

# Understanding Latex Allergy in the Healthcare Setting

A SELF-STUDY GUIDE

An information and educational program for  
the hospital and medical community

**Ansell Cares**

## OVERVIEW

Ansell Healthcare Products LLC has an ongoing commitment to the development of quality hand barrier products and services for the healthcare industry. This self-study Clinical Reference Manual: *Understanding Latex Allergy in the Healthcare Setting* is one in a series of continuing educational services provided by Ansell. This educational module provides basic knowledge of the origins and manufacture of latex gloves and the allergic reactions associated with their use.

## PROGRAM OBJECTIVES

Upon completion of this educational activity, the learner should be able to:

1. Discuss historical events in the development of latex allergy among healthcare workers.
2. Explain Three adverse reactions associated with the use of natural rubber latex (NRL)
3. List populations at risk for developing latex allergies.
4. Identify methods of testing available to diagnose latex allergy
5. Describe the problems encountered by individuals exposed to glove powder.

## INTENDED AUDIENCE

The information contained in this self-study guidebook is intended for use by healthcare professionals who are responsible for or involved in the following activities related to this topic:

- Educating healthcare workers
- Establishing institutional or departmental policies and procedures
- Decision-making responsibilities for hand-barrier products
- Maintaining regulatory compliance with agencies such as OSHA, ADA and CDC
- Managing employee health and infection control services

## INSTRUCTIONS

Ansell Healthcare is a provider approved by the California Board of Registered Nursing, Provider # CEP 15538 for 2 contact hour(s). Obtaining full credit for this offering depends on completion of the self-study materials on-line as directed below.

This continuing education activity is approved for 2 CE credits by the Association of Surgical Technologists, Inc., for continuing education for the Certified Surgical Technologist and Certified Surgical First Assistant. This recognition does not imply that AST approves or endorses any product or products that are included in the presentation.

To receive contact hours for this program, please go to the "Program Tests" area and complete the post-test. You will receive your certificate via email.

### AN 85% PASSING SCORE IS REQUIRED FOR SUCCESSFUL COMPLETION

Any learner who does not successfully complete the post-test will be notified and given an opportunity to resubmit for certification.

For more information about our educational programs or hand-barrier-related topics, please contact Ansell Healthcare Educational Services at 1-732-345-2162 or e-mail us at [edu@ansellhealthcare.com](mailto:edu@ansellhealthcare.com).

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*The planning committee members declare that they have an affiliation and financial relationship as employees of Ansell Healthcare, which could be perceived as posing a potential conflict of interest with development of this self-study module. This module will include discussion of commercial products referenced in generic terms only.*



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## WHAT IS NATURAL RUBBER LATEX (NRL)?

Natural rubber latex (NRL), commonly referred to as “latex,” is a natural milky substance harvested from the *Hevea brasiliensis* tree that grows in the tropical climate of Southeast Asia. It is used in the manufacture of many household, industrial, and medical products, including surgical and examination gloves. Latex is primarily composed of rubber, water, and low levels of different types of proteins (compounds that occur naturally in all plants and animals).

In technical terms, the generic word “latex” may be used to refer to natural rubber latex or synthetic latex. There are a variety of synthetic latex formulations such as nitrile and neoprene. These materials do not contain natural rubber latex proteins, but may contain chemicals used in their manufacture and processing that are also used in the manufacture of natural rubber latex. Throughout this study guide, natural rubber latex, or NRL, will be used to designate products made from *Hevea brasiliensis* “latex,” the milky fluid obtained when the tree bark is scored.

### ***THE ORIGIN AND EVOLUTION OF NATURAL RUBBER LATEX MEDICAL GLOVES***

One of the pioneers in the study of surgical infections was Dr. William S. Halstead at John Hopkins Hospital. Because of the dermatitis produced by the mercuric chloride solutions used to disinfect hands and instruments in the surgical suite, Dr. Halstead was in danger of losing one of his operating room nurses. He therefore requested two pairs of rubber gloves with gauntlets for his nurse and assistant from the Goodyear Rubber Company in 1889.

The gloves protected the assistants from the harsh disinfecting agents, and in addition, it soon became apparent that they reduced the transmission of infection. Thus, by the early 1900's the use of rubber gloves was common in the surgical suite in both Europe and the United States. Although the use of latex gloves in surgery became routine after World War I, gloves were not consistently used in other areas of patient care until the onset of the AIDS epidemic and the spread of hepatitis.

The Centers for Disease Control (CDC) instituted Universal Precautions in 1987, followed by the Occupational Safety and Health Administration's (OSHA's) Bloodborne Pathogen Standards Mandate in 1992, requiring the use of medical gloves upon contact with blood or bodily fluid. This changed healthcare, and glove usage soared.

With the increased use of gloves by healthcare workers, there appeared to be an increase in reported reactions to the latex gloves. Reports initially limited to skin irritation and delayed allergic reactions were received; however, the incidence of Immediate (Type I) allergic reactions began to be reported to the U.S. Food and Drug Administration (FDA).

These are of much greater concern because of their potentially serious outcome. Many theories have been proposed to explain the sudden increase in the number of persons affected by latex allergy starting in the 1980's. Even in retrospect, this key question has been difficult to answer because many essential bits of information are missing.

One important factor related to the increasing recognition of latex allergy was the discovery that it existed. Once a new disease has been identified and criteria for diagnosis have been formulated, it is much easier for others to recognize similar cases. Also important was the dissemination of information about latex allergy to healthcare workers and the general public through a variety of media sources. This information allowed many affected persons to recognize their problem and seek diagnosis. With the increased use of latex gloves, it is likely that increased sensitization to latex, the prevalence of symptoms, and recognition happened simultaneously.

Also, with the considerable increase in demand for both sterile and non-sterile gloves, there may have been changes in glove manufacturing methods by some manufacturers. Seemingly minor changes, such as shorter wash times and shorter shelf times, produced gloves with high protein content. There was also the proliferation of many new companies with less manufacturing skill that began making gloves, and the quality of those gloves was suspect. According to experts, retention of more proteins, or antigens, than usual in the finished product may have resulted, causing an increase in reactions.

Adverse skin reactions from the use of natural rubber latex gloves have been classified into three distinct diagnostic categories: Irritant Contact Dermatitis; Delayed Type IV, or Allergic Contact Dermatitis; and Immediate Type I, or Latex Allergy.

### *IRRITANT CONTACT DERMATITIS*

Irritant Contact Dermatitis is a non-immune reaction. It is a local reaction from damage to the skin from such things such as:

- detergents
- frequent hand washing
- inadequate drying
- climate extremes
- pre-existing dermatitis
- aggressive scrubbing techniques
- glove powders

This reaction is simply an irritation of the skin and should not be confused with an allergy. Symptoms can include redness, chapping, chafing, dryness, scaling, cracking, and subjective symptoms such as itching and burning.

An irritant contact dermatitis is a surface condition affecting the skin. Avoiding contact with the irritants, including glove powders, and a regular regimen of proper skin care will help keep hands healthier and free of irritation. Damaged skin more often harbors increased numbers of pathogens. Moreover, washing damaged skin is less effective at reducing numbers of bacteria than washing normal skin, and the number of organisms shed from damaged skin is often higher than from healthy skin. Moisturizing is beneficial for skin health and reducing microbial dispersion from the skin. To improve the skin condition of healthcare workers and reduce their chances of harboring and shedding microorganisms, the following measures are recommended:

1. For damaged skin, mild, nonantimicrobial skin cleansing products may be used to remove dirt and debris. If antimicrobial action is needed (before invasive procedures or handling of highly susceptible patients), a waterless, alcohol-based product may be used.

2. In clinical areas such as the operating room, and neonatal and transplant units, shorter, less traumatic washing regimens may be employed instead of lengthy scrub protocols with brushes or other harsh mechanical actions.
3. Effective skin emollients or barrier creams may be used in skin-care regimens and procedures for staff (and possibly patients as well).
4. Skin moisturizing products should be carefully assessed for compatibility with any topical antimicrobial products being used and for physiological effects on the skin.

### *PHYSIOLOGY OF THE IMMUNE RESPONSE*

The immune response is activated whenever the body is invaded by a foreign body or outside agent. The invader is most often a protein, called an antigen. When the antigen is detected it stimulates the lymph nodes and reticuloendothelial system to produce specific antibodies and T-cells against the invading antigen. In an **inflammatory** response specialist T-cells, produced during an earlier initial contact with the antigen, the immune response recognizes it again as foreign and stimulates the local release of cytokines and macrophages. A **Type I** allergic response to an antigen is mediated by IgE antibodies. This IgE mediated response activates a histamine release and others to create the allergic symptoms. There are two immune response reactions associated with natural rubber latex: Delayed Contact Dermatitis – Type IV and Immediate Type I Response Latex Allergy.

### *DELAYED CONTACT DERMATITIS —TYPE IV*

The usual delayed hypersensitivity reaction of allergic contact dermatitis is caused not by latex, but by the chemicals added during rubber manufacture. These chemicals were recognized as problematic more than 50 years ago, as reactions were being caused by exposure not just to latex gloves, but also to many other types of rubber products. Clinically, a red, raised, and palpable area at, and sometimes slightly beyond, the area of contact with the glove is observed, accompanied by subjective symptoms such as itching, burning, and tingling. The mechanism for the development of a delayed response requires the antigen to penetrate the skin, where it then interacts with the cellular components of the immune system. This results in the production of cells of a certain sub-population of the immune system (T-Lymphocytes), which are able to “recognize” the antigen as “foreign” (Figure 1).

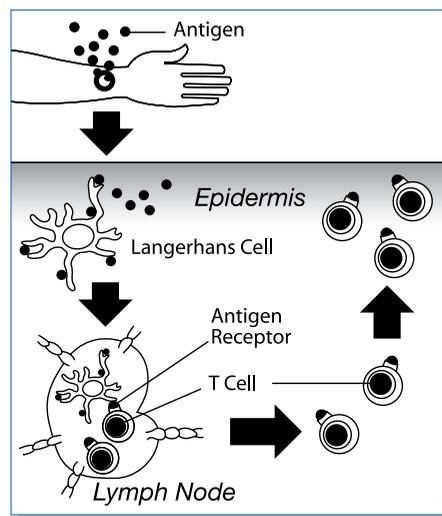


Figure 1.

When re-exposed to the antigen, these cells stimulate the local release of a number of compounds, including inflammatory agents, resulting in the clinical response described previously (Figure 2).

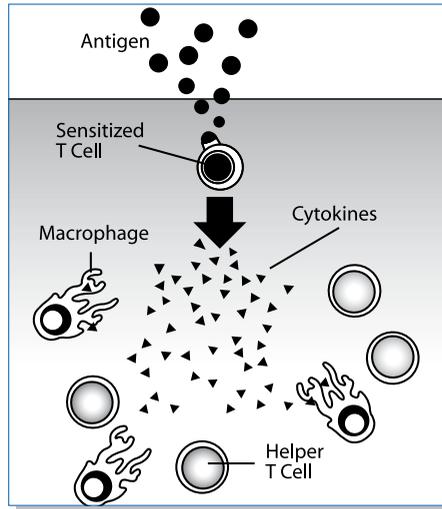


Figure 2.

These effects typically appear anywhere from 6-48 hours following exposure to the antigen-containing product, and can last for up to 4 days. Use of latex gloves while you have active, open breaks in the skin is believed to contribute to latex protein sensitization. This is due to absorption of solubilized latex proteins associated with the product. A return to latex gloves can be made after the open breaks in the skin have healed. A healthcare provider experienced in chemical allergy testing can make the diagnosis by patch testing or skin prick testing, the two tests commonly used to determine the offending chemical. With this information and the assistance of your glove expert, you can usually find a glove that has had the chemical “washed” or “leached” significantly enough from the surface of the glove to be worn successfully, or you may select a different glove that has been manufactured without the offending chemical.

Prolonged exposure to the causative agent can lead to a chronic condition characterized by dry, cracked, and scaly skin.

### IMMEDIATE TYPE I RESPONSE LATEX ALLERGY

Nutter first reported this immune reaction in 1979 (Figures 3 and 4). It is not solely the result of exposure to gloves, but also to other natural rubber latex-based products such as condoms, balloons, rubber nipples, and other latex medical equipment. While much less common than delayed reactions, the immediate allergic response has received more attention, both from researchers and in the literature, because of its potentially more serious outcome. In the majority of cases reported, the only symptoms are a swelling and redness (commonly described as a “wheal and flare” reaction) local to the site of exposure, accompanied by non-specific symptoms such as itching and burning.

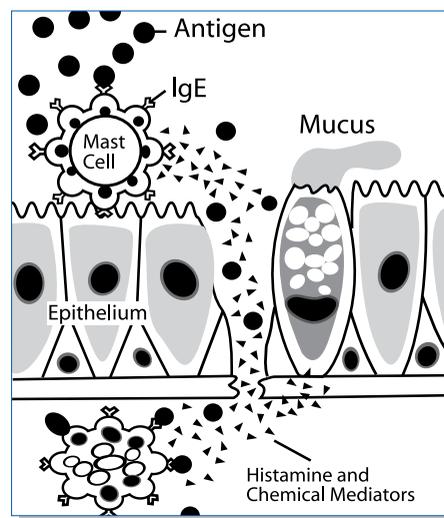


Figure 3. *IgE-mediated hypersensitivity to latex involves a rapidly developing early phase and a late phase. In the early phase, circulating latex antigens cross-link IgE receptors on mast cells, activating the cells to release histamine and other chemical mediators in the respiratory tract. Mediator release occurs within minutes of exposure to the antigen and correlates with the onset of allergic symptoms.*

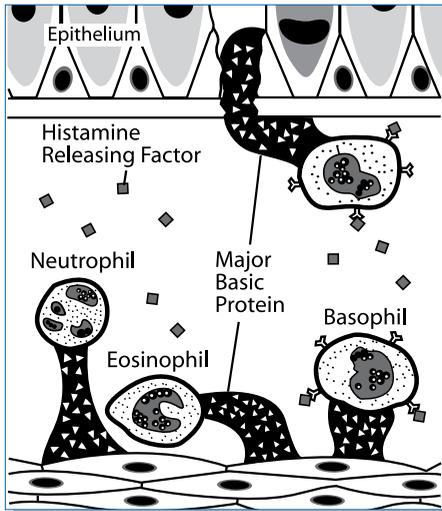


Figure 4. In the late phase, symptoms become active again several hours later, when there is an influx of basophils, eosinophils, and neutrophils. This is followed by production of histamine-releasing factors, some of which cross-link basophil-bound IgE and stimulate inflammatory cell release mediators.

In contrast to a delayed response, an immediate reaction can occur almost instantly (within 30 minutes) following exposure to the relevant antigen.

A Type I latex allergic response can illicit a more systemic symptomology such as conjunctivitis, rhinitis, and bronchial obstruction. More seriously, and fortunately more rarely, symptoms of anaphylaxis, and in extreme cases, anaphylactic shock, can occur.

The route of exposure for NRL allergens can include:

- Skin absorption/skin contact with NRL products like gloves.
- Inhalation/aerosolization of latex proteins bound to glove powder that occurs with donning and removing powdered gloves. Latex allergens are suspended in the air as aeroallergens.
- Mucosal contact, including eye, nose, mouth, urethra, rectum, and vagina.
- Intravenous absorption from syringes, IV catheters, central line catheters, and arterial catheters.
- Ingestion from eating foods without proper handwashing after contact with NRL proteins or eating food that has been handled with latex gloves.

## ESTABLISHING A LATEX-SAFE HEALTHCARE ENVIRONMENT

Management of Type I latex allergy includes avoidance of latex products for all NRL allergic individuals and education for all healthcare workers, patients, and family members. For Type I allergic individuals, avoidance of NRL protein through the use of synthetic gloves is essential. Creation of a powder-free, latex-safe environment is also an important step toward risk reduction in the healthcare setting.

Forming a multidisciplinary committee is suggested for the establishment of a latex safe healthcare environment. The committee should be responsible for developing uniform policies and procedures to protect both patients and employees. All healthcare products containing latex should be identified. Historically, gloves have been the largest contributor of the latex load in a healthcare setting. The next step is to, at a minimum, convert to powder-free gloves that are low protein and eliminate powdered gloves from the environment. All latex products that come into contact with patients, staff, and visitors should be systematically reviewed, and alternatives evaluated.

Education of the staff is critical to the success of a latex-safe environment.

By verifying everyone's understanding and competence, it minimizes the potential risk when a latex allergic individual presents for care. Latex education should be a yearly competency for all staff members.

By creating a latex-safe environment, many healthcare organizations have been able to return workers with NRL allergies back to work, and potentially reduce further sensitization of staff members. This provides an overall safer healthcare environment for patients and healthcare workers alike. The decision to avoid glove-related incidents is a prudent risk management strategy.

## WHO IS AT RISK FOR LATEX ALLERGY?

Reports from the medical literature on the level of sensitization among different population groups vary somewhat. It has been clear for several years that latex allergy occurs predominantly in certain high-risk groups, namely healthcare and dental workers. The rate of sensitization in these individuals ranges from 8 - 17%. Other high-risk individuals include people with spina bifida, individuals with a history of multiple surgeries, atopic individuals, or individuals with existing plant or food allergies.

## OCCUPATIONAL ASTHMA

More and more healthcare workers are developing occupational asthma, a lung disease caused by inhaling workplace fumes, gases, or, in the healthcare environment, glove powder. In developed countries, it is the most common work-related lung disease. Although its exact prevalence is unknown, some researchers estimate it may account for 9 percent of asthma cases.

Occupational asthma can develop even if you have never had asthma before or had childhood asthma that previously cleared. It can worsen any pre-existing asthma. With treatment, occupational asthma is usually reversible. However, the only way to prevent its worst complication – permanent lung damage – is to completely avoid the substance causing the disease. It is possible to develop occupational asthma in almost any workplace, but the risk is highest in certain occupations. The Mayo Clinic listed the top 15 jobs at risk, and healthcare workers were part of that list. The asthma-producing substance found in the hospital setting is the latex particles contained in aerosolized glove powder.

Signs and symptoms may include wheezing, coughing, shortness of breath, chest tightness, difficulty exercising, runny nose, and eye irritation. During the early stages of the disease, symptoms develop shortly after exposure, and up to 12 hours after exposure. Asthma may worsen as the workweek progresses, and subside during weekends and vacations, only to reoccur upon return to work.

In the later stages, symptoms may also develop away from work. Once the lungs have developed a pattern of overreacting to the offending substance, sensitivities to other substances may develop, such as house dust, cigarette smoke, and cold air.

The diagnosis for occupational asthma is made by an allergist on the basis of medical history and physical exam. The physician may perform pulmonary function tests, spirometry, and peak flow tests. The best treatment is to completely avoid the substance that causes symptoms. Asthma medications to help relieve symptoms may be prescribed. It might be necessary for healthcare workers to transfer to another job to prevent exposure to glove powder.

Once again, the healthcare organization that removes powdered gloves from the organization is being proactive in ensuring the health and safety of employees and patients. Research has shown that the reduction of residual extractable proteins in latex gloves has a significant impact on reducing the incidence of allergic reactions to latex. Recent studies in the U.S., Canada, and Europe demonstrate that wearing lowprotein, powder-free latex gloves greatly reduces the risk of allergic reactions and the likelihood of developing latex sensitivity.

In addition, studies have shown that the use of low-protein, powder-free gloves allowed latex-sensitive individuals donning synthetic gloves to work safely alongside their colleagues. The National Institute for Occupational Safety and Health (NIOSH) now recommends using powder-free, low-protein latex gloves. The Association of periOperative Registered Nurses (AORN) and the American Nurses Association, as well as other industry organizations, also now recommend powder-free gloves with low protein content (consistently below 50 µg/g).

When testing comparisons are made, it is imperative to recognize that each testing method is unique. When comparing testing results, it is essential to compare results from the same testing method. It is vital to keep in mind the FDA statement in a March 1995 citation, titled *FDA March 1995 interim guidance on protein content of latex medical gloves*: "Although there are insufficient clinical data to set a protein level that dramatically reduces the incidence of reactions to latex protein, there is scientific consensus that reduced protein levels will lower the potential for both sensitization of non-sensitized individuals and allergic reactions in sensitized individuals."

## METHODS USED FOR THE ESTIMATION OF THE PROTEIN CONTENT AND/OR ALLERGENICITY OF NATURAL RUBBER LATEX PRODUCTS

TEST	Modified Lowry Assay (ASTM method D 5712-99)	Elisa Assay (ASTM method D 6499-00) (Enzyme-linked immunosorbent assay)
INDICATIONS	<p>Tests for the amount of total water-extractable protein associated with NRL and its products.</p> <p>Tests for residual protein content in NRL material such as gloves.</p>	<p>Measurement of total latex protein and, more importantly, immunologically reactive latex protein.</p>
METHODOLOGY	<p>Dye-binding test.</p> <p>Residual water-soluble proteins are extracted in accordance with ASTM method D 5712 at a temperature of <math>37 \pm 2^\circ\text{C}</math>, then precipitated to remove interfering water-soluble substances.</p> <p>It is calibrated to measure at a minimum of 50 micrograms/gram NRL.</p> <p>The protein content is then determined by the Lowry method of protein analysis, using a protein standard.</p> <p>The FDA mandates this as the measurement technique for total protein content. The FDA has stated that the lowest claim that can be made is as follows: "This latex glove contains 50 micrograms or less of total water-extractable protein per gram." No one is allowed to claim a lower protein content.</p>	<p>Indirect ELISA colorimetric technique in which latex proteins are immobilized by adsorption to plastic and reacted with rabbit anti-latex antisera.</p> <p>After washing, the plate is reacted with a second HRP-labeled, anti-rabbit IgG and, finally, a substrate is added that results in a color change.</p> <p>The spectro-photometric absorbance of the orange-colored reaction product is measured at 492nm.</p>
RESULTS	<p>Protein content will be measured in a range from microgram to milligram quantities.</p>	<p>This assay can easily detect latex proteins in extract solutions and is sensitive to 15 ng/ml (1 ng = <math>10^{-9}</math> g).</p>
ADVANTAGES	<p>An inexpensive test, rapid and easily performed. Allows for alterations of chemical impediment.</p>	<p>Test is very sensitive and reproducible. Specific for latex protein and immunologically reactive protein, making it relevant for latex allergy. Does not utilize radioisotopes and is therefore easy to use. Can be performed as an ELISA Inhibition Assay.</p>
DISADVANTAGES	<p>A large number of substances often added to NRL during compounding can cause interference to these assays.</p> <p>Limited sensitivity.</p> <p>Lack of specificity.</p> <p>Erroneous results can occur due to the complex mixture of polypeptides in the latex.</p> <p>No certified standard reference material is currently available to assess the accuracy of this test method.</p>	<p>Uses latex proteins extracted from non-compounded ammoniated latex films.</p> <p>Uses rabbit, rather than human, sera.</p> <p>Has not been validated against specific allergen-measuring methods, such as SPT or RAST Inhibition.</p>

**It is important to understand that all of these tests are not 100% accurate; testing methods continue to evolve. It is also vital to remember that over 240 proteins have been identified in latex, with about 50 of them being allergenic. Only 14 proteins in NRL (*Hevea brasiliensis* [Hev b]) that bind human IgE have been isolated and characterized as Hev b allergens by the International Nomenclature Committee of Allergens (<http://www.allergen.org> [accessed August 12, 2010].**

## DIAGNOSTIC SCREENING AND ALLERGENICITY TESTING

Tests available for the diagnosis of individuals with natural rubber latex and chemical allergy.

### ALLERGENICITY TEST METHODS

TEST	DEFINITION	METHOD	INDICATIONS
Patch Test	Patch testing determines allergic sensitivity. A suspected allergen is applied to the skin on a small surgical pad for a period of time, indicating whether that substance causes inflammation of the skin.	A drop of elutable glove extract or a piece of rubber glove is placed on the client's forearm. The area is checked in a specified length of time, typically 20 minutes.	Assessment for hypersensitivity to both chemical and protein allergens.
Rast Test (Radio-allergosorbent test)	This IgE blood test looks at the total amount of antibodies. It identifies what types of IgE proteins trigger allergic reactions, signifying that an individual is prone to latex allergy.	This method uses a blood sample from a suspected NRL-sensitized individual. It measures specific IgE antibodies against NRL allergens. This method is reported to have an 80% sensitivity and 100% specificity in non-atopic individuals.	Quantitative measurement of allergen-specific IgE antibody in the patient's serum.
Skin Prick Test (SPT)	A test for latex allergy or sensitivity. This is considered to be the "gold standard" for allergy testing because of its reliability.	Elutable proteins are extracted by cutting 1 gram of glove into small pieces and soaking the pieces at room temperature in 5ml of normal saline for 15 minutes. A drop of this solution is placed on the forearm, which is then pierced by a lancet, and the resulting reaction compared to saline as a negative control.	Assessment for hypersensitivity to protein allergens.  Would not be used for routine diagnosis of latex hypersensitivity.

**The FDA mandates that manufacturers who include total extractable protein figures also include this statement: "Caution: Safe use of this glove by or on latex-sensitized individuals has not been established." The FDA prohibits products to be labeled with total extractable protein levels lower than 50 micrograms per gram, as this is the sensitivity limit of the ASTM Lowry test method.**

## THE ORIGINS OF GLOVE POWDER

Glove powders have a long history dating back to the late 19th century. The early thick, gauntlet-style gloves that the Goodyear Rubber Company developed were reusable, as they were capable of being sterilized by boiling, and the gloves were donned over wet hands. As sterilization techniques were refined, wet glove over wet hand donning could be abandoned. A dry method was needed in order to don gloves, and powdered lubricants began to be used. Gloves continued to be reused, but were hand-

powdered in a powder box before being wrapped and steam-sterilized. By 1966, single-use gloves became available, and continue to be the standard of care today.

### POWDERED LUBRICANTS

There are three different points in the manufacturing process where powder could be used:

1. Mold release agents can contain powder in a slurry that coats the glove former so that the latex uniformly covers the former and the finished glove is able to be removed from the former.

## Early Dates in Glove History

1917 – First reported talc granuloma (Shattock)

1933 – Post-op FB granuloma reported by Antopol found to contain *Lycopodium* (club moss)

1935 – Erb reported 6 cases of *Lycopodium* granuloma

1936 – Owen described peritoneal nodules from use of glove powder containing talc

1943 – German reported 50 instances of talc granuloma

1947 – Roberts reported talc deposited in peritoneal cavity had migrated to fallopian tubes, causing sterility in 5 women

1952 – Talc powder replaced by Bio-Sorb

1952 – Lehman and Wilder recommended washing glove powder off gloves before use during surgery

1955 – Sneierson and Woo, cornstarch responsible for wound granuloma

1960 – Myers, “starch peritonitis” with replication of same in animal models

1960-1980 – Multiple reports from all over the world of cornstarch complications involving larger studies series

1973 – Jagel and Ellis, adhesion formation

1976 – Cade and Ellis, peritoneal reaction

1978 – Walker, inflammatory reaction

Source: Woods et al., 1997

2. On the finished glove, a powder may be used to keep the gloves from sticking together, also referred to as “blocking.”
3. On the finished glove, donning powder is applied to the inside of the glove so that the wearer is able to put the glove on smoothly. The powder also acts to absorb sweat from the hands of the wearer.

### GLOVE MOLD RELEASING AGENTS

Talc has been used in the glove manufacturing process in order to remove the finished product from the dipping mold. Cornstarch was trialed early on but could not be used because it would dissolve and disperse in the dipping solution. Today, a release agent such as calcium carbonate may be used. A powder-free coagulant can also be used. Due to the continued reporting of talc complications, the ASTM specified in 1991 that the use of talc as a mold release agent was to be discontinued.

### BLOCKING

To prevent blocking, some manufacturers use a powder to coat the glove so it does not stick to itself. A cornstarch powder would be used for powdered gloves and a post-process wash would be used for powder-free gloves.

### DONNING LUBRICANT AGENTS

*Lycopodium clavatum*, or club moss, was one of the early lubricants in use by approximately 1890. With its use came early reports of complications, including masses and adhesions. Talcum powder is a combination of magnesium silicate (chemically pure talc) and calcium magnesium carbonate, calcium magnesium

silicate, and possibly other substances. It was an inexpensive donning powder. Talcum powder is not absorbed and behaves like a foreign body, leading to an inflammatory response. A talc foreign body microscopically appears flat and irregular in shape (Woods, 1997). Talc was implicated early in its use for producing granulomas in tissue. Despite the reports in the literature describing granuloma, adhesion, and inflammatory response to talc, it took a while before a suitable substitute could be found. Various powders were experimented with, but they could not withstand the time and pressure in the autoclave without clumping. Additionally, removing glove powders was not a precaution practiced by the surgical team.

The search for a suitable substitute to replace the above products ensued. Experiments by Lee and Lehman (1947) led to the discovery of a mixture of cornstarch powder treated with epichlorhydrin and other ingredients that was able to withstand the autoclave and would be acceptable to the wearer. This cornstarch product replaced the others. It was not without its problems, however, and further experiments by Lee demonstrated that even this compound produced a foreign body-like reaction, and adhesions were formed when the cornstarch was clumped together.

Today, gloving powders used for exam and surgical gloves must meet the USP monograph for absorbable dusting powder or be shown to be equivalent in terms of safety and effectiveness (Medical Glove Guidance Manual, January 22, 2008). American Society for Testing and Materials (ASTM) standards also apply.

## POWDER ISSUES

Cornstarch powder has been determined to carry latex allergens (Hesse, 1997). It has been suggested that the use of powdered gloves may be related to increases in occupational asthma and latex allergies in healthcare workers. Skin breakdown from the irritation caused by glove powder is also an issue with some healthcare workers. In experiments by Newsom and Shaw, it was demonstrated that Methicillin-resistant *S. aureus* (MRSA) and Vancomycin-resistant Enterococci (VRE) may be able to use glove powder as a vector and/or food source in a hospital environment (Newsom & Shaw, 1997).

In 1971 the FDA required manufacturers to label their glove packages with the following warning:

*“Caution: Powder should be removed from the gloves after donning by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method.”*

Poor compliance with printed instructions has been cited in the literature, and washing powder off gloves prior to surgery is not completed consistently. Some of the reasons for poor compliance include the cost of materials and the time necessary to complete the activity. Additionally, powdered gloves may be used in departments that cannot wash them properly, as they do not have the materials readily available to do so (i.e., ER, outpatient clinics, bedside, and interventional radiology). A response to this situation has been to remove powdered gloves from the facility. Several professional organizations have recommended the use of powder-free gloves to reduce and/or eliminate the problems associated with powder use, such as:

American Academy of Allergy,  
Asthma & Immunology  
<http://www.aaaai.org>

American College of Allergy,  
Asthma & Immunology  
<http://www.acaai.org>

Association of periOperative  
Registered Nurses  
<http://www.aorn.org>

National Institute of Occupational  
Safety and Health  
<http://www.cdc.gov/niosh/topics/latex>

American Academy of Dermatology  
<http://www.aad.org>

## GLOVE MANUFACTURING PROCESS

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The manufacturing of gloves is a complex process involving latex concentrates mixed with various compounding chemicals, antioxidants, and accelerants to produce the thin barrier protection required by healthcare professionals. Gloves are manufactured using machines that have proprietary features suited to their own manufacturing processes. The sequence is illustrated below for powder-free gloves (Diagram 1).

Formers, made of material that can withstand high temperatures (usually porcelain), are used to manufacture gloves. Formers must be clean so that the latex deposition can be even and continuous. The former is then coated with a coagulant, which assists in controlling the amount of latex that will be deposited on the glove, and also ensures that the rubber will not adhere to the former. The clean and newly coated former then passes into a latex solution. The solution may be an NRL or non-latex/synthetic compound, depending on what gloves are scheduled for manufacture on the particular run. The latex is allowed to

build up some wet-gel strength before an initial leaching. The leaching is effective in removing residual calcium nitrate and soluble proteins. Hot water is used and the tanks are continuously replenished with freshwater. It is here that the process deviates, depending on whether powder-free or powdered gloves are being manufactured. Powder-free glove manufacturing includes the application of an inner surface polymer (for ease of donning) and curing. Polymer coatings are classified as hydrogels and non-hydrogels. Hydrogel coatings are composed of materials that absorb water many times their weight and become swollen and slippery so that the glove may be donned. Non-hydrogel polymers such as acrylic polyurethane, silicon polymer, or polymer blends repel water and the surface coating mimics the characteristics of a powdered surface. Polymers are used as

coatings on the inner surface of gloves for ease of donning, while chlorination is applied to the outer surface to improve the grip feature of the glove. Gloves that are double-chlorinated (leached) have a smoother feel and will not stick together (referred to as blocking) in the package. On-line leaching (washing), the use of the chlorination process, and high-temperature washing of gloves after they are removed from the formers are all highly effective methods to reduce water-soluble latex allergenic proteins from the final latex glove product (powder-free and powdered).

### *ROLE OF CHEMICAL ACCELERATORS*

Compounding of the raw “field” latex or non-latex material to a final solution suitable for the manufacturer’s glove products is another proprietary process. Chemicals are used in this “recipe.” These chemicals

accelerate the bonding process of the gloving material during the manufacturing process. Accelerator chemicals help to tighten the glove matrix, improve and enhance barrier performance, and stabilize the raw gloving material. Sulfur is used to assist bonding of the glove material to form a product with superior stretch and recoil. It also adds strength to the glove, gives integrity to the latex during use, and stabilizes the latex for long-term storage.

Chemical accelerators are, for the most part, used up during curing and in the washing and leaching portions of the manufacturing process. Accelerator chemicals can cause Type IV allergies in those individuals at risk. The chemicals most often implicated in Type IV allergies are mercaptobenzothiazoles (MBTs), thiurams, and carbamates (dithiocarbamates).

Thiurams are regarded as the most common cause of Type IV delayed contact dermatitis. Thiurams decompose during vulcanization, liberating the sulfur and carbamates (dithiocarbamates).

MBTs are an important accelerator because of their solubility in natural rubber latex. Their use in glove production is less frequent, and so the incidence of sensitization is lower than for other accelerator compounds.

Carbamates (dithiocarbamates) facilitate cross-linking and curing by absorbing sulfur and carrying it into the glove material. There are more than 34 types of dithiocarbamates, and they are even less sensitizing than thiurams and MBTs. These compounds contain zinc, which is important to the solubility of the accelerator in natural rubber latex and its ability to react with sulfur.

### DEVELOPMENTS IN NATURAL RUBBER LATEX MANUFACTURING

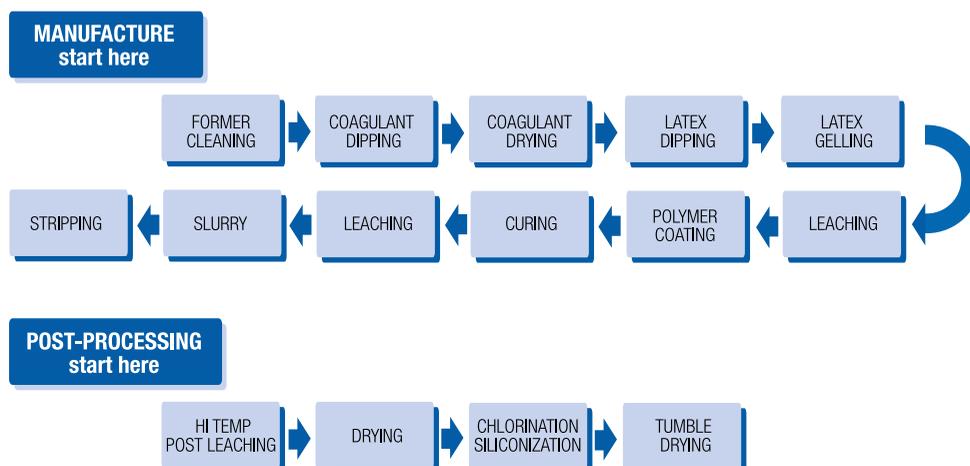
Manufacturers are constantly working to produce latex products that contain less latex allergen. As these products become more readily available, the risk of reactions in people sensitive to latex, as well as the risk of more people developing latex allergy, should decrease.

Improved test methodologies have been developed that allow manufacturers to easily conduct testing within their labs, and they have been able to investigate the various parts of their processes that will impact the reduction of water-soluble latex proteins. Various approaches have been employed to reduce these proteins; for example:

- High-temperature post-washing (described and diagrammed previously)
- On-line leaching and washing (described and diagrammed previously)
- Utilization of chlorination processes (described and diagrammed previously)
- The development of de-proteinized and purified (DPNR) NRL – entails treating the latex obtained in the field with proteolytic enzymes

NRL gloves still remain the barrier of choice among healthcare professionals. Manufacturers have developed technologies that allow them to produce low-allergen as well as synthetic gloves. Due to the water-soluble nature of latex proteins, most are leached out in the washing phases of the manufacturing process. High-temperature washing is a proven technology and the most effective way to reduce the allergen content of NRL gloves.

Diagram 1. MANUFACTURE AND POST-PROCESSING OF POWDER FREE GLOVES





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## POST-TEST

WRITE THE LETTER THAT CORRESPONDS WITH THE CORRECT ANSWER TO THE FOLLOWING QUESTIONS ON THE ANSWER SHEET LOCATED INSIDE THE BACK COVER.

1. There is only one factor identified that is related to the development of latex Allergy  
a) True                      b) False

**Write the letter of the best answer to the following questions (2-11):**

- a. Irritant contact dermatitis  
b. Delayed Type IV  
c. Type I Response
2. Caused by chemical added during manufacture \_\_\_\_\_
3. IgE-mediated \_\_\_\_\_
4. Caused by aggressive scrubbing technique \_\_\_\_\_
5. The allergic mechanism involves the formation of T-lymphocytes, sensitized to the specific antigen \_\_\_\_\_
6. Caused by the abrasive action of glove powder \_\_\_\_\_
7. Caused by direct or airborne exposure \_\_\_\_\_
8. Symptoms of anaphylaxis \_\_\_\_\_
9. Clinical signs are limited to the area of contact of the glove with the skin \_\_\_\_\_
10. Clinical signs may include conjunctivitis, rhinitis, and bronchial obstruction \_\_\_\_\_
11. Onset in 6 to 48 hours \_\_\_\_\_
12. Which is NOT an important step in establishing a latex-safe environment?  
a) Uniform policies  
b) Use of low protein powder-free gloves  
c) Replace all the air handling units  
d) Education
13. The following are among the at risk population(s)  
a) Teens, factory workers, teachers  
b) HCW, Nuns, police  
c) Spina Bifida and atopic individuals  
d) Individuals with history of multiple surgeries, young adults

*NOTE: This activity expires July 30, 2012. Post-test must be completed on line and submitted to Ansell 30 days prior to this date in order to receive a certificate.*

14. This latex allergy test is considered to be the “gold standard” test because of its reliability.
- a) Rast Test
  - b) Patch test
  - c) ASTM Test
  - d) Skin Prick Test
15. Unless clinical evidence can be verified, FDA mandates manufacturers who include total extractable protein figures to also include which of the following statements?
- a) “Caution: Safe use of this product by or on latex sensitized individuals has been established to be dangerous.”
  - b) “Caution: Those with latex allergies should not use this glove until tested for sensitization.”
  - c) “Caution: Safe use of this glove by or on latex sensitized individuals has not been established.”
  - d) “Caution: Safe use of this product by or on latex sensitized individuals can only occur with a physician’s recommendation.”
16. FDA prohibits products to be labeled with total extractable proteins levels lower than \_\_\_\_\_, as this is the sensitivity limit of the ASTM Lowry test method.
- a) 50 micrograms per gram
  - b) 25 micrograms per gram
  - c) 10 micrograms per gram
  - d) 100 micrograms per gram
17. Cornstarch has demonstrated in experiments that it:
- a) Remains insoluble
  - b) Cannot withstand autoclaving
  - c) Produces a foreign body-like reaction
  - d) Is always removed by the user after donning
18. Cornstarch particles can carry latex allergens.
- a) True
  - b) False
19. Chemicals are used in the manufacturing process to:
1. Tighten the glove matrix
  2. Sterilize the raw latex
  3. Enhance barrier performance
  4. Stabilize the raw gloving material
- a) 1, 2, & 3
  - b) 1, 3, & 4
  - c) 2, 3, & 4
  - d) All of the above
20. High temperature washing is a proven technology and the most effective way to reduce NRL allergen content.
- a) True
  - b) False





