SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name: **BioPlex® 2200 APLS IgG, IgM and IgA Control Sets**

Product Number: **663-1930 [**APLS IgG Control] (6 X 1.5 mL)
663-2030 [APLS IgM Control] (6 X 1.5 mL)
663-2130 [APLS IgA Control] (6 X 1.5 mL)

Intended Use: The BioPlex 2200 Antiphospholipid Syndrome (APLS) IgG, IgM and IgA Control Sets are each intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and the corresponding BioPlex 2200 APLS IgG, IgM and IgA Reagent Packs in the clinical laboratory. The performance of the BioPlex 2200 APLS IgG, IgM and IgA Control Sets has not been established with any other Antiphospholipid assay.

Manufactured by: **Bio-Rad Laboratories, Inc.**

Address: 6565 185th Avenue NE
Redmond, WA 98052-5039, USA

Website: www.bio-rad.com

Phone Number: 1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT)

SDS e-mail contact: ro-sds@bio-rad.com

Technical Information Contacts: Bio-Rad provides a toll free line for technical assistance, available 24 hours a day, 7 days a week. In the United States of America and Puerto Rico, call toll free 1-800-2-BIORAD (1-800-224-6723). Outside the U.S.A., please contact your regional Bio-Rad office for assistance. *Refer to section 16 for non-US local Bio-Rad agent contact information*.

Authorized Representative in the European Community: ***FRANCE:*** *Bio-Rad Labotratories*
3 boulevard Raymond Poincaré
92430 Marnes-la-Coquette
Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33
[fds-msds.fr@bio-rad.com]

Emergency Phone Number: **This SDS is listed with CHEMTREC 1-800-424-9300 / 1-703-527-3887.** Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product. ***Refer to section 16 for non-US local Bio-Rad agent contact information.***

SECTION 2: HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety. Refer to Section 16 for the full text of any *Risk (R)* and *Safety (S)* statement provided below.

Component	Content
Negative Controls BioPlex 2200 APLS IgG Two (2) 1.5 mL vials *Catalog # 663-1930*  **WARNING**	- The APLS IgG negative controls are provided in a human serum matrix made from defibrinated plasma. - Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/HIV-2. - Preserved with **≤ 0.3% ProClin 300** (≤ 0.009% active ingredient)**,** EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with **≤ 0.1% sodium benzoate** [$C_7H_5O_2$•Na], CAS# 532-32-1, EC No 208-534-8 [Not subject to GHS and EU 2008/1272/EC or 1999/45/EC Regulatory requirements.] - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.]

Component	Content
Positive Controls **BioPlex 2200** **APLS IgG** Four (4) 1.5 mL vials *Catalog # 663-1930* **WARNING**	- The APLS IgG positive controls are provided in a human serum matrix made from defibrinated plasma with added IgG, IgM or IgA antibodies to Cardiolipin (CL) and Beta-2 Glycoprotein I (ß2GPI) derived from human disease state plasma. - Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/HIV-2. - Preserved with **≤ 0.3% ProClin 300** (≤ 0.009% active ingredient)**,** EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with **≤ 0.1% sodium benzoate** [$C_7H_5O_2$•Na], CAS# 532-32-1, EC No 208-534-8 [Not subject to GHS and EU 2008/1272/EC or 1999/45/EC Regulatory requirements.] - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.]
Negative Controls **BioPlex 2200** **APLS IgM** Two (2) 1.5 mL vials *Catalog # 663-2030* **WARNING**	- The APLS IgM negative controls are provided in a human serum matrix made from defibrinated plasma. - Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/HIV-2. - Preserved with **≤ 0.3% ProClin 300** (≤ 0.009% active ingredient)**,** EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.] - Controls for **APLS IgM** also contain **Amikacin** (≤ 0.003%), **Cycloheximide** ($C_{15}H_{23}NO_4$) (≤ 0.009%), **Amphotericin B** (≤ 0.002%), **Cefotaxime Sodium** (≤ 0.002%), and **Ciprofloxacin** (≤ 0.005%).
Positive Controls **BioPlex 2200** **APLS IgM** Four (4) 1.5 mL vials *Catalog # 663-2030* **WARNING**	- The APLS IgM positive controls are provided in a human serum matrix made from defibrinated plasma with added IgG, IgM or IgA antibodies to Cardiolipin (CL) and Beta-2 Glycoprotein I (ß2GPI) derived from human disease state plasma. - Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/HIV-2. - Preserved with **≤ 0.3% ProClin 300** (≤ 0.009% active ingredient)**,** EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with **≤ 0.1% sodium benzoate** [$C_7H_5O_2$•Na], CAS# 532-32-1, EC No 208-534-8 [Not subject to GHS and EU 2008/1272/EC or 1999/45/EC Regulatory requirements.] - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.] - Controls for **APLS IgM** also contain **Amikacin** (≤ 0.003%), **Cycloheximide** ($C_{15}H_{23}NO_4$) (≤ 0.009%), **Amphotericin B** (≤ 0.002%), **Cefotaxime Sodium** (≤ 0.002%), and **Ciprofloxacin** (≤ 0.005%).
Negative Controls **BioPlex 2200** **APLS IgA** Two (2) 1.5 mL vials *Catalog # 663-2130* **WARNING**	- The APLS IgA negative controls are provided in a human serum matrix made from defibrinated plasma. - Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/HIV-2. - Preserved with **≤ 0.3% ProClin 300** (≤ 0.009% active ingredient)**,** EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with **≤ 0.1% sodium benzoate** [$C_7H_5O_2$•Na], CAS# 532-32-1, EC No 208-534-8 [Not subject to GHS and EU 2008/1272/EC or 1999/45/EC Regulatory requirements.] - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.]

Component	Content
Positive Controls **BioPlex 2200** **APLS IgA** Four (4) 1.5 mL vials *Catalog # 663-2130*  **WARNING**	- The APLS IgA positive controls are provided in a human serum matrix made from defibrinated plasma with added IgG, IgM or IgA antibodies to Cardiolipin (CL) and Beta-2 Glycoprotein I (ß2GPI) derived from human disease state plasma. - Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/HIV-2. - Preserved with **≤ 0.3% ProClin 300** (≤ 0.009% active ingredient)**,** EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317;, P280; P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with **≤ 0.1% sodium benzoate** [$C_7H_5O_2$•Na], CAS# 532-32-1, EC No 208-534-8 [Not subject to GHS and EU 2008/1272/EC or 1999/45/EC Regulatory requirements.] - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.]

Markings according to the *United Nations* (UN) Globally Harmonized System (GHS), *United States* Hazard Communication Standard (HCS) and *European Community* (EU) 2008/1272/EC guidelines:

This product has been conservatively classified and labeled in accordance with applicable *United Nations (UN)* GHS, *United States* Hazard Communication Standard (HCS) and related *European Community (EC)* 2008/1272/EC guidelines. The following regulated hazardous chemical concentrations are found in product component(s):

≤ 0.3% ProClin 300 [≤ 0.009% active ingredients – reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (C_4H_4ClNOS; CAS# 26172-55-4, EC No 247-500-7) and 2-methyl-2H -isothiazol-3-one (C_4H_5NOS; CAS# 2682-20-4, EC No 220-239-6) (3:1)**]**, EC Index No 613-167-00-5 with CAS# 55965-84-9.

GHS \ 2008/1272/EC Classification *[* denotes precautionary statements included on the product label]*: **Skin Sensitizer Category 1**

Label(s):	**GHS07**
Signal Word:	**WARNING**
Label Hazard Statement:	**H317: May cause an allergic skin reaction.**
Supplemental Hazard Statement:	*None Specified*
Precautionary Statement – Prevention:	**P261**: Avoid breathing mist / vapours / spray **P272**: Contaminated work clothing should not be allowed out of the workplace. **P280**: Wear protective gloves/protective clothing/eye protection/face protection. *
Precautionary Statement – Response:	**P302** + **P352**: IF ON SKIN: Wash with plenty of soap and water. * **P333** + **P313**: If skin irritation or rash occurs: Get medical advice/ attention. *
Precautionary Statement – Storage:	*None Specified*
Precautionary Statement – Disposal:	**P501**: Dispose of contents and container in accordance to local, regional, national and international regulations. *

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Note that the information here is often based on data from the chemical raw material (LD_{50}, exposure limits, etc.) and that the product contains a significantly diluted concentration in an aqueous solution, thus this assessment has taken hazard reduction processing into consideration when possible. The GHS and EU classifications were made according to the latest editions and expanded upon from company and literature data. Refer to Section 16 for the Key / legend to abbreviations and acronyms.

Chemical Ingredient	Data / Information
ProClin 300 [≤ 0.3% (≤ 0.009% active ingredient)]  **WARNING**	Hazardous ingredient concentration in raw material – According to the manufacturer, Supelco, the concentrated preservative is a mixture with 3-3.6% Active Ingredients in 3:1 ratio: 5-chlor-2-methyl-4-isothiazolin-3-one (C_4H_4ClNOS; CAS# 26172-55-4, EC# 247-500-7) and 0.6-1.1% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS; CAS# 2682-20-4, EC# 220-239-6), Index No. 613-167-00-5 and CAS# 55965-84-9. Also contains 91-94% glycol and 3.5-5% Modified Alkyl Carboxylate (no CAS# or formula given for last two). RTECS#: NE — Flash Point: 244° F / 118° C (100%) + LD_{50} (oral-rat): 862 mg/kg (100%) + — LD_{50} (skin-rabbit): 2,800 mg/kg (100%) + PEL/TLV: NE IATA/DOT ID: UN3265, Class 8 (undiluted, 100%) + / IATA/DOT ID: NE (dilution) ++ HMIS codes: H=2, F=0, R=0 ++ — RCRA Code: Non-RCRA ++ EU Classification per 1999/45/EC and 2001/59/EC: Irritant: Xi, R 43; S 24-35-37 (≤ 0.06% and > 0.0015 % Active Ingredient) ++ *GHS / 2008/1272/EC Classification*: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501 ++ The chemical, physical and toxicological properties have not been thoroughly investigated. At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit). **ProClin 300** is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317]. Wear protective gloves/protective clothing/eye protection/face protection [P280]. Contaminated work clothing should not be allowed out of the workplace. Avoid breathing mist/vapours/spray. IF ON SKIN: Wash with plenty of soap and water [P302 + P352]. If skin irritation or rash occurs: Get medical advice/ attention [P333 + P313]. The potential for adverse health effects is unknown for the highly diluted, small volume of **ProClin** in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501] EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Toxic: T, Environmental Danger: N R 23/24/25: Toxic by inhalation, in contact with skin and if swallowed. R 34: Causes burns. R 43: May cause sensitisation by skin contact. R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S (2-): Keep out of the reach of children. S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S 28: After contact with skin, wash immediately with plenty of *soap and water*. S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S 45: In case of accident or if you feel unwell, seek medical advice immediately. S 60: This material and its container must be disposed of as hazardous waste. S 61: Avoid release to the environment. Refer to special instructions/safety data sheets..
Sodium azide [< 0.1%] *CONTINUED ON NEXT PAGE*	CAS#: 26628-22-8 (100%) + — RTECS#: VY8050000 (100%) EC No: 247-852-1 (100%) + Chemical Formula: NaN_3 (100%) + — Flash Point: NE LD50 (oral-rat): 27 mg/kg (100%) + — LC50 (inhalation-rat): 37 mg/m3 (100%) + PEL/TLV: 0.3 mg/m3 (ceiling) (100%) + IATA/DOT ID: UN1687, Class 6.1 (undiluted, 100%) + / IATA/DOT ID: NE (dilution) ++ HMIS codes: H=1, F=0, R=1 ++ — RCRA Code: P105 (undiluted, 100%) + EU Classification per 1999/45/EC: None (due to dilution, < 0.1%); S 35-36 ++ *GHS / 2008/1272/EC Classification: None (due to dilution, < 0.1%)* ++ **Sodium azide** is a biocidal preservative, which may be detrimental if enough is ingested (quantities above those found in the kit). Avoid contact with metals; sodium azide may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up. The potential for adverse health effects is unknown for the highly diluted, small volume of **sodium azide** in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations.

Chemical Ingredient	Data / Information
Sodium azide [< 0.1%] *CONTINUED*	EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - from Annex I to Directive 67/548/EEC: Toxic: T, Environmental Danger: N R 28: Very toxic if swallowed. R 32: Contact with acids liberates very toxic gas. R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S (1/2-): Keep locked up and out of the reach of children. S 28: After contact with skin, wash immediately with plenty of soap and water. S 45: In case of accident or if you feel unwell, seek medical advice immediately. S 60: This material and its container must be disposed of as hazardous waste. S 61: Avoid release to the environment. Refer to special instructions/safety data sheet.

Biological Ingredient	Data / Information
Human Serum [reactive and non-reactive] 	The Human sera in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2) by FDA approved methods. No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *Universal Precautions* when handling these reagents and all human blood or specimens. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* or WHO *Laboratory Biosafety Manua*. Avoid splashing, spills and the generation of aerosols. Secure in secondary containment with proper biohazard labeling. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures with appropriate decon agent or disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg. #1043-87), or equiv.) before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional, national and international regulations. Handle appropriately with the requisite Good Laboratory Practices, *Standard* and *Universal Precautions*. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

+ The Kit Concentration was not tested; the values refer to the solution concentration as tested, designated by Percentage within parentheses.
++ The Kit Concentration was tested or the values given were estimated for the general diagnostic laboratory usage of the kit reagent dilution.
NE: Not Established or Unknown (unable to locate data); typically for concentrate form unless otherwise specified.
Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity.

Related product information:

- Refer to section 2 for the full text of any *GHS* /2008/1272/EC statement coded above.
  Refer to section 16 for the full text of any *Risk (R)* and *Safety (S)* statement for the above kit component concentration.
- According to the concept of *Universal Precautions* (29 CFR 1910.1030), all human blood and certain human body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens. No known test method can offer complete assurance that products derived from human blood will not transmit infection; thus, they should be handled as though they contain infectious agents. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.
- Do not eat, drink or smoke when using this product
- Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

SECTION 4: EMERGENCY FIRST AID MEASURES

Health Effects:	Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. May cause allergic skin reaction upon repeated exposure; generally at concentrations and volumes that greatly exceed that of this kit. Call a POISON CENTER or doctor/physician if you feel unwell.
Eye Contact:	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
Skin Contact:	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs, or if more severe symptoms develop, consult a physician.
Inhalation:	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
If Swallowed:	If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
Notes to Physician:	According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered hepatitis B vaccination prior to working with human source material**.**

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Combustion Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
Special Firefighting Procedures:	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab Personal Protective Equipment (PPE) including gloves, lab coat and eye/face protection.
- In the event of a hazardous material spill, contain the spill if it is safe to do so and immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.
- Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA hazardous material spill and/or NFPA/Fire Code guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. Avoid release to the environment.
- Wear appropriate PPE. Immediately, and on-site if possible, Decontaminate Biohazard/Human Source Material spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon agent or disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% Ethanol or Isopropanol, an iodophor (such as Wescodyne Plus), or a phenolic, etc.).
- Clean the spill area with water and wipe dry. Spills can also be absorbed with appropriate inert materials (e.g. spill pillows, absorbent pads, etc.), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, Chemical and Laboratory wastes must be handled and discarded in accordance with all local, regional, national and international regulations.
- Refer to Sections 8 and 13 for more specifics.

SECTION 7: HANDLING AND STORAGE INFORMATION

Handling:	This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper good laboratory practices and safety guidelines for handling chemical, biological and laboratory hazards. Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all human source specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per *Standard* and *Universal Precautions*. All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics. Avoid release to the environment. Do not allow undiluted product hazardous chemical ingredient or large quantities of it to reach ground water or water course. Consult with your Environmental Health & Safety Office for assistance.
Storage:	Store the kit components as specified on the product label and/or in the product instructions provided with the test kit.
Caution, consult accompanying documents. Refer to the *Instructions For Use / Package Insert* for additional product information. Read and follow *BioPlex® 2200 System Instrument Manual* instructions.	
This product is intended for use with the Bio-Rad BioPlex® 2200 System.	

SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES

Control Parameters – *Component chemicals with limit values that require monitoring at the workplace*:

Sodium Azide [CAS# 26628-22-8]:		
REL (United States) *TLV (United States)*	*Short-term value: C 0.3** mg/m³, C 0.1* ppm* *Short-term value: C 0.29** mg/m³, C 0.11* ppm*	**as HN_3 vapor; **as NaN_3; Skin* **as HN_3 vapor **as NaN_3*
EL (Canada)	*Short-term value: C 0,29* mg/m³, C 0,11**ppm*	**sodium azide;**hydrazoic acid vapour*
IOELV (European Union)	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	*Skin* *Skin*
WEL (United Kingdom)	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	*(as NaN_3) Sk* *(as NaN_3) Sk*
NES (AUS)	*0.3* mg/m³, 0.11 ppm*	**Peak limitation*
VME (France)	*Short-term value: 0,3 mg/m³, 0,1 ppm*	*risque de pénétration percutanée*
VL (Belgium, (France)	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	*D, M* *D, M*
AGW (Germany)	0,2 mg/m³	2(I);DFG
MAK (Austria, (Germany))	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	
TWA (Italy)	*Short-term value: C 0,29 mg/m³, C 0,11* ppm* *A4; sodio azide; *come azido idrazonico, vapore*	
MAK (Switzerland, (Germany))	*Short-term value: 0,4 e mg/m³* *Long-term value: 0,2 e mg/m³*	
GV (Denmark)	*0,1 mg/m³*	*EH*
MAK (Netherland)	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	
OEL (Sweden)	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	*H* *H*

Additional information: The lists that were valid during the creation were used as basis.

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes and eyes, or hazardous inhalation, under normal conditions of use and for the time during which the protective equipment is utilized**:**

Ventilation:	Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material / patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.
Eye / Face Protection:	Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.
Protective Gloves:	Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves, such as Nitrile, Neoprene and Vinyl, are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never be reused. Wash hands thoroughly after removing gloves.
Respiratory Protection:	Do not breathe mist / vapours / spray.
Protective Clothing:	Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.
Other:	All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal.
Note:	Occupational Exposure limit values and health hazard data were given in section 3. Environmental Controls are included in following sections.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Amber colored aqueous liquids.		
Odour:	No applicable information was found.	**Odour threshold:**	Not established.
pH:	The liquid chemical components are between pH 6 and 8.		
Boiling point:	Undetermined.	**Melting point:**	Undetermined.
Flash point:	Not Applicable. Flammable limits: LEL/LFL is Not applicable; UEL/UFL is Not applicable.		
Evaporation rate:	No applicable information was found.		
Fire hazard:	Although the components have not been tested for fire hazard and explosion data, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.		
Vapor pressure:	No applicable information was found.		
Vapor density:	No applicable information was found.		
Relative density:	Approximately 1.		
Solubility:	Miscible in water.		
Partition coefficient (n-octanol/water):	No applicable information was found.		
Auto igniting:	Product is not known to be self-igniting.		
Decomposition temperature:	No applicable information was found.		
Viscosity:	No applicable information was found.		
Danger of explosion:	**Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up.		
No Other Standard Characteristics applicable to the identification or hazards of the product are known.			

SECTION 10: STABILITY AND REACTIVITY INFORMATION

NOTE: Chemical reactions that could result in a hazardous situation (e.g. generation of flammable or toxic chemicals, fire or detonation) are listed here. Although not intended to be complete, an overview of important reactions involving common chemicals is provided to assist in the development of safe work practices.

Chemical Stability / Reactivity:	Components are stable with no known inherent significant reactivity.
Conditions and/or Materials to Avoid:	**Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up.
Hazardous Decomposition Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
Hazardous Polymerization:	Has not been reported to occur.

SECTION 11: TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE

Refer to Sections 2 and 3 for the kit component concentrations. The composite toxicological information for this product is:

Acute Health Effects

Toxicity:	May be detrimental if enough is ingested (typically in quantities above those found in the kit).
Primary Irritant Effect:	May slightly irritate respiratory system, eyes or skin, depending on amount and contact time.
Serious Eye Damage / Irritation:	May slightly irritate eyes, depending on amount and contact time.
STOT-Single Exposure:	No applicable information was found.
STOT-Repeated Exposure:	No applicable information was found.
Aspiration Hazard:	No applicable information was found.
Other Acute Health Effects:	No significant other acute health effect known.

Biohazard Potential:

Each human donor unit used to manufacture this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human agents capable of transmitting infectious disease. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens. Employ *Standard* and *Universal Precautions*; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* or WHO *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Sensitization:	May cause an allergic skin reaction. Contains a small volume of a very dilute, sensitizing preservative (**ProClin 300**); though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown, thus handle accordingly.
Carcinogenicity:	No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC or OSHA.
Germ Cell Mutagenicity:	No applicable information was found.
Reproductive hazard:	**Cycloheximide** is known to the State of California to cause developmental toxicity. (Note: This designation is for concentrated Cycloheximide, which is diluted to < 0.01% in the kit component.)

Additional Toxicological Information; The chemical, physical and toxicological properties have not been thoroughly investigated.

SECTION 12: ECOLOGICAL INFORMATION

This product was not tested. The following assessment is based on information for the ingredients.	
Ecotoxicity:	**100% Sodium Azide [CAS# 26628-22-8]***: Fish LC_{50} - Lepomis macrochirus - 0.68 mg/l - 96 h Daphnia EC_{50} - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h * *Source: Raw Material Vendor Safety Data Sheet*
Persistence and degradability:	No information found.
Bioaccumulation potential:	No information found.
Mobility in soil:	No information found.
PBT and vPvB assessment:	No information found.
Other adverse affects:	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Avoid release to the environment.

General notes: Water hazard class 1 (Self-assessment): slightly hazardous for water.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional, national and international regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the kit components may change waste management requirements and options. Contact your Environmental Health & Safety Office for your specific disposal procedures.

Recommended Product Disposal:

- **Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up; check your international, national, regional and local ordinances accordingly.
- All **human source** and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your international, national, regional and local ordinances accordingly.

Do not allow undiluted product or large quantities of it to reach ground water or water course.

Recommended Unclean Packaging Disposal: Dispose in accordance with all applicable local, regional, national and international regulations.

SECTION 14: TRANSPORT INFORMATION

Shipping of product, packaging and waste must be conducted in accordance with all applicable local, regional, national and international regulations. Processing, use or contamination of the kit components may change shipping requirements and options. Contact your Environmental Health & Safety Office for your specific shipping procedures.

Recommended Unused Product Multi-Modal Transportation: According to US DOT, IATA and UN "Model Regulations", the product must be transported as follows: No known transport restrictions.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

SECTION 15: REGULATORY INFORMATION

Composite HMIS Rating: Health: 2 Flammability: 0 Reactivity: 1

California Proposition 65: WARNING: THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE REPRODUCTIVE TOXICITY.

Chemicals known to cause reproductive Toxicity: **Cycloheximide**, CAS# 66-81-9.

Note: Because he Cyclohexamide is diluted well below the 1% standard cutoff for hazardous material designation, the product does not classify as hazardous under OSHA 29 CFR 1910.1200 / 2008/1272/EC / or GHS regulation. Conversely, California Proposition 65 does not have a minimum cutoff for these chemicals.

Carcinogenicity Categories: No component, mixture or constituent has been classified as a carcinogen by NTP (National Toxicity Program), IARC (International Agency for Research on Cancer), TLV-CAR (Threshold Limit Value established by ACGIH) or OSHA (Occupational Health and Safety Administration, U.S. Department of Labor).

National Regulations:

WHMIS Classification: This SDS contains the required information in accordance with the **Workplace Hazardous Materials Information System (WHMIS) Canadian Standard** for the hazard classification criteria for this product.

Mexican Standard: This SDS contains the required information for preparation in accordance with the **Mexican Standard (NMX-R-019-SCFI-2011)** *SISTEMA ARMONIZADO DE CLASIFICACIÓN Y COMUNICACIÓN DE PELIGROS DE LOS PRODUCTOS QUÍMICOS GLOBALLY HARMONIZED SYSTEM (GHS)*.

Australian Code: This SDS contains the required information for preparation in accordance with the *Australian Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety Act**). *Australian Inventory of Chemical Substances*: All pertinent ingredients are listed.

Water hazard class: Water hazard class 1(German Regulation) (Self-assessment): slightly hazardous for water.

Markings according to European Community 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC guidelines:
This product has been classified and labeled in accordance with applicable *European Community (EC) Directives* 1999/45/EC, 2001/59/EC, 2001/60/EC and 2006/102/EC.

Hazard Designation of Composite Product: IRRITANT: Xi 

Hazard Determining substance(s) of labeling: **≤ 0.3% ProClin 300**, per 2001/59/EC Index No 613-167-00-5 with CAS# 55965-84-9 [Irritant: Xi; R 43; S 24-35-37 (≤ 0.06% and > 0.0015% Active Ingredient).]

SECTION 16: OTHER INFORMATION

Risk Phrases:

R 43	May cause sensitisation by skin contact.
Caution	Contains human source material. Handle as if capable of transmitting potentially infectious agents (Universal Precautions).

Safety Phrases:

S 24	Avoid contact with skin.
S 35	This material and its container must be disposed of in a safe way.
S 37	Wear suitable gloves.
S 56	Dispose of this material and its container to hazardous or special waste collection point.

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

This product is intended for use with the Bio-Rad BioPlex® 2200 System

Sources of key data used to compile the Safety Data Sheet:
Raw Material Vendor Safety Data Sheets
United Nations (UN) Globally Harmonized System (GHS)
United States OSHA Hazard Communication Standard (HCS) 1910.1200
Canadian Workplace Hazardous Materials Information System (WHMIS)
European Community (EC) Regulations 2008/1272/EC, 2010/453/EC, 2006/1907/EC
Mexican Standard *(NMX-R-019-SCFI-2011)*

Australian Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the Work Health and Safety Act)
EU Directives 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC
Registry of Toxic Effects of Chemical Substances (RTECS)
International Agency for Research on Cancer (IARC)
American Conference of Governmental Industrial Hygienists (ACGIH)
Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)
National Toxicity Program (NTP)
National Institute for Occupational Safety and Health (NIOSH)
World Health Organization. *Laboratory Biosafety Manual*
CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
Australian Inventory of Chemical Substances (ACIS) [7-27-2012]
California Proposition 65

Chemical safety assessment: Mixtures covered in this SDS were classified using the EU Regulation 1272/2008/EC and/or UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Fourth edition unless otherwise specified.

Key / legend to abbreviations and acronyms used in the safety data sheet:
ACGIH – American Conference of Governmental Industrial Hygienists
ACIS – Australian Inventory of Chemical Substances
ANSI – American National Standards Institute
CAS – Chemical Abstracts Service
CDC – Centers for Disease Control, USA
CNS – Central Nervous System
DOT – Department of Transportation
EC_{50} – half maximal effective concentration
EU – European Union
GHS – Globally Harmonized System
HCS – Hazard Communication Standard, USA
IARC – International Agency for Research on Cancer
IATA – International Air Transport Association
ICAO - International Civil Aviation Organization
IDLH – Immediately Dangerous to Life or Health
IMDG – International Maritime Dangerous Goods
IPCS – International Programme on Chemical Safety
LC_{50} – median lethal concentration, 50%
LD_{50} – median lethal dose, 50%
NIOSH – National Institute for Occupational Safety and Health
NTP – National Toxicity Program
OEL – Occupational Exposure Limit
PEL – Permissible Exposure Limit
ppm – parts per million
RTECS – Registry of Toxic Effects of Chemical Substances
SDS – Safety Data Sheet
STEL – Short Term Exposure Limit
TLV/TWA – Threshold Limit Value / Time-Weighted Average
UN – United Nations
US EPA – United States Environmental Protection Agency
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
WHMIS –Workplace Hazardous Materials Information System (Canadian)
WHO – World Health Organization (United Nations)

Additional information: The lists that were valid during the creation were used as basis.

This Revision: Reviewed existing information and made minor updates.

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