

ARDL Chemical, Physical and Microbiological Glove Testing

ARDL services all aspects of the polymer glove industry. From 510 (k) application support to formulation reconstruction or development to complete Chemical, Physical and Microbiological testing, ARDL has provided independent testing and consulting to glove manufacturers and end users for decades. Put ARDL's experience to work for you. Whether it is benchmarking a glove for a particular application, evaluating failure modes of existing gloves, reconstructing a glove formulation or clearing US FDA detention, ARDL can help solve all of your polymer glove-related problems.



Chemical Services

- ASTM D6978 - Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ASTM D7558 - Standard Test Method for Colorimetric/Spectrophotometric Procedure to Quantify Extractable Chemical Dialkyldithiocarbamate, Thiuram, and Mercaptobenzothiazole Accelerators in Natural Rubber Latex and Nitrile Gloves
- ASTM F739 - Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact
- ASTM F903 - Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Liquids
- ASTM F1383 - Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Intermittent Contact
- ASTM F1670 - Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
- ARDL 3138, 3174 - Contact Sensitizers/Residual Accelerators Testing by HPLC Analysis
- ARDL 3171 - Based on 21CFR 177.2600 for Rubber Articles (Gloves) Intended for Repeated Use
- BS EN 374-3 - Determination of Resistance to Permeation by Chemicals
- *Pending implementation in house (currently outsourced to accredited laboratories):*
 - ASTM F1671 - Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System
- Custom Testing:
 - Reverse Engineering/Formula Reconstruction of various glove compounds
 - Various *Immersion Studies* of gloves versus lotions, synthetic sweat (ISO, EN or ASTM recipes), plasticizer/phthalate content analysis, heavy metals content, etc.



Physical Services

- ASTM D120 - Standard Specification for Rubber Insulating Gloves
- ASTM D3577 - Standard Specification for Rubber Surgical Gloves
- ASTM D3578 - Standard Specification for Rubber Examination Gloves
- ASTM D5151 - Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D5250 - Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
- ASTM D6124 - Standard Test Method for Residual Powder on Medical Gloves
- ASTM D6319 - Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6977 - Standard Specification for Polychloroprene Examination Gloves for Medical Application
- ASTM D7160 - Standard Practice for Determination of Expiration Dating for Medical Gloves
- ASTM D7161 - Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
- ASTM D7198 - Standard Specification for Disposable Embalming Gloves for Single-Use Applications
- ASTM D7246 - Standard Test Method for Detection of Holes in Polyethylene Food Service Gloves
- ASTM D7329 - Standard Specification for Food Preparation and Food Handling (Food Service Gloves)
- ARDL 2140 - Lubricant Testing on Gloves
- BS EN 374-2 - Determination of Resistance to Water Penetration (Method is not on our scope, though testing is performed at ARDL)
- BS EN 455-1:2000 - Medical Gloves for Single Use - Part 1: Requirements and Testing for Freedom from Holes
- BS EN 455-2:2009 +A2:2013 - Medical Gloves for Single Use - Part 2: Requirements and Testing for Physical Properties

Microbiological Services

- ASTM D5712 - Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method
 - ASTM D6499 - Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products
 - ASTM D7427 - Standard Test Method for Immunological Measurement of Four Principal Allergenic Proteins (Hev b 1, 3, 5 and 6.02) in Natural Rubber and Its Products Derived from Latex
 - BS EN 455-3 - Requirements and Testing for Biological Evaluation - Method for the Determination of Aqueous Extractable Proteins in Natural Rubber Gloves Using the Modified Lowry Assay
- Pending implementation in house (currently outsourced to accredited laboratories):*
- Cytotoxicity Testing per ISO 10993-5

Additional Services:

FDA Detention/FDA Compliance Services

- As an importer of latex/rubber medical devices, sooner or later you will be likely to experience US FDA Detention at Port of Entry. When this occurs, ARDL can help you.

ARDL Provides:

- On-Site Sampling by ARDL Personnel
- Training of Third Party Personnel to Sample
- Overnighting of Test Data to FDA Compliance Officers
 - Telephone & Fax Contact with FDA Compliance Officers to Resolve Problems
 - Familiarity with Special Requirements of Specific FDA Branch Offices

