




**SAFETY DATA SHEET (SDS)****SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER**

<b>Product Name:</b>	<b>BioPlex<sup>®</sup> 2200 System Celiac IgA and IgG Reagent Pack</b>
<b>Product Number:</b>	<b>665-2250</b> (100 tests; IgG) <b>665-2350</b> (100 tests; IgA)
<b>Intended Use:</b>	The BioPlex <sup>®</sup> 2200 Celiac IgA and IgG kits are multiplex flow immunoassays intended for the semi-quantitative detection of IgA and IgG autoantibodies to deamidated gliadin peptide (DGP) and tissue Transglutaminase (tTG) in human serum or EDTA plasma. In conjunction with clinical findings and other diagnostic tests, the test system is used as an aid in the diagnosis of Celiac Disease (gluten-sensitive enteropathy) and the associated skin disorder Dermatitis Herpetiformis (DH). The BioPlex 2200 Celiac IgA and IgG Reagent kits are intended for use with the Bio-Rad BioPlex 2200 System.
<b>Manufactured by:</b>	<b>Bio-Rad Laboratories, Inc.</b>
<b>Address:</b>	6565 185th Avenue NE Redmond, WA 98052-5039, USA
<b>Website:</b>	<a href="http://www.bio-rad.com">www.bio-rad.com</a>
<b>Phone Number:</b>	1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT)
<b>SDS e-mail contact:</b>	<a href="mailto:ro-sds@bio-rad.com">ro-sds@bio-rad.com</a>
<b>Technical Information Contacts:</b>	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>
<b>Authorized Representative in the European Community:</b>	<b>France : Bio-Rad Laboratories</b> 3 boulevard Raymond Poincaré 92430 Marnes-la-Coquette Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33 <a href="mailto:fds-msds.fr@bio-rad.com">[fds-msds.fr@bio-rad.com]</a>
<b>Emergency Phone Number:</b>	<b>This SDS is listed with CHEMTREC 1-800-424-9300 / 1-703-527-3887.</b> Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product. <i>Refer to section 16 for non-US local Bio-Rad agent contact information.</i>

**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
<p><b>Bead Set</b>  <b>BioPlex 2200</b>  <b>Celiac IgA and IgG</b>                      One (1) 10 mL vial                      (Faint brown liquid)</p>  <p><b>WARNING</b></p>	<ul style="list-style-type: none"> <li>- Dyed beads coated with recombinant antigens; an Internal Standard bead (ISB), a Serum Verification bead (SVB) and IgA Verification Bead (AVB) (in Celiac IgA only), in MOPS (3-[N-Morpholino] propanesulfonic acid) buffer supplemented with Glycerol and protein stabilizer (bovine CAS# 9048-46-8 and porcine) [pH 7.4].</li> <li>- <b>50-100% water</b> [H<sub>2</sub>O] CAS# 7732-18-5, EC No 231-791-2 [Not subject to GHS and EU 2008/1272/EC regulatory requirements.]</li> <li>- <b>&lt; 20% Glycerol</b> [C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>], CAS# 56-81-5, EC No 200-289-5 [Not subject to GHS and EU 2008/1272/EC regulatory requirements.]</li> <li>- <b>2% Sodium chloride</b> [NaCl], CAS# 7647-14-5, EC No 231-598-3. [Not subject to GHS and EU 2008/1272/EC regulatory requirements.]</li> <li>- <b>&lt; 1% MOPS free acid</b> buffer (3-[N-Morpholino]propanesulfonic acid - C<sub>4</sub>H<sub>8</sub>ON(CH<sub>2</sub>)<sub>3</sub>SO<sub>3</sub>H], CAS# 1132-61-2, EC No 214-478-5 [<b>&lt; 20% dilution is not subject to GHS and EU 2008/1272/EC Regulation or 1999/45/EC Directive labeling requirements.</b>]</li> <li>- Preserved with <b>≤ 0.3% ProClin 300</b> (≤ 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.]</li> <li>- Preserved with <b>≤ 0.1% sodium benzoate</b> [C<sub>7</sub>H<sub>5</sub>O<sub>2</sub>•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.]</li> <li>- Preserved with <b>&lt; 0.1% sodium azide</b> [NaN<sub>3</sub>], CAS# 26628-22-8 and EC No 247-852-1 [<b>&lt; 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.</b>]</li> </ul>
<p><b>Conjugate</b>  <b>BioPlex 2200</b>  <b>Celiac IgA and IgG</b>                      One (1) 5 mL vial                      (Pink aqueous liquid)</p>  <p><b>WARNING</b></p>	<ul style="list-style-type: none"> <li>- Phycoerythrin conjugated murine monoclonal anti-human IgA or IgG and phycoerythrin conjugated sheep anti-human FXIII in MOPS (3-[N-Morpholino] propanesulfonic acid) buffer supplemented with bovine (CAS# 9048-46-8) protein stabilizers (pH 7.4).</li> <li>- <b>50-100% water</b> [H<sub>2</sub>O] CAS# 7732-18-5, EC No 231-791-2 [Not subject to GHS and EU 2008/1272/EC regulatory requirements.]</li> <li>- <b>≤ 1% MOPS free acid</b> buffer (3-[N-Morpholino]propanesulfonic acid - C<sub>4</sub>H<sub>8</sub>ON(CH<sub>2</sub>)<sub>3</sub>SO<sub>3</sub>H], CAS# 1132-61-2, EC No 214-478-5 [<b>&lt; 20% dilution is not subject to GHS and EU 2008/1272/EC Regulation or 1999/45/EC Directive labeling requirements.</b>]</li> <li>- <b>1% Sodium chloride</b> [NaCl], CAS# 7647-14-5, EC No 231-598-3. [Not subject to GHS and EU 2008/1272/EC regulatory requirements.]</li> <li>- Preserved with <b>≤ 0.3% ProClin 300</b> (≤ 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.]</li> <li>- Preserved with <b>≤ 0.1% sodium benzoate</b> [C<sub>7</sub>H<sub>5</sub>O<sub>2</sub>•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.]</li> <li>- Preserved with <b>&lt; 0.1% sodium azide</b> [NaN<sub>3</sub>], CAS# 26628-22-8 and EC No 247-852-1 [<b>&lt; 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.</b>]</li> </ul>
<p><b>Sample Diluent</b>  <b>BioPlex 2200</b>  <b>Celiac IgA and IgG</b>                      One (1) 10 mL vial                      (Yellow aqueous liquid)</p>  <p><b>WARNING</b></p>	<ul style="list-style-type: none"> <li>- Containing bovine (CAS# 9048-46-8) and murine protein stabilizers in triethanolamine buffer (pH 7.4).</li> <li>- <b>50-100% water</b> [H<sub>2</sub>O] CAS# 7732-18-5, EC No 231-791-2 [Not subject to GHS and EU 2008/1272/EC regulatory requirements.]</li> <li>- <b>&lt; 1% Sodium chloride</b> [NaCl], CAS# 7647-14-5, EC No 231-598-3. [Not subject to GHS and EU 2008/1272/EC regulatory requirements.]</li> <li>- <b>&lt; 1% Triethanolamine hydrochloride</b> [C<sub>6</sub>H<sub>15</sub>NO<sub>3</sub>•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.]</li> <li>- Preserved with <b>≤ 0.3% ProClin 300</b> (≤ 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.]</li> <li>- Preserved with <b>≤ 0.1% sodium benzoate</b> [C<sub>7</sub>H<sub>5</sub>O<sub>2</sub>•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.]</li> <li>- Preserved with <b>&lt; 0.1% sodium azide</b> [NaN<sub>3</sub>], CAS# 26628-22-8 and EC No 247-852-1 [<b>&lt; 0.1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels.</b>]</li> </ul>

**Markings according to the United Nations (UN) Globally Harmonized System (GHS), United States Hazard Communication Standard (HCS) and European Community (EC) 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<sub>4</sub>H<sub>4</sub>CINOS; CAS# 26172-55-4, EC No 247-500-7) and 2-methyl-2H -isothiazol-3-one (C<sub>4</sub>H<sub>5</sub>NOS; 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**



<u>Label(s):</u>	<b>GHS07</b>
<u>Signal Word:</u>	<b>WARNING</b>
<u>Label Hazard Statement:</u>	<b>H317: May cause an allergic skin reaction.</b>
<u>Supplemental Hazard Statement:</u>	<i>None Specified</i>
<u>Precautionary Statement – Prevention:</u>	<b>P261:</b> Avoid breathing mist / vapours / spray <b>P272:</b> Contaminated work clothing should not be allowed out of the workplace. <b>P280:</b> Wear protective gloves/protective clothing/eye protection/face protection. *
<u>Precautionary Statement – Response:</u>	<b>P302 + P352:</b> IF ON SKIN: Wash with plenty of soap and water. * <b>P333 + P313:</b> If skin irritation or rash occurs: Get medical advice/ attention. *
<u>Precautionary Statement – Storage:</u>	<i>None Specified</i>
<u>Precautionary Statement – Disposal:</u>	<b>P501:</b> 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<sub>50</sub>, 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 Section 16 for the Key / legend to abbreviations and acronyms.

<b>Chemical Ingredient</b>	<b>Data / Information</b>
<b>Glycerol</b> [< 20% in the Bead Set]	CAS#: 56-81-5 (100%) + EC No: 200-289-5 (100%) + Chemical Formula: C <sub>3</sub> H <sub>8</sub> O <sub>3</sub> (100%) + LD <sub>50</sub> (oral-rat): 12,600 mg/kg (100%) + TLV and PEL: 10 mg/m <sup>3</sup> total mist (100%) + HMIS Codes: H=1, F=0, R=1 ++ RTECS#: MA8050000 (100%) + Flash Point: 320 F / 160° C (100%) + LC <sub>50</sub> (inhalation-rat): > 570 mg/m <sup>3</sup> /1H (100%) + IATA/DOT ID: NE RCRA Code: NE GHS / 2008/1272/EC Classification: Not subject to EU 2008/1272/EC and GHS regulatory requirements. ++ Keep <b>glycerol</b> 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 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



Chemical Ingredient	Data / Information
<b>Sodium azide</b> [< 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
<b>Animal proteins</b>	This material is of animal origin ( <b>bovine, porcine and murine</b> ) 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.

+ 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.
- ◆ No significant adverse health effects are expected by any route for the sodium chloride, triethanolamine hydrochloride, miscellaneous salts, MOPS free acid 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.

### **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. 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 <i>Standard</i> and <i>Universal Precautions</i> . 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 documents. Refer to the <i>Instructions For Use / Package Insert</i> for additional product information. Read and follow <i>BioPlex<sup>®</sup> 2200 System Instrument Manual</i> instructions.	
For <i>in vitro</i> diagnostic use.	

**SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES**
**Control Parameters – Component chemicals with limit values that require monitoring at the workplace:**

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

<b>Glycerol [CAS# 56-81-5]:</b>		
PEL (United States)	15* 5** mg/m <sup>3</sup>	*total dust **respirable fraction
TLV (United States)	10* ppm	*Mist
EL (Canada)	10* 3** mg/m <sup>3</sup>	*mist; **mist, resirable
WEL (United Kingdom)	10 mg/m <sup>3</sup>	
NES (AUS)	10 mg/m <sup>3</sup>	
VME (France)	10 mg/m <sup>3</sup>	
VL (Belgium, (France))	10 mg/m <sup>3</sup>	
MAK (Germany)	50E mg/m <sup>3</sup>	
TWA (Italy)	10 mg/m <sup>3</sup>	
MAK (Switzerland, (Germany))	Short-term value: 100 e mg/m <sup>3</sup> Long-term value: 50 e mg/m <sup>3</sup>	

*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.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Plastic cartridge containing various bottles with aqueous solutions		
<b>Odour:</b>	No applicable information was found.	<b>Odour Threshold:</b>	Not Established.
<b>pH:</b>	The liquid chemical components are between pH 6 and 8.		
<b>Boiling Point:</b>	Undetermined	<b>Melting Point:</b>	Undetermined
<b>Flash point:</b>	Not Applicable. Flammable limits: LEL/LFL is <u>Not applicable</u> ; UEL/UFL is <u>Not applicable</u> .		
<b>Evaporation rate:</b>	No applicable information was found.		
<b>Fire hazard:</b>	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.		
<b>Vapor pressure:</b>	No applicable information was found.		
<b>Vapor density:</b>	No applicable information was found.		
<b>Relative density:</b>	Undetermined.		
<b>Solubility:</b>	The liquid chemical components are soluble in water. The bead set is not miscible or is difficult to mix.		
<b>Partition coefficient (n-octanol/water):</b>	No applicable information was found.		
<b>Auto ignition temperature:</b>	Product is not known to be self-igniting.		
<b>Decomposition temperature:</b>	No applicable information was found.		
<b>Viscosity:</b>	No applicable information was found.		
<b>Danger of explosion:</b>	<p><b>Sodium azide</b> 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.</p> <p>Keep <b>Glycerol</b> solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures.</p>		
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:	<b>Sodium azide</b> 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 <b>Glycerol</b> 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.

**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 respiratory 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:

Patient blood samples tested with this kit represent an unknown, heightened hazard. 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*, 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 ( <b>ProClin 300</b> ); 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:	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.



**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.

**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<sup>®</sup> 2200 System.

For *in vitro* diagnostic use.

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 Regulations (EC) 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, USA  
EC<sub>50</sub> – 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<sub>50</sub> – median lethal concentration, 50%  
LD<sub>50</sub> – 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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