

MATERIAL SAFETY DATA SHEET

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

Product Name: BioPlex® 2200 System Syphilis IgM (*T. pallidum*) Reagent Pack

Product Number: 665-1550 (100 tests)

Intended Use: The Bio-Rad Syphilis IgM kit is a multiplex flow immunoassay intended for the qualitative detection of *Treponema pallidum* IgM (*T. pallidum*) antibodies in human serum. The test system can be used in conjunction with a syphilis IgG test as a screen of active or past infection. In addition, the Syphilis IgM kit can be used in conjunction with treponemal and/or non-treponemal tests as an aid in the identification of acute infection with *T. pallidum*. The Syphilis IgM test is intended for use with the Bio-Rad BioPlex 2200 System. The BioPlex 2200 Syphilis IgM kit is not intended for use in screening blood or plasma donors.

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)


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
3 boulevard Raymond Poincaré
92430 Marnes-la-Coquette
Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33
[\[fds-msds.fr@bio-rad.com\]](mailto:fds-msds.fr@bio-rad.com) or [\[fds.msds@bio-rad.com\]](mailto:fds.msds@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. Refer to section 16 for non-US local Bio-Rad agent contact information.

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. Refer to Section 16 for the full text of each *Risk (R)* and *Safety (S)* statement provided below.

Component	Content
<p>Conjugate BioPlex 2200 Syphilis IgM One (1) 5 mL vial (Pink aqueous liquid)</p> <div style="text-align: center; margin-top: 20px;">  WARNING! </div>	<ul style="list-style-type: none"> - Donkey anti-human IgM/phycoerythrin conjugate and murine monoclonal anti- human FXIII/phycoerythrin conjugate, with protein stabilizers (bovine CAS# 9048-46-8) in a phosphate buffer (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.] - < 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; P272, P280; P302 + P352, P309 + 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 [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.] - 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.]

Component	Content
<p>Bead Set BioPlex 2200 Syphilis IgM One (1) 10 mL vial (Faint brown liquid)</p>  <p>WARNING!</p>	<ul style="list-style-type: none"> - Dyed beads coated with affinity-purified E. coli derived recombinant proteins T. pallidum (17 kDa, and 47 kDa) an Internal Standard (ISB), a Serum Verification (SVB), and a Reagent Blank (RBB), with Glycerol and protein stabilizers (bovine CAS# 9048-46-8) in a MOPS (3-[N-Morpholino] propanesulfonic acid) [CAS# 1132-61-2] buffer (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.] - < 20% Glycerol [C₃H₈O₃], CAS# 56-81-5, EC No 200-289-5 [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% 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.] - 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; P272, P280; P302 + P352, P309 + 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 [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.] - 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.]
<p>Sample Diluent BioPlex 2200 Syphilis IgM One (1) 10 mL vial (Yellow aqueous liquid)</p>  <p>WARNING!</p>	<ul style="list-style-type: none"> - Goat anti-human IgG and protein stabilizers (bovine, CAS# 9048-46-8) in a HEPES (4-[2-hydroxyethyl]-1-piperazineethanesulfonic acid, CAS# 7365-45-9) buffer (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% HEPES (4-[2-hydroxyethyl]-1-piperazineethanesulfonic acid), CAS# 7365-45-9; EC No 230-907-9 [Not subject to GHS and EU 2008/1272/EC Regulation 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; P272, P280; P302 + P352, P309 + 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 [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.] - 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.]

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 [* denotes precautionary statements included on the product label]:




<u>Label(s):</u>	GHS07
<u>Signal Word:</u>	WARNING!
<u>Label Hazard Statement:</u>	H317: May cause an allergic skin reaction.
<u>Supplemental Hazard Statement:</u>	<i>None Specified</i>
<u>Precautionary Statement – Prevention:</u>	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. *
<u>Precautionary Statement – Response:</u>	P302 + P352: IF ON SKIN: Wash with plenty of soap and water. * P309 + P313: If exposed or if you feel unwell: Get medical advice/ attention. *
<u>Precautionary Statement – Storage:</u>	<i>None Specified</i>
<u>Precautionary Statement – Disposal:</u>	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 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	Data / Information
Glycerol [< 20% in the Bead Set]	CAS#: 56-81-5 (100%) + EC No: 200-289-5 (100%) + Chemical Formula: C ₃ H ₈ O ₃ (100%) + LD ₅₀ (oral-rat): 12,600 mg/kg (100%) + TLV and PEL: 10 mg/m ³ total mist (100%) + IATA/DOT ID: NE HMIS Codes: H=1, F=0, R=1 ++ 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. EU Classification per 1999/45/EC: None ++ EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - <i>from Annex I to Directive 67/548/EEC</i> : Not Listed RTECS#: MA8050000 (100%) + Flash Point: 320 F / 160° C (100%) + LC ₅₀ (inhalation-rat): > 570 mg/m ³ /1H (100%) + RCRA Code: NE

Chemical Ingredient	Data / Information
<p>ProClin 300 [≤ 0.3% (≤ 0.009% active ingredient)]</p>  <p>WARNING!</p>	<p>Hazardous ingredient concentration in raw material - According to the supplier, Sigma-Aldrich, the concentrated preservative is a mixture with 3-3.6% Active Ingredients in 3:1 ratio: 5-chlor-2-methyl-4-isothiazolin-3-one (C₄H₄CINOS) and 2-methyl-4-isothiazolin-3-one (C₄H₅NOS), 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).</p> <p>RTECS#: NE Flash Point: 244° F / 118° C (100%) + LD₅₀ (oral-rat): 862 mg/kg (100%) + LD₅₀ (skin-rabbit): 2,800 mg/kg (100%) + PEL/TLV: NE IATA/DOT ID: UN3265, Class 8 (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) ++ <i>GHS / 2008/1272/EC Classification:</i> WARNING! GHS07; H317; P272, P280; P302 + P352, P309 + 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 [P272]. 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. If exposed or if you feel unwell: Get medical advice/ attention [P309 + 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 - <i>from Annex I to Directive 67/548/EEC:</i> 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 <i>soap and water</i>. 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.</p>
<p>Sodium azide [< 0.1%]</p> <p><i>CONTINUED ON NEXT PAGE</i></p>	<p>CAS#: 26628-22-8 (100%) + EC No: 247-852-1 (100%) + Chemical Formula: NaN₃ (100%) + LD₅₀ (oral-rat): 27 mg/kg (100%) + PEL/TLV: 0.3 mg/m³ (ceiling) (100%) + HMIS Codes: H=1, F=0, R=1 ++ EU Classification per 1999/45/EC: None (due to dilution, < 0.1%); S 35-36 ++ <i>GHS / 2008/1272/EC Classification:</i> 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.</p> <p>RTECS#: VY8050000 (100%) Flash Point: NE LC₅₀ (inhalation-rat): 37 mg/m³ (100%) + IATA/DOT ID: UN1687 (undiluted, 100%) + RCRA Code: P105 (undiluted, 100%) +</p>

Chemical Ingredient	Data / Information
Sodium azide [< 0.1%] CONTINUED	EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - <i>from Annex I to Directive 67/548/EEC</i> : 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 <i>soap and water</i> . 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
Animal proteins	This material is of animal origin (bovine, goat 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.

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

Related product information:

- ◆ Refer to section 2 for the full text of each *GHS* /2008/1272/EC statement coded above.
Refer to section 16 for the full text of each *Risk* (R) and *Safety* (S) statement for the above kit component concentration.
- ◆ No significant adverse health effects are expected by any route for the sodium chloride, miscellaneous salts, MOPS free acid buffer, HEPES buffer, buffers, protein-stabilizers, antibodies, conjugates, water, dyes, sodium benzoate, catalytic or other non-reactive ingredients, in the kit volumes and/or concentrations present [dilution not subject to EU or GHS hazard labeling].
- ◆ 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.

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.
Hazardous Decomposition 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.

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. 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. 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.

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. 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 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, read accompanying material. Refer to the *Instructions For Use / Package Insert* for additional product information. Read and follow *BioPlex[®] 2200 System Instrument Manual* instructions.

For *in vitro* diagnostic use.

EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):

Control Parameters – Components with limit values that require monitoring at the workplace:

Sodium Azide [CAS# 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 Skin
WEL (Great Britain)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	(as NaN ₃) Sk (as NaN ₃) Sk
NES (AUS)	0.3* mg/m ³ , 0.11 ppm	*Peak limitation
VME (France)	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 D, M
AGW (Germany)	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)	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)	0,1 mg/m ³	EH
MAK (Netherland)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	
OEL (Sweden)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	H H

Glycerol [CAS# 56-81-5]:		
REL (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)	10 mg/m ³	
NES (AUS)	10 mg/m ³	
VME (France)	10 mg/m ³	
VL (Belgium, (French))	10 mg/m ³	
MAK (Germany)	50E mg/m ³	
TWA (Italy)	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.
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.
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.
Respiratory Protection:	Do not breathe mist / vapours / spray.
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.

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.
Relative density:	Undetermined.
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.

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

Hazardous Polymerization: Has not been reported to occur.

TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):

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.
 Other Acute Health Effects: No significant other acute health effect known.

Biohazard Potential:

Patient blood samples tested with this kit represent an unknown, heightened hazard. Employ 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 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.
 Reproductive hazard: No reproductive toxic effect known.

Additional Toxicological Information: To the best of our knowledge, the chemical, physical and toxicological properties have NOT been thoroughly investigated for some of the component chemicals and/or mixtures.

ECOLOGICAL INFORMATION (12):

Toxicity:	100% Sodium Azide [26628-22-8]: Fish LC ₅₀ - <i>Lepomis macrochirus</i> - 0.68 mg/l – 96 h Daphnia EC ₅₀ - <i>Daphnia pulex</i> (Water flea) - 4.2 mg/l - 48 h <i>Source: Raw Material Vendor Safety Data Sheet</i>
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.

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.

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.

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 (Occupational Health and Safety Administration, U.S. Department of Labor).

National Regulations:

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.

This SDS contains the required information for preparation in accordance with the **Mexican Standard (NOM-018-STPS-2000)** except that some of the sections were renumbered in accordance to GHS as follows:

Information required to be in **Section II** (data about the chemical substance) and **Section III** (identification of the dangerous chemical substance) are found in **Sections 2, 3 and 8.**

Information required to be in **Section IV** (physical and chemical properties) is found in **Section 9.**

Information required to be in **Section V** (fire and explosion risk) is found in **Section 5.**

Information required to be in **Section VI** (reactivity data) is found in **Section 10.**

Information required to be in **Section VII** (health risks) is found in **Section 11.**

Information required to be in **Section VIII** (directions for the case of leaks or spills) and **Section IX** (special protection for emergency situations) are found in **Section 4.**

Information required to be in **Section X** (transportation) is found in **Section 14.**

Information required to be in **Section XI** (ecology) is found in **Section 12.**

Information required to be in **Section XII** (special precautions) is found in **Section 8.**

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.

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.

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.

For *in vitro* diagnostic use.

Sources of key data used to compile the Safety Data Sheet:

Raw Material Vendor Safety Data Sheets

Registry of Toxic Effects of Chemical Substances (RTECS)

European Community (EC) 2008/1272/EC, 2010/453/EC, 2006/1907/EC Regulations

EU Directives 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC

United Nations (UN) Globally Harmonized System (GHS)

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)

Translation of Official Mexican Standard NOM-018-STPS-2000 [<http://www.ilpi.com/msds/other/mexico/nom018appc.html>]

California Proposition 65

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

This Revision: New MSDS.

Department issuing MSDS: Environmental Health and Safety.

Contact: Redmond Operations, Environmental Health & Safety, 6565 185th Ave. NE, Redmond, WA 98052, USA,
Phone: 425-881-8300 (8 am to 5 pm PT), www.bio-rad.com

Contact Local Bio-Rad Agents for general information:

- Australia**, Bio-Rad Laboratories Pty. Ltd., Level 5, 446 Victoria Road, Gladesville NSW 2111 • Phone 61-2-9914-2800 • Telefax 61-2-9914-2888
- Austria**, Bio-Rad Laboratories Ges.m.b.H., Hummelgasse 88/3-6, A-1130 Vienna • Phone 43-1-877-8901 • Telefax 43-1-876-5629 •
[\[techsupport.austria@bio-rad.com\]](mailto:techsupport.austria@bio-rad.com)
- Belgium**, Bio-Rad S.A.-N.V. Begoniastraat 5, B-9810 Nazareth Eke • Phone 3293855511 • Telefax 3293856554 • [\[Clinsupport.belgium@bio-rad.com\]](mailto:Clinsupport.belgium@bio-rad.com)
- Brazil**, Bio-Rad do Brasil, Praia de Botafogo, 440-3rd Floor, Botafogo, RJ CEP 22250-040, Rio de Janeiro • Phone 5521-3237-9400 •
Telefax 55 21 2527-3099
- Canada**, Bio-Rad Laboratories, Ltd., 2403 Guénette Street, Montréal, Québec H4R 2E9 • Phone 1-514-334-4372 or 1-800-361-1808 •
Telefax 1-514-334-4415
- China**, Bio-Rad Laboratories Shanghai Ltd. 3rd Floor, #18 Dong Fang Road, Bldg E, Poly Plaza, Pudong, Shanghai PRC • Phone 86-21-64260808 •
Telefax 86-21-64264988
- Czech Republic**, Bio-Rad spol. s r.o., Nad ostrovem 1119/7, 147 00 Prague 4 • Phone 420-241-430-532 • Telefax 420-241-431-642
- Denmark**, Bio-Rad Laboratories, Symbion Science Park, Fruebjergvej 3, DK-2100 Copenhagen East • Phone +45 44 52-10 00 • Telefax +45 44 52-10 01 •
[\[nordic_helpdesk@bio-rad.com\]](mailto:nordic_helpdesk@bio-rad.com)
- Finland**, Bio-Rad Laboratories, Linnanherrankuja 16, FIN-00950 Helsinki • Phone 358-9-804-22-00 • Telefax 3589-7597 5010
- France**, Bio-Rad, 3 boulevard Raymond Poincaré, 92430 Marnes-la-Coquette • Phone +33 (0)1 47 95 60 00 • Telefax +33 (0)1 47 41 91 33 •
[\[fds-msds.fr@bio-rad.com\]](mailto:fds-msds.fr@bio-rad.com) or fds.msds@bio-rad.com
- Germany**, Bio-Rad Laboratories GmbH, Heidemannstrasse 164, D-80939 Munich • Phone +49-(0)89-318840 • Telefax +49-(0)89-31884100 •
[\[diagnostics.germany@bio-rad.com\]](mailto:diagnostics.germany@bio-rad.com)
- Greece**, Bio-Rad Laboratories M.E.P.E, 2-4 Mesogeion Street, Fourth Floor 115 27 Athens • Phone 30-210-7774396 • Telefax 30-210-7774376
- Hong Kong**, Bio-Rad Pacific Ltd., Unit 1101, 11/F DCH Commercial Centre, 25 Westlands Road, Quarry Bay • Phone 852-2789-3300 •
Telefax 852 2789-1290
- Hungary**, Bio-Rad Hungary Ltd., Futó Street 47-53, H-1082 Budapest, Hungary • Phone 36-1-459-6100 • Telefax + 36-1-459-6101
- India**, Bio-Rad Laboratories (India) Pvt. Ltd., Bio-Rad House, 86-87, Udyog Vihar, Phase - IV, Gurgaon, Haryana 122 015 • Phone 91-124-4029300 •
Telefax 91-124-2398115
- Israel**, Bio-Rad Laboratories Ltd., 14 Homa Street, New Industrial Area, Rishon Le Zion 75655 • Phone 972-3-9636050 • Telefax 972-3-9514129
- Italy**, Bio-Rad Laboratories S.r.l., Via Cellini 18/A, 20090 Segrate, Milan • Phone +39 02 216091 • Telefax +39 02 21609398 •
[\[diagnostics_italy@bio-rad.com\]](mailto:diagnostics_italy@bio-rad.com)
- Japan**, Bio-Rad Laboratories K.K., Tennoz Central Tower 20F, 2-2-24 Higashi-Shinagawa, Shinagawa-ku, Tokyo 140-0002 • Phone 81-3-6361-7070 •
Telefax 81-3-5463-8483
- Korea**, Bio-Rad Korea Ltd., 10th Floor, Hyunjuk Building, 832-41, Gangnam-gu, Seoul 135-080 • Phone 82-2-3473-4460 • Telefax 82-2-3472-7003
- Mexico**, Bio-Rad, S.A., Avenida Eugenia 197, Piso 10-A, Col. Narvarte, Delegacion Benito Juarez, C.P. 03020 Mexico, D.F. •
Phone +52 (55) 5488-7670 • Telefax +52 (55) 1107-7246 • [\[cdg_mexico@bio-rad.com\]](mailto:cdg_mexico@bio-rad.com)
- The Netherlands**, Bio-Rad Laboratories B.V., Fokkerstraat 2-8, 3905 KV Veenendaal • Phone +31-318-540666 • Telefax +31-318542216
- New Zealand**, Bio-Rad New Zealand, 189 Bush Road Unit B, Albany, Auckland • Phone 6494152280 • Telefax 6494152284
- Norway**, Bio-Rad Laboratories, Johan Scharffenbergs vei 91, N-0694 Oslo • Phone 4723384130 • Telefax 4723384139
- Poland**, Bio-Rad Polska Sp. z o.o., Nakielska Str. 3, 01-106 Warsaw • Phone 48-22-3319999 • Telefax 48-22-3319988
- Portugal**, Bio-Rad Laboratories, Lda., Edificio Prime, Av. Quinta Grande, 53 – Fracção 3B Alfragide 26114-521 Amadora • Phone 351-21-472-7700 •
Telefax 351-21-472-7777 • [\[literature_cdg_portugal@bio-rad.com\]](mailto:literature_cdg_portugal@bio-rad.com)
- Russia**, Bio-Rad Laboratorii, Business Centre “West Bridge”, Leningradsky pr-t H.37A Bld. 14, 125167 Moscow • Phone 7-495-72114 04 •
Telefax 7-495-721-14-12
- Singapore**, Bio-Rad Laboratories (Singapore) Pte. Ltd., 27 International Business Park, #01-02 iQuest @IBP, Singapore 609924 • Phone 65-6415-3170 •
Telefax 656415-3189
- South Africa**, Bio-Rad Laboratories (Pty) Ltd., 34 Bolton Road, Parkwood, Johannesburg 2193 • Phone 27-11-442-85-08 • Telefax 27-11-442-85-25
- Spain**, Bio-Rad Laboratories, S.A., C/ Caléndula, 95, Edificio M. Miniparc II, El Soto de la Moraleja, 28109 Madrid • Phone 34-91-590-5200 •
Telefax 34-91-590-5211 • [\[ofertas_lsg_spain@bio-rad.com\]](mailto:ofertas_lsg_spain@bio-rad.com)
- Sweden**, Bio-Rad Laboratories A.B., Vintergatan 1, Box 1097, S-172 22 Sundbyberg • Phone 46-8-555-127-00 • Telefax 46-8-555-127-80 •
[\[nordic_helpdesk@bio-rad.com\]](mailto:nordic_helpdesk@bio-rad.com)
- Switzerland**, Bio-Rad Laboratories AG, Nenzlingerweg 2, CH-4153 Reinach BL • Phone 41-61-717-95-55 • Telefax 41-61-717-95-50 • [\[service.switzerland@bio-rad.com\]](mailto:service.switzerland@bio-rad.com)
- Thailand**, Bio-Rad Laboratories Ltd., 1st & 2nd Floor, Lumpini I Bldg., 239/2 Rajdamri Rd., Lumpini, Pathumwan, Bangkok 10330 • Phone 662-651-8311 •
Telefax 662-651-8312
- United Kingdom**, Bio-Rad Laboratories Ltd., Bio-Rad House, Maxted Road, Hemel Hempstead, Herts HP2 7DX • Phone +44-(0)20-8328-2000 •
Telefax +44-(0)20-8328-2550 • [\[techsupport.uk@bio-rad.com\]](mailto:techsupport.uk@bio-rad.com)

This document was developed from information obtained from reputable sources, but does not purport to be all-inclusive. The data contained herein, which is based on our present knowledge and is intended for information purposes only, shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Regulatory requirements are subject to change and vary from one location to another thus, it is the buyer's responsibility to ensure that its activities comply with international, national, regional and local laws and regulations. Bio-Rad Laboratories makes no warranty, expressed or implied, regarding the accuracy or completeness of these data or the results to be obtained from the use thereof. Since the use of this information and the conditions of use of the product are not within the control of Bio-Rad Laboratories, it is the user's obligation to determine the suitability of the information for the intended application and use appropriate safety procedures.