

MATERIAL SAFETY DATA SHEET

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

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 MSDS 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.

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

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

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

Emergency Phone Number: This MSDS is listed with CHEMTREC (800) 424-9300. Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

COMPOSITION / INFORMATION ON INGREDIENTS -- 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.

Component*	Contents
R1: Anti-Borrelia (Lyme) Microplate (12 X 8 microwell strips)	- Anti-Borrelia (Lyme) microplate strips [Reaction Wells], coated with <i>borrelia burgdorferi</i> sensu stricto (strain B31) extract and P39 recombinant protein. Clear plastic solid. - Potential residue of sodium azide [NaN ₃] used as production preservative (aspirated prior to drying).
R2: Specimen Diluent, 1 bottle (50 mL) Catalog No. 25268	- 0.01M Phosphate buffered saline (PBS, pH 6.2-7.6) and carrier protein. Clear orange liquid. - Preserved with < 0.1% sodium azide [NaN ₃], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8, dilution below EU regulated labeling levels (1999/45/EC– dilution < 0.1%).
S1: Calibrator 1 vial (0.3 mL) Catalog No. 25269	- Human <i>anti-B. burgdorferi</i> (Lyme) serum (prediluted to 1:20) that has been tested by an FDA approved method and found negative for Hepatitis B surface antigen (HBsAg), antibody to Hepatitis C virus (HCV) and Human immunodeficiency virus type 1 and 2 (HIV-1/HIV-2), in Specimen Diluent (R2). Clear to pale yellow liquid. - Preserved with < 0.1% sodium azide [NaN ₃], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8, dilution below EU regulated labeling levels (1999/45/EC– dilution < 0.1%).
C0: Negative Control 1 vial (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). Clear to pale yellow liquid. - Preserved with < 0.1% sodium azide [NaN ₃], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8, dilution below EU regulated labeling levels (1999/45/EC– dilution < 0.1%).
C1: Positive Control 1 vial (0.1 mL) Catalog No. 25271	- Human <i>anti-B. burgdorferi</i> (Lyme) 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). Clear to pale yellow liquid. - Preserved with < 0.1% sodium azide [NaN ₃], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8, dilution below EU regulated labeling levels (1999/45/EC– dilution < 0.1%).
R3: Borrelia Blocker 1 bottle (25 mL) Catalog No. 25272	- <i>E. coli</i> protein in 0.01M phosphate buffered saline (PBS, pH 6.2-7.6) and carrier protein. Clear yellow liquid. - Preserved with < 0.1% sodium azide [NaN ₃], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8, dilution below EU regulated labeling levels (1999/45/EC– dilution < 0.1%).

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R4: Wash Buffer Concentrate (20X) 1 bottle (50 mL) Catalog No. 25273	- 0.2M Phosphate buffered saline (PBS) and 1.0% Tween (final solution pH 6.2-7.6). Clear liquid.
R5: Conjugate, 1 bottle (12 mL) Catalog No. 25274	- Peroxidase-conjugated goat anti-human antibodies (IgG, IgM and IgA) in 0.01M phosphate buffered saline (PBS, pH 6.2-7.6), carrier protein and preservatives [dilution not subject to EU labeling according to EU Directives]. Clear blue liquid.
R6: Substrate Buffer 1 bottle (25 mL) Catalog No. 25275	- 0.1M Sodium citrate (pH 4.4-4.6) and 0.01% hydrogen peroxide [H ₂ O ₂], EINECS/ELINCS No: 231-765-0, CAS# 7722-84-1 [(S25-36) [dilution not subject to EU labeling according to EU Directives]. Clear liquid.
R7: Substrate Concentrate, 1 vial (1.5 mL) Catalog No. 25276	- 2.19% ABTS [®] (2-2'-azino-di-[3-ethylbenzthiazoline sulfonate]), C ₁₈ H ₁₈ N ₄ O ₆ S ₄ .(NH ₃), CAS# 30931-67-7 [dilution not subject to EU labeling according to EU Directives] in 0.1M sodium citrate (pH 4.4-4.6). Clear green liquid.
R8: Stop Solution 1 bottle (25 mL) Catalog No. 25277	- 0.25M Oxalic acid [C ₂ H ₂ O ₄], EINECS/ELINCS No: 205-634-3, CAS# 144-62-7 [Harmful (Xn) R: 21/22; S: 24/25-26-35-36]. Clear liquid.

* Replacement, optional and separately purchased component catalog numbers are provided in this column.

Markings according to the *United Nations (UN) Globally Harmonized System (GHS), United States Hazard Communication Standard (HCS) and European Community (EC) 2008/1272/EC guidelines:*

This product has been conservatively classified and labeled in accordance with applicable *United Nations (UN) GHS, United States Hazard Communication Standard (HCS) and related European Community (EC) 2008/1272/EC guidelines*. The following regulated hazardous chemical concentrations are found in product component(s):

0.1% sodium azide [NaN₃], 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]:

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

HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (3):

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The following information is furnished for those kit hazardous constituents that require regulatory control or disclosure at the concentration found in the kit. Note that the information here is often based on data from the chemical raw material (LD50, exposure limits, etc.). The kit contains a significantly diluted concentration in an aqueous solution; thus, the assessment below has taken hazard reduction processing into consideration when possible. The EU classification was made according to the latest editions of the EU lists and expanded upon from company and literature data.

Chemical Ingredient	Chemical Data/Information
<p>Sodium Azide [NaN₃], < 0.1% in components R2, R3, S1, C0, C1, potential dried plate residue in component R1</p>	<p>CAS# 26628-22-8 (100%) + RTECS# VY8050000 (100%) LD50 (oral-rat): 27 mg/kg (100%) + PEL/TLV: 0.3 mg/m³ (ceiling)(100%) + HMIS codes: H=1, F=0, R=1 ++ EU Classification: None (due to dilution, < 0.1%); S35-36 ++</p> <p>Sodium azide is a biocidal preservative which may be detrimental if enough is ingested (quantities above those found in the kit). Avoid contact with metals; sodium azide may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup. This material and its container must be disposed of in a safe way and in accordance with local, regional and national regulations. The potential for adverse health effects is unknown for the highly diluted, small volume of sodium azide in this kit, but unlikely if handled appropriately, with the requisite Good Laboratory Practices and Universal Precautions.</p> <p>EINECS/ELINCS No: 247-852-1 (100%) + Flash Point: NE LC50 (inhalation-rat): 37 mg/m³ (100%) + IATA/DOT ID: UN1687 (undiluted, 100%) + RCRA Code: P105 (undiluted, 100%) +</p>
<p>0.25M Oxalic Acid [C₂H₂O₄] in component R8</p>	<p>CAS# 144-62-7 (100%) + LD50 (oral rat): 375-475 mg/kg (100%) + PEL/TLV: 1mg/m³; 2mg/m³ (ceiling) (100%) + RCRA Code: D002 (if not neutralized) ++ HMIS codes: H=2, F=0, R=0 ++ EU Classification: Harmful (Xn) R: 21/22; S: 24/25-26-35-36 ++</p> <p>Dilute (0.25M) oxalic acid solutions are harmful in contact with skin and if swallowed and are irritating to skin and severely irritating to eyes (greater exposures may cause eye damage). In case of contact with eyes, immediately rinse with copious water and seek medical attention. This material and its container must be disposed of in a safe way; it can typically be neutralized to pH 5-8 for disposal if trained and equipped to do so; however, always dispose of dilute alkaline solutions as required by local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices.</p> <p>RTECS# RO2450000 (100%) + LD50 (skin rabbit): 20000 mg/kg Flash point: NE IATA/DOT ID: NE (100%) + EINECS/ELINCS No: 205-634-3 (100%) +</p>
<p>Human Serum reactive and non-reactive in C0, C1 and S1</p>	<p>The Human sera in the components of this product were tested by an FDA approved method and found non-reactive 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). 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 Universal Precautions when handling these reagents and all human blood, specimens or patient samples, which represent an unknown, heightened hazard. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH <i>Biosafety in Microbiological and Biomedical Laboratories</i>. 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 during kit use and sample handling. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures, with appropriate decon agent/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 and national regulations. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Persons handling blood samples should have the option of receiving hepatitis B vaccination.</p>

+ 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)

Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity

Anti-Borrelia (Lyme) Microplate EIA**General Kit Composite Health Hazards:**

- ◆ No significant adverse health effects are expected by any route for the following chemical constituents in the kit volumes and concentrations present when handled with requisite Good Laboratory Practices [dilution not subject to EU Directive labeling]:

Chemical Constituent Details	Component
0.2M Phosphate buffered saline (PBS) and 1.0% Tween (final solution pH 6.2-7.6).	R4
0.1M Sodium citrate (pH 4.4-4.6) and 0.01% hydrogen peroxide [H ₂ O ₂], EINECS/ELINCS No: 231-765-0, CAS# 7722-84-1 (S25-36) [dilution not subject to EU labeling according to EU Directives].	R6
2.19% ABTS [®] (2-2'-azino-di-[3-ethylbenzthiazoline sulfonate]), C18H18N4O6S4 (NH3), CAS# 30931-67-7 [dilution not subject to EU labeling according to EU Directives].	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.	R5

- ◆ The manufacturer's proprietary preservative in R5 is corrosive in its concentrated form, but at this concentration is no longer corrosive, but might be irritating to skin or eyes and may be a potential skin sensitizer.
- ◆ No significant adverse health effects are expected by any route for the miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water or other non-reactive ingredients, in the kit volumes and/or concentrations present.
- ◆ 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.

EMERGENCY FIRST AID MEASURES (4):

Health Effects:	Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Skin contact may cause stinging, transient redness or dermatitis. May cause allergic skin reaction upon repeated exposure.
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. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present. Treat symptomatically and supportively.
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.
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.

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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. 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.
- ◆ Wear appropriate PPE. Immediately, and on-site if possible, neutralize corrosive acidic spills with the appropriate *acid adsorbent* product. Follow established laboratory policy for appropriate spill response and cleanup.
- ◆ Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows, acid 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 and national regulations.

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. 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 specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per Universal Precautions. Refer to Section 8 for more specifics. Consult with your Environmental Health & Safety Office for assistance.
- Storage:** Store according to product label instructions (generally at 2-8°C).
Read and follow all the precautions and warnings in the kit product instructions. Refer to the *Package Insert* for additional product information.

EXPOSURE CONTROL/PERSONAL PROTECTION MEASURES (8):

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, 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 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 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.
- 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.

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Note: 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 microtiter plate and related materials. Refer to Section 2.
- 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.
- Flash Point: Not applicable.
- Auto-igniting: Product is not known to be self-igniting.
- Danger of Explosion: Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup.
- Solubility: The liquid chemical components are soluble in water. The acidic solutions may release heat.
- pH: Most of the liquid chemical components are between pH 5 and 9. Exceptions are the following acidic solutions: The Substrate Concentrate, 2.19% ABTS[®] in 0.1M sodium citrate at pH 4.4 to pH 4.6; the Substrate Buffer, 0.1M sodium citrate and 0.01% hydrogen peroxide at pH 4.4 to pH 4.6; and the Stop Solution, 0.25M oxalic acid at pH 1 to pH 2.
- Specific Gravity: Not established.
- No other standard characteristics applicable to the identification or hazards of the kit are known.

STABILITY AND REACTIVITY INFORMATION (10):

- Stability: Stable under ordinary conditions of use and storage.
- Materials to Avoid: Do not allow the acidic solutions to come in contact with strong bases, oxidizing agents and metals.
- Conditions to Avoid: Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup.
- Hazardous Decomposition Products: May emit toxic oxides of carbon and nitrogen under fire conditions.
- Hazardous Polymerization: Has not been reported to occur.

TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):

Refer to Section 3 for the kit component concentrations. The composite toxicological information for this product is:

Acute Health Effects

Toxicity: May be harmful in contact with skin and if swallowed.

Primary Irritant Effect: A skin and severe eye irritant; prolonged contact may cause eye injury.

Other Acute Health Effects: Risk of serious damage to eyes.

Biohazard Potential

The Human sera in the components of this product were tested by an FDA approved method and found non-reactive 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). 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.

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Employ Universal Precautions; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH Biosafety in Microbiological and Biomedical Laboratories or equivalent. Persons handling blood samples should have the option of receiving Hepatitis B vaccination. The Microplate coated with *Borrelia burgdorferi* sensu strictu (strain B31) extract and P39 recombinant protein, and the Borrelia Blocker with *E. coli* protein should be handled following general biosafety guidelines and Universal Precautions.

Chronic Toxicity

- Sensitization: May cause allergic skin reaction upon repeated exposure.
- Carcinogenicity: No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC or OSHA.
- Reproductive Hazard: No reproductive toxic effect known.

Additional Toxicological Information

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

ECOLOGICAL INFORMATION (12):

The **corrosive** Stop Solution, substrate buffer and concentrate components are hazardous for drinking water and toxic to aquatic organisms by pH modification if not neutralized.

DISPOSAL CONSIDERATIONS (13):

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional and national 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; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup; check your 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 national, regional and local ordinances accordingly.

Dilute acidic substrate concentrate and substrate buffer wastes, with a pH 4.4 to pH 4.6, may need to be neutralized to pH 5-8 for safe sewer disposal in many areas; check your local and regional ordinances accordingly.

The acidic Stop Solution waste at pH 1 to pH 2 should be neutralized to pH 5-8 for safe sewer disposal; check your local and regional ordinances accordingly. In addition, if the final pH measures ≤ 2 , it requires disposal as a corrosive material in an RCRA approved waste facility (or equivalent); the US RCRA waste disposal code for this waste, if not neutralized, is D002; check your national and regional ordinances accordingly.

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

TRANSPORT INFORMATION (14):

Recommended product shipping: Shipping must be conducted in accordance with all applicable local, regional and national 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.

Unused product multi-modal transport: No known transport restrictions.

Anti-Borrelia (Lyme) Microplate EIA**REGULATORY INFORMATION (15):**

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

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

Carcinogenicity Categories: No component, mixture or constituent has been classified as a carcinogen by NTP (National Toxicity Program), IARC (International Agency for Research on Cancer), TLV-CAR (Threshold Limit Value established by ACGIH) or OSHA.

WHMIS Classification: This MSDS contains the required information in accordance with the WHMIS hazard classification criteria for this product.

Markings according to European guidelines:

This product has been classified and labeled in accordance with applicable European Community (EC) Directives (refer to 1999/45/EC, 2001/59/EC and 2001/60/EC).

Hazard Designation of Composite Product: HARMFUL (Xn);



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

0.25M Oxalic acid [C₂H₂O₄], EINECS/ELINCS No: 205-634-3, CAS# 144-62-7 [Harmful (Xn) R 21/22; S 24/25-26-35-36].
< 0.1% Sodium azide, EINECS/ELINCS No: 247-852-1, CAS# 26628-22-8 [S 35-36].

Risk Phrases:

R 21/22: Harmful in contact with skin and if swallowed.
Caution Contains human source material. Handle as if capable of transmitting potentially infectious agents (Universal Precautions).

Safety Phrases:

S 24/25 Avoid contact with skin and eyes.
S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 35 This material and its container must be disposed of in a safe way.
S 36 Wear suitable protective clothing.

OTHER INFORMATION (16):

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

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

This revision: Reformatted existing information.

Contact for general information: Bio-Rad Laboratories, Redmond Operations
Environmental Health & Safety
6565 185th Ave. NE
Redmond, WA 98052
Phone: 425-881-8300 (8 am to 5 pm PST)



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