SAFETY DATA SHEET (SDS)

SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER

Product Name: **Anti-Borrelia (Lyme) Microplate EIA**

Product Number: **Catalog 32507** (96 Determinations)
Catalog number(s) for replacement, separately purchased components that can be obtained for use with this kit, and which are covered by this SDS, include**: 25268, 25269, 25270, 25271, 25272, 25273, 25274, 25275, 25276**, and **25277** (refer to Section 2).

Intended Use: For the qualitative and/or semi-quantitative detection of *borrelia burgdorferi* total antibodies (IgG, IgM, and IgA) in serum by enzyme immunoassay (EIA) to be used as an aid in the diagnosis of Lyme disease. For *in vitro* diagnostic use.

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** (US) or **001-703-527-3887** (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. American Association of Poison Control Centers call (800) 222 1222 (*24h/365d*)

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*	Contents
R1: Anti-Borrelia (Lyme) Microplate (12 X 8 microwell strips)	- *Anti-Borrelia* microplate strips [Reaction Wells], coated *with borrelia burgdorferi* sensu strictu (strain B31) extract and P39 recombinant protein. - Potential residue of sodium azide [NaN_3] used as production preservative (aspirated prior to drying). Clear plastic solid.
R2: Specimen Diluent, 1 x 50 mL Catalog No. 25268	- **0.01M Phosphate buffered saline** (PBS, pH 6.2-7.6) with carrier protein. - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. Clear orange liquid.
S1: Calibrator 1 x 0.3 mL Catalog No. 25269	- Human *anti-B. burgdorferi* serum (prediluted to 1:20) that has been tested by an FDA approved method and found negative for Hepatitis B surface antigen (HBsAg) and antibody to Hepatitis C virus (HCV) and Human immunodeficiency virus type 1 and 2 (HIV-1/HIV-2), in Specimen Diluent (R2). - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. Clear to pale yellow liquid.

C0: Negative Control 1 x 0.3 mL Catalog No. 25270	- Nonreactive Human serum that has been tested by an FDA approved method and found negative for Hepatitis B surface antigen (HBsAg) and antibody to Hepatitis C virus (HCV) and Human immunodeficiency virus type 1 and 2 (HIV-1/HIV-2). - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. Clear to pale yellow liquid.
C1: Positive Control 1 x 0.1 mL Catalog No. 25271	- Human *anti-B. burgdorferi* serum that has been tested by an FDA approved method and found negative for Hepatitis B surface antigen (HBsAg) and antibody to Hepatitis C virus (HCV) and Human immunodeficiency virus type 1 and 2 (HIV-1/HIV-2). - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. Clear to pale yellow liquid.
R3: Borrelia Blocker 1 x 25 mL Catalog No. 25272	- *E. coli* protein in **0.01 M phosphate buffered saline** (PBS, pH 6.2-7.6) with carrier protein. - Preserved with **< 0.1% sodium azide** [NaN_3], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. Clear yellow liquid.
R4: Wash Buffer Concentrate (20X) 1 x 50 mL Catalog No. 25273	- **0.2 M Phosphate buffered saline** (PBS) and 1.0% Tween (final solution pH 6.2-7.6). Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. Clear liquid.
R5: Conjugate, 1 x 12 mL Catalog No. 25274	- Peroxidase-conjugated goat anti-human antibodies (IgG, IgM and IgA) in **0.01 M phosphate buffered saline** (PBS, pH 6.2-7.6), carrier protein and preservatives. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. Clear blue liquid.
R6: Substrate Buffer 1 x 25 mL Catalog No. 25275	- **0.1 M Sodium citrate** (pH 4.4-4.6) and **0.01% hydrogen peroxide** [H_2O_2], EC No 231-765-0, CAS# 7722-84-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. Clear liquid.
R7: Substrate Concentrate, 1 x 1.5 mL Catalog No. 25276	- **2.19% ABTS** [2-2'-azino-di-(3-ethylbenzthiazoline sulfonate) - $C_{18}H_{18}N_4O_6S_4\bullet(NH_3)$], CAS# 30931-67-7 in **0.1 M sodium citrate** (pH 4.4-4.6). Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. Clear green liquid.
R8: Stop Solution 1 x 25 mL Catalog No. 25277	- **0.25 M Oxalic acid** [~2.25% $C_2H_2O_4$], CAS# 144-62-7, EC No 205-634-3. Not subject to US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. Clear liquid.

Markings according to the *United Nations* (UN) Globally Harmonized System (GHS), *United States* Hazard Communication Standard (US HCS), *European Community* (EC) 2008/1272/EC (EC CLP) guidelines and analogous GHS-based global regulations: The chemical dilutions in this product are not subject to classification or labeling according *United Nations (UN)* GHS, *United States* Hazard Communication Standard (US HCS), related *European Community (EC)* 2008/1272/EC (EC CLP) guidelines and applicable analogous GHS-based global regulations.

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 (LD_{50}, 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 UN 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 for the key / legend to abbreviations and acronyms.

Chemical Ingredient Data / Information

Chemical Ingredient: Sodium azide

Chemical concentrations found in this product: **< 0.1% in an aqueous solution (**in components R2, R3, S1, C0, C1, potential dried plate residue in component R1)

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

CAS#: 26628-22-8 (100%)
EC No: 247-852-1 (100%)
Index No: 011-004-00-7 (100%)
RTECS#: VY8050000 (100%)
Chemical Formula: NaN_3 (100%)

LD_{50} (oral-rat): 27 mg/kg
LC_{50} (inhalation-rat): 37 mg/m^3
LD_{50} (skin-rat): 50 mg/kg
Fish LC_{50} – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h
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: Oxalic acid

Chemical concentrations found in this product: **2M in an aqueous solution**

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

CAS#: 144-62-7 (100%)
EC No: 205-634-3 (100%)
Index No: 607-006-00-8
RTECS#: RO2450000 (100%)
Chemical Formula: $C_2H_2O_4$ (100%)
Molecular weight: 90.03 g/mol (100%)

LD_{50} (oral-rat): 1080 mg/kg
LC_{50} (inhalation-rat): NE
LD_{50} (skin-rabbit): 20000 mg/kg
LC_{50} (48 hr-fish): static test LC_{50} - Leuciscus idus melanotus - 160 mg/l
Flash Point: NE
pH ~ 1.3 at 9 g/l

Synonyms/Trade Names: Ethanedioic acid; 144-62-7; Aktisal; Aquisal; Oxalate
Serious eye damage/eye irritation – Eyes – Rabbit – Result: Risk of serious damage to eyes. - 24 h (OECD Test Guideline 405)

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

DANGER!

Acute Tox. – oral Cat. 4, Acute Tox. – skn. Cat. 4, Eye Damage Cat. 1
H302 + H312, H318
P260, P270, P280; P301 + P312 + P330, P302 + P352 + P312, P305 + P351 + P338 + P310, P363; P501

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

Biological Ingredient	Data / Information
Human Serum reactive and non-reactive in C0, C1 and S1 	The Human sera in certain 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 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 *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* 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 following chemical constituents in the kit volumes and concentrations present [chemical or dilution is not subject to GHS, EC CLP or GHS-based hazard labeling]:
  - 0.2M Phosphate buffered saline (PBS) and 1.0% Tween (final solution pH 6.2-7.6). (component R4)
  - 0.1M Sodium citrate (pH 4.4-4.6) and 0.01% hydrogen peroxide [H_2O_2], EC No 231-765-0, CAS# 7722-84-1. (component R6)
  - 2.19% ABTS® (2-2'-azino-di-[3-ethylbenzthiazoline sulfonate]), $C_{18}H_{18}N_4O_6S_4$ (NH_3), CAS# 30931-67-7. (component R7)
  - Peroxidase-conjugated goat anti-human antibodies (IgG, IgM and IgA) in 0.01M phosphates buffered saline (PBS, pH 6.2-7.6) with carrier protein. (component R5)
  - The miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water or other non-reactive ingredients.
- According to the manufacturer, their proprietary preservative in R5 is corrosive in its concentrated form, but at this concentration is no longer corrosive / regulated, but might be slightly irritating to skin or eyes with extended contact.
- 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.

SECTION 4: EMERGENCY FIRST AID MEASURES

Health Effects:	May slightly irritate eyes or skin, depending on amount and contact time. 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

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 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.).
  - Neutralize corrosive acidic spills with the appropriate *Acid 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), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical, and laboratory wastes must be handled and discarded in accordance with all local, regional, national, and international regulations.
- Refer to Sections 8 and 13 for more specifics.

SECTION 7: HANDLING AND STORAGE INFORMATION

Handling:	This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper Good Laboratory Practices and safety guidelines for handling chemical, biological and laboratory hazards. Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent, and eye/face protection. Keep containers tightly closed; avoid splashing, spills, and the generation of aerosols. Handle all human source materials, specimens, 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. (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 *in vitro* diagnostic use.

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/m3, 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/m³, 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/m³ 0.1* ppm / 0.3** mg/m³	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]

Concentrated Oxalic acid [CAS# 144-62-7] - OEL:

ARAB Republic of Egypt:	TWA	1 mg/m^3	1993
AUSTRALIA:	TWA STEL	1 mg/m^3 2 mg/m^3	2008
AUSTRIA:	MAK-TMW	1 mg/m^3, inhal, skin	2007

Concentrated Oxalic acid [CAS# 144-62-7] - OEL:			
BELGIUM:	TWA STEL	1 mg/m^3 2 mg/m^3	 2002
DENMARK:	TWA	1 mg/m^3	2011
EC (European Union):	TWA	1 mg/m3	2006
FINLAND:	TWA STEL	1 mg/m^3 3mg/m^3, skin	 2011
FRANCE:	VME	1 mg/m^3	2006
HUNGARY:	TWA	1 mg/m^3	2000
ICELAND:	STEL	1 mg/m^3	2011
KOREA:	TWA STEL	1 mg/m^3 2 mg/m^3	 2006
MEXICO:	TWA STEL k	1 mg/m^3 2 mg/m^3	 2004
THE NETHERLANDS:	MAC-TGG	1 mg/m^3	2003
NEW ZEALAND:	TWA STEL	1 mg/m^3 2 ppm	 2002
NORWAY:	TWA	0.01 mg(Ag)/m^3	1999
PERU:	TWA	1 mg/m3; 2 mg/m^3	 2005
POLAND:	MAC(TWA) MAC(STEL)	1 mg/m^3 2 mg/m^3	 1999
SWEDEN:	TWA STEL	1 mg/m3 2 mg/m^3	 2005
SWITZERLAND:	MAK-W	1 mg/m^3, inhal	2011
UNITED KINGDOM:	TWA STEL	1 mg/m^3 2 mg/m^3	 2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES*:	TLV-TWA TLV–STEL PEL-T-TWA PEL-T-STEL REL-TWA REL-STEL	1 mg/m³ 2 mg/m³ 1 mg/m³ 2 mg/m³ 1 mg/m³ 2 mg/m³	 ACGIH, 1971 OSHA 29,1910.1000 Z-1, 1994 NIOSH Recommended Exposure Limits
Remarks: Eye, skin, & Upper Respiratory Tract irritation.			
[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. It is recommended that users handle potentially infectious human source material / patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.
Eye / Face Protection:	Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.

Protective Gloves:	Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves, such as Nitrile, Neoprene and Vinyl, are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never be reused. Wash hands thoroughly after removing gloves.
Protective Clothing:	Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.
Respiratory Protection:	Do not breathe mist / vapors/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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Variable, generally aqueous liquids. Exceptions are the solid microtiter plate and related materials. Refer to Section 2 for details.		
Odor/odour:	No applicable information was found.	**Odor/odour threshold:**	Not established.
pH:	Most of the liquid chemical components are between pH 5 and 9. Exceptions are the following acidic solutions: **Substrate Concentrate**, 2.19% ABTS® in 0.1M sodium citrate at pH 4.4 to pH 4.6 **Substrate Buffer**, 0.1M sodium citrate and 0.01% hydrogen peroxide at pH 4.4 to pH 4.6 **Stop Solution**, 0.25M oxalic acid at pH 1 to pH 2.		
Boiling point:	Undetermined.	**Melting point:**	Undetermined.
Flash point:	Not Applicable. Flammable limits: LEL/LFL is Not Applicable; UEL/UFL is Not Applicable		
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/vapour pressure:	No applicable information was found.		
Vapor/vapour density:	No applicable information was found.		
Relative density:	Approximately 1.		
Solubility:	The liquid chemical components are soluble in water. The acidic solutions may release heat.		
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:	***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.		
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 and/or materials 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. Do not allow the ***acidic solutions*** to come in contact with strong bases, oxidizing agents and metals.
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:	May be harmful if enough is ingested (generally quantities above those found in the kit).
Primary Irritant Effect:	May slightly irritate eyes or skin, depending on amount and contact time.
Serious Eye Damage / Irritation:	Contact with the ***Stop Solution*** 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 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) 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* or the WHO *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 **Source: Raw Material vendor SDS, RTECS, CCOHS databases and/or regulatory research*
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:	The ***corrosive Stop Solution*** and are hazardous for drinking water and toxic to aquatic organisms by pH modification if not neutralized: 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.

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 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.
- Dilute **Acidic *Substrate Buffer*** and ***Substrate Concentrate*** **Wastes** with a pH 4.4 to pH 4.6 may need to be neutralized to pH 6-8 for safe sewer disposal in many areas, check your local, regional, national and international ordinances accordingly.
- The **Acidic *Stop Solution*** **waste** at pH 1 to pH 2 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 ≤ 2, 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 and regional ordinances accordingly.

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

Recommended cleansing agent: Water, if necessary with appropriate cleanser. Contact your Environmental Health & Safety Office for your specific cleansing materials and procedures.

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: According to the manufacturer, their ***Stop Solution*** containing an aqueous **0.25 M Oxalic acid** dilution is no longer a regulated corrosive, thus has no transport restrictions.

T**ransport 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**: 0

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** – Regulation **Lao-An-3-Tzu-No. 0960145703** / Published National Standard **CNS 15030**
3. **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
4. **People's Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
5. **New Zealand** – *Hazardous Substances and New Organisms* Act 1996 (**HSNO**), *Hazardous Substances (Classification)* Regulations 2001 and *Thresholds and Classifications* January 2012 (as published in 2008)
   Composite HSNO Hazard Class: Based on available data, the classification criteria are not met.
6. **Mexico – Standard NOM-018-STPS-2015, NMX-R-019-SCFI-2011**
7. **Korea** – ***Public Notice 2013-37, MoEL 2016-19,*** *Standard for classification and labeling of chemical substances and MSDS*
8. **Japan** – Industrial Safety and Health Law (ISHL) National Standard **JIS Z7252, JIS Z7253**
9. **European Community** (EC) – applicable ***CLP*** related regulations **(2010/453/EC, 2008/1272/EC, 2006/1907/EC** etc.)
10. **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.
11. **Brazil** – Regulation **NRB 14725**
12. **Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety** (WHS) Act.
13. 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
Europe European Inventory of Existing Commercial Chemical Substances (EINECS) or Europe 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)

Regulation (EC) No. 1907/2006 (REACH):

Chemicals included in the Candidate List of Substances of Very High Concern (SVHC): **None**

REACH No.: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

United States SARA:

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
- ***Hydrogen peroxide*****,** CAS# 7722-84-1; Revision Date: 1993-04-24

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.

Japan *– Industrial Safety and Health Law (ISHL) National Standard* ***JIS Z7252, JIS Z7253***

Classification JIS – listed in Class 1 **-** Listed substances: ***Sodium Azide***, CAS# 26628-22-8 [No. PRTR Law: 11], product concentration: **< 0.1%**.

Water hazard class: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous to water.

California Proposition 65: 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)
Eye Damage.	Serious eye damage
Aquatic Acute	Acute aquatic toxicity
Aquatic Chron.	Chronic aquatic toxicity
Cat.	Category
H300 + H310	Fatal if swallowed or in contact with skin.
H302 + H312	Harmful if swallowed or in contact with skin.
H318	Causes serious eye damage.
H410	Very toxic to aquatic life with long lasting effects.
P260	Do not breathe mist / vapors/vapours / spray.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product
P273	Avoid release to the environment.
P280	Wear protective gloves / protective clothing / eye protection / face protection.
P301 + P312 + P330	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
P302 + P350	IF ON SKIN: Gently wash with plenty of soap and water.
P302 + P352 + P312	IF ON SKIN: Wash with plenty of soap and water. Call a POISON CENTER or doctor/physician if you feel unwell.
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.
P363	Wash contaminated clothing before reuse
P501	Dispose of contents/ container to an approved waste disposal plant.
P501	Dispose in accordance with all applicable local, regional, national and international regulations.
Caution	Contains human source material. Handle as if capable of transmitting potentially infectious agents (*Standard* and *Universal Precautions*).

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.

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 1996 (HSNO)
The *People's Republic of China* National Standard GB/T 17519-2013, GB 30000-2013 [regulatory translation if available and summaries]
Taiwan Regulation Lao-An-3-Tzu-No. 0960145703 / Published National Standard CNS 15030 [regulatory translation if available / summaries]
Korean 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*
Australian Inventory of Chemical Substances (ACIS) Listing
California *Proposition 65*

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
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
EC_{50} – 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
HNOC – 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
LC_{50} – median lethal concentration, 50%
LD_{50} – 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.

This Revision: Updated, reformatted and added new GHS information.

Preparation date: Refer to the date in the footer.

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