

KIMTECH™

Data Pack

**Kimtech™ G5
Co-Polymer Gloves**



Table of Contents

Technical Data Sheet	3
Certificate of Analysis	5
Case & Package Labels	7
Test Methods	12
Glossary of Terms	17



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Technical Data Sheet



KIMTECH™ G5 Co-Polymer Glove, 12" Ambidextrous

Product Information

Code	Size	Affiliate #	Palm Width (mm)*	Length (mm)*	Quantity
61001	S/6.0-6.5	NA	85	285	100 gloves/bag; 10 bags/case
61002	M/7.0-7.5	NA	95	285	100 gloves/bag; 10 bags/case
61003	L/8.0-8.5	NA	105	285	100 gloves/bag; 10 bags/case
61004	XL/9.0-10.0	NA	115	285	100 gloves/bag; 10 bags/case

*As measured by ASTM D 6319¹

Property	Description
General Description	Controlled environment vinyl powder free, clear, non-sterile, smooth, ambidextrous gloves with beaded cuff and polymer coating on the donning side, not made with silicone.

Physical Property	Unit	Upper Limit	Test Method (2.5 AQL)
Watertightness	NA	Pass	ASTM D 5151

Thickness	Minimum	Test Method (4.0 AQL)
Middle Finger	3.15 mil (0.08 mm)	ASTM D 6319
Palm	3.15 mil (0.08 mm)	ASTM D 6319
Cuff	2.36 mil (0.06 mm)	ASTM D 6319

Property	Tensile Strength Before Aging	Ultimate Elongation Before Aging	Median Force At Break
Result	9 Mpa	300%	NA
Test Method (4.0 AQL ¹)	ASTM D 412 ASTM D 573 ASTM D 3578 ASTM D 6319	ASTM D 412 ASTM D 573 ASTM D 6319	

¹ AQL levels defined according to ISO 2859-1 (current edition) Sampling Procedures for Inspection by Attributes.

Workmanship Requirement: Gloves shall be made in accordance with reasonable industry practice with respect to defects, dirt and contamination. Gloves should be packaged as specified having described size and color in the appropriate quantity as listed. Shipping Case and inner packaging shall be labeled with product name, size, lot/batch and catalog number.

For Additional information: Contact your Kimberly-Clark representative, our North America Customer Service Team (888)-346-GOKC (4652), KCPInfo@kcc.com; our European (EU) Customer Service Team +44(0) 1737 736000, infofax@kcc.com; or our Asia-Pacific (AP) Customer Service Team +603 7807 8210

Certificate of Conformance available online at www.kimtech.com/certificates. Declaration of Conformity is available at: www.kimtech.eu

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Certificate of Analysis





Kimberly-Clark Professional*1400 Holcomb Bridge Rd. Roswell, GA 30076 USA

CERTIFICATE OF ANALYSIS

Product Description : KIMTECH G5 Co-Polymer Gloves 12" Ambidextrous

Catalog Numbers : 61001-01 S (6.0-6.5), 61002-01 M (7.0-7.5), 61003-01 L (8.0-8.5), 61004-01 XL (9.0-10)

Lot # : 470419
Batches : YE9120

Date of Manufacture : Apr-19
Expiration Date : 2024-04

Physical Test Data**							
	Watertight	Visual Defects			Dimensions	Elongation (%)	Tensile (MPa)
		Critical Visual	Major	Minor		Pre Aging	Pre Aging
Sample Size :	200	200	200	200	52	52	52
AQL Level :	2.5	2.5	2.5	10.0	4.0	4.0	4.0
Failures Allowed per AQL :	12	12	20	40	4	4	4
Failures :	0	0	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept
Averages:						445	22

Test Methods : Water tight test ASTM D 5151, EN 455-1, Elongation and Tensile ASTM D 412, Dimension EN 455-2

Particle Test Data**				
Particle Size (µm)	Min	Max	Standard Deviation	Average Particles/cm ²
0.5 - 1.0	4537	6916	1074	5370
1.0 - 2.0	319	567	108	411
2.0 - 5.0	47	75	11	60
5.0 - 10.0	2	5	1	4
10.0 - 20.0	1	1	0	1
>20	0	0	0	0
Total per Sample	4979	7503	1187	5846

Test Method : IEST-RP-CC005.4

Extractable Ion Test Data**							
	Anions Results						Sulfate SO ₄ ²⁻
	Fluoride F ⁻	Chloride Cl ⁻	Nitrite NO ₂ ⁻	Bromide Br ⁻	Nitrate NO ₃ ⁻	Phosphate PO ₄ ³⁻	
µg/g glove	0.759	10.019	2.276	2.276	2.276	3.793	104.904
µg/cm ²	0.004	0.050	0.012	0.012	0.012	0.019	0.522
	Cations Results				Trace Element Results		
	Sodium Na ⁺	Ammonium NH ₄ ⁺	Potassium K ⁺	Magnesium Mg ²⁺	Calcium Ca ²⁺	Zinc Zn	
µg/g glove	81.947	1.517	1.972	1.517	5.546	3.67	
µg/cm ²	0.409	0.008	0.010	0.008	0.028	0.02	

Test Method : IEST-RP-CC005.4

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Review By :

[Signature] 23 May 2019
(QA Manager - SSMT)

FORM-21936/2





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Case & Package Labels



G5 Co-Polymer Gloves

L (8.0-8.5)

 100 x  10 = 1000
12" (30.5cm)

- Ⓝ G5 Co-Polymer Gloves
- Ⓛ G5 Gants en copolymère
- Ⓢ Guantes copoliméricos G5
- Ⓞ G5 copolymer Handschuhe
- Ⓝ G5 copolymeer handschoenen
- Ⓜ G5 Guanti in copolimero
- Ⓡ G5 Сополимерные перчатки
- Ⓟ Luvas de copolímero G5
- Ⓚ G5 코폴리머 장갑
- Ⓜ G5コポリマーグローブ

Code #

Batch #

Lot

Family



(US)

61003 **10**

LOT 95 0214 / SM403201X

Lot Number
Номер партии
製造番号

 **02-2014**
Date of Manufacturing
Дата производства
製造年月

 **2019-01**
Expiration Date
Использовать до
使用期限



LM61003OL-01

1 00 36000 61003 8

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S (6.0 - 6.5) = 61001
 M (7.0 - 7.5) = 61002
 L (8.0 - 8.5) = 61003
 XL (9.0 - 10.0) = 61004

G5 Co-Polymer Gloves

12" Ambidextrous / 30.5cm

- ㉔ G5 Co-Polymer Gloves, Ambidextrous 12"/30.5cm
- ㉔ G5 Gants en copolymère Ambidextres Longueur 12"/30.5 cm
- ㉔ G5 Copolymer Handschuhe Beidhändig tragbar 12"/30.5 cm Länge
- ㉔ G5 Copolymer handschoenen Aan beide handen te dragen 30.5 cm/12 inch lang
- ㉔ G5 Guanti in copolimero Ambidestri Lunghezza 12"/30.5 cm
- ㉔ G5 Guantes copoliméricos Ambidestros 12 pulg./30.5 cm de largo
- ㉔ G5 Luvas de copolimero Ambidextros 12"/30.5 cm de comprimento
- ㉔ G5 코폴리머 장갑 양손잡이용 12"/30.5cm 길이
- ㉔ G5 コポリマーグローブ 両手用 長さ30.5 cm



100

㉔ For the Cleanroom Environment • For Industrial Use Only
 ㉔ Pour l'environnement contrôlé de salle blanche • Pour usage industriel uniquement
 ㉔ Para el entorno controlado de sala blanca • Solo para uso industrial
 ㉔ Für die kontrollierte Reiraumumgebung • Nur für den industriellen Gebrauch
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61003
L (8.0 - 8.5)
850214 / SM403201X
 02-2014
 2019-01





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Test Methods



Test Method for Analyzing Liquid Particle Counts

This test method is used to analyze the mobile particle contaminants from cleanroom gloves.

1. Scope
 - 1.1. The test method covers the average particulate contamination found on gloves designated for cleanroom applicability.
 - 1.2. The average contaminant concentration will be reported in particles per cm² in two ways:
 - 1.2.1. By size grouping, 0.5 to 1.0 microns, 1.0 to 2.0 microns, 2.0 to 5.0 microns, 5.0 to 10.0 microns, 10.0 to 20.0 microns, greater than 20.0 microns, and a total particle count greater than 0.5 microns.
 - 1.2.2. Statistical analysis of each grouping consisting of Minimum Value, Maximum Value, Standard Deviation, and Average Value, for each group of individual gloves.
 - 1.3. The safe and proper use of gloves is beyond the scope of this test method.
 - 1.4. This test method does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Test Method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.
2. Referenced Documents
 - 2.1. IEST-RP-CC005.3 Recommended Practice for Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments
 - 2.2. Work Instruction
3. Apparatus
 - 3.1. Analytical Balance, capable of readability and repeatability to 0.1 mg
 - 3.2. Particle Measuring Systems CLS-900 Liquid Particle Counting System
 - 3.3. 2000 mL glass beaker or 1000mL glass conical flask
 - 3.4. Stainless Steel Forceps, 10" length
 - 3.5. 250 ml Volumetric Flask
 - 3.6. 500 ml Volumetric Flask
 - 3.7. High Purity Deionized Water System, capable of producing 18.2 MOhm quality water
 - 3.8. Point of Use Filter, 0.2 micron size
 - 3.9. Orbital Shaker, ¾" orbit, capable of 200 rpm
 - 3.10. Circular Die, 1.5 inch diameter, calibrated
4. Procedure
 - 4.1. Test Preparation
 - 4.1.1. Prior to extraction, all Erlenmeyer flasks will be cleaned no less than five times with high purity deionized water filtered to 0.2 microns at point of use.
 - 4.1.2. All related equipment (forceps, volumetric flasks, etc.) must be rinsed with high purity deionized water prior to use.
 - 4.2. Extraction
 - 4.2.1. Randomly pull a glove from the package.
 - 4.2.2. Place glove finger-first into the one liter Erlenmeyer flask and hold open by cuff using the rinsed forceps.
 - 4.2.3. Empty into the inside of the glove 500 ml high purity filtered deionized water.
 - 4.2.4. Allow the glove to settle into the Erlenmeyer flask.
 - 4.2.5. Place an additional 250 ml high purity filtered deionized water over the glove within the Erlenmeyer flask.
 - 4.2.6. Allow the Erlenmeyer flask with glove to agitate on the shaker for 10 minutes ± 10 seconds at a rate of 150 rpm ± 10 rpm.
 - 4.2.7. Using clean tongs, immediately remove the glove from the container. Drain any trapped liquid into the beaker by manipulating the fingers on the glove, with the tongs
 - 4.2.8. Dispose of the glove.
 - 4.2.9. Repeat the extraction two additional times to complete the set.
 - 4.2.10. Prepare a process blank, using all the steps in section 4.2, without placing the glove in the Erlenmeyer flask.

4.3. Measurement

4.3.1. Follow the Work Instruction for the Liquid Particle Counter for analyzing the solutions.

4.4. Glove Surface Area

4.4.1. Pull three gloves from the production package and weigh to the nearest 0.1 mg.

4.4.2. Record as A.

4.4.3. Cut the 3 gloves with square die (5X5 cm.) by wheel cutter at palm. This will give you six cut-out sections.

4.4.4. Weight the six cut-out sections. Record this as B.

4.4.5. Calculate the surface area of the glove using the following equation :

$$\frac{A \times 5 \times 5 \times 4}{B}$$

5. Calculations

5.1. Calculate counts/cm² by channel size using the following equation:

$$\frac{(\text{Sample (counts/mL)} - \text{Blank (Counts/mL)}) \times \text{Extraction volume (mL)} \times \text{DF}}{\text{Surface area (in cm}^2\text{)}}$$

5.2. Total Counts/cm² : = \sum *AllChannelSizes*

6. Reporting

6.1. The final report should include the Lot Number, Batch number, Product Description, Part Number, and any other pertinent information about the sample, as well as the final calculated counts/cm² by channel size and a total counts/cm² greater than 0.5 microns.

6.2. Statistics will be calculated and reported on sample sizes greater than three.

Test Method for Analyzing Extractables

This test method is used to analyze the soluble ionic extractable contaminants from cleanroom gloves.

1. Scope
 - 1.1. The test method covers the average ionic contamination found on gloves designated for cleanroom applicability.
 - 1.2. The average contaminant concentration will be reported in one of two ways:
 - 1.2.1. Micrograms of ionic contaminant per gram of glove weight (ug/g), also described as ppm.
 - 1.2.2. Micrograms of ionic contaminant per square centimeter of glove area (ug/cm²)
 - 1.3. This test method does not cover contaminants that are insoluble in water, or organic macromolecules.
 - 1.4. The safe and proper use of gloves is beyond the scope of this test method.
 - 1.5. This test method does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Test Method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.
2. Referenced Documents
 - 2.1. IEST-RP-CC005.2 Recommended Practice for Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments.
 - 2.2. Work Instruction WI 10-05-26, Work Instruction for Performing Ion Chromatography Analysis of Gloves
3. Apparatus
 - 3.1. Analytical Balance, capable of readability and repeatability to 0.1 mg
 - 3.2. Ion Chromatograph
 - 3.3. Extraction Containers, 1 liter capacity, HDPE with screw type lids
 - 3.4. Stainless Steel Forceps, 10" length
 - 3.5. 500 ml Volumetric Flask
 - 3.6. High Purity Deionized Water System, capable of producing 18.0 MOhm quality water
 - 3.7. Point of Use Filter, 0.1 micron size
 - 3.8. Circular Die, 1.5 inch diameter, calibrated
4. Procedure
 - 4.1. Test Preparation
 - 4.1.1. Prior to extraction, all extraction containers will be cleaned using high purity deionized water high purity deionized water filtered to 0.2 microns at point of use.
 - 4.1.2. All related equipment (forceps, volumetric flasks, etc.) must be rinsed with high purity de-ionized water prior to use.
 - 4.2. Extraction
 - 4.2.1. Randomly pull a glove from the package.
 - 4.2.2. Place glove finger-first into the one liter Erlenmeyer flask and hold open by cuff using the rinsed forceps.
 - 4.3. Empty into the inside of the glove approximately 250 ml high purity filtered deionized water.
 - 4.4. Allow the glove to settle into the extraction container.
 - 4.5. Pour remaining 250 ml high purity filtered deionized water over the glove within the extraction container.
 - 4.6. Place the lid upon the container and seal tightly.
 - 4.7. Gently swirl the container to ensure that all surfaces of the glove are wetted.
 - 4.8. Allow the glove to extract in the deionized water for at least 10 minutes, but no longer than 11 minutes.
 - 4.9. Remove the glove by the fingers, allowing most of the water trapped in the fingers to drain back in to the extraction container.
 - 4.10. Dispose of the glove.
 - 4.11. Repeat extraction two additional times to complete the set.
 - 4.12. Prepare a sample blank, using all the steps in section 2, without placing the glove in the extraction container.

4.13. Measurement

4.13.1. Follow the guidelines for the Ion Chromatograph for analyzing aqueous solutions.

4.14. Glove weight and surface area

4.14.1. Pull three gloves from the production package and weigh to the nearest 0.1 mg.

4.14.2. Record as A.

4.14.3. Cut the 3 gloves with square die (5X5 cm.) by wheel cutter at palm. This will give you six cut-out sections.

4.14.4. Weight the six cut-out sections. Record this as B.

4.14.5. Calculate the surface area of the glove using the following equation :

$$\text{Surface area} = \frac{A \times 5 \times 5 \times 4}{B}$$

5. Calculations

5.1. Once the data output from the Chromatograph has been reviewed for errors, calculate the following:

$$5.1.1. \text{ ug/g (ppm) contamination: } = \frac{(\text{AnalyteConc.}) * (500\text{ml})}{\text{GloveWeight}}$$

$$5.1.2. \text{ ug/cm}^2 \text{ contamination: } = \frac{(\text{AnalyteConc.}) * (500\text{ml})}{\text{SurfaceArea}}$$

6. Reporting

6.1. The final report should include the Lot number, Batch number, Product description, Part number, and any other pertinent information about the sample, as well as the final calculated contaminant concentration in ug/g and ug/cm².



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Glossary of Terms



Item	Definition
Anion	The ion in an electrolyzed solution that migrates to the anode when voltage is generated; broadly: a negatively charged ion. Typical examples include Chloride (Cl-), Phosphate (PO4-3), Sulfate (SO4-2), Nitrate (NO3-).
AQL	Acceptable Quality Level. Applies to product attributes and defines the allowable number of defects for various sample sizes. For example, AQL 1.5 means that the sample must demonstrate that it exceeds 1.5% defects in order to reject the sample.
ASTM	American Society of Testing and Materials. The ASTM issues testing standards and specifications. The FDA utilizes many of the standards developed by the ASTM to establish medical device requirements.
Average	The sum of individual observations divided by the total number of observations. Average represents the central tendency of a "sample" group. The sample group can be used to make inferences about the entire population.
Bioburden	Bioburden is the population of viable microorganisms on a raw material, component, a finished product and/or a package. When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.
Biocompatibility	The property of not causing cytological change when introduced to a biological system or model.
Calcium carbonate	A mold-release agent often used that facilitates the release of latex gloves from their porcelain molds (formers). Calcium carbonate is a non water-soluble crystal. It occurs in nature as oyster shells, chalk and limestone.
Calibration	Comparison of a measurement standard or instrument of unknown accuracy with another standard or instrument of known accuracy to detect, correlate, report, or eliminate by adjustment, any variation in the accuracy of the unknown standard or instrument.
Cation	The ion in an electrolyzed solution that migrates to the cathode when voltage is generated; broadly: a positively charged ion. Typical examples include: Sodium (Na+), Calcium (Ca2+), Magnesium (Mg2+), Potassium (K+).
CE Mark	What is CE Marking? CE Marking is the symbol as shown on the top of this page. The letters "CE" are the abbreviation of French phrase "Conformité Européene" which literaturly means "European Conformity".
Certificate of Analysis (CoA) for cleanroom gloves	An authenticated document issued by the manufacturing plant that certifies the quality and purity of the cleanroom glove products being exported.
Certificate of Irradiation (Col) for cleanroom sterile gloves	An authenticated document issued by the sterilization plant that certifies the sterile cleanroom gloves as having been irradiated. Document includes the manufacturer lot & batch number. Irradiation data, allowable dose range and actual dose.
CFU (colony forming units)	Either one or an aggregate of many microbial cells which, when cultivated on solid media, will develop into a single visual colony. The unit of measure used for reporting bioburden (CFU/product).
Cleanroom	A room in which the concentration of airborne particles is controlled to specified limits. Federal Standard 209E - A document that establishes standard classes of air cleanliness for airborne particulate levels in cleanrooms and clean zones.
Contact sensitizer (other keywords: accelerators, MBT, carbamate, thiurams, mercaptobenzothiazole)	A chemical agent used in the manufacturing process of gloves that may elicit a delayed type allergic reaction (Type IV) after repeatedly exposing the substance to a susceptible individual.
Deionize	To remove ions. Deionization is generally the removal of ions from water by a process called ion exchange. Water is passed over a resin (plastic) exchange bed. The ions in the water have a greater attraction to the exchange bed than to the water.
Do we have sulfur in our gloves?	All latex (both NRL and Nitrile) use native S as a cross link element. Vinyl gloves do not typically have sulfur.
Dose audit	A check to make sure the dose is still correct. The population and sterilization resistance of microorganisms vary with environmental conditions such as temperature and moisture.
Dose mapping	Product dose mapping is conducted to identify the zones of minimum and maximum dose, within the product load with the specified loading pattern, and to assess the reproducibility of the process.
Dose setting	"Dose Setting using Bioburden Information." Determine the number of organisms on the packaged, pre-sterilized gloves.
Dosimeter	A device that measures the amount of radiation which reaches the position where the dosimeter is placed.
Elongation	Measurement in percent of the length a glove material can be stretched before it breaks.
Endotoxin	Pieces off the cell wall of dead bacteria, capable of causing multiple local and systemic pathological problems, including fever, complement activation, cell lysis, tissue inflammation, diarrhea, microthrombi formation (clots) and disseminated intravascula.

Enzyme-Linked Immunosorbent Assay (ELISA)	A highly sensitive immunoassay for specific antibodies or antigens (including allergens) depending on how the test is set up. Results expressed as mg/g or mL; ppm; Au/g or mL.
Gamma Irradiation	The process of product sterilization utilizing gamma wave radiation. It is the most compatible sterilization process for latex gloves.
Good Manufacturing Practices (GMPs)	What are GMPs? Good Manufacturing Practices (GMPs) are regulations that describe the methods, equipment, facilities, and controls required for producing: human and veterinary products (21 CFR 210-211), medical devices (21 CFR 820), processed food.
IEST	Institute of Environmental Standards and Technology. A consortium that develops standards and recommended practices and provides training by industry experts. The standards and recommended practices are developed by committees comprised of scientists.
Ion	An atom or group of atoms that carries a positive or negative electric charge.
ISO	The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. ISO has developed a series of standards relating to Quality Systems known as the ISO 9000 family standards.
ISO 9002	A quality system model for quality assurance in production and installation. I would skip ISO 9003 because it implies like 9002 doesn't cover inspection and testing.
Latex	Commonly, it is a milky, usually whitish fluid obtained from over 1,000 species of trees and plants. Relating to gloves, it is natural rubber latex, the raw material which comes from the Hevea brasiliensis tree.
Leaching	Process applied in the production of gloves by which chemicals or contaminants are dissolved and carried away by water to reduce chemical residual levels. Wet gel leaching occurs right after latex is dipped onto the mold.
Lowry	Determines the concentration of total protein present in a sample. A Modified Lowry assay was developed for use with latex products.
Mean	Represents the "Central Tendency" or average of an entire population. The formula is the same as for the average, except the mean includes the entire population. It is typically impractical to measure every member of any population.
Method 1	Dose setting utilizing the number (bioburden) and resistance of micro-organisms on the products to determine the level of irradiation necessary for sterilization with the desired safety margin (e.g. 10-6).
Micrometer (micron)	A unit of measurement equal to one-millionth of a meter or approximately 0.0003937 inch (e.g. 25 micrometers are approximately 0.001 inch).
Micron	A unit of length equal to one millionth (10 ⁻⁶) of a meter.
Modified Lowry assay	See Lowry.
Modulus	A measurement of the resistance to stretch. A lower modulus represents a glove in which it is easier to move and thus less fatiguing.
Non-pyrogenic	Non-fever causing. Reflects low levels of endotoxins which cause fever, inflammation, endotoxic shock, elicit micro-thrombi formation and numerous other adverse conditions. (See Endotoxin)
NVR (Non-Volatile Residues)	Refers to materials or components that do not evaporate at normal temperature and pressure.
Particle	A solid or liquid object, generally between .001 micron and 1000 microns in size.
Particle Size	The maximum linear dimension of a particle as observed with an optical microscope or the equivalent diameter of a particle detected by an instrument.
Particle Size Distribution	The relative percentage by weight or number of different particle size fractions.
Particulate	A substance that consists of particles (minute quantities of solid or liquid matter).
pH	Hydrogen ion concentration; measurement of how acidic or basic a glove extract is.
Product Dose Mapping	See "Dose Mapping."
Protein content	Regarding latex gloves, protein content is the measurement of total protein regardless of allergenic content. The ASTM D5712 Modified Lowry assay is the method recognized by the government for use with gloves.
Proteins	Any of a class of naturally occurring complex combinations of amino acids (containing carbon, hydrogen, oxygen, nitrogen, usually sulfur, occasionally phosphorus) which are essential constituents of all living cells.
Pyrogen	A fever-producing substance. Endotoxin is a pyrogen.
Pyrogenic	Capable of eliciting a fever.
SAL	See "Sterility Assurance Level."
SAL Dose	The level of radiation delivered to the product to achieve the required SAL (sterility assurance level).
Sampling	A process consisting of the withdrawal or isolation of the fractional part of a whole. In air or gas analysis, the separation of a portion of an ambient atmosphere with or without the simultaneous isolation of selected components.
Silicone [gloves]	Silicone is a synthetic polymer, or macro-molecule, whose backbone is a repeating chain of Si-O molecules, with various organic groups attached to the silicon. The most common silicone is PDMS, poly-dimethylsiloxane [(CH ₃) ₂ Si-O].

Silicone-free gloves	Currently, all our cleanroom nonsterile products are silicone free. We do not make the same claim with our boxed products. Some of them have silicone in them.
SPC (Statistical Process Control)	Statistical process control is the practice of using statistical methods such as control charts and capability analysis to monitor and control a process. The application of statistics to determine non-random changes in a process. Any changes or “shifts” in the process will be reflected as non-random occurrences and can be studied for root cause.
Specification – Design	A concise document defining technical requirements in sufficient detail to form the basis for a product or process. It indicates when appropriate, the procedure that determines whether or not the given requirements are satisfied.
Specification – Performance	A concise document that details the performance requirements for a product. The performance specification includes procedures and/or references for testing and certification of the product.
Standard Deviation	A statistical measurement of variability equal to the square root of the arithmetic average of the squares of the deviations from the mean in a frequency distribution.
Static Decay	The materials ability to dissipate a charge. Normally tested by placing a known charge (5000 volts) on the material (glove). A non-contact meter measures the charge on the material.
Static Dissipative	A property of material having a surface resistivity of at least 105 OHMs per square, but less than 1.0×10^{12} OHMs per square surface resistivity.
Statistical Capability	A process with a Cpk > 1.0 (although this can be defined as > 1.33 as well).
Statistical Control	A process which, when sampled on a regular basis, demonstrates an average that is consistent with the population central tendency and variability. In other words, the sample is statistically from the same population as previous samples.
Sterile	Assurance that a given device is without living organisms.
Sterility Assurance Level (SAL)	The expected probability of an item being non-sterile after exposure to a valid sterilization process. This is a safety factor over and above demonstrating that all microorganisms are killed.
Sterilization	A physical or chemical process that completely destroys or eliminates all forms of microbial life.
Sterilization Dose	Minimum absorbed dose required to achieve the specified sterility assurance level.
Sterilization Label	Label on the outside of every sterile cleanroom glove case showing the certificate number and sterilization batch. The label also provides a sterility indication showing the case has been irradiated/sterilized.
Sterilization Validation	Establishing documented evidence the sterilization process, dose range and dwell time are appropriate for the product being sterilized.
Synthetic rubber	Not of natural origin; produced by chemical synthesis. Synthetic gloves include, but are not limited to, vinyl (PVC), neoprene (chloroprene), nitrile, viton (fluorocarbon rubber), styrene butadiene (SBR), Tactylon (Styrene-Ethylene- Butadiene-Styrene—SE).
Talc	Magnesium silicate, $Mg_3Si_4O_{10}(OH)_2$, used as a solid lubricant. Banned from use on surgical gloves after found to cause granulomas and adhesions in surgical wounds.
Technical Data Sheet	Data sheet summarizing Kimberly-Clark’s glove technical claims for our customers.
Tensile strength	Measurement of the amount of stretch or pull required to rupture or break the glove material. Measurement is in Pa’s or MPa’s.
Validation	Establishing documented evidence that a system does what it purports to do.
Vulcanization	The process of treating crude latex, subjecting it to heat and sulfur to render it non-sticky, increasing its strength and elasticity.
What is a polymer?	Polymers are primarily made of carbon, hydrogen and oxygen. The structure of polymers is like a chain where repeating units (-mers) are connected many (-poly) times.
What is ESD (Electrostatic Discharge)? [cleanroom gloves]	The rapid, spontaneous transfer of electrostatic charge. Usually the charge flows as a spark between two bodies with differing electrostatic potentials (voltages) as they approach one another. (ESD Assoc.)
What is the melting point of latex and nitrile gloves?	Akron Rubber Development Laboratory has determined that the melting point of nitrile is at 283.4 Celsius.
What is the relationship between non-volatile residue testing and particle counting? (gloves)	NVR is determined by weight, and particles definitely have weight, but not enough to be a measurable part of the NVR for most cleanroom consumables. The weight of particles depends on their volume and what their made of.

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