MATERIAL SAFETY DATA SHEET

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

Product Name: **TOXOPLASMA IgM EIA**

Product Number: **25176** (96 Test Kit)

Intended Use: For the qualitative and quantitative detection of human IgM antibodies to Toxoplasma in human serum by enzyme immunoassay, to aid in the diagnosis of Toxoplasma infection. A positive result is presumptive for the detection of anti-*Toxoplasma gondii* antibodies and presumptive for the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infection. Patient testing with anti-*Toxoplasma gondii* IgM antibody assay must be accompanied by an anti-*Toxoplasma gondii* IgG antibody assay. The assay's performance characteristics have not been established for neonatal toxoplasmosis diagnosis. This assay has not been cleared/approved by the FDA for blood/plasma donor screening. *For In Vitro Diagnostic Use Only.*

Catalog number(s) for replacement components that can be obtained for use with this kit, and which are covered by this MSDS include: **25187, 25190, 25191** and **25192** (refer to Section 2).

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
Coated Wells, 12 eight-well strips	- Coated with sonicated/inactivated *Toxoplasma gondii* Antigen, Strain RH. [Color ID: Orange]
Well Support, One	- No known hazardous ingredients.
Diluent, (pink color) 25 mL bottle Catalog # 25187	- Phosphate-buffered saline with a protein stabilizer and absorbents for rheumatoid factor and human IgG. - Preserved with 0.1% sodium azide [NaN_3], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8; Xn: Harmful; R 22; S 24-35-37 (1999/45/EC – dilution < 0.25% but ≥ 0.1%).
Calibrator 1, 0.6 mL vial	- Normal human serum strongly reactive for Toxoplasma IgM antibodies. Index and IU/mL values shown on vial label. - Preserved with 0.1% sodium azide [NaN_3], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8; Xn: Harmful; R 22; S 24-35-37 (1999/45/EC – dilution < 0.25% but ≥ 0.1%).
Calibrator 2, 0.6 mL vial	- Normal human serum moderately reactive for Toxoplasma IgM antibodies. Index and IU/mL values shown on vial label. - Preserved with 0.1% sodium azide [NaN_3], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8; Xn: Harmful; R 22; S 24-35-37 (1999/45/EC – dilution < 0.25% but ≥ 0.1%).
Positive Control, 0.6 mL vial	- Normal human serum, reactive Toxoplasma IgM antibodies. Index and IU/mL values shown on vial label. - Preserved with 0.1% sodium azide [NaN_3], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8; Xn: Harmful; R 22; S 24-35-37 (1999/45/EC – dilution < 0.25% but ≥ 0.1%).
Negative Control, 0.6 mL vial	- Normal human serum, non-reactive for Toxoplasma IgM antibodies. - Preserved with 0.1% sodium azide [NaN_3], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8; Xn: Harmful; R 22; S 24-35-37 (1999/45/EC – dilution < 0.25% but ≥ 0.1%).

Component*	Contents
Conjugate, (green color) Two (2) 12 mL bottles	- Goat anti-human IgM labeled with calf alkaline phosphatase. - Preserved with 0.1% sodium azide [NaN_3], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8; Xn: Harmful; R 22; S 24-35-37 (1999/45/EC – dilution < 0.25% but ≥ 0.1%).
Substrate, 12 mL bottle Catalog # 25192	- Dilute p-nitrophenyl phosphate, CAS# 4264-83-9 [dilution not subject to EU classification according to EU Directives].
Wash, 30 mL bottle Catalog # 25190	- Tris-buffered saline with Tween 20, pH 8.0. - Preserved with 0.1% sodium azide [NaN_3], EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8; Xn: Harmful; R 22; S 24-35-37 (1999/45/EC – dilution < 0.25% but ≥ 0.1%).
Stop Reagent, 12 mL bottle Catalog # 25191	- Trisodium phosphate, 0.5M, pH ≥ 10, CAS# 10101-89-0; S 25-35-36 (1999/45/EC).

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

HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (3):

The following information is furnished for those hazardous constituents in the kit that require regulatory control or disclosure at the concentration found in the kit. Note that the information here is often based on data for 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
Sodium Azide [0.1% w/v in the Diluent, Calibrators Positive and, Negative Controls, Conjugate, and Wash Reagents]	CAS# 26628-22-8 (100%) + EINECS/ELINCS No: 247-852-1 (100%) + RTECS# VY8050000 (100%) Flash Point: NE LD50 (oral-rat): 27 mg/kg (100%) + LC50 (inhalation-rat): 37 mg/m^3 (100%) + PEL/TLV: 0.3 mg/m^3 (ceiling)(100%) + IATA/DOT ID: UN1687 (100%) + HMIS Codes: H=2, F=0, R=1 ++ RCRA Code: P105 (undiluted, 100%) + EU Classification: Harmful (Xn); R 22; S 24-35-37 (≥ 0.1% and < 0.25%) ++ Sodium azide, a biocidal preservative, is harmful if swallowed; it has been evident to kill at low concentrations, if enough is ingested (more than supplied in kit). May cause eye, skin or tissue irritation. If swallowed, seek medical advice immediately. 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. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions.
Trisodium Phosphate Solution [0.5M in the Stop Reagent]	CAS#: 10101-89-0 (Dodecahydrate) (100%) + RTECS#: TC9757000 (100%) + LD50 (oral-rat): 7400 mg/kg (100%) + LC50 (inhalation-rat): NE TLV and PEL: NE Flash Point: Not combustible (100%) + RCRA Code: D002 (if not neutralized) ++ IATA/DOT ID: None + HMIS Codes: H=0-1, F=0, R=0 ++ EINECS/ELINCS No: NE + EU Classification: None (due to dilution), S 25-26-36 ++ Keep dilute alkaline trisodium phosphate solutions away from strong acids. May slightly irritate eyes or skin depending on amount and contact time. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Wastes can typically be neutralized to pH 5-8 for disposal; however, always dispose of dilute alkaline solutions in accordance with local, regional, and national regulations. Handle appropriately with the requisite Good Laboratory Practices.
Microwell Coated Plate	The microwells in this test kit have been coated with Toxoplasma antigen (Strain RH), which has been certified by the supplier to be inactivated; however, according to Universal Precautions, it should be handled as though capable of transmitting infection.

Chemical Ingredient	Chemical Data / Information
Human Serum [Reactive and Non-reactive in the Positive and Negative Control Reagents]	The human sera in the components was tested and certified by the supplier to be non-reactive for hepatitis B surface antigen and antibodies to HCV, HIV-1 and HIV-2 by 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. Universal Precautions apply; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories.* 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. Persons handling blood samples should have the option of receiving hepatitis B vaccination. 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. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional and national regulations.

\+ 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 component 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

General Kit Composite Health Hazards:

- No significant adverse health effects are expected by any route for the miscellaneous salts, water, Tris and phosphate saline buffers, protein stabilizers, Tween 20 [CAS# 9005-64-5], p-nitrophenyl phosphate [CAS# 4264-83-9] and other chemicals found in the alkaline-phosphatase-labeled antibodies and other kit reagents, in the kit volumes and 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. Inhalation and ingestion of component ingredients capable of transmitting infectious disease are not expected to result in disease transmission based on the components of this kit. However, no known test method can offer complete assurance that the products derived from human blood will not transmit infection. Thus, all human blood derivatives should be handled as though they contain an infectious agent. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Therefore, aerosolization, mucous membrane exposure, inhalation and ingestion should be avoided during sample and kit handling.

EMERGENCY FIRST AID MEASURES (4):

Health Effects:	Skin contact may result in irritation or dermatitis. Symptoms of overexposure may include headache and dizziness, generally at concentrations and volumes that greatly exceed that of this kit. The Stop solution may cause serious eye irritation with possible corneal damage with extended 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 taking immunosuppressant drugs may be more susceptible to infectious pathogens. Persons handling human blood 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.

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; immediately move to a safe area to decontaminate and/or safely remove any contaminated clothing, as necessary. Isolate the hazard area and ventilate if appropriate. Ensure that suitable spill cleanup materials and PPE are available and used.
- Follow established laboratory policy and/or regulatory guidelines for appropriate spill response and cleanup. Biohazards should be decontaminated and the basic Stop reagent should be neutralized on site if possible with *a base adsorbent* product.
- Human source material spills should be treated as potentially infectious. Immediately decontaminate the area, spill materials and any contaminated surfaces or equipment with an appropriate chemical 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.). Wipe the cleaned-up spill area with water and wipe dry.
- Spills can also be absorbed with an inert material (e.g. spill pillow and pads) and secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious and chemical 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 laboratory hazards. Wear appropriate personal protective equipment (PPE) including gloves, lab coat and eye/face protection. Avoid splashing, spills and the generation of aerosols. Handle all specimens and materials used to perform the test as though they were capable of transmitting infectious disease, as per Universal Precautions. Consult with your Environmental Health & Safety Office for assistance.

Storage: Store the kit according to product label instructions (generally at 2-8°C).

Read and follow PRECAUTIONS section in the kit product instructions. Refer to the product 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 the user handle potentially infectious human source material/patient samples in a biological safety cabinet (BSC), especially 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.
Notes:	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 wells and supports.
Fire Hazard:	Although the components have not been tested for fire 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.
Auto Igniting:	Product is not self-igniting.
pH:	Most of the liquid chemical reagents are between pH 5 and 8, with the exception of the alkaline Stop solution at pH ≥ 10.
Solubility:	All chemical reagents are soluble in water.

No other standard characteristics are known to be applicable to the identification or hazards of the kit components.

STABILITY AND REACTIVITY INFORMATION (10):

Stability:	Stable under ordinary conditions of use and storage. The alkaline Stop reagent may react exothermically with certain chemicals, particularly strong acids.
Materials to Avoid:	Do not allow the dilute alkaline trisodium phosphate Stop reagent to come in contact with strong acids.
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 release toxic oxides of carbon, nitrogen, sodium and phosphorus.
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: Harmful if swallowed; it has been evident to kill at low concentrations, if enough is ingested (typically in quantities above those found in the kit).

Primary Irritant Effect: May cause skin or tissue irritation and is a potentially severe eye irritant (alkaline Stop reagent); contact may cause eye injury.

Other Health Effects: No significant other health effect is known.

Chronic Toxicity:

Sensitization: No sensitization effect known.

Carcinogenicity: This product is not classifiable as to its carcinogenicity to humans based on its IARC, ACGIH and NTP classification.

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 alkaline Stop reagent may be hazardous for drinking water and toxic to aquatic organisms by pH modification if not neutralized.

When the materials in this kit are properly disposed of (refer to the *DISPOSAL CONSIDERATIONS* section), they should pose no ecological threat.

DISPOSAL CONSIDERATIONS (13):

Disposal of hazardous and/or laboratory, product or packaging wastes must be conducted according to 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 and/or Packaging Disposal:

All human source and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material.

Waste Stop reagent (0.5M trisodium phosphate, pH > 10) should be neutralized to pH 6-8 for safe sewer disposal or may be required to be disposed of as a corrosive material in an RCRA approved waste facility. The US RCRA Waste Disposal Codes for the basic Stop reagent waste [if not neutralized] is D002 if the final pH measures ≥ 12.5.

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.

TRANSPORT INFORMATION (14):

Shipping and disposal of product and packaging waste must be conducted in accordance to 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.

Recommended Unused Product Transportation:

Unused product Multi-Modal Transport: Not regulated.

Note: The Stop reagent, the only component in the test kit that is potentially corrosive, has been evaluated with the CORROSITEX® test method to determine its potential for regulated corrosive shipping requirements. The test results specified that the Stop reagent was classified as non-corrosive for shipping purposes.

REGULATORY INFORMATION (15):

Composite HMIS Rating:	Health: 2 Flammability: 1 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.

Class D3 (Biohazardous Infectious Material),Class D2 (Material Causing Other Toxic Effects).

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: 0.1% Sodium Azide (< 0.25% and ≥ 0.1%), EINECS/ELINCS No: 247-852-1 and CAS# 26628-22-8 [Xn: Harmful; R 22; S 24-35-37 (1999/45/EC)].

Risk Phrases:

R 22	Harmful if swallowed.
Caution	Contains human source material. Handle as if capable of transmitting potentially infectious agents (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 protective gloves.

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.

The kit replacement components, identical to those found in the kits, are to be used exclusively with this Bio-Rad Laboratories kit.

This revision: Update information in Sections 2, 3, 11, 13 and 15.

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)