TEST & TECHNICAL DATA	Test	Objective	Relevance	FDA Requirement (Eff. 12/08)	ASTM D6319 Requirement	Descriptions	PURPLE NITRILE* Results
PHYSICAL PROPERTIES	ASTM D5151 Detection of Holes in Medical Gloves (Water Leak)†	Determine acceptability of gloves with respect to freedom from holes. The lower the Acceptance Quality Level (AQL), the better.	Measures potential for glove barrier integrity failure using ASTM standards.	Pass @ 2.5 AQL	Pass @ 2.5 AQL		Pass @ 1.0 AQL
	ASTM D412 Standard Test method for Vulcanized Rubber and Thermoplastic Elastomers-Tension (Tensile Strength)†	To assess the amount of force applied to a glove until it breaks. The lower the Acceptance Quality Level (AQL), the better.	The lower the tensile strength, the more easily materials of the same thickness can break when snagged or pressure is applied.	14 MPa (4.0 AQL)	14 MPa (4.0 AQL)	Tensile Strength	21 MPa Before Aging 21 MPa After Aging (2.5 AQL)
	ASTM D412 Standard Test method for Vulcanized Rubber and Thermoplastic Elastomers-Tension (Ultimate Elongation)†	To assess the breaking point of a glove when stretched. The lower the Acceptance Quality Level (AQL), the better.	Stretchability is very important at the microscopic level where the glove material must be able to give rather than break when stressed or snagged by instruments, fingernails, ridges on caps, twisting stop cocks on IV sets, or snapping off enclosures.	400% (4.0 AQL)	400% (4.0 AQL)	Ultimate Elongation	550% Before Aging (2.5 AQL) 500% After Aging (2.5 AQL)
	ASTM 3767 Standard Practice for Rubber-Measurement of Dimensions (Thickness)†	To measure glove thickness in millimeters (mm) utilizing a micrometer at specified locations on the finger and palm. The lower the Acceptance Quality Level (AQL), the better.	Thickness is a metric that can be used in determining both tactile sensitivity and barrier protection. Consistency for this metric is key for both durability and chemical permeation protection.	0.05mm 0.05mm (4.0 AQL)	0.05mm 0.05mm (4.0 AQL)	Finger Palm Cuff	0.15 mm 0.12 mm 0.09 mm (2.5 AQL)
	ASTM 3767 Standard Practice for Rubber-Measurement of Dimensions (Length)†	To measure glove length in millimeters (mm) utilizing a rule or tape from the upper finger tip to cuff. The lower the Acceptance Quality Level (AQL), the better.	This measurement helps ensure appropriate length and size correctness.	230 mm (4.0 AQL)	230 mm (4.0 AQL)	U.S. Requirements	242 mm (2.5 AQL) ††
	ASTM 6124 Residual Powder on Medical Gloves	Determine amount of residual powder on the glove surface; ASTM specifies the maximum allowed level of filter-retained substances for a powder-free claim.	A powder-free glove helps reduce powder-associated wound healing complications caused by starch glove powder and helps reduce irritant reactions and the transfer of proteins and chemicals that could potentially result in Type IV or I reactions.	<2mg			<2mg
SYSTEM BIOCOMPATIBILITY	Systemic Toxicity ISO 10993-11	Evaluate the potential for harmful effects to organs or systems using specific product extracts.	Measures the likelihood of adverse systemic and local response from contact with the product.	Optional			Pass

KIMBERLY-CLARK* KC500 PURPLE NITRILE* Powder-Free Exam Gloves have been tested according to the tests listed above.

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†D6319-00a Standard Specification for Nitrile Examnination Glove for Medical Applications
††Sterile PURPLE NITRILE-XTRA* = 305 mm†D6319-00a Standard Specification for Nitrile Examination Glove for Medical Applications

KIMBERLY-CLARK* KC500 PURPLE NITRILE* Exam Gloves

TEST & TECHNICAL DATA	Test	Objective	Relevance	FDA Requirement (Eff. 12/08)	ASTM D6319 Requirement	Descriptions	PURPLE NITRILE* Results
IRRITATION AND SENSITIZATION	Primary Skin Irritation ISO 10993-10	Estimate the potential to induce skin irritation from direct exposure.	Measures the likelihood of dermal irritation from contact with the product.	Pass			Pass
	Sensitization ISO 10993-10	Estimate the potential to induce contact sensitization Type IV delayed hypersensitivity immunological response via product extracts.	Measures the likelihood of adverse immunological dermal response from contact with the product over time.	Pass			Pass
RESIDUAL CHEMICALS	High Pressure Liquid Chromatography (HPLC)	Measure the type and amount of residual chemicals left on the glove.	Lower levels of residual chemicals decrease the risk of developing irritant and Type IV reactions.	Optional			Pass
VIRAL PENETRATION	Penetration by Bloodborne Pathogens Using Phi-X174 Bacteriophage (Viral Penetration) ASTM F1671-97b	Measure the resistance of materials used in protective apparel to penetration by bloodborne pathogens.	Measures resistance to potentially infectious body fluids permeating through the protective material.	Optional	Pass		Pass

KIMBERLY-CLARK* KC500 PURPLE NITRILE* Powder-Free Exam Gloves have been tested according to the tests listed above.

The following chemotherapy drugs and had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15 mg/ml)	Doxorubicin HCl (2.0 mg/ml)	Mechlorethamine HCl (1.0 mg/ml)
Busulfan (6 mg/ml)	Epirubicin (Ellence) (2 mg/ml)	Melphalan (5 mg/ml)
Carboplatin (10 mg/ml)	Etoposide (20.0 mg/ml)	Methotrexate (25 mg/ml)
Cisplatin (1.0 mg/ml)	Fludarabine (25 mg/ml)	Mitomycin-C (0.5 mg/ml)
Cyclophosphamide (20.0 mg/ml)	Fluorouracil (50.0 mg/ml)	Mitoxantrone (2.0 mg/ml)
Cytarabine HCl (100 mg/ml)	Gemcitabine HCl (38.0mg/ml)	Paclitaxel (6.0 mg/ml)
Dacarbazine (10 mg/ml)	Idarubicin HCl (1.0mg/ml)	Rituximab (10 mg/ml)
Daunorubicin HCl (5.0 mg/ml)	Ifosfamide (50.0 mg/ml)	Trisenox (0.1 mg/ml)
Docetaxel (10.0 mg/ml)	Irinotecan HCl (20.0 mg/ml)	Vincristine Sulfate (1.0 mg/ml)

PURPLE NITRILE-XTRA* sterile exam gloves also provide protection against the following drugs.

Breakthrough times listed:	STERILE	NON-STERILE
ThioTEPA (10.0 mg/ml)	No breakthrough to 240 minutes	No breakthrough to 240 minutes
Carmustine (3.3 mg/ml)	Breakthrough detected in 48 minutes	Breakthrough detected in 30.7 minutes

Chemotherapy Permeation Testing per ASTM D6978-05 "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs"

The following chemicals had NO breakthrough detected up to 240 minutes:

Ethidium Bromide, 0.4%	Povidone Iodine, 10%
Sodium Hydroxide, 40%	Chlorhexidine Gluconate, 4%
Sulfuric Acid, 50%	Sodium Hypochlorite, 10-13%
Formalin, 10%	Quaternary Disinfectant Cleaner
Glutaraldehyde, 4%	

PURPLE NITRILE-XTRA* sterile exam gloves provide additional protection against the following chemicals. Breakthrough times listed:

Hydrogen Peroxide, 30%	20 minutes
n-Hexane, 96.1%	19 minutes
Isopropyl Alcohol, 70%	52 minutes
Ortho-phthalaldehyde/Cidex OPA	93 minutes
HCL, 37%	230 minutes

ASTM F739 Standard Test Method for Permeation of Liquids and Gases through Protective Clothing materials under Conditions of Continuous Contact

Infection prevention website:
www.HAIwatch.com NOT ON MY WATCH

For more information, please call your sales representative, or visit our web site at www.kchealthcare.com.

The KIMBERLY-CLARK ADVANTAGE*

KNOWLEDGE NETWORK* Accredited Education
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All Chemical Permeation Testing was done on a single layer of glove material.

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