

# SAFETY DATA SHEET

## 1 PRODUCT IDENTIFICATION

**Product Name:**

Standards for IgA aCL, Standards for IgG aCL, Standards for IgM aCL, Negative Control for IgG/IgM/IgA aCL, Positive Control for IgA aCL High, Positive Control for IgA aCL Medium, Positive Control for IgA aCL Low, Positive Control for IgG aCL High, Positive Control for IgG aCL Medium, Positive Control for IgG aCL Low, Positive Control for IgM aCL High, Positive Control for IgM aCL Medium, Positive Control for IgM aCL Low, Positive Control for IgA aB2GPI, Positive Control for IgG aB2GPI, Positive Control for IgM aB2GPI, Positive Sample for IgA aCL High, Positive Sample for IgA aCL Medium, Positive Sample for IgA aCL Low, Positive Sample for IgG aCL High, Positive Sample for IgG aCL Medium, Positive Sample for IgG aCL Low, Positive Sample for IgM aCL High, Positive Sample for IgM aCL Medium, Positive Sample for IgM aCL Low, Positive Sample for IgA aB2GPI, Positive Sample for IgG aB2GPI, Positive Sample for IgM aB2GPI.

**Product Number:**

LAPL-A-001, LAPL-GM-300, LAPL-GM-300G, LAPL-GM-300M, LAPL-00-GMA, LAPL-A-003H, LAPL-A-003M, LAPL-A-003L, LAPL-GM-004H, LAPL-GM-004M, LAPL-GM-004L, LAPL-MM-004H, LAPL-MM-004M, LAPL-MM-004L, LAPL-B2A-004, LAPL-B2G-004, LAPL-B2M-004, LAPL-A-004H, LAPL-A-004M, LAPL-A-004L, LAPL-GM-005H, LAPL-GM-005M, LAPL-GM-005L, LAPL-MM-005H, LAPL-MM-005M, LAPL-MM-005L, LAPL-B2A-005, LAPL-B2G-005, LAPL-B2M-005

**Components:**

Standards, Controls, and Samples are from Human serum

**Recommended Application**

Standards are suitable for *in vitro* diagnostics use, Controls and Samples are for *Research Use Only*.

**Manufacturer/Supplier:**

Louisville APL Diagnostic, INC  
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Texas City, TX 77590-7451 - USA

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[support@louisvilleapl.com](mailto:support@louisvilleapl.com)

**Telephone:** +1 770-455-7129

**Fax:** +1 844-721-8193

**Emergency Information:** In case of an emergency call +1 770-455-7129.

## 2 HAZARDS IDENTIFICATION

**Emergency Overview:**

All donors of human serum supplied in these products have been serum tested by FDA required assays and have been found negative for hepatitis B surface antigen (HBsAg) and antibodies to immunodeficiency virus HIV-1 and HIV-2 and hepatitis C virus. However, these results cannot guarantee the absence of infective agents. These products should be handled by personnel trained in the proper procedures for handling potential viral contaminants. All wastes should be properly labeled and disposed of according to all international, national and local regulations

Product is not classified as hazardous.

Product has no hazards for Emergency responders if spilled and has no hazard if in a fire.

Sodium azide (<0.1%) is included as a preservative and it is not considered hazardous at this level.

**OSHA Hazards:**

Not Hazardous Substance

**GHS Label elements:**

Not Hazardous Substance

**HNOC Hazards (Hazards not otherwise classified):**

Not Hazardous Substance

## 3 INFORMATION ON INGREDIENTS

**Chemical Characterization:** Human Serum

**Description:** Product contains Human Serum.

**CAS registry number:** Not applicable

**LD50 (species and route):** Not applicable

**LC50 (species and route):** Not applicable

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## 4 FIRST AID MEASURES

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### Description of first aid measures

**General advice:** Consult a physician. Provide SDS document to physician. Move out of dangerous area.

**If inhaled:** Move exposed individual to fresh air. Loosen clothing as necessary and place individual in a comfortable position. Provide oxygen if breathing is difficult. Give artificial respiration if not breathing. Get medical attention.

**In case of skin contact:** Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water.

**In case of eye contact:** Rinse thoroughly with plenty of water for at least 15 minutes and if needed consult a physician. Remove contact lens(es) if able to do so during rinsing.

**If swallowed:** Do NOT induce vomiting. Rinse mouth thoroughly with water. Have exposed individual drink sips of water. Never give anything by mouth to an unconscious person. Seek immediate medical attention.

**Most important symptom and effects, both acute and delayed:** The most important known symptoms and effects are described in the labeling (see Section 2)

**Recommendations for immediate medical attention and special treatment needed:** No data available.

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## 5 FIREFIGHTING MEASURES

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**Suitable extinguishing media:** Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Special hazards arising from the substance or mixture:** Nature of decomposition products not known.

**Advice for firefighters:** Wear self-contained breathing apparatus for firefighting if necessary.

**Further information:** No data available.

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## 6 ACCIDENTAL RELEASE MEASURES

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**Personal precautions, protective equipment, and emergency procedures:** Avoid breathing vapors, mist or gas. Ensure adequate ventilation. For personal protection see Section 8.

**Environmental precautions:** No special environmental precautions required.

**Methods and materials for containment and cleaning up:** Contain and soak up spills with an inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

**Reference to other sections:** For disposal recommendations see Section 13. For personal protection see Section 8.

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## 7 HANDLING AND STORAGE

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**Precautions for safe handling:** Avoid skin and eye contact and breathing in vapor, mists and aerosols. Wear personal protective equipment. Wash hands thoroughly after handling. For precautions refer to Section 2.

**Conditions for safe storage, including any incompatibilities:** It is recommended that all products be stored at  $\leq -20^{\circ}\text{C}$  until the expiration date, both before and after containers are opened. Each product should be reconstituted with the volume indicated in the label of sterile, distilled water. Allow the reconstituted material to stand for 15-30 minutes; swirl gently or vortex to dissolve any remaining un-dissolved material. After the material has dissolved completely, divide each sample in aliquots (for example 10-20  $\mu\text{l}$ ). Aliquots of each sample should be stored at temperatures  $\leq -20^{\circ}\text{C}$  for future use.

**Specific end use(s):** Refer to Section 1; no other specific uses are stipulated.

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## 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

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### Exposure guidelines:

**Engineering controls:** No special environmental precautions required. Ensure adequate ventilation. Ensure that eyewash stations are close to the workstation location. Practice general industrial hygiene.

### Personal protective equipment

**Eye/face protection:** Use eye protection tested and approved under appropriate government standards such as OSHA's eye and face protection regulations in 29 CFR 1910.133 (US) or European Standard EN166 (EU).

**Skin protection and body protection:** Handle with nitrile rubber gloves. Gloves must be inspected prior to use. Use proper glove removal technique to avoid skin contact with the product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. Wear long sleeved clothing to prevent skin exposure.

**Respiratory protection:** Respiratory protection not required. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

**Hygiene measures:** Handle in accordance with good industrial hygiene and safety practice.

## 9 PHYSICAL AND CHEMICAL PROPERTIES

### Properties Summary:

|                              |                |  |                               |
|------------------------------|----------------|--|-------------------------------|
| Appearance                   | lyophilized    | Flash Point                            | not determined                |
| Odor                         | not determined | Evaporation Rate                       | not determined                |
| Odor Threshold               | not determined | Flammability (Solids, Gasses)          | not available                 |
| pH                           | not determined | Partition coefficient: n-octanol/water | not determined                |
| Melting Point/Freezing Point | not determined | Auto-Ignition Temperature              | not determined                |
| Flammable/Explosive Limits   | not determined | Decomposition temperature              | not determined                |
| Vapor Pressure               | not determined | Viscosity                              | not determined                |
| Vapor Density                | not determined | Explosive properties                   | not determined                |
| Relative Density             | not determined | Oxidizing properties                   | not determined                |
| Initial Boiling Point/Range  | not determined | Solubility                             | All products soluble in water |

**Other safety information:** No data available.

## 10 STABILITY AND REACTIVITY

**Reactivity:** This product is stable under recommended storage conditions.

**Chemical stability:** This product is stable under recommended storage conditions.

**Possibility of hazardous reactions:** Hazardous reactions are not anticipated to occur under normal conditions of storage and use.

**Conditions to avoid:** avoid freeze and thaw of the reconstituted material repeatedly.

See Section 5 in the event of a fire.

## 11 TOXICOLOGICAL INFORMATION

**Acute:** This product is not known to have any specific health or toxicological effects if used as offered for its intended purpose.

**Chronic:** None known if used as offered for its intended purpose.

**Skin corrosion/irritation:** No data available

**Serious eye damage/eye irritation:** No data available

**Respiratory or skin sensitization:** No data available

**Germ cell mutagenicity:** No data available

**Carcinogenicity:**

**NTP:** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by the National Toxicology Program (NTP), Report on Carcinogens, 14<sup>th</sup> Report.

**IARC:** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by the International Agency for Research on Cancer (IARC), Monographs, Volumes 1-122.

**OSHA:** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by the Occupational Safety and Health Administration (OSHA).

**Comments:** Refer to Section 3 for individual chemical toxicological information. Additional information is as follows:

|                     |           |         |          |
|---------------------|-----------|---------|----------|
| <u>Sodium azide</u> | LD50 Oral | 27mg/kg | (rat)    |
|                     | LD50 Skin | 20mg/kg | (rabbit) |

## 12 ECOLOGICAL INFORMATION

**Ecotoxicity:** No information available.

**Persistence and degradability:** No information available.

**Bioaccumulation/Accumulation:** No information available.

**Absorption/Leaching:** No information available.

**Other adverse effects:** No data available.

## 13 DISPOSAL CONSIDERATIONS

Chemical waste generators must consult local, regional, and national hazardous waste regulations to ensure complete compliance and accurate classification and disposal of hazardous wastes, product, or packaging.

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## 14. TRANSPORT INFORMATION

**Special requirements:** None. This product must be shipped in accordance with all applicable local, state, and federal regulations.

**DOT, IATA, IMDG, and ADR Information:** Not dangerous goods. Special Precautions: None required

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## 15. REGULATORY INFORMATION

### US Federal and State Regulations

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| <b>SARA 311/312 Hazards:</b>                   | Components do not reach threshold values |
| <b>SARA 313 Components:</b>                    | Components do not reach threshold values |
| <b>SARA 302 Components:</b>                    | Components do not reach threshold values |
| <b>CERCLA Reportable Quantity:</b>             | Components do not reach threshold values |
| <b>Clean Water Act:</b>                        | Components do not reach threshold values |
| <b>Clean Air Act:</b>                          | Components do not reach threshold values |
| <b>OSHA Hazards:</b>                           | No known OSHA hazards                    |
| <b>Canadian DSL/NDSK Status:</b>               | Not Applicable                           |
| <b>EU Classification (90/492/EEC):</b>         | Not Applicable                           |
| <b>EU Hazard and Precautionary Statements:</b> | See Section 2                            |

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## 16. OTHER INFORMATION

Serum supplied in these products has been tested by FDA required assays and have been found negative for hepatitis B surface antigen (HBsAg) and antibodies to immunodeficiency virus HIV-1 and HIV-2 and hepatitis C virus. **WARNING:** Because no test method can offer complete assurance that HIV, HCB, HBsAg or other infectious agents are absent, these results cannot guarantee the absence of infective agents. Proper handling and disposal methods should be established as for all potentially infective material and only personnel adequately trained in such methods should be permitted to perform the procedures.

Louisville APL Diagnostic, INC provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the kit by properly trained personnel using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose.