SAFETY DATA SHEET (SDS)

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

Product Name: **GS HIV Combo Ag/Ab EIA**

Product Number: **26217** (192 tests)
26218 (960 tests)
Catalog number(s) for replacement, separately purchased components that can be obtained for use with this kit, and which are covered by this SDS include**: 25260, 25261, 26181, 26182, 26220, 26221, 26222, 26223, 26224, 26225, 26226, 26227 and 26228** (refer to Section 2).

Intended Use: The GS HIV Combo Ag/Ab EIA is an enzyme immunoassay (EIA) kit for the simultaneous qualitative detection of Human Immunodeficiency Virus (HIV) p24 antigen and antibodies to HIV Type 1 (HIV-1 Groups M and O) and HIV Type 2 (HIV-2) in human serum or plasma. This kit is intended as an aid in the diagnosis of HIV-1 and/or HIV-2 infection, including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection in pediatric subjects (i.e, children as young as 2 years of age). The GS HIV Combo Ag/Ab EIA is intended for manual use and for use with the Bio-Rad EVOLIS™ and Elite™ Automated Microplate Systems. Results from the GS HIV Combo Ag/Ab EIA cannot be used to distinguish between the presence of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody in a sample. The GS HIV Combo Ag/Ab EIA is not intended for routine use in screening blood or plasma donors, as the effectiveness of this test for use in the screening of these donors has not been established. However, in urgent situations where traditional licensed blood donor screening tests are unavailable or their use is impractical, this assay can be used as a blood donor screening assay.

Manufactured by: **Bio-Rad Laboratories, Inc.**

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

Website: www.bio-rad.com

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

SDS e-mail contact: ro-sds@bio-rad.com

Technical Information Contacts: Bio-Rad provides a toll free line for technical assistance; in the United States of America call toll free 1-800-2-BIORAD (1-800-224-6723). *Outside the U.S.A., please contact your regional Bio-Rad office for assistance*.

Emergency Phone Number: **This SDS is listed with CHEMTREC 1-800-424-9300 / 1-703-527-3887**. Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

HAZARDS IDENTIFICATION -- 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. Refer to section 16 for the full text of any *Risk (R)* and *Safety (S)* statement provided below.

Component *	Content
R1. Microwell Strip Plate (2 or 10 plates)	- Microwell plate coated with monoclonal antibodies to HIV p24 (mouse) and purified HIV-1 and HIV-2 antigens. - Potential residue of ProClin 300 used as a production preservative (aspirated prior to drying strips). - Tabs are labeled "JJ" - 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.

R2. Wash Solution Concentrate (30X) 1 or ** bottle (120 mL) *Catalog No. 25261*	- **Sodium chloride** (NaCl) [CAS# 7647-14-5, EC No 231-598-3] aqueous solution with < 2% **Tween 20** ($C_{58}H_{114}O_{26}$) [CAS# 9005-64-5, EC No 585-580-06-X] (clear liquid). [Not subject to GHS and EU 2008/1272/EC regulatory requirements.]
C0. Negative Control 1 or 2 vial(s) (1.5 mL) *Catalog No. 26220*	- Normal human serum/plasma that is non-reactive for HBsAg, HIV Ag and antibodies to HIV and HCV (amber / yellow liquid). - Preserved with **0.16% ProClin 950** containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); CAS# 2682-20-4, EC No 220-239-6 [< 1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels]. - Preserved with **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9 **[**< 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements**.]**
C1. HIV-1 Ab Positive Control 1 or 2 vial(s) (1.5 mL) *Catalog No. 26221*	- Heat-treated human serum/plasma containing HIV-1 antibody, non-reactive for HBsAg and antibody to HCV (yellow or green aqueous solution). - Preserved with **0.16% ProClin 950** containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); CAS# 2682-20-4, EC No 220-239-6 [< 1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels]. - Preserved with **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9 **[**< 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements**.]**
C2. HIV-2/O Ab Positive Control 1 or 2 vial(s) (1.5 mL) *Catalog No. 26222*	- Murine monoclonal antibody to HIV-2 and Rabbit HIV-1 Group O antibody diluted in normal human serum/plasma; non-reactive for HBsAg, and antibodies to HCV (yellow or green aqueous solution). - Preserved with **0.16% ProClin 950** containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); CAS# 2682-20-4, EC No 220-239-6 [< 1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels]. - Preserved with **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9 **[**< 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements**.]**
C3. HIV Ag Positive Control 1 or 2 vial(s) (1.5 mL) *Catalog No. 26223*  **WARNING**	- **Purified HIV-1 viral lysate** antigen inactivated with heat and a chaotropic agent in synthetic diluent / buffer with protein stabilizers (bovine),-≤ 20% Glycerol [$C_3H_8O_3$, CAS# 56-81-5, EC No 200-289-5] and dye (blue-green aqueous solution). Not subject to GHS and EU 2008/1272/EC regulatory requirement. - Preserved with **0.5% ProClin 300** (0.015%active ingredient)**,** EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P280; P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Contains **< 0.1% Tartrazine** [FD&C Yellow #5, Acid Yellow 23; $C_{16}H_9N_4O_9S_2$•3Na]; CAS# 1934-21-0; EC 217-699-5 [Dilution is not subject to GHS and EU 2008/1272/EC Regulation or 1999/45/EC Directive labeling requirements.] - Preserved with **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9 **[**< 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements**.]**
C4. Cutoff Calibrator 3 or 4 vial(s) (1.7 mL) *Catalog No. 26224*	- Normal human serum/plasma that is non-reactive for HBsAg, HIVAg and antibodies to HIV and HCV (amber / yellow aqueous solution). - Preserved with **0.16% ProClin 950** containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_4H_5NOS); CAS# 2682-20-4, EC No 220-239-6 [< 1% dilution is not subject to GHS and EU 2008/1272/EC or 1999/45/EC regulated labeling levels]. - Preserved with **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9 **[**< 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements**.]**
R6. Conjugate 1 1 or 4 bottle(s) (10 mL) *Catalog No. 26225*  **WARNING**	- Biotinylated polyclonal antibodies to HIV-1 p24 (sheep) in a buffer with protein stabilizers (bovine and sheep) and dye (green aqueous solution): -< 0.1% Bromocresol Purple, Sodium Salt ($C_{21}H_{15}Br_2O_5S$•Na); CAS# 62625-30-3; EC No. 263-655-3) [dilution is not subject to GHS and EU 2008/1272/EC Regulatory requirements]. - Preserved with **0.5% ProClin 300** (0.015% active ingredient)**,** EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P280; P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9 **[**< 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements**.]**

R7a. Conjugate 2 2 vials (18 mL) or 4 vials (40 mL) *Catalog No. 26226 or 26227*  **WARNING**	- Lyophilized, peroxidase-labeled Streptavidin and peroxidase-labeled HIV-1 and HIV-2 antigens (white to off-white solid). - Prior Lyophilization, the solution was preserved with: + **0.5% ProClin 300** (0.015% active ingredient)**,** EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P280; P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] + **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9 **[**< 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements**.]**
R7b. Conjugate 2 Diluent, 1 or 4 bottle(s) (40 mL) *Catalog No. 26228*  **WARNING**	- Buffer (pH neutral) with protein stabilizers (bovine and sheep) and red dye (red aqueous liquid). - < 0.1% Amaranth **[FD&C Red #2;** $C_{20}H_{11}N_2O_{10}S_3$•3Na], CAS# 915-67-3, EC No 213-022-2 (Not subject to GHS and EU 2008/1272/EC regulatory requirements).] - Preserved with **0.5% ProClin 300** (0.015% active ingredient)**,** EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P280; P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.] - Preserved with **0.005% gentamicin sulfate**, CAS# 1405-41-0, EC No 215-778-9 **[**< 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements**.]**
R8. Substrate Buffer, 1 or 2 bottle(s) (120 mL) *Catalog No. 26181*	- Dilute **citric acid/sodium acetate buffer**, (pH ~ 4.0, clear liquid). - **< 5% dimethylsulfoxide** [DMSO - C_2H_6OS], CAS# 67-68-5, EC No 200-644-3. - **< 0.1% hydrogen peroxide** [H_2O_2], CAS# 7722-84-1, EC No 231-765-0. [Dilution is not subject to GHS and EU 2008/1272/EC regulatory requirements.]
R9. Chromogen (11X) 1 or 2 bottle(s) (12 mL) *Catalog No. 26182*	- ≤ **0.25% 3,3',5,5' tetramethylbenzidine dihydrochloride** [TMB– $C_{16}H_{20}N_2$•2HCl], CAS# 207738-08-7, EC No 264-769-6. - ≤ **0.04 N hydrochloric acid** [~ 0.3% HCl, CAS# 7647-01-0, EC No 231-595-7] solution (pH ~ 1.5, clear liquid). [Dilution is not subject to GHS and EU 2008/1272/EC regulatory requirements.]
R10. Stopping Solution 1 or ** bottle (120 mL) *Catalog No. 25260*  **DANGER!**	- **1N H_2SO_4 (4.4% w/w Sulfuric acid),** CAS# 7664-93-9, EC No 231-639-5 [pH ≤ 2, clear liquid]; severely irritating to skin, corrosive to eyes [GHS / 2008/1272/EC Classification**:** DANGER! GHS05; H290, H314; P280; P301 + P330 + P331, P305 + P351 + P338; P501**]** [EU Classification per 1999/45/EC and 2001/60/EC: Corrosive: C R 34 (eyes)-36/38-41; S 24/25-26-36/37/39-45-60.]

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

** Stopping Solution and Wash Solution Concentrate need to be purchased separately for the 50-plate (4800 test) kit. Refer to catalog number 25260 for the Stopping Solution and catalog number 25261 for the Wash Solution Concentrate. These reagents are included in the 5-plate (480 test) and 10-plate (960 test) kits.

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

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

Component R10: **1N H_2SO_4 [**4.4% w/w Sulfuric acid], CAS# 7664-93-9, EC No 231-639-5 (pH ≤ 2); severely irritating to skin, corrosive to eyes. [This STOP solution has been evaluated with the CORROSITEX® test method to determine its corrosive potential and classification. The results of this testing classified this STOP solution as Class: **8,** Packing group **II (UN2796)]**

GHS \ 2008/1272/EC Classification *[* denotes precautionary statements included on the product label]***:***

Label(s):	**GHS05**
Signal Word:	**DANGER**!
Label Hazard Statement:	**H290: May be corrosive to metals.** **H314: Causes severe skin burns and eye damage.**
Supplemental Hazard – Statement:	*None Specified*
Precautionary Statement – Prevention:	**P260**: Do not breathe dust/fume/ gas/mist/vapours/spray. **P280**: Wear protective gloves/protective clothing/eye protection/face protection.*
Precautionary Statement – Response:	**P301** + **P330** + **P331**: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. * **P303** + **P361** + **P353**: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. **P304** + **P340:** IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. **P305** + **P351** + **P338:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. * **P309** + **P313**: If exposed or if you feel unwell: Get medical advice/ attention.
Precautionary Statement – Storage:	**P405**: Store locked up.
Precautionary Statement – Disposal:	**P501**: This material and its container must be disposed of as hazardous waste. *

Components C3, R6, R7a, R7b: **0.5% ProClin 300 [**0.015% active ingredients – reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (C_4H_4ClNOS; CAS# 26172-55-4, EC No 247-500-7) and 2-methyl-2H -isothiazol-3-one (C_4H_5NOS; CAS# 2682-20-4, EC No 220-239-6) (3:1)]**,** EC Index No 613-167-00-5 with CAS# 55965-84-9.

GHS \ 2008/1272/EC Classification *[* denotes precautionary statements included on the product label]***:***

Label(s):	**GHS07**
Signal Word:	**WARNING**
Label Hazard Statement:	**H317: May cause an allergic skin reaction.**
Supplemental Hazard Statement:	*None Specified*
Precautionary Statement – Prevention:	**P261**: Avoid breathing dust/fume/ gas/mist/vapours/spray **P272**: Contaminated work clothing should not be allowed out of the workplace. **P280**: Wear protective gloves/protective clothing/eye protection/face protection. *
Precautionary Statement – Response:	**P302** + **P352**: IF ON SKIN: Wash with plenty of soap and water. * **P333** + **P313**: If skin irritation or rash occurs: Get medical advice/ attention. *
Precautionary Statement – Storage:	*None Specified*
Precautionary Statement – Disposal:	**P501**: Dispose of contents and container in accordance to local, regional, national and international regulations. *

COMPOSITION/INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS (3):

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Note that the information here is often based on data from the chemical raw material (LD_{50}, exposure limits, etc.) and that the product contains a significantly diluted concentration in an aqueous solution, thus this assessment has taken hazard reduction processing into consideration when possible. The GHS and EU classifications were made according to the latest editions and expanded upon from company and literature data. Refer to Section 16 for the Key / legend to abbreviations and acronyms.

Chemical Ingredient	Data / Information
Glycerol [≤ 20% in C3]	CAS#: 56-81-5 (100%) + RTECS#: MA8050000 (100%) + EC No: 200-289-5 (100%) + Chemical Formula: $C_3H_8O_3$ (100%) + Flash Point: 320 F / 160° C (100%) + LD_{50} (oral-rat): 12,600 mg/kg (100%) + LC_{50} (inhalation-rat): > 570 mg/m^3/1H (100%) + TLV and PEL: 10 mg/m^3 total mist (100%) + IATA/DOT ID: NE HMIS Codes: H=1, F=0, R=1 ++ RCRA Code: NE *GHS / 2008/1272/EC Classification*: Not subject to EU 2008/1272/EC and GHS regulatory requirements. ++ Keep **glycerol** solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulation. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Not Listed
1.0N Sulfuric Acid [4.4% w/w H_2SO_4 in water, R10]  **DANGER!** 	CAS#: 7664-93-9 (Conc. sulfuric acid 100%) + RTECS#: WS5600000 (100%) + EC No: 231-639-5 (100%) + pH ≤ 2 ++ Chemical Formula: H_2SO_4 (100%) + Flash Point: NE LD_{50} (oral-rat): 2,140 mg/kg (100%) + LC_{50} (inhalation-rat): 510 mg/m^3/2H (100%) + TWA-PEL: 1 mg/m^3 (100%) + TWA-TLV: 0.2 mg/m^3 (100%) + STEL: 3 mg/m^3 (100%) + IDLH: 15 mg/m^3 (100%) + IATA/DOT ID: UN2796, Class 8 (< 51% sulfuric acid solutions) ++ HMIS Codes: H=2, F=0, R=1 ++ RCRA Code: D002 (if not neutralized) ++ EU Classification per 1999/45/EC and 2001/60/EC: Corrosive: C; R 34 (eyes)-36/38-41; S 24/25-26-36/37/39-45-60 [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.] ++ *GHS / 2008/1272/EC Classification*: DANGER! GHS05; H290, H314; P280; P301 + P330 + P331, P305 + P351 + P338; P501 ++ *[This STOP solution has been evaluated with the CORROSITEX® test method to determine its corrosive potential and classification. The results of this testing classified this STOP solution as Class: 8, Packing group II (UN2796)]* 1.0 N **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. Causes severe skin burns and eye damage [H314]. Risk of serious eye damage. May be corrosive to metals [H290]. Wear protective gloves/protective clothing/eye protection/face protection [P280]. Do not breathe mist/vapours/spray. IF exposed or if you feel unwell: Get medical advice/ attention. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/ physician. [P301 + P330 + P331] IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. [P305 + P351 + P338] Keep away from strong bases and reducing agents. Store locked up. 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, national and international regulations [P501]. Handle appropriately with the requisite Good Laboratory Practices. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Corrosive: C R 35: Causes severe burns. S (1/2-): Keep locked up and out of the reach of children. S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S 30: Never add water to this product. S 45: In case of accident or if you feel unwell, seek medical advice immediately.

Chemical Ingredient	Data / Information
Tartrazine Solution [< 2% in C3]	CAS#: 1934-21-0 (100%) + RTECS#: UQ6400000 (100%) EC No: 217-699-5 (100%) + Synonyms: Acid Yellow 23; Yellow no. 4; FD&C Yellow #5 Chemical Formula: $C_{16}H_9N_4O_9S_2$•3Na Flash Point: NE LD_{50} (oral-mouse): 12750 mg/kg (100%) + PEL/TLV: NE IATA/DOT ID: NE HMIS Codes: H=1, F=0, R=0 ++ RCRA Code: NE *GHS / 2008/1272/EC Classification*: Dilution not subject to EU 2008/1272/EC and GHS regulatory requirements ++ Diluted **Tartrazine** may be detrimental in contact with skin. Tartrazine is Suspected to be a SENsitizer by inhalation or skin contact, prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals, including triggering asthma. There is limited experimental evidence of teratogenic and mutagenic reproductive effects The potential for adverse health effects is unknown for the highly diluted, small volume of **Tartrazine** 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, national and international regulation. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Not Listed
ProClin 300 [0.5% (0.015% active ingredient) in C3, R6 and R7b, 0.5% in R7a prior Lyophilization]  **WARNING** [Potential residue dried on plates in R1]	Hazardous ingredient concentration in raw material - According to the supplier, Sigma-Aldrich, the concentrated preservative is a mixture with 3-3.6% Active Ingredients in 3:1 ratio: 5-chlor-2-methyl-4-isothiazolin-3-one (C_4H_4ClNOS; CAS# 26172-55-4, EC# 247-500-7)and 2-methyl-4-isothiazolin-3-one (C_4H_5NOS; CAS# 2682-20-4, EC# 220-239-6), Index No. 613-167-00-5 and CAS# 55965-84-9. Also contains 91-94% glycol and .3.5-5% Modified Alkyl Carboxylate (no CAS# or formula given for last two). RTECS#: NE Flash Point: 244° F / 118° C (100%) + LD_{50} (oral-rat): 862 mg/kg (100%) + LD_{50} (skin-rabbit): 2,800 mg/kg (100%) + PEL/TLV: NE\ IATA/DOT ID: UN3265, Class 8 (undiluted, 100%) + / IATA/DOT ID: NE (dilution) ++ HMIS Codes: H=2, F=0, R=0 ++ RCRA Code: Non-RCRA ++ EU Classification per 1999/45/EC and 2001/59/EC: Irritant: Xi, R 43; S 24-35-37 (≤ 0.06% and > 0.0015 % Active-Ingredient) ++ *GHS / 2008/1272/EC Classification*: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501 ++ 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 [H317]. Wear protective gloves / protective clothing / eye protection / face protection [P280]. Contaminated work clothing should not be allowed out of the workplace. Avoid breathing mist / vapours / spray. IF ON SKIN: Wash with plenty of soap and water [P302 + P352]. If skin irritation or rash occurs: Get medical advice/ attention[P333 + P313]. The potential for adverse health effects is unknown for the highly diluted, small volume of **ProClin 300** in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501]. *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 (R43; S36), so apply the above precautions accordingly. ProClin 150 is used in the microplate production, which contains the same ratio of active ingredients as ProClin 300, at half the original concentration (still falls under Index No: 613-167-00-5, CAS # 55965-84-9).* EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Toxic: T, Environmental Danger: N R 23/24/25: Toxic by inhalation, in contact with skin and if swallowed. R 34: Causes burns. R 43: May cause sensitisation by skin contact. R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S (2-): Keep out of the reach of children. 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 36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S 45: In case of accident or if you feel unwell, seek medical advice immediately. 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 sheets.

Chemical Ingredient	Data / Information
≤ 0.04N Hydrochloric acid [~0.3% v/v HCl in R9]	CAS#: 7647-01-0 (100%) + RTECS#: MW4025000 (100%) + EC No: 231-595-7 (100%) + (pH ~ 1.5) ++ Chemical Formula: HCl (100%) + Flash Point: NE LD_{50} (oral-rabbit): 900 mg/kg (100%) + LC_{50} (inhalation-rat): 3124 ppm/1H (100%) + TLV and PEL: 5 ppm (ceiling) (100%) + IATA/DOT ID: UN1789, Class 8 (100%) + / IATA/DOT ID: NE (dilution) ++ HMIS Codes: H=1, F=0, R=1 ++ RCRA Code: D002 (if not neutralized) ++ EU Classification per 1999/45/EC: None (due to dilution, < 1%) ++ *GHS / 2008/1272/EC Classification*: None (due to dilution, < 1%) ++ Dilute ≤ **0.04N hydrochloric acid** solutions may be detrimental if swallowed and by contact, particularly to eyes. Keep away from strong bases and reducing agents. Wastes can typically be neutralized to pH 6-8 for disposal if trained and equipped to do so, however always dispose of dilute acidic / corrosive solutions in accordance with local, regional, national and international regulations. Handle appropriately with the requisite Good Laboratory Practices. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Toxic : T ; Corrosive: C ++ R 23: Toxic by inhalation. R 35: Causes severe burns. S (1/2-): Keep locked up and out of the reach of children. S 9: Keep container in a well-ventilated place. S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S 45: In case of accident or if you feel unwell, seek medical advice immediately.
3,3',5,5'-Tetramethyl-benzidine, Dihydrochloride [≤ 0.25% w/v TMB in R9]	CAS#: 207738-08-7 (54827-17-7 Free base) (100%) + RTECS#: DV2300000 (100%) + EC No: 264-769-6 (100%) + Chemical Formula: $C_{16}H_{20}N_2 \bullet 2HCl$ (100%) + Flash Point: NE LD_{50} (ipr-mouse): 135 mg/kg (100%) + TLV and PEL: NE IATA/DOT ID: NE HMIS Codes: H=0, F=0, R=0 ++ RCRA Code: NE *GHS / 2008/1272/EC Classification*: Not subject to GHS and EU 2008/1272/EC regulatory requirements ++ The chemical, physical and toxicological properties have not been thoroughly investigated. **3,3',5,5'-Tetramethylbenzidine Dihydrochloride (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; the potential for adverse health effects is unknown for the small volume of **TMB** in this product, but is unlikely if handled appropriately with the requisite Good Laboratory Practices. Dispose of this material in accordance with local, regional, national and international regulation. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Not Listed

Chemical Ingredient	Data / Information
ProClin 950 [0.16% in C0, C1, C2, and C4]	Hazardous ingredient concentration in raw material: According to the supplier, Sigma-Aldrich, the concentrated preservative contains 9.5-9.9% 2-methyl-4-isothiazolin-3-one. CAS#: 2682-20-4 (active ingredient) RTECS#: NE EC No: 220-239-6 (active ingredient) + Chemical Formula: C_4H_5NOS (active ingredient) Flash Point: NE LD_{50} (oral-rat): Data not found (100%) + PEL/TLV: NE IATA/DOT ID: UN3265, Class 8 (undiluted, 100%) + / IATA/DOT ID: NE (dilution)++ HMIS Codes: H=2, F=0, R=0 ++ RCRA Code: Non-RCRA ++ *GHS / 2008/1272/EC Classification*: None (due to dilution, < 1%) ++ 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 950** is a potential sensitizer by skin contact; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. Wear protective gloves / protective clothing / eye protection / face protection. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice / attention. The potential for adverse health effects is unknown for the highly diluted, small volume of **ProClin 950** in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Not Listed
Gentamicin Sulfate [0.005% from a 50 mg/mL Solution in C0, C1, C2, C3, C4, R6 R7a, and R7b]	CAS#: 1405-41-0 (100%) + RTECS#: LY2625000 (100%) + EC No: 215-778-9 (100%) + Flash Point: NE LD_{50} (oral-rat): > 5000 mg/kg (100%) + PEL/TLV: NE IATA/DOT ID: NE HMIS codes: H=1, F=0, R=0 ++ RCRA Code: NE *EU Classification per 1999/45/EC*: None (due to dilution, < 0.01%) ++ *GHS / 2008/1272/EC Classification*: None (due to dilution, < 0.1%) ++ **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, national and international regulation. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Not Listed

Biological Ingredient	Data / Information
Human Serum [reactive and non-reactive in the Negative Control (C0), HIV-1 Ab Positive Control (C1) and HIV-2/O Ab Positive Control (C2), Cutoff Calibrator (C4) components] 	The **HIV-1 Ab Positive Control** (C1) was heat-treated to inactivate the HIV. **Human sera** in reagents were tested and found non-reactive for Hepatitis B surface antigen and antibodies to HCV (the **Negative Control** (C0), **HIV-1 Ag Positive Control** (C3) and **Cutoff Calibrator** (C4) are also non-reactive for antibodies to HIV). No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *Universal Precautions* when handling these reagents and all human blood or specimens. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* or WHO *Laboratory Biosafety Manual*. 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, national and international regulations. Handle appropriately with the requisite Good Laboratory Practices, *Standard* and *Universal Precautions*. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Biological Ingredient	Data / Information
Animal proteins	This material is of animal origin (bovine, rabbit, murine and sheep) and may be a potential contact irritant. Hazard Unknown. Handle as potentially infectious. The chemical, physical and toxicological properties have not been thoroughly investigated. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulation.
Inactivated HIV-1 virus [C3]	**Inactivated Human Immunodeficiency Virus, Type 1** (HIV-1), though verified to be non-infectious. Handle as if capable of transmitting infectious disease, with Universal Precautions in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* or WHO *Laboratory Biosafety Manual*.. Employ aseptic technique for personal protection and to avoid product contamination; use of a Biosafety Cabinet (BSC) may be warranted or desired in certain situations. 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, national and international regulation. Handle appropriately with the requisite Good Laboratory Practices *Standard* and *Universal Precautions.*

Key:

+ 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 concentrate form unless otherwise specified.
Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity.

Related product information:

- Refer to section 2 for the full text of any *GHS* / 2008/1272/EC statement coded above.
  Refer to section 16 for the full text of any *Risk (R)* and *Safety (S)* statement for the above kit component concentration.
- 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 or GHS Directive labeling]:
  - **Tween 20** [$C_{58}H_{114}O_{26}$], CAS# 9005-64-5, EC No 585-580-06-X, ≤ 2% v/v in R2.
  - **Dimethyl sulfoxide** [DMSO - C_2H_6OS], CAS# 67-68-5, EC No 200-644-3, ≤ 5% v/v in R8.
  - **Hydrogen peroxide** [H_2O_2], CAS# 7722-84-1, EC No 231-765-0,-≤ 0.1% v/v in R8.
  - The miscellaneous salts, sugars, buffers, water, animal sera, and other chemicals found in the HRP conjugate, buffers with protein stabilizers, dyes, and citric acid/sodium acetate solutions.
- The **GS HIV Combo Ag/Ab Microwell Strip Plate Component R1** contains < 0.1% of **Cobalt (II) Chloride** [CAS# 7646-79-9, EC 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, EC 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).
  These materials are pelletized and sealed in a desiccant 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.
- Do not eat, drink or smoke when using this product.
- Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

EMERGENCY FIRST AID MEASURES (4):

Health Effects:	Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. 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 that greatly exceed that of this kit. Causes severe skin burns and eye damage. 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. 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.
Hazardous Combustion Products:	May release toxic oxides of carbon, nitrogen and sulfur or toxic hydrogen chloride gas.
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. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.
- Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA and/or NFPA/Fire Code hazardous material spill guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. Avoid release to the environment.
- Wear appropriate PPE. Immediately, and on-site if possible:
  - Decontaminate Biohazard/Human Source Material spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon agent or disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% Ethanol or Isopropanol, an iodophor (such as Wescodyne Plus), or a phenolic, etc.).
  - Neutralize corrosive acidic spills with the appropriate a*cid* neutralization / *adsorbent* product.
- Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows, 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, national and international regulations.
- Refer to Sections 8 and 11 for more specifics.

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. Do not smoke, eat, or drink in areas where patient samples and kit reagents are handled. Wash your hands after use. Wear appropriate personal protective equipment (PPE), including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all human source specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per *Standard* and *Universal Precautions.* All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics. Avoid release to the environment. Do not allow undiluted product hazardous chemical ingredient or large quantities of it to reach ground water or water course. Consult with your Environmental Health & Safety Office for assistance.
Storage:	Store according to product and label instructions (generally at 2-8 °C).
Caution, consult accompanying documents. Read and follow all the precautions and warnings in the kit product instructions*)*. Refer to the *Instructions For Use / Package Insert* for additional product information.	
For *in vitro* diagnostic use.	

EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):

Control Parameters – *Component chemicals with limit values that require monitoring at the workplace*:

Chemical	CAS-No.	Value	Control parameter	Update	Basis
Sulfuric acid	***7664-93-9***	TWA – TLV	0.2 mg/m^3 (thoracic fraction)	2004-01-01	USA. ACGIH Threshold Limit Values (TLV)
		TWA – PEL	1 mg/m^3 *	1993-06-30	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		REL IDLH	1 mg/m^3 15 mg/m^3	2005-149 [SEP-2007]	USA. National Institute for Occupational Safety and Health (NIOSH)
	* The value in mg/m^3 is approximate ***Remarks***: TLV CARCINOGENICITY DESIGNATION A2 – Suspected Human Carcinogen: Substance is carcinogenic in laboratory animals under conditions that are considered relevant to worker exposure. Available human studies are conflicting or insufficient to confirm an increased risk of cancer in exposed humans. Worker exposure to an A2 carcinogen should be controlled to levels as low as reasonably achievable below the TLV. The A2 Carcinogenicity Designation refers to sulfuric acid contained in **strong inorganic acid mists**.				
Hydrochloric acid	***7647-01-0***	TLV – C	2 ppm	2007-01-01	USA. ACGIH Threshold Limit Values (TLV)
		PEL – C	7 mg/m^3 * 5 ppm	2006-02-28	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		REL – C IDLH	7 mg/m^3 5 ppm 50 ppm	2005-149 [SEP-2007]	USA. National Institute for Occupational Safety and Health (NIOSH)
	* The value in mg/m^3 is approximate. Ceiling limit is to be determined from breathing-zone air samples. ***Remarks***: TLV CARCINOGENICITY DESIGNATION A4 – Not Classifiable as a Human Carcinogen: Inadequate data on which to classify the substance as a human and/or animal carcinogen.				
Hydrogen peroxide	***7722-84-1***	TWA – TLV	1 ppm	2007-01-01	USA. ACGIH Threshold Limit Values (TLV)
		TWA – PEL	1.4 mg/m^3 * 1 ppm	1997-08-04	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		REL IDLH	1.4 mg/m^3 1 ppm 75 ppm	2005-149 [SEP-2007]	USA. National Institute for Occupational Safety and Health (NIOSH)
	* The value in mg/m^3 is approximate ***Remarks***: TLV CARCINOGENICITY DESIGNATION A3 – Animal Carcinogen: Substance is carcinogenic in laboratory				

Chemical	CAS-No.	Value	Control parameter	Update	Basis
	animals under conditions that are not considered relevant to worker exposure. Available human studies and evidence suggest that the substance is not likely to cause cancer in humans except under unusual or unlikely routes or levels of exposure. Worker exposure to an A3 carcinogen should be controlled to levels as low as reasonably achievable below the TLV.				

Additional information: *The lists that were valid during the creation were used as basis.*

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes and eyes, or hazardous inhalation, under normal conditions of use and for the time during which the protective equipment is utilized**:**

Ventilation: **Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material / patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.**

Eye / Face Protection: **Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.**

Protective Gloves: **Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves, such as Nitrile, Neoprene and Vinyl, are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never be reused. Wash hands thoroughly after removing gloves.**

Protective Clothing: **Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.**

Respiratory Protection: **Do not breathe mist / vapours / spray.**

Other: **All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal. 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: **Occupational exposure limit values and health hazard data were given in section 3. Environmental Controls are included in following sections.**

PHYSICAL AND CHEMICAL PROPERTIES (9):

Appearance:	Variable, refer to section 2; generally aqueous liquids. Exceptions are the solid microtiter plate and related materials.		
Odor:	Data is not available.	**Odor Threshold:**	Not Established.
pH:	Most of the liquid chemical components are between pH 6 and 8, Exceptions are the following acidic solutions: **Substrate Buffer** at pH~4, **Stopping Solution** at pH ≤ 2, and **Chromogen** at pH ~1.5		
Boiling point:	Not Established.	**Melting point:**	Not Established.
Flash point:	Not Applicable. Flammable limits: LEL/LFL is Not applicable; UEL/UFL is Not applicable.		
Evaporation rate:	Data is not available.		
Fire hazard:	Although the kit has not been tested for fire hazard and explosion data, it is not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.		
Vapor pressure:	Data is not available.		
Vapor density:	Data is not available.		
Relative density:	Variable; approximately 1.		

Solubility:	The liquid chemical components are soluble in water. The **acidic solutions** may release heat.
Partition coefficient (n-octanol/water):	Data is not available.
Auto igniting:	Product is not known to be self-igniting.
Decomposition temperature:	Data is not available.
Viscosity:	Data is not available.
Danger of explosion:	Product is not known to present an explosion hazard.
No Other Standard Characteristics applicable to the identification or hazards of the product are known.	

STABILITY AND REACTIVITY INFORMATION (10):

NOTE: Chemical reactions that could result in a hazardous situation (e.g. generation of flammable or toxic chemicals, fire or detonation) are listed here. Although not intended to be complete, an overview of important reactions involving common chemicals is provided to assist in the development of safe work practices.

Chemical Stability / Reactivity:	Components are stable with no known inherent significant reactivity, 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 toxic hydrogen chloride gas.
Hazardous Polymerization:	Has not been reported to occur.

TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):

Refer to Sections 2 and 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:	Causes severe skin burns and eye damage. The ***Stopping Solution*** (R10) is Corrosive, able to cause severe burns of the mucous membranes, skin and eyes; can cause permanent eye damage or blindness. Causes severe skin burns and eye damage. Destructive to tissue of the skin, respiratory tract, mucous membranes, and eyes; may cause permanent eye injury, or blindness. May cause ingestion corrosive effects, including burning throat, mouth and stomach.
Serious Eye Damage / Irritation:	The ***Stopping Solution*** (R10) is Corrosive, able to cause severe burns of the mucous membranes, skin and eyes; can cause permanent eye damage or blindness. Harmful to eyes upon contact; in case of contact with eyes, immediately rinse with copious water and seek medical attention. The **Stopping Solution** poses a risk of serious damage to eyes.
STOT-Single Exposure:	Data is not available.
STOT-Repeated Exposure:	Data is not available.
Aspiration Hazard:	Data is not available.
Other Acute Health Effects:	The **Stopping Solution** (R10) poses a risk of serious damage to eyes.

Biohazard Potential:

The **HIV-1 Ag Positive Control** (C3) contains **Inactivated Human Immunodeficiency Virus, type 1 (HIV-1),** though verified to be non-infectious [inactivation evidenced by a ≥ 99% reduction in RT activity (example: 10^{-5} viable ≥ 10^{-1} disrupted) by standard RT assay], should be handled with *Standard* and *Universal Precautions*, as if capable of transmitting infectious disease. The **HIV-1 Ab Positive Control** (C1) was heat-treated to inactivate the HIV. Human sera in reagents were tested and found non-reactive for Hepatitis B surface antigen and antibodies to HCV (the **Negative Control** (C0), **HIV-1 Ag Positive Control** (C3) and **Cutoff Calibrato**r (C4) are also non-reactive for antibodies to HIV). No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *Universal Precautions*; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories,* WHO *Laboratory Biosafety Manual* 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 Group 2B and EU Category 2 carcinogen) and **silica quartz** (CAS# 14808-60-7, ACGIH class A2 and IARC Group 1 carcinogen). Keep the desiccant packet intact as received in the component package. Component **R10** contains **1N Sulfuric Acid,** CAS# 7664-93-9: IARC Group 1, The agent is Carcinogenic to Humans, NTP listed as Known to be a Human Carcinogen and ACGIH-TLV Group A2, Suspected Human Carcinogen. *Note: The IARC Group and ACGIH A2 1classifications refers specifically to sulfuric acid contained in strong inorganic acid mists are and does not apply to sulfuric acid or sulfuric acid solutions.*
Germ Cell Mutagenicity:	Data is not available.
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.)

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):

This product was not tested. The following assessment is based on information for the ingredients.	
Toxicity:	**Concentrated Sulfuric acid [CAS# 7664-93-9]** *: Fish LC_{50} - Gambusia affinis (Mosquito fish) – 42 mg/l - 96 h **Concentrated Hydrochloric acid [CAS# 7647-01-0]** *: Fish LC_{50} - Bluegill/Sunfish – 3.6 mg/l - 48 h **Concentrated *2-methyl-4-isothiazolin* [CAS# 2682-20-4] **:** Fish LC_{50} – Lepomis macrochirus (Bluegill) – 300 µg/l [min. 240 µg/l max. 320 µg/l] - 96 h Fish LC_{50} - Oncorhynchus mykiss (rainbow trout) – 190 µg/l [min. 130 µg/l max. 310 µg/l] - 96 h Fish LC_{50} - Oncorhynchus mykiss (rainbow trout) – 70 µg/l [min. 60 µg/l max. 90 µg/l] - 96 h ** Source: Raw Material Vendor Safety Data Sheets* *** Source: PAN Pesticides Database – Chemical Studies on Aquatic Organisims [obtained 3/7/2012]*
Persistence and degradability:	No information found.
Bioaccumulation potential:	No information found.

Mobility in soil:	No information found.
PBT and vPvB assessment:	No information found.
Other adverse affects:	The acidic corrosive 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. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Avoid release to the environment.

DISPOSAL CONSIDERATIONS (13):

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional, national and international regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the kit components may change waste management requirements and options. Contact your Environmental Health & Safety Office for your specific disposal procedures.

Recommended Product Disposal:

- The **HIV-1 Ag control** (C3) and all **human source** and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your applicable ordinances accordingly.
- **Acidic Stopping Solution** (sulfuric acid, pH ≤ 2), **Chromogen** (pH ~1.5), and **Substrate Buffer** (pH ~4.0) wastes can be neutralized to pH 6-8 for safe sewer disposal if allowed; check your applicable ordinances accordingly. In addition, if the final pH measures ≤ 2, it requires disposal as a corrosive material in a RCRA approved dangerous waste facility (or equivalent); the US RCRA Waste disposal Code for this waste, if not neutralized, is D002, check your applicable ordinances accordingly.

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

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

TRANSPORT INFORMATION (14):

Shipping of product, packaging and waste must be conducted in accordance with all applicable local, regional, national and international regulations. Processing, use or contamination of the kit components may change shipping requirements and options. Contact your Environmental Health & Safety Office for your specific shipping procedures.

Recommended Unused Product Multi-Modal Transportation: According to US DOT, IATA, and UN "Model Regulations," the STOPPING SOLUTION in the kit must be transported as follows:

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]**
UN Class: **8** Packing group **II** UN 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:

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 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: **Corrosive Liquid n.o.s.**
UN Class: **8** Packing group **III** UN ID Number: **UN 1760**

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable

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 Group 2B and EU Category 2 carcinogen) and **silica quartz** (CAS# 14808-60-7, in dust form is an ACGIH class A2 and IARC Group 1 carcinogen) in a pelletized desiccant sealed packet. Keep the desiccant packet intact as received in the component package.

Component R10 contains **IN Sulfuric Acid,** CAS# 7664-93-9: .IARC Group 1, The agent is Carcinogenic to Humans, NTP listed as Known to be a Human Carcinogen and ACGIH-TLV Group A2, Suspected Human Carcinogen
Note: The IARC Group and ACGIH A2 1classifications refers specifically to sulfuric acid contained in strong inorganic acid mists are and does not apply to sulfuric acid or sulfuric acid solutions.

National Regulations:

WHMIS Classification: This SDS contains the required information in accordance with the **Workplace Hazardous Materials Information System (WHMIS) Canadian Standard** hazard classification criteria for this product.

Composite WHMIS Hazard Class: Class D2B - Materials causing other toxic effects (Toxic material)
Class E - Corrosive material

Mexican Standard: This SDS contains the required information for preparation in accordance with the **Mexican Standard (NMX-R-019-SCFI-2011)** *SISTEMA ARMONIZADO DE CLASIFICACIÓN Y COMUNICACIÓN DE PELIGROS DE LOS PRODUCTOS QUÍMICOS GLOBALLY HARMONIZED SYSTEM (GHS).*

Australian Code: This SDS contains the required information for preparation according to the *Australian* Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals under Section 274 of the ***Work Health and Safety Act.*** *Australian Inventory of Chemical Substances*: All pertinent ingredients are listed.

Markings according to *European Community* 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC guidelines: This product has been classified and labeled in accordance with applicable *European Community (EC) Directives* 1999/45/EC, 2001/59/EC, 2001/60/EC and 2006/102/EC.

Hazard Designation of Composite Product: CORROSIVE: C  ; IRRITANT: Xi 

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

1N Sulfuric acid (4.4% w/w H_2SO_4), CAS# 7664-93-9, EC No 231-639-5 [pH ≤ 2], [Corrosive: C; R 34 (eyes)-36/37/38-41; S 24/25-26-36/37/39-45-60 (1999/45/EC and 2001/60/EC).]

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 (≤ 0.06% and > 0.0015% Active Ingredient).]

OTHER INFORMATION (16):

Risk Phrases:

R 34	Causes burns.
R 36/38	Irritating to eyes and skin.
R 36/37/38	Irritating to eyes, respiratory system and skin.
R 41	Risk of serious damage to eyes.
R 43	May cause sensitisation by skin contact.

Caution	Contains human source material and inactivated pathogen. Handle as if capable of transmitting potentially infectious agents (*Standard* and *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 36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S 37	Wear suitable gloves.
S 56	Dispose of this material and its container to hazardous or special waste collection point.
S 60	This material and its container must be disposed of as hazardous waste.

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

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

For *in vitro* diagnostic use.

Sources of key data used to compile the Safety Data Sheet:
Raw Material Vendor Safety Data Sheets
United Nations (UN) Globally Harmonized System (GHS)
United States OSHA Hazard Communication Standard (HCS) 1910.1200
Canadian Workplace Hazardous Materials Information System (WHMIS)
European Community (EC) Regulations 2008/1272/EC, 2010/453/EC, 2006/1907/EC
Mexican Standard NMX-R-019-SCFI-2011
Australian Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the Work Health and Safety Act)
EU Directives 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC
Registry of Toxic Effects of Chemical Substances (RTECS)
International Agency for Research on Cancer (IARC)
American Conference of Governmental Industrial Hygienists (ACGIH)
Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)
National Toxicity Program (NTP)
National Institute for Occupational Safety and Health (NIOSH)
World Health Organization. *Laboratory Biosafety Manual*
CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
PAN Pesticides Database – Chemical Studies on Aquatic Organisims
Australian Inventory of Chemical Substances (ACIS) Listing
California Proposition 65

Chemical safety assessment: Mixtures covered in this SDS were classified using the EU Regulation 1272/2008/EC and/or UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Fourth edition unless otherwise specified.

Key / legend to abbreviations and acronyms used in the safety data sheet:
ACGIH – American Conference of Governmental Industrial Hygienists
ACIS – Australian Inventory of Chemical Substances
ANSI – American National Standards Institute
CAS – Chemical Abstracts Service
CDC – Centers for Disease Control, USA
CNS – Central Nervous System
DOT – Department of Transportation
EC_{50} – half maximal effective concentration
EU – European Union
GHS – Globally Harmonized System
HCS – Hazard Communication Standard, USA
IATA – International Air Transport Association
IARC – International Agency for Research on Cancer
ICAO - International Civil Aviation Organization
IDLH – Immediately Dangerous to Life or Health
IMDG – International Maritime Dangerous Goods

IPCS – International Programme on Chemical Safety
LC_{50} – median lethal concentration, 50%
LD_{50} – median lethal dose, 50%
NIOSH – National Institute for Occupational Safety and Health
NTP – National Toxicity Program
OEL – Occupational Exposure Limit
PEL – Permissible Exposure Limit
ppm – parts per millón
RTECS # – Registry of Toxic Effects of Chemical Substances number
SDS – Safety Data Sheet
STEL – Short Term Exposure Limit
TLV/TWA – Threshold Limit Value / Time-Weighted Average
UN – United Nations
US EPA – United States Environmental Protection Agency
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
WHMIS –Workplace Hazardous Materials Information System, Canada
WHO – World Health Organization (United Nations)

Additional information: The lists that were valid during the creation were used as basis.

This Revision: ProClin 300 concentration change from 0.1% to 0.5% in the **HIV Ag** Positive Controls R3; minor corrections.

Bio-Rad Laboratories:

Department issuing SDS: Environmental Health and Safety.

Contact for general SDS information: Redmond Operations, Environmental Health & Safety, 6565 185th Ave. NE, Redmond, WA 98052, USA, Phone: 425-881-8300 (8 am to 5 pm PT), ro-sds@bio-rad.com

Customer support contact: Clinical Diagnostics Group, 4000 Alfred Nobel Drive, Hercules, CA 94547, USA Phone: 1-800-224-6723, www.bio-rad.com/diagnostics