MATERIAL SAFETY DATA SHEET

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

Product Name: **GS rLAV EIA**

Product Number: **32511** (480 tests)**, 32510** (960 tests)**, 32513** (4800 tests)

Intended Use: GS rLAV EIA, Human Immunodeficiency Virus Types 1 (Viral Lysate and *E. coli* Recombinant Antigen) is an Enzyme Immunoassay (EIA) for the detection of circulating antibodies to Human Immunodeficiency Virus Types 1 (HIV-1) in human serum, plasma or dried blood spots. The rLAV EIA is intended to be used as a screening test for donated blood or plasma and as an aid in the diagnosis of infection with HIV-1.
Catalog number(s) for replacement components that can be obtained for use with this kit, and which are covered by this MSDS include**: 25260, 25261, 26181, 26182, 32568, 32569, 32570, 32571,** and **32572** (refer to Section 2).

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

Phone Number: 1-800-2-BIORAD (1-800-224-6723); or (425) 881-8300 (daytime PST)
Address: 6565 185th Avenue NE
Redmond, WA 98052-5039, USA

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 rLAV HIV-1 Coated Microwell Plates, 5, 10 or 50 plates	- Microwell strips coated with HIV-1 antigens (viral lysate and *E. coli* recombinant). The virus is inactivated using a chaotropic agent and heat. - Potential residue of 0.1% ProClin™ 300, a production preservative (aspirated before drying strips). - Tabs are labeled "AA." - Contains sealed pelletized desiccant packet: There are no health hazards associated with intact desiccant container; however, health hazards could result from dusts generated if the packet is cut, split or otherwise compromised and is crushed.
C0 rLAV HIV-1 Negative Control, 1, 1 or 5 vial(s) (1.7 mL) *Spares Catalog No. 32572*	- Normal human serum/plasma, non-reactive for HBsAg and antibody to HIV-1, HIV-2 and HCV. - Preserved with 0.005% gentamicin sulfate, CAS# 1405-41-0 [R 43-61; S 24-36]. - Preserved with 0.16% ProClin™ 950, containing active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); CAS# 2682-20-4 [Irritant: Xi, R 36/38-43; S 24/25-35-36/37 (0.052% – 0.63% / 50 – 600 ppm Active Ingredient)].
C1 rLAV HIV-1 Positive Control, 1, 1 or 5 vial(s) (1.6 mL) *Spares Catalog No. 32571*	- Heat-treated human serum/plasma containing HIV-1 immunoglobulin, non-reactive for HBsAg and antibody to HCV. - Preserved with 0.005% gentamicin sulfate, CAS# 1405-41-0 [R 43-61; S 24-36]. - Preserved with 0.16% ProClin™ 950, containing active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); CAS# 2682-20-4 [Irritant: Xi, R 36/38-43; S 24/25-35-36/37 (0.052% – 0.63% / 50 – 600 ppm Active Ingredient)].
R2 Wash Solution Concentrate (30X), 2, 2 or 10 bottle(s) (120 mL) *Catalog No. 25261*	- Sodium chloride (NaCl) [CAS# 7647-14-5, EINECS/ELINCS No. 231-598-3] aqueous solution with < 2% Tween 20 ($C_{58}H_{114}O_{26}$) [CAS# 9005-64-5, EINECS/ELINCS No. 585-580-06-X].
R3 rLAV HIV-1 Conjugate Concentrate, 1, 1 or 5 vial(s) (1.4 mL) *Spares Catalog No. 32568*	- Goat anti-human IgM and IgG horseradish peroxidase conjugate in a buffer with protein stabilizers. - Preserved with 0.5% ProClin™ 300, per 2001/59/EC Index No 613-167-00-5 with CAS# 55965-84-9 [Irritant: Xi, R 43; S 24-35-37 (0.015% active ingredient)].

Component*	Contents
R4 rLAV HIV-1 Conjugate Diluent, 1, 1 or 5 bottle(s) (120 mL) *Spares Catalog No. 32569*	- Buffer with protein stabilizers, including normal bovine and normal goat sera, and red dye (food grade). - Preserved with 0.1% ProClin™ 150, per 2001/59/EC Index No 613-167-00-5 with CAS# 55965-84-9 [Irritant: Xi, R 43; S 24-35-37 (0.0015% active ingredient)].
R5 rLAV HIV-1 Specimen Diluent, 3, 5 or 25 bottle(s) (120 mL) *Spares Catalog No. 32570*	- Buffer with protein stabilizers containing normal bovine serum and blue dye (food grade). - Preserved with 0.1% ProClin™ 300, per 2001/59/EC Index No 613-167-00-5 with CAS# 55965-84-9 [Irritant: Xi, R 43; S 24-35-37 (0.003% active ingredient)].
R8. Substrate Buffer, 1, 1 or 5 bottle(s) (120 mL) *Catalog No. 26181*	- Dilute citric acid/sodium acetate buffer, (pH ~ 4.0). - < 0.1% hydrogen peroxide (H_2O_2), CAS# 7722-84-1. - < 5% dimethylsulfoxide (DMSO - C_2H_6OS), CAS# 67-68-5-4.
R9. Chromogen (11X) 1, 1 or 5 bottle(s) (12 mL) *Catalog No. 26182*	- ≤ 0.04 N hydrochloric acid (~ 0.3% HCl, CAS# 7647-01-0) solution (pH ~ 1.5). - ≤ 0.25% 3,3',5,5' tetramethylbenzidine (TMB – $C_{16}H_2ON_2$, CAS# 64285-73-0).
R10 Stopping Solution, 1N Sulfuric Acid, 1, 1 or 5 bottle(s) (120 mL) *Catalog No. 25260*	- 1N sulfuric acid (4.4% w/w H_2SO_4), CAS# 7664-93-9 (pH ≤ 2); irritating to skin, corrosive to eyes [R 34 (eyes)-36/38-41; S 24/25-26-36/37/39-60 (2001/60/EC, 1999/45/EC)].
Plate Sealers	- Clear plastic sealers.

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

HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (3):

The following information is furnished for those 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 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
3,3',5,5'-Tetramethyl-benzidine, Dihydrochloride [≤ 0.25% w/v TMB, $C_{16}H_2ON_2$ in R9]	CAS#: 64285-73-0 (TMB Dihydrochloride, 100%) + RTECS#: DV2300000 (100%) + EINECS/ELINCS No: 264-769-6 (100%) + Flash Point: NE LD50 (ipr-mouse): 135 mg/kg (100%) + LC50: NE TLV and PEL: NE IATA/DOT ID: NE HMIS Codes: H=0, F=0, R=0 ++ RCRA Code: NE EU Classification: None (due to dilution, < 20%); S 36 ++ The chemical, physical and toxicological properties have not been thoroughly investigated. **Tetramethyl-benzidine** 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; the potential for adverse health effects is unknown for the small volume of TMB in this product, but 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.
Gentamicin Sulfate [0.005% from a 50 mg/mL solution in C0 and C1]	CAS#: 1405-41-0 (100%) + RTECS#: LY2625000 (100%) + EINECS/ELINCS No: 215-778-9 (100%) + Flash Point: NE LD50 (oral-rat): > 5000 mg/kg (100%) + LC50: NE PEL/TLV: NE IATA/DOT ID: NE HMIS Codes: H=2, F=0, R=0 ++ RCRA Code: NE EU Classification: None (due to dilution, < 1%); R 43-61; S 24-36 ++ **Gentamicin sulfate** is an antimicrobial toxin solution which is considered a photosensitizer, is a known reproductive toxin and sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. Gentamicin sulfate is known to the State of California to cause developmental toxicity; classified under the generic class of *Aminoglycosides*. The potential for adverse health effects is unknown for the highly diluted, small volume of gentamicin in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional and national regulations.

Chemical Ingredient	Chemical Data / Information
ProClin™ 150 [0.1% in R4]	Hazardous ingredient concentration in raw material: According to the manufacturer, Supelco, the concentrated preservative is a mixture of 4 ingredients in 74-77% water: 1.05-1.20% 5-chlor-2-methyl-4-isothiazolin-3-one (C_4H_4ClNOS; CAS# 26172-55-4), 0.3-0.45% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS; CAS# 2682-20-4), 21-23.5% magnesium nitrate ($Mg(NO_3)$); CAS# 10377-60-3) and 0.5-1.0% magnesium chloride ($MgCl_2$; CAS# 7786-30-3). Note that the ratio of active ingredients in this preservative (at double the concentration) is listed in 2001/59/EC under Index No: 613-167-00-5 with the CAS# 55965-84-9. RTECS#: NE — Flash Point: NE LD50 (oral-rat): 2630 mg/kg (100%) + — LC50: NE PEL/TLV: NE — IATA/DOT ID: UN1760 (undiluted, 100%) + HMIS Codes: H=1, F=0, R=0 ++ — RCRA Code: Non-RCRA ++ EU Classification: Irritant: Xi, R 43; S 24-35-37 (≤ 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 150** 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 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.
ProClin™ 300 [0.1% in R1 and R5; 0.5% in C0, C1 and R3] [Potential residue dried on plates in R1]	Hazardous ingredient concentration in raw material: According to the vendor, 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% of 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: Non-RCRA ++ EU Classification: Irritant: Xi, R 43; S 24-35-37 (≤ 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 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. *Note: The potential trace residue of ProClin used as a production preservative for the microplate (R1) no longer requires EU labeling; however, the sensitization threshold is unknown (R 43; S 36), so apply the above precautions accordingly.*
1.0N Sulfuric Acid [4.4% w/w H_2SO_4 in R10]	CAS#: 7664-93-9 (concentrated (conc.) sulfuric acid) + — RTECS#: WS5600000 (conc.) + EINECS/ELINCS No: 231-639-5 (conc.) + — Flash Point: NE LD50 (oral-rat): 2,140 mg/kg (100%) + — LC50 (inhalation-rat): 510 mg/m^3/2H (conc.) + PEL/TLV: 1 mg/m^3 (conc.) — STEL: 3 mg/m^3 (conc.) + IATA/DOT ID: 2796 (< 51% sulfuric acid solutions) + — RCRA Code: D002 (if not neutralized) ++ HMIS Codes: H=2, F=0, R=1 ++ EU Classification: Corrosive: C; R 34 (eyes)-36/38-41; S 24/25-26-36/37/39-60 [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.] ++ **1N sulfuric acid** (H_2SO_4) solutions are irritating to skin and severely irritating or corrosive to the 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 and 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 must be disposed of as hazardous acidic waste. It may be neutralized to pH 6-8 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.

Chemical Ingredient	Chemical Data / Information
Human Serum/Plasma [Reactive and Non-reactive in the Positive and Negative Control Components Respectively]	The **human sera/plasmas** in the components was tested and found non-reactive for HBsAg and antibodies to HCV (Component C0 is also *negative* for antibodies to HIV-1 and HIV-2). Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. 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/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 equivalent) 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); typically for concentrated form unless otherwise specified.
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:
  - Dilute **Tween 20** [$C_{58}H_{114}O_{26}$], CAS# 9005-64-5, ≤ 2% v/v in R2.
  - **Dimethyl sulfoxide** [DMSO - C_2H_6OS], CAS# 67-68-5, ≤ 5% v/v in R8.
  - Dilute **hydrogen peroxide** [H_2O_2], CAS# 7722-84-1, ≤ 0.1% v/v in R8.
  - Dilute ≤ **0.04N hydrochloric acid solution** [HCl], CAS# 7647-01-0, ~0.3% v/v in R9.
  - The miscellaneous salts, sugars, buffers, water, animal sera (bovine, goat, etc.) and other chemicals found in the HRP conjugate, buffers with protein stabilizers, dyes and citric acid/sodium acetate solutions.
- The **HIV-1 Coated Microwell Plate** component (R1) contains < 0.1% of Cobalt (II) Chloride [CAS# 7646-79-9, EINECS/ELINCS No. 231-589-4], which is classified as an IARC Group 2B (possible human carcinogen) and EU Category 2 carcinogen, and silica quartz [CAS# 14808-60-7, EINECS/ELINCS No. 238-87-4], which in dust form is classified as an ACGIH Class A2 (suspected human carcinogen) and IARC Group 1 (carcinogenic to humans). This material is in a pelletized desiccant sealed packet within the plate pouch, which is unlikely to generate significant dust under normal conditions of use and is thus not typically considered a health hazard. However, health hazards could result from dusts generated if the packet is cut, split or otherwise compromised and a significant number of pellets were crushed to a powder form. Keep the desiccant packet intact as received in the microwell plate component package.
- 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, congestion and dizziness. Skin contact may result in dermatitis and may cause allergic skin reaction upon repeated exposure. May be toxic to developing fetus, generally at concentrations and volumes greatly exceeding that of this kit. Severely irritating or corrosive to eyes; greater exposures can cause eye damage, including permanent impairment of vision. May cause ingestion corrosive effects, including burning throat, mouth and stomach.

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, wash 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 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, 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.).
  - Neutralize corrosive acid spills immediately with an *acid adsorbent* product.
- Clean the spill area with water and wipe dry. Spills can also be absorbed with appropriate inert materials (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 chemicals and biologicals and/or laboratory hazards. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. 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 and label instructions (generally at 2-8°C).

Read and follow all the Precautions and Warnings in the kit product instructions (e.g. PREPARATION AND STORAGE OF REAGENTS, *WARNINGS FOR USERS* and *PRECAUTIONS FOR USERS*. 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, eyes, mouth or other mucous membranes 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), especially if aerosols might be generated.
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.
Eye Protection:	Wear ANSI-approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn.
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 plate and related materials.
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.
Flash Point:	Not applicable.
Auto Igniting:	Product is not 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.
Specific Gravity:	Not established.
pH:	The liquid chemical reagents are between pH 5 and 9, with the exception of the acidic Stopping Solution at pH $\leq$ 2.

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

STABILITY AND REACTIVITY INFORMATION (10):

Stability:	Components are stable with no known inherent significant reactivity, except the acidic solutions, which may have an exothermic reaction with certain chemicals, particularly strong bases and reducing agents.
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 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: May be detrimental in contact with skin, if swallowed, and to eyes upon contact; in case of contact with eyes, immediately rinse with copious water and seek medical attention.

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 Health Effects: Risk of serious damage to eyes.

Biohazard Potential

The **human sera** in the components was tested and found non-reactive for HBsAg and antibodies to HCV (Component C0 is also *negative* for antibodies to HIV-1 and 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; 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: Contains a small volume of very dilute, potentially skin-contact sensitizing preservatives, **ProClin™** and **gentamicin sulfate** (an antimicrobial biocide that is also a photosensitizer); prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.

Carcinogenicity: Component R1 contains < **0.1% Cobalt (II) chloride** (CAS# 7646-79-9, IARC class 2B and EU Category 2 carcinogen) and **silica quartz** (CAS# 14808-60-7, in dust form is an ACGIH class A2 and IARC class 1 carcinogen) in a pelletized desiccant sealed packet. Keep the desiccant packet intact as received in the microwell plate component package.

Reproductive Hazard: Reasonably anticipated to be a reproductive toxin. May cause harm to unborn child. **Gentamicin sulfate** is known to the State of California to cause developmental toxicity (teratogen), classified under the generic class of aminoglycosides. (Designation is for concentrated gentamicin sulfate, which is diluted to 0.005% in kit components; effects are unknown, but unlikely for the diluted, small volume found in the kit, handled with the requisite Good Laboratory Practices and Universal Precautions.)

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):

Components **R8 (pH 4), R9 (pH 1.5)** and **R10 (pH < 2)** 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 and Safety Office for your specific disposal procedures.

Recommended Product Disposal:

- The acidic **Stopping Solution** (sulfuric acid, pH ≤ 2), **Chromogen** (pH ~1.5), and **Substrate Buffer** (pH ~4.0) wastes should be neutralized to pH 6-8 for safe sewer disposal; check your local and regional ordinances accordingly. If the final pH measures ≤ 2, it requires disposal as a corrosive material in an RCRA approved dangerous waste facility (or equivalent). The US RCRA Waste Disposal Code for this waste, if not neutralized, is D002; check your applicable ordinances accordingly.

- 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.

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 and Safety Office for your specific shipping procedures.

Recommended Multi-Modal Unused Product Transportation:

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 pH ≥ 12.5 per Method 9040 [USEPA Publication SW-846] or 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**

Recommended Used Product Hazardous Waste Disposal Transportation: Potential air and land transportation information for discarded kit components and waste from this product when used as intended is:

The acidic **chromogen** is at pH ~ 1.5 and the 1N sulfuric acid **Stopping Solution** is at pH < 2; thus, any un-neutralized discarded kit component or waste generated from its use resulting in a corrosive liquid (pH ≤ 2 per Method 9040 [USEPA Publication SW-846] or Corrodes Steel [NACE Standard TM-01-69]) must be transported as follows:

Proper Shipping Name: **Corrosive Liquid n.o.s.**

DOT Class: **8** Packing group **III** DOT ID Number: **UN 1760**

REGULATORY INFORMATION (15):

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

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

Chemicals known to cause reproductive Toxicity: **Gentamicin sulfate** CAS# 1405-41-0, classified under the generic class of aminoglycosides.

Carcinogenicity Categories: Component R1 contains **< 0.1% Cobalt (II) chloride** (CAS# 7646-79-9, IARC class 2B and EU Category 2 carcinogen) and **silica quartz** (CAS# 14808-60-7, in dust form is an ACGIH class A2 and IARC class 1 carcinogen) in a pelletized desiccant sealed packet. Keep the desiccant packet intact as received in the microwell plate component package

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

Composite WHMIS Hazard Class: Class D2B (Material Causing Other Toxic Effects)
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:

C: CORROSIVE  ; Xi: IRRITANT 

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

- 0.005% **Gentamicin sulfate** (< 0.01%), CAS#: 1405-41-0, EINECS/ELINCS No: 215-778-9 [R 43-61; S 24-36].
- 0.5% or 0.1% **ProClin™ 300**, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9 [Xi: Irritant; R 43; S 24-35-37 (≤ 0.06% and > 0.0015% active ingredient)].
- 0.1% **ProClin™ 150**, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9 [Xi: Irritant, R 43; S 24-35-37 (≤ 0.06% and > 0.0015% active ingredient)].
- 0.16% **ProClin™ 950**, containing 9.5-9.9% active ingredient 2-methyl-4-isothiazolin-3-one (C_4H_5NOS; CAS# 2682-20-4, no EINECS/ELINCS # found) [Irritant: Xi, R 36/38-43; S 24/25-35-36/37 (0.052% – 0.63% / 50 – 600 ppm Active Ingredient)].
- **1N Sulfuric acid** (H_2SO_4) [pH ≤ 2], CAS# 7664-93-9, EINECS/ELINCS No: 231-639-5; [R 34 (eyes)-36/38-41; S 24/25-26-36/37/39-60].

Risk Phrases:

R 34	Causes burns.
R 36/38	Irritating to eyes and skin.
R 41	Risk of serious damage to eyes.
R 43	May cause sensitization by skin contact.
R 61	May cause harm to unborn child. (Designation is for concentrated gentamicin, which is diluted to 0.005% in kit components; effects are unknown, but unlikely for this highly diluted, small volume, handled with the requisite Good Laboratory Practices.)
Caution	Contains human source material. Handle as if capable of transmitting infectious agents (Universal Precautions).

Safety Phrases:

S 24	Avoid contact with skin.
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.
S 36/37	Wear suitable protective clothing and gloves.
S 37	Wear suitable gloves.
S 36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S 60	This material and/or its container must be disposed of as hazardous waste.

OTHER INFORMATION (16):

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

This Revision: Changes: Chromogen Reagent (R6) replaced with Chromogen 11X (R9), Chromogen Diluent (R7) replaced with Substrate Buffer (R8) and the 0.5% ProClin™ 300 preservative in C0 and C1 replaced with 0.16% ProClin™ 950; updated.

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