ABSORBABLE DUSTING POWDER Glove powder used to ease the donning of gloves. It is made of edible modified corn-starch with a small percentage of magnesium oxide, as defined by USP, the United States Pharmacopoeia.

ACCELERATOR Chemicals that are used as a catalyst which accelerate the process of turning liquid latex into a gel form. These additional chemicals, which are added in during the manufacturing of latex gloves, are added mainly for elasticity and durability.

AEROSOLIZATION To disperse as an aerosol. A suspension of fine solid in gas, such as air. A common factor in powdered latex gloves.

ALLERGEN A substance, usually a protein, that is able to elicit an IgE antibody response and activate mast cells. Every allergen is an antigen but not every antigen is an allergen.

ALLERGIC CONTACT DERMATITIS An allergic rash (Type IV) with physiological memory to the chemical sensitizer that caused it. This means that it will cause the allergic rash again with subsequent exposure.

AMBIDEXTROUS Can be used on either the left or right.

AMMONIA Ammonia is a preservative and stabilizer in latex concentrate.

ANAPHYLACTIC SHOCK Often severe and sometimes fatal systemic reaction in a susceptible individual upon exposure to a specific antigen after previous sensitization. Is usually characterized by respiratory symptoms, fainting, itching and urticaria.

ANTIGEN A protein or carbohydrate substance which is capable of eliciting an immune (antibody or cellular) response; a molecule that causes the creation of and subsequently combines with the antibody or antigen-specific receptor on a T-cell. Both thiuram (Type IV contact sensitizer) and natural rubber latex proteins (Type I allergen) are antigens.

AQL Acceptable Quality Limit, is a quality specification that all glove manufacturers use to specify the pinhole rate in surgical and examination gloves. The FDA specifies an AQL of 1.5 for surgical gloves and 2.5 for examination gloves. An AQL of 2.5 means the defect level from a large sampling of gloves will not be more than 2.5%. The EU, via the EN455 series of standards, requires that both examination and surgical gloves meet AQL 1.5.

ASTM (American Society of Testing and Materials) Organized in 1898, The ASTM is a not-for-profit organization that provides a forum for the development and publication of voluntary standards for materials, products, systems and services in various industries. The FDA uses some of the standards and specifications developed by the ASTM to establish its requirements for examination gloves.

ASTM D3577 – Standard Specification for Rubber Surgical Gloves This specifies dimensions, tolerances and physical requirements for latex surgical gloves.

ASTM D3578 – Standard Specification of Rubber Examination Gloves This specifies dimensions, tolerances and physical requirements for latex examination gloves.

ASTM D5151 – Standard Test Method for the Detection of Holes in Medical Gloves This test method covers the detection of holes that allow water leakage under conditions described in the test.

ASTM D5250-00e4 – Standard Specification for Poly Vinyl Chloride (PVC) Examination Gloves This specifies dimensions, tolerances and physical requirements for vinyl examination gloves.

ASTM D5712-95 – Analysis of Protein in Natural Rubber and its Products An analytical test method to determine the amount of extractable protein associated with natural rubber and its products. All protein labelled latex gloves may only contain a maximum of 50 micrograms of protein per gram of glove when tested.

ASTM D6124 – STANDARD TEST METHOD FOR RESIDUAL POWDER ON MEDICAL GLOVES This test method determines the average powder or filter retained mass found on a sample of medical gloves as described in the test. The target amount of powder per powdered glove is 120mg and powder free gloves may only contain a maximum of 2.0mg powder per glove.

B GRADE/MULTI PURPOSE - RUN OF THE LINE GLOVES Also known as industrial grade gloves, for non-medical use. These gloves are either made to not meet medical glove standards in the first place, or they fail in pinhole rates or specifications in

quality control, and are downgraded from medical grade to B grade. These gloves are usually labelled as disposable gloves and cannot be labelled as exam gloves. May also be known as "run of the line" gloves.

BEADED CUFF A rolled or "bead" at the open end of a glove. The beading increases the glove strength when donning and effectively adds protection against any fluid drips.

BISQUE A glove finish characterized by a less glossy surface and decreased slickness. Also known as a matted surface.

BLOOD-BORNE PATHOGENS Infectious organisms in the blood, of which the predominant medical interest is their contamination of gloves, etc. all of which health workers are exposed to.

BREAK THROUGH TIME The time elapsed between the initial chemical reaction and the detection of the chemical inside the glove.

CALCIUM CARBONATE A mould-release agent added in the beginning of the production cycle to help the release of gloves from the hand moulds or formers. Calcium carbonate is a naturally occurring substance found in chalk, limestone and sea shells.

CAUTION STATEMENT This is an FDA requirement for Natural Rubber Latex (NRL) glove products which must state that "This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions." Within the EU, medical devices containing natural rubber latex must be labelled as containing latex, the following symbol can be used;

CHEMOTHERAPY GLOVES Within the EU, these should be tested and certified to EN374. The FDA currently requires testing to publish the claim that any glove is appropriate for use with chemotherapy drugs. These are thicker (greater than 0.10 mm) latex and nitrile examination gloves.

CHLORINATION Instead of powdering gloves, some manufacturers dip gloves into a chlorinated solution. This process reacts with the natural rubber latex to reduce tackiness, thus eliminating the need for additional dusting powder. Extra washing during the chlorination process provides an added benefit by greatly reducing the level of soluble latex proteins. It also affects some cosmetic and physical glove characteristics (softness and colour).

CLASS I MEDICAL DEVICE (US) A device for which the controls authorized by or under sections of the Federal Food, Drug and Cosmetic act are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

CLASS I MEDICAL DEVICE (EU) A device which is self-certified by the manufacturer and sold within the EU. These are generally lower risk products but are subject to certification if the device is either sterile or has a measuring function. Examination gloves are class I unless they are sterile in which case they are class Ia.

CLASS IIa MEDICAL DEVICE (EU) A surgically invasive device intended for short-term use, surgical gloves are class IIa.

CLASS II MEDICAL DEVICE (US) A device that cannot be classified as Class I device because the sections of the Federal Food, Drug and Cosmetic Act by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device for which there is sufficient information to establish special controls to provide such assurance, including the dissemination of guidelines. Medical Examination Gloves are considered Class II Devices.

CLEAN ROOM A contained room in which contaminants such as dust are reduced to a very low level by special processes so that operations such as the manufacture and assembly of delicate equipment, manufacture and handling of pharmaceuticals or working with biological materials, can be performed effectively. Clean room gloves are widely found in the electronic and pharmaceutical laboratory industries. There are several clean room class types, the lower the class number the cleaner the environment/less particulate allowed: Class 1 (M1.5), Class 10 (M2.5), Class 100 (M3.5), Class 1000 (M4.5) and Class 10000 (M5.5).

COMPOUNDING During the glove manufacturing process, chemicals are added, including accelerators (to help control the later vulcanization process) and antioxidants (to prevent deterioration of the rubber molecules in the final product by heat, moisture and ozone).

CONTACT URTICARIA Contact urticaria or hives can appear within minutes or up to an hour or more after a sensitized individual

comes in contact with allergens to which they are allergic. It is a Type I hypersensitivity reaction.

CONTROLLED ENVIRONMENT GLOVES Controlled environment glove, also known as Clean Room Gloves, materials must provide protection against particulate contamination. They are widely used in electronics and pharmaceutical industries. Critical environment gloves are typically Class M 3.5 (Class 100) and M 5.5 (Class 10,000) and higher. Controlled environment gloves are made from polyester, nitrile and nitrile/rubber combinations, natural rubber latex, polyvinyl chloride (PVC) and polyurethane.

COPOLYMER A compound made by polymerizing (joining) two or more dissimilar monomers.

CORNSTARCH A medical grade donning agent made from corn, under United States Pharmacopia (USP) requirements which is used as a donning agent for medical grade gloves.

CROSS LINKING The cross wise connecting part that connects parallel chains in a complex chemical molecule (as a polymer).

CUFF The upper portion of a glove which encircles the wrist. Designs range from straight, rolled (beaded) or fluted. Gauntlet cuffs offer the benefits of a safety cuff, plus a flared design that fits over the garment sleeve of the wearer.

DEGRADATION Damaging effects that liquid chemicals, extreme heat, ozone, fatigue or other substances have on the physical properties of the gloves. Signs of degradation may include softening and tackiness, brittleness, loss of elasticity, growth or ballooning at the finger tips.

DEHP (di-2-ethylhexyl phthalate) Sometimes known as DOP (di-octyl phthalate) is a commonly used plasticizer from the phthalate ester family and has been in use in flexible PVC (Poly Vinyl Chloride) products since the 1930's in medical and packaging applications. Phthalates have been continuously monitored to ensure that their use is safe as small amounts of plasticizers can leach out of products under certain circumstances. Through the years there has been debates by the scientific community as to the safety of these plasticizers. This is currently covered under REACH as a substance of very high concern (SVHC).

DERMATITIS A general term referring to any inflammation of the skin; may be caused by irritation or Type IV (delayed type) hypersensitivity. Characterized by erythema (redness), pain, pruritus (itching) vesicles (tiny blisters) and papules (hard bumps). If the dermatitis continues for a long period of time (becomes chronic), symptoms may expand to include drying, scaling, peeling and keratosis (thickening and hardening of the skin).

DIPPING This is the process of submerging glove formers (moulds) into tanks containing a compound or a solution. The hand shaped formers are coated with a coagulant (e.g. calcium nitrate) and dipped into the latex to coat them with a thin film of latex. The coagulant converts the liquid latex into a wet gel on the former. Subsequent passage through a warm oven completes the coagulation process.

DONNING POWDER CAUTION STATEMENT As glove powder represents a potential hazard to the user and patient, particularly in association with NRL proteins. The FDA recommends the following statement appear on glove packaging: "Caution: Users should consider the circumstances of use in deciding whether to remove residual powder on glove after donning. Powder can be removed by wiping gloves thoroughly with a wet sponge, sterile wet towel or other effective methods."

DOUBLE GLOVING The practice of wearing two layers of medical gloves to reduce the risks of infection from glove failure or sharps penetration. Double gloving has been shown to offer significantly greater protection against inner glove perforation in surgical procedures compared to the use of a single glove layer.

DRAIZE TEST Sometimes known as a Modified Draize Test. This is a 200-person challenge test which is utilized to determine irritant or dermal reactions caused by chemicals of a given product. Samples of the test glove are patch tested repeatedly on each of the individuals over a 6-week period.

DRY GEL LEACHING Occurs after gloves pass through ovens, transforming them from a gel into a basic solid form. When the gloves are dry gel leached, their proteins may be reduced significantly.

ECZEMA Contact Dermatitis and inflammation of the skin, marked initially by redness, itching, minute papules and vesicles, weeping, oozing and crusting; and later by scaling. This can

This can develop into a thickening and hardening of the skin. Causes may be allergic or non-allergic.

ELONGATION The measurement of the length a glove that can be stretched before it breaks. It is expressed as a percent of the original length of the glove at the moment it breaks. The higher the percent, the more stretchable the glove material.

EN455 SERIES A series of standard for medical gloves covering freedom from holes, physical properties, biological evaluation and shelf life.

ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) A highly sensitive immunoassay for specific antibodies or antigens (including allergens). Results are expressed in microgram per gram or millilitre (µg/g or mL); parts per million (ppm); allergen units per gram or millilitre (Au/g or mL).

ERYTHEMA Inflammatory redness of the skin.

FDA 510(k) Number Section 510(k) of the Food, Drug and Cosmetic Act requires that all device manufacturers must register to notify the FDA, at least 90 days in advance, of their intent to market any medical device. This is known as a Premarket Notification, and allows the FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories (Class I, II, III). Devices are awarded specific numbers for each product. Major product modifications may require a new 510(k) number. Search FDA releasable 510(k) database at http://www.fda.gov/cdrh/510khome.html

FILM The finished, cured or semi cured material made from suspended latex compound, used to form a glove.

FINISH The finish of a glove can provide better grip control in wet or dry applications. Patterns are cut directly onto the glove former, as it is cast, for embossed, sandblast or recessed diamond finish. For a bisque (matte) finish, the glove former is cast and then slightly roughened. For additional gripping power, some supported (heavy duty utility) gloves receive a textured wrinkle, applied rough particle, or embossed self-flushing (tire or tractor tread) finish. Gloves with a smooth finish rely solely on the gripping qualities of the material itself.

GAMMA IRRADIATION/STERILIZATION A popular method of sterilization utilized in the healthcare industry which uses electromagnetic radiation (bombardment of high energy photons and gamma rays) as opposed to chemicals such as Ethylene Oxide.

GAUGE (THICKNESS) A glove thickness is measured in gauge, mil or millimetre. Low gauge (thin) gloves provide more flexibility and sensitive touch, while higher gauge (thicker) gloves offer enhanced protection.

HYPERSENSITIVITY This is a term used to describe a heightened response to a substance (I.e. an antigen), that has developed after repeated exposure, and causes a genetically predisposed (atopic) individual to become sensitized or allergic (Type I or Type IV).

HYPOALLERGENIC With regard to gloves, the claim hypoallergenic was developed to describe a reduced potential for developing a dermatological response to chemicals utilized in production of a given product. The 200-person modified Draize test is used to determine potential irritancy or allergic contact dermatitis (Type IV) to the product. After manufacturing product to meet these requirements, manufacturers could utilize the term hypoallergenic as an identifier for the product (a claim). However, in recent years individuals have also developed Type I allergic reactions in association with the proteins from the gloves. Because the label claim of hypoallergenic was being interpreted as to refer to both Type IV and Type I allergies, rather than just Type IV, this claim was removed from all gloves on September 30, 1998.

INDUSTRIAL GRADE GLOVES See B grade gloves.

IRRITATION An inflammatory reaction of tissues to an injury. An irritation is not an allergic response, it possesses no physiological memory of the substance that caused it. Repeated contact or long-term exposure may result in irritant contact dermatitis on the skin or chronic inflammation in a surgical wound, potentially developing into granulomas or adhesions.

LATEX Natural Rubber Latex is a milky sap-like substance produced by the rubber tree (Hevea Brasiliensis), found in Southeast Asia, India and South America. When the trunks of these rubber trees are tapped, they produce latex. This latex is then collected and used in manufacturing. Natural Rubber Latex is harvested from the rubber tree by a process of shallow cuts

in the bark, called "tapping". Latex coagulates on exposure to air, so the tapped liquid is "preserved" with ammonia. Then the solids are separated, like cream from milk. The Latex used for medical examination and surgical gloves is filtered and combined with selected chemical ingredients to enhance elasticity, strength, durability, and resistance to damage from ozone and other ageing effects.

LATEX FREE Containing NO natural rubber latex (e.g. nitrile, vinyl, polychloroprene etc.).

LEACHING The washing process, commonly used during the manufacturing of gloves, to remove or denature natural water-soluble proteins and remove adverse materials such as processing chemical residues. Water or wet gel leaching is the process of immersing the latex coated formers into a bath or spray of water, to wash out excess additives from previous stages, such as coagulant. Chemical and protein content is reduced at this stage. The effectiveness of the process is dependent on the temperature of the water, the duration of the process and the rate of water exchange. Dry Film leaching is similar to wet film leaching, except it is carried out on the dry/vulcanized latex film. The effectiveness of this process in reducing water extractives is a function of time and temperature.

LEAP **L**atex, **E**LISA, **A**ntigenic, **P**roteins (enzyme-linked immunosorbent) assays that use antibodies which are sensitive to latex proteins to quantitatively measure the level of antigenic proteins in latex extracts. The antibodies (IgG) are generated from rabbits that are immunized with purified latex protein. LEAP assay is not a valid measurement under ASTM or FDA guidelines.

LENGTH Glove length is determined by the depth of hand/arm immersion in the solution and the extent of splash protection required. To protect the hand and wrist, select a glove 9-14" long (23-36cm). Elbow length, typically 14-18" (36-46 cm) protects the forearm. Shoulder length, about 31" (78cm) gives full arm protection.

LINING Lining, a natural or synthetic fibre that covers the inside surface of an unsupported glove, and offers greater hand comfort by absorbing perspiration and providing easy donning and removal of glove.

LOWRY PROTEIN ASSAY A test method to determine the concentration of total protein present in a sample. A modified Lowry was developed for use with latex products. Cited in both EN420 and EN455-2, this is the only method currently accepted by the FDA for the measure of protein levels in latex products.

MAGNESIUM OXIDE A very fine, white, odourless powder which is added to modified corn-starch that prevents caking in the production of USP absorbable dusting powder. No more than 2% is allowed.

MAJOR DEFECTS A defect that may cause the product to fail, cause poor performance or shortened life of the unit (e.g. pinhole).

MIL Measurement used for thickness of glove. Millimetres divided by 0.25=mil. One mill=0.001 inches=0.025mm

MINOR DEFECT A cosmetic defect that is not likely to reduce materially the usability of the glove (e.g. discoloration).

MODULUS Modulus measures the resistance to stretch. This calculation is the amount of pull required to stretch the material to 500% elongation (given in megapascals). The lower the modulus rating, the softer the glove feels to the wearer. If a glove is less resistant to stretch, it is less fatiguing to the hand. The ASTM establishes the maximum requirements for modulus in medical gloves. Latex examination gloves must conform to physical requirements of ASTM standard D3578. Modulus requirements for a latex examination glove are 5.5 MPa at 500% elongation. A low modulus glove is softer and easier to stretch and flex, whereby a high modulus glove is harder to move and stretch.

NEOPRENE DuPont's registered trademark for polychloroprene.

NITRILE Nitrile gloves are made from a synthetic polymer composed of three monomers: acrylonitrile, butadiene and a carboxylic acid. The polymer properties are dependent on variations in composition. The term "nitrile" is used as a description because many of the distinguishing features of these polymers are due to the monomer acrylonitrile. The monomer imparts permeation resistance, allowing the material to withstand exposure to a wide variety of solvents and chemicals. It also determines the softness of the product and permits nitrile to be made with either a high or low modulus.

NON-CHLORINATED The elimination of chlorine treatment through use of coatings. Non-chlorinated gloves generally have improved shelf life, colour and scent.

OZONE A powerful oxidising agent and gas (O3) that is produced by the interaction of oxygen and an energy source. Generators, fans, electrocautery units, X-Ray machines, etc. all produce ozone when running. Ozone exposure can lead to deterioration of latex and most synthetic gloves.

PERMEATION The movement of a chemical through a glove on a molecular level. Data displaying permeation values represent breakthrough times when the glove is under continuous contact with the test chemical.

PINHOLES Minute holes that may be present in glove film. They are often created by presence of debris (dust, dirt, etc.) during the manufacturing process. See AQL.

POLYCHLOROPRENE GLOVES Polychloroprene gloves are made of a synthetic material, yet possess the stretch, fit and feel of natural latex. They are made of resilient chloroprene (a colourless liquid organic compound which is used in the synthesis of neoprene and certain other rubbers) allowing for the increased dexterity and sensitivity necessary for delicate procedures. They are more puncture resistant than vinyl or latex, yet more comfortable than regular nitrile or vinyl gloves.

POLYISOPRENE A colourless, volatile liquid compound distilled from raw rubber or manufactured synthetically, which is used mainly to make synthetic rubber.

POLYMER COATING A synthetic material (compounded by polymerization and consisting of repeating structural units) applied to the inside of the glove during manufacturing to eliminate or reduce the need for donning powders such as corn-starch.

POLYURETHANE Various synthetic resins that can become flexible or set when heated and that are used for coatings, padding, insulation, adhesives, and medical/industrial gloves.

POWDER Donning powder on gloves is composed of modified corn-starch (USP absorbable dusting powder). Powder facilitates donning and absorbs moisture. Studies have shown powder to function as abrasive particles, immunological activators, and possibly as vehicles for the dissemination of chemicals, proteins and microorganisms. Powder has been implicated in lowering of resistance to infection. It also has been shown to interfere with wound healing processes, increasing the risk for incremental complications in OR and post-operative care.

PRIMARY SKIN IRRITATION TEST A test to determine if a certain material can cause skin irritation. The test material, such as a piece of glove material, is attached to the skin of test subjects, such as rabbits or guinea pigs. After maintaining the skin contact for 24 hours, the contact area is observed for up to 72 hours for any kind of skin reactions.

RADIOALLERGOSORBENT TEST (RAST) A radio immunoassay designed to detect allergens responsible for tissue hypersensitivity. The protein allergen is bound to a surface such as plastic plates or spheres. The patient's serum is added. If the serum contains antibody to the allergen, the antibodies will attach to the allergen. The level of attachment is measured and the amount quantified. The test may be designed the other way where the IgE antibodies are placed on the surface. Then an extract of the product, such as a glove, is added to the test to determine if allergens are present.

SENSITISE To increase the specific sensitivity of an individual to an antigen or allergen as the result of exposure. Sensitisation is asymptomatic (without symptoms) until threshold level is reached through repeated exposure. Subsequent exposure may elicit symptoms.

SIZE Glove size is determined by measuring the circumference of the hand around the palm area with a tape measure. For example, if your hand circumference is 9", your closest glove size is a 9. Glove sizing varies, depending on manufacturer, origin, and style. Typically, examination gloves are sized as extra-small through to extra-large and surgical gloves are sized from sizes 5.5 through 9.0.

STERILIZATION The use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial spores.

STRIPPING The manual or automated process of removing gloves from the formers, where the outside of the glove becomes the inside of the glove.

SYNTHETIC RUBBER Manufactured and not of natural origin; produced by chemical synthesis. Synthetic gloves include, butare not limited to, neoprene (chloroprene), nitrile, polyisoprene and styrene butadiene (SBR).

TACTILE SENSITIVITY The degree to which an object or substance can be discerned with sense of touch.

TENSILE STRENGTH The measurement of the amount of stretch or pull required to rupture or break the glove material.

TEXTURED The visual or tactile surface characteristics and appearance of something (e.g. a glove) represented by an uneven surface.

THERMALLY ACTIVATED "Body Heat Activated". The increase in temperature of the glove, by body heat when worn, improving the fit and comfort. This is particularly applicable to gloves manufactured with nitrile butadiene and some stretch vinyl.

THICKNESS The measurement of glove surface depth protecting skin from exposure to elements. Often given in mils. Conversion: 1mil = 0.001in. = 0.025mm.

TYPE I HYPERSENSITIVITY (PROTEIN ALLERGY) An IgE-mediated immediate hypersensitivity reaction, characterized by contact urticaria (hives), angioedema, rhinitis, respiratory complications, drop in blood pressure and rapid heart rate which may potentially progress to anaphylaxis. Severe cases can be fatal. Examples include Type I allergies to: penicillin, peanuts, strawberries, bee stings and natural rubber latex proteins.

TYPE IV HYPERSENSITIVITY (CHEMICAL ALLERGY) A cell-mediated delayed hypersensitivity reaction, characterized by dermatitis, eczema, erythema, vesiculation (blisters), keratosis, hyperplasty (thickening of skin) and cracking. The area affected usually increases with repeated exposure. Examples include Type IV allergies to: poison oak, nickel, soaps and fragrances.

UNIVERSAL PRECAUTIONS A method of infection control in which all human blood and certain other potentially infectious materials are considered infectious for HIV, HBV, and other blood borne pathogens. It encompasses a variety of practices to prevent occupational exposure, such as the use of personal protective equipment, proper disposal of sharps, housekeeping, etc.

URTICARIA An allergic disorder marked by raised edematous patches of skin or mucous membrane and intense itching caused by contact with a specific precipitating factor. Also known as hives.

VINYL GLOVES Usually referring to polyvinyl chloride (PVC) gloves. PVC is used as a latex substitute in many medical and industrial applications. Although the material itself is a barrier to most microorganisms, its non-elastic properties do not allow for maintenance of barrier integrity after extended use, or in rigorous procedures. Vinyl Gloves are sometimes known as "Synthetic Gloves".

VIRAL PENETRATION The ability of a virus to pass through a solid.

VULCANISATION Vulcanisation was a key discovery in the manufacture of rubber products. Chemical agents such as sulphur are used to create strong chemical cross-links between the intertwined rubber polymers. This chemical transformation results in a network structure much stronger and more elastic than that of the initial (raw) material.

WATER EXTRACTABLE PROTEINS The measurable amount of proteins, in terms of micrograms or milligrams, produced by water extraction on natural rubber latex gloves. ASTM D5712 provides an analytical test for determining the amount of total water extractable protein associated with natural rubber and its products. The test method involves an extraction and precipitation procedure followed by an assay of protein content (Modified Lowry Protein Assay).

WATER LEAK TEST A test procedure recognized under EN455-1, ASTM D5151 and FDA protocols to determine the AQL level of an exam glove for pin holes. The latex glove is filled with a prescribed amount of water (1000ml) and must remain completely leak-proof over a defined period of time.

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