SAFETY DATA SHEET (SDS)

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

Product Name: **GS HIV-2 EIA - Human Immunodeficiency Virus Type 2**

Product Number: **32536** (480 tests)
Catalog number(s) for replacement and/or separately purchased components that can be obtained for use with this kit and which are covered by this SDS include**: 25260, 25261, 26181** and **26182**.

Intended Use: The GS HIV-2 EIA is an Enzyme Immunoassay (EIA) for the detection of circulating antibodies to Human Immunodeficiency Virus Type 2 (HIV-2) in human serum or plasma, and is indicated as an aid in the diagnosis of infection with Human Immunodeficiency Virus Type 2 (HIV-2).

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

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

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*	Contents
R1 HIV-2 Coated Microwell Plates 5 plates	- Microwell strips in a holder with adsorbed inactivated HIV-2. - **Potential residue of thimerosal** [$C_9H_9HgNaO_2S$] used as a production preservative aspirated prior to drying strips). - Tabs are labeled "Y" - Contains sealed pelletized desiccant packet(s): 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); 2 bottles (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]. [Dilution is not subject to EU 2008/1272/EC, 1999/45/EC and GHS regulatory requirements.]
C0 HIV-2 EIA Negative Control 1 vial (0.8 mL)	- Human serum/plasma, non-reactive for HBsAg and antibodies to HCV, HIV-1 and HIV-2. - Preserved with **0.1% sodium azide** [NaN_3], EC No 247-852-1 and CAS# 26628-22-8; [GHS / 2008/1272/EC Classification: WARNING; H303, H313; P312] [EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (dilution < 1%, but ≥ 0.1%).] - Preserved with **0.01% thimerosal** [$C_9H_9HgNaO_2S$], EC No 200-210-4, CAS# 54-64-8; [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements. Requires hazardous waste disposal (US RCRA D009) - P501.] [EU Classification per 1999/45/EC: R 43-61; S 24/25-28-36-53-60-61 (dilution < 0.1%).]

Component*	Contents
C1 HIV-2 EIA Positive Control 1 vial (0.8 mL)	- Heat-treated human serum/plasma containing HIV-2 immunoglobulin. - Non-reactive for HBsAg and antibodies to HCV. - Preserved with **0.1% sodium azide** [NaN_3], EC No 247-852-1 and CAS# 26628-22-8; [GHS / 2008/1272/EC Classification: WARNING; H303, H313; P312] [EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (dilution < 1%, but ≥ 0.1%).] - Preserved with **0.01% thimerosal** [$C_9H_9HgNaO_2S$], EC No 200-210-4, CAS# 54-64-8; [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements. Requires hazardous waste disposal (US RCRA D009) - P501.] [EU Classification per 1999/45/EC: R 43-61; S 24/25-28-36-53-60-61 (dilution < 0.1%).]
R3 HIV-2 EIA Conjugate Concentrate 1 vial (1.5 mL)	- Goat anti-human IgM and IgG horseradish peroxidase conjugated buffered solution with protein stabilizers. - Preserved with **0.01% thimerosal** [$C_9H_9HgNaO_2S$], EC No 200-210-4, CAS# 54-64-8; [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements. Requires hazardous waste disposal (US RCRA D009) - P501.] [EU Classification per 1999/45/EC: R 43-61; S 24/25-28-36-53-60-61 (dilution < 0.1%).]
R4 HIV-2 EIA Conjugate Diluent 1 bottle (120 mL)	- Citrate buffer with protein stabilizers (normal goat sera) and red dye (food grade). - Preserved with **0.01% thimerosal** [$C_9H_9HgNaO_2S$], EC No 200-210-4, CAS# 54-64-8; [< 0.1% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements. Requires hazardous waste disposal (US RCRA D009) - P501.] [EU Classification per 1999/45/EC: R 43-61; S 24/25-28-36-53-60-61 (dilution < 0.1%).]
R5 HIV-2 EIA Specimen Diluent Concentrate (10X) 1 bottle (120 mL)  **WARNING**	- Diluent for specimen; buffer with protein stabilizers and blue dye (food grade). - Preserved with **0.1% thimerosal** [$C_9H_9HgNaO_2S$], EC No 200-210-4, CAS# 54-64-8; [GHS / 2008/1272/EC Classification: WARNING; GHS07, GHS08; H303, H317, H373; P273, P281; P314, P302 + P352, P333 + P313; P501] [EU Classification per 1999/45/EC: Harmful: Xn; R 20/21/22-33-43-61; S 24/25-28-36/37-53-60-61.]
R8 Substrate Buffer, 1 bottle (120 mL) *Catalog No. 26181*	- Dilute **citric acid/sodium acetate buffer**, (pH ~ 4.0, clear liquid). - **< 0.1% hydrogen peroxide** [H_2O_2], CAS# 7722-84-1, EC No 231-765-0. - **< 5% dimethylsulfoxide** [DMSO - C_2H_6OS], CAS# 67-68-5, EC No 200-644-3. [Dilution is not subject to EU 2008/1272/EC and GHS regulatory requirements.]
R9 Chromogen (11X) 1 bottle (12 mL) *Catalog No. 26182*	- **≤ 0.04 N hydrochloric acid** [~ 0.3% HCl, CAS# 7647-01-0, EC No 231-595-7] solution (pH ~ 1.5, clear liquid). - **≤ 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. [Dilution is not subject to EU 2008/1272/EC and GHS regulatory requirements.]
R10 EIA Stopping Solution 1 bottle (120 mL) *Catalog No. 25260*  **DANGER!**	- **1N Sulfuric acid** [~4.4% H_2SO_4 w/w], 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; H314P280; P301 + P330 + P331P305 + P351 + P338; P501] [EU Classification per 1999/45/EC and 2001/60/EC: Corrosive: C; R 34 (eyes) R 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.

Markings according to the *United Nations* (UN) Globally Harmonized System (GHS) and *European Community* (EC) 2008/1272/EC guidelines:

This product has been conservatively classified and labeled in accordance with applicable *United Nations (UN) Global Harmonized System (GHS*) 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:	**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. *

[Component R5] 0.1% thimerosal [$C_9H_9HgNaO_2S$], CAS# 54-64-8, EC No 200-210-4 (dilution < 0.5% but ≥ 0.05 %).

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

Label(s):	**GHS08** **GHS07**
Signal Word:	**WARNING**
Label Hazard Statement:	**H303**: **Many be harmful if swallowed.** **H317: May cause an allergic skin reaction.** **H373: May cause damage to organs through prolonged or repeated exposure.**
Supplemental Hazard Statement:	*None Specified*
Precautionary Statement – Prevention:	**P202**: Do not handle until all safety precautions have been read and understood. **P272**: Contaminated work clothing should not be allowed out of the workplace. **P273**: *Avoid release to the environment.** **P281**: Use personal protective equipment as required. *
Precautionary Statement – Response:	**P314**: Get medical advice/attention if you feel unwell. * **P391**: Collect spillage. **P301** + **P310**: IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. **P302** + **P352**: IF ON SKIN: Wash with plenty of soap and water. * **P308** + **P313**: IF exposed or concerned: Get medical advice/attention. **P333** + **P313**: If skin irritation or rash occurs: Get medical advice/ attention. *
Precautionary Statement – Storage:	*None Specified*
Precautionary Statement – Disposal:	**P501:** This material and its container must be disposed of as hazardous waste. *

Component C0 and C1] 0.1% sodium azide [NaN_3], CAS# 26628-22-8 and EC No 247-852-1 (dilution < 1%, but ≥ 0.1%).

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

Label(s):	*No Pictogram; none required due to dilution*
Signal Word:	**WARNING**
Label Hazard Statement:	**H303: May be harmful if swallowed.** **H313: May be harmful in contact with skin.**
Supplemental Hazard Statement:	*None Specified*.
Precautionary Statement – Prevention:	**P264**: Wash thoroughly after handling.
Precautionary Statement – Response:	**P312**: Call a POISON CENTER or doctor/physician if you feel unwell. *
Precautionary Statement – Storage:	*None Specified*
Precautionary Statement – Disposal:	**P501**: Dispose of contents and container in accordance to local, regional, national and international regulations.

[Component R3, R4, C0 and C1] 0.01% thimerosal [$C_9H_9HgNaO_2S$], CAS#54-64-8, EC No 200-210-4 (dilution < 0.05%).

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

Label(s):	*No Pictogram; None required due to dilution*
Signal Word:	*None required due to dilution*
Label Hazard Statement:	*None required due to dilution*
Supplemental Hazard Statement:	*None Specified*
Precautionary Statement – Prevention:	**P272**: Contaminated work clothing should not be allowed out of the workplace. **P273**: *Avoid release to the environment.* **P280**: Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement – Response:	**P312**: Call a POISON CENTER or doctor/physician if you feel unwell. **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**: This material and its container must be disposed of as hazardous waste. *

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 for the chemical raw material (LD_{50}, exposure limits, etc.) and that the product contains a significantly diluted concentration in an aqueous solution; thus, the assessment below 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	Data / Information
1N Sulfuric acid [4.4% w/w H_2SO_4 in R10]  **DANGER!** *Continued on next page*	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 (< 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; 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. 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.

Chemical Ingredient	Data / Information
1N Sulfuric acid  **DANGER!** *Continued*	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.
≤ 0.04N Hydrochloric acid [~0.3% v/v HCl in R9]	CAS#: 7647-01-0 (100%) + EC No: 231-595-7 (100%) + Chemical Formula: HCl (100%) + LD_{50} (oral-rabbit): 900 mg/kg (100%) + TLV and PEL: 5 ppm (ceiling) (100%) + IATA/DOT ID: UN1789 (100%) + HMIS Codes: H=1, F=0, R=1 ++ RTECS#: MW4025000 (100%) + (pH ~ 1.5) ++ Flash Point: NE LC_{50} (inhalation-rat): 3124 ppm/1H (100%) + 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 ≤ **0.1N 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 component R9]	CAS#: 207738-08-7 *(*64285-73-0 anhydrous) (100%) + EC No: 264-769-6 (100%) + Chemical Formula: $C_{16}H_{20}N_2 \bullet 2HCl$ (100%) + LD_{50} (ipr-mouse): 135 mg/kg (100%) + IATA/DOT ID: NE HMIS codes: H=0, F=0, R=0 ++ RTECS#: DV2300000 (100%) + Flash Point: NE TLV and PEL: NE RCRA Code: NE EU 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. **3,3',5,5'-Tetramethylbenzidine** (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 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
Sodium Azide [0.1 % w/v in components C0 and C1] **WARNING**	CAS#: 26628-22-8 (100%) + RTECS#: VY8050000 (100%) + EC No: 247-852-1 (100%) + Chemical Formula: NaN_3 (100%) + Flash Point: NE LD_{50} (oral-rat): 27 mg/kg (100%) + LC_{50} (inhalation-rat): 37 mg/m^3 (100%) + PEL/TLV: 0.3 mg/m^3 (ceiling) (100%) + IATA/DOT ID: UN1687 (undiluted, 100%) + HMIS Codes: H=2, F=0, R=1 ++ RCRA Code: P105 (undiluted, 100%) + EU Classification per 1999/45/EC: Harmful: Xn; R 22; S 24-35-37 (< 1% and ≥ 0.1%) ++ *GHS / 2008/1272/EC Classification*: WARNING; H303, H313; P312 ++ **Sodium azide**, a biocidal preservative, may be harmful if swallowed [H303]; it has been evident to kill at low concentrations, if enough is ingested (more than supplied in kit). May be harmful in contact with skin. [H313]. May cause eye, skin or tissue irritation. May cause long lasting harmful effects to aquatic life. Avoid contact. Wash thoroughly after handling. Call a POISON CENTER or doctor/physician if you feel unwell [P312]. Avoid release to the environment. Avoid contact with metals; sodium azide may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up. The potential for these adverse health effects is unknown for the highly diluted, small volume of **sodium azide** 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*: Toxic: T, Environmental Danger: N R 28: Very toxic if swallowed. R 32: Contact with acids liberates very toxic gas. R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S (1/2-): Keep locked up and out of the reach of children. S 28: After contact with skin, wash immediately with plenty of *soap and water*. 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 sheet.

Chemical Ingredient	Data / Information
Thimerosal [0.1% w/v in R5]   **WARNING**	CAS#: 54-64-8 (Thimerosal powder, 100%) + RTECS#: OV8400000 (100%) + EC No: 200-210-4 (100%) + Synonyms: Merthiolate Sodium, Sodium o-(ethylmercurithio)benzoate ; Ethylmercurithiosalicylic acid, sodium salt Chemical Formula: $C_9H_9HgNaO_2S$ (100%) + Flash Point: NE LD_{50} (oral-rat): 75 mg/kg (100%) + PEL/TLV: 0.01 mg Hg/m^3 TWA (skin) (100%) + IATA/DOT ID: UN2025 (100%) + CA Proposition 65: Chemical known to the State of California to cause reproductive toxicity ++ HMIS Codes: H=2, F=0, R=0 ++ RCRA Code: D009 (to 0.2 mg/L - USA) ++ EU Classification per 1999/45/EC: Harmful: Xn; R 21/22-33-43-61; S 24/25-28-36/37-53-60-61 (< 0.5% and ≥ 0.1%) ++ *GHS / 2008/1272/EC Classification*: WARNING; GHS07, GHS08; H303, H317, H373; P273, P281; P314, P302 + P352, P333 + P313; P501 ++ **Thimerosal** (merthiolate sodium) is an organo-mercury biocidal preservative, which may be detrimental if enough is ingested, targets the central nervous system (CNS) and is a significant sensitizer, prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals; there are ample cases of sensitization resulting from exposure to dilute thimerosal solutions. May cause an allergic skin reaction [H317]. The chemical, physical and toxicological properties have not been thoroughly investigated. May cause damage to organs through prolonged or repeated exposure [H373]. Suspected of damaging fertility or the unborn child. May be harmful in contact with skin and if swallowed [H303, H313]. **Thimerosal**, classified under the generic class of mercury compounds, is known to the State of California to cause developmental toxicity. Avoid exposure – obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist/vapours/spray. Avoid contact with skin and eyes. Use only in a well-ventilated area. Use personal protective equipment as required [P281]. Contaminated work clothing should not be allowed out of the workplace. IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. IF ON SKIN: Wash with plenty of soap and water [P302 + P352]. If skin irritation or rash occurs: Get medical advice/ attention [P333 + P313]. IF exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell [P314]. Mercury compounds are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. Harmful to aquatic life with long lasting effects. Danger of cumulative effects. Avoid release to the environment [P273]. Collect spillage. Spent mercury-containing solutions with a concentration greater than 0.2 ppm are considered RCRA hazardous waste (D009). This material and its container must be disposed of as hazardous waste and in accordance with local, regional, national and international regulations [P501]. Handle appropriately with the requisite Good Laboratory Practices and *Universal Precautions*. *(Note: mercury (Hg) makes up 49.55% of the thimerosal molecule thus, a component with 0.1% thimerosal contains ~0.05% (500 ppm) mercury w/v).* EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: Organic compounds of mercury, Index No. 080-004-00-7 Toxic: T, Environmental Danger: N R 26/27/28: Very toxic by inhalation, in contact with skin and if swallowed. R 33: Danger of acumulative affects. R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S (1/2-): Keep locked up and out of the reach of children. S 13: Keep away from food, drink and animal feeding stuffs. S 28: After contact with skin, wash immediately with plenty of water. S 36: Wear suitable protective clothing. 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.

Chemical Ingredient	Data / Information
Thimerosal [0.01% w/v in components C0, C1, R1, R3, and R4]	CAS#: 54-64-8 (Thimerosal powder, 100%) + RTECS#: OV8400000 (100%) + EC No: 200-210-4 (100%) + Synonyms: Merthiolate Sodium, Sodium o-(ethylmercurithio)benzoate ; Ethylmercurithiosalicylic acid, sodium salt Chemical Formula: $C_9H_9HgNaO_2S$ (100%) + Flash Point: NE LD_{50} (oral-rat): 75 mg/kg (100%) + PEL/TLV: 0.01 mg Hg/m^3 TWA (skin) (100%) + IATA/DOT ID: UN2025 (100%) + CA Proposition 65: Chemical known to the State of California to cause reproductive toxicity ++ HMIS Codes: H=2, F=0, R=0 ++ RCRA Code: D009 (to 0.2 mg/L - USA) ++ EU Classification per 1999/45/EC: Dilution below 1999/45/EC labeling requirement (< 0.1%); R 43-61; S 24/25-28-36-53-60-61 ++ *GHS / 2008/1272/EC Classification*: < 0.1% dilution is not subject to GHS and EU 2008/1272/EC labeling requirements. Requires hazardous waste disposal (US RCRA D009) - P501 ++ **Thimerosal** (merthiolate sodium) is an organo-mercury biocidal preservative which may be detrimental if enough is ingested, targets the central nervous system (CNS) and is a significant skin sensitizer, prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals; there are ample cases of sensitization resulting from exposure to dilute thimerosal solutions. The chemical, physical and toxicological properties have not been thoroughly investigated. **Thimerosal**, classified under the generic class of mercury compounds, is known to the State of California to cause developmental toxicity. Avoid exposure. Wear protective gloves/protective clothing/eye protection/face protection. Call a POISON CENTER or doctor/physician if you feel unwell. After contact with skin, wash immediately with plenty of water. If skin irritation or rash occurs: Get medical advice/ attention. Mercury compounds are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. May cause long lasting harmful effects to aquatic life. Danger of cumulative effects. Avoid release to the environment]. Spent mercury-containing solutions with a concentration greater than 0.2 ppm are considered RCRA hazardous waste (D009). This material and its container must be disposed of as hazardous waste and in accordance with local, regional, national and international regulations [P501]. Handle appropriately with the requisite Good Laboratory Practices and *Universal Precautions*. *(Note: Mercury (Hg) makes up 49.55% of the thimerosal molecule thus, a component with 0.01% thimerosal contains ~0.005% (50 ppm) mercury w/v).* EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - *from Annex I to Directive 67/548/EEC*: **Refer to prior record.**

Biological Ingredient	Data / Information
Human Serum [Reactive and non-reactive in the Positive (C1) and Negative (C0) Control components respectively]	**The human sera** in the components of this product were tested and found non-reactive for HBsAg and antibodies to HCV (Component C0 is also *negative* for antibodies to HIV-1/2). No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard* and *Universal Precautions* when handling these reagents and all human blood, specimens or patient samples. 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. Persons handling blood samples should have the option of receiving hepatitis B vaccination. Employ decontamination procedures, with appropriate decon agent/disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg. #1043-87), or equiv.), before discarding any materials utilized or returning equipment used to general use. 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.
Animal proteins	This material is of animal origin (bovine, goat and rabbit) 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, *Standard* and *Universal Precautions*. Dispose of this material in accordance with local, regional, national and international regulation.

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).
Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity
GHS = Globally Harmonized System
RTECS # - Registry of Toxic Effects of Chemical Substances number
PEL - Permissible Exposure Limit / Occupational exposure limit
TLV/TWA – Threshold Limit Value / Time-Weighted Average
STEL - Short Term Exposure Limit
IDLH - Immediately Dangerous to Life or Health

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 hazard labeling]:
  - **Tween 20** [$C_{58}H_{114}O_{26}$], CAS# 9005-64-5, EC No 585-580-06-X, ≤ 2% v/v in component R2.
  - **Hydrogen peroxide** [H_2O_2], CAS# 7722-84-1, EC No 231-765-0; ≤ 0.1% v/v in component R8.
  - **Dimethyl sulfoxide** [DMSO - C_2H_6OS], CAS# 67-68-5, EC No 200-644-3, ≤ 5% v/v in component 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.
- 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 an infectious agent. 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.
- 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). This material is in a pelletized desiccant sealed packet within the plate pouch, which is unlikely to generate significant dust under normal conditions of use and is thus not typically considered a health hazard. However, health hazards could result from dusts generated if the packet is cut, split or otherwise compromised and a significant number of pellets were crushed to a powder form. Keep the desiccant packet intact as received in the microwell plate component package.
- 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. Causes severe skin burns and eye damage. Risk of serious damage to eyes. 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. The thimerosal-containing components may be toxic to developing fetus. May be toxic to developing fetus, generally at concentrations and volumes that greatly exceed that of this kit. May cause damage to organs through prolonged or repeated exposure. May be harmful if swallowed. May be harmful in contact with skin.
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 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 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 Decomposition Products:	May release toxic oxides of carbon, nitrogen and sulfur or mercury.
Special Firefighting Procedures	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

ACCIDENTAL RELEASE MEASURES (6):

- Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.
- In the event of a hazardous material spill, contain the spill if it is safe to do so; immediately move to a safe area, 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 suitable spill cleanup materials and PPE are available and used.
- Follow established laboratory policy and/or appropriate CDC/NIH biosafety, and/or OSHA/WISHA hazardous material spill and/or NFPA/Fire Code guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. 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/disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% ethanol or isopropanol, an iodophor (such as Wescodyne Plus) or a phenolic, etc.).
  - Neutralize corrosive acidic spills with the appropriate *acid neutralization / adsorbent* product.
  - Absorb thimerosal-containing reagents, handle and dispose of as RCRA hazardous waste.
- Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows and absorbent pads, etc.) which is secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious and chemical laboratory wastes must be handled and discarded in accordance with all local, regional, national and international regulations.
- Refer to Sections 8 and 13 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. 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 *Product 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*:

Sodium Azide [CAS# 26628-22-8]:		
REL (United States) *TLV (United States)*	*Short-term value: C 0.3** mg/m³, C 0.1* ppm* *Short-term value: C 0.29** mg/m³, C 0.11* ppm*	**as HN_3 vapor; **as NaN_3; Skin* **as HN_3 vapor **as NaN_3*
EL (Canada (LSG) English)	*Short-term value: C 0,29* mg/m³, C 0,11**ppm*	**sodium azide;**hydrazoic acid vapour*
IOELV (European Union)	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	*Skin* *Skin*
WEL (United Kingdom)	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	*(as NaN_3) Sk* *(as NaN_3) Sk*
NES (AUS)	*0.3* mg/m³, 0.11 ppm*	**Peak limitation*
VME (France)	*Short-term value: 0,3 mg/m³, 0,1 ppm*	*risque de pénétration percutanée*
VL (Belgium, (French)	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	*D, M* *D, M*
AGW (Germany)	0,2 mg/m³	2(I);DFG
MAK (Austria, (German))	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	
TWA (Italy)	*Short-term value: C 0,29 mg/m³, C 0,11* ppm* *A4; sodio azide; *come azido idrazonico, vapore*	
MAK (Switzerland, (German))	*Short-term value: 0,4 e mg/m³* *Long-term value: 0,2 e mg/m³*	
GV (Denmark)	*0,1 mg/m³*	*EH*
MAK (Netherland)	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	
OEL (Sweden)	*Short-term value: 0,3 mg/m³* *Long-term value: 0,1 mg/m³*	*H* *H*

Chemical	CAS-No.	Value	Control parameter	Update	Basis
Sulfuric acid	***7664-93-9***	TWA – TLV	0.2 mg/m³ (thoracic fraction)	2004-01-01	USA. ACGIH Threshold Limit Values (TLV)
		TWA – PEL	1 mg/m³ *	1993-06-30	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		REL IDLH	1 mg/m³ 15 mg/m³	2005-149 [SEP-2007]	USA. National Institute for Occupational Safety and Health (NIOSH)
	* The value in mg/m³ 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**.				

Chemical	CAS-No.	Value	Control parameter	Update	Basis
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 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.				

Chemical *	CAS-No.	Value	Control parameter	Update	Basis
Thimerosal	***54-64-8***	CEIL	0.1 mg/m^3	1989-03-01	USA. OSHA - Table Z-1 Limits for Air Contaminants - 29 CFR 1910.1000
Remarks:	Skin Contact does contribute to exposure. See Table Z-2.				

**Source: Raw Material Vendor Safety Data Sheet*

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 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 dust / fume / gas / mist / vapors / 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, generally aqueous liquids. Exceptions are the solid microtiter plate and related materials.
pH:	Most of the liquid chemical components are between pH 5 and 9, 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 components have not been tested for fire and explosion data, being water-based, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.
Auto-igniting:	Product is not self-igniting.
Danger of Explosion:	**Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; buildup in metal plumbing has led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive buildup.
Relative Density:	Not established.
Solubility:	The liquid chemical components are soluble in water. The acidic solutions may release heat.
Partition coefficient (n-octanol/water):	Data is not available.
Decomposition temperature:	Data is not available.
Viscosity:	Data is not available.

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

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.
Materials to Avoid:	Do not allow the **acidic solutions** to come in contact with strong bases, oxidizing agents and metals.
Conditions and/or Materials to Avoid:	**Sodium azide** may react with lead or copper plumbing to form highly explosive metal azides; build-up in metal plumbing has led to laboratory explosions, so flush with copious water when pouring diluted solutions down the drain to prevent such explosive build-up.
Hazardous Decomposition Products:	May release toxic oxides of carbon, nitrogen and sulfur or mercury.
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: Harmful in contact with skin and if swallowed. Toxic if enough is ingested; it has been evident to kill at low concentrations if enough is ingested (typically in quantities above those found in the kit). Harmful 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. 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. 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: Acidic **Stopping Solution** (R10) poses a risk of serious damage to eyes. **Thimerosal** targets the central nervous system (CNS), lungs, gastrointestinal tract, liver, kidneys and blood (large or prolonged dosages).

Biohazard Potential

The positive control (C1) was heat-treated to inactivate the HIV. The human sera in the components of this product were tested and found non-reactive for HBsAg and antibodies to HCV (Component C0 is also negative for antibodies to HIV-1 and HIV-2). No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *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,* the WHO *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Sensitization: **Thimerosal** (organ-mercury compound) is a significant sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. There are ample cases of sensitization resulting from exposure to dilute thimerosal solutions.

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 **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: **Thimerosal** (merthiolate sodium), an organo-mercury biocidal preservative mercury compound, is a known reproductive toxin, listed by the State of California to cause developmental toxicity.

Additional Toxicological Information

Mercury compounds, such as **thimerosal** (merthiolate sodium), an organo-mercury biocidal preservative, are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. Danger of cumulative effects; avoid release to the environment. To the best of our knowledge the chemical, physical and toxicological properties have NOT been thoroughly investigated for some of the component chemicals and/or mixtures.

ECOLOGICAL INFORMATION (12):

This product was not tested. The following assessment is based on information for the ingredients.	
Toxicity:	**100% *Sodium Azide* [CAS# 26628-22-8] ***: Fish LC_{50} - Lepomis macrochirus - 0.68 mg/l - 96 h Daphnia EC_{50} - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h **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 *Thimerosal* [CAS# 54-64-8] *:** Fish LC_{50} - Oncorhynchus mykiss (rainbow trout) – 21.2 mg/l - 48 h ** Source: Raw Material Vendor Safety Data Sheets*
Persistence and degradability:	No information found.
Bioaccumulation potential:	Mercury and its compounds are expected to significantly bioaccumulate.
Mobility in soil:	No information found.
PBT and vPvB assessment:	No information found.
Other adverse affects:	The ecological information for the dilute organo-mercury preservative, **Thimerosal** has not been thoroughly investigated however, United States regulation considers mercury hazardous to the environment to 0.2 ppm mercury (0.01% thimerosal contains ~50 ppm mercury, which makes up ~50% of the molecule); at or above this level, any waste must be handled as dangerous waste. The 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:

- **Human source** and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your applicable ordinances accordingly.
- Waste containing **thimerosal**, an organo-mercury compound, is a regulated hazardous waste if the final concentration is ≥ 0.2 mg/L = ≥ 0.2 ppm. The components in this kit that contain 0.01% thimerosal equate to 0.005% = 50 mg/L = 50 ppm mercury w/v. The components in this kit that contain 0.1% thimerosal equate to 0.05% = 500 mg/L = 500 ppm mercury w/v. If the thimerosal-containing waste has a final concentration that is ≥ 0.2 mg/L = ≥ 0.2 ppm mercury, it requires disposal as a toxic environmental pollutant material in an RCRA approved waste facility (or equivalent); the US RCRA waste disposal code for this waste is D009; check your applicable ordinances accordingly.
- Note that the Negative (C0) and Positive (C1) Controls must be decontaminated prior to thimerosal-containing hazardous waste disposal.
- The acidic **Stopping Solution** (sulfuric acid, pH ≤ 2) waste should be neutralized to pH 6-8 for safe sewer disposal; check your applicable ordinances accordingly. In addition, if the final pH measures ≤ 2, it requires disposal as a corrosive material in an RCRA approved dangerous waste facility (or equivalent). The US RCRA waste disposal code for this waste, if not neutralized, is D002; check your applicable ordinances accordingly.

- Sodium azide may react with lead or copper plumbing to form highly explosive metal azides; build up in metal plumbing has lead to laboratory explosions, so flush with copious water when pouring dilute solutions down the train to prevent such explosive build-up; check your applicable accordingly.

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

Recommended Unclean Packaging Disposal: Dispose of 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:

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 Corrodes Steel [NACE Standard TM-01-69]) must be transported as follows:

Proper Shipping Name: **Sulphuric acid [with not more than 51% acid]**

DOT Class: **8** Packing group **II** DOT ID Number: **UN 2796**

Recommended Used Product 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 unneutralized discarded kit component or waste generated from its use resulting in a corrosive liquid (pH ≤ 2 per Method 9040 (USEPA Publication SW-846) or corrodes steel (NACE Standard TM-01-69) must be transported as follows:

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

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

- Components R3, R4, C0 and C1 in this kit contain approximately 0.005 % = 50 mg/L = 50 ppm mercury (w/v) from the 0.01% **thimerosal** preservative. Component R5 in this kit contains approximately 0.05 % = 500 mg/L = 500 ppm mercury (w/v) from the 0.1% **thimerosal** preservative. Therefore, any discarded kit component or waste generated from its use, resulting in a final concentration that is greater than or equal to 0.2 mg/L (ppm) must be transported as follows:

  Proper Shipping Name: **Environmentally Hazardous substance n.o.s.**

  DOT Class: **9** Packing group: **III** DOT ID Number: **UN 3082**

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: **Thimerosal** (merthiolate sodium), CAS# 54-64-8; classified under the generic class of mercury compounds.

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 R**10** 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.*

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 (Material Causing Other Toxic Effects)
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)*.

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 (refer to 1999/45/EC, 2001/59/EC, 2001/60/EC and 2006/102/EC).

Hazard Designation of Composite Product: CORROSIVE: C,  HARMFUL: Xn, 

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

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

0.1% Thimerosal, EC No 200-210-4, CAS# 54-64-8 [Harmful: Xn; R 20/21/22-33-43-61; S 24/25-28-36/37-53-60-61].

0.1% Sodium azide[NaN_3], EC No 247-852-1 and CAS# 26628-22-8 [Harmful: Xn; R 22; S 24-35-37 (< 1% and ≥ 0.1%)]

0.01% Thimerosal, EC No 200-210-4, CAS# 54-64-8 [R 43-61; S 24/25-28-36-53-60-61].

OTHER INFORMATION (16):

Risk Phrases:

R 20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
R 22	Harmful if swallowed.
R 33	Danger of cumulative effects.
R 34	Causes burns.
R 36/38	Irritating to eyes and skin.
R 41	Risk of serious damage to eyes.
R 43	May cause sensitization by skin contact.
R 61	May cause harm to unborn child. (Designation is for concentrated thimerosal (mercury compounds), which is diluted to 0.1% -0.01% in kit components.)
Caution	Contains human source material and 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 28	After contact with skin, wash immediately with plenty of soap and water.
S 35	This material and its container must be disposed of in a safe way.
S 36	Wear suitable protective clothing.
S 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 protective gloves.
S 45	In case of accident or if you feel unwell, seek medical advice immediately
S 53	May cause long-term adverse effects in the aquatic environment.
S 60	This material and/or its container must be disposed of as hazardous waste.
S 61	Avoid release to the environment.

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)
European Community (EC) 2008/1272/EC, 2010/453/EC, 2006/1907/EC Regulations
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*
Mexican Standard (NMX-R-019-SCFI-2011)
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
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
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
WHO – World Health Organization (United Nations)

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

This Revision: Updated, reformatted and added new GHS information. Significant changes – Review the revised information in sections 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 12, 14, 15, and 16.

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