

SAFETY DATA SHEET (SDS)

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

Product Name:	GS HIV-1 Western Blot HUMAN IMMUNODEFICIENCY VIRUS TYPE I
Product Number:	32508 (40 tests) Catalog number(s) for replacement components that can be obtained for use with this kit, and which are covered by this SDS include: 32573 and 32574 (refer to Section 2).
Intended Use:	The GS HIV-1 Western Blot Kit is an <i>in vitro</i> qualitative assay for the detection and identification of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) in human serum, plasma or dried blood spots. It is intended for use with persons of unknown risk as an additional, more specific test on human serum, plasma or dried blood spot specimens found to be repeatedly reactive using a screening procedure, such as Enzyme-Linked Immunosorbent Assay (ELISA), and as an additional, more specific test for use with serum, plasma or dried blood spot specimens obtained from subjects found to be reactive using rapid HIV-1 tests.
Manufactured by:	Bio-Rad Laboratories, Inc.
Address:	6565 185th Avenue NE Redmond, WA 98052-5039, USA
Website:	www.bio-rad.com
Phone Number:	1-800-2-BIORAD (1-800-224-6723); or 1-425-881-8300 (daytime PT)
SDS e-mail contact:	ro-sds@bio-rad.com
Technical Information Contacts:	Bio-Rad provides a toll free line for technical assistance; in the United States of America call toll free 1-800-2-BIORAD (1-800-224-6723). <i>Outside the U.S.A., please contact your regional Bio-Rad office for assistance.</i>
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-1 Western Blot Strips (40), 2 packages of 20 strips  WARNING	- Package contains 20 strips, sufficient for 20 tests. Nitrocellulose strips preblotted with resolved HIV-1 viral proteins. - Blotting paper buffer is preserved with: 0.1% sodium azide [NaN ₃], CAS# 26628-22-8 and EC No 247-852-1 [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%).] 0.1% ProClin 150 (0.0015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]
C0. Western Blot Negative Control, 1 vial (0.2 mL)  WARNING	- Normal Human serum / plasma, non-reactive for HBsAg and antibodies to HIV1/2 and HCV. - Preserved with 0.1% sodium azide [NaN ₃], CAS# 26628-22-8 and EC No 247-852-1 [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 0.5% ProClin 300 (0.015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]

C1. HIV-1 Western Blot Low Positive Control, 1 vial (0.2 mL)  WARNING	- Heat inactivated Human serum / plasma containing antibodies reactive to HIV-1. - Non-reactive for HBsAg and antibody to HCV. - Preserved with 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1 [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 0.5% ProClin 300 (0.015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]
C2. HIV-1 Western Blot High Positive Control, 1 vial (0.2 mL)  WARNING	- Heat inactivated Human serum / plasma containing antibodies reactive to HIV-1. - Non-reactive for HBsAg and antibody to HCV. - Preserved with 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1 [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 0.5% ProClin 300 (0.015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]
R2. Western Blot Specimen Diluent/Wash (5X), 2 bottles (100 mL) Catalog No. 32574  WARNING	- Tris buffered saline solution with milk proteins, Tween 20 [C₁₂H₂₂O₆], CAS# 9005-64-5, EC No 585-580-06-X and dilute (≤ 0.2%) EDTA, disodium salt, dihydrate, CAS# 6381-92-6, EC No 205-358-3 [Not subject to GHS and EU 2008/1272/EC regulatory requirements.] - Preserved with 0.5% ProClin 300 (0.015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]
R3. HIV-1 Western Blot Conjugate, 1 bottle (80 mL)  WARNING	- Anti-human IgG, IgA and IgM (Goat) alkaline phosphatase conjugated solution with protein stabilizers. - Preserved with 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1 [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 0.5% ProClin 300 (0.015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] [EU Classification per 2001/59/EC and 1999/45/EC: Irritant: Xi; R 43; S 24-35-37.]
R4. Western Blot Color Development Reagent, 1 bottle (100 mL) Catalog No. 32573	- 5-bromo-4-chloro-3-indolyl phosphate (BCIP) with ≤ 0.5% nitro blue tetrazolium (NBT) in an organic base/tris buffer with ≤ 5% 1,2,-propanediol, CAS# 57-55-6, EC No 200-338-0 [dilution is not subject to GHS and EU 2008/1272/EC Regulation requirements.]
Disposable Reaction Trays 8 trays	- Disposable, slotted reaction trays. - Lids.

* Replacement component catalog numbers are provided in this column whenever 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)* GHS and related *European Community (EC)* 2008/1272/EC guidelines. The following regulated hazardous chemical concentrations are found in product component(s):

[Components C0, C1, C2, R1, R2, R3] **0.1% ProClin 150** and **0.5% ProClin 300** [0.0015% or 0.015% active ingredients – reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (C₄H₄ClNOS; CAS# 26172-55-4, EC No 247-500-7) and 2-methyl-2H-isothiazol-3-one (C₄H₅NOS; CAS# 2682-20-4, EC No 220-239-6) (3:1)], EC Index No 613-167-00-5 with CAS# 55965-84-9.

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

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

[Component C0, C1, C2, R1, R3] **0.1% Sodium Azide** [NaN₃], 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]:

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

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

The following information is furnished for those 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 (LD₅₀, 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 classification were made according to the latest editions and expanded upon from company and literature data. (Refer to the Key below.)

Chemical Ingredient	Data / Information
Propylene glycol [≤ 5% in R4]	CAS#: 57-55-6 (100%) + EC No: 200-338-0 (100%) + Chemical Formula: C ₃ H ₈ O ₂ (100%) + LD ₅₀ (oral-rat): 20,000 mg/kg (100%) + IATA/DOT ID: NE HMIS Codes: H=1, F=0, R=0 ++ RCRA Code: NE 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. Propylene glycol solutions may cause slight irritation by all routes of entry. The potential for these adverse health effects is unknown for the small volume of Propylene glycol in this product, but is unlikely if handled appropriately with the requisite Good Laboratory Practices. Dispose of this material in accordance with local, regional, national and international regulation. EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - from Annex I to Directive 67/548/EEC: Not Listed

Chemical Ingredient	Data / Information
ProClin 300 [0.5% v/v (0.015% active ingredient) in components C0, C1, C2, R2 and R3]  WARNING <i>2008/1272/EC Table 3.2 Classification on next page</i>	Hazardous ingredient concentration in raw material - According to the supplier, Sigma-Aldrich, the concentrated preservative is a mixture with 3-3.6% Active Ingredients in 3:1 ratio: 5-chlor-2-methyl-4-isothiazolin-3-one (C₄H₄CINOS; CAS# 26172-55-4, EC# 247-500-7) and 2-methyl-4-isothiazolin-3-one (C₄H₅NOS; CAS# 2682-20-4, EC# 220-239-6), Index No. 613-167-00-5 and CAS# 55965-84-9. Also contains 91-94% glycol and .3.5-5% Modified Alkyl Carboxylate (no CAS# or formula given for last two). RTECS#: NE LD₅₀ (oral-rat): 862 mg/kg (100%) + PEL/TLV: NE HMIS Codes: H=2, F=0, R=0 ++ EU Classification per 1999/45/EC and 2001/59/EC: Irritant: Xi, R 43; S 24-35-37 (≤ 0.06% and > 0.0015 % Active Ingredient) ++ GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501 ++ The chemical, physical and toxicological properties have not been thoroughly investigated. At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit). ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317]. Wear protective gloves/protective clothing/eye protection/face protection [P280]. Contaminated work clothing should not be allowed out of the workplace. Avoid breathing mist/vapours/spray. IF ON SKIN: Wash with plenty of soap and water [P302 + P352]. If skin irritation or rash occurs: Get medical advice/ attention [P333 + P313]. The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501].
ProClin 150 [0.1% v/v (0.0015% active ingredient) in R1]  WARNING <i>2008/1272/EC Table 3.2 Classification on next page</i>	Hazardous ingredient concentration in raw material: According to the supplier, Sigma-Aldrich, the concentrated preservative is a mixture of 4 ingredients in 74-77% water (H₂O; CAS# 7732-18-5, EC# 231-791-2): 1.05-1.20% 5-chlor-2-methyl-4-isothiazolin-3-one (C₄H₄CINOS; CAS# 26172-55-4, EC# 247-500-7), 0.3-0.45% 2-methyl-4-isothiazolin-3-one (C₄H₅NOS; CAS# 2682-20-4, EC# 220-239-6), 21-23.5% Magnesium Nitrate (Mg(NO₃); CAS# 10377-60-3, EC# 233-826-7) and 0.5-1.0% Magnesium Chloride (MgCl₂; CAS# 7786-30-3, EC# 232-094-6). Note that the ratio of active ingredients in this preservative (at double the concentration) is listed in 2001/59/EC under Index No. 613-167-00-5 with the CAS# 55965-84-9. RTECS#: NE LD₅₀ (oral-rat): 2,630 mg/kg (100%) + IATA/DOT ID: UN3265 (undiluted, 100%) + HMIS Codes: H=2, F=0, R=0 ++ EU Classification per 1999/45/EC and 2001/59/EC: Irritant: Xi, R 43; S 24-35-37 (≤ 0.06% and > 0.0015 % Active Ingredient) ++ GHS / 2008/1272/EC Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501 ++ The chemical, physical and toxicological properties have not been thoroughly investigated. At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit). ProClin 150 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317]. Wear protective gloves/protective clothing/eye protection/face protection [P280]. Contaminated work clothing should not be allowed out of the workplace. Avoid breathing mist/vapours/spray. IF ON SKIN: Wash with plenty of soap and water [P302 + P352]. If skin irritation or rash occurs: Get medical advice/ attention [P333 + P313]. The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 150 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501].

Chemical Ingredient	Data / Information
ProClin 300 [0.5% v/v in C0, C1, C2, R2 and R3] ProClin 150 [0.1% v/v in R1]  WARNING	EU Labeling Classification for 100% chemical concentration per Table 3.2 of 2008/1272/EC - <i>from Annex I to Directive 67/548/EEC</i> : Toxic: T, Environmental Danger: N R 23/24/25: Toxic by inhalation, in contact with skin and if swallowed. R 34: Causes burns. R 43: May cause sensitisation by skin contact. R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S (2-): Keep out of the reach of children. S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S 28: After contact with skin, wash immediately with plenty of <i>soap and water</i> . S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S 45: In case of accident or if you feel unwell, seek medical advice immediately. S 60: This material and its container must be disposed of as hazardous waste. S 61: Avoid release to the environment. Refer to special instructions/safety data sheets.
Sodium Azide [NaN ₃] [0.1 % w/v in components R1, C0, C1, C2 and R3] WARNING	CAS#: 26628-22-8 (100%) + EC No: 247-852-1 (100%) + Chemical Formula: NaN ₃ (100%) + LD ₅₀ (oral-rat): 27 mg/kg (100%) + PEL/TLV: 0.3 mg/m ³ (ceiling) (100%) + HMIS Codes: H=2, F=0, R=1 ++ 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 ++ RTECS#: VY8050000 (100%) + Flash Point: NE LC ₅₀ (inhalation-rat): 37 mg/m ³ (100%) + IATA/DOT ID: UN1687 (undiluted, 100%) + RCRA Code: P105 (undiluted, 100%) + 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 - <i>from Annex I to Directive 67/548/EEC</i> : 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 <i>soap and water</i> . 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.

Biological Ingredient	Data / Information
NP-40 Inactivated HIV-1 virus	NP-40 Inactivated Human Immunodeficiency Virus, type 1 (HIV-1) virus, though verified to be non-infectious, should be handled as if capable of transmitting infectious disease, with Universal Precautions in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH <i>Biosafety in Microbiological and Biomedical Laboratories</i> or WHO <i>Laboratory Biosafety Manual</i> . Employ aseptic technique for personal protection and to avoid product contamination; use of a Biosafety Cabinet (BSC) may be warranted or desired in certain situations. Avoid splashing, spills and the generation of aerosols. Secure in secondary containment with proper biohazard labeling. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures, with appropriate decon agent/disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg. #1043-87), or equivalent) before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional, national and international regulations. Handle appropriately with the requisite Good Laboratory Practices, <i>Standard</i> and <i>Universal Precautions</i> .
Human Serum [reactive and non-reactive in C0, C1, C2]	The human sera in the components was tested and found non-reactive for HBsAg and antibodies to HCV (Component C0 is also <i>negative</i> for antibodies to HIV1/2). No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Employ <i>Standard</i> and <i>Universal Precautions</i> when handling these reagents and all human blood, specimens or patient samples, which represent an unknown, heightened hazard. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH <i>Biosafety in Microbiological and Biomedical Laboratories</i> or WHO <i>Laboratory Biosafety Manual</i> . 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 during kit use and sample handling. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures, with appropriate decon agent/disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg. #1043-87), or equivalent) before discarding any materials utilized or returning equipment to general use. Dispose of this material in accordance with local, regional, national and international regulations. Handle appropriately with the requisite Good Laboratory Practices, <i>Standard</i> and <i>Universal Precautions</i> . Persons handling blood samples should have the option of receiving hepatitis B vaccination.
Animal proteins, [≤ 10% v/v in component R3]	This material is of animal origin (bovine and goat) 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, <i>Standard</i> and <i>Universal Precautions</i> . Dispose of in accordance with local, regional, national and international regulations.

Key:

- + The kit concentration was not tested; the values refer to the solution concentration as tested, designated by percentage within parentheses.
 - ++ The kit concentration was tested or the values given were estimated for the general diagnostic laboratory usage of the kit reagent dilution.
 - NE: Not Established or Unknown (unable to locate data); typically for concentrate form unless otherwise specified.
- Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity
- GHS - Globally Harmonized System
- RTECS # - Registry of Toxic Effects of Chemical Substances number
- PEL - Permissible Exposure Limit / Occupational Exposure Limit (OEL)
- 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]:
 - **EDTA disodium salt, dihydrate** (C₁₀-H₁₂-N₂-O₈-Na₄•2H₂O), CAS# 6381-92-6, EC No 200-573-9 [≤ 0.2% w/v, in component R2.
 - **Tween 20** (C₅₈H₁₁₄O₂₆) CAS# 9005-64-5, EC No 585-580-06-X [≤ 2.5% v/v in component R2].
 - **5-bromo-4chloro-3indolyl phosphate** (BCIP) with ≤ 0.5% **nitro blue tetrazolium** (NBT) in an organic base/Tris buffer [component R4].

- The miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water, and other chemicals found in the conjugated-antibody solution with protein stabilizers, and Tris buffered saline solution with milk proteins.
- ◆ 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 the 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.
- ◆ Do not eat, drink or smoke when using this product.
- ◆ Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

EMERGENCY FIRST AID MEASURES (4):

Health Effects:	Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Skin contact may result in dermatitis and may cause allergic skin reaction upon repeated exposure. May be 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. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations. Treat symptomatically and supportively.
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 emit toxic oxides of carbon and nitrogen under fire conditions.
Special Firefighting Procedures:	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

ACCIDENTAL RELEASE MEASURES (6):

- ◆ Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.
- ◆ In the event of a hazardous material spill, contain the spill if it is safe to do so and immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.
- ◆ Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA 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.).
- ♦ 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 is secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all local, regional, national and international regulations. 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.
- ♦ 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. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all human source specimens, materials, and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per Standard and Universal Precautions. All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics. Avoid release to the environment. Do not allow undiluted product hazardous chemical ingredient or large quantities of it to reach ground water or water course. Consult with your Environmental Health & Safety Office for assistance.

Storage: Store according to product and label instructions (generally at 2-8°C).

Caution, consult accompanying documents. Read and follow all the precautions and warnings in the kit product instructions. Refer to the 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)	Short-term value: C 0.3** mg/m ³ , C 0.1* ppm	*as HN ₃ vapor; **as NaN ₃ ; Skin
TLV (United States)	Short-term value: C 0.29** mg/m ³ , C 0.11* ppm	*as HN ₃ vapor **as NaN ₃
EL (Canada (LSG) English)	Short-term value: C 0,29* mg/m ³ , C 0,11**ppm	*sodium azide;**hydrazoic acid vapour
IOELV (European Union)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	Skin Skin
WEL (United Kingdom)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	(as NaN ₃) Sk (as NaN ₃) Sk
NES (AUS)	0.3* mg/m ³ , 0.11 ppm	*Peak limitation
VME (France)	Short-term value: 0,3 mg/m ³ , 0,1 ppm	risque de pénétration percutanée
VL (Belgium, (French)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	D, M D, M
AGW (Germany)	0,2 mg/m ³	2(I);DFG
MAK (Austria, (German))	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	
TWA (Italy)	Short-term value: C 0,29 mg/m ³ , C 0,11* ppm	A4; sodio azide; *come azido idrazonico, vapore
MAK (Switzerland, (German))	Short-term value: 0,4 e mg/m ³ Long-term value: 0,2 e mg/m ³	

Sodium Azide [CAS# 26628-22-8]:		
GV (Denmark)	0,1 mg/m ³	EH
MAK (Netherland)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	
OEL (Sweden)	Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³	H H

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

Ventilation:	Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material/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 / vapours / spray.
Other:	All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal. Protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent pads used to cover equipment and/or surfaces must be removed and replaced if they become overtly contaminated.
Note:	Occupational exposure limit values and health hazard data were given in Section 3. Environmental controls are included in following sections.

PHYSICAL AND CHEMICAL CHARACTERISTICS (9):

Appearance:	Variable, generally aqueous liquids. Exceptions are the solid Western Blot Strips and disposable reaction trays.		
pH:	The liquid chemical components are between pH 5 and 9.		
Boiling Point:	Not Established.	Melting Point:	Not Established.
Flash Point:	Not Applicable.		
Fire Hazard:	Although the components have not been tested for fire hazard and explosion data, being water-based, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.		
Auto Igniting:	Product is not known to be self-igniting.		
Danger of Explosion:	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.		
Relative Density:	Not Established.		
Solubility:	The liquid chemical components are soluble in water.		

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:	Stable under ordinary conditions of use and storage.
Conditions and/or Materials to Avoid:	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.
Hazardous Decomposition Products:	May emit toxic oxides of carbon and nitrogen under fire conditions.
Hazardous Polymerization:	Has not been reported to occur.

TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):

Refer to Sections 2 and 3 for the kit component concentrations. The composite toxicological information for this product is:

Acute Health Effects

- Toxicity: May be harmful in contact with skin. May be harmful if swallowed.
- Primary Irritant Effect: May slightly irritate eyes or skin, depending on amount and contact time.
- Serious Eye Damage / Irritation: May slightly irritate eyes or skin, depending on amount and contact time.
- STOT-Single Exposure: Data is not available.
- STOT-Repeated Exposure: Data is not available.
- Aspiration Hazard: Data is not available.
- Other Acute Health Effects: No other significant health effect is known.

Biohazard Potential

Inactivated HIV virus, though verified to be non-infectious, should be handled with *Standard* and *Universal Precautions*, as if capable of transmitting infectious disease. The human sera in the components was tested and found non-reactive for HBsAg and antibodies to HCV (Component C0 is also negative for antibodies to HIV 1/2). 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: Contains a small volume of a very dilute, sensitizing preservative (**ProClin 300** and **ProClin 150**); though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
- Carcinogenicity: No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC or OSHA.
- Germ Cell Mutagenicity: Data is not available.
- Reproductive Hazard: No reproductive toxic effect known.

Additional Toxicological Information: To the best of our knowledge, the chemical, physical and toxicological properties have NOT been thoroughly investigated for some of the component chemicals and/or mixtures.

ECOLOGICAL INFORMATION (12):

This product was not tested. The following assessment is based on information for the ingredients.

Toxicity:

100% Sodium Azide [CAS# 26628-22-8] *:

Fish LC₅₀ - *Lepomis macrochirus* - 0.68 mg/l - 96 h

Daphnia EC₅₀ - *Daphnia pulex* (Water flea) - 4.2 mg/l - 48 h

**Source: Raw Material Vendor Safety Data Sheet*

Persistence and degradability:

No information found.

Bioaccumulation potential:

No information found.

Mobility in soil:

No information found.

PBT and vPvB assessment:

No information found.

Other adverse affects:

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:

- **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; check your applicable ordinances accordingly.
- 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.

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

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

TRANSPORT INFORMATION (14):

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

Recommended Unused Product Multi-Modal Transportation: No known transport restrictions.

REGULATORY INFORMATION (15):

Composite HMIS Rating:

Health: 2

Flammability: 0

Reactivity: 1

California Proposition 65:

The product does not contain listed substances.

Carcinogenicity Categories:

genicity Categories: No component, mixture or constituent has been classified as a carcinogen by NTP (National Toxicity Program), IARC (International Agency for Research on Cancer), TLV-CAR (Threshold Limit Value established by ACGIH) or OSHA (Occupational Health and Safety Administration).

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.

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: HARMFUL: Xn; IRRITANT: Xi

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

0.5% ProClin 300 and 0.1% ProClin 150, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9 [Irritant: Xi; R 43; S 24-35-37 ($\leq 0.06\%$ and $> 0.0015\%$ Active Ingredient)].

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

OTHER INFORMATION (16):

Risk Phrases:

- | | |
|---------|---|
| R 22 | Harmful if swallowed. |
| R 43 | May cause sensitization by skin contact. |
| Caution | Contains human source material. Handle as if capable of transmitting potentially infectious agents (<i>Standard and Universal Precautions</i>). |

Safety Phrases:

- | | |
|------|--|
| S 24 | Avoid contact with skin. |
| S 35 | This material and its container must be disposed of in a safe way. |
| S 37 | Wear suitable protective gloves. |

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
EC₅₀ – 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
LC₅₀ – median lethal concentration, 50%
LD₅₀ – 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..

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