



SAFETY DATA SHEET

Section 1: Identification	
Product Name(s):	LAPL™ aβ 2GPI HRP ELISA Kit IgA LAPL™ aβ 2GPI HRP ELISA Kit IgG LAPL™ aβ 2GPI HRP ELISA Kit IgM
Product Number:	LAPL-K-aβ2-GPI-1A, LAPL-K-aβ2-GPI-1G, LAPL-K-aβ2-GPI-1M
<p>Anti-Beta 2 GP1 is an Enzyme-Linked Immunosorbent Assay (ELISA) for the semi-quantitative determination of IgG, IgM and IgA anti-Beta 2 Glycoprotein (β2GP1) antibodies in human serum or citrated plasma. Intended for professional in vitro diagnostic use only.</p>	
Manufacturer:	Corgenix, Inc. 11575 Main Street, Suite 400 Broomfield, CO 80020 USA Phone: (800) 729-5661 (303) 457-4345 Fax: (303) 457-4519 www.corgenix.com info@corgenix.com
Supplier:	Louisville APL Diagnostics, Inc. 702 9 TH ST N, STE A Texas City, TX 77590 USA Phone: (770) 455-7129 (800) 624-3192 (US & Canada only) Fax: (844) 721-8193 www.louisvilleapl.com support@louisvilleapl.com

Section 2: Hazards Identification	
Emergency Overview:	<p>Product is not classified as hazardous based on the physical and/or chemical nature and/or concentration of ingredients.</p> <p>Product has little to no hazards for Emergency responders if spilled and has no unusual hazard if in a fire.</p> <p>Sodium azide (<0.1%) is included as a preservative. Although it is not considered hazardous at this level, note that accumulated sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Thorough flushing of plumbing is recommended.</p>
OSHA Hazards:	<p>Not Hazardous</p> <p>While the materials in this diagnostic kit are not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.</p>
GHS Classification & Symbols:	<p>ProClin 300 and 950 at the concentrations of 0.1% or less may cause sensitization by skin contact.</p> <p>Low level of sulfuric acid in stop solution considered an irritant if contact made with skin, eyes and/or respiratory system.</p> <p>Salt-based wash solution considered an irritant if contact made with skin or eyes and affected area not washed immediately.</p> <p>Human Serum, even at the low volumes included in this kit, is considered biohazardous. The Human Serum or Plasma used in these products has been tested and found negative for HIV 1 and 2 antibodies, Hepatitis C Virus (HCV), and Hepatitis B Surface antigen. Because no method can absolutely guarantee the absence of infectious agents, handle reagents of human origin and patient samples as if capable of transmitting infectious disease (Universal Precaution).</p> <div style="display: flex; justify-content: space-between; align-items: center; margin-top: 10px;"> <div style="text-align: right; width: 60%;">  </div> <div style="text-align: right; width: 35%;">  </div> </div>

Section 3: Composition / Information on Ingredients		
COMPONENT	COMPOSITION	KIT CONTENT
Coated Microplate:	96 stabilized β 2GP1 (from human sera) coated microwells (12 strips of 8 breakaway wells) with frame.	1 microplate
Calibrators 1, 2 & 3:	Human serum; (1-high, 2-moderate, 3-low) Preservative: <0.1% Sodium Azide	3 vials per isotype each at 0.25mL
Positive and Negative Controls:	Human serum Preservative: <0.1% Sodium Azide	2 vials per isotype each at 0.25mL
Enzyme Conjugate:	Goat anti-human IgG HRP-conjugated antibody solution (blue), IgM (red) and IgA (orange). Consists of HRP Conjugate Stabilizer and PBS. Preservative: < 0.1% ProClin® 300 & 950	1 bottle at 15mL for each isotype
Sample Diluent:	Phosphate buffered saline (PBS). Contains bovine serum albumin. Preservative:< 0.1% ProClin® 150 & 950	1 bottle at 60mL
Wash Buffer:	33X phosphate buffered saline. Contains < 0.4% Tween 20.	2 bottles at 30mL each
Substrate Solution:	Aqueous solution of TMB (3,3',5,5'-Tetramethylbenzidine) and hydrogen peroxide (H ₂ O ₂).	1 bottle at 15mL
Stop Solution:	Aqueous solution of 0.36N sulfuric acid.	1 bottle at 15mL

Section 4: First Aid Measures	
Skin Contact:	Immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse.
Eye Contact:	After contact with the eyes, carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
Ingestion:	If swallowed, wash out mouth with water provided individual is conscious; call physician.
Inhalation:	Remove individual to fresh air. If breathing becomes difficult, call physician.

Section 5: Firefighting Measures	
Extinguishing Media:	Use dry chemical powder, water spray, foam or carbon dioxide.

Section 6: Accidental Release Measures	
Personal Precautions:	Wear disposable gloves, eye protection, and appropriate protective clothing.
Environmental Precautions:	Do not discard human-source reagents and contaminated wastes in the drain.
Methods for Clean-Up:	Collect reagents with absorbent paper. Treat solutions and materials contaminated by human source material (materials or samples) with freshly diluted bleach at ~12% bleach.
Disposal:	Refer to section 13. Discard human source reagents and contaminated material as potentially infectious biological material.

Section 7: Handling and Storage	
Handling:	Special measures are not required.
Storage:	Store at 2 to 8°C. Protect from light. Store reagents in their original containers

Section 8: Exposure Controls / Personal Protection	
Engineering Measures:	Comply with Good Laboratory Practices to avoid all direct contact with reagents.
Personal Protective Equipment:	Disposable gloves, protective glasses, protective clothing.
Hygiene Measures:	Comply with Good Laboratory Practices. Wash hands thoroughly.

Section 9: Physical and Chemical Properties	
Coated Microplate:	Polystyrol microwells in foil pouch.
Calibrators:	Yellow fluid in HDPE vials.
Enzyme Conjugate:	Blue fluid in polyethylene bottle (IgG) Red fluid in polyethylene bottle (IgM) Orange fluid in polyethylene bottle (IgA).
Sample Diluent:	Green-blue fluid in polyethylene bottle.
Wash Buffer:	Colorless fluid in polyethylene bottle.
Substrate Solution:	Colorless fluid in amber polyethylene bottle.
Stop Solution:	Colorless fluid in polyethylene bottle.

Section 10: Stability and Reactivity
Stability of component is given on each individual label. Used according to intended use, no dangerous reactions known.

Section 11: Toxicological Information
Used according to intended use, no toxicological reactions known.

Section 12: Ecological Information
Used according to intended use, no ecological reactions known.

Section 13: Disposal Considerations
Waste should be disposed of in accordance with federal, state and local environmental control regulations. When disposing of conjugate solution, sample diluent, or wash buffer, flush drains with copious amounts of water. Disposal of packaging according to the instructions of the public authorities. Some materials such as calibrators, controls, patient samples and microplates that have been used in testing should be treated as a biohazard and disposed of accordingly.

Section 14: Transport Information
This product is not subject to official transport regulations.

Section 15: Regulatory Information

United States (TSCA): All ingredients are on the inventory or exempt from listing.

Canada (DSL / NDSL): All ingredients are on the inventory or exempt from listing.

SARA 302 Components: Sodium Azide: CAS 26628-22-8

SARA 313 Components: Sodium Azide: CAS 26628-22-8

SARA 311 / 312 Hazards: Sodium Azide: Acute health hazard

ProClin® : Acute health hazard

California Prop. 65 Components: This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Section 16: Other Information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier assumes any liability whatsoever for the accuracy or completeness of the information contained herein. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.