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 MSDS 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 infection with HIV-1 and/or HIV-2.

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 PST)

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 MSDS 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.

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.

<table>
<thead>
<tr>
<th>Component *</th>
<th>Content</th>
</tr>
</thead>
</table>
| 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_{18}H_{14}O_{26}) [CAS# 9005-64-5, EC No 585-580-06-X].  
[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.  
- 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.]  
- Preserved with 0.16% ProClin 950 containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C_{6}H_{5}NOS); CAS# 2682-20-4 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P261, P272, P280; P312, P363, P302 + P352, P333 + P313; P501] [EU Classification per 1999/45/EC: Irritant: Xi, R 36/38-43; S 24/25-35-36/37.] |

WARNING!
## C1. HIV-1 Ab Positive Control

<table>
<thead>
<tr>
<th>Catalog No. 26221</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Heat-treated human serum containing HIV-1 antibody, non-reactive for HBsAg and antibody to HCV.</td>
</tr>
<tr>
<td>- Preserved with <strong>0.005% gentamicin sulfate</strong>, CAS# 1405-41-0, EC No 215-778-9 [&lt;= 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements.]</td>
</tr>
<tr>
<td>- Preserved with <strong>0.16% ProClin 950</strong> containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C₆H₄NOS); CAS# 2682-20-4 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P261, P272, P280; P312, P363, P302 + P352, P333 + P313; P501] [EU Classification per 1999/45/EC: Irritant: Xi, R 36/38-43; S 24/25-35-36/37.]</td>
</tr>
</tbody>
</table>

### WARNING!

## C2. HIV-2/O Ab Positive Control

<table>
<thead>
<tr>
<th>Catalog No. 26222</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Murine monoclonal antibody to HIV-2 and Rabbit HIV-1 Group O antibody diluted in normal human serum; non-reactive for HBsAg, and antibodies to HCV.</td>
</tr>
<tr>
<td>- Preserved with <strong>0.005% gentamicin sulfate</strong>, CAS# 1405-41-0, EC No 215-778-9 [&lt;= 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements.]</td>
</tr>
<tr>
<td>- Preserved with <strong>0.16% ProClin 950</strong> containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C₆H₄NOS); CAS# 2682-20-4 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P261, P272, P280; P312, P363, P302 + P352, P333 + P313; P501] [EU Classification per 1999/45/EC: Irritant: Xi, R 36/38-43; S 24/25-35-36/37.]</td>
</tr>
</tbody>
</table>

### WARNING!

## C3. HIV-1 Ab Positive Control

<table>
<thead>
<tr>
<th>Catalog No. 26223</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Purified HIV-1 viral lysate antigen inactivated with a chaotropic agent and heat in synthetic diluent</td>
</tr>
<tr>
<td>- &lt; 0.1% Tartrazine [FD&amp;C Yellow #5, Acid Yellow 23; C₆H₄N₂O₂S•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.]</td>
</tr>
<tr>
<td>- Preserved with <strong>0.1% ProClin 300</strong> (0.003%active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P261, P272, P280; P312, P363, P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]</td>
</tr>
</tbody>
</table>

### WARNING!

## C4. Cutoff Calibrator

<table>
<thead>
<tr>
<th>Catalog No. 26224</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Normal human serum/plasma that is non-reactive for HBsAg, HIVAg and antibodies to HIV and HCV.</td>
</tr>
<tr>
<td>- Preserved with <strong>0.005% gentamicin sulfate</strong>, CAS# 1405-41-0, EC No 215-778-9 [&lt;= 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements.]</td>
</tr>
<tr>
<td>- Preserved with <strong>0.16% ProClin 950</strong> containing 0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C₆H₄NOS); CAS# 2682-20-4 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P261, P272, P280; P312, P363, P302 + P352, P333 + P313; P501] [EU Classification per 1999/45/EC: Irritant: Xi; R 36/38-43; S 24/25-35-36/37.]</td>
</tr>
</tbody>
</table>

### WARNING!

## R6. Conjugate 1

<table>
<thead>
<tr>
<th>Catalog No. 26225</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Biotinylated polyclonal antibodies to HIV-1 p24 (sheep) in a buffer with protein stabilizers and yellow-green dye</td>
</tr>
<tr>
<td>- &lt; 0.1% Bromocresol Purple, Sodium Salt (C₆H₅Br₂O₂S•Na); CAS# 62625-30-3; EC No. 263-655-3. [Dilution is not subject to GHS and EU 2008/1272/EC Regulatory requirements.]</td>
</tr>
<tr>
<td>- Preserved with <strong>0.005% gentamicin sulfate</strong>, CAS# 1405-41-0, EC No 215-778-9 [&lt;= 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements.]</td>
</tr>
<tr>
<td>- Preserved with <strong>0.5% ProClin 300</strong> (0.015%active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P261, P272, P280; P312, P363, P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]</td>
</tr>
</tbody>
</table>

### WARNING!

## R7a. Conjugate 2

<table>
<thead>
<tr>
<th>Catalog No. 26226 or 26227</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Lyophilized, peroxidase-labeled Streptavidin and peroxidase-labeled HIV-1 and HIV-2 antigens.</td>
</tr>
<tr>
<td>- Prior Lyophilization, the solution was preserved with:</td>
</tr>
<tr>
<td>- <strong>0.005% gentamicin sulfate</strong>, CAS# 1405-41-0, EC No 215-778-9 [&lt;= 0.01% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements.]</td>
</tr>
<tr>
<td>- <strong>0.5% ProClin 300</strong> (0.015%active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P261, P272, P280; P312, P363, P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]</td>
</tr>
</tbody>
</table>

### WARNING!
### R7b. Conjugate 2 Diluent

**Catalog No. 26228**

- Buffer (pH neutral) with protein stabilizers (bovine and sheep) and red dye.
- < 0.1% Amaranth [FD&C Red #2; C20H11N2O10S3Na], CAS# 915-67-3, EC No 213-022-2 (Not subject to GHS and EU 2008/1272/EC regulatory requirements.)
- Preserved with 0.005% gentamicin sulfate. CAS# 1405-71-0, EC No 200-644-3. [Dilution is not subject to GHS and EU 2008/1272/EC labeling 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; P261, P272, P280; P312, P363, P302 + P352, P333 + P313; P501] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]

### R8. Substrate Buffer

**Catalog No. 26181**

- Dilute citric acid/sodium acetate buffer, (pH ~ 4.0).
- < 0.1% hydrogen peroxide [H2O2], CAS# 7722-84-1, EC No 231-765-0.
- < 5% dimethylsulfoxide [DMSO - C6H12O], CAS# 67-68-5, EC No 200-644-3. [Dilution is not subject to GHS and EU 2008/1272/EC regulatory requirements.]

### R9. Chromogen (11X)

**Catalog No. 26182**

- ≤ 0.04 N hydrochloric acid (~ 0.3% HCl, CAS# 7647-01-0, EC No 231-639-5) solution (pH ~ 1.5).
- ≤ 0.25% 3,3',5,5' tetramethylbenzidine dihydrochloride [TMB– C16H20N2•2HCl], CAS# 207738-08-7, EC No 264-769-6. [Dilution is not subject to GHS and EU 2008/1272/EC regulatory requirements.]

### R10. Stopping Solution

**Catalog No. 25260**

**DANGER!**

- 1N H2SO4 (4.4% w/w Sulfuric acid), CAS# 7664-93-9, EC No 231-639-5 (pH ≤ 2); severely irritating to skin, corrosive to eyes [GHS / 2008/1272/EC Classification: DANGER! GHS05; H314; P260, P264, P280; P310, P363, P301 + P330 + P331, P303 + P361 + P353, P304 + P340, P305 + P351 + P338; P405; P501] [EU Classification per 1999/45/EC and 2001/60/EC: Corrosive: C R 34 (eyes)-36/37/39-60.]

### Plate Sealers

- Clear plastic sealers.

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* 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) and European Community (EU) 2008/1272/EC guidelines:

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

<table>
<thead>
<tr>
<th>Components</th>
<th>GHS 2008/1272/EC Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>C3, R6, R7b, R7b</td>
<td>0.1% &amp; 0.5% ProClin 300 [0.003% &amp; 0.015% active ingredients – reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC No 247-500-7) and 2-methyl-2H -isothiazol-3-one (EC No 220-239-6) (3:1)], EC Index No 613-167-00-5 with CAS# 55965-84-9.</td>
</tr>
</tbody>
</table>

**GHS 2008/1272/EC Classification:**

- **Label(s):**
- **Signal Word:**
- **Label Hazard Statement:**
- **Supplemental Hazard Statement:**
- **Precautionary Statement – Prevention:**
- **Precautionary Statement – Response:**
- **Precautionary Statement – Storage:**
- **Precautionary Statement – Disposal:**

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MSDS26217-26218 Rev A (July 2011)
**Component C0, C1, C2, C4:** 0.16% ProClin 950 [0.016% active ingredient: 9.5-9.9% 2-methyl-4-isothiazolin-3-one (C₄H₅NOS); CAS# 2682-20-4].

**GHS \ 2008/1272/EC Classification:**

<table>
<thead>
<tr>
<th>Label(s):</th>
<th>GHS07</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Word:</td>
<td>WARNING!</td>
</tr>
<tr>
<td>Label Hazard Statement:</td>
<td>H317: May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>Supplemental Hazard Statement:</td>
<td>None Specified</td>
</tr>
<tr>
<td>Precautionary Statement – Prevention:</td>
<td>P261: Avoid breathing dust/fume/ gas/mist/vapours/spray</td>
</tr>
<tr>
<td>P272: Contaminated work clothing should not be allowed out of the workplace.</td>
<td></td>
</tr>
<tr>
<td>P280: Wear protective gloves/protective clothing/eye protection/face protection.</td>
<td></td>
</tr>
<tr>
<td>Precautionary Statement – Response:</td>
<td>P312: Call a POISON CENTER or doctor/physician if you feel unwell.</td>
</tr>
<tr>
<td>P363: Wash contaminated clothing before reuse.</td>
<td></td>
</tr>
<tr>
<td>P302 + P352: IF ON SKIN: Wash with plenty of soap and water.</td>
<td></td>
</tr>
<tr>
<td>P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.</td>
<td></td>
</tr>
<tr>
<td>Precautionary Statement – Storage:</td>
<td>None Specified</td>
</tr>
<tr>
<td>Precautionary Statement – Disposal:</td>
<td>P501: Dispose of contents and container in accordance to local, regional, national and international regulations.</td>
</tr>
</tbody>
</table>

**Component #R10: 1N H₂SO₄ [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:**

<table>
<thead>
<tr>
<th>Label(s):</th>
<th>GHS05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Word:</td>
<td>DANGER!</td>
</tr>
<tr>
<td>Label Hazard Statement:</td>
<td>H314: Causes severe skin burns and eye damage.</td>
</tr>
<tr>
<td>Supplemental Hazard – Statement:</td>
<td>None Specified</td>
</tr>
<tr>
<td>P264: Wash thoroughly after handling.</td>
<td></td>
</tr>
<tr>
<td>P280: Wear protective gloves/protective clothing/eye protection/face protection.</td>
<td></td>
</tr>
<tr>
<td>P363: Wash contaminated clothing before reuse.</td>
<td></td>
</tr>
<tr>
<td>P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.</td>
<td></td>
</tr>
<tr>
<td>P303 + P361 + P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.</td>
<td></td>
</tr>
<tr>
<td>P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.</td>
<td></td>
</tr>
<tr>
<td>P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</td>
<td></td>
</tr>
<tr>
<td>Precautionary Statement – Storage:</td>
<td>None Specified</td>
</tr>
<tr>
<td>Precautionary Statement – Disposal:</td>
<td>P501: This material and its container must be disposed of as hazardous waste.</td>
</tr>
</tbody>
</table>

**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 (LD₅₀, 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 the Key below)
### Chemical Ingredient

<table>
<thead>
<tr>
<th>Gentamicin Sulfate [0.005% from a 50 mg/mL Solution in C0, C1, C2, C4, R6 R7a, and R7b]</th>
<th>Chemical Data / Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS#: 1405-41-0 (100%) +</td>
<td>RTECS#: LY2625000 (100%) +</td>
</tr>
<tr>
<td>EC No: 215-778-9 (100%) +</td>
<td>Flash Point: NE</td>
</tr>
<tr>
<td>LD₅₀ (oral-rat): &gt; 5000 mg/kg (100%) +</td>
<td>PEL/TLV: NE</td>
</tr>
<tr>
<td>IATA/DOT ID: NE</td>
<td></td>
</tr>
<tr>
<td>HMIS codes: H=1, F=0, R=0 ++</td>
<td>RCRA Code: NE</td>
</tr>
<tr>
<td>EU Classification per 1999/45/EC: None (due to dilution, &lt; 0.01%) ++</td>
<td></td>
</tr>
<tr>
<td>GHS / 2008/1272/EC Classification: None (due to dilution, &lt; 0.1%) ++</td>
<td></td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>ProClin 300 [0.1% in C3; 0.5% in R6, R7b and 0.5% in R7a prior Lyophilization]</th>
<th>Chemical Data / Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous ingredient concentration in raw material: According to the manufacturer, Supelco, the concentrated preservative is a mixture of 4 ingredients: 2.1-2.9% 5-chlor-2-methyl-4-isothiazolin-3-one (C₆H₄ClNOS; CAS# 26172-55-4), 0.6-1.1% 2-methyl-4-isothiazolin-3-one (C₄H₅NOS; 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.</td>
<td></td>
</tr>
<tr>
<td>RTECS#: NE</td>
<td>Flash Point: 121° F / 49.4° C (100%) +</td>
</tr>
<tr>
<td>LD₅₀ (oral-rat): 3600 mg/kg (100%) +</td>
<td>PEL/TLV: NE</td>
</tr>
<tr>
<td>IATA/DOT ID: UN1760 (undiluted, 100%) +</td>
<td></td>
</tr>
<tr>
<td>HMIS codes: H=2, F=0, R=0 ++</td>
<td>RCRA Code: Non-RCRA ++</td>
</tr>
<tr>
<td>EU Classification per 1999/45/EC and 2001/59/EC: Irritant: Xi, R 43; S 24-35-37 (≤ 0.06% and &gt; 0.0015 % ActiveIngredient) ++</td>
<td></td>
</tr>
<tr>
<td>GHS / 2008/1272/EC Classification: WARNING! GHS07; H317; P261, P272, P280; P312, P363, P302 + P352, P333 + P313; P501 ++</td>
<td></td>
</tr>
</tbody>
</table>

**WARNING!**

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. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/ attention. Call a POISON CENTER or doctor/physician if you feel unwell. The potential for adverse health effects is unknown for the highly diluted, small volume of **ProClin** 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.

**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.
<table>
<thead>
<tr>
<th>Chemical Ingredient</th>
<th>Chemical Data / Information</th>
</tr>
</thead>
</table>
| **ProClin 950** [0.16% in C0, C1, C2, and C4] | Hazardous ingredient concentration in raw material: According to the manufacturer, Supelco, the concentrated preservative contains 9.5-9.9% 2-methyl-4-isothiazolin-3-one.  
CAS#: 2682-20-4 (active ingredient)  
EC No: NE  
Chemical Formula: C₆H₅NOS (active ingredient)  
LD₅₀ (oral-rat): 3600 mg/kg (100%) +  
IATA/DOT ID: UN1760 (undiluted, 100%) +  
HMIS codes: H=2, F=0, R=0 ++  
RTECS#: NE  
Flash Point: NE  
PEL/TLV: NE  
**WARNING!**  
Hazardous ingredient concentration in raw material: According to the manufacturer, Supelco, the concentrated preservative contains 9.5-9.9% 2-methyl-4-isothiazolin-3-one.  
CAS#: 2682-20-4 (active ingredient)  
EC No: NE  
Chemical Formula: C₆H₅NOS (active ingredient)  
LD₅₀ (oral-rat): 3600 mg/kg (100%) +  
IATA/DOT ID: UN1760 (undiluted, 100%) +  
HMIS codes: H=2, F=0, R=0 ++  
RTECS#: NE  
Flash Point: NE  
PEL/TLV: NE  
**WARNING!**  
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. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Call a POISON CENTER or doctor/physician if you feel unwell. The potential for adverse health effects is unknown for the highly diluted, small volume of **ProClin** 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. |
| **3,3’,5,5’-Tetramethylbenzidine, Dihydrochloride** [≤ 0.25% w/v TMB in R9] | CAS#: 207738-08-7 (64285-73-0 anhydrous) (100%) +  
EC No: 264-769-6 (100%) +  
Chemical Formula: C₆H₆N₂O₂+2HCl (100%) +  
LD₅₀ (ipr-mouse): 135 mg/kg (100%) +  
IATA/DOT ID: NE  
HMIS codes: H=0, F=0, R=0 ++  
RTECS#: DV2300000 (100%) +  
Flash Point: NE  
PEL/TLV: NE  
**EG Classification per 1999/45/EC:** Irritant: Xi, R 36/38-43; S 24/25-35/36/37 (0.052% – 0.63% Active Ingredient) ++  
**GHS / 2008/1272/EC Classification:** WARNING! GHS07; H317; P261, P272, P280; P312, P363, P302 + P352, P333 + P313; P501 ++  
The chemical, physical and toxicological properties have not been thoroughly investigated. **Tetramethylbenzidine** 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. |
| **Tartrazine Solution** [< 2% in C3] | CAS#: 1934-21-0 (100%) +  
EC No: 217-699-5 (100%) +  
Synonyms: Acid Yellow 23; Yellow no. 4; FD&C Yellow #5  
Chemical Formula: C₁₆H₉N₄O₉S₂·3Na  
LD₅₀ (oral-mouse): 12750 mg/kg (100%) +  
IATA/DOT ID: NE  
HMIS codes: H=1, F=0, R=0 ++  
RTECS#: UQ6400000 (100%) +  
Flash Point: NE  
PEL/TLV: NE  
**EG Classification per 1999/45/EC:** None (due to dilution, < 20%) ++  
**GHS / 2008/1272/EC Classification:** Not subject to EU 2008/1272/EC and GHS regulatory requirements ++  
The chemical, physical and toxicological properties have not been thoroughly investigated. **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. |
### Chemical Ingredient: 1.0N Sulfuric Acid

<table>
<thead>
<tr>
<th>Chemical ID</th>
<th>CAS#: 7664-93-9 (Conc. sulfuric acid 100%) +</th>
<th>RTECS#: WS5600000 (100%) +</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC No:</td>
<td>231-639-5 (100%) +</td>
<td>pH ≤ 2</td>
</tr>
<tr>
<td>Chemical Formula:</td>
<td>H$_2$SO$_4$ (100%) +</td>
<td>Flash Point: NE</td>
</tr>
<tr>
<td>LD$_{50}$ (oral-rat):</td>
<td>2,140 mg/kg (100%) +</td>
<td>LC$_{50}$ (inhalation-rat): 510 mg/m$^3$/2H (100%) +</td>
</tr>
<tr>
<td>TWA-PEL: 1 mg/m$^3$ (100%) +</td>
<td>TWA-TLV: 0.2 mg/m$^3$ (100%) +</td>
<td>IDLH: 15 mg/m$^3$ (100%) +</td>
</tr>
<tr>
<td>STEL: 3 mg/m$^3$ (100%) +</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IATA/DOT ID:</td>
<td>UN2796 (&lt; 51% sulfuric acid solutions) +</td>
<td>RCRA Code: D002 (if not neutralized) +</td>
</tr>
<tr>
<td>HMIS codes:</td>
<td>H=2, F=0, R=1 ++</td>
<td></td>
</tr>
<tr>
<td>EU Classification per 1999/45/EC and 2001/60/EC:</td>
<td>Corrosive: C; R 34 (eyes)-36/38/41; S 24/25-26-36/37/39-60</td>
<td></td>
</tr>
<tr>
<td>GHS / 2008/1272/EC Classification:</td>
<td>DANGER! GHS05; H314; P260, P264, P280; P310, P363, P301 + P330 + P331, P303 + P361 + P353, P304 + P340, P305 + P351 + P338; P405; P501 ++</td>
<td></td>
</tr>
</tbody>
</table>

**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 regulations.

**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. 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. 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/amphiphenol such as 0.8% Vepshene (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 and Universal Precautions.
General Kit Composite Health Hazards:

No significant adverse health effects are expected by any route for the following chemical constituents in the kit volumes and concentrations present [dilution not subject to EU or GHS Directive labeling]:

- **Tweeen 20** [C₈₅H₁₁₄O₂₈], CAS# 9005-64-5, EC No 585-580-06-X, ≤ 2% v/v in R2.
- **Dimethyl sulfoxide** [DMSO - C₅H₄O], CAS# 67-68-5, EC No 200-644-3, ≤ 5% v/v in R8.
- **Hydrogen peroxide** [H₂O₂], CAS# 7722-84-1, EC No 231-765-0, ≤ 0.1% v/v in R8.
- Dilute 0.04N hydrochloric acid solution [CAS# 7647-01-0, −0.3% v/v in R9].
- The miscellaneous salts, sugars, buffers, water, animal sera (bovine, rabbit, murine and sheep), 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.
EMERGENCY FIRST AID MEASURES (4):

Health Effects: Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Risk of serious damage to eyes. Causes severe skin burns and eye damage. 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.

Eye Contact: Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.

Skin Contact: Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs, or if more severe symptoms develop, consult a physician.

Inhalation: Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.

If Swallowed: If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

Notes to Physician According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered hepatitis B vaccination prior to working with human source material.

FIREFIGHTING MEASURES (5):

Extinguishing Media: Use extinguishing media appropriate for the surrounding fire.

Special Firefighting Procedures: Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

ACCIDENTAL RELEASE MEASURES (6):

♦ Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab Personal Protective Equipment (PPE), including gloves, lab coat and eye/face protection.

♦ In the event of a hazardous material spill, contain the spill if it is safe to do so and immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

♦ 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:
  o 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.).
  o Neutralize corrosive acidic spills with the appropriate Acid 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, acid absorbent pads, etc.), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all local, regional and national regulations.
HANDLING AND STORAGE INFORMATION (7):

Handling: This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper good laboratory practices and safety guidelines for handling chemical, biological and laboratory hazards. Wear appropriate personal protective equipment (PPE), including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all human source material and 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, PRECAUTIONS FOR USERS). Refer to the Instructions For Use / Package Insert for additional product information.

EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):

Component chemicals with workplace control parameters:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS-No.</th>
<th>Value</th>
<th>Control parameters</th>
<th>Update</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric acid</td>
<td>7664-93-9</td>
<td>TWA – TLV</td>
<td>0.2 mg/m³ (thoracic fraction)</td>
<td>2004-01-01</td>
<td>USA, ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>REL</td>
<td>1 mg/m³ *</td>
<td>1993-06-30</td>
<td>USA, Occupational Exposure Limits (OSHA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IDLH</td>
<td>15 mg/m³</td>
<td></td>
<td>USA, National Institute for Occupational Safety and Health (NIOSH)</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>7647-01-0</td>
<td>TLV – C</td>
<td>2 ppm</td>
<td>2007-01-01</td>
<td>USA, ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL – C</td>
<td>7 mg/m³ *</td>
<td>2006-02-28</td>
<td>USA, Occupational Exposure Limits (OSHA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Table Z-1; Limits for Air Contaminants</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>* The value in mg/m³ is approximate. Ceiling limit is to be determined from breathing-zone air samples.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>7722-84-1</td>
<td>TWA – TLV</td>
<td>1 ppm</td>
<td>2007-01-01</td>
<td>USA, ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>REL</td>
<td>7 mg/m³</td>
<td>2005-149 [SEP-2007]</td>
<td>USA, National Institute for Occupational Safety and Health (NIOSH)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IDLH</td>
<td>5 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Remarks: TLV CARCINOGENICITY DESIGNATION A3 – Animal Carcinogen: Substance is carcinogenic in laboratory 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA – PEL 1.4 mg/m³ *</td>
<td>1997-08-04</td>
<td>USA, Occupational Exposure Limits (OSHA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Table Z-1; Limits for Air Contaminants</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>REL</td>
<td>1.4 mg/m³ 1 ppm</td>
<td>2005-149 [SEP-2007]</td>
<td>USA, National Institute for Occupational Safety and Health (NIOSH)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IDLH</td>
<td>1 ppm 75 ppm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.
- **Respiratory Protection**: Do not breathe mist / vapours / spray.
- **Eye Protection**: Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.
- **Protective Gloves**: Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves, such as Nitrile, Neoprene and Vinyl, are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never 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.
- **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, generally aqueous liquids. Exceptions are the solid microtiter plate and related materials.
- **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
  - **Chromogen** at pH ~1.5
- **Boiling Point**: Not Established.
- **Melting Point**: Not Established.
- **Flash Point**: Not Applicable.
- **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.
- **Auto Igniting**: Product is not known to be self-igniting.
- **Danger of Explosion**: Product is not known to present an explosion hazard.
- **Specific gravity**: Variable; approximately 1.
- **Solubility**: The liquid chemical components are soluble in water. The **acidic solutions** may release heat.

No Other Standard Characteristics applicable to the identification or hazards of the kit 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.
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 toxic hydrogen chloride gas.

Hazardous Polymerization: Has not been reported to occur.

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### 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. Corrosive to eyes, with greater exposures may cause eye injury.

- **Other Acute Health Effects:** 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 \( \geq 99\% \) reduction in RT activity (example: \( 10^{-5} \) viable \( \geq 10^{-1} \) disrupted) by standard RT assay], should be handled with Universal Precautions, as if capable of transmitting infectious disease. Employ Universal Precautions; handle this product in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH Biosafety in Microbiological and Biomedical Laboratories or equivalent. 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) 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 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, ACGIH class A2 and IARC class 1 carcinogen). Keep the desiccant packet intact as received in the 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.)
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.
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Avoid release to the environment.
General notes: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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 international, national, regional and local 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 local, regional, national and international 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 international, national and regional ordinances accordingly.

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 Transportation: According to US DOT and IATA, R8 and R9 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]
DOT Class: 8 Packing group II DOT ID Number: UN 2796

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.
DOT Class: 8 Packing group III DOT ID Number: UN 1760
REGULATORY INFORMATION (15):

Composite HMIS Rating:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

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 component package.
Component R10 contains 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 classifications refers specifically to sulfuric acid contained in strong inorganic acid mists are and does not apply to sulfuric acid or sulfuric acid solutions.

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 - Materials causing other toxic effects (Toxic material)
- Class E - Corrosive material

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 H₂SO₄), CAS# 7664-93-9, EC No 231-639-5 [pH ≤ 2], [Corrosive: C; R 34 (eyes)-36/37/38-41; S 24/25-26-36/37/39-60 (1999/45/EC and 2001/60/EC).]

0.5% & 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 (≤ 0.06% and > 0.0015% Active Ingredient).]

0.16% ProClin 950, CAS# 2682-20-4 [Irritant: Xi; R 36/38-43; S 24/25-35-36/37 (0.63% - 0.052% 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.
- 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 and Universal Precautions).

Caution Contains human source material & inactivated pathogen. Handle as if capable of transmitting potentially 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 36/37 Wear suitable protective clothing and gloves.
- 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.

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

**This Revision:** New MSDS

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**Contact for general MSDS information:**

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