SAFETY DATA SHEET (SDS)

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

Product Name: **Kallestad™ HEp-2 Cell Line Substrate**

Product Number: **30471** (12 Wells/Slide, 60 Tests/Kit)
30472 (12 Wells/Slide, 240 Tests/Kit)
32583 (6 Wells/Slide, 48 Tests/Kit)
Catalog number(s) for replacement, optional and separately purchased components that can be obtained for use with this kit, and which are covered by this SDS include**: 26100, 26101, 26102, 26103, 26104, 26105, 26106, 30403, 30431, 30446, 30480, 31098** and **31996** (refer to Section 2).

Intended Use: An indirect fluorescent antibody procedure for the detection and semi-quantitation of human nuclear autoantibodies to aid in the diagnosis of autoimmune disease. The Kallestad HEp-2 Test detects autoantibodies to nuclear (ANA) antigens.

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

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

Website: www.bio-rad.com

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

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

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

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

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

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 any *Risk (R)* and *Safety (S)* statement provided below.

Component *	Content
R1 HEp-2 Substrate Slides 6 Well/Slide *Catalog # 26100, 26101* 12 Well/Slide *Catalog # 26102, 26103, 26104* *Optional Materials Available:* 24 Well/Slide *Catalog # 26105, 26106*	- **HEp-2** substrate fixed onto glass slides. - Handle slides by the edges. Do not apply pressure to surface of foil bag.
C0 Negative Control, 1 or 2 vials, 0.5 mL **WARNING**	- Pooled **normal human serum**, 1% bovine serum albumin. - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 **[**GHS / 2008/1272/EC Classification: WARNING; H303, H313; P312**]** [EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (dilution < 1%, but ≥ 0.1%).]

Component *	Content
C1 Positive Control, 1 vial, 0.5 mL **WARNING**	- Pooled **human serum** with a specific autoantibody activity, 1% bovine serum albumin. - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 **[**GHS / 2008/1272/EC Classification: WARNING; H303, H313; P312**]** [EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (dilution < 1%, but ≥ 0.1%).]
R2 FITC Conjugate, 1 or 4 vials, 2.5 mL *Catalog # 30446* *Optional Materials Available:* **FITC Conjugate,** 100 mL, *Catalog # 30480* **WARNING**	- Fluorescein conjugated **antiserum to human immunoglobulins** with 1% bovine serum albumin. in a phosphate buffered saline solution (pH ~ 7). - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 **[**GHS / 2008/1272/EC Classification: WARNING; H303, H313; P312**]** [EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (dilution < 1%, but ≥ 0.1%).]
R3 Mounting Media, 1 or 2 vials, 2.5 mL *Catalog # 30403*	- A semi-permanent buffered mounting media in a Trizma buffered solution, pH 7 - 8, containing: - **≤ 7.5% Polyvinyl alcohol** [PVA – $C_2H_4O)n$], CAS# 9002-89-5, EC No 209-183-3 [dilution is not subject to GHS and EU 2008/1272/EC Regulation or 1999/45/EC Directive labeling requirements.] - **≤ 20% 1,2-Propanediol** [propylene glycol – $C_3H_8O_2$], CAS# 57-55-6, EC No 200-338-0 [dilution is not subject to GHS and EU2008/1272/EC or 1999/45/EC labeling requirements].
R4 Phosphate Buffered Saline, pH 7.3, 11.34 g, 2 or 4 vials, *Catalog # 31098*	- **Phosphate buffered saline** (PBS) prepared with dibasic sodium phosphate, monobasic sodium phosphate and sodium chloride (dissolved pH 7.3). [Not subject to GHS and EU 2008/1272/EC regulatory requirements.]
R5 Evans Blue Counterstain, 1 vial, 2.5 mL *Catalog # 30431* **WARNING**	- **≤ 2% Evans blue stain** [$C_{34}H_{24}N_6O_{14}S_4$•4Na], CAS# 314-13-6, EC No 206-242-5, [dilution is not subject to GHS and EU 2008/1272/EC Regulation or 1999/45/EC Directive labeling requirements.] - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 **[**GHS / 2008/1272/EC Classification: WARNING; H303, H313; P312**]** [EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (dilution < 1%, but ≥ 0.1%).]
Blotting Strips 1/slide or 2/slide	- Paper blotting strips
Optional Materials Available: **Patient Sample Diluent,** 100 mL *Catalog # 31996* **WARNING**	- **1% bovine serum albumin**. - Buffer with protein stabilizers (bovine serum albumin) in a phosphate buffered saline solution (pH ~ 7). - Preserved with **0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 **[**GHS / 2008/1272/EC Classification: WARNING; H303, H313; P312**]** [EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (dilution < 1%, but ≥ 0.1%).]

***** Replacement, optional and separately purchased component Catalog numbers are provided in this column where available.

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):

[Component C0, C1, C2, R5, FITC Conjugate and the Patient Sample Diluent]

0.1% sodium azide [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 (dilution < 1%, but ≥ 0.1%).

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

Label(s):	*No Pictogram; none required due to dilution*
Signal Word:	**WARNING**
Label Hazard Statement:	**H303: May be harmful if swallowed.** **H313: May be harmful in contact with skin.**
Supplemental Hazard Statement:	*None Specified.*
Precautionary Statement – Prevention:	**P264**: Wash thoroughly after handling.
Precautionary Statement – Response:	**P312**: Call a POISON CENTER or doctor/physician if you feel unwell. *
Precautionary Statement – Storage:	*None Specified*
Precautionary Statement – Disposal:	**P501**: Dispose of contents and container in accordance to local, regional, national and international regulations.

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

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

Chemical Ingredient	Data / Information
Propylene glycol [≤ 20% v/v in component R3]	CAS#: 57-55-6 (100%) + RTECS#: TY2000000 (100%) + EC No: 200-338-0 (100%) + Synonyms: 1,2,-Propanediol Chemical Formula: $C_3H_8O_2$ (100%) + Flash Point: 217°F / 103°C (100%) + LD_{50} (oral-rat): 20,000 mg/kg (100%) + TLV and PEL: NE IATA/DOT ID: NE HMIS codes: H=1, F=0, R=0 ++ RCRA Code: NE *GHS / 2008/1272/EC Classification*: Not subject to EU 2008/1272/EC and GHS regulatory requirements ++ The chemical, physical and toxicological properties have not been thoroughly investigated. Propylene glycol solutions may cause slight irritation by all routes of entry. The potential for these adverse health effects is unknown for the small volume of **Propylene glycol** in this product, but is unlikely if handled appropriately with the requisite Good Laboratory Practices. Dispose of this material in accordance with local, regional, national and international regulation. EU Labelling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: **Not Listed**
Polyvinyl alcohol [≤ 7.5% w/v PVA in component R3]	CAS#: 9002-89-5 (100%) + RTECS#: TY2000000 (100%) + EC No: 209-183-3 (100%) + Chemical Formula: $(C_2H_4O)n$ (100%) + Flash Point: 174°F / 79°C (100%) + LD_{50} (oral-rat): >20,000 mg/kg (100%) + TLV and PEL: NE IATA/DOT ID: NE HMIS codes: H=1, F=0, R=0 ++ RCRA Code: NE *GHS / 2008/1272/EC Classification*: Not subject to EU 2008/1272/EC and GHS regulatory requirements ++ **Polyvinyl alcohol** solutions (<20%) are potentially irritating. [NOTE: this chemical has been designated by IARC with a carcinogen Classification 3, which indicates that "the Agent is NOT CLASSIFIABLE as Carcinogenic"]. The chemical, physical and toxicological properties have not been thoroughly investigated. The potential for adverse health effects is unknown for the diluted, small volume of **polyvinyl alcohol** in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulation. EU Labelling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: **Not Listed**

Chemical Ingredient	Data / Information
Sodium azide [0.1% w/v in component C0, C1, R2, R5, FITC Conjugateand *Optional* Patient Sample Diluent] **WARNING**	CAS#: 26628-22-8 (100%) + RTECS#: VY8050000 (100%) + EC No: 247-852-1 (100%) + Chemical Formula: NaN_3 (100%) + Flash Point: NE LD_{50} (oral-rat): 27 mg/kg (100%) + LC_{50} (inhalation-rat): 37 mg/m^3 (100%) + PEL/TLV: 0.3 mg/m^3 (ceiling) (100%) + IATA/DOT ID: UN1687, Class 6.1 (undiluted, 100%) + / IATA/DOT ID: NE (dilution) ++ HMIS Codes: H=2, F=0, R=1 ++ RCRA Code: P105 (undiluted, 100%) + EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (< 1% and ≥ 0.1%) ++ *GHS / 2008/1272/EC Classification*: WARNING; H303, H313; P312 ++ **Sodium azide**, a biocidal preservative may be harmful if swallowed [H303]; it has been evident to kill at low concentrations, if enough is ingested (more than supplied in kit). May be harmful in contact with skin. [H313]. May cause eye, skin or tissue irritation. May cause long lasting harmful effects to aquatic life. Avoid contact. Wash thoroughly after handling. Call a POISON CENTER or doctor/physician if you feel unwell [P312]. Avoid release to the environment. 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 these 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. EU Labelling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Toxic: T, Environmental Danger: N R 28: Very toxic if swallowed. R 32: Contact with acids liberates very toxic gas. R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S (1/2-): Keep locked up and out of the reach of children. S 28: After contact with skin, wash immediately with plenty of *soap and water*. S 45: In case of accident or if you feel unwell, seek medical advice immediately. S 60: This material and its container must be disposed of as hazardous waste. S 61: Avoid release to the environment. Refer to special instructions/safety data sheet.

Biological Ingredient	Data / Information
Human Serum [reactive and non-reactive in C0, C1]	The Human sera in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2) by FDA approved methods. No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ Standard and Universal Precautions when handling these reagents and all human blood or specimens. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* or WHO *Laboratory Biosafety Manual*. Avoid splashing, spills and the generation of aerosols. Secure in secondary containment with proper biohazard labeling. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures with appropriate decon agent or disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg. #1043-87), or equiv.) before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional, national and international regulations. Handle appropriately with the requisite Good Laboratory Practices, Standard and Universal Precautions. Persons handling blood samples should have the option of receiving hepatitis B vaccination.
Animal sera [≤ 1% v/v in component C1, C0, FITC Conjugate, and *Optional* Patient Sample Diluent]	This material is of animal origin (bovine) 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, Standard and Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulation.

HEp-2 Cell Line [Slide Component]	HEp-2 cell (well characterized human epithelial cell line) substrate slides have been solvent fixed and are not considered infectious. Handle appropriately with the requisite Good Laboratory Practices, Standard and Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulation. These Slides consist of 96-100% inert glass with a ~0-4% inert polymer coating, which have been biologically and chemically processed; because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped, so handle carefully, wear suitable gloves and/or other appropriate personal protective equipment and follow Good Laboratory Practices. Do not handle broken slides with unprotected hands.

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 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 following chemical constituents in the kit volumes and concentrations present [dilution not subject to EU or GHS hazard labeling]:
  - Fluorescein conjugated antiserum to human immunoglobulins with 1% bovine serum albumin [in component R2].
  - **< 1% Tris** (TRIZMA HCl) Buffer solution; Tris(hydroxymethyl)aminomethane: 2-amino-2-(hydroxy-methly)-1, 3-propanediol [$C_4H_{11}NO_3$•HCl], CAS# 1185-53-1, EC No 214-684-5 [in component R3].
  - **< 1% Tris** (TRIZMA BASE) Buffer solution; 2-Amino-2-(hydroxymethyl)-3,1-propanediol, [$C_4H_{11}NO_3$], CAS# 77-86-1, 25149-07-9; 108195-86-4, EC No 201-064-4 [in component R3].
  - **≤ 2% Evans blue stain** [$C_{34}H_{24}N_6O_{14}S_4$•4Na], CAS# 314-13-6, EC No 206-242-5 [in component R5]. [NOTE: this chemical has been designated by IARC with a carcinogen Classification 3, which indicates that "the Agent is NOT CLASSIFIABLE as Carcinogenic"]. The chemical, physical and toxicological properties have not been thoroughly investigated.
  - **Phosphate buffered saline** (PBS) prepared with dibasic sodium phosphate, monobasic sodium phosphate, and sodium chloride (dissolved pH 7.3) [in component R4].
  - The miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water, catalytic or other non-reactive ingredients.
- 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.

EMERGENCY FIRST AID MEASURES (4):

Health Effects: Symptoms of over exposure may include headache, dizziness, congestion and breathing difficulty. May be harmful if swallowed. May be harmful in contact with skin.

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. Isolate the hazard area and ventilate if appropriate. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Ensure that appropriate spill cleanup materials and PPE are available and used.
- Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA hazardous material spill and/or NFPA/Fire Code guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. Avoid release to the environment.
- Wear appropriate PPE. Immediately, and on-site if possible:
  - Decontaminate **Biohazard/Human Source Material** spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon agent or disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% ethanol or isopropanol, an iodophor (such as Wescodyne Plus), or a phenolic, etc.).
  - **Broken slides** contaminated with blood or other human source or potentially infectious material must be handled as ***Sharps*** per 29 CFR 1910.1030, OSHA Bloodborne Pathogen and other regulations however, dispose of this material in accordance with local, regional, national and international regulation.
    Slides processed with material that is not of human origin and is not pathogenic to humans, if broken, can typically be handled as normal uncontaminated broken glass labware however, dispose of this material in accordance with local, regional, national and international regulations.
- 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 *Standard* and *Universal Precautions.* All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics. Avoid release to the environment. Do not allow undiluted product hazardous chemical ingredient or large quantities of it to reach ground water or water course. Consult with your Environmental Health & Safety Office for assistance.
Storage:	Store the kit components as specified on the product label and/or in the product instructions provided with the test kit.
Caution, consult accompanying documents. Read and follow all the Precautions and Warnings in the kit product instructions (e.g. *PREPARATION AND STORAGE OF REAGENTS, WARNINGS FOR USERS, PRECAUTIONS FOR USERS)*.	
For *in vitro* diagnostic use.	

EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):

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

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

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

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes and eyes, and to prevent hazard 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 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. Protective coverings such as plastic wrap, aluminum foil or imperviously-backed absorbent pads used to cover equipment and/or surfaces must be removed and replaced if they become overtly contaminated.
Note:	Occupational exposure limit values and health hazard data were given in Section 3. Environmental controls are included in the following sections.

PHYSICAL AND CHEMICAL PROPERTIES (9):

Appearance:	Variable, generally aqueous liquids. Exceptions are the solid slides and related materials.		
Odour:	Data is not available.	**Odour threshold:**	Not established.
pH:	The liquid chemical components are between pH pH 6 and 9.		
Boiling point:	Not Established.	**Melting point:**	Not Established.
Flash point:	Not Applicable. Flammable limits: LEL/LFL is Not applicable; UEL/UFL is Not applicable.		
Evaporation rate:	Data is not available.		
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:	Data is not available.		
Vapor Density:	Data is not available.		
Relative density:	Variable; Approximately 1.		
Solubility:	The liquid chemical components are soluble in water.		
Partition coefficient (n-octanol/water):	Data is not available.		
Auto igniting:	Product is not known to be self-igniting.		
Decomposition temperature:	Data is not available.		
Viscosity:	Data is not available.		
Danger of explosion:	**Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up.		
No other standard characteristics applicable to the identification or hazards of the product are known.			

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.

Chemical Stability / Reactivity:	Stable under ordinary conditions of use and storage.

Conditions and/or Materials to Avoid:	**Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up.
Hazardous Decomposition Products:	Oxides of carbon or nitrogen may form when heated to decomposition.
Hazardous Polymerization:	Has not been reported to occur.

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 harmful if swallowed. May be harmful in contact with skin.
Primary Irritant Effect:	May slightly irritate eyes or skin, depending on amount and contact time.
Serious Eye Damage / Irritation:	May slightly irritate eyes or skin, depending on amount and contact time.
STOT-Single Exposure:	Data is not available.
STOT-Repeated Exposure:	Data is not available.
Aspiration Hazard:	Data is not available.
Other Acute Health Effects:	Because these slides are made of glass, they could potentially pose a slight physical cutting hazard, especially if broken or chipped, so handle carefully, wear suitable gloves and/or other appropriate personal protective equipment and follow Good Laboratory Practices. Do not handle broken slides with unprotected hands.

Biohazard Potential:

Uninfected human cells have been solvent fixed and are not considered infectious or carcinogenic. The Human sera in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2) on FDA licensed 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 *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,* the WHO *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Sensitization:	No sensitization effect known..
Carcinogenicity:	IARC designates **Evans Blue** (CAS# 314-13-6) in the carcinogen Group 3, which specifies "the Agent is NOT CLASSIFIABLE as Carcinogenic." IARC designates **Polyvinyl Alcohol** (CAS# 9002-89-5) in the carcinogen Group 3, which specifies, "the Agent is NOT CLASSIFIABLE as Carcinogenic."
Germ Cell Mutagenicity:	Data is not available
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):

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

Avoid release to the environment.

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

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.

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.

Broken slides contaminated with blood or other human source or potentially infectious material must be handled as ***Sharps*** per 29 CFR 1910.1030, OSHA Bloodborne Pathogen and other regulations however, dispose of this material in accordance with local, regional, national and international regulation.
Slides processed with material that is not of human origin and is not pathogenic to humans, if broken, can typically be handled as normal uncontaminated broken glass labware however, dispose of this material in accordance with local, regional, national and international regulation.

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: According to US DOT, IATA and UN "Model Regulations", the product must be transported as follows: No known transport restrictions.

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

REGULATORY INFORMATION (15):

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

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

Carcinogenicity Categories:

IARC (International Agency for Research on Cancer):

IARC Group 3, *The Agent is NOT CLASSIFIABLE as Carcinogenic to Humans*: **Polyvinyl alcohol**, CAS# 9002-89-5.

IARC Group 3, *The Agent is NOT CLASSIFIABLE as Carcinogenic to Humans*: **Evans blue**, CAS# 314-13-6.

NTP (National Toxicity Program): The product does not contain listed ingredients.

ACGIH TLV-CAR (Threshold Limit Value established by American Conference of Governmental Industrial Hygienists): The product does not contain listed ingredients.

OSHA Subpart Z (Occupational Safety and Health Administration, U.S. Department of Labor): The product does not contain listed ingredients.

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 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: HARMFUL: Xn 

Hazard Determining substance(s) of labeling (rated under 1999/45/EC unless otherwise specified):

0.1% Sodium azide, EC No 247-852-1, CAS# 26628-22-8 [Harmful: Xn; R 22; S 24-35-37 (< 1% and ≥ 0.1%).]

OTHER INFORMATION (16):

Risk Phrases:

R 22	Harmful if swallowed.
Caution	Contains human source material. Handle as if capable of transmitting potentially infectious agents (Standard and Universal Precautions).

Safety Phrases:

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

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards.

Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

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)
- *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
- 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*
- *Mexican Standard (NMX-R-019-SCFI-2011)*
- *Australian Inventory of Chemical Substances* (ACIS) [7-27-2012]
  (http://www.nicnas.gov.au/Industry/AICS/ViewChemical.asp?SingleHit=1&Chemical_Id=15270&docVer=)
- 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 Labelling 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;
- CNS – Central Nervous System
- DOT – Department of Transportation
- EC_{50} . half maximal effective concentration
- EU – European Union
- GHS - Globally Harmonized System
- IATA - International Air Transport Association
- IARC – International Agency for Research on Cancer
- ICAO - International Civil Aviation Organization
- IDLH - Immediately Dangerous to Life or Health
- IMDG - International Maritime Dangerous Goods
- IPCS – International Programme on Chemical Safety
- LC_{50} median lethal concentration, 50%
- LD_{50} - median lethal dose, 50%
- NIOSH – National Institute for Occupational Safety and Health
- NTP – National Toxicity Program
- OEL - Occupational Exposure Limit
- PEL - Permissible Exposure Limit
- ppm – parts per millón
- RTECS # - Registry of Toxic Effects of Chemical Substances number
- 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 ProtectionAgency
- US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
- WHO – World Health Organization (United Nations)

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

This Revision: Reformatted and updated existing information.

Bio-Rad Laboratories:

Department issuing SDS: Environmental Health and Safety.

Contact for general SDS information: Redmond 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

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
Belgium, Bio-Rad S.A.-N.V. Begoniastraat 5, B-9810 Nazareth Eke • Phone 3293855511 • Telefax 3293856554
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
Finland, Bio-Rad Laboratories, Linnanherrankuja 16, FIN-00950 Helsinki • Phone 358-9-804-22-00 • Telefax 3589-7597 5010
France, Bio-Rad Laboratories, 3 boulevard Raymond Poincaré, 92430 Marnes-la-Coquette • Phone +33 (0)1 47 95 60 00• Telefax +33 (0)1 47 41 91 33
Germany, Bio-Rad Laboratories GmbH, Heidemannstrasse 164, D-80939 Munich • Phone +49-(0)89-318840 • Telefax +49-(0)89-31884100
Greece, Bio-Rad Laboratories M.EPE, 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 +39-02-21609-398
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
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
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
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
Switzerland, Bio-Rad Laboratories AG, Nenzlingerweg 2, CH-4153 Reinach BL• Phone 41-61-717-95-55 • Telefax 41-61-717-95-50
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