

Negative – Structurally Related
Concentration in µg/mL of listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is NOT clinically significant, and is not generally encountered in individuals taking the listed drug.

For example, Dextromethorphan is listed as 120 for the Phencyclidine assay. This means that it takes 120 µg/mL (120,000 ng/mL) of Dextromethorphan to produce an instrument response equal to the 25 ng/mL Phencyclidine calibrator. This concentration of drug in urine is higher than normally seen in patients taking this drug.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

Phencyclidine

The Phencyclidine Assay has one cutoff: 25 ng/mL phencyclidine.

Positive – The drugs listed are in ng/mL at which they will cross-react equivalent to the phencyclidine cutoff.

	25 Cutoff
1-(1-Phenylcyclohexyl)morpholine (PCM)	41
1-(1-Phenylcyclohexyl)pyrrolidine (PCPy)	54
1-(4-Hydroxypiperidino)phenylcyclohexane	420
1-[1-(2-Thienyl)-cyclohexyl]morpholine (TCM)	80
1-[1-(2-Thienyl)-cyclohexyl]piperidine (TCP)	37
1-[1-(2-Thienyl)-cyclohexyl]pyrrolidine (TCPy)	83
4-Phenyl-4-piperidinocyclohexanol	32
N,N-Diethyl-1-phenylcyclohexylamine (PCDE)	234
Chlorpromazine	#

While chlorpromazine does not cross-react, patients taking chlorpromazine may produce positive results with this assay.

The Phencyclidine Assay has one cutoff: 25 ng/mL phencyclidine.

Negative – Structurally Related – The drugs listed are in µg/mL at which they will cross-react equivalent to the phencyclidine cutoff.

	25 Cutoff
Dextromethorphan	120
Dextrorphan	97
Meperidine	67
Mesoridazine	50

Phencyclidine

Negative – The compounds below were negative for the Phencyclidine 25 cutoff at the concentrations shown. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alendronate	1,000
Alprazolam	1,000
5-Aminosalicyclic Acid	1,000
Amitriptyline	125
Amlodipine	1,000
Amoxicillin	1,000
d-Amphetamine	1,000
Atomoxetine	1,000
Atorvastatin	1,000
Azithromycin	1,000
AZT (Zidovudine)	2,000
Benazepril	1,000
Benzoylecgonine	1,000
Buprenorphine	1,000
Bupropion	1,000
Bupropion, *erythro*-dihydro metabolite	1,000
Butorphanol	63
Caffeine	1,000
Celecoxib	1,000
Cephalexin	1,000
Cetirizine	1,000
Chlorpheniramine	125
Cimetidine	1,000
Ciprofloxacin	1,000
Citalopram	750
Clomipramine	2.5
Clonazepam	1,000
Clonidine	1,000
Clopidogrel Hydrogen Sulfate	1,000
Clotrimazole	1,000
Codeine	500
Cotinine	100
Cyclobenzaprine	62
Desipramine	800
Diazepam	1,000
Diclofenac	1,000
Diltiazem	1,000
Diphenhydramine	1,000
Doxepin	250
Doxycycline	1,000
Doxylamine	1,000
EDDP (2-Ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine)	1,000
Enalapril Maleate	1,000
Ephedrine	1,000
Escitalopram	750
Escomeprazole	1,000
Eszopiclone	1,000
Ezetimibe	1,000
Fentanyl	1,000
Fexofenadine	1,000
Fluconazole	1,000
Fluoxetine	1,000
Fluticasone Proprionate	1,000
Furosemide	1000
Gabapentin	1,000
Glutethimide	500
Glyburide	1,000
Griseofulvin	1,000
Guaifenesin	1,000
Hydrochlorothiazide	1,000
Hydrocodone	250
Hydromorphone	500
Ibuprofen	1,000
Isoniazid	1,000
d,l-Isoproterenol	1,000
Isoxsuprine	1,000
Ketamine	100
Ketoprofen	1,000
Ketorolac Tromethamine	1,000
LAMM (l-α-Acetylmethadol)	25
dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	15
Lamotrigine	1,000
Lansoprazole	1,000
Levetiracetam	1,000
Levofloxacin	1,000
Lidocaine	1,000
Lisinopril	1,000
Lormetazepam	1
Lorsartan	1,000
LSD (Lysergic acid diethylamide)	0.01
MDA (Methylenedioxyamphetamine)	5

Phencyclidine

MDMA (Methylenedioxymethamphetamine)	200
Meloxicam	1,000
Meprobamate	1,000
Metaproterenol	1,000
Metformin	1,000
Methadone	1,000
d-Methamphetamine	35
Methaqualone	1,500
Metoprolol Tartrate	1,000
Metronidazole	1,000
Mirtazapine	1,000
Modafinil	1,000
Morphine	58
Nalbuphine	1,000
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	1,000
Norsertraline	10
Nortriptyline	1,000
Nylidrin	1,000
Omeprazole	1,000
Oxazepam	300
Oxycodone	1,000
Oxymorphone	1,000
Paroxetine	1,000
Phenethylamine	1,000
Phenytoin (DPH)	1,000
Pioglitazone	1,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	100
Promethazine	170
Propofol	1,000
Propoxyphene	1,000
Propranolol	1,000
Pseudoephedrine	1,000
Quetiapine Fumerate	1,000
Quinapril	1,000
Rabeprazole	1,000
Ramipril	1,000
Ranitidine	900
Risedronate	1,000
Rifabutin	1,000
Risperidone	1,000
Rofecoxib	1,000
Ropinirole	250
Scopolamine	500
Secobarbital	1,000
Sertraline	1,000
Sibutramine HCL	1,000
Sildenafil	1,000
Simvastatin	1,000
Sulfamethoxazole	1,000
Tapentadol	250
11-nor-Δ^9-THC-9-COOH	50
Thioridazine	48
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	1,000
Topiramate	1,000
Tramadol	1,000
Tranylcypromine	1,000
Trazadone	1,000
Trifluoperazine	1,000
Trihexylphenidyl	125
Trimethoprim	1,000
Tyramine	100
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100

Propoxyphene

Definitions of Categories

Positive
The concentration in ng/mL of the listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is clinically significant, and may be encountered in individuals taking the listed drug.

For example, Norpropoxyphene is listed as 800 for the Propoxyphene assay. This means that it takes a concentration of 800 ng/mL Norpropoxyphene in urine to produce an instrument response equal to the 300 ng/mL Propoxyphene calibrator. This concentration of drug in urine may be achieved in patients taking Propoxyphene.

Negative – Equivalent Concentration
Concentration in µg/mL of listed drug that gives an assay response equal to the cutoff calibrator. The concentration of the listed compound is NOT clinically significant, and is not generally encountered in individuals taking the listed drug.

For example, Imipramine is listed as 30 for the Propoxyphene assay. This means that it takes 30 µg/mL (30,000 ng/mL) of Imipramine to produce an instrument response equal to the 300 ng/mL Propoxyphene calibrator. This concentration of drug in urine is higher than normally seen in patients taking this drug.

Negative
Concentration of drug tested in µg/mL that gave an assay response less than the cutoff calibrator. The concentration of the listed compound is higher than normally seen in patients taking this drug.

User Notes:

Propoxyphene

The Propoxyphene Assay has one cutoff: 300 ng/mL propoxyphene.

Positive – The drugs listed are in ng/mL at which they will cross-react equivalent to the propoxyphene cutoff.

	300 Cutoff
Chlorpromazine	7,800
Norpropoxyphene	800

Negative – Equivalent Concentration – The drugs listed are in µg/mL at which they will cross-react equivalent to the propoxyphene cutoff.

	300 Cutoff
EDDP (2-Ethylidene-1,5-dimethyl-3, 3-diphenylpyrrolidine)	5,000
Imipramine	30

Negative – The compounds below were negative for the Propoxyphene 25 cutoff at the concentrations shown. Concentrations listed are in µg/mL.

Acetaminophen	1,000
Acetaminophen	1,000
Acetylsalicylic Acid	1,000
Albuterol	1,000
Alendronate	1,000
Alprazolam	1,000
5-Aminosalicyclic Acid	1,000
Amitriptyline	125
Amlodipine	1,000
Amoxetine	31
Amoxicillin	1,000
d-Amphetamine	1,000
Atomoxetine	1,000
Atorvastatin	1,000
Azathioprine	1,000
Azithromycin	1,000
AZT (Zidovudine)	2,000
Benazepril	1,000
Benzoylecgonine	1,000
Buprenorphine	1,000
Bupropion	1,000
Bupropion, *erythro*-dihydro metabolite	1,000
Butorphanol	1,000
Caffeine	1,000
Celecoxib	1,000
Cephalexin	1,000
Cetirizine	1,000
Chlorpheniramine	500
Cimetidine	1,000
Ciprofloxacin	1,000
Citalopram	1,000
Clomipramine	2.5
Clonazepam	1,000
Clonidine	1,000
Clopidogrel Hydrogen Sulfate	1,000
Clotrimazole	1,000
Codeine	500
Cotinine	100
Cyclobenzaprine	7.8
Desipramine	5
Dextromethorphan	1,000
Diazepam	1,000
Diclofenac	1,000
Diltiazem	1,000
Diphenhydramine	1,000
Doxepin	31
Doxycycline	1,000
Doxylamine	500
Enalapril Maleate	1,000
Ephedrine	1,000
Escitalopram	1,000
Escomeprazole	1,000
Eszopiclone	1,000
Ezetimibe	1,000
Fentanyl	1,000
Fexofenadine	1,000
Fluconazole	1,000
Fluoxetine	125
Fluticasone Proprionate	1,000
Furosemide	1,000
Gabapentin	1,000
Glutethimide	500
Glyburide	1,000
Griseofulvin	1,000
Guaifenesin	1,000
Hydrochlorothiazide	1,000

Propoxyphene

Hydrocodone	900
Hydromorphone	1,000
Ibuprofen	1,000
Isoniazid	1,000
d,l-Isoproterenol	1,000
Isoxsuprine	1,000
Ketamine	100
Ketoprofen	1,000
Ketorolac Tromethamine	1,000
LAMM (l-α-Acetylmethadol)	25
dinor-LAAM (l-α-Acetyl-N, N-dinormethadol)	25
Lamotrigine	1,000
Lansoprazole	1,000
Levetiracetam	1,000
Levofloxacin	1,000
Lidocaine	1,000
Lisinopril	1,000
Lormetazepam	1
Lorsartan	1,000
LSD (Lysergic acid diethylamide)	0.01
MDA (Methylenedioxyamphetamine)	5
MDMA (Methylenedioxymethamphetamine)	200
Meloxicam	1,000
Meperidine	1,000
Meprobamate	1,000
Metaproterenol	1,000
Metformin	1,000
Methadone	100
d-Methamphetamine	35
Methaqualone	1,500
Metoprolol Tartrate	1,000
Metronidazole	1,000
Mirtazapine	1,000
Modafinil	1,000
Morphine	1,000
Myoglobin	287
Nalbuphine	1,000
NAPA (N-Acetylprocainamide)	400
Naproxen	1,000
Nefazodone	1,000
Norsertraline	10
Nortriptyline	31
Nylidrin	1,000
Omeprazole	1,000
Oxazepam	300
Oxycodone	1,000
Oxymorphone	1,000
Paroxetine	1,000
Phenazopyridine	300
PCP (Phencyclidine)	250
Phenytoin (DPH)	1,000
Pioglitazone	1,000
Pravastatin	1,000
Prednisone	1,000
Pregabalin	100
Promethazine	125
Propofol	1,000
Propranolol	1,000
Pseudoephedrine	1,000
Quetiapine Fumerate	1,000
Quinapril	1,000
Rabeprazole	1,000
Ramipril	1,000
Ranitidine	1,000
Rifabutin	1,000
Risedronate	1,000
Risperidone	1,000
Rofecoxib	1,000
Ropinirole	1,000
Scopolamine	500
Secobarbital	1,000
Sertraline	31
Sibutramine HCL	1,000
Sildenafil	1,000
Simvastatin	1,000
Sulfamethoxazole	1,000
Tapentadol	1,000
11-nor-Δ9-THC-9-COOH	100
Thioridazine	100
Thyroxine	1,000
Tizanidine	1,000
Tolmetin Sodium	1,000
Topiramate	1,000
Tramadol	1,000
Tranylcypromine	1,000
Trazadone	1,000
Trifluoperazine	125
Trihexylphenidyl	1,000
Trimethoprim	1,000
Tyramine	100
Venlafaxine	1,000
Verapamil	1,000
Warfarin	1,000
Zaleplon	1,000
Zolpidem	100

Absorbance Flags

The compounds listed below may cause absorbance flags with any of the Emit II Plus Drug of Abuse assays, if present in high concentrations.

Call your local Technical Solutions Center at 800-227-8994 if instrument errors or flags are encountered in the presence of these compounds.

Amiodarone
Ciprofloxacin
Diflunisal
Griseofluvin
Mefenamic Acid
Metronidazole
Ofloxacin
Phenazopyridine
Sulindac
Sulfasalazine
Tolmetin Sodium
Zomepirac

The information contained in this document was compiled from the Package Inserts for each EMIT Drugs-of-Abuse Assay, as well as additional crossreactivity testing performed internally. The Package Inserts (IFU's) should always be consulted for the most recent information on specificity and crossreactivity.

Siemens Healthcare Diagnostics, a global leader in clinical diagnostics, provides healthcare professionals in hospital, reference, and physician office laboratories and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. Our innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Global Division

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
www.siemens.com/diagnostics

Global Siemens Headquarters

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters

Siemens AG
Healthcare Sector
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91052 Erlangen, Germany
Phone: +49 9131 84 - 0
www.siemens.com/healthcare

www.usa.siemens.com/diagnostics

Order No. A91DX-100211-UC2-4A00 | 08-2011 |

SIEMENS

RFP # 13-2013

Drug Testing for Community Corrections

Due: April 30, 2013 @ 2:00 p.m., CST.

Lexington-Fayette Urban County Government

Room 338, Government Center

200 East Main Street

Lexington, KY 40507

Todd Slatin

Small Business Participation:

No small businesses are proposed.

Supplier Diversity is a critical component of our company's business strategy, and Siemens Healthcare Diagnostics has numerous suppliers that are minority-owned businesses. Unfortunately, this sale affords no opportunities to subcontract.

This sale is for in-vitro diagnostic chemical and biological reagents and consumables used in the testing process. The reagents are categorized by the U.S. Food and Drug Administration as "medical devices". Consequently, the manufacturing process is subjected to rigorous testing which can take anywhere from weeks to months, depending on how many products use that particular raw material. As a result, the company does not switch suppliers for any of the chemical or biological agents used in the manufacturing process unless absolutely necessary. Similar constraints are imposed on the instrument-manufacturing and consumables-manufacturing process. There is not an opportunity to subcontract on labeling, packaging, or shipping services because we are locked into long-term contracts with existing suppliers. Siemens Healthcare Diagnostics is committed in word and deed to supplier diversity but, as indicated above, we are unable to subcontract any of the goods or services under this contract.

DEPARTMENT OF VETERANS AFFAIRS
Office of Acquisition and Logistics
National Acquisition Center
P. O. Box 76
Hines, IL 60141

In Reply Refer To: 003A4B

September 6, 2012

David Anderson
Siemens Healthcare Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591

Dear Mr. Anderson:

Your Small Business Subcontracting Plan submitted under contract numbers V797P-4767a and V797P-7032a has been accepted and approved for the period of 10/01/2012 – 09/30/2013.

The Small Business Administration encourages contractors to advertise their subcontracting opportunities in SBA's Sub-net. Sub-net can be accessed through SBA's internet site located at http://web.sba.gov/subnet/ .

Determining compliance with your subcontracting plan is monitored on-line. Sub-contracting achievements are recorded through the Electronic Subcontracting Reporting System (eSRS) at www.esrs.gov, an on-line reporting system for contractors to report their accomplishments. **I will be the person responsible for reviewing your report. Please ensure you include my name and email address at lydia.mckay@va.gov, along with the agency code 3600, to ensure proper notification.**

Only one approval letter is being sent to your company. Please provide a copy to the appropriate contracting officials in your company who will monitor your FSS contract, if applicable. In addition, you are responsible for providing an updated subcontracting plan to our office within 30 days of your current plan's expiration date.

Should you have any questions or concerns, please feel free to call me at (708) 786-5837. Thank you for your patience and cooperation in this matter.

Sincerely,

Lydia L McKay

FSS Contract Specialist
Federal Supply Schedule (FSS) Service

Enclosure

cc: SBA Regional Office
VA OSDBU

SIEMENS

August 20, 2012

Lydia McKay
Contracting Officer
VA National Acquisition Center
Federal Supply Schedule Service

Dear Ms. McKay,

Siemens Healthcare Diagnostics (Siemens Diagnostics) designs and manufactures in-vitro diagnostic testing instruments and reagents, and the consumables used in the testing process. It is a global division of Siemens, with manufacturing locations in both US and Europe.

Due to the nature of our business (chemicals, biologically-derived materials), many of our critical raw materials are sole-sourced; most of these firms are large businesses. This is because the we are a global business, with manufacturing facilities in both the United States and Europe, requires that our suppliers both have the capacity to meet our demands and also have the logistical capabilities to deliver to our various locations. Additionally, a portion of our supply base is in Europe to support our European operations. As always, there are practical restraints on our ability to move business from one vendor to another. Our products are classified as "medical devices". As such, the manufacturing process is subject to stringent FDA regulations, and our products must also satisfy international safety and quality standards (ISO). Every time we switch vendors for a product used in manufacturing, we must conduct extensive validation testing in order to comply with FDA regulations. Consequently, we do not switch vendors for products used in manufacturing unless there is a strong business case to do so (e.g. quality/reliability concerns).

Additionally, 2012 Goals do not correlate to 2012 Actuals as discrepancies between the two reporting periods became apparent. The previous admin submitted the Subcontracting plan 2012 Goals reflecting Siemens Global suppliers spend in EURO; additionally, Global sales figures in EURO were also reported in the Siemens 2012 Small Business Subcontract plan. 2012 Actuals, reported by the new admin, reflect US vendor spend in USD; therefore, 2012 goals and 2012 actuals do not reflect the same data sets or currency and should not be used to compare adherence to 2012 goals stipulated in last year's plan.

The reasoning above provides some background to our FY12 Actual numbers both in amount and percent not meeting FY12 goals. We anticipate that our FY13 US purchasing spend will not vary significantly from that of FY12. For this reason, our FY13 goals will reflect our FY12 Actuals.

Please accept our submission of the FY13 SBA Subcontracting Plan, and do not hesitate to contact me with any questions.

David Anderson
Sr. Manager Procurement
Small Business Liaison Officer

Siemens Healthcare Diagnostics Inc.

511 Benedict Avenue
Tarrytown, NY 10591
USA

914-524-2726
www.siemens.com/diagnostics

LM Reid 8/30/12

SMALL BUSINESS SUBCONTRACTING PLAN
(Model Outline*)

SUBCONTRACTING PLAN PERIOD: October 1, 2012 to September 30, 2013

Individual plans should cover the entire period of performance, and commercial plans should coincide with the company's fiscal year. In the event your company's fiscal year is for a period that will end before the contract periods of any federal contracts you hold which include the requirement to have a small business subcontracting plan, **you will be required to submit a new subcontracting plan for approval thirty (30) days prior to expiration of the existing subcontracting plan.** In the event an acceptable plan cannot be negotiated prior to expiration of the existing subcontracting plan, your contract(s) may be terminated.

DATE SUBMITTED: August 20, 2012

NAME OF PLANHOLDER: Siemens Healthcare Diagnostics

SUBSIDIARIES INCLUDED: None

ADDRESS: 511 Benedict Avenue
Tarrytown, NY 10591
USA

ITEM/SERVICE: Medical Diagnostic instruments, reagents, and assays

1. TYPE OF PLAN

List the total estimated dollar value of all planned subcontracting (to all types of business concerns, both **large and small**). Select only one of the following:

a) Individual Plan (This Contract Only) Contract #/Solicitation # _____)
Total value of projected subcontracts (both **large and small** businesses) $ _____

b) Commercial Division-wide Plan
Total projected sales $ 1,955,000,000
Total value of projected subcontracts (both **large and small** businesses) $ 935,000,000
(Subcontracts Represent 47.8% of Total Annual Sales)

c) Commercial Company-wide Plan
Total projected sales $ _____
Total value of projected subcontracts (both **large and small** businesses) $ _____
(Subcontracts Represent _____% of Total Annual Sales)

** Federal Acquisition Regulation (FAR), paragraph 19.708(b)(1), prescribes the use of the clause at FAR 52.219-9 entitled "Small Business Subcontracting Plan." The following is a suggested model for use when formulating such subcontracting plan. While this model plan has been designed to be consistent with FAR 52.219-9, other formats of a subcontracting plan may be acceptable. However, failure to include the essential information as exemplified in this model may be cause for either a delay in acceptance or the rejection of an offer where the clause is applicable. Further, the use of this model is not intended to waive other requirements that may be applicable under FAR 52.219-9 or that may appear in the Government's solicitation. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a federal government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.*

2. GOALS

State separate dollar and percentage goals, expressed in terms of **percentages of the total available subcontracting dollars** listed in the previous section.

a) Total estimated dollar value and percent of planned subcontracting with **small businesses (SB)** (including ANCs and Indian tribes), veteran-owned small, service-disabled veteran-owned small, HUBZone small, small disadvantaged (including ANCs and Indian tribes), and women-owned small business concerns:

$ 238,425,000 and 25.50%

b) Total estimated dollar value and percent of planned subcontracting with **veteran-owned small businesses (VO)**:

$ 12,155,000 and 1.30%

c) Total estimated dollar value and percent of planned subcontracting with **service-disabled veteran-owned small businesses (SDVO)** (Note: This is a subset of veteran-owned):

$ 374,000 and 0.04%

d) Total estimated dollar value and percent of planned subcontracting with **small disadvantaged businesses (SDB)** (including ANCs and Indian tribes):

$ 3,459,500 and 0.37%

e) Total estimated dollar value and percent of planned subcontracting with **women-owned small businesses (WO)**:

$ 13,744,500 and 1.47%

f) Total estimated dollar value and percent of planned subcontracting **with HUBZone small businesses (HUB)**:

$ 1,028,500 and 0.11%

3. PRODUCTS AND/OR SERVICES

The **principal types** of products and/or services that will be subcontracted under this plan to **all types** of businesses (both large and small) are as follows: All types of goods and services with relation to medical device manufacturing, especially facilities-related goods and services, IT-related goods and services, consulting and professional services, chemicals, biologicals, printing, packaging, fabricated plastic parts, fabricated metal parts, and electronics.

The types of products and/or services to be subcontracted to SBs and the subcategories are:

SB: Computers, computer peripherals, molded plastics, ceramics, blood products, electronics, electronic assemblies, professional services (contractors, legal, consultants, temporary), mobility logistics, packaging, metal parts, chemicals, chemical gases, medical equipment, optics, R&D technology, distribution channel partners, power supplies/components/subassemblies.

VO: Medical equipment, validation testing, electronics, leasing, optics, packaging, magnetic products, R&D design, rubber/metal/plastic parts, components, fasteners, pest control, bearings, sterilization services, professional services.

SDVO: Bearings, biological chemicals, distributors, optics,

SDB: Chemical gases, professional services (engineering, IT, general consult), blood products, validation testing, fiber optics, optics, machine tooling.

WO: Translation services, packaging, tax accounting services, professional services (IT, engineering, general consult), distributors, flooring, communications, chemicals, biologicals, electronics, graphics/visual arts/marketing, computing, logistics

HUB: Thermo-electric cooling, product integration, graphics, legal, electronics, automation, hardware, bearings

4. GOAL DEVELOPMENT

The following method was used in developing the subcontracting goals:

To develop Siemens Healthcare Diagnostics, three factors were focused upon:
- FY13 business needs which are expected to remain similar to FY12 business needs
- The global marketplace and how the current economy affects opportunities to utilize small businesses
- Siemens AG FY13 Global Procurement strategy, which emphasizes consolidation of spending among fewer vendors, with increased usage of national and global contracts

It was concluded that the overall usage of small businesses is likely to drop, but the percentage for each subcategory may remain the same. Consequently, the goals for each subcategory were adopted for FY13.

5. IDENTIFYING POTENTIAL SOURCES

The following methods were used to identify potential sources for solicitation purposes (See FAR 52.219-9(d)(5) for examples of methods that may be used.

We rely primarily on our own procurement spend database cleansed by D&B to identify SBA suppliers, D&B reports, and state-government sponsored lists, such as, SAM "CCRSBA" small business search, www.wbenc.org, National Minority Supplier Development council (nmdsc.org) including regional councils.

Ensuring that subcontract procurement RFQs (Through internally developed RFQ Toolkit) are designed to permit participation of Small Business, Small Disadvantaged, Woman-Owned Small Business, HUBZone Small Business, Veteran-Owned Small Business and Service Disabled Veteran Small Business concerns.

Through the attendance of Siemens sponsored Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, etc.
In addition, we conduct Internet searches and read the corporate information section of supplier websites to identify those likely to be small businesses.

6. INDIRECT COSTS

Indirect costs ☒ have ☐ have not been included in the dollar and percentage subcontracting goals stated above. (Check one.)

If "have been" is checked (and you are proposing an individual plan), explain the method used in determining the proportionate share of indirect costs to be incurred with small business (including Alaska Native Corporations and Indian tribes), veteran-owned small business, service-disabled veteran-owned small business, small disadvantaged business (including ANCs and Indian tribes), women-owned small business, and HUBZone small business concerns. *Note: Commercial planholders who choose to include indirect costs will not need to provide the aforementioned explanation because the costs will be applied at 100%.*

7. PROGRAM ADMINISTRATOR

The following individual will administer the subcontracting program:

NAME: David Anderson

TITLE: Sr. Manager Procurement

ADDRESS: 511 Benedict Avenue
Tarrytown, NY 10591
USA

TELEPHONE: 914-524-2726

E-MAIL: david.anderson@siemens.com

This individual's specific duties, as they relate to the firm's subcontracting program, are as follows:

- Gather and analyze data, prepare and submit the annual subcontracting plan and annual eSRS report.
- Coordinate the company's activities during compliance review by federal agencies.

8. EQUITABLE OPPORTUNITY

The following good faith efforts (internal and external) will be taken to assure that small business, veteran-owned small business, service-disabled veteran-owned small business, small disadvantaged business, women-owned small business, and HUBZone small business concerns will have an equitable opportunity to compete for subcontracts:

We will continue to use our own database and the SBA's database, as well as other databases and lists to identify small businesses as outlined under section 5 of the plan.
We will continue to educate requestors, buyers and commodity managers on the importance of giving small businesses the opportunity to compete as outlined by Siemens Healthcare USA Policy Stated below:
Ensuring that subcontract procurement RFQs are designed to permit participation of Small Business, Small Disadvantaged, Woman-Owned Small Business, HUBZone Small Business, Veteran-Owned Small Business and Service Disabled Veteran Small Business concerns.

We will continue to use our own database and the SBA's database, as well as other sources (i.e. Small Business Conferences) to identify small businesses for existing and future business.

We will continue to educate our organization including procurement buyers and commodity managers on the importance including small businesses in their supplier selection strategies

We will continue to work with the Siemens companies throughout the U.S. to share best practices and improve our recordkeeping activities with respect to small businesses.

We will continue to work with the SBLO in our parent company and other Siemens companies throughout the U.S. to share best practices and improve our recordkeeping activities with respect to small businesses.
Through Siemens parent company which has membership in the minority supplier development council MSDC; we will participate in the 2013 Procurement Confernce and Trade Show hosted by MSDC to further expand and engage the small business community.

9. FLOW-DOWN CLAUSE

The offeror agrees that the FAR clause of this contract entitled "Utilization of Small Business Concerns" (52.219-8) will be included in all subcontracts which offer further subcontracting opportunities, and all subcontractors (except small business concerns) that receive subcontracts in excess of $650,000 with further subcontracting possibilities will be required to adopt a subcontracting plan that complies with the requirements of this clause.

NOTE: FAR 52.219-9(j) states that "subcontracting plans are not required from subcontractors when the prime contract [i.e. your VA contract] contains the clause at 52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders – Commercial Items". This clause is in all VA FSS and NCS contracts. Therefore, only the first part of the above flow-down language, that is the requirement to flow-down 52.219-8, is applicable.

10. REPORTING & COOPERATION

The offeror agrees to

(i) Cooperate in any studies or surveys as may be required;

(ii) Submit periodic reports so that the Government can determine the extent of compliance by the offeror with the subcontracting plan;

(iii) Submit the Individual Subcontracting Report (ISR) and/or the Summary Subcontract Report (SSR), in accordance with the paragraph (l) of this clause using the Electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov . The reports shall provide information on subcontract awards to small business concerns (including ANCs and Indian tribes that are not small businesses), veteran-owned small business concerns, service-disabled veteran-owned small business concerns, HUBZone small business concerns, small disadvantaged business concerns (including ANCs and Indian tribes that have not been certified by the Small Business Administration as small disadvantaged businesses), women-owned small business concerns, and Historically Black Colleges and Universities and Minority Institutions. Reporting shall be in accordance with this clause, or as provided in agency regulations;

(iv) Ensure that its subcontractors with subcontracting plans agree to submit the ISR and/or the SSR using eSRS;

(v) Provide its prime contract number, its DUNS number, and the e-mail address of the offeror's official responsible for acknowledging receipt of or rejecting the ISRs, to all first-tier subcontractors with subcontracting plans so they can enter this information into the eSRS when submitting their ISRs; and

(vi) Require that each subcontractor with a subcontracting plan provide the prime contract number, its own DUNS number, and the e-mail address of the subcontractor's official responsible for acknowledging receipt of or rejecting the ISRs, to its subcontractors with subcontracting plans.

11. RECORDKEEPING

The following is a description of the types of records that will be maintained concerning procedures that have been adopted to comply with the requirements and goals in the plan, including establishing source lists; and a description of the offeror's efforts to locate small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns and award subcontracts to them. The records shall include at least the following (on a plant-wide or company-wide basis, unless otherwise indicated):

(i) Source lists (*e.g.*, CCR), guides, and other data that identify small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns.

(ii) Organizations contacted in an attempt to locate sources that are small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, or women-owned small business concerns.

(iii) Records on each subcontract solicitation resulting in an award of more than $150,000, indicating --

(A) Whether small business concerns were solicited and if not, why not;

(B) Whether veteran-owned small business concerns were solicited and, if not, why not;

(C) Whether service-disabled veteran-owned small business concerns were solicited and, if not, why not;

(D) Whether HUBZone small business concerns were solicited and, if not, why not;

(E) Whether small disadvantaged business concerns were solicited and if not, why not;

(F) Whether women-owned small business concerns were solicited and if not, why not; and

(G) If applicable, the reason award was not made to a small business concern.

(iv) Records of any outreach efforts to contact --

(A) Trade associations;

(B) Business development organizations;

(C) Conferences and trade fairs to locate small, HUBZone small, small disadvantaged, and women-owned small business sources; and

(D) Veterans service organizations.

(v) Records of internal guidance and encouragement provided to buyers through --

(A) Workshops, seminars, training, etc., and

(B) Monitoring performance to evaluate compliance with the program's requirements.

(vi) On a contract-by-contract basis, records to support award data submitted by the offeror to the Government, including the name, address, and business size of each subcontractor. Contractors having commercial plans need not comply with this requirement.

Signed: _____

Typed Name: David Anderson

Title: Sr. Manager Procurement

Date Signed: 8.28.2012

Plan Approved by (Government official): Lydia L McKay

Typed Name: Lydia L McKay
Contracting Officer

Date Approved: 9/6/2012

	**2012 Goals	**2012 Actuals	2013 Goals
Total Subcontracting Dollars +	€ 1,170,020,443	$ 934,196,038	$ 935,000,000
Small Business Dollars	€ 292,505,111	$ 238,425,935	$ 238,425,000
Small Business Percent	25.00%	25.52%	25.5%
Small Veteran-owned Dollars #	€ 17,550,307	$ 11,769,968	$ 12,155,000
Small Veteran-owned Percent #	1.50%	1.26%	1.3%
Service-Disabled Veteran-Owned Dollars #	€ 5,850,102	$ 346,843	$ 374,000
Service-Disabled Veteran-Owned Percent #	0.05%	0.04%	0.04%
Small Disadvantaged Dollars	€ 7,020,123	$ 3,414,565	$ 3,459,500
Small Disadvantaged Percent	0.60%	0.37%	0.37%
Small Women-owned Dollars	€ 23,400,409	$ 13,746,065	$ 13,744,500
Small Women-owned Percent	2.00%	1.47%	1.47%
HUBZone Small Business Dollars	€ 5,850,102	$ 1,034,877	$ 1,028,500
HUBZone Small Business Percent	0.5%	0.11%	0.11%

**2012 Goals do not correlate to 2012 Actuals as discrepancies between the two reporting periods became apparent. The previous admin submitted the Subcontracting plan 2012 Goals reflecting Siemens Global suppliers spend in EURO; additionally, Global sales figures in EURO were also reported in the Siemens 2012 Small Business Subcontract plan. 2012 Actuals, reported by the new admin, reflect US vendor spend in USD; therefore, 2012 goals and 2012 actuals do not reflect the same data sets or currency and should not be used to compare adherence to 2012 goals stipulated in last year's plan.

Round percentages to two decimal places and dollar figures to the nearest whole dollar.

* If total prior year contract achievements are not available, use actual figures and estimate/prorate balance.

+ Including subcontracting dollars for small and large businesses

Dollars for Small Vet-owned and Service-Disabled Vet-owned businesses cannot be included in your actual achievements unless the company has been "verified" in the Vendor Information Pages (VIP) database on VetBiz.gov.

Siemens Healthcare Diagnostics Inc.
EQUAL OPPORTUNITY POLICY STATEMENT

Siemens Healthcare Diagnostics Inc., is firmly committed to Equal Employment Opportunity (EEO) and to compliance with all Federal, State and local laws that prohibit employment discrimination on the basis of age, race, color, gender, national origin, religion, sexual orientation, disability, protected veteran status and any other legally protected classifications. This policy applies to all employment decisions including, but not limited to, recruiting, hiring, training, promotions, pay practices, benefits, disciplinary actions and terminations.

As a government contractor, Siemens Healthcare Diagnostics Inc. is also committed to taking affirmative action to hire and advance minorities and women as well as qualified individuals with disabilities and covered veterans.

We invite employees who are disabled or protected veterans and wish to be included under our Affirmative Action Program to self-identify as such with the EEO Coordinator by contacting your local Human Resource Representative. This self-identification is strictly voluntary and confidential and will not result in retaliation of any sort.

Employees of and applicants to Siemens Healthcare Diagnostics Inc. will not be subject to harassment, intimidation, threats, coercion, or discrimination because they have engaged or may engage in filing a complaint, assisting in a review, investigation, or hearing or have otherwise sought to obtain their legal rights related to any Federal, State, or local law regarding EEO for qualified individuals with disabilities or qualified protected veterans or any other legally protected status.

As CEO of Siemens Healthcare Diagnostics Inc., I am committed to the principles of Affirmative Action and Equal Employment Opportunity. In order to ensure dissemination and implementation of equal employment opportunity and affirmative action throughout all levels of the company, I have selected Michael Bolinger as the EEO Coordinator for Siemens Healthcare Diagnostics Inc.. One of the EEO Coordinator's duties will be to establish and maintain an internal audit and reporting system to allow for effective measurement of the company's programs.

In furtherance of Siemens Healthcare Diagnostics Inc.'s policy regarding Affirmative Action and Equal Employment Opportunity, Siemens Healthcare Diagnostics Inc. has developed a written Affirmative Action Program which sets forth the policies, practices and procedures which the company is committed to applying in order to ensure that its policy of non-discrimination and affirmative action for qualified individuals with disabilities and qualified protected veterans or other legally protected bases as appropriate is accomplished. This Affirmative Action Program for qualified individuals with disabilities and qualified protected veterans is available for inspection by any employee or applicant for employment upon request, between 9:00AM and 4:00pm at the Human Resources department. Any questions should be directed to me, your supervisor, or Michael Bolinger, EEO Coordinator.

Michael Reitermann
CEO

May, 2010

SIEMENS

To Whom it May Concern:

Siemens Healthcare Diagnostics manufactures in-vitro diagnostic (IVD) instruments, and the reagents and consumables used in those instruments.

The U.S. Food and Drug Administration classifies IVD instruments as "medical devices." To ensure the integrity of test results, the manufacturing of instruments, reagents, and consumables entails many complex processes that must be done under strict quality controls, adhering to stringent regulatory requirements.

The vast majority of reagents are manufactured in-house. Instruments are manufactured in-house or by proven suppliers, with oversight by appropriate Siemens personnel. Consumables are manufactured to strict specifications by proven suppliers, with oversight by appropriate Siemens personnel.

Raw materials are bought only from highly qualified, proven suppliers. Every raw material is subjected to lengthy and rigorous testing to ensure that customers obtain consistent results. Raw materials for reagents include chemicals and biologicals (some of which are obtained from the animals on Siemens farms). Materials and subassemblies for instruments include custom-made hardware and software.

When switching suppliers for a particular chemical or biological, scientists must test every reagent that relies on that particular raw material. Testing can take anywhere from weeks to months. Similarly, when switching suppliers for a particular piece of hardware or software, engineers must test every instrument function that could be affected by the change. Due to the extensive testing requirements, switching suppliers is very costly. Consequently, Siemens does not switch suppliers for these goods unless absolutely necessary.

Reagents are provided in sealed containers that must go through similarly rigorous testing to ensure that they remain intact under normal shipping and handling conditions, and do not in any way threaten the integrity of the reagents or diagnostic testing process.

The labels on the containers, the labels on the outside packaging, the outside packaging itself, and the protective foam inserts are all manufactured under contracts with proven suppliers.

Shipping of instruments, reagents, and consumables is handled by various shipping firms under long-term, mostly national contracts.

Field service and technical support are provided by highly trained Siemens employees, not outside contractors.

Siemens has a track record of using suppliers that are minority-owned and woman-owned. However, for all the reasons above, Siemens is unable to subcontract any of the goods or services under this contract.

If you have any questions regarding Siemens' supplier diversity efforts, please call me at the number below or email me at jennifer.l.wright@siemens.com.

Sincerely,

Jennifer L Wright
Supplier Diversity Liaison
Siemens Healthcare Diagnostics

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