

ADDENDUM #1

Bid Number: 88-2025 Date: July 21, 2025

Subject: Disposable Gloves

Please address inquiries to: Conni Hayes, Buyer (859) 258-3320

TO ALL PROSPECTIVE BIDDERS:

Please be advised of the following clarifications to the above referenced bid:

1) Previous bid tabulation sheet has been posted.

Todd Slatin, Director

Division of Central Purchasing

All other terms and conditions of the Bid and specifications are unchanged. This letter should be signed, attached to and become a part of your Bid.

COMPANY NAME:

ADDRESS:

SIGNATURE OF BIDDER:



Lexington-Fayette Urban County Government

Lexington, Kentucky Horse Capital of the World

Division of Procure	ement D	Date of Issue: July 21,2025
	INVITATION TO BID #88-2025 Disposable Glove	es
Bid Opening Date: Address:	08/04/2025 All bids must be submitted on line at https://lexingtonky.ionwave.net/	g Time: 2:00 PM
ype of Bid:	Price Contract	
Pre Bid Meeting: Address:	N/A Pre Bid Tim	e: N/A
e submitted/uproaded	be received online at https://lexingtonky.ionwave.net/ until 2:00 PM , prevailing locally by the above-mentioned date and time. shipping, handling and associated fees to the point of delivery (unless otherwise specific), KY	
Bid Specifi	Check One: cations MetExceptions to Bid Specifications. Exceptions shall be itemized and real submitted.	Proposed Delivery: 3-5 days after acceptance of bid.
Procurement Care services and also to	d Usage—The Lexington-Fayette Urban County Government may be using Procuren make payments. Will you accept Procurement Cards? Yes	
To expedit	e award, the forms in this document should be completed and uplo	paded with your bid.
Submitted b	y: PH+S Products, LLC FIRM Name BOX 344	
Bid must b	e signed Address City, State & Zip Address City, State & Zip Signeture of Authorized Company Representative – Tity	
	Representative's Name (Typed or printed)	mepresentative

The Affidavit in this bid must be completed before your firm can be considered for award of this contract.

	AFFIDAVIT
ре	Comes the Affiant, Comes the Affiant Comes the Affia
1.	His/her name is <u>Sennifer Karlen</u> and he/she is the individual submitting the bid or is the
	authorized representative of PH&S Products, LLC
	the entity submitting the bid (hereinafter referred to as "Bidder")
2.	Bidder will pay all taxes and fees, which are owed to the Lexington-Fayette Urban County Government at the time the bid 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.	Bidder will obtain a Lexington-Fayette Urban County Government business license, if applicable, prior to award of the contract.
4.	Bidder has authorized the Division of Procurement 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.	Bidder 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 Bidder will not violate any provision of the campaign finance laws of the Commonwealth.
6.	Bidder has not knowingly violated any provision of Chapter 25 of the Lexington-Fayette Urban County Government Code of Ordinances, known as "Ethics Act."
7.	Bidder 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.
STA	ATE OF
co	UNTY OFCarrol(
	The foregoing instrument was subscribed, sworn to and acknowledged before me
ру	Jennifer Karlen on this the 31 day
of _	July 20,25
	My Commission expires: 7 (15/28
	Deborch K Carle
	NOTARY DIRECT STATE AT LARGE

Please refer to Section II. Bid Conditions, Item "U" prior to completing this form.

I. GREEN PROCUREMENT

A. ENERGY

The Lexington-Fayette Urban County Government is committed to protecting our environment and being fiscally responsible to our citizens.

The Lexington-Fayette Urban County Government mandates the use of Energy Star compliant products if they are available in the marketplace (go to www.Energystar.gov). If these products are available, but not submitted in your pricing, your bid will be rejected as non-compliant.

ENERGY STAR is a government program that offers businesses and consumers energy-efficient solutions, making it easy to save money while protecting the environment for future generations.

Key Benefits

These products use 25 to 50% less energy
Reduced energy costs without compromising quality or performance
Reduced air pollution because fewer fossil fuels are burned
Significant return on investment
Extended product life and decreased maintenance

B. GREEN SEAL CERTIFIED PRODUCTS

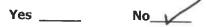
The Lexington-Fayette Urban County Government is also committed to using other environmentally products that do not negatively impact our environment. Green Seal is a non-profit organization devoted to environmental standard setting, product certification, and public education.

Go to **www.Greenseal.org** to find available certified products. These products will have a reduced impact on the environment and on human health. The products to be used must be pre-approved by the LFUCG prior to commencement of any work in any LFUCG facility. If a Green Seal product is not available, the LFUCG must provide a signed waiver to use an alternate product. Please provide information on the Green Seal products being used with your bid response.

C. GREEN COMMUNITY

The Lexington-Fayette Urban County Government (LFUCG) serves as a principal, along with the University of Kentucky and Fayette County Public Schools, in the Bluegrass Partnership for a Green Community. The Purchasing Team component of the Partnership collaborates on economy of scale purchasing that promotes and enhances environmental initiatives. Specifically, when applicable, each principal is interested in obtaining best value products and/or services which promote environment initiatives via solicitations and awards from the other principals.

If your company is the successful bidder on this Invitation For Bid, do you agree to extend the same product/service pricing to the other principals of the Bluegrass Partnership for a Green Community (i.e. University of Kentucky and Fayette County Schools) if requested?



II. Bid Conditions

- A. No bid may be withdrawn for a period of sixty (60) days after the date and time set for opening.
- B. No bid may be altered after the date and time set for opening. In the case of obvious errors, the Division of Procurement may permit the withdrawal of a bid. The decision as to whether a bid may be withdrawn shall be that of the Division of Procurement.
- C. Acceptance of this proposal shall be enactment of an Ordinance by the Urban County Council.
- D. The bidder agrees that the Urban County Government reserves the right to reject any and all bids for either fiscal

- or technical reasons, and to award each part of the bid separately, all parts to one vendor or all parts to multiple vendors.
- E. Minor exceptions may not eliminate the bidder. The decision as to whether any exception is minor shall be entirely that of the head of the requisitioning Department or Division and the Director of the Division of Procurement. The Urban County Government may waive technicalities and informalities where such waiver would best serve the interests of the Urban County Government.
- Manufacturer's catalogue numbers, trade names, etc., where shown herein are for descriptive purposes and are to guide the bidder in interpreting the standard of quality, design, and performance desired, and shall not be construed to exclude proposals based on furnishing other types of materials and/or services. However, any substitution or departure proposed by the bidder must be clearly noted and described; otherwise, it will be assumed that the bidder intends to supply items specifically mentioned in this Invitation for Bids.
- G. The Urban County Government may require demonstrations of the materials proposed herein prior to acceptance of this proposal.
- H. Bids must be submitted on this form and must be signed by the bidder or his authorized representative. Unsigned bids will not be considered.
- I. Bids must be submitted prior to the date and time indicated for opening. Bids submitted after this time will not be considered.
- J. All bids mailed must be submitted in the Ion Wave online portal at https://lexingtonky.ionwave.net/
- K. Bidder is requested to show both unit prices and lot prices. In the event of error, the unit price shall prevail.
- L. A certified check or Bid Bond in the amount of XX percent of the bid price must be attached hereto. This check must be made payable to the Lexington-Fayette Urban County Government, and will be returned when the material and/or services specified herein have been delivered in accordance with specifications. In the event of failure to perform within the time period set forth in this bid, it is agreed the certified check may be cashed and the funds retained by the Lexington-Fayette Urban County Government as liquidated damages. Checks of unsuccessful bidders will be returned when the bid has been awarded.
- M. The delivery dates specified by bidder may be a factor in the determination of the successful bidder.
- N. Tabulations of bids received may be mailed to bidders. Bidders requesting tabulations must enclose a stamped, self-addressed envelope with the bid.
- O. The Lexington-Fayette Urban County Government is exempt from Kentucky Sales Tax and Federal Excise Tax on materials purchased from this bid invitation. Materials purchased by the bidder for construction projects are not tax exempt and are the sole responsibility of the bidder.
- P. All material furnished hereunder must be in full compliance with OSHA regulations.
- Q. If more than one bid is offered by one party, or by any person or persons representing a party, all such bids shall be rejected.
- R. Signature on the face of this bid by the Bidder or his authorized representative shall be construed as acceptance of and compliance with all terms and conditions contained herein.
- S. 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, religion, sex (including pregnancy, sexual orientation or gender identity), national origin, disability, age, genetic information, political affiliation, or veteran status.
- T. 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 provisions of the non-discrimination 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 contractor is required to comply to the Kentucky Equal Employment Opportunity Act of 1978 (KRS 45.560 to KRS 45.640)

U. Any party, firm or individual submitting a proposal pursuant to this invitation must be in compliance with the requirements of the Lexington-Fayette Urban County Government regarding taxes and fees before they can be considered for award of this invitation and must maintain a "current" status with regard to those taxes and fees throughout the term of the contract. The contractor must be in compliance with Chapter 13 from the Code of Ordinances of the Lexington-Fayette Urban County Government. The contractor must be in compliance with Ordinance 35-2000 pursuant to contractor registration with the Division of Building Inspection. If applicable, said business must have a Fayette County business license.

Pursuant to KRS 45A.343 and KRS 45A.345, the contractor shall

- (1) Reveal any final determination of a violation by the contractor within the previous five year period pursuant to KRS Chapters 136 (corporation and utility taxes), 139 (sales and use taxes), 141 (income taxes), 337 (wages and hours), 338 (occupational safety and health of employees), 341 (unemployment and compensation) and 342 (labor and human rights) that apply to the contractor; and
- (2) Be in continuous compliance with the above-mentioned KRS provisions that apply to the contractor for the duration of the contract.

A contractor's failure to reveal the above or to comply with such provisions for the duration of the contract shall be grounds for cancellation of the contract and disqualification of the contractor from eligibility for future contracts for a period of two (2) years.

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

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

III. Procurement Contract Bid Conditions

- A. The terms of this agreement shall be for <u>1</u> year(s) from the date of acceptance of this contract by the Lexington-Fayette Urban County Government. This agreement may be automatically extended for an additional <u>1</u> year(s) renewal. This contract may be canceled by either party thirty (30) days after delivery by canceling party of written notice of intent to cancel to the other contracting party.
- B. Price Changes (Space Checked Applies)
- (XXX)1. Prices quoted in response to the Invitation shall be firm prices for the first 365 days of the Procurement Contract. After 365 days, prices may be subject to revision and such changes shall be based on general industry changes. Revision may be either increases or decreases and may be requested by either party. There will be no more than one (1) price adjustment per year. Requests for price changes shall be received in writing at least twenty (20) days prior to the effective date and are subject to written acceptance before becoming effective. Proof of the validity of a request for revision shall be responsibility of the requesting party. The Lexington-Fayette Urban County Government shall receive the benefit of any decline that the seller shall offer his other accounts.
 - () 2. No provision for price change is made herein. Prices are to be firm for the term of this contract.
 - () 3. See bid specifications.
- C. If any contract item is not available from the vendor, the Lexington-Fayette Urban County Government, at its option, may permit the item to be back-ordered or may procure the item on the open market.
- D. All invoices must bear reference to the Lexington-Fayette Urban County Government Purchasing document numbers which are being billed.
- E. This contract may be canceled by the Lexington-Fayette Urban County Government if it is determined that the Bidder has failed to perform under the terms of this agreement, such cancellation to be effective upon receipt of written notice of cancellation by the Bidder.
- F. No substitutions for articles specified herein may be made without prior approval of the Division of Procurement.

EQUAL OPPORTUNITY AGREEMENT

Standard Title VI Assurance

The Lexington Fayette-Urban County Government, (hereinafter referred to as the "Recipient") hereby agrees that as a condition to receiving any Federal financial assistance from the U.S. Department of Transportation, it will comply with Title VI of the Civil Rights Act of 1964, 78Stat.252, 42 U.S.C. 2000d-4 (hereinafter referred to as the "Act"), and all requirements imposed by or pursuant to Title 49, Code of Federal Regulations, U.S. Department of Transportation, Subtitle A, Office of the Secretary, (49 CFR, Part 21) Nondiscrimination in Federally Assisted Program of the Department of Transportation – Effectuation of Title VI of the Civil Rights Act of 1964 (hereinafter referred to as the "Regulations") and other pertinent directives, no person in the United States shall, on the grounds of race, color, national origin, sex, age (over 40), religion, sexual orientation, gender identity, veteran status, or disability be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity for which the Recipient receives Federal financial assistance from the U.S. Department of Transportation, including the Federal Highway Administration, and hereby gives assurance that will promptly take any necessary measures to effectuate this agreement. This assurance is required by subsection 21.7(a) (1) of the Regulations.

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.
- 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 disability.
- 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.

The Lexington-Fayette Urban County Government practices Equal Opportunity in recruiting, hiring and promoting. 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 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.

Name of Business

poducts, LLC

GENERAL PROVISIONS OF BID CONTRACT

By signing the below, bidder acknowledges that it understands and agrees with the following provisions related to its bid response and the provision of any goods or services to LFUCG upon selection by LFUCG pursuant to the bid request:

- 1. Bidder shall comply with all Federal, State & Local regulations concerning this type of service or good. All applicable state laws, ordinances and resolutions (including but not limited to Section 2-33 (Discrimination due to sexual orientation or gender identity) and Chapter 13 (Licenses and Regulations) of the Lexington-Fayette Urban County Government Code of Ordinances, and the regulations of all authorities having jurisdiction over the project shall apply to the contract, and shall be deemed to be incorporated herein by reference.
- 2. Failure to submit ALL forms and information required by LFUCG may be grounds for disqualification.
- 3. Addenda: All addenda and IonWave Q&A, if any, must be considered by the bidder in making its response, and such addenda shall be made a part of the requirements of the bid contract. Before submitting a bid response, it is incumbent upon bidder to be informed as to whether any addenda have been issued, and the failure of the bidder to cover any such addenda may result in disqualification of that response.
- 4. Bid Reservations: LFUCG reserves the right to reject any or all bid responses, 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 bidder in the preparation of its response.
- 6. Changes/Alterations: Bidder 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 bid response, and received by LFUCG prior to the scheduled closing time for receipt of bids, will be accepted. The bid response 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 bid response".
- 7. Clarification of Submittal: LFUCG reserves the right to obtain clarification of any point in a bid or to obtain additional information from any bidder.
- 8. Bribery Clause: By his/her signature on its response, bidder 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 bidder may include any product brochures, software documentation, sample reports, or other documentation that may assist LFUCG in better understanding and evaluating the bid response. Additional documentation shall not serve as a substitute for other documentation which is required by the LFUCG to be submitted with the bid response.
- 10. Ambiguity, Conflict or other Errors: If a bidder discovers any ambiguity, conflict, discrepancy, omission or other error in the bid request of LFUCG, 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 its bid response, the bidder agrees that it has carefully examined the specifications and all provisions relating to LFUCG's bid request, including but not limited to the bid contract. By submission of its bid response, bidder states that it understands the meaning, intent and requirements of LFUCG's bid request and agrees to the same. The successful bidder 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 bidder shall be authorized for services, expenses, or goods reasonably covered under these provisions that the bidder omits from its bid response.
- 12. Cancellation: LFUCG may unilaterally terminate the bid contract with the selected bidder(s) at any time, with or without cause, by providing at least thirty (30) days advance written notice unless a different advance written notice period is negotiated prior to contract approval. 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 selected bidder(s) shall not assign or subcontract any portion of the bid contract with LFUCG 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 bid proposal or bid contract shall affect the rights, remedies, powers or privileges of LFUCG hereunder or shall operate as a waiver thereof.
- Authority to do Business: Each bidder must be authorized to do business under the laws of the Commonwealth of 15. Kentucky and must be in good standing and have full legal capacity to provide the goods or services specified in the bid proposal. Each bidder must have all necessary right and lawful authority to submit the bid response and enter into the bid contract for the full term hereof including any necessary corporate or other action authorizing the bidder to submit the bid response and enter into this bid contract. If requested, the bidder will provide LFUCG with a copy of a corporate resolution authorizing this action and/or a letter from an attorney confirming that the proposer is authorized to do business in the Commonwealth of Kentucky. All bid responses must be signed by a duly authorized officer, agent or employee of the bidder.
- 16. Governing Law: This bid request and bid 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 matter, the bidder agrees that the venue shall be the Fayette County Circuit Court or the U.S. District Court for the Eastern District of Kentucky, Lexington Division and that the bidder expressly consents to personal jurisdiction and venue in such Court for the limited and sole purpose of proceedings relating to these matters or any rights or obligations arising thereunder.
- 17. Ability to Meet Obligations: Bidder affirmatively states that there are no actions, suits or proceedings of any kind pending against bidder or, to the knowledge of the bidder, threatened against the bidder 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 bidder to perform its obligations under this bid response or bid contract, or which question the legality, validity or enforceability hereof or thereof.
- 18. Price Discrepancy: When applicable, in case of price discrepancy, unit bid price written in words will prevail followed by unit price written in numbers then total amount bid per line item.
- 19. Bidder understands and agrees that its employees, agents, or subcontractors are not employees of LFUCG for any purpose whatsoever. Bidder is an independent contractor at all times related to the bid response or bid contract.
- 20. Contractor [or Vendor's Employees] will not appropriate or make use of the Lexington-Fayette Urban County Government (LFUCG) name or any of its trade or service marks or property (including but not limited to any logo or seal), in any promotion, endorsement, advertisement, testimonial or similar use without the prior written consent of the government. If such consent is granted LFUCG reserves the unilateral right, in its sole discretion, to immediately terminate and revoke such use for any reason whatsoever. Contractor agrees that it shall cease and desist from any unauthorized use immediately upon being notified by LFUCG.

21. If any term or provision of this bid 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. Sigfature Karlen

7/31/25 Date



Lexington-Fayette Urban County Government Division of Police Bid #88-2025 Disposable Nitrile Gloves – High Performance

The Lexington-Fayette Urban County Government is accepting bids to establish a price contract for Disposable Nitrile Gloves – High Performance for the Division of Police at 2269 Frankfort Ct, Lexington, Kentucky, 40510, as per the following specifications:

NOTES TO BIDDER:

- The LFUCG orders gloves as needed and will not accept contingent pricing based on a maximum order. Prices should reflect per case order and prices should reflect all shipping costs to the above address.
- Unit price constitutes a case and have at least 100 gloves per box and must be
 of good quality and meet division standards.
- Gloves should be made of high-performance Nitrile to protect from bodily fluids and additional chemicals, to include Heroin and Fentanyl. The outside of the gloves must have raised diamond grip for wet and dry conditions.
- Once price contract is awarded, products may not be substituted without prior written approval from the Lexington Fayette Urban County Government and the respective division for the duration of the contract.
- Contract may be awarded to various vendors by item, section, or as a whole based upon the vendor that submits the most responsive bid determined to be in the best interest of the Lexington-Fayette Urban County Government (LFUCG).
- All shipping, delivery and handling to the above address should be included in pricing.
- For questions regarding these specifications or the bidding process, please post to the published bid on IonWave – https://lexingtonky.ionwave.net. Phone calls or emails are not accepted.
- The Division of Police used the following sizes and amounts of gloves/cases in the last year. <u>LFUCG in no way guarantees these quantities and should be</u> <u>used for bidding purposes only.</u>

Small 20Medium 25Large 40X-Large 40

• Gloves specifications should meet or exceed current glove being used by the Division of Police:

Manufacturer Part No X-Large

X-Large 79750PF-BKGR

Manufacturer Part No Large 79740PF-BKGR.

o Manufacturer Part No Medium 79730PF-BKGR

o Manufacturer Part No Small 79720PF-BKGR

Manufacturer
 PH&S Products

Series 797 Series

Color
 Black or Blue

Packaging
 100 gloves/box

o Length 9,5"

o 6mil Fingertip

Medical Use Exam Grade

Finish
 Full raised diamond pattern

o 100% Nitrile Powder Free



Gloves currently being used.

CHACTP®

POWDER-FREE NITRILE EXAM GLOVES WITH DIAMOND PATTERN





797 SERIES—A SINGLE-USE, 2-TONE VERSATILE GLOVE WITH SUPERIOR STRENGTH AND STRETCH

Made using a special formulated nitrile compound, these gloves have a high degree of force of break. The diamond pattern provides an ultimate grip in dry and wet environments, and the green interior lets you know when the glove has been compromised. These gloves have been deemed safe and effective by the FDA for protection against fentanyl, heroin and gastric acid for up to 240 min.

PRODUCT FEATURES

- Permeation tested against fentanyl, heroin and gastric acid
- Nitrile examination glove
- Powder-free
- 6 mil fingertip
- 9.5" length
- 2-tone color—black or reflex blue with green interior
- · Raised diamond pattern
- · Ambidextrous, single-use, non-sterile
- · Not made with natural rubber latex
- Sizes: S, M, L, XL, 2XL, 3XL

PACKAGED

- Small-Large: 100 pcs/box by weight
- XLarge-3XLarge: 90 pcs/box by weight
- 10 boxes per master carton





PERMEATION TESTED



CHEMICAL TESTING DATA



FENTANYL, HEROIN AND GASTRIC ACID BARRIER TESTED PER ASTM D6978-05(2019) STANDARDS FOR > 240 MIN.

PPE CATEGORY III GLOVES: COMPLEX DESIGN—CERTIFIED TO PROTECT AGAINST MORTAL DANGER AND IRREVERSIBLE HARM

CE 2777: This means the manufacturing facility is audited and certified. A technical file must be completed and submitted for EC type examination by a notified body. (PPE Category III gloves are a minimum requirement for personal protection in applications where there is exposure to chemicals or microorganisms. It does not mean protection against all chemicals and microorganisms or bloodborne pathogens.)

EN388:2016 FORCE AT BREAK 16(n)

What is Puncture Resistance?: The amount of force required to pierce a glove sample with a standard sized point. Specimen samples are cut from four gloves and each one is tested by mechanically pushing the stylus down onto the sample with a different force (20, 60, 100 and 150 newtons) and noting the force that the material was able to withstand each time. The overall performance level is taken to be the lowest of the forces that was recorded across the four tests without breaking through the glove specimen.

Newton: Newton is the Standard International (SI) unit of force. In physics and engineering documentation, the term newton(s) is/are usually abbreviated (n). One newton is the force required to cause a mass of one kilogram to accelerate at a rate of one meter per second squared in the absence of other force-producing effects.

CHART #1: LIST OF TESTED CHEMICALS SPECIFIED IN EN ISO 374-1:2016						
CODE LETTER	CHEMICAL	CAS NUMBER	CLASS	PERMEATION PERFORMANCE LEVEL		
J	n-Heptane	142-82-5	Saturated Hydrocarbon	3		
K	40% Sodium Hydroxide	1310-73-2	Inorganic Base	6		
0	25% Ammonium Hydroxide	1336-21-6	Organic Base	2		
Р	30% Hydrogen Peroxide	7722-84-1	Peroxide	3		
T	37% Formaldehyde	50-00-0	Aldehyde	6		
S	40% Hydrofluoric Acid	7664-39-3	Inorganic Mineral Acid	1		

	CHART #2: TYPE OF GLOVE			
TYPE OF GLOVE	REQUIREMENT	MARKING		
EN ISO 374-1 TYPE A	Penetration Resistance (EN ISO 374-2): Breakthrough time is > 30 min for at least 6 chemicals in the new list (EN 16523-1)	EN ISO 374— 1:2016/Type A		
EN ISO 374-1 TYPE B	Penetration Resistance (EN ISO 374-2): Breakthrough time is > 30 min for at least 3 chemicals defined in Chart #1	EN ISO 374— 1:2016/Type B	JKOPT LI	
EN ISO 374-1 TYPE C	Penetration Resistance (EN ISO 374-2): Breakthrough time is > 10 min for at least 1 chemical in the new list (EN 16523-1)	EN ISO 374— 1:2016/Type C		

CHART #3: PERMEATION PERFORMANCE LEVELS EN 16523-1					
MEASURED BREAKTHROUGH TIME (MIN.)	PERMEATION PERFORMANCE LEVEL				
> 10	1				
> 30	2				
> 60	3				
> 120	4				
> 240	5				
> 480	6				

REQUIREMENTS—CHEMICAL PROTECTIVE GLOVES

Penetration: A glove shall not leak when tested with an air and water leak test, and shall be tested and inspected in compliance with the acceptable quality level.

Permeation: A glove shall pass the minimum requirements of Type C—at least Level 1 (more than 10 min.) against one chemical on the list of chemicals defined in Chart #1.

Degradation: The change of puncture resistance after chemical contact shall be tested for all claimed chemicals in Chart #1.

PPE Category III Gloves Complex Design



EN ISO 374-5:2016



VIRUS





	GE	NERAL PRODUC	T DESCRIPTION		
MATERIAL	LENGTH	FT THICKNESS	PROCESS	SURFACE	CUFF/FIT
Nitrile, examination grade; black or reflex blue with green interior	9.5"/240 mm minimum	6 mil/.15 mm	Interior surface powder-free	Full surface raised diamond pattern	Beaded/ambi

FENTANYL, HEROIN AND GASTRIC ACID PERMEATION TESTED

FENTANYL, HEROIN AND GASTRIC ACID THIRD-PARTY TESTED—SEE ADDENDUM

Contact the PH&S Products LLC main office at 888-688-6768 or sales@PHS-products.com for addendum.

	CERTIFICATIONS/TEST STANDARDS
STANDARD/NUMBER	TITLE
ASTM D5712	Standard Test Method for Protein Content on Medical Gloves
ASTM D6319	Standard Specification for Nitrile Exam Gloves
ASTM D6124	Standard Test Method for Residual Powder on Medical Gloves
ASTM D5151	Standard Test Method for Detection of Holes in Medical Grade Gloves
ASTM D6978	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
EN ISO 374-1: 2016/Type B	Modified Standard for Chemical Protective Gloves
EN 388	European Standards for Protective Gloves

PHYSICAL DIMENSIONS AND TOLERANCES							
DESIGNATION	TOLERANCE	s	M	L	XL	2XL	3XL
Width (mm)	±3	86	97	109	115	121	131
Length (mm)	Minimum	240	240	240	240	240	240
Thickness single wall (mm)—finger	±.02	0.15	0.15	0.15	0.15	0.15	0.15
Thickness single wall (mm)-palm	±.02	0.13	0.13	0.13	0.13	0.13	0.13
Thickness single wall (mm)—cuff	±.02	0.08	0.08	0.08	0.08	0.08	0.08

		FORMANCE REQUIREMENTS—SAMPLING PLAN lucts to Be Sampled in Accordance to ANSI/ASQ Z1.4-2008					
Lot and Batch Control	Lot Size: NTE 900,000	Batch Size:	NTE 40,000				
CHARACTERISTIC	RELATED DEFECT	INSPEC. LEVEL	AQL				
Watertight	Holes—pinholes	G-1	1.5				
Dimensions	Width, length, thickness	S-2	4.0				
Physical properties	Before, after aging	S-2	4.0				
Visual defects—major	Rips or tears, visible holes, sticking pleats (>10mm), embedded visual defects major foreign matter (>5mm), large lumps, permanent dirt, torn beads and/or cuffs, extreme thin spots, improper size, stickiness	G–1	2.5				
Visual defects—minor	Stains and discoloration, sticking pleats (<10mm), embedded G-1 4.0 foreign matter (<5mm), small lumps, removable dirt, defective beads	G-1	4.0				





PHYSICAL REQUIREMENTS							
TEST METHOD	TOLERANCE	TENSILE (M	IPa) +/-3%	ELONGATI	ON +/-5%		
ASTM D6319	A AIA I	BEFORE	AFTER	BEFORE	AFTER		
	MIN	26	28	550%	550%		
EN 388 Force at Break (n)	+/-3	16n	16n	N/A	N/A		

PACKAGING AND MARKING REQUIREMENTS

GENERAL REQUIREMENTS

- Each carton and inner box must be labeled with size, lot number, Summit Glove name and address, country of origin, product description and date of manufacture.
- · Each box contains:
 - S-L: 100 gloves by weight
 - XL-3XL: 90 gloves by weight
 - 10 boxes per case
- All cases and boxes must be printed clearly.
- Inner box to be 450 gram weight box, dual fold, and able to withstand box ends opening during use. Outer carton to be a standard corrugated box and must be able to withstand crushing during container stacking and subsequent shipment.

STORAGE AND SHELF LIFE REQUIREMENTS

- . Shelf Life: If product is stored at optimum storage condition listed below, then product shelf life shall be no less than 5 years.
- Storage Temperature: Do not store in temperatures >104 °F or in damp/high humidity areas.
- Optimum Storage Conditions: Temperature-controlled environment with no exposure to direct sunlight.

CERTIFICATION	S
21 CFR	510K NO.
Meets Title 21 CFR Section 6250 Non-Powdered Patient Examination Glove requirements	K220371 K220373

GET-A-GRIP TECHNICAL SPECS



MEDICAL GRADE DIAMOND PATTERN GLOVES

1.0 SCOPE

1.1 Purchase of examination grade nitrile (9.5" length, 6 mil at the fingertip) high-risk gloves for use primarily in emergency medical hand PPE applications.

2.0 DEFINITIONS

- 2.1 ASTM (American Society for Testing and Materials):
 A volunteer organization which executes standards
 used to certify products for consumer purchase.
- 2.2 Batch: A quantity of gloves produced from a single incoming shipment of raw material—subset of a lot. Batch sizes shall be traceable to production line, operators, and packaging.
- 2.3 Batch Number: A unique number assigned to all gloves produced from a single batch used in tracking materials through the production process and in tracing quality problems to their source.
- 2.4 Date of Manufacture: A distinct and separate number that clearly identifies the date of manufacture—not the lot number. Cannot be coded.
- 2.5 FDA 510(k): Pre-market medical device clearance issued by the United States Food and Drug Administration.

 Required for a medical glove to be imported and marketed in the United States.
- 2.6 Lot: A quantity of gloves produced in a given time period based on a formula or recipe.
- 2.7 Importer of Record: The entity or person in the destination country responsible for ensuring compliance requirements are met when importing goods internationally.
- 2.8 Lot Number: Unique number assigned to specific dates of production and utilized to trace quality problems to their source.
- 2.9 Manufacturer: A factory that operates the production line and controls the quality of the end product.
- 2.10 Package: The wrapping or enclosure directly containing the smallest number of gloves from which the user withdraws product for use, commonly referred to as a box.

- 2.11 Private Labeler: The entity that procures product from a manufacturer or importer of record and whose name appears on the product labeling.
- 2.12 Shall: This term indicates a mandatory requirement.
- 2.13 Standard: The established requirements of ASTM D6319 or other standards as referenced and set forth in this document.
- 2.14 Thickness: The referenced measurement of a glove thickness will be taken from the locations set forth in the ASTM Standard Testing Method D3578-19 and recorded in mils or mm (see Addendum 1).
- **2.15** Patent: License giving the sole right of the inventor to exclude others from making, using or selling an invention.
- **2.16 UDI:** FDA required Unique Device Identifying number and bar code applied to the box and the master carton.

GET-A-GRIP TECHNICAL SPECS



MEDICAL GRADE DIAMOND PATTERN GLOVES

3.0 CERTIFICATIONS AND SPECIFICATIONS

- 3.1 BIDDERS SHALL MEET ALL CERTIFICATIONS AND SPECIFICATIONS CONTAINED IN THIS DOCUMENT. IF A BIDDER DOES NOT MEET A CERTIFICATION OR SPECIFICATION LISTED, THEY WILL BE DECLARED NON-RESPONSIVE. SEE ATTACHED SPECIFICATION WORKSHEET.
- 3.2 ISO 9001 (current edition) for Factory and Importer
- 3.3 FDA 510K Registration
- 3.4 Meets 21 CFR 880.6250 Patient Examination Glove Requirement
- 3.5 Packaging
 - 3.5.1 Each package of gloves shall be marked with a lot #, separate batch #, separate uncoded date of manufacture, model # and design, UDI information and glove size (for bid samples and on each post bid shipment).
 - **3.5.2** Each package will have printed legibly the shelf life warranty and recommended storage conditions.
 - 3.5.3 All gloves shall be in original manufacturer's packaging (for bid samples on each post bid shipment). This packaging shall not be tampered with. No area should be cut out or covered by labels other than those put on by the manufacturer (except for bid sample labeling requirements).
- 3.6 Shelf Life
 - 3.6.1 Will not accept any product that has a manufacturing date older than thirty-six (36) months from the date of manufacture.
- 4.0 DOCUMENTATION REQUIRED

(All Technical Data Packages shall include the following):

4.1 ALL REQUIRED DOCUMENTATION SHALL BE PROVIDED AT THE TIME OF BID SUBMISSION. THE OMISSION OF ANY REQUIRED DOCUMENTATION OR SAMPLES WILL RESULT IN THE BIDDER BEING DECLARED NON-RESPONSIVE.

- **4.2** ISO Certification for both Manufacturer and Importer of Record and/or Private Labeler (with Design)
- 4.3 FDA 510K Registration for Manufacturer and/or Importer of Record of product submitted, including process and color
- 4.4 Third Party Testing—ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation for > 240 Min. Against Fentanyl, Heroin, Gastric Acid, and Xylazine
 - 4.4.1 Lot and Batch Control
 - **4.4.1.1** Each test data will be for a lot: < 900,000 gloves and < 40,000 gloves
 - **4.4.1.2** Manufacturer lot and batch traceability key
 - 4.4.2 Physical Requirements
 - 4.4.2.1 Data will clearly show that all physical and dimension requirements, including tensile, elongation, length, thickness, package count and watertight AQL, have been achieved
 - **4.4.2.2** One (1) data set required to verify physical requirements are adhered to
- 4.5 Literature Sheets
 - 4.5.1 Bidders shall submit literature sheets that declare minimum tolerances for thickness properties. Average thickness dimensions will not be allowed unless literature sheet declares +/- tolerances. If either minimum or average thickness is not declared, vendor will be deemed non-responsive and will be immediately disqualified. Literature sheets shall not be altered.
- **4.6** Factory invoices will be submitted for the same lots provided for test data in Section 4.4.

GET-A-GRIP TECHNICAL SPECS



MEDICAL GRADE DIAMOND PATTERN GLOVES

5.0 SAMPLES

- 5.1 Bidder will submit for evaluation a minimum of one (1) box of each size for each glove model considered for bid. All sample gloves will be submitted with all required documentation upon bid submission. Failure to submit samples will result in bidder being declared non-responsive.
- 5.2 Samples submitted will be the exact item offered and shall be an exact representation of how the product will be delivered to agencies with respect to quality, packaging and number of units per package.

6.0 EVALUATION

- 6.1 Gloves submitted will be tested by a panel of Protocol Committee Members. The gloves will meet the following criteria:
 - **6.1.1** Less than 5% breakage while routinely trying on the gloves
 - **6.1.2** Gloves will be field tested to assure that the sizes conform to the needs of various department personnel
 - 6.1.3 Gloves shall provide maximum sensitivity so that the user can perform such medical tasks as feeling a pulse, intubation, and picking up small objects in the course of treating a patient. Gloves shall provide a secure grip of smooth, hard objects that are handled by field providers during patient treatment.
 - 6.1.4 Gloves will provide non-adherence properties when used in conjunction with veniguards, EKG patches, or Transpore and other medical tape(s). No glove shall rip or need to be removed during testing.
 - **6.1.5** Gloves will contain a green inside wear indicator layer to advise the wearer that the glove has been compromised.

7.0 QUALITY ASSURANCE

7.1 Testing as specified by this standard in Section 4.4 shall be conducted on a pre-shipment lot-to-lot basis. Test data shall be supplied for each shipment of gloves received by the agencies request for pre-shipment approval. This test data shall be used to verify.

- **7.1.1** All gloves received must be compliant with ASTM D6319 standard
- 7.1.2 No gloves are received from non-certified manufacturers or factories
- 7.1.3 Gloves received are not "seconds" or otherwise substandard

8.0 WARRANTY

- 8.1 All products are to be warranted against all defects in parts or workmanship. The vendor shall replace any and all products which are found to be defective or substandard.
- **8.2** The Procurement Department shall be notified immediately in the event of any of the following:
 - **8.2.1** Problems regarding good manufacturing practices in the production of the product
 - **8.2.2** Any and all problems with compliance to the standards outlined above
 - **8.2.3** Any changes affecting the form, fit or function of the product
 - 8.2.4 Any and all recalls of the product
- **8.3** Any gloves identified by lot and/or batch number as recalled will be replaced at no cost to the customer

GLOVE SPECIFICATIONS WORKSHEET GET A GRIP

CITY COUNTY OF						
NITRILE GLOVE SPECIFICATION REQUIREMENTS	GET-A-GRIP (OR EQUIVALENT)	BIDDER'S RESPONSE CHECKLIST (/ FOR COMPLIANCE)				
Material	Acrylonitrile Butadiene Rubber					
Minimum Length	9.5" Rolled Cuff (240 mm)					
Palm Widths (mm) Tolerance +/-3	Small - 86 // Medium - 97 // Large - 109 XLarge - 115 // 2XLarge - 121 // 3XLarge - 131					
Fingertip Thickness (mils) +/02	6.0 (0.15 mm)					
Palm Thickness (mils) +/02	5.0 (0.13 mm)					
Cuff Thickness (mils) +/02	3.5 (0.08 mm)					
Certifications and Test Standards	ASTM D6319-Standard Specification for Nitrile Gloves ASTM D6124-Standard Test Method for Residual Powder on Medical Gloves ASTM D515-Standard Test Method for Detection of Holes in Medical Gloves ASTM D5712-Standard Test Method for Protein Content in Medical Gloves ASTM D6978-05(2019)-Standard Practice for Assessment of Resistance of Medical Gloves to Permeation for > 240 min. against Fentanyl, Heroin & Gastric Acid					
Surface Properties	Full Surface Specialized Atypical Diamond Pattern					
Properties	Examination Grade, Powder Free, Permeation 3rd Party Tested against Fentanyl, Heroin, Gastric Acid & Xylazine					
Watertight Barrier AQL	1.5					
Avg. Tensile Before Aging (MPa)	26					
Avg. Tensile After Aging (MPa)	28	**************************************				
Avg. Elongation Before Aging %	550	Made a special control of the special control				
Avg. Elongation After Aging %	550					
EN ISO 374-1: 2016/Type B Certification	Standard for Chemical Protective Gloves JKOPT					
Lot Control	< 900,000					
Batch Control	< 40,000					
Sampling Plan	ANSI / ASQ Z1.4-2008					
Glove Color	510K No. K220373 Black/Green 510K No. K220371 Blue/Green					
Sizes Available	Small - 3XLarge					
Box Count/Case Count	Small-Large 100 Gloves by Weight / 10 Disp. Boxes/Case XLarge-3XLarge 90 Gloves by Weight / 10 Disp. Boxes/Case					
Certification Requirements	MANUFACTURER: ISO 9001 & 13485 PRIVATE LABELER: ISO 9001 (with Design)					
Average Force of Break 16n	EN 388 - Standard Test Method for Resistance to Puncture					
Country of Origin	Malaysia					
Annual Case Usage Per Year by Size	SMALL MEDIUM LARGE XLARGE _	2XLARGE 3XLARGE				



July 26, 2023

-TEST REPORT

PN 170619B

CC

PHARMACEUTICAL SERVICES

Prepared For:

Tracy Calkins

Summit Glove Inc. and its subsidiaries, PH&S Products LLC, & KAZ Guantes
310 South Grant St., P.O. Box 328

Minerva, OH 44657

Prepared By:

//Tiffany Heller

DCN 1176

Manager, Pharmaceutical Services

Approved By:

Ana C. Barbur

Vice President, Analytical & Chemical Services



180 9001;2015

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July 26, 2023

Tracy Calkins

Summit Glove Inc. and its subsidiaries, PH&S Products LLC, & KAZ Guantes

Page 2 of 5 PN 170619B

SUBJECT:

Permeation Testing per ASTM D6978-05(2019) on samples submitted by the above company.

RECEIVED:

One (1) glove type identified by customer as; Black/Green two toned 6 mil Fingertip Powder Free Nitrile

Gloves, Lot Number 21C4YXL0322181AA.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE		
Fentanyl Citrate Injection, 50 mcg/ml	USP; Lot# R128C0; Expiration 07/2024		
Xylazine HCl, 100 mg/ml (100,000 ppm)	VWR; Batch# GH5QM-WU; Expiration 06/2025		
Heroin	As Received by the Jefferson County Sheriff's Departme		
Simulated Gastric Acid	Made in house with reagent grade solvents; 0.2% (w/v) Sodium Chloride in 0.7% (v/v) Hydrochloric Acid		

COLLECTION MEDIA:

Table 2. Collection Media for Test Drug

TESTING CHEMOTHERAPY DRUGS	COLLECTION MEDIA	
Fentanyl Citrate/ Gastric Acid/ Heroin/ Xylazine HCl Solution (10/1/10/1) (w/w/w/w)	Distilled Water	

TESTING CONDITIONS:

Standard Test Method Used:

ASTM D6978-05(2019)

Permeation Test Cell Size:

1" Permeation Cell UV/VIS Spectrometry

Analytical Method:

35.0°C ± 2.0

Testing Temperature: Collection System:

Closed Loop

Specimen Area Exposed:

5.067 cm²

Selected Data Points:

25/test

Number of Specimens Tested:

3/test

Location Sampled From:

Cuff

Tracy Calkins

Summit Glove Inc. and its subsidiaries, PH&S Products LLC, & KAZ Guantes

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DETECTION METHOD OF CHEMICAL PERMEATION:

UV/VIS ABSORPTION SPECTROMETRY:

Instrument:

Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)	
Fentanyl Citrate/ Gastric Acid/ Heroin/ Xylazine HCl Solution (10/1/10/1) (w/w/w/w)	211	

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: Black/Green two toned 6 mil Fingertip Powder Free Nitrile Gloves. Lot Number 21C4YXL0322181AA.

Testing Drug	Thickness (mm)			
	Sample 1	Sample 2	Sample 3	Average (mm)
Fentanyl Citrate/ Gastric Acid/ Heroin/ Xylazine HCl Solution (10/1/10/1) (w/w/w/w)	0.113	0.113	0.113	0.113
Weight/Unit Area (g/m2)			105.5	

RESULTS:

Table 5. Permeation Test Results on testing of: Black/Green two toned 6 mil Fingertip Powder Free Nitrile Gloves, Lot Number 21C4YXL0322181AA.

TEST CHEMOTHERAPY DRUGS	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Fentanyl Citrate/ Gastric Acid/ Heroin/ Xylazine HCl Solution (10/1/10/1) (w/w/w/w)	>240 min.	N/A	Slight swelling

SAMPLES RECEIVED:
Black/Green two toned 6 mil Fingertip Powder Free Nitrile Gloves,
Lot Number 21C4YXL0322181AA



July 26, 2023

Tracy Calkins

Summit Glove Inc. and its subsidiaries, PH&S Products LLC, & KAZ Guantes

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APPENDIX

Testing Location: 2887 Gilchrist Road, Akron Ohio 44305

Decision Rules

Customer Selected Decision Rule: Decision Rule 1

RULE 1.

This is the way test results have traditionally been reported by ARDL. If ARDL runs a test for you that has pass/fail requirements, ARDL will report the values observed and then state "Pass" or "Fail", based on those values only. By default, ARDL will apply this rule to all Category I tests and those tests which are not on ARDL's Scope of Accreditation.

RULE 2.

This rule takes into account the calculated measurement uncertainty of test results generated. Every test and piece of test equipment has an inherent amount of measurement uncertainty associated with it. Rule 2 establishes "Guard Bands", where the measurement uncertainty value is added to the Minimum Passing requirement and is subtracted from the Maximum Passing requirement. The Pass/Fail requirements thus become tighter and customers may be more "Certain" of their Pass/Fail result.

RULE 3.

This rule also takes into account measurement uncertainty but does not set up guard bands. Rule 3 may be used when values are reported, but there is no Pass/Fail requirement called out in the test specification. Rule 3 simply states that the measurement uncertainty is reported to the customer, along with the testing result generated, and the customer decides if the results are suitable for their purposes.

REPORT REVISIONS:

DATE 07/26/2023

REVISION #

N/A

DETAILS

Original Final Report

Prepared By:

A Aiffany Heller

Manager, Pharmaceutical Services

Approved By:

Ana C. Barbur

Vice President, Analytical & Chemical Services