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KIMBERLY-CLARK* STERLING* Nitrile Exam Glove Test Method and Claim Summary

TEST & TECHNICAL DATA	Test	Objective	Relevance	FDA Requirement	ASTM Requirement	Kimberly-Clark Requirement	Descriptions	STERLING* Results/Target
	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.	4.0 AQL	2.5 AQL	1.5 AQL		Pass @ 1.5 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.	4.0 AQL	4.0 AQL	2.5 AQL	Before Aging After Aging	42 MPa 38 MPa
	ASTM D412 Standard Test method for Vulcanized Rubber and Thermoplastic Elastomers-Tension (Ultimate Elongation)	The ability to stretch a glove until it breaks. 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.	4.0 AQL	4.0 AQL	2.5 AQL	Before Aging After Aging	650% 550%
	ASTM 3767 Standard Practice for Rubber-Measurement of Dimensions (Thickness)	Thickness is measured in millimeters (mm) utilizing a micrometer at specified locations on the finger, palm and cuff. 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.	4.0 AQL	4.0 AQL	2.5 AQL	Finger Palm Cuff	0.09 mm 0.08 mm 0.07 mm
	ASTM 3767 Standard Practice for Rubber-Measurement of Dimensions (Length)	Length is measured 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.	4.0 AQL 230 mm	4.0 AQL 230 mm	2.5 AQL 232 mm	U.S.	2.5 AQL 242 mm
	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	<2mg		<2mg; Pass
SYSTEM BIOCOMPATIBILITY	Systemic Toxicity ISO 10993-11	Evaluate the potential for harmful effects to organs or systems using specific product extracts.	Reduce risk of adverse systemic and local response due to contact with product.	Optional		Pass		Pass

KIMBERLY-CLARK* STERLING* Nitrile Powder-Free Exam Gloves have been tested according to the tests listed above.

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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		Pass
	Sensitization ISO 10993-10	Estimate the potential to induce contact sensitization Type IV delayed hypersensitivity immunological response via product extracts.	Decrease the likelihood of adverse immunological dermal response from product use over time.	Yes		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		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.	Pass		Pass		Pass
BARRIER	Resistance of Protective Materials to permeation by Liquids ASTM F739	Determine the level of barrier protection to chemicals which are commonly used in a laboratory environment.	Helps measure barrier effectiveness against chemicals for aid in selecting appropriate PPE.					Specific breakthrough times on record

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Tested Chemotherapy Drug and Concentration	Average Breakthrough Detection Time (Minutes)
Cyclophosphamide (20.0 mg/ml)	No breakthrough up to 240 minutes
Doxorubicin HCl (2.0 mg/ml)	No breakthrough up to 240 minutes
Etoposide (20.0 mg/ml)	No breakthrough up to 240 minutes
5-Fluorouracil (50.0 mg/ml)	No breakthrough up to 240 minutes
Paclitaxel (Taxol) (6.0 mg/ml)	No breakthrough up to 240 minutes
Cisplatin (1.0 mg/ml)	No breakthrough up to 240 minutes
Dacarbazine (10 mg/ml)	No breakthrough up to 240 minutes
Ifosfamide (50.0 mg/ml)	No breakthrough up to 240 minutes
Mitoxantrone (2.0 mg/ml)	No breakthrough up to 240 minutes
Vincristine Sulfate (1.0 mg/ml)	No breakthrough up to 240 minutes
Carmustine (3.3 mg/ml)	Not for Use with Carmustine
ThioTEPA (10.0 mg/ml)	Not for Use with ThioTEPA

The STERLING and STERLING NITRILE-XTRA* Powder-Free Exam Glove material was tested with the above chemotherapy drug concentrations in accordance with ASTM D 6978 , Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.*

***CAUTION:** The testing conditions used are intended to approximate the worst case conditions for clinical use. Testing was conducted on single layer glove material. It is the users' responsibility to determine the applicability of these gloves for their intended use with chemotherapy drugs.*