MATERIAL SAFETY DATA SHEET

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

Product Name: **PLATELIA® TOXOPLASMA IgM MICROPLATE TMB EIA**

Product Number: **25095** (96 test)

Intended Use: The Platelia® Toxoplasma IgM TMB Microplate EIA is an *in-vitro* diagnostic test kit for allowing the qualitative detection of anti-*Toxoplasma gondii* in human serum or plasma (EDTA, heparin, citrate).

Manufacturer's Name: Bio-Rad, France
Address: 3, Boulevard Raymond-Poincarė
92430 – Marnes la Coquette – France

Supplier's Name: Bio-Rad Laboratories
Address: 6565 185th Avenue NE
Redmond, WA, US 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 *T. gondii* Coated Microplate, 1 plate	- Microwell plate consisting of 12 strips with 8 break-away wells, coated with antibodies to human IgM.
R2 Concentrated Washing Solution (10X), 1 vial (100 mL)	- TRIS-NaCl (sodium chloride) buffer, pH 7.4 with 1% Tween® 20[$C_{58}H_{114}O_{26}$], EINECS/ELINCS No 585-580-06-X, CAS# 9005-64-5. - Preserved with 0.01% thimerosal [$C_9H_9HgNaO_2S$], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R43-61; S24/25-28-36-53-60-61 (1999/45/EC – dilution < 0.05%).
R3 Non-Reactive Control, 1 vial (1 mL)	- TRIS-NaCl (sodium chloride) buffer, pH 8 with bovine serum albumin, glycerol, E102 and E122. - Preserved with < 0.5% ProClin® 300, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9; (0.015% active ingredient), Xi: Irritant; R43; S24-35-37.
R4a Cut-off Control, 1 vial (1 mL)	- Human serum IgM low reactive for anti-*T. gondii* antigen and non-reactive for HBsAg and antibodies to HIV-1, HIV-2 and HCV. - Preserved with < 0.01% thimerosal [$C_9H_9HgNaO_2S$], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R43-61; S24/25-28-36-53-60-61 (1999/45/EC – dilution < 0.05%).
R4b Positive Control, 1 vial (1 mL)	- Human serum IgM reactive for anti-*T. gondii* antigen and non-reactive for HBsAg and antibodies to HIV-1, HIV-2 and HCV. - TRIS-NaCl (sodium chloride) buffer, pH ~8 with bovine serum albumin, glycerol, E102 and E122. - Preserved with < 0.01% thimerosal [$C_9H_9HgNaO_2S$], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R43-61; S24/25-28-36-53-60-61 (1999/45/EC – dilution < 0.05%). - Preserved with < 0.5% ProClin® 300, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9; (0.015% active ingredient), Xi: Irritant; R43; S24-35-37.
R6a *T. gondii* Antigen, 2 vials (7 mL each)	- Inactivated *T. gondii* antigen (RH strain); lyophilized.
R6b Concentrated Conjugate (50X), 1 vial (0.4 mL)	- Murine monoclonal antibody *T. gondii* (P30) conjugated with horseradish peroxidase (50X). - Preserved with 0.01% thimerosal [$C_9H_9HgNaO_2S$], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R43-61; S24/25-28-36-53-60-61 (1999/45/EC – dilution < 0.05%).

R7 Diluent, 2 vials (80 mL each)	- TRIS-NaCl (sodium chloride) buffer (pH 7.7), with bovine serum albumin, 0.1% Tween® 20 [($C_{58}H_{114}O_{26}$), EINECS/ELINCS No 585-580-06-X, CAS# 9005-64-5] and phenol red. - Preserved with 0.01% thimerosal [$C_9H_9HgNaO_2S$], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R43-61; S24/25-28-36-53-60-61 (1999/45/EC – dilution < 0.05%).
R8 Substrate Buffer, 1 vial (60 mL)	- Solution of citric acid and sodium acetate containing 0.015% hydrogen peroxide (H2O2) and 4% dimethyl sulfoxide [DMSO -C2H6OS], EINECS/ELINCS No: 200-644-3, CAS# 67-68-5-4 [< 20% dilution not subject to EU labeling according to EU Directives], pH ~4.
R9 Chromogen – TMB Solution, 1 vial (5 mL)	- Solution containing 0.25% 3,3',5,5'-tetramethylbenzidine (TMB).
R10 Stopping Solution, 1 vial (28 mL)	- 1N sulfuric acid solution (~4.8% v/v; pH ≤ 2), EINECS/ELINCS No: 231-639-5, CAS# 7664-93-9; Corrosive (C); R34-41; S24/25-26-36/39-60 [Note: Per Directive 1999/45/EC, 4% H_2SO_4 is rated an Irritant (Xi), but was upgraded to Corrosive (C) with the conservative application of 2001/60/EC].

HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (3):

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
Thimerosal [Merthiolate Sodium, $C_9H_9HgNaO_2S$ 0.01% in R2, R3, R4a, R4b, R4c, R6 and R7]	CAS# 54-64-8 (thimerosal powder, 100%) + EINECS/ELINCS No: 200-210-4 (100%) + RTECS# OV8400000 (100%) + Flash Point: NE LD50 (oral-rat): 75 mg/kg (100%) + LC50: NE PEL/TLV: 0.01 mg Hg/m^3 TWA (skin) (100%) + IATA/DOT ID: UN2025 (100%) + CA Proposition 65: Chemical known to the State of California to cause reproductive toxicity ++ HMIS Codes: H=2, F=0, R=0 ++ RCRA Code: D009 (to 0.2 mg/L - USA) ++ EU Classification: Dilution below 1999/45/EC labeling requirement (< 0.05%); R43-61; S24/25-28-36-53-60-61 ++ Thimerosal (merthiolate sodium) is an organo-mercury biocidal preservative which may be detrimental if enough is ingested, targets the central nervous system (CNS) and is a significant sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. There are ample cases of sensitization resulting from exposure to dilute thimerosal solutions. The chemical, physical and toxicological properties have not been thoroughly investigated. Thimerosal, classified under the generic class of mercury compounds, is known to the State of California to cause developmental toxicity. Avoid exposure. After contact with skin, wash immediately with plenty of water. Mercury compounds are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. Danger of cumulative effects. Avoid release to the environment. Spent mercury-containing solutions with a concentration greater than 0.2 ppm are considered RCRA hazardous waste (D009). This material and its container must be disposed of as hazardous waste and in accordance with local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. (Note: Mercury (Hg) makes up 49.55% of the thimerosal molecule; thus, a component with 0.01% thimerosal contains ~0.005% (50 ppm) mercury w/v).

ProClin® 300 [0.5% in R4a, R4b, R4c]	Hazardous ingredient concentration in raw material: According to the manufacturer, Supelco, the concentrated preservative is a mixture of 4 ingredients: 2.1-2.9% 5-chlor-2-methyl-4-isothiazolin-3-one (C_4H_4ClNOS; CAS# 26172-55-4), 0.6-1.1% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS; CAS# 2682-20-4), 91-94% glycol and 2.1-2.9% modified alkyl carboxylate (no CAS# or formula given for last two). Note that this ratio of active ingredients is listed in 2001/59/EC under Index No: 613-167-00-5 with the CAS# 55965-84-9. RTECS#: NE — Flash Point: 121°F / 49.4°C (100%) + LD50 (oral-rat): 3600 mg/kg (100%) + — LC50: NE PEL/TLV: NE — IATA/DOT ID: UN1760 (undiluted, 100%) + HMIS Codes: H=2, F=0, R=0 ++ — RCRA Code: NE (for dilution) ++ EU Classification: Irritant (Xi), R43; S24-35-37 (≤ 0.06% and > 0.0015 % active ingredient per 2001/59/EC) ++ The chemical, physical and toxicological properties have not been thoroughly investigated. At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit). ProClin® 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. 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 these adverse health effects is unknown for the highly diluted, small volume of ProClin® in this kit, but unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions.
3,3',5,5'-Tetramethyl-benzidine [TMB, $C_{16}H_2ON_2$ in R9]	CAS#: 64285-73-0 (TMB dihydrochloride, 100%)+ — CAS#: 54827-17-7 (TMB free base, 100%) + RTECS#: DV2300000 (100%) + — Flash Point: NE LD50 (ipr-mouse): 135 mg/kg (100%) + — LC50: NE TLV and PEL: NE — RCRA Code: NE HMIS Codes: H=1, F=0, R=0 ++ — IATA/DOT ID: NE EINECS/ELINCS No: 264-769-6 (TMB dihydrochloride, 100%), 259-364-6 (TMB base, 100%) + EU Classification: None (due to dilution, < 20%); S36 ++ The chemical, physical and toxicological properties have not been thoroughly investigated. TMB is considered a non-carcinogenic and non-mutagenic analog of benzidine suitable as an EIA chromogen for peroxidase. The raw material supplier indicates that it may cause slight irritation by all routes of entry, but this potential is unlikely if handled with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional and national regulations.
Sulfuric Acid [1N (~4.8% w/w) H_2SO_4 in R10]	CAS# 7664-93-9 (Conc. sulfuric acid 100%)+ — RTECS# WS5600000 + LD50 (oral-rat): 2,140 mg/kg (100%) + — LC50 (inhalation-rat): 510 mg/m^3/2H (100%) + PEL/TLV: 1 mg/m^3 (100%)+ STEL (100%) 3 mg/m^3 (100%) + Flash point: NE IATA/DOT ID: 2796 (< 51% sulfuric acid solutions)+ — RCRA Code: D002 (if not neutralized) ++ HMIS Codes: H=2, F=0, R=1 ++ — EINECS No: 231-639-5 (100%) + EU Classification: Corrosive (C); R34 (eyes) R41; S24/25-26-36/39-60 [Note: Per Directive 1999/45/EC, < 5% H_2SO_4 is rated an Irritant (Xi), but was upgraded to Corrosive (C) with the conservative application of 2001/60/EC.] ++ 1.0N sulfuric acid (H_2SO_4) solutions are irritating to skin and severely irritating or corrosive to eyes, depending on the amount and length of exposure; greater exposures can cause eye damage, including permanent impairment of vision or blindness. May be harmful if swallowed or in contact with skin or eyes. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Keep away from strong bases and reducing agents. This material and/or its container must be disposed of as hazardous acidic waste. It may be neutralized to pH 5-8 for disposal if trained and equipped to do so; however, always dispose of acidic solutions as required by local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices.
Toxoplasma gondii antigen [R6a]	*Toxoplasma gondii* antigens (RH strain) have been inactivated and are not considered infectious. Handle in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH Biosafety in Microbiological and Biomedical Laboratories. Employ decontamination procedures with appropriate decon agent or disinfectant 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.

Human Serum (reactive and non-reactive) [R3, R4a, R4b, R4c]	The human sera in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2) by French approved methods. No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. 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 *Biosafety in Microbiological and Biomedical Laboratories.* Avoid splashing, spills and the generation of aerosols. Secure in secondary containment with proper biohazard labeling. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures with appropriate decon agent or disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg.# 4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg.# 1043-87), or equiv.) before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional 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.

+ 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

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 [dilution not subject to EU Directive labeling]:

Chemical Constituent Details	Component
Diluted (≤ 1%) Tween® 20 [$C_{58}H_{114}O_{26}$], EINECS/ELINCS No 585-580-06-X, CAS# 9005-64-5.	R2, R7
Diluted (≤ 4%) dimethyl sulfoxide [DMSO -C_2H_6OS], EINECS/ELINCS No: 200-644-3, CAS# 67-68-5- 4 [< 20% dilution not subject to EU labeling according to EU Directives].	R8
Diluted (≤ 0.015%) hydrogen peroxide [H_2O_2], EINECS/ELINCS No: 231-765-0, CAS# 7722-84-1 < 1% dilution not subject to EU labeling according to EU Directives].	R8

- No significant adverse health effects are expected by any route for TRIS-NaCl, glycerol, citrate acid and sodium acetate, or bovine serum albumin containing solutions in the kit volumes and concentrations present [dilution not subject to EU Directive labeling].
- According to the concept of Universal Precautions (29 CFR 1910.1030), all human blood and certain human body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens. No known test method can offer complete assurance that products derived from human blood will not transmit infection; thus, they should be handled as though they contain infectious agents. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.

EMERGENCY FIRST AID MEASURES (4):

Health Effects: Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Skin contact may result in dermatitis. May cause allergic skin reaction upon repeated exposure. May be toxic to developing fetus, 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.

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 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:
  - 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 adsorbent* product.
  - Absorb thimerosal-containing reagents; handle and dispose of as RCRA hazardous waste.
- 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). Avoid freezing reagents.

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, and to prevent hazard inhalation, under normal conditions of use and for the time during which the protective equipment is utilized:

Ventilation:	Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material or 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.
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.
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:	Product is not known to present an explosion hazard.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	The liquid chemical components are soluble in water. The acidic solutions may release heat.
pH:	All liquid chemical reagents are between pH 5 and 9; exceptions are the following acidic solutions: Substrate buffer at pH ~4. Stopping solution at pH ≤ 2.

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.
Conditions to Avoid:	None known when used as intended.
Materials to Avoid:	Do not allow the acidic solutions to come in contact with strong bases, oxidizing agents and metals.
Hazardous Decomposition Products:	May release toxic oxides of carbon, nitrogen and sulfur or toxic mercury oxides and hydrogen chloride gas.
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 or lethal; 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: Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.

Corrosivity: Corrosive to eyes; with greater exposures may cause eye injury.

Other acute health effects: Targets the central nervous system (CNS), lungs, gastrointestinal tract, liver, kidneys and blood (large or prolonged dosages). Risk of serious damage to eyes.

Biohazard Potential

The human sera in the components of this product were tested and found non-reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1 and HIV-2 with French approved 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 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.

Chronic Toxicity

Sensitization: Significant sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.

Carcinogenicity: No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC or OSHA.

Reproductive hazard: Thimerosal (merthiolate sodium), an organo-mercury biocidal preservative mercury compound, is known to the State of California to cause developmental toxicity.

Additional Toxicological Information

Mercury compounds, such as thimerosal (merthiolate sodium), an organo-mercury biocidal preservative, are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. Danger of cumulative effects; avoid release to the environment. 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):

Various Harmful Effects:

The ecological information for the dilute organo-mercury preservative, **thimerosal**, has not been thoroughly investigated; however, mercury and its compounds are expected to significantly bioaccumulate. United States regulation considers mercury hazardous to the environment to 0.2 ppm mercury (0.01% thimerosal contains ~50 ppm mercury, which makes up ~50% of the molecule); at or above this level, any waste must be handled as dangerous waste.

The **corrosive** 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:

Waste containing **thimerosal**, an organo-mercury compound, is a regulated hazardous waste if the final concentration is ≥ 0.2 mg/L (0.2 ppm). The components in this kit that contain 0.01% thimerosal equate to 0.005% = 50 mg/L (50 ppm) mercury w/v. If the thimerosal-containing waste has a final concentration that is ≥ 0.2 mg/L (≥ 0.2 ppm) mercury, it requires disposal as a toxic environmental pollutant material in an RCRA approved waste facility (or equivalent); the US RCRA Waste Disposal Code for this waste is D009; 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. Note that the thimerosal preserved Negative and Positive Controls must be decontaminated prior to hazardous chemical waste disposal.

Acidic waste **stopping solution** 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.

Dilute acidic waste **substrate buffer** pH ~4 may need to be neutralized to pH 5-8 for safe sewer disposal in many areas; check your local and regional ordinances accordingly.

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

TRANSPORT INFORMATION (14):

Shipping and disposal of product and packaging waste 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

Recommended Unused Product Transportation:

The **Concentrated Washing Solution, Cut-off Control, Positive Control, Concentrated Conjugate** and **Diluent** components in this kit contain approximately 0.005% = 50 mg/L = 50 ppm mercury (w/v) from the 0.01% **thimerosal** preservative. Therefore, any discarded kit components and waste generated from their use which results in a final concentration that is greater than or equal to 0.2 mg/L (0.2 ppm) must be transported as follows:

Proper Shipping Name: **Hazardous Waste Liquid n.o.s.**
DOT Class: **9** Packing group: **III** DOT ID Number: **UN 3082**

Acidic component **stopping solution** in this kit contains **1N sulfuric acid**; thus, any un-neutralized discarded kit component or waste generated from its use resulting in a corrosive liquid (pH ≤ 2 or an pH ≥ 12.5 per Method 9040 (USEPA Publication SW-846) or which corrodes steel (NACE Standard TM-01-69) must be transported as follows:

Proper Shipping Name: **Sulphuric Acid [with not more than 51% acid]**
DOT Class: **8** Packing group **II** DOT ID Number: **UN 2796**

REGULATORY INFORMATION (15):

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

California Proposition 65: WARNING: THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE REPRODUCTIVE TOXICITY.

Chemical(s) known to cause cancer: The product does not contain listed substances.

Chemicals known to cause reproductive toxicity: Thimerosal (merthiolate sodium), CAS# 54-64-8; classified under the generic class of mercury compounds.

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.

Composite WHMIS Hazard Class: Class D1B - Materials causing immediate and serious toxic effects (toxic material)
Class D2B - Materials causing other toxic effects (toxic material)
Class E - Corrosive material

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); IRRITANT (Xi)

CORROSIVE (C)

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

0.01% Thimerosal (< 0.05%), EINECS/ELINCS No: 200-210-4, CAS# 54-64-8 [R43-61; S24/25-28-36-53-60-61]

0.5% ProClin® 150, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9 [Xi: Irritant; R43; S24-35-37 (≤ 0.06% and > 0.0015% active ingredient)]

1N Sulfuric acid, EINECS/ELINCS No: 231-639-5; CAS# 7664-93-9, [C: Corrosive; R34-41; S24/25-26-36/39-60 (1999/45/EC and 2001/60/EC)].

Risk Phrases:

R 34	Causes burns.
R 41	Risk of serious damage to eyes.
R 43	May cause sensitisation by skin contact.
R 61	May cause harm to unborn child. (Designation is for concentrated thimerosal [mercury compounds], which is diluted to 0.01 % in kit components).
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 24	Avoid contact with skin.
S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 28	After contact with skin, wash immediately with plenty of soap and water.
S 35	This material and its container must be disposed of in a safe way.
S 36	Wear suitable protective clothing.
S 37	Wear suitable gloves.
S 36/39	Wear suitable protective clothing and eye/face protection.
S 53	Avoid exposure – obtain special instructions before use.
S 60	This material and its container must be disposed of as hazardous waste.
S 61	Avoid release to the environment. Refer to special instructions/safety data sheet.

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 into new 16 part format.

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