

# SAFETY DATA SHEET

## 1 PRODUCT IDENTIFICATION

**Product Name:**

APL ELISA™ IgG AP Kit for detection of IgG aCL antibodies  
 APL ELISA™ IgM AP Kit for detection of IgM aCL antibodies  
 APL ELISA™ IgA AP Kit for detection of IgA aCL antibodies

**Product Number:**

LAPL-K-AP-G-0  
 LAPL-K-AP-M-0  
 LAPL-K-AP-A-0

**Components:**

APL ELISA™ Cardioliipin Antigen-coated polystyrene microwell strips, APL ELISA™ IgG/IgM/IgA AP Conjugate (contains sodium azide), APL ELISA™ IgG/IgM/IgA Calibrators (contain sodium azide), APL ELISA™ AP Substrate (contains trometamol), APL ELISA™ AP Stopping Solution (contains sodium hydroxide), APL ELISA™ Sample Diluent (contains sodium azide), APL ELISA™ AP Negative/IgG Positive/IgM Positive/IgA Positive Controls (contain sodium azide), and APL ELISA™ AP PBS Concentrate (contains sodium azide).

**Recommended Application**

Identified uses: The APL ELISA™ AP Kit is a semi-quantitative enzyme linked immunosorbent assay (ELISA) for use as an aid in diagnosing the Antiphospholipid Syndrome (APS).

**Manufacturer/Supplier:**

Louisville APL Diagnostic, INC  
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Telephone: +1 770-455-7129  
 USA/Canada: 1-800-624-3192  
 Fax: +1 844-721-8193

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

## 2 HAZARDS IDENTIFICATION

**Emergency Overview:**

Product is not classified as hazardous based on the physical and/or chemical nature and/or concentration of ingredients.

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

Sodium azide (<0.2%) 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.

**OSHA Hazards:**

Not Hazardous

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.

**Sodium Azide (in APL ELISA™ IgG/IgM/IgA AP Conjugate, APL ELISA™ IgG/IgM/IgA Calibrators, APL ELISA™ Sample Diluent, APL ELISA™ AP Negative/IgG Positive/IgM Positive/IgA Positive Controls, and APL ELISA™ AP PBS Concentrate)**

**Classification:** This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

**GHS Label Elements:**

Signal word: Warning

Pictogram:



Hazard class:

Hazardous to the aquatic environment, Chronic

Category 3

**Hazard Statements:**

H412 Harmful to aquatic life with long lasting effects

**Precautionary statements:**

P273 Avoid release to the environment  
 P501 Dispose of contents/ container to comply with local, state, and federal regulations

**Hazards not otherwise classified (HNOC) or not covered by GHS:**

Very toxic to aquatic life with long lasting effects  
 Contact with acids liberates very toxic gas  
 May react with lead and copper plumbing to form highly explosive metal azides  
 Rapidly absorbed through skin

**Sodium Hydroxide (in APL ELISA™ AP Stopping Solution)**

**Classification:** This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

**GHS Label elements:**

**Signal word:** Danger

**Hazard class:**

**Skin Corrosion / Irritation**  
**Eye Damage / Irritation**  
**Corrosive to Metals**  
**Specific Target Organs / Systemic Toxicity**  
**Following Single Exposure**

**Pictograms:**



**Category 1A**  
**Category 1**  
**Category 1**  
**Category 1**

**Hazard Statements:**

H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H370	Causes damage to organs

**Precautionary statements:**



P234	Keep only in original container.
P260	Do not breathe dust/fumes/gas/mist/vapours/spray
P264	Wash thoroughly after handling
P270	Do not eat, drink or smoke when using this product
P280	Wear protective gloves/protective clothing/eye protection/face protection
P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304+P340	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P307+P311	IF exposed: Call a POISON CENTER or physician.
P310	Immediately call a POISON CENTER or physician.
P321	Specific treatment (Wash areas of contact with water immediately).
P363	Wash contaminated clothing before reuse
P390	Absorb spillage to prevent material damage
P405	Store locked up.
P406	Store in corrosive resistant container with a resistant inner liner.
P501	Dispose of contents in accordance with local, state, federal, and international regulations.

### 3 INFORMATION ON INGREDIENTS



**Chemical Characterization: Mixtures**

**Description:** Product contains mixtures of the substances listed below with nonhazardous additions.

**APL ELISA™ IgG/IgM/IgA AP Conjugate, APL ELISA™ IgG/IgM/IgA Calibrators, APL ELISA™ Sample Diluent, APL ELISA™ AP Negative/IgG Positive/IgM Positive/IgA Positive Controls, and APL ELISA™ AP PBS Concentrate**

Hazardous	CAS#	EINECS#	GHS Symbols	GHS Classification	%
Sodium Azide	26628-22-8	247-852-1	 	Acute Toxicity, Oral (Category 2), H300 Acute Toxicity, Dermal (Category 1), H310 Hazardous to the Aquatic Environment, Acute (Category 1), H400 Hazardous to the Aquatic Environment, Chronic (Category 1), H410	≤ 0.2%

**APL ELISA™ AP Stopping Solution**

Hazardous	CAS#	EINECS#	GHS Symbols	GHS Classification	%
Sodium Hydroxide	1310-73-2	215-185-5	 	Skin corrosion/irritation (Category 1), H314 Eye Damage/irritation (Category 1), H318 Specific Target Organs/Systemic Toxicity Following Single Exposure (Category 1), H370 Corrosive to metals (Category 1), H290	≤ 11

### 4 FIRST AID MEASURES

**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. May cause serious damage to the skin. Effects may include redness, pain, skin bumps. Consult a physician.

**In case of eye contact:** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lens(es) if able to do so during rinsing. Seek immediate medical attention. Rinse under the eyelids during flushing and continue to rinse eyes during transport to hospital.

**If swallowed:** Do NOT induce vomiting. Rinse mouth thoroughly with water. Have exposed individual drink sips of water or milk. 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.

### 5 FIREFIGHTING MEASURES

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

**Special hazards arising from the substance or mixture:** Thermal decomposition of sodium azide can lead to release of irritating gasses and vapors. Runoff to sewer may create fire or explosion hazard. Do not allow run-off from fire fighting to enter drains or water courses.

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

**Further information:** No data available.

### 6 ACCIDENTAL RELEASE MESURES

**Personal precautions, protective equipment and emergency procedures:** Wear respiratory protection. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Wear protective gloves and eye protection. **For personal protection see Section 8.**

**Environmental precautions:** Do not let products enter drains or otherwise release product into the environment.

**Methods and materials for containment and cleaning up:** Sweep or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Collect APL ELISA™ AP Stopping Solution and dilute with water. Neutralize with dilute acid solutions. Contain and soak up larger 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.

## 7 HANDLING AND STORAGE

**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. *APL ELISA™ AP Stopping Solution* is an irritant.

**Conditions for safe storage, including any incompatibilities:** It is recommended that all components of the *APL ELISA™ AP Kit* be stored 2-8°C until the expiration date, both before and after containers are opened. Do not freeze any of the components. Store away from incompatible materials as described in Section 10. Keep containers tightly closed in a dry and well-ventilated place. Keep containers upright to prevent leakage.

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

## 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure guidelines:**

	CAS#	ACGIH TLV	OSHA PEL	NIOSH IDLH	Mexico OEL (TWA)
<b>Sodium Azide</b>	26628-22-8	Ceiling: 0.1ppm (0.29 mg/m <sup>3</sup> )	Ceiling: 0.1 ppm (0.3 mg/m <sup>3</sup> ) Skin, Vacated	Ceiling: 0.1 ppm (0.3 mg/m <sup>3</sup> )	N/A
<b>Sodium Hydroxide</b>	1310-73-2	TWA: 2mg/m <sup>3</sup>	TWA: 2mg/m <sup>3</sup>	REL: 2mg/m <sup>3</sup>	Ceiling: 2mg/m <sup>3</sup>

**Legend**

ACGIH - American Conference of Governmental Industrial Hygienists

OSHA - Occupational Safety and Health Administration

NIOSH IDLH: The National Institute for Occupational Safety and Health Immediately Dangerous to Life or Health

**Engineering controls:** Ensure adequate ventilation. Ensure that eyewash stations and safety showers are close to the workstation location. Practice general industrial hygiene. Use only under a chemical fume hood. Use explosion-proof electrical/ ventilating/ lighting/ equipment.

**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:** Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA 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:**

Component	Appearance	Color	Odor	pH
<i>APL ELISA™ Sample Diluent</i>	Liquid	Pale Yellow	Characteristic	No data available
<i>APL ELISA™ AP Negative Control</i>	Liquid	Pale Yellow	Characteristic	No data available
<i>APL ELISA™ AP IgG Positive Control</i>	Liquid	Pale Yellow	Characteristic	No data available
<i>APL ELISA™ AP IgM Positive Control</i>	Liquid	Pale Yellow	Characteristic	No data available
<i>APL ELISA™ AP IgA Positive Control</i>	Liquid	Pale Yellow	Characteristic	No data available
<i>APL ELISA™ AP IgG Conjugate</i>	Liquid	Pale Yellow	Characteristic	No data available
<i>APL ELISA™ AP IgM Conjugate</i>	Liquid	Pale Yellow	Characteristic	No data available
<i>APL ELISA™ AP IgM Conjugate</i>	Liquid	Pale Yellow	Characteristic	No data available
<i>APL ELISA™ AP Substrate</i>	Liquid	Pale Yellow	Mild sweet odor	No data available
<i>APL ELISA™ AP Stopping Solution</i>	Liquid	Colorless	Mild base odor	>13

**For all *APL ELISA™ IgG, IgM and IgA AP Kit* Components:**

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

**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:** Do not freeze any of the components in the *APL ELISA™ AP Kits*. Avoid excessive heat, fire, static electricity, and direct sunlight.

See Section 5 in the event of a fire.

Component	Incompatible Materials	Hazardous Decomposition Products
<i>APL ELISA™ Sample Diluent</i>	Strong acids, strong oxidizers, copper, and lead	May react with plumbing systems to form highly explosive compounds (lead or copper azide in laboratory plumbing which may explode on percussion)
<i>APL ELISA™ AP Negative/IgG Positive/IgM Positive Controls</i>	Strong acids, strong oxidizers, copper, and lead	May react with plumbing systems to form highly explosive compounds (lead or copper azide in laboratory plumbing which may explode on percussion)
<i>APL ELISA™ AP IgG/IgM/IgA Conjugates</i>	Strong acids, strong oxidizers, copper, and lead	May react with plumbing systems to form highly explosive compounds (lead or copper azide in laboratory plumbing which may explode on percussion)
<i>APL ELISA™ AP Substrate</i>	Strong oxidizing agents such as sulfuric acid, nitrates, and perchlorates.	May release carbon dioxide, carbon monoxide, nitrogen oxides, and formaldehyde under fire conditions
<i>APL ELISA™ AP Stopping Solution</i>	Oxidizers, bases, and metals	May release carbon dioxide, carbon monoxide, hydrogen chloride gas, and sulfur oxides
<i>APL ELISA™ AP PBS Concentrate</i>	No information available	Oxides of phosphorus, hydrogen chloride gas, potassium oxides, and sodium oxides formed under fire conditions

## 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.

**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)
<u>Sodium hydroxide</u>	LDL0 Oral	No information available	(rat)
	LD50 Skin	500mg/24H	(rat)
	LD50 Eye	50µg/24H	(rat)

## 12 ECOLOGICAL INFORMATION

**Ecotoxicity:** Sodium azide is expected to be very toxic to aquatic life. The LC50/96-hour values for fish are less than 1 mg/L.

**Persistence and degradability:** Sodium azide is not expected to biodegrade.

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

**Absorption/Leaching:** Sodium azide is expected to leach into the groundwater and may become moderately degraded by photolysis when released into the air.

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

## 13 DISPOSAL CONSIDERATIONS

Some reagents in this kit contain sodium azide as a preservative. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. 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. Use or contamination of the kit components may change waste management requirements.

## 14. TRANSPORT INFORMATION

**Special requirements:** None.

**This product must be shipped in accordance with all applicable local, state, and federal regulations. As offered for shipping (based on a single kit only):**

**DOT, IATA, IMDG, and ADR Information:**

**APL ELISA™ AP Substrate**

Not a dangerous good.

**APL ELISA™ AP Stopping Solution**

UN Number:	1824
UN Proper Shipping Name:	Sodium Hydroxide Solution
Transport Hazard Class	8
Packing Group:	II

**APL ELISA™ Sample Diluent, APL ELISA™ IgG/IgM/IgA AP Conjugate, and APL ELISA™ AP Negative/IgG Positive/IgM Positive Controls**

Not a dangerous good.

## 15. REGULATORY INFORMATION

**US Federal and State Regulations**

**Toxic Substances Control Act (TSCA):**

Sodium azide and Sodium hydroxide are listed on TSCA inventory

**SARA 311/312 Hazards:**

Components do not reach threshold values

**SARA 313 Components:**

Components do not reach threshold values

**SARA 302 Components:**

Components do not reach threshold values

**CERCLA Reportable Quantity:**

Components do not reach threshold values

**Clean Water Act:**

Components do not reach threshold values

**Clean Air Act:**

Components do not reach threshold values

**OSHA Hazards:**

No known OSHA hazards

**Extremely Hazardous Substances:**

No components in the *APL ELISA™ IgG and IgM AP Kit* are listed

**California Proposition 65:**

No components are listed.

**Right To Know Components:**

State	Right To Know Components
Massachusetts	Sodium hydroxide CAS# 1310-73-2; Sodium azide CAS# 26628-22-8
Minnesota	Sodium azide (≥0.1%) is listed on Minnesota Pollution Control Agency: List of Acute Hazardous Waste
New Jersey	Sodium hydroxide CAS# 1310-73-2; Sodium azide CAS# 26628-22-8
Pennsylvania	Sodium hydroxide CAS# 1310-73-2; Sodium azide CAS# 26628-22-8
Rhode Island	Sodium azide CAS# 26628-22-8

**Canadian DSL/NDSK Status:**

Sodium azide and Sodium hydroxide are listed on DSL

**EU Classification (90/492/EEC):**



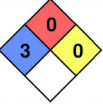

Not Applicable

**EU Hazard and Precautionary Statements:**

See Section 2

## 16. OTHER INFORMATION

### NFPA and Directive 1999/45/EC Ratings and Statements

Component	NFPA Rating	1999/45/EC Classification	Directive 1999/45/EC Caution Statements			
<b>APL ELISA™ Sample Diluent</b> <b>APL ELISA™ AP Negative Control</b> <b>APL ELISA™ AP IgG Positive Control</b> <b>APL ELISA™ AP IgM Positive Control</b> <b>APL ELISA™ AP IgG/IgM/IgA Conjugate</b>		 Xn (Harmful)	R20 Harmful if inhaled. R21 Avoid contact with skin. R22 Harmful if swallowed. R32 Contact with acids liberates very toxic gas.	S2 Keep out of the reach of children. S13 Wear suitable protective clothing. S37 Use gloves. S46 If swallowed, seek medical advice immediately and show this container or label.		
<b>APL ELISA™ AP Stopping Solution</b>		 Xi (Irritant)	R36 Irritating to eyes. R38 Irritating to skin.	S62/S64 If swallowed, rinse mouth with water. Do not induce vomiting. Seek medical advice immediately. S27/S28 If on skin, take off immediately all contaminated clothing and wash immediately with plenty of water. S63 If inhaled, remove person to fresh air and keep comfortable for breathing. S26 If in eyes, rinse immediately with plenty of water, remove contact lenses, and keep rinsing.		

#### Full Text of Hazard Codes Listed in Sections 2 and 3

H290	May be corrosive to metals	H370	Causes damage to organs
H314	Causes severe skin burns and eye damage	H412	Harmful to aquatic life with long-lasting effects
H318	Causes serious eye damage		

**APL ELISA™ AP Stopping Solution** contains a caustic solution (NaOH-3N). Use with care to avoid contact with skin and eyes. Avoid exposure to acids, metals, and other compounds which may react with bases. Spills should be cleaned up immediately.

Serum supplied in this kit 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.