

SAFETY DATA SHEET (SDS)**SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER**





Product Name:	Multispot HIV-1/HIV-2 Rapid Test
Product Number:	25228 (50 tests).
Intended Use:	The Multispot HIV-1/HIV-2 rapid test is a single use qualitative immunoassay to detect and differentiate circulating antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1, HIV-2) in fresh or frozen human serum and plasma. This rapid HIV-1/HIV-2 test kit is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in fresh or frozen human serum or plasma. This test is suitable for use in multi-test algorithms designed for statistical validation of an HIV test screening result or as a part of an HIV-1/HIV-2 diagnostic test algorithm that includes differentiation of HIV-1 and HIV-2 antibodies.
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, available 24 hours a day, 7 days a week. In the United States of America and Puerto Rico, 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. <i>Refer to section 16 for non-US local Bio-Rad agent contact information.</i>
Emergency Phone Number:	This SDS is listed with CHEMTREC 1-800-424-9300 (US) / 001-703-527-3887 (international – can be called collect). Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

SECTION 2: HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS

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. The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Refer to Section 16 for the full text of any solely abbreviated or coded hazard statements provided below and for the Key / legend to abbreviations and acronyms.

Component	Contents
1. Multispot HIV-1/HIV-2 Cartridge (50)	- Foil-sealed base container with specimen prefilter; Membrane with 1 Procedural Control Spot (anti-human IgG (goat)) and 3 Test Spots (HIV-1 recombinant (rDNA), HIV-1 peptide and HIV-2 peptide).
2. Positive Control Serum, 1 dropper bottle (1 mL)	- Heat-inactivated human serum/plasma containing anti-HIV-1 and anti-HIV-2 immunoglobulin; non-reactive for detectable HBsAg and antibody to HCV. - Preserved with 0.5% ProClin 300 (0.015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] - Preserved with 0.1% sodium azide [NaN ₃], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration.



<p>3. Negative Control Serum, 1 dropper bottle (1 mL)</p>  <p>WARNING</p> <p><i>Catalog No. 26166</i></p>	<ul style="list-style-type: none"> - Normal human serum; nonreactive for detectable HBsAg and antibodies to HIV-1 and HIV-2 and HCV. - Preserved with 0.5% ProClin 300 (0.015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9 [GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] - Preserved with 0.1% sodium azide [NaN₃], CAS# 26628-22-8 and EC No 247-852-1. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements without Cat 5 Acute Toxic designations in this product mixture and concentration.
<p>4. Specimen Diluent, 1 dropper bottle (25 mL)</p>  <p>WARNING</p>	<ul style="list-style-type: none"> - Diluent for specimens and controls, containing protein [goat] stabilized buffer solution with ≤ 1% Tween 20 [C₅₈H₁₁₄O₂₆], CAS# 9005-64-5, EC No 585-580-06-X. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with 0.1% ProClin 150 and 0.125% ProClin 300 (≤ 0.005% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9. GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.]
<p>5. Conjugate, 1 dropper bottle (9.5 mL)</p>  <p>WARNING</p>	<ul style="list-style-type: none"> - Anti-human IgG (H+L) (goat) alkaline phosphatase conjugated solution in a protein [goat] stabilized buffer solution. - ≤ 50% Glycerol [C₃H₈O₃], CAS# 56-81-5, EC No 200-289-5. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with ≤ 0.125% ProClin 150 (≤ 0.0015% active ingredient), EC Index No 613-167-00-5 with CAS# 55965-84-9. GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.]
<p>6. Wash Solution, 2 dropper bottles (85 mL each)</p>  <p>WARNING</p>	<ul style="list-style-type: none"> - Tris buffered saline solution with diluted ≤ 10% Urea [CH₄N₂O], CAS# 57-13-6, EC No 200-315-5. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Contains 26% 1,2,-propanediol [propylene glycol – C₃H₈O₂]; CAS# 57-55-6, EC No 200-338-0. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with ≤ 0.1% ProClin 150 (≤ 0.0015% active ingredient), per 2001/59/ EC Index No 613-167-00-5 with CAS# 55965-84-9. GHS \ US HCS \ EC CLP Classification: WARNING; GHS07; H317; P280; P302 + P352, P333 + P313; P501.] - Contains < 0.001% nitro blue tetrazolium [NBT- C₄₀H₃₀N₁₀O₆Cl₂], CAS# 298-83-9, EC No 206-067-4. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
<p>7. Development Reagent, 1 dropper bottle (8.5 mL)</p>	<ul style="list-style-type: none"> - ≤ 0.5% 3-Indoxyl phosphate in a < 10% AMP Buffer [CAS# 124-68-5, EC No 204-709-8] solution with a pH ~ 10. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
<p>8. Stop Solution, 1 dropper bottle (55 mL)</p>	<ul style="list-style-type: none"> - 0.1N Sulfuric Acid (≤ 0.48% H₂SO₄), CAS# 7664-93-9, EC No 231-639-5 (pH ≤ 2, Clear Liquid). Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
<p>9. Disposable Transfer Pipets (60)</p>	<ul style="list-style-type: none"> - Polyethylene transfer pipets. - No known hazardous chemical ingredients.
<p>10. Eyedropper (1)</p>	<ul style="list-style-type: none"> - Polyethylene eyedropper and cap with rubber bulb. <i>Note: The dropper bulb used in this bottle (supplied separately in the kit, but then placed in the Specimen Diluent bottle for kit use) contains Dry Natural Rubber, a potential sensitizer.</i>

Replacement Component Catalog Numbers are provided in this column where available.

Markings according to the United Nations (UN) Globally Harmonized System (GHS), United States Hazard Communication Standard (HCS) and European Community (EC) 2008/1272/EC guidelines and analogous GHS-based global regulations: This product has been conservatively classified and labeled in accordance with applicable *United Nations (UN) GHS*, *United States Hazard Communication Standard (US HCS)* and related *European Community (EC) 2008/1272/EC (EC CLP)* guidelines and applicable analogous GHS-based global regulations. The following regulated hazardous chemical concentrations are found in product component(s):

Component 2, 3, 4, 5, 6 - 0.1% ProClin 150 or ≤ 0.5% ProClin 300 [0.0015% or 0.0075% 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.

Comprehensive GHS Based Classification: Skin Sensitizer Category 1



Label(s):

Signal Word:

WARNING

Label Hazard Statements:

H317 May cause an allergic skin reaction.

Precautionary Statements (statements for product intended use and as codified on the product label):

P280 Wear protective gloves / protective clothing / eye protection / face protection.
 P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
 P501 Dispose of contents and container in accordance to local, regional, national and international regulations.

Supplemental Precautionary Statements (additional precautions to consider relative to specific customer use):

P261 Avoid breathing mist / vapors/vapours / spray.
 P272 Contaminated work clothing should not be allowed out of the workplace.

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

NOTE: 0.1% Sodium Azide concentration falls under the UN GHS Cat 5 Acute Toxic which is not recognized in much of the world. [Acute toxic Cat. 5 rating would be: Warning; H303, H313; P312]

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

The following information is furnished for those hazardous constituents in the product 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.) Chemical constituents that do not require regulatory disclosure are not generally included here. This product contains a significantly diluted concentration in an aqueous solution, thus the assessment below has not considered the dilution reduction effect on the hazard. That hazard communication information is provided in Section 2 above. Some components were tested at the concentration found in the kit. In that case, the assessment is provided for the chemical dilution tested and the tested concentration will be provided at the beginning of the *Chemical Ingredient Data/Information* box. The UN GHS, US HCS, EC CLP and analogous GHS-based global regulation classifications were made according to the existing editions and expanded upon from company and literature data. Refer to section 16 for the full text of any *Comprehensive GHS-based Classification* statements coded below, for the list of sources utilized in the assessment and for the Key / legend to abbreviations and acronyms.

Chemical Ingredient Data / Information

Chemical Ingredient: Glycerol

Chemical concentrations found in this product: **≤ 50% in component 5 (aqueous solution)**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 56-81-5 (100%)	LD ₅₀ (oral-rat): 12,600 mg/kg (100%)
EC No: 200-289-5 (100%)	LC ₅₀ (inhalation-rat): > 570 mg/m ³ /1H (100%)
RTECS#: MA8050000 (100%)	LD ₅₀ (skin-rabbit): > 10000 mg/kg (100%)
Index No: NA (100%)	LC ₅₀ (96 hr-fish): NE (100%)
Chemical Formula: C ₃ H ₈ O ₃ (100%)	Flash Point: 320 F / 160° C (100%)
Molecular weight: 92.09 g/mol (100%)	Flammable limits: LEL/LFL is <u>0.9%</u> vv in air.
Synonyms/Trade Names: 1,2,3-Propanetriol; 1,2,3-Trihydroxypropane; 90 Technical glycerine; Citifluor AF 2; lyzerin, wasserfrei, Glycerin; Glycerin mist; Glycerin anhydrous; Glycerin, synthetic; Glycerine; Glyceritol; Glycyl alcohol; Grocolene; MOON; Osmoglyn; Star; Synthetic glycerin; Trihydroxypropane	

Raw Material GHS / US HCS / EC CLP Classification (100%): Not a dangerous substance according to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements.

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Chemical Ingredient: Propylene glycol

Chemical concentrations found in this product: **26% w/v in component 6**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 57-55-6 (100%)	LD ₅₀ (oral-rat): 20,000 mg/kg (100%)
EC No: 200-338-0 (100%)	LC ₅₀ (inhalation-rat): NE
RTECS#: TY2000000 (100%)	LD ₅₀ (skin-rabbit): 20,800 mg/kg (100%)
Index No: NE	LC ₅₀ (96 hr-fish): NE (100%)
Chemical Formula: C ₃ H ₈ O ₂ (100%)	Flash Point: 217°F / 103°C (100%)
Molecular weight: 76.09 g/mol (100%)	Flammable limits: LEL/LFL is <u>2.6%</u> ; UEL/UFL is <u>12.5%</u> vv in air.
Synonyms/Trade Names: 1,2,-Propanediol	

Raw Material GHS / US HCS / EC CLP Classification (100%): Not a dangerous substance according to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements.

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Chemical Ingredient: AMP Buffer [2-amino-2-methyl-propanol]

Chemical concentrations found in this product: **≤ 10% in component 7**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 124-68-5 (100%)	LD ₅₀ (oral-rat): 2900 mg/kg (100%)
EC No: 204-709-8 (100%)	LC ₅₀ (inhalation-rat): NE
RTECS#: UA5950000 (100%)	LD ₅₀ (skin-rabbit): >2000 mg/kg (100%)
Index No: 603-070-00-6 (100%)	LC ₅₀ (96 hr-fish): >100 mg/L (100%)
Chemical Formula: C ₄ H ₁₁ NO (100%)	Flash Point: 154.4°F / 68°C (100%)
Molecular weight: 89.14 g/mol (100%)	pH value ~ 11-12 (8.9g/L) at 25 °C (77 °F) (100%)
Synonyms/Trade Names: 2-amino-2-methyl-propanol	
Skin corrosion/irritation: Skin - rabbit - Draize Test - Irritating to skin (100%)	
Serious eye damage/eye irritation: Eyes - rabbit - Corrosive to eyes - Draize Test (100%)	
Respiratory or skin sensitization: Buehler Test - guinea pig - Did not cause sensitisation on laboratory animals (100%)	

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER

Acute Tox. – oral. Cat. 5, Acute Tox. – skn. Cat. 5, Skin Irrit. Cat. 2, Eye damage Cat. 1, Aquatic Acute Cat. 3
 Aquatic Chronic Cat. 3,

H303 + H313, H315, H318, H412
 P273, P280, P305 + P351 + P338, P501



[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Chemical Ingredient Data / Information

Chemical Ingredient: Urea

Chemical concentrations found in this product: **≤ 10% w/v in Component 6**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 57-13-6 (100%)	LD ₅₀ (oral-rat): 8471 mg/kg (100%)
EC No: 200-315-5 (100%)	LC ₅₀ (inhalation-rat): No data available (100%)
RTECS#: YR6250000 (100%)	LD ₅₀ (skin-rabbit): No data available mg/kg (100%)
Index No: NA (100%)	LC ₅₀ (96 hr-fish): Poecilia reticulata (guppy) - 17500 mg/l (100%)
Chemical Formula: CH ₄ N ₂ O (100%) +	Flash Point: NE +
Molecular weight: 60.06 g/mol (100%)	
Synonyms/Trade Names: Carbamide, Carbonyldiamide	

Raw Material GHS / US HCS / EC CLP Classification (100%): Not a dangerous substance according to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements.

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Chemical Ingredient: ProClin 300

Chemical concentrations found in this product: **0.5% v/v (0.015% active ingredient) in Components 2 and 3**
≤ 0.125% in Component 4

Hazardous ingredient concentration in raw material:

60-100% Glycols;

1-5% Mixture (3:1) of 5-Chloro-2-methyl-4-isothiazolin-3-one (C₄H₅NOS; CAS# 2682-20-4, EC# 220-239-6)
and **2-Methyl-2H -isothiazol-3-one** (C₄H₄CINOS; CAS# 26172-55-4, EC# 247-500-7)
CAS#: 55965-84-9
Index No: 613-167-00-5

Data for chemical used in the product (concentration tested):

RTECS#: NE
Synonyms/Trade Names: **Synonyms/Trade Names:** 5-Chloro-2-methyl-4-isothiazolin-3-one solution; Kathon 300; Isothiazolinone chloride solution
pH value: 4.1 at 100 g/L (concentrated solution)
Flash Point: 244° F / 118° C (concentrated solution)
LD₅₀ (oral-rat): 862 mg/kg (concentrated solution)
LD₅₀ (skin-rabbit): 2,800 mg/kg (concentrated solution)
LC₅₀ (inhalation-rat): NE
LD₅₀ (skin-rabbit): NE
Skin corrosion/irritation - rabbit – Corrosive (concentrated solution)
Serious eye damage/eye irritation - rabbit - Corrosive to eyes (concentrated solution)
Respiratory or skin sensitization - May cause allergic skin reaction (concentrated solution)

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER!

Acute Tox. – oral Cat. 4, Skin Corr. Cat. 1B, Eye Damage.1, Skin. Sens. Cat.1, Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1
H302,, H314, H317, H410
P261, P264, P270, P272, P273, P280, P301 + P312 + P330, P301 + P330 + P331,
P303 + P361 + P353, P305 + P351 + P338 + P310, P333 + P313, P363, P391, P405, P501



[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Chemical Ingredient Data / Information

Chemical Ingredient: Sulfuric acid

Chemical concentrations found in this product: **0.1 N (< 0.5% (w/w) H₂SO₄ in water) in Component 8**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 7664-93-9 (Conc. sulfuric acid 100%) LD₅₀ (oral-rat): 2,140 mg/kg (100%)
 EC No: 231-639-5 (100%) LC₅₀ (inhalation-rat): 510 mg/m³/2H (100%)
 Index No: 016-020-00-8 (100%) LD₅₀ (skin-rabbit): NE (100%)
 Registration No: 01-2119458838-20-XXXX LC₅₀ (96 hr-fish): Gambusia affinis (Mosquito fish) – 42 mg/l (100%)
 RTECS#: WS5600000 (100%) pH value: 1.2 at 5 g/L
 Skin corrosion/irritation: Skin - rabbit - Extremely corrosive and destructive to tissue.
 Serious eye damage/eye irritation: Eyes - rabbit - Severe eye irritation
 Chemical Formula: H₂SO₄ (100%)
 Molecular weight: 98.08 g/mol (100%)
 Synonyms/Trade Names: Acide sulfurique ; Acido solforico; BOV; Battery acid; Dihydrogen sulfate; Dipping acid; Electrolyte acid; Mattling acid; Oil of vitriol; Schwefelsaeureloesungen; Strong inorganic acid mists containing sulfuric acid; Sulfuric acid; Sulfuric acid, aerosol; Sulphuric acid; Vitriol Brown Oil; Zwavelzuuroplossingen

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER!

Skin Corr. Cat. 1A, Eye Damage Cat. 1, Aquatic Acute Cat. 3, Aquatic Chronic Cat. 3
 H314, H412



P264, P273, P280, P301 + P330 + P331, P303 + P361 + P353, P304 + P340, P305 + P351 + P338, P310, P363, P405, P501

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Chemical Ingredient: ProClin 150

Chemical concentrations found in this product: **0.1% v/v (0.0015% active ingredient) in Components 4, 5 and 6**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

Hazardous ingredient concentration in raw material (in water):

10-30% Magnesium nitrate MgCl₂; CAS# 7786-30-3, EC No: 232-094-6

Classification: Ox. Sol. 3; Skin Irrit. 2; Eye Irrit. 2; STOT SE 3; H272, H315, H319, H335

1-5% Mixture (3:1) of 5-Chloro-2-methyl-4-isothiazolin-3-one (C₄H₅NOS; CAS# 2682-20-4, EC# 220-239-6)

and **2-Methyl-2H -isothiazol-3-one** (C₄H₄CINOS; CAS# 26172-55-4, EC# 247-500-7), CAS#: 55965-84-9, Index No: 613-167-00-5

Classification: Acute Tox. 3; Skin Corr. 1B; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1; H301 + H311 + H331, H314, H317, H410

RTECS#: NE

Synonyms/Trade Names: 5-Chloro-2-methyl-4-isothiazolin-3-one solution; Kathon 150; Isothiazolinone chloride solution

Flash Point: NE

LD₅₀ (oral-rat-female): 2630 mg/kg (concentrated solution)

LD₅₀ (oral-rat-male): 3350 mg/kg (concentrated solution)

LC₅₀ (inhalation-rat): NE

LD₅₀ (skin-rabbit): NE

Skin corrosion/irritation - rabbit – Corrosive (concentrated solution)

Serious eye damage/eye irritation - rabbit - Corrosive to eyes (concentrated solution)

Respiratory or skin sensitization - guinea pig - May cause sensitisation by skin contact (concentrated solution)

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER!

Acute Tox. – oral Cat. 4, Skin Corr. Cat. 1B,

Eye Damage Cat. 1, Skin. Sens. Cat. 1, Aquatic Acute Cat. 2, Aquatic Chronic Cat. 1

H302, H314, H317, H410

P220, P261, P264, P270, P272, P273, P280, P301 + P312 + P330, P301 + P330 + P331,

P303 + P361 + P353, P305 + P351 + P338, P310, P333 + P313, P363, P391, P405, P501

[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]



Chemical Ingredient Data / Information

Chemical Ingredient: Sodium azide

Chemical concentrations found in this product: **0.1 % w/v in Components 2 and 3**

Data for Concentrated / 100% chemical used in the product mixture (concentration tested):

CAS#: 26628-22-8 (100%)	LD ₅₀ (oral-rat): 27 mg/kg (100%)
EC No: 247-852-1 (100%)	LC ₅₀ (inhalation-rat): 37 mg/m ³ (100%)
Index No: 011-004-00-7 (100%)	LD ₅₀ (skin-rat): 50 mg/kg (100%)
RTECS#: VY8050000 (100%)	Fish LC ₅₀ – Lepomis macrochirus (Bluegill) – 0.68 mg/l – 96 h (100%)
Chemical Formula: NaN ₃ (100%)	
Molecular weight: 65.01g/mol (100%)	
Synonyms/Trade Names: Azide, sodium; Azoture de sodium; Azydek sodu; NSC 3072; Kazoe; Natriumazid; Natriumazide; NCI-C06462; Nemazyd; Sodium azide; Sodium, azoture de; Sodium, azoturo di, Smitte; U-3886;	

Raw Material GHS / US HCS / EC CLP Classification (100%):

DANGER!



Acute Tox. – oral. Cat. 2, Acute Tox. – skn. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1

H300 + H310, H410

P264, P273, P280, P302 + P350, P310, P501



[Source: Raw Material vendor SDS, CCOHS databases and regulatory research]

Biological Ingredient	Data / Information
Procedural Control	Spot 1: Anti-human IgG (goat).
3 (three) Test Spots 	Spot 2: HIV-2 peptide representing the immunodominant epitope of the HIV-2 virus gp36 envelope glycoprotein. Spot 3: HIV-1 recombinant gp41 (HIV-1 envelope glycoprotein) expressed in E. coli. Spot 4: HIV-1 peptide representing the immunodominant epitope of the HIV-1 virus gp41 envelope glycoprotein.
Animal proteins, [Components 4 and 5]	This material is of animal origin (goat and bovine) 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 and Universal Precautions</i> . Dispose of this material in accordance with local, regional, national and international regulations.
Human Serum [Reactive and Non-reactive in the Positive (2) and Negative Control (3) Components] 	The positive control (2) was heat-treated to inactivate the HIV. Human sera in reagents were tested and found non-reactive for hepatitis B surface antigen and antibodies to HCV (the negative control (3) is also non-reactive for antibodies to HIV-1/HIV-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 and 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. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures, with appropriate decon agent or disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% dil 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, <i>Standard and Universal Precautions</i> . Persons handling blood samples should have the option of receiving hepatitis B vaccination.

NA: Not applicable.

NE: Not Established or Unknown (unable to locate data); typically for concentrate form unless otherwise specified.

Related product information:

- ◆ Refer to Section 16 for the full text of any *Comprehensive GHS-based Classification* statements coded above.
- ◆ Refer to Section 16 for the list of sources utilized in the assessment and the Key / legend to abbreviations and acronyms.
- ◆ No significant adverse health effects are expected by any route for the following chemical constituents in the kit volumes and concentrations present [chemical or dilution is not subject to GHS, US HCS, EC CLP or other GHS-based hazard labeling]:
 - **Tween® 20** [C₃₈H₁₁₄O₂₆], CAS# 9005-64-5, EC No 585-580-06-X, ≤ 1% w/v in component 4.

- Nitro blue tetrazolium (NBT – $C_{40}H_{30}N_{10}O_6Cl_2$), CAS# 298-83-9, EC No 206-067-4, $\leq 0.001\%$ w/v in component 6.
- 3-Indoxyl phosphate [$C_8H_8NO_4P \cdot 2(C_4H_{11}NO_2)$], CAS# 107475-12-7 $\leq 0.5\%$ v/v in component 7.
- The miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water and other nonreactive ingredients

- ◆ **The dropper bulb used in this bottle (supplied separately in the kit, but then placed in the Specimen Diluent bottle for kit use) contains Dry Natural Rubber, a potential sensitizer.**
- ◆ 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 infectious agents. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.
- ◆ Do not eat, drink or smoke when using this product.
- ◆ Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

SECTION 4: EMERGENCY FIRST AID MEASURES

Health Effects:	Symptoms of overexposure may include headache and congestion. May cause an allergic skin reaction upon repeated exposure, generally at concentrations and volumes that greatly exceed that of this kit.
Eye Contact:	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
Skin Contact:	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs, or if more severe symptoms develop, consult a physician.
Inhalation:	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
If Swallowed:	If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
Notes to Physician	According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered hepatitis B vaccination prior to working with human source material.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media:	Use extinguishing media appropriate for the surrounding fire.
Hazardous Combustion Products:	May release toxic oxides of carbon, nitrogen and sulfur.
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.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- ◆ 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 appropriate spill cleanup materials and PPE are available and used.
- ◆ Prevent material from entering sewers, waterways or confined spaces.

- ◆ Follow established laboratory policy, OSHA/WISHA hazardous material spill and/or CDC/NIH biosafety guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup. Avoid release to the environment.
- ◆ Wear appropriate PPE. Immediately, and on-site if possible:
 - Decontaminate **biohazard/human source material** spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon agent or disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% ethanol or isopropanol, an iodophor (such as Wescodyne Plus) or a phenolic, etc.).
 - Neutralize corrosive **acidic** spills with the appropriate *acid neutralization / adsorbent* product.
 - Neutralize corrosive **alkaline** spills with the appropriate *base neutralization / adsorbent* product.
- ◆ Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows, absorbent pads, etc.), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all local, regional, national and international regulations.
- ◆ Refer to Sections 8 and 13 for more specifics.

SECTION 7: HANDLING AND STORAGE INFORMATION

Handling:	<p>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.</p> <p>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 and eye/face protection.</p> <p>Keep containers tightly closed; avoid splashing, spills and the generation of aerosols.</p> <p>Handle all human source specimens, materials and equipment used to perform the test as though they were capable of transmitting infectious disease, as per <i>Standard and Universal Precautions</i>.</p> <p>All personal protective equipment should be removed before leaving the work area. Refer to Section 8 for more specifics.</p> <p>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.</p> <p>Consult with your Environmental Health & Safety Office for assistance.</p>
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.	
For <i>in vitro</i> diagnostic use.	

SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES

Control Parameters – Component chemicals with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

100% Glycerol [CAS# 56-81-5] - OEL:			
BELGIUM:	TWA	10 mg/m ³	MAR2002
FINLAND:	TWA	20 mg/m ³	NOV2011
FRANCE:	VME	10 mg/m ³	FEB2006
GERMANY:	MAK	50 mg/m ³ , inhal	2011
ITALY:	TWA	10 mg/m ³	
KOREA:	TWA	10 mg/m ³ (mist)	2006
MEXICO:	TWA	10 mg/m ³ (inhalable)	2004
THE NETHERLANDS:	MAC-TGG	10 mg/m ³	2003
NEW ZEALAND:	TWA	10 mg/m ³ (mist)	JAN2002
PERU:	TWA	10 mg/m ³	JUL2005

100% Glycerol [CAS# 56-81-5] - OEL:			
SWITZERLAND:	MAK-W KZG-W	50 mg/m ³ 100 mg/m ³ , inhal	JAN2011
UNITED KINGDOM:	TWA	10 mg/m ³	OCT2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV [Professionally Translated 1-2016]	
UNITED STATES:	TLV-TWA PEL-T-TWA	10* ppm (*total mist) 15* 5** mg/m ³ (*total dust **respirable fraction) Remarks: Upper Respiratory Tract irritation	ACGIH Threshold Limit Values (TLV) OSHA 29,1910.1000 Z-1, 1989
<i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i>			

100% Sodium Azide [CAS# 26628-22-8] - OEL:			
AUSTRALIA:	CL	0.11 ppm (0.3 mg/m ³)	JUL2008
AUSTRIA:	MAK-TMW KZW	0.1 mg/m ³ 0.3 mg/m ³ , skin	2007
BELGIUM:	TWA STEL	0.1 mg/m ³ , 0.3 mg/m ³ , skin	MAR2002
DENMARK:	TWA	0.1 mg/m ³ , skin	MAY2011
EC (European Union):	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	JUN2000
FINLAND:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	NOV2011
FRANCE:	VME VLE	0.1 mg/m ³ 0.3 mg/m ³ , Skin	FEB2006
GERMANY:	MAK	0.2 mg/m ³ , inhal	2011
HUNGARY:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³	SEP2000
ICELAND:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	NOV2011
ITALY	TWA	<i>Valore a breve termine: C 0,29 mg/m³, C 0,11* ppm A4; sodio azide; *come azido idrazonico, vapore</i>	
KOREA:	CL	0.1 ppm (0.3 mg/m ³)	2006
THE NETHERLANDS:	MAC-TGG	0.1 mg/m ³ , skin	2003
NEW ZEALAND:	CL	0.11 ppm (0.29 mg/m ³)	JAN2002
PERU:	TWA STEL	0.1 mg/m ³ 0.29 mg/m ³	JUL2005
SWEDEN:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , Skin	JUN2005
SWITZERLAND:	MAK-W KZG-W	0.2 mg/m ³ 0.4 mg/m ³ , inhal	JAN2011
UNITED KINGDOM:	TWA STEL	0.1 mg/m ³ 0.3 mg/m ³ , skin	OCT2007
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES:	TLV-TWA-Ceiling REL-Ceiling	0.11* ppm / 0.29** mg/m ³ 0.1* ppm / 0.3** mg/m ³	ACGIH, 1996, 2013 NIOSH Recommended Exposure Limits *as HN ₃ vapor; **as NaN ₃ ; Skin
<i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i>			

Concentrated Active Ingredient ratio in ProClin 150 and ProClin 300 [CAS# 55965-84-9] - OEL:			
GERMANY:	MAK	0.2 mg/m ³ , inhal	2011
THE NETHERLANDS:	MAC-TGG	0.2 mg/m ³	2003

Concentrated Active Ingredient ratio in ProClin 150 and ProClin 300 [CAS# 55965-84-9] - OEL:			
SWITZERLAND:	MAK-W KZG-W	0.2 mg/m ³ [Professionally Translated 1-2016] 0.4 mg/m ³ , inhal, sen	JAN2011
<i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i>			
Concentrated Sulfuric acid [CAS# 7664-93-9] - OEL:			
ARAB Republic of Egypt:	TWA	1 mg/m ³	JAN1993
AUSTRALIA:	TWA STEL	1 mg/m ³ 3 mg/m ³	JUL2008
AUSTRIA:	MAK-TMW KZW	1 mg/m ³ 2 mg/m ³ , inhal	2007
BELGIUM:	TWA STEL	1 mg/m ³ 3 mg/m ³	MAR2002
DENMARK:	TWA	1 mg/m ³	MAY2011
FINLAND:	TWA	0.05 mg/m ³ 0.1 mg/m ³	NOV2011
FRANCE:	VME VLE	1 mg/m ³ 3 mg/m ³	FEB2006
GERMANY:	MAK	0.1 mg/m ³ , inhal	2011
HUNGARY:	TWA STEL	1 mg/m ³ 1 mg/m ³	SEP2000
ICELAND:	TWA	1 mg/m ³	NOV2011
JAPAN:	CL	1 mg/m ³	MAY2012
KOREA:	TWA	1 mg/m ³	2006
MEXICO:	TWA	1 mg/m ³	2004
THE NETHERLANDS:	MAC-TGG	1 mg/m ³	2003
NEW ZEALAND:	TWA	1 mg/m ³	JAN2002
NORWAY:	TWA	1 mg/m ³	JAN1999
PERU:	TWA STEL	1 mg/m ³ 3 mg/m ³	JUL2005
POLAND:	MAC(TWA) MAC(STEL)	1 mg/m ³ 3 mg/m ³	JAN1999
RUSSIA:	STEL	1 mg/m ³ , skin	JUN2003
SWEDEN:	TWA STEL	1 mg/m ³ 3 mg/m ³	JUN2005
SWITZERLAND:	CL	0.1 mg/m ³ , inhal	JAN2011
TURKEY:	TWA	1 mg/m ³	JAN1993
THAILAND:	TWA	1 mg/m ³	JAN1993
ARGENTINA, BULGARIA, COLOMBIA, JORDAN, SINGAPORE, VIETNAM		check ACGIH TLV	
UNITED STATES:	TLV-TWA PEL-T-TWA STEL-T-TWA REL IDLH	0.2 mg/m ³ (thoracic fraction) 1 mg/m ³ 3 mg/m ³ 1 mg/m ³ 15 mg/m ³	[ACGIH, 2004] [OSHA 29,1910.1000 Z-1, 1993] [NIOSH 2007]
<p>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.</p>			
<i>[Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet]</i>			

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 mist / vapors/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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Variable, generally aqueous liquids. Exceptions are the solid cartridges and transfer pipets.		
Odor/odour:	No applicable information was found.	Odor/odour threshold:	Not established.
pH:	Most of the liquid chemical reagents are between pH 6 and 8; exceptions are the following solutions: <i>Development Reagent</i> at pH ~10, and the acidic <i>Stop solution</i> at pH ≤ 2.		
Boiling point	Undetermined	Melting Point:	Undetermined
Flash point:	Not applicable. Flammable limits: LEL/LFL is <u>Not applicable</u> ; UEL/UFL is <u>Not applicable</u> .		
Evaporation rate:	No applicable information was found.		
Fire hazard:	Although the components have not been tested for fire hazard data, being water-based, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.		
Vapor/vapour pressure:	No applicable information was found.		
Vapor/vapour density:	No applicable information was found.		
Relative density:	Variable.		
Solubility:	All chemical reagents are soluble in water; the acidic and corrosive solutions may release heat. (The solid cartridges and transfer pipets are not soluble).		
Auto igniting:	Product is not known to be self-igniting.		
Partition coefficient (n-octanol/water):	No applicable information was found.		
Decomposition temperature:	No applicable information was found.		
Viscosity:	No applicable information was found.		

Danger of explosion:	<i>Sodium azide</i> 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.
No other standard characteristics are known to be applicable to the identification or hazards of the product are known.	

SECTION 10: STABILITY AND REACTIVITY INFORMATION

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

Chemical stability / Reactivity:	Stable under ordinary conditions of use and storage.
Conditions to Avoid:	<i>Sodium azide</i> 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.
Materials to Avoid:	Do not allow the acidic Stop Solution to come in contact with strong bases or reducing agents (may lead to a violent exothermic reaction). Keep Glycerol solutions away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as could potentially form explosive mixtures. Keep urea away from oxidizers and bleach (can form explosive nitrogen trichloride when mixed with sodium hypochlorite). Sulfuric Acid - Bases, Halides, Organic materials, Carbides, fulminates, Nitrates, picrates, Cyanides, Chlorates, alkali halides, Zinc salts, permanganates, e.g. potassium permanganate, Hydrogen peroxide, Azides, Perchlorates., Nitromethane, phosphorous, Reacts violently with: cyclopentadiene, cyclopentanone oxime, nitroaryl amines, hexalithium disilicide, phosphorous(III) oxide, Powdered metals
Incompatible materials:	Sulfuric acid: Although concentrated sulfuric acid is referred to as an oxidizing agent in some sources, it is not a very strong oxidizing agent. The 98% acid has some oxidizing ability when hot. Sulfuric acid does not polymerize and does not form peroxides. Sulfuric acid is a very reactive substance. The concentrated acid dehydrates, or sulfonates most organic compounds. Sulfuric acid reacts vigorously, violently or explosively with many organic and inorganic chemicals including water, acrylonitrile, alkali solutions, carbides, chlorates, fulminates, nitrates, perchlorates, permanganates, picrates, powdered metals, metal acetylides or carbides, epichlorohydrin, aniline, ethylenediamine, alcohols with strong hydrogen peroxide, chlorosulfonic acid, cyclopentadiene, hydrofluoric acid, nitromethane, 4-nitrotoluene, phosphorus (III) oxide, potassium, sodium, ethylene glycol, isoprene, styrene. Hazardous gases, such as hydrogen, hydrogen cyanide, hydrogen sulfide and acetylene, are evolved on contact with chemicals such as metals, cyanides, sulfides and mercaptans and carbides respectively.
Hazardous decomposition products:	May release toxic oxides of carbon, nitrogen and sulfur.
Hazardous polymerization:	Has not been reported to occur.

SECTION 11: TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE

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

Acute Health Effects

Acute Toxicity:	May be harmful if swallowed. May be harmful in contact with skin.
Primary Irritant Effect:	May slightly irritate eyes or skin, depending on amount and contact time.
Serious Eye Damage / Irritation:	Can irritate eyes depending on concentration, amount and contact time.

STOT-Single Exposure:	No applicable information was found.
Aspiration Hazard:	No applicable information was found.
Other Acute Health Effects:	No significant other acute health effect known.

Biohazard Potential:

The **Positive Control (2)** was heat-treated to inactivate the HIV. Human sera in reagents were tested and found nonreactive for hepatitis B surface antigen and antibodies to HCV (the **Negative Control (3)**) is also nonreactive for antibodies to HIV. No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard and Universal Precautions*; handle these reagents, all human blood and specimens, as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, the WHO *Laboratory Biosafety Manual*. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Respiratory or Skin Sensitization:	The dropper bulb used in this bottle (supplied separately in the kit, but then placed in the Specimen Diluent bottle for kit use) contains Dry Natural Rubber, a potential sensitizer. May cause an allergic skin reaction. Contains a small volume of a very dilute, sensitizing preservative (ProClin 300 or ProClin 150); though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown, thus handle accordingly.
Carcinogenicity:	Component 8 contains 0.1N 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. <i>Note: The IARC Group and ACGIH A2 classifications refers specifically to sulfuric acid contained in strong inorganic acid mists and does not apply to sulfuric acid or sulfuric acid solutions.</i>
Germ Cell Mutagenicity:	No applicable information was found.
Reproductive hazard:	No reproductive toxic effect known.
STOT-Repeated Exposure:	No applicable information was found.

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.

SECTION 12: ECOLOGICAL INFORMATION

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

Ecotoxicity:	<p>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</p> <p>Concentrated Sulfuric acid [CAS# 7664-93-9] *: Fish LC₅₀ - Gambusia affinis (Mosquito fish) – 42 mg/l - 96</p> <p>Concentrated Urea [CAS#: 57-13-6]*: Toxicity to fish LC₅₀ – Poecilia reticulata (guppy) - 17500 mg/l - 96 h Daphnia EC₅₀ – Daphnia magna (Water flea) – 3910 mg/l - 48 h</p> <p>Concentrated Propane-1,2-diol [CAS# 57-55-6]*: Toxicity to fish mortality NOEC – Pimephales promelas (fathead minnow) – 52930 mg/l – 96 h Daphnia EC₅₀ – Daphnia magna (Water flea) – < 10000 mg/l – 48 h – mortality NOEC - Daphnia - 13020 mg/l - 48 h</p> <p><i>* Source: Raw Material Vendor Safety Data Sheet, RTECS and/or CCOHS Cheminfo</i></p>
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 effects:	<p>Concentrated AMP Buffer [CAS# 124-68-5]*: Biochemical Oxygen Demand (BOD): < 10 mg/l Concentration: 1 g/l Chemical Oxygen Demand (COD): 2,050 mg/g <i>* Source: Raw Material Vendor Safety Data Sheet</i></p> <p>AMP Buffer may be harmful to aquatic organisms and/or the aquatic environment. The Stop Solution (dilute sulfuric acid) is 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.</p>

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

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 and Safety Office for your specific disposal procedures.

Recommended Product Disposal:

All **human source** and other **potentially infectious** material must be appropriately decontaminated or disposed of as infectious material; 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 led to laboratory explosions, so flush with copious water when pouring dilute solutions down the drain to prevent such explosive build-up; check your applicable ordinances accordingly.

Acidic Waste **Stop Solution** (sulfuric acid, **pH ≤ 2**) must be neutralized to pH 6-8 for safe sewer disposal; check your local and regional ordinances accordingly. In addition, if the final pH measures ≤ 2, it requires disposal as a corrosive material in an RCRA approved waste facility (or equivalent). The US RCRA Waste disposal Code for this waste, if not neutralized, is D002; check your applicable ordinances accordingly.

Dilute Basic Waste; the **Development Reagent pH ≥ 10** may need to be neutralized to pH 6-8 for safe sewer disposal in many areas. Check your applicable ordinances accordingly. [Note: if the final pH measures ≥ 12.5, it requires disposal as a corrosive material in an RCRA approved waste facility (or equivalent), the RCRA Waste Code for this waste, if not neutralized is D002.]

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.

SECTION 14: TRANSPORT INFORMATION

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 and Safety Office for your specific shipping procedures.

Recommended Product Multi-Modal Transport: According to US DOT, IATA and UN “Model Regulations”, the product must be transported as follows: No known transport restrictions.

The Waste **Stop Solution** is the only component in this test kit that is potentially corrosive for shipping purposes. This Stop Solution has been evaluated with the CORROSITEX[®] test method to determine its corrosive potential and any packing group classification. The results of this testing classified this Stop solution as non-corrosive for shipping purposes.

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

SECTION 15: REGULATORY INFORMATION

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

Carcinogenicity Categories: Component 8 contains **0.1N 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 – Other Domestic / Foreign Laws:

Hazard communication compliance – This SDS contains the required information for preparation in accordance with the following GHS-based global regulations:

1. **United States** – Occupational Safety Health Administration *Hazard Communication Standard 29 CFR 1910.1200 (US HCS)*
2. **Taiwan** – Regulation **Lao-An-3-Tzu-No. 0960145703** / Published National Standard **CNS 15030**
3. **People’s Republic of China** – National Standard **GB/T 17519-2013, GB 30000-2013**
4. **New Zealand** – *Hazardous Substances and New Organisms Act 1996 (HSNO), Hazardous Substances (Classification) Regulations 2001 and Thresholds and Classifications January 2012* (as published in 2008) *Composite HSNO Hazard Class: Subclass 6.5 Category B (contact sensitizers)*
5. **Mexico** – **Standard NMX-R-019-SCFI-2011**
6. **Korea** – **Public Notice 2013-37 Standard for Classification and Labeling of Chemical Substances and Material Safety Data Sheets**
7. **Japan** – Industrial Safety and Health Law (ISHL) National Standard **JIS Z7252, JIS Z7253**
8. **European Community (EC)** – applicable **CLP** related regulations (**2010/453/EC, 2008/1272/EC, 2006/1907/EC** etc.)
9. **Canada** – Standard *Workplace Hazardous Materials Information System (WHMIS-GHS) Canadian Standard* for the hazard classification criteria for this product.
Composite WHMIS Hazards: Skin Sensitization
10. **Brazil** – Regulation **NRB 14725**
11. **Australia** – Code of Practice *Preparation of Safety Data Sheets for Hazardous Chemicals* under Section 274 of the **Work Health and Safety (WHS) Act**.
12. Analogous GHS-based global regulations

Inventory status

Country(s) or region Inventory name	In Compliance (yes/no)*
Australia Australian Inventory of Chemical Substances (AICS)	Yes
Canada Domestic Substances List (DSL)	Yes
Canada Non-Domestic Substances List (NDSL)	Yes
China Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe European Inventory of Existing Commercial Chemical Substances (EINECS) or Europe European List of Notified Chemical Substances (ELINCS)	Yes
Japan Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea Existing Chemicals List (ECL)	Yes
New Zealand New Zealand Inventory	Yes
Philippines Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan inventory (CSNN):	Yes
United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory	Yes

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

Regulation (EC) No. 1907/2006 (REACH):

Chemicals included in the Candidate List of Substances of Very High Concern (SVHC): None

REACH No.: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

United States SARA:

SARA 302 (extremely hazardous substance) components: The following components are subject to reporting levels established by SARA Title III, Section 302: **Sulfuric Acid**, CAS# 7664-93-9; Revision Date: 2007-07-01

SARA 313 components: The following components are subject to reporting levels established by SARA Title III, Section 313: **Sulfuric Acid**, CAS# 7664-93-9; Revision Date: 2007-07-01

California Proposition 65: The Product does not contain listed substances.

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s):

Acute Tox. – oral.	Acute toxicity – ingested (swallowed)
Acute Tox. – skn.	Acute toxicity – skin contact (dermal)
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritant
Eye Damage.	Serious Eye damage
Skin Sens.	Skin sensitisation
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Met. Corr.	Corrosive to Metals
Cat.	Category
H300 + H310	Fatal if swallowed or in contact with skin.
H302	Harmful if swallowed
H303 + H313	May be harmful if swallowed or in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
P220	Keep/Store away from clothing/ combustible materials.
P261	Avoid breathing mist / vapors/vapours / spray.
P264	Wash skin thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
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.
P301 + P312 + P330	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
P301 + P330 + P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P302 + P350	IF ON SKIN: Gently wash with plenty of soap and water.
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.
P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.
P310	Immediately call a POISON CENTER or doctor/ physician
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
P363	Wash contaminated clothing before reuse.
P391	Collect spillage.
P405	Store locked up.
P501	Dispose of this material in a safe way, and in accordance with local, regional, national and international regulations.
P501	This material and its container must be disposed of as hazardous waste.
Caution	Contains human source material. Handle as if capable of transmitting potentially infectious agents (Universal Precautions).

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.

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.

Sources of key data used to compile the Safety Data Sheet:

- Raw Material Vendor Safety Data Sheets
- United Nations (UN) Globally Harmonized System (GHS)
- United States OSHA Hazard Communication Standard (HCS) 1910.1200
- Canadian Workplace Hazardous Materials Information System (WHMIS)

Mexican Standard (NMX-R-019-SCFI-2011) [regulatory translation and summaries]
European Community (EC) Regulations 2008/1272/EC, 2010/453/EC, 2006/1907/EC
Australian Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the Work Health and Safety Act)
New Zealand – Hazardous Substances and New Organisms Act 1996 (HSNO)
The People's Republic of China National Standard GB/T 17519-2013, GB 30000-2013 [regulatory translation if available and summaries]
Taiwan Regulation Lao-An-3-Tzu-No. 0960145703 / Published National Standard CNS 15030 [regulatory translation if available / summaries]
Korean Public Notice 2008-26 [regulatory translation if available and summaries]
Japanese Industrial Standard JIS Z7252, JIS Z7253 [regulatory translation if available and summaries]
Registry of Toxic Effects of Chemical Substances (RTECS)
Canadian Centre for Occupational Health and Safety (CCOHS) *CHEMINFO databases, etc.*
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*
Australian Inventory of Chemical Substances (ACIS)
California Proposition 65

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
CCOHS – Canadian Centre for Occupational Health and Safety
CDC – Centers for Disease Control, USA
CNS – Central Nervous System
DGSMA – Dangerous Goods Safety Management Act
DOT – Department of Transportation
EC₅₀ – half maximal effective concentration
EC CLP – European Commission regulation for the Classification, Labeling and Packaging of chemical substances and mixtures
EU – European Union
GHS – Globally Harmonized System
HNOC – Hazard Not Otherwise Classified
HSNO – Hazardous Substances and New Organisms Act 1996 (New Zealand)
IARC – International Agency for Research on Cancer
IATA – International Air Transport Association
ICAO – International Civil Aviation Organization
IDLH – Immediately Dangerous to Life or Health
IMDG – International Maritime Dangerous Goods
IPCS – International Programme on Chemical Safety
ISHA – Industrial Safety and Health Act
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 million
RTECS – Registry of Toxic Effects of Chemical Substances
SDS – Safety Data Sheet
STEL – Short Term Exposure Limit
STOT – Specific Target Organ Toxicity
TCCA – Toxic Chemical Control Act
TLV/TWA – Threshold Limit Value / Time-Weighted Average
UN – United Nations
US EPA – United States Environmental Protection Agency
US HCS – Hazard Communication Standard, USA
US OSHA – Occupational Safety and Health Administration, U.S. Department of Labor
WHMIS – Workplace Hazardous Materials Information System (Canadian)
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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Multispot HIV-1/HIV-2 Rapid Test

[Catalog 25228]

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