



AKRON RUBBER DEVELOPMENT LABORATORY, INC.  
2887 Gilchrist Road • Akron, Ohio 44305  
1-800-830-ARDL • (330) 794-6600 • FAX (330) 794-6610  
Website: www.ardl.com • E-mail: info@ardl.com

December 21, 2007

Mr. Peter M. Larson  
Larson Medical Products, Inc.  
2844 Banwick Road  
Columbus, OH 43232

**SUBJECT:** Analytical testing on sample submitted by the above company.  
PO# 00007842

**RECEIVED:** One sample identified as Splint Material with Coating.

**TEST METHOD**

**Sample preparation and extraction.** Samples were weighed and measured after which the samples were cut to allow buffer contact with all surfaces. Extractions were performed for 2 hours with constant agitation at  $25\pm 5^{\circ}\text{C}$  in 100 mM phosphate buffered saline pH 7.4 (PBS). The extraction ratio used (mls buffer/gram sample) was 5:1. The extracts were centrifuged to remove particulates and then assayed.

**ELISA Inhibition Assay (ASTM D 6499-03):**

The samples were assayed using seven 2-fold serial dilutions in duplicate. The resulting data was calculated by using latex protein extracted from non-compounded ammoniated latex as the reference standard. The data is expressed as antigenic latex protein in micrograms/gram of sample and micrograms/dm<sup>2</sup>.

**RESULTS:**

|         | $\mu\text{g/g}$ | $\mu\text{g/dm}^2$ |
|---------|-----------------|--------------------|
| Coating | <0.2            | <2.6               |

The sample shows a "below detection" result. Therefore, no antigenic protein is present.

Prepared By: Steve Case  
Steve Case  
Chemist

Approved By: Ana Camelia Barbur  
Ana Camelia Barbur, M.S.  
Manager, Chemical Services

PN# 76608

csn



# American Association for Laboratory Accreditation

## SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

AKRON RUBBER DEVELOPMENT LABORATORY, INC.  
2887 Gilchrist Road  
Akron, OH 44305  
Walter Samples Phone: 330 794 6600

### MECHANICAL

Valid To: January 31, 2008

Certificate Number: 0255.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on rubber, plastics, latex, condoms, adhesives, sealers and adhesive tapes:

| <u>Test</u>   | <u>Test Method(s)</u>  |
|---|--|
| Abrasion Resistance   | ASTM: D1630, D2228, D3389, D5963;<br>DIN 53 516;<br>ISO 4649   |
| AC Loss Characteristics and Permittivity<br>(Dielectric Constant)               | ASTM D150  |
| Accelerated Aging and Heat Resistance   | ASTM: D572, D573, D794, D865, D3045;<br>DIN 53 508;<br>ISO 188 |
| Adhesives, Sealers and Adhesive Tapes   | AFG-01   |
| Brittleness Point   | ASTM D2137   |
| Cellular Plastics Test  | ASTM: D1055 (except Sec. 20-23), D3576                         |
| Chemical Resistance   | ASTM: D471, D543   |
| Chloramine Resistance   | ASTM D6284   |
| Chlorine, Bromine, or Iodine in Organic<br>Compounds by Oxygen Flask Combustion | ASTM E442-91 ( <i>withdrawn 1997</i> )                         |
| Color Evaluation  |  |
| Spectrophotometer – Fluorescent   | ASTM: D1003, D1925-77, E313, E991, E1164                       |
| Spectrophotometer – Non-Fluorescent   | ASTM: D2244, E308, E1349                                       |
| Gray Scale  | ISO 105/A04;<br>SAE J1545                                      |



| <u>Test</u>                                      | <u>Test Method(s)</u>  |
|--|--|
| Compressibility and Recovery of Gasket Materials | ASTM F36   |
| Compression                                      | ASTM: D395, D575, D623, D695, D1229;<br>ISO: 815, 1653, 3384, 6056                       |
| Conditioning Plastics for Testing                | ASTM D618  |
| Condom and Latex Gloves Test                     | ASTM: D3492, D5151, D6124;<br>ARDL: 2139, 2140;<br>BS 3704;<br>ISO 4074;<br>WHO          |
| Crack Resistance                                 | ASTM: D813, D1693  |
| DC Resistance and Conductance                    | ASTM D257  |
| Density  | ASTM D792;<br>DIN 53 479;<br>ISO 1183-1 (Methods A and B)                                |
| Dielectric Strength                              | ASTM D149  |
| Dynamic and Predictive Testing                   | ASTM: D4065, D5992, F355, F1292;<br>ARDL: 8105, 8106, 8110, 8111;<br>SAE J1085a          |
| Dynamic Ozone Cracking                           | ASTM D3395   |
| Electrical Resistance                            | ASTM: D257, D991   |
| Effects of Exposure to Fluids on Rubber          | DIN 53 521   |
| Extension Cycling Fatigue                        | ASTM D4482   |
| Flammability                                     | ASTM: D635, D3801, D5132;<br>FMVSS-302;<br>ISO: 1210, 3795;<br>UL: 94, 746B (UL 94 only) |
| Flex Properties                                  | ASTM D790;<br>ISO 178  |
| Fluid Resistance of Gasket Materials             | ASTM F146  |
| Fluorescent UV Exposure of Plastics              | ASTM D4329   |

*PAU*

*"Progress Through Innovation, Technology  
and Customer Satisfaction"*



AKRON RUBBER DEVELOPMENT LABORATORY, INC.  
2887 Gilchrist Road • Akron, Ohio 44305  
1-800-830-ARDL • (330) 794-6600 • FAX (330) 794-6610  
Website: www.ardl.com • E-mail: info@ardl.com

December 21, 2007

• **TEST REPORT** •

PN 76608

PO 00007842

**CHEMICAL ANALYTICAL SERVICES**

Prepared For:

Mr. Peter M. Larson  
Larson Medical Products, Inc.  
2844 Banwick Road  
Columbus, OH 43232

Prepared By: \_\_\_\_\_

*Steve Case*  
Steve Case  
Chemist

Approved By: \_\_\_\_\_

*Ana Camelia Barbur*  
Ana Camelia Barbur, M.S.  
Manager, Chemical Services

An A2LA Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02  
ISO 9001:2000 Registered  
Member of ACIL: The American Council of Independent Laboratories



**ISO 9001:2000**  
Registered



Letters and reports are for the exclusive use of the clients to whom they are addressed and shall not be reproduced, except in full, without the written permission of Akron Rubber Development Laboratory, Inc. (ARDL). The information contained herein applies to the specific material, products or processes tested or evaluated. No warranty of any kind is herein construed or implied. The liability of ARDL, Inc. shall be limited to the amount of consideration paid for services. ARDL, Inc. is accredited by A2LA for the test methods listed on the attached scope.

| <u>Test</u>   | <u>Test Method(s)</u>  |
|---|--|
| Fogging Characteristics   | CHRYSLER LP-463DB-12-01;<br>GM: 9068P, 9305P;<br>SAE J1756 (except Sec. 5.2)                       |
| Friction Properties   | ASTM D1894   |
| General Methods   | ASTM: D380, D1056, D3182, D3577, D3578;<br>ISO: 293, 4074-1, 6056;<br>JIS K6301 (except Sec. 11.0) |
| Hardness  |  |
| Barcol Hardness – Rigid Plastics  | ASTM D2583   |
| Durometer Hardness – Rubber   | ASTM D2240 (Type A and D);<br>DIN 53 505;<br>ISO 868 (Type A and D)                                |
| International Rubber Hardness   | ASTM D1415   |
| Rockwell Hardness of Plastics   | ASTM D785 (R, M Scales)  |
| Rockwell Hardness and Rockwell<br>Superficial Hardness of<br>Metallic Materials   | ASTM E18   |
| HDT/Vicat Softening Point   | ASTM: D648, D1525;<br>ISO: 75, 306   |
| Ignition Loss   | ASTM D2584   |
| Impact  | ASTM: D256, D3763, D4812, D5420;<br>ISO: 179, 180;<br>GM 9904P                                     |
| Injection Molding Test Specimens  | ASTM D3641   |
| Instrumented Impact   | ASTM D3763   |
| Low Temperature Brittleness   | ASTM: D746, D1329;<br>ISO 812  |
| Melt Flow   | ASTM: D1238, D3364;<br>ISO 1133  |
| Operating Fluorescent Light Apparatus for<br>UV Exposure of Nonmetallic Materials | ASTM G154  |
| Ozone Testing   | ASTM: D518, D1149, D1171;<br>ISO 1431  |
| Peel Test   | ASTM: D413, D429   |
| Protective Clothing Material Resistance<br>to Puncture                            | ASTM F1342 (Procedure A)   |

*RAU*

| <u>Test</u>   | <u>Test Method(s)</u>   |
|---|---|
| Resilience by Vertical Rebound  | ASTM D2632-86   |
| Resistance of Rubber to Ozone Cracking –<br>Reference Methods for Determining<br>Ozone Concentration in Laboratory<br>Test Chambers | DIN 53 509-2  |
| Rubber Belting, Flat Type   | ASTM D378   |
| Rubber Properties in Compression or Shear<br>(Mechanical Oscillograph)  | ASTM D945   |
| Salt Spray Corrosion  | ASTM B117;<br>JIS Z2371   |
| Specific Optical Density of Smoke<br>Generated by Solid Materials   | ASTM E662   |
| Stain Resistance  | ASTM D925   |
| Standard Test Methods for Flexible Cellular<br>Materials Made From Olefin Polymers  | ASTM D3575 (except Suffixes R <sub>2</sub> , V,<br>W (Test Method B), CC)                   |
| Standard Test Methods for Urethane Foams  | ASTM D3574 (except B <sub>1</sub> , B <sub>2</sub> , G, H, I <sub>1</sub> -L <sub>4</sub> ) |
| Stiffness Test  | ASTM D1053  |
| Tear Propagation and Peel   | DIN 53 539  |
| Tear Resistance   | ASTM: D624, D1004;<br>ISO: 34, 6383   |
| Tensile Properties  | ASTM: D412, D638, D882, D1708, D3137;<br>DIN 53 504;<br>ISO: 37, 99, 527-1                  |
| Tension Testing of Nonmetallic<br>Gasket Materials  | ASTM F152   |
| Trouser Tear Strength of Rubber   | DIN 53 507  |
| Vapor Transmission of Volatile Liquids  | ASTM D814   |
| Viscosity   | ASTM D1646  |
| Volatile Loss   | ASTM D1203  |
| Vulcanization Using Oscillating<br>Disk Cure Meter  | ASTM D2084  |

*RAM*

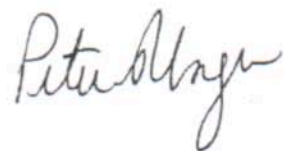
| <u>Test</u>          | <u>Test Method(s)</u>  |
|----------------------|--|
| Water Absorption     | ASTM D570;<br>ISO 62   |
| Weatherability       |  |
| Carbon Arc           | ASTM: D750, G152   |
| QUV                  | ASTM G154  |
| Xenon                | ASTM: G26, G147, G155;<br>ISO 4892-2;<br>SAE: J1885, J1960, J2412, J2527 |
| Xenon and Carbon Arc | JIS D0205  |

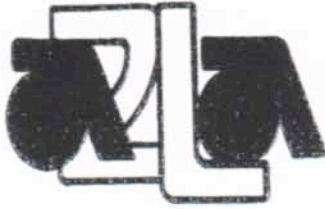
*The laboratory is accredited for the test methods listed above. The accredited test methods are used in determining compliance with the material specifications listed below; however, the inclusion of these material specifications on this Scope does not confer laboratory accreditation to the material specifications:*

GM: GM7001M, GMP.ABS.018R, GMP.E/P.003, GMP.E/P.029, GMP.E/P.071, GMP.TES.012,  
GMP.PE.001, GMP.PE.002, GMP.PE.003, GMP.PE.004, GMP.PE.005, GMP.PE.006,  
GMP.PE.007, GMP.PE.009

DaimlerChrysler: MS-AR-20, MS-AR-23, MS-AR-24, MS-AR-26, MS-AR-30, MS-AR-80, MS-DC-16

Ford: ESF-M4D101-A, ESF-M4D423-A, WSK-MR4695-A, WSS-M2D378-B1, WSS-M2D379-B1,  
WSS-M2D380-B1, WSS-M2D381-B1, WSS-M2D382-B1





THE AMERICAN  
ASSOCIATION  
FOR LABORATORY  
ACCREDITATION

## ACCREDITED LABORATORY

A2LA has accredited

**AKRON RUBBER DEVELOPMENT  
LABORATORY, INC.**  
Akron, OH

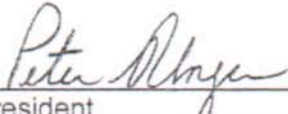
for technical competence in the field of

### **Mechanical Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated 18 June 2005*).

Presented this 31<sup>st</sup> day of August 2006.



  
\_\_\_\_\_  
President  
For the Accreditation Council  
Certificate Number 0255.01  
Valid to January 31, 2008

For the tests or types of tests to which this accreditation applies,  
please refer to the laboratory's Mechanical Scope of Accreditation.



# American Association for Laboratory Accreditation

## SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

AKRON RUBBER DEVELOPMENT LABORATORY, INC.  
2887 Gilchrist Road  
Akron, OH 44305  
Walter Samples Phone: 330 794 6600

### CHEMICAL

Valid To: January 31, 2008

Certificate Number: 0255.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on rubber and plastic materials:

| <u>Test Technology</u>  | <u>Test Method(s)</u>   |
|---|---|
| Spectroscopy<br>ICP/AA<br>Infrared  | ASTM: D4004, E663<br>ASTM D3677   |
| Chromatography<br>Gas Chromatography<br>HPLC<br>TLC<br>Gel Permeation<br>GC/MS        | ASTM D4626; ARDL 3112<br>ASTM E682; ARDL 3138<br>ASTM D3156; ARDL 3110<br>ASTM D5296; ARDL 3134<br>ARDL 3160                            |
| Physical Properties<br>Density<br><br>Melting Point (DSC and Capillary)<br>Melt Range | ASTM: D297 (Sec. 16.3.1), D1817; ARDL 3103;<br>ISO 1183-1 (Methods A and B)<br>ASTM D3418; ARDL 3164<br>ASTM D1519; ISO 3146 (Method A) |
| Wet Chemistry<br>Gravimetric  | ASTM D297   |
| Failure Analysis (Using LOM and SEM/EDX)  | ARDL 3812   |
| Formula Evaluation and Extractable Testing  | 21 CFR 177.2600; ARDL 3171  |
| Physicochemical Tests Plastics  | USP29NF24VSP661   |
| Crosslink Density   | ARDL 3135   |



| <u>Test Technology</u>   | <u>Test Method(s)</u>   |
|--|---|
| Microscopy   |   |
| Light Optical (LOM)  |   |
| - Carbon Black/Inorganic Filler Dispersion                         | ARDL: 3801, 3809  |
| - Particle Size Distribution - Recycled Rubber                     | ARDL 3800   |
| - Particle Size Distribution - Carbon Blacks/Inorganic Fillers     | ARDL 3803   |
| - Cell Size-Cellular Plastics                                      | ASTM D3576; ARDL 3802   |
| - Failure Analysis   | ARDL 3812   |
| - Carbon Black Type  | ASTM D2663  |
| Scanning Electron (SEM/EDX)  | ARDL: 3804, 3806, 3814  |
| - Microdispersion of Inorganic Fillers                             | ARDL 3815   |
| - Elemental Analysis   | ARDL 3813   |
| - Polymer Morphology by CUM/TEM                                    | ARDL 3805   |
| Transmission Electron (TEM)  |   |
| - Primary Aggregate  | ASTM D3849-95a; ARDL 3803   |
| Gas Permeability - Plastic Film/Sheeting                           | ASTM D1434 (Procedure V)  |
| Gas/Liquid Permeability Resistance - Protective Clothing Materials | ASTM: D6978, F739, F1383  |
| Differential Scanning Calorimetry (DSC)                            | ASTM: D3417-83 ( <i>reapproved 1988</i> ), D3418, D3895, D4419, D4591, E793, E794, E1356; ISO 11357-2, -3 |
| Dynamic Mechanical Analysis (DMA)                                  | ASTM D5992; ISO 11359-1   |
| Linear Thermal Expansion (TMA)                                     | ASTM E831; ISO 11359-2  |
| Thermal Gravimetric Analysis (TGA)                                 | ASTM E1131  |
| Sulfur Determination (LECO)  | ASTM E1019  |
| Chloroform Coagulation   | Vanderbilt Latex Handbook (3 <sup>rd</sup> Edition)   |
| Toluene Swell Test   | ARDL 3130   |
| Latex Testing  | ASTM D1076 (except Sec. 36)   |
| Leaching for Halides and Sulfur                                    | ASTM: D512, D1179, D1246; Mil-Std: 2041 D (SH), 2190 (SH) 1987  |
| Test for Volatiles in Silicone Rubber                              | Daimler Chrysler LP-461J-127; Ford AV-102-01; GM 9009P  |

*PMU*

Test Technology

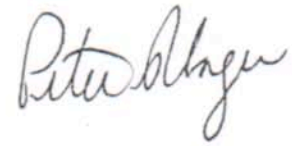
Test Method(s)

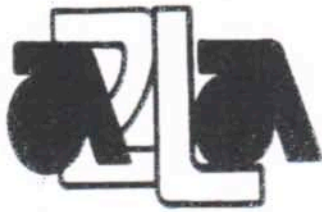
Resistance of Materials Used in Protective  
Clothing to Penetration by Liquids

ASTM F903

Resistance of Materials Used in Protective  
Clothing to Penetration by Synthetic Blood

ASTM F1670





THE AMERICAN  
ASSOCIATION  
FOR LABORATORY  
ACCREDITATION

## ACCREDITED LABORATORY

A2LA has accredited

**AKRON RUBBER DEVELOPMENT  
LABORATORY, INC.**

**Akron, OH**

for technical competence in the field of

### **Chemical Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated 18 June 2005*).

Presented this 31<sup>st</sup> day of August 2006.



A handwritten signature in black ink, appearing to read 'Peter Abney', written over a horizontal line.

President  
For the Accreditation Council  
Certificate Number 0255.02  
Valid to January 31, 2008

For the tests or types of tests to which this accreditation applies,  
please refer to the laboratory's Chemical Scope of Accreditation.