

SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name: **EBV EA-D IgG EIA**

Product Number: **12008530** (96 tests)
Catalog number(s) for replacement, optional and/or separately purchased components that can be obtained for use with this kit, and which are covered by this SDS include: **25186, 25190, 25191** and **25192** (refer to Section 2).

Intended Use: For the qualitative detection of human IgG antibodies to EpsteinBarr virus early antigen diffuse (EA-D) in human serum by enzyme immunoassay. This assay uses a 28 kd *E. coli* expressed recombinant Epstein-Barr virus early antigen. When performed in conjunction with other EBV serological tests, this assay can be used as an aid in the laboratory diagnosis of EBV infectious mononucleosis in patients with signs and symptoms of EBV infectious mononucleosis.
These reagents have not received FDA clearance for use in testing blood or plasma donors. Assay performance characteristics have not been established for neonatal, immunocompromised populations, cord blood, infants, or pre-transplant patients. Assay performance characteristics have not been established for the diagnosis of nasopharyngeal carcinoma, Burkitt's lymphoma, and others.
For In Vitro Diagnostic Use Only.
For Prescription Use Only

Supplier's Name: **Bio-Rad Laboratories, Inc.**

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

Website: www.bio-rad.com

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

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

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

Emergency Phone Number: **This SDS is listed with CHEMTREC 1-800-424-9300 or 1-703-527-3887 (US/CA) / +1-703-741-5970** (international – can be called collect). Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

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. The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Refer to Section 16 for the full text of any solely abbreviated or coded hazard statements provided below and for the key / legend to abbreviations and acronyms.

Component	Content
Coated Wells, 12 eight-well strips	- Coated with 28 kd recombinant antigen of Epstein Barr Virus Early Antigen (diffuse) expressed in <i>E. coli</i> . [Color ID: Turquoise]
Well Support, 1 Frame	- No known hazardous ingredients.
Diluent, 25 mL bottle, (pink color) <i>Catalog #25186</i>	- Phosphate-buffered saline with 6% BSA as protein stabilizer, pH 7.4. - Preserved with 0.09% sodium azide [NaN ₃], CAS# 26628-22-8 and EC No 247-852-1. Not subject to UN GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.

Component	Content
Calibrator, 0.6 mL vial	<ul style="list-style-type: none"> - Human serum; strongly reactive for antibodies to EBV EA-D. Index value is shown on vial label. - Preserved with 0.09% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Not subject to UN GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.
Positive Control, 0.6 mL vial	<ul style="list-style-type: none"> - Human serum; reactive for antibodies to EBV EA-D. Index value is shown on vial label. - Preserved with 0.09% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Not subject to UN GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.
Negative Control, 0.6 mL vial	<ul style="list-style-type: none"> - Human serum, nonreactive for antibodies to EBV EA-D. - Preserved with 0.09% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Not subject to UN GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.
Conjugate, 2 x 12 mL bottles (green color)	<ul style="list-style-type: none"> - Goat anti-human IgG labeled with Alkaline phosphatase (calf). - Contains 0.01% of MIT - 2-Methyl-4-isothiazolin-3-one hydrochloride - Contains 0.02% of 5-Bromo-5-nitro-1, 3-dioxane. <p>Not subject to UN GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.</p>
Substrate, 12 mL bottle <i>Catalog #25192</i>	<ul style="list-style-type: none"> - Diluted p-Nitrophenyl phosphate [C₆H₅NO₆P•2Na], CAS# 4264-83-9, EC No 224-246-5 in a 0.1 M bicarbonate buffer, pH 9.6. Not subject to UN GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.
Wash Concentrate, 30 mL bottle <i>Catalog #25190</i>	<ul style="list-style-type: none"> - Tris-buffered saline with <1% Tween 20, pH 8.0. Not subject to GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with 0.09% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Not subject to UN GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.
Stop Reagent, 12 mL bottle <i>Catalog #25191</i>	<ul style="list-style-type: none"> - 0.5M Sodium Phosphate Tribasic, [$< 1\% \text{ Na}_3\text{PO}_4 \cdot 12\text{H}_2\text{O}$], CAS# 10101-89-0 (Dodecahydrate)], pH < 12. Not subject to UN GHS, US HCS, EC CLP, and analogous global GHS-based regulatory requirements in this product mixture and concentration.

Markings according to the United Nations (UN) Globally Harmonized System (GHS), United States Hazard Communication Standard (US HCS), European Commission (EC) 2008/1272/EC (EC CLP) guidelines and analogous GHS-based global regulations:

No Known Regulated Hazards: This product contains no hazardous constituents, or the concentrations of all chemical constituents are below the regulatory threshold limits requiring hazard communication and labeling. The information included here is in compliance with chemical hazard classification, hazard communication and Safety Data Sheets (SDS) requirements as per the **United States – Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200 (US HCS)**.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure regardless of the concentration found in the product. Note that the information here is often based on data from the chemical raw material safety data sheet and literature (LD₅₀, exposure limits, etc.). Chemical constituents that do not require regulatory disclosure are not generally included here. This product contains a significantly diluted concentration in an aqueous solution, thus the assessment below has not considered the dilution reduction effect on the hazard. That hazard communication information is provided in Section 2 above. Some components were tested at the concentration found in the kit. In that case, the assessment is provided for the chemical dilution tested and the tested concentration will be provided at the beginning of the *Chemical Ingredient Data/Information* box. The GHS, US HCS, EC CLP and analogous GHS-based global regulation classifications were made according to the existing editions and expanded upon from company and literature data. Refer to Section 16 for the full text of any *Comprehensive GHS-based Classification* statements coded below, for the list of sources utilized in the assessment and the key / legend to abbreviations and acronyms.

Chemical Ingredient Data / Information

Chemical Ingredient: Sodium Phosphate, Tribasic, Dodecahydrate (TSP)

Chemical concentrations found in this product: **0.5M in the Stop reagent (< 1%) in an aqueous solution**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 10101-89-0 (Dodecahydrate) (100%)	LD ₅₀ (oral-rat): 7400 mg/kg (100%)
EC No: 231-509-8 (100%)	LC ₅₀ (inhalation-rat): No data available (100%)
RTECS#: TC9575000 (100%)	LD ₅₀ (skin-rabbit): No data available mg/kg (100%)
Index No: NE (100%)	LC ₅₀ (48 hr-fish): <i>Leuciscus idus</i> (Golden orfe) - 2,400 mg/L
Chemical Formula: Na ₃ PO ₄ ·12H ₂ O (100%)	Flash Point: NSF / NS°C (100%)
Molecular weight: 380.12 g/mol (100%)	pH value: ~11.9 (1%)
Synonyms/Trade Names: TSP, Phosphoric acid, trisodium salt dodecahydrate	

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER!

Skin Corr. Cat. 1B, Eye Damage Cat. 1

H314

P260, P264, P280, P301 + P330 + P331, P303 + P361 + P353, P304 + P340, P305 + P351 + P338, P310, P363, P405, P501

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]



Chemical Ingredient: Sodium azide

Chemical concentrations found in this product: **0.09% in an aqueous solution**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 26628-22-8 (100%)	LD ₅₀ (oral-rat): 27 mg/kg
EC No: 247-852-1 (100%)	LC ₅₀ (inhalation-rat): 37 mg/m ³
Index No: 011-004-00-7 (100%)	LD ₅₀ (skin-rat): 50 mg/kg
RTECS#: VY8050000 (100%)	Fish LC ₅₀ – <i>Lepomis macrochirus</i> (Bluegill) – 0.68 mg/l – 96 h
Chemical Formula: NaN ₃ (100%)	Molecular weight: 65.01g/mol (100%)
Synonyms/Trade Names: Azide, sodium; Azoture de sodium; Azydek sodu; NSC 3072; Kazoe; Natriumazid; Natriummazide; NCI-C06462; Nemazyd; Sodium azide; Sodium, azoture de; Sodium, azoturo di, Smite; U-3886;	

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER!

Acute Tox. – oral Cat. 2, Acute Tox. – skn. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chron. Cat. 1

H300 + H310, H410

P264, P273, P280, P302 + P350, P310, P501

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]



Chemical Ingredient Data / Information
Chemical Ingredient: 5-Bromo-5-nitro-1, 3-dioxane

 Chemical concentrations found in this product: **0.02% in an aqueous solution (Conjugate)**
Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 30007-47-7 (100%)	LD ₅₀ (oral-rat): 455 mg/kg
EC No: 250-001-7 (100%)	LC ₅₀ (inhalation-rat): NE
RTECS#: JG9650000 (100%)	LD ₅₀ (skin-rabbit): NE
Index No: NE	LC ₅₀ (96 hr-fish): NE
Chemical Formula: C ₄ H ₆ BrNO ₄ (100%)	Molecular weight: 212.02 g/mol (100%)
Synonyms/Trade Names: BND, Brom-5-nitro-1,3-dioxan; 5-Bromo-5-nitro-m-dioxane; 5-Bromo-5-nitro-1,3-dioxane; Bronidox; 1,3-Dioxane, 5-bromo-5-nitro-	

Raw Material GHS / US HCS / EC CLP Classification (100%):
WARNING

Acute Tox. – oral. Cat. 4, Skin Irrit. Cat. 2
 H302, H315
 P264, P270, P280, P301 + P312, P302 + P352, P330, P332 + P313, P362, P501

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]


Chemical Ingredient: 2-methyl-4-isothiazolin-3-one

 Chemical concentrations found in this product: **0.02% in an aqueous solution (Conjugate)**
Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 2682-20-4	LD ₅₀ (oral-rat): No data available
EC No: 220-239-6	LC ₅₀ (inhalation-rat): No data available
RTECS#: NE	LD ₅₀ (skin-rabbit): No data available
Chemical Formula: C ₄ H ₅ NOS	pH value: No data available
Synonyms/Trade Names: MIT	

Raw Material GHS / US HCS / EC CLP Classification (100%):
DANGER!

Acute Tox. – inhl. Cat. 3, Skin Corr. Cat. 1B, Eye Damage Cat. 1,
 Skin Sens. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chron. Cat. 1
 H314, H317, H331, H410,
 P261, P264, P271, P272, P273, P280, P301 + P330 + P331, P303 + P361 + P353,
 P305 + P351 + P338, P310, P403 + P233, P405, P501

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]



Biological Ingredient	Data / Information
Microwell Coated Plate	The microwells in this test kit have been coated 28 kd recombinant antigen of Epstein Barr Virus Early Antigen (diffuse) expressed in E. coli, which has been certified by the supplier to not be infectious; however, according to Universal Precautions, it should be handled as though capable of transmitting infection.
Human Serum [reactive and non-reactive in the Calibrator, Positive Control and Negative Control Reagents] <div> </div>	The Human sera in the components of this product was tested and certified to be non-reactive for HBsAg and antibodies to HCV and HIV 1 / HIV 2 by FDA licensed or CE Marked tests. 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 <i>Standard</i> and <i>Universal Precautions</i> 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 <i>Biosafety in Microbiological and Biomedical Laboratories</i> or WHO <i>Laboratory Biosafety Manual</i> or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

NA: Not Applicable.

NE: Not Established or Unknown (unable to locate data); typically for concentrate form unless otherwise specified.

Related product information:

- ◆ Refer to section 16 for the full text of any *Comprehensive GHS-based Classification* statements, for the list of sources utilized in the assessment and for the key / legend to abbreviations and acronyms.
- ◆ No significant adverse health effects are expected by any route for the miscellaneous salts, water, tris and phosphate saline buffers, protein stabilizers, Tween 20 [CAS# 9005-64-5], p-nitrophenyl phosphate [CAS# 4264-83-9], dyes, and other chemicals found in the alkaline-phosphatase-labeled antibodies and other kit reagents, in the kit volumes and concentrations present. [Chemical or dilution is not subject to EC CLP, US HCS 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. Take off contaminated clothing and wash before reuse.

SECTION 4: EMERGENCY FIRST AID MEASURES

Health Effects:	May be detrimental if enough is ingested (typically in quantities above those found in the kit). The alkaline Stop Reagent can irritate eyes depending on amount and contact time; prolonged contact may cause eye injury (generally at concentrations and volumes that greatly exceed that of this kit).
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

Fire Hazard Summary:	This product is aqueous based so is not considered flammable or combustible.
Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Combustion Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
Protection of Fire Fighters:	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.
- ◆ Prevent material from entering sewers, waterways or confined spaces.
- ◆ Follow established laboratory policy and applicable WHO/CDC/NIH biosafety and/or WHO/OSHA hazardous material and/or equivalent 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 decontaminant 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.).
 - Neutralize corrosive alkaline spills with the appropriate *Base* neutralization / *adsorbent* product
- ◆ 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:	<p>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.</p> <p>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.</p> <p>Keep containers tightly closed; avoid splashing, spills and the generation of aerosols.</p> <p>Handle all human source materials, specimens 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>.</p> <p>All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics.</p> <p>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.</p> <p>Consult with your Environmental Health & Safety Office for assistance.</p>
Storage:	Store according to product and label instructions (generally at 2-8°C).
Caution, consult accompanying documents. Read and follow all the precautions and warnings in the kit product instructions for use.	
For <i>in vitro</i> diagnostic use.	
For Prescription Use Only.	

SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES

Control Parameters – Component chemicals with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

100% Sodium Azide [CAS# 26628-22-8] - OEL:			
AUSTRALIA:	CL	0.11 ppm (0.3 mg/m ³)	2008
AUSTRIA:	MAK-TMW KZW	0.1 mg/m ³ 0.3 mg/m ³ , skin	2007
BELGIUM:	TWA STEL	0.1 mg/m ³ , 0.3 mg/m ³ , skin	2002
DENMARK:	TWA	0.1 mg/m ³ , skin	2011
EC (European Union):	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	2000
FINLAND:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	2011
FRANCE:	VME VLE	0.1 mg/m ³ 0.3 mg/m ³ , Skin	2006
GERMANY:	MAK	0.2 mg/m ³ , inhal	2011
HUNGARY:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³	2000
ICELAND:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	2011
ITALY	TWA	C 0.29 mg/m ³ , C 0.11* ppm	*sodium azide, vapor
KOREA:	CL	0.1 ppm (0.3 mg/m ³)	2006
THE NETHERLANDS:	MAC-TGG	0.1 mg/m ³ , skin	2003
NEW ZEALAND:	CL	0.11 ppm (0.29 mg/m ³)	2002
PERU:	TWA STEL	0.1 mg/m ³ 0.29 mg/m ³	2005
SWEDEN:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , Skin	2005
SWITZERLAND:	MAK-W KZG-W	0.2 mg/m ³ 0.4 mg/m ³ , inhal	2011
UNITED KINGDOM:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES:	TLV-TWA-Ceiling REL-Ceiling	0.11* ppm / 0.29** mg/m ³ 0.1* ppm / 0.3** mg/m ³	ACGIH, 1996, 2013 NIOSH Recommended Exposure Limits *as HN ₃ vapor; **as NaN ₃ ; Skin

[Source: CCOHS CHEMINFO 2013, RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]

100% Sodium Phosphate, Tribasic, Dodecahydrate (TSP) [CAS# 10101-89-0] - OEL:			
UNITED STATES:	STEL	5 mg/m ³	USA, Workplace Environmental Exposure Levels (WEEL)

[Source: Raw Material Vendor Safety Data Sheet]

Concentrated 5-BROMO-5-NITRO-1,3-DIOXANE (BRONIDOX) [CAS# 30007-47-7] - OEL:			
RUSSIA:	STEL	10 mg/m ³	2003
UNITED STATES:	WEEL	10 mg/m ³	Workplace Environmental Exposure Level

[Source: CCOHS CHEMINFO 2013, RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]

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.
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:	Not 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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Variable, generally aqueous liquids. Refer to section 2.		
Odor:	No applicable information was found.	Odor Threshold:	Not established.
pH:	Most of the liquid chemical reagents are between pH 5 and 10, with the exception of the alkaline Stop solution at pH < 12.5.		
Boiling Point:	Undetermined.	Melting Point:	Undetermined.
Flash Point:	Not Applicable. Flammable limits: LEL/LFL is <u>Not Applicable</u> ; UEL/UFL is <u>Not Applicable</u>		
Evaporation rate:	No applicable information was found.		
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.		
Vapor Pressure:	No applicable information was found.		
Vapor Density:	No applicable information was found.		
Relative Density:	Approximately 1.		
Solubility:	The liquid chemical components are soluble in water.		
Partition coefficient (n-octanol/water):	No applicable information was found.		
Auto Igniting:	Product is not known to be self-igniting.		
Decomposition temperature:	No applicable information was found.		
Viscosity:	No applicable information was found.		
Danger of Explosion:	<i>Sodium azide</i> 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.		
Molecular mass:	Mixtures.		
No other standard characteristics applicable to the identification or hazards of the product are known.			
Source: Raw Material vendor SDS, CCOHS databases and/or regulatory research			

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 to avoid:	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.
Materials to avoid:	Do not allow the basic Stop Reagent to come in contact with strong acids or chlorinated solvents (may react exothermically).
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

Acute Toxicity:	Harmful if enough is ingested (generally quantities above those found in the kit).
Primary Irritant Effect:	Not generally considered an irritant. Prolong contact with the Stop Reagent may slightly irritate skin, depending on amount and contact time.
Serious Eye Damage / Irritation:	The alkaline Stop Reagent can irritate eyes depending on amount and contact time; prolonged contact may cause eye injury.
STOT-Single 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:

The **Human sera (plasma)** in the components were tested and found non-reactive for HBsAg and antibodies to HCV and HIV. The microwells in this test kit have been coated 28 kd recombinant antigen of Epstein Barr Virus Early Antigen (diffuse) expressed in E. coli, that has been certified by the supplier to not be infectious. 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* or WHO the *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Respiratory or Skin Sensitization:	No sensitization effect known.
Carcinogenicity:	No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC, 2008/1272/EC (EC CLP) or OSHA.
Germ Cell Mutagenicity:	No applicable information was found.
Reproductive hazard:	No reproductive toxic effect known.
STOT-Repeated Exposure:	No applicable information was found.

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.

SECTION 12: ECOLOGICAL INFORMATION

This product was not tested. The following assessment is based on information for the ingredients.

Ecotoxicity:	100% Sodium Azide [CAS# 26628-22-8]*: Fish LC ₅₀ – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h Daphnia EC ₅₀ – Daphnia pulex (Water flea) – 4.2 mg/l – 48 h Concentrated 2-methyl-4-isothiazolin [CAS# 2682-20-4]**: Fish LC ₅₀ – Lepomis macrochirus (Bluegill) – 0.30 mg/l [min. 0.24 mg/l, max. 0.32 mg/l] – 96 h Fish LC ₅₀ – Oncorhynchus mykiss (rainbow trout) – 0.19 mg/l [min. 0.13 mg/l, max. 0.31 mg/l] – 96 h Daphnia EC ₅₀ – Daphnia pulex (Water flea) – min. 0.71 mg/l, max. 1.8 mg/l – 48 h 100% Sodium Phosphate, Tribasic, Dodecahydrate (TSP) [CAS# 10101-89-0]*: TLC ₅₀ (96 hr-fish): 2,400 mg/L (100%) – 48H (Leuciscus idus (Golden orfe)) * Source: Raw Material Vendor Safety Data Sheet, RTECS and/or CCOHS Cheminfo ** Source: PAN Pesticides Database – Chemical Studies on Aquatic Organisms [obtained 3/7/2012]
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 effects:	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

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

Recommended Product Disposal:

- **Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up; check your applicable ordinances accordingly.
- All **human source** and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your international, national, regional and local ordinances accordingly.
- Basic / Alkaline Waste **Stop Reagent (0.5M trisodium phosphate, pH < 12.5)** should be neutralized to pH 6-8 for safe sewer disposal, check your local, regional, national and international ordinances accordingly.
 In addition, if the final pH measures ≥ 12.5 , it requires disposal as a corrosive material in a RCRA approved dangerous waste facility (or equivalent); the US RCRA Waste disposal Code for this waste, if not neutralized, is D002, check your international, national, regional and local ordinances accordingly.

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

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

SECTION 14: TRANSPORT INFORMATION

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

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

Note: The Waste **STOP Reagent** in this product has been evaluated with the CORROSITEX test method to determine its corrosive potential and any packing group classification. The results of this testing classified this STOP solution as non-corrosive for shipping purposes and GHS hazard labeling.

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

SECTION 15: REGULATORY INFORMATION

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

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), OSHA (Occupational Health and Safety Administration, U.S. Department of Labor) or 2008/1272/EC (EC CLP).

National Regulations – Other Domestic / Foreign Laws:

Hazard communication compliance – This SDS contains the required information for preparation in accordance with the following GHS-based global regulations:

1. **United States** – Occupational Safety Health Administration *Hazard Communication Standard 29 CFR 1910.1200 (US HCS)*
2. **Taiwan** – OSHA Published National Standard **CNS 15030** Classification and Labelling of Chemicals
3. **Singapore** – SS 586 - 2 : 2014
4. **Russia** – GOST 31340-2013, GOST 32419-2013, GOST 32423-2013, GOST 32424-2013, GOST 32425-2013, R 50.1.102-2014, R 50.1.101-2014
5. **People's Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
6. **New Zealand** – *Hazardous Substances and New Organisms Act (HSNO)*
Composite HSNO Hazard Class: Based on available data, the classification criteria are not met.
7. **Mexico** – Standard **NOM-018-STPS-2015, NMX-R-019-SCFI-2011**
8. **Korea** – *MoEL-Public Notice 2016-19, 2013-37 Standard for classification and labeling of chemical substances and MSDS*
9. **Japan** – Industrial Safety and Health Law (ISHL) National Standard **JIS Z7252, JIS Z7253**
10. **European Commission (EC)** – applicable **CLP** related regulations (**2010/453/EC, 2008/1272/EC, 2006/1907/EC** etc.)
11. **Canada** – Hazardous Products Regulations (HPR) / Standard *Workplace Hazardous Materials Information System (WHMIS-GHS)*
Canadian Standard for the hazard classification criteria for this product.
Composite WHMIS Hazards: Based on available data, the classification criteria are not met.
12. **Brazil** – Regulation **ABNT NRB 14725**
13. **Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety (WHS) Act**.
14. Analogous GHS-based global regulations

Inventory status

Country(s) or region Inventory name	In Compliance (yes/no)*
Australia - Australian Inventory of Chemical Substances (AICS)	Yes
Canada - Domestic Substances List (DSL)	Yes
Canada - Non-Domestic Substances List (NDSL)	Yes
China - Inventory of Existing Chemical Substances in China (IECSC)	Yes
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) or European List of Notified Chemical Substances (ELINCS)	Yes
Japan - Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea - Existing Chemicals List (ECL)	Yes
New Zealand - New Zealand Inventory	Yes
Philippines - Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan inventory - CSNN	Yes
United States & Puerto Rico - Toxic Substances Control Act (TSCA) Inventory	Yes

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

United States SARA (Superfund Amendments and Reauthorization Act of 1986):

SARA 302 (extremely hazardous substance) components: The following components are subject to reporting levels established by SARA Title III, Section 302 in greater quantities than found in this product:

Sodium Azide, CAS# 26628-22-8; Revision Date: 2007-07-01

SARA 313 components: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

California Proposition 65 (California Safe Drinking Water and Toxic Enforcement Act of 1986):

The Product does not contain listed substances.

SECTION 16: OTHER INFORMATION
Hazard statement abbreviation(s)

Acute Tox. – oral.	Acute toxicity – ingested (swallowed)
Acute Tox. – skn.	Acute toxicity – skin contact (dermal)
Acute Tox. – inhl.	Acute toxicity – inhaled
Skin Corr.	Skin corrosion
Eye Damage.	Serious eye damage
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitisation
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Cat.	Catalog
H300 + H310	Fatal if swallowed or in contact with skin.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H410	Very toxic to aquatic life with long lasting effects.
P260	Do not breathe mist / vapors/vapours / spray.
P261	Avoid breathing mist / vapors/vapours / spray.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves / protective clothing / eye protection / face protection.*
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P302 + P350	IF ON SKIN: Gently wash with plenty of soap and water.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P303 + P361 + P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/ physician.
P330	Rinse mouth.
P332 + P313	If skin irritation occurs: Get medical advice/ attention.
P362	Take off contaminated clothing and wash before reuse.
P363	Wash contaminated clothing before reuse.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of this material in a safe way, and in accordance with local, regional, national and international regulations.
P501	Dispose of contents/ container to an approved waste disposal plant.
P501	This material and its container must be disposed of as hazardous waste.
Caution	Contains human source material. Handle as if capable of transmitting potentially infectious agents (<i>Standard and Universal Precautions</i>).

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.

For *in vitro* diagnostic use.

For Prescription Use Only.

Chemical safety assessment: Mixtures covered in this SDS were classified using the US HCS, EC CLP and/or UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Fifth edition unless otherwise specified.

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 (US HCS) 1910.1200
 Canadian Workplace Hazardous Materials Information System (WHMIS)
 Mexican Standard (NOM-018-STPS-2015, NMX-R-019-SCFI-2011) [regulatory translation and summaries]
 European Commission (EC) Regulations 2008/1272/EC, 2010/453/EC, 2006/1907/EC (EC CLP)
 Australian Code of Practice – Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the *Work Health and Safety Act*)
 New Zealand – Hazardous Substances and New Organisms Act (HSNO)
 The People's Republic of China National Standard GB/T 17519-2013, GB 30000-2013 [regulatory translation if available and summaries]
 Taiwan OSHA Published National Standard CNS 15030 [regulatory translation if available / summaries]
 Korean MoEL-Public Notice 2016-19, 2013-37 [regulatory translation if available and summaries]
 Japanese Industrial Standard JIS Z7252, JIS Z7253 [regulatory translation if available and summaries]
 Registry of Toxic Effects of Chemical Substances (RTECS)
 Canadian Centre for Occupational Health and Safety (CCOHS) *CHEMINFO* databases, etc.
 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*
 PAN Pesticides Database – *Chemical Studies on Aquatic Organisms*
 Australian Inventory of Chemical Substances (AICS) Listing
 California Proposition 65

Key / legend to abbreviations and acronyms used in the safety data sheet:

ACGIH – American Conference of Governmental Industrial Hygienists
 AICS – Australian Inventory of Chemical Substances
 ANSI – American National Standards Institute
 CAS – Chemical Abstracts Service
 CCOHS – Canadian Centre for Occupational Health and Safety
 CDC – Centers for Disease Control, USA
 CNS – Central Nervous System
 DGSMA – Dangerous Goods Safety Management Act
 DOT – Department of Transportation, USA
 EC₅₀ – half maximal effective concentration
 EC CLP – European Commission regulation for the Classification, Labeling and Packaging of chemical substances and mixtures
 EU – European Union
 GHS – Globally Harmonized System
 HNOG – Hazard Not Otherwise Classified
 HSNO – Hazardous Substances and New Organisms Act 1996 (New Zealand)
 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
 ISHA – Industrial Safety and Health Act
 LC₅₀ – median lethal concentration, 50%
 LD₅₀ – median lethal dose, 50%
 MSDS – Material Safety Data Sheet
 NIH – National Institute of Health
 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
 STOT – Specific Target Organ Toxicity
 TCCA – Toxic Chemical Control Act
 TLV/TWA – Threshold Limit Value / Time-Weighted Average
 UN – United Nations
 US EPA – United States Environmental Protection Agency, USA

US HCS – Hazard Communication Standard, USA
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
WHMIS – Workplace Hazardous Materials Information System, Canada
WHO – World Health Organization (United Nations)

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

Other requested languages can be obtained from your local Bio-Rad agent.

This Revision: New Safety Data Sheet (SDS).

Bio-Rad Laboratories:

Department issuing SDS: Environmental Health and Safety.

Contact for general SDS information: Seattle Operations, Environmental Health & Safety, 6565 185th Ave. NE, Redmond, WA 98052, USA, Phone: 425-881-8300 (8 am to 5 pm PT), ro-sds@bio-rad.com

Customer support contact: Clinical Diagnostics Group, 4000 Alfred Nobel Drive, Hercules, CA 94547, USA
Phone: 1-800-224-6723, www.bio-rad.com/diagnostics

Emergency Contact (24h/365d) – Chemtrec:: 1-800-424-9300 or 1-703-527-3887 (USA/CAN) / +1-703-741-5970
(international – can be called collect).

American Association of Poison Control Centers call (800) 222-1222 (24h/365d)

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