

MATERIAL SAFETY DATA SHEET

IDENTIFICATION OF PRODUCT (SUBSTANCE) AND SUPPLIER (1):

Product Name:	BioPlex® 2200APLS IgG, IgM and IgA Reagent Packs
Product Number:	665-1950 [APLS IgG Reagent Pack] (100 tests) 665-2050 [APLS IgM Reagent Pack] (100 tests) 665-2150 [APLS IgA Reagent Pack] (100 tests)
Intended Use:	The BioPlex 2200 Antiphospholipid Syndrome (APLS) IgG, IgM and IgA kits are multiplex flow immunoassays intended for the semi-quantitative detection of IgG, IgM and IgA antibodies to Cardiolipin (CL) and Beta-2 Glycoprotein I (β_2 GPI) in human serum and heparinized or citrated plasma. In conjunction with other clinical findings, the test systems are used as an aid in the diagnosis of primary Antiphospholipid Syndrome (APS) and those secondary to systemic lupus erythematosus (SLE) or SLE-like disorders. The BioPlex 2200 APLS IgG, IgM and IgA kits are intended for use with the Bio-Rad BioPlex 2200 System.
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 PST)
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. <i>Refer to section 16 for non-US local Bio-Rad agent contact information.</i>
Authorized Representative in the European Community:	FRANCE, Bio-Rad 3 boulevard Raymond Poincaré 92430 Marnes-la-Coquette Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33 [biorecherche.techsupport@bio-rad.com]
Emergency Phone Number:	This MSDS 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. Canada: 1-514-334-4372 United Kingdom: +44-(0)20-8328-2000 France: +33 (0) 1 47 95 60 00

HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (2):

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.

BioPlex® 2200APLS IgG, IgM, IgA Reagent Packs

[Catalog 665-1950, 665-2050, 665-2150]

Component	Content
Bead Set One (1) 10 mL vial (Faint brown liquid)  WARNING!	- Dyed beads coated with CL and β_2GPI; an Internal Standard bead (ISB), a Serum Verification bead (SVB), and a Reagent Blank bead (RBB) in a MOPS (3-[N-Morpholino] propanesulfonic acid) [CAS# 1132-61-2] buffer (pH 7.4).supplemented with Glycerol and protein stabilizers (porcine). - 50-100% water [H₂O] CAS# 7732-18-5, EC No 231-791-2 [Not subject to GHS and EU 2008/1272/EC regulatory requirements.] - ≤ 20% Glycerol [C₃H₈O₃], CAS# 56-81-5, EC No 200-289-5 [Not subject to GHS and EU 2008/1272/EC regulatory requirements.] - < 1% MOPS free acid buffer (3-[N-Morpholino]propanesulfonic acid - C₄H₈ON(CH₃)₃SO₃H], CAS# 1132-61-2, EC No 214-478-5 [< 20% dilution is not subject to GHS and EU 2008/1272/EC Regulation or 1999/45/EC Directive labeling requirements.] - < 0.1% Sodium chloride [NaCl], CAS# 7647-14-5, EC No 231-598-3. [Not subject to GHS and EU 2008/1272/EC regulatory requirements.] - 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; P261, P272, P280; P312, P363, 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 [NaN₃], 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.] - Preserved with ≤ 0.1% sodium benzoate [C₇H₅O₂•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.]
Conjugate One (1) 5 mL vial (Pink aqueous liquid)  WARNING!	- Phycoerythrin conjugated murine monoclonal anti-human IgG, IgM or IgA antibody and phycoerythrin conjugated murine monoclonal anti-human FXIII antibody in MOPS (3-[N-Morpholino] propanesulfonic acid) buffer supplemented with protein stabilizers (bovine, CAS# 9048-46-8) (pH 7.4). - 50-100% water [H₂O] CAS# 7732-18-5, EC No 231-791-2 [Not subject to GHS and EU 2008/1272/EC regulatory requirements.] - < 2% MOPS free acid buffer (3-[N-Morpholino]propanesulfonic acid - C₄H₈ON(CH₃)₃SO₃H], CAS# 1132-61-2, EC No 214-478-5 [< 20% dilution is not subject to GHS and EU 2008/1272/EC Regulation or 1999/45/EC Directive labeling requirements.] - < 1% Sodium chloride [NaCl], CAS# 7647-14-5, EC No 231-598-3. [Not subject to GHS and EU 2008/1272/EC regulatory requirements.] - 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; P261, P272, P280; P312, P363, 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 [NaN₃], 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.] - Preserved with ≤ 0.1% sodium benzoate [C₇H₅O₂•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.]
Sample Diluent One (1) 10 mL vial (Yellow aqueous liquid)  WARNING!	- Buffer with protein stabilizers (bovine and murine) and bovine serum albumin (CAS# 9048-46-8) (pH 7.4). - 50-100% water [H₂O] CAS# 7732-18-5, EC No 231-791-2 [Not subject to GHS and EU 2008/1272/EC regulatory requirements.] - < 2% Sodium chloride [NaCl], CAS# 7647-14-5, EC No 231-598-3. [Not subject to GHS and EU 2008/1272/EC regulatory requirements.] - < 1% Magnesium Chloride Hexahydrate [MgCl₂•6H₂O], CAS# 7791-18-6; EC No 232-094-6 [Not subject to GHS and EU 2008/1272/EC Regulation requirements.] - ≤ 1% Triethanolamine hydrochloride [C₆H₁₅NO₃•HCl] CAS 637-39-8, EC No 211-284-2. [Dilution is not subject to GHS and EU 2008/1272/EC Regulation or 1999/45/EC Directive labeling requirements.] - 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; P261, P272, P280; P312, P363, 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 [NaN₃], 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.] - Preserved with ≤ 0.1% sodium benzoate [C₇H₅O₂•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.]

Markings according to the United Nations (UN) Globally Harmonized System (GHS) and European Community (EU) 2008/1272/EC guidelines:

This product has been conservatively classified and labeled in accordance with applicable *United Nations (UN)* GHS 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 (EC No 247-500-7) and 2-methyl-2H -isothiazol-3-one (EC No 220-239-6) (3:1)], EC Index No 613-167-00-5 with CAS# 55965-84-9.

GHS \ 2008/1272/EC Classification:

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 dust/fume/ gas/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:

P312: Call a POISON CENTER or doctor/physician if you feel unwell.

P363: Wash contaminated clothing before reuse.

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.

COMPOSITION/INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS (3):

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 (LD₅₀, 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 the *Key* below)

Chemical Ingredient	Chemical Data / Information
Sodium azide [< 0.1%]	CAS#: 26628-22-8 (100%) + RTECS#: VY8050000 (100%) EC No: 247-852-1 (100%) + Chemical Formula: NaN ₃ (100%) + Flash Point: NE LD ₅₀ (oral-rat): 27 mg/kg (100%) + LC ₅₀ (inhalation-rat): 37 mg/m ³ (100%) + PEL/TLV: 0.3 mg/m ³ (ceiling) (100%) + IATA/DOT ID: UN1687 (undiluted, 100%) + 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.

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Chemical Ingredient	Chemical 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 of 4 ingredients: 2.1-2.9% 5-chlor-2-methyl-4-isothiazolin-3-one (C₄H₄ClNOS; CAS# 26172-55-4), 0.6-1.1% 2-methyl-4-isothiazolin-3-one (C₄H₅NOS; CAS# 2682-20-4), 91-94% glycol and 2.1-2.9% Modified Alkyl Carboxylate (no CAS# or formula given for last two). Note that this ratio of active ingredients is listed in 2001/59/EC under Index No. 613-167-00-5 with the CAS# 55965-84-9. RTECS#: NE Flash Point: 121° F / 49.4° C (100%) + LD₅₀ (oral-rat): 3600 mg/kg (100%) + PEL/TLV: NE IATA/DOT ID: UN1760 (undiluted, 100%) + 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; P261, P272, P280; P312, P363, 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. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/ attention. Call a POISON CENTER or doctor/physician if you feel unwell. 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.
Glycerol [< 20% in the Bead Set]	CAS#: 56-81-5 (100%) + RTECS#: MA8050000 (100%) + EC No: 200-289-5 (100%) + Flash Point: 320 F / 160° C (100%) + Chemical Formula: C₃H₈O₃ (100%) + LD₅₀ (oral-rat): 12,600 mg/kg (100%) + LC₅₀ (inhalation-rat): > 570 mg/m³/1H (100%) + TLV and PEL: 10 mg/m³ total mist (100%) + IATA/DOT ID: NE HMIS codes: H=1, F=0, R=1 ++ RCRA Code: NE EU Classification per 1999/45/EC: None ++ GHS / 2008/1272/EC Classification: Not subject to EU 2008/1272/EC and GHS regulatory requirements. ++ Keep glycerol solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulation.
Animal proteins	This material is of animal origin (bovine, porcine and murine) and may be a potential contact irritant. Hazard Unknown. Handle as potentially infectious. The chemical, physical and toxicological properties have not been thoroughly investigated. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulation.
Human Plasma Derived Antigen [Bead Set component]	Highly purified, human plasma derived antigens may be incorporated onto certain BioPlex 2200 dyed beads. 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 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. 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% Vespene (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 and Universal Precautions. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

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Key:

- + 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.
- GHS = Globally Harmonized System
- RTECS # - Registry of Toxic Effects of Chemical Substances number
- PEL - Permissible Exposure Limit / Occupational Exposure Limit (OEL)
- TLV/TWA - Threshold Limit Value / Time-Weighted Average
- STEL - Short Term Exposure Limit
- IDLH - Immediately Dangerous to Life or Health

General Kit Composite Health Hazards:

- ◆ No significant adverse health effects are expected by any route for the miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water, dyes, catalytic or other non-reactive ingredients, in the kit volumes and/or concentrations present.
- ◆ 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.
- ◆ Wear protective gloves/protective clothing/eye protection/face protection. Do not eat, drink or smoke when using this product.

EMERGENCY FIRST AID MEASURES (4):

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.

FIREFIGHTING MEASURES (5):

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
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.

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ACCIDENTAL RELEASE MEASURES (6):

- ◆ 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. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.
- ◆ IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
- ◆ 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.

HANDLING AND STORAGE INFORMATION (7):

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. 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 Universal Precautions. Refer to Section 8 for more specifics. 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, read accompanying material. Refer to the *Instructions For Use / Package Insert* for additional product information. Read and follow *BioPlex® 2200 System Instrument Manual* instructions.

EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):

Components with limit values that require monitoring at the workplace:

Sodium Azide [26628-22-8]:	
REL (United States)	Short-term value: C 0.3** mg/m ³ , C 0.1* ppm *as HN ₃ vapor; **as NaN ₃ ; Skin
TLV (United States)	Short-term value: C 0.29** mg/m ³ , C 0.11* ppm *as HN ₃ vapor **as NaN ₃
EL (Canada (LSG) English)	Short-term value: C 0,29* mg/m ³ , C 0,11**ppm *sodium azide, **hydrazoic acid vapour
IOELV (European Union)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³ Skin
WEL (Great Britain, (English))	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³ (as NaN ₃) Sk

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Sodium Azide [26628-22-8]:	
NES (AUS)	0.3* mg/m ³ , 0.11 ppm *Peak limitation
VME (France, (French))	Short-term value: 0,3 mg/m ³ , 0,1 ppm risque de pénétration percutanée
VL (Belgium, (French))	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³ D, M
AGW (Germany, (German))	0,2 mg/m ³ 2(I);DFG
MAK (Austria, (German))	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³
TWA (Italy, (Italian))	Short-term value: C 0,29 mg/m ³ , C 0,11* ppm A4; sodio azide; *come azido idrazonico, vapore
MAK (Switzerland, (German))	Short-term value: 0,4 e mg/m ³ Long-term value: 0,2 e mg/m ³
GV (Denmark, (Danish))	0,1 mg/m ³ EH
MAK (Netherland, (Dutch))	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³
OEL (Sweden, (Swedish))	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³ H

Glycerol [56-81-5]:	
PEL (United States)	15* 5** mg/m ³ *total dust **respirable fraction
TLV (United States)	10* ppm *Mist
EL (Canada (LSG) English)	10* 3** mg/m ³ *mist; **mist, resirable
WEL (Great Britain, (English))	10 mg/m ³
NES (AUS)	10 mg/m ³
VME (France, (French))	10 mg/m ³
VL (Belgium, (French))	10 mg/m ³
MAK (Germany, (German))	50E mg/m ³
TWA (Italy, (Italian))	10 mg/m ³
MAK (Switzerland, (German))	Short-term value: 100 e mg/m ³ Long-term value: 50 e mg/m ³
WEL ()	Long-term value: 10 mg/m ³

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.
- Respiratory Protection: Do not breathe mist / vapours / spray.
- Eye 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.

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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.
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. Protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent pads used to cover equipment and/or surfaces must be removed and replaced if they become overtly contaminated.
Note:	Occupational Exposure limit values and health hazard data were given in section 3. Environmental Controls are included in following sections.

PHYSICAL AND CHEMICAL PROPERTIES (9):

Appearance:	Plastic cartridge containing various bottles with aqueous solutions
pH:	The liquid chemical components are between pH 6 and 8.
Boiling Point:	Undetermined.
Melting Point:	Undetermined.
Flash Point:	Not Applicable.
Fire Hazard:	Although the components have not been tested for fire hazard and explosion data, being water-based, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.
Auto Igniting:	Product is not known to be self-igniting.
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. Keep Glycerol solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures.
Specific gravity:	Approximately 1.
Solubility:	The liquid chemical components are soluble in water. The bead set is not miscible or is difficult to mix.
No Other Standard Characteristics applicable to the identification or hazards of the kit are known.	

STABILITY AND REACTIVITY INFORMATION (10):

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.

Stability:	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. Keep Glycerol solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures.

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Hazardous Decomposition: Oxides of carbon or nitrogen may form when heated to decomposition.

Products:

Hazardous Polymerization: Has not been reported to occur.

TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):

Refer to Section 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: Irritating to eyes and skin.
Other Acute Health Effects: No significant other acute health effect known.

Biohazard Potential:

Highly purified, human plasma derived antigens may be incorporated onto certain BioPlex 2200 dyed beads. 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.

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.
Reproductive hazard: No reproductive toxic effect known.

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

ECOLOGICAL INFORMATION (12):

This information is not available.

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

DISPOSAL CONSIDERATIONS (13):

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.

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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.

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

TRANSPORT INFORMATION (14):

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: No known transport restrictions.

REGULATORY INFORMATION (15):

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

California Proposition 65: The Product does not contain listed substances.

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.

WHMIS Classification: This MSDS contains the required information in accordance with the WHMIS hazard classification criteria for this product.

National Regulations:

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 (rated under 1999/45/EC unless otherwise specified):

≤ 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).]

OTHER INFORMATION (16):**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.

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- 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.

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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