

SAFETY DATA SHEET (SDS)




SECTION 1: IDENTIFICATION OF PRODUCT (MIXTURE) AND SUPPLIER



Product Name:	MONOLISA™ Anti-HBc IgM EIA
Product Number:	26174 (192 tests) Catalog number(s) for replacement, separately purchased components that can be obtained for use with this kit, and which are covered by this SDS include: 25261, 25262, 26181, 26182, 26198, 26199, 26200, 26201, 26202 and 26203 (refer to Section 2).
Intended Use:	The MONOLISA™ Anti-HBc IgM EIA is an enzyme immunoassay intended for use in the qualitative detection of IgM antibodies to hepatitis B core antigen (anti-HBc IgM) in human serum or plasma. Assay results may be used with other HBV serological markers for the laboratory diagnosis of HBV disease associated with HBV infection. Refer to the instructions for use accompanying the product for applicable processing systems.
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. Refer to section 16 for non-US local Bio-Rad agent contact information.
Authorized Representative in the European Community:	FRANCE: Bio-Rad 3 boulevard Raymond Poincaré 92430 Marnes-la-Coquette Phone: +33 (0) 1 47 95 60 00 / Fax: +33 (0) 1 47 41 91 33 [fds-msds.fr@bio-rad.com]
Emergency Phone Number:	This SDS is listed with CHEMTREC 1-800-424-9300 (US) / 1-703-527-3887 (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 *	Content
R1 Anti-HBc IgM EIA Microwell Strip Plates, (2)	<ul style="list-style-type: none"> - Microwell strips in holder, coated with goat anti-human IgM. - Potential residue of ProClin used as production preservative (aspirated prior to drying strips). - Tabs are labeled "HH" - Contains sealed pelletized desiccant packet: There are no health hazards associated with intact desiccant container; however, health hazards could result from dusts generated if the packet is cut, split or otherwise compromised and is crushed.
R2 Wash Solution Concentrate (30X), 1 bottle (120 mL) <i>Catalog No. 25261</i>	- Sodium chloride (NaCl) [CAS# 7647-14-5, EC No 231-598-3] aqueous solution with < 2% Tween 20 (C ₅₈ H ₁₁₄ O ₂₆) [CAS# 9005-64-5, EC No 585-580-06-X] (clear liquid). Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.

Component *	Content
<p>R3 Anti-HBc IgM EIA Specimen Diluent, 4 bottles (30 mL) Red liquid <i>Catalog No. 26199</i></p>  <p>WARNING</p>	<ul style="list-style-type: none"> - Buffer with protein stabilizers containing bovine serum albumin and red indicator dye ($\leq 0.01\%$), pH neutral. - 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.
<p>C0 Anti-HBc IgM Negative Control, 1 vial (0.8 mL) Straw-colored liquid <i>Catalog No. 26201</i></p>	<ul style="list-style-type: none"> - Normal human serum/plasma, non-reactive for detectable hepatitis B surface antigen (HBsAg) and antibodies to human immunodeficiency virus (HIV-1 and HIV-2), hepatitis C virus (HCV), hepatitis B core antigen (HBc) and HBs. - Preserved with 0.16% ProClin 950, containing $< 0.016\%$ active ingredient: 9.5-9.9% active ingredient 2-methyl-4-isothiazolin-3-one [C₄H₅NOS]; CAS# 2682-20-4, EC No 220-239-6. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with 0.005% gentamicin sulfate, CAS# 1405-41-0, EC No 215-778-9. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
<p>C1 Anti-HBc IgM EIA Positive Control, 1 vial (1.6 mL) Red liquid <i>Catalog No. 26200</i></p>  <p>WARNING</p>	<ul style="list-style-type: none"> - Prediluted human serum/plasma; prepared from infectious material positive for anti-HBc IgM and HBsAg, which has been treated to reduce the potential for HBV infectivity. - Non-reactive for detectable antibodies to human immunodeficiency virus (HIV-1 and HIV-2) and hepatitis C virus (HCV). - Buffer with protein stabilizers and red indicator dye (≤ 0.01), pH neutral. - 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.
<p>C2 Anti-HBc IgM EIA Cutoff Calibrator, 1 vial (1.5 mL) Straw-colored liquid <i>Catalog No. 26203</i></p>	<ul style="list-style-type: none"> - Normal human serum/plasma, non-reactive for detectable hepatitis B surface antigen (HBsAg) and antibodies to human immunodeficiency virus (HIV-1 and HIV-2), hepatitis C virus (HCV), hepatitis B core antigen (HBc) and HBs. - Preserved with 0.16% ProClin 950, containing $< 0.016\%$ active ingredient: 9.5-9.9% active ingredient 2-methyl-4-isothiazolin-3-one [C₄H₅NOS]; CAS# 2682-20-4, EC No 220-239-6. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration. - Preserved with 0.005% gentamicin sulfate, CAS# 1405-41-0, EC No 215-778-9. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
<p>R4 Anti-HBc IgM EIA Conjugate, Lyophilized, 4 vials (7.5 mL) <i>Catalog No. 26202</i></p>  <p>WARNING</p>	<ul style="list-style-type: none"> - HBc recombinant conjugate to HRP, lyophilized. - Prior to lyophilization, the solution was preserved with $\leq 0.1\%$ ProClin 300 (0.003% 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.

Component *	Content
R5 Anti-HBc IgM EIA Conjugate Diluent , 1 bottle (30 mL) Light green liquid <i>Catalog No. 26198</i>  WARNING	- Buffer (pH neutral) with protein stabilizers and green dye (food grade). - Diluted ≤ 15% glycerol [C ₃ H ₈ O ₃], 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 0.5% 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.
R8 Substrate Buffer , 1 bottle (120 mL) <i>Catalog No. 26181</i>	- Dilute citric acid (C ₆ H ₈ O ₇ , CAS# 79-92-9, EC No 201-069-1) / sodium acetate buffer , [pH ~4.0, clear liquid]. - < 5% Dimethylsulfoxide [DMSO -C ₂ H ₆ OS], CAS# 67-68-5-4, EC No 200-644-3. - < 0.1% hydrogen peroxide [H ₂ O ₂], CAS# 7722-84-1, EC No 231-765-0. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
R9 Chromogen (11X) , 1 bottle (12 mL) <i>Catalog No. 26182</i>	- ≤ 0.25% tetramethylbenzidine dihydrochloride [TMB – C ₁₆ H ₂ ON ₂ •2HCl, CAS# 64285-73-0]. - ≤ 0.04N hydrochloric acid (~0.3% HCl, CAS# 7647-01-0, EC No 231-595-7) solution [pH ~1.5, clear liquid]. Not subject to GHS, US HCS, EC CLP and analogous global GHS-based regulatory requirements in this product mixture and concentration.
R10 Stopping Solution , 1 bottle (120 mL) <i>Catalog No. 25260</i>  DANGER!	- 1N H₂SO₄ (4.4% w/w sulfuric acid), CAS# 7664-93-9 [pH ≤ 2, clear liquid]; severely irritating to skin, corrosive to eyes. GHS / 2008/1272/EC Classification: DANGER! GHS05; H314; P280; P301 + P330 + P331, P305 + P351 + P338; P501]

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

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

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

The following information is furnished for those product hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Note that the information here is often based on data for the chemical raw material safety data sheet and literature (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. 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: **≤ 10% in R5**

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 0.9% vv in air.
Synonyms/Trade Names: 1,2,3-Propanetriol; 1,2,3-Trihydroxypropane; 90 Technical glycerine; Citi fluor AF 2; lyzerin, wasserfrei, Glycerin; Glycerin mist; 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: Sulfuric acid

Chemical concentrations found in this product: **1 N (< 5% H₂SO₄ in water) in R10**

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

CAS#: 7664-93-9 (Conc. sulfuric acid 100%)	LD ₅₀ (oral-rat): 2,140 mg/kg (100%)
EC No: 231-639-5 (100%)	LC ₅₀ (inhalation-rat): 510 mg/m ³ /2H (100%)
Index No: 016-020-00-8 (100%)	LD ₅₀ (skin-rabbit): NE (100%)
Registration No: 01-2119458838-20-XXXX	LC ₅₀ (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: H ₂ SO ₄ (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 Data / Information

Chemical Ingredient: Dimethyl-sulfoxide [DMSO]

Chemical concentrations found in this product: **≤ 5 % in R8, an aqueous solution**

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

CAS#: 67-68-5 (100%)	LD ₅₀ (oral-rat): 14500 mg/kg (100%)
EC No: 200-644-3 (100%)	LC ₅₀ (inhalation-rat): 1600 mg/m ³ (4 hr) (100%)
RTECS#: PV6210000 (100%)	LD ₅₀ (skin-rabbit): >5000 mg/m ³ (100%)
Index No: NA (100%)	LC ₅₀ (96 hr-fish): NE mg/L (100%)
Chemical Formula: C ₂ H ₆ OS (100%)	Flash point: 188-192°F / 86.7-88.9°C (100%)
Molecular weight: 78.13 g/mol (100%)	Flammable limits: LEL/LFL is 3.5%; UEL/UFL is 42% vv in air (100%)

Synonyms/Trade Names: Dimethyl sulfoxide; Dimethyl sulphoxide; Dimexide; Dipirartril-tropico; DMS-70; DMS-90; DMSO; Dolicur; Domoso; Dromisol; Durasorb; A 10846; Deltan; Demeso; Demasorb; Demavet; Demsodrox; Dermasorb; Gamasol 90; Hyadur; Infiltrina; M 176, Methane, sulfinylbis-; Methylsulfinylmethane; Somipront; SQ 9453, Topsyim; NSC-763; Rimso-50; Sulfinylbis(methane); Syntexan

Raw Material GHS / US HCS / EC CLP Classification (100%): No Pictogram required

WARNING

Fla. Liq. Cat. 4
H227
P210, P280, P370 + P378, P403 + P235, P501

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

Chemical Ingredient: Citric acid

Chemical concentrations found in this product: **≤1.5% w/v in R8**

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

CAS#: 77-92-9 (100%)	LD ₅₀ (oral-rat): 5400 mg/kg
EC No: 201-069-1 (100%)	LC ₅₀ (inhalation-rat): NE
RTECS#: GE7350000 (100%)	LD ₅₀ (skin-rabbit): >2000 mg/kg
Index No: NA (100%)	

Toxicity to fish mortality LC₅₀ - Leuciscus idus melanotus - 440 mg/l - 48 h Method: OECD Test Guideline 203
Chemical Formula: C₆H₈O₇ (100%) pH value: 1.8 at ca.50 g/l at 25 °C (77 °F)
Molecular weight: 192.12 g/mol (100%)
Synonyms/Trade Names: Aciletten; Anhydrous citric acid; Citretten; Citro; 2-Hydroxy-1,2,3-propanetricarboxylic acid; beta-Hydroxytricarballic acid; Kyselina citronova
Skin corrosion/irritation: Skin - rabbit - Mild skin irritation - OECD Test Guideline 404
Serious eye damage/eye irritation: Eyes - rabbit - Irritating to eyes. - OECD Test Guideline 405
Respiratory or skin sensitization: Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

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

WARNING

Acute Tox. – skn Cat. 5, Skin Irrit. Cat. 1, Eye Irrit. Cat. 2A
H313, H316, H319
P264, P280, P305 + P351 + P338, P337 + P313



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

Chemical Ingredient Data / Information

Chemical Ingredient: Hydrochloric acid

Chemical concentrations found in this product: **≤ 0.04N (< 0.4% v/v HCl)**

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

CAS#: 7647-01-0 (concentrate solution)	LD ₅₀ (oral, rat): 700 mg/kg (unconfirmed)
EC No: 231-595-7 (concentrate solution)	LC ₅₀ (inhalation-rat): 3124 ppm/1H
Index No: 017-002-01-X (concentrate solution)	LD ₅₀ (skin-rabbit): Greater than 5010 mg/kg (unconfirmed)
RTECS#: MW4025000 (concentrate solution)	Fish LC ₅₀ – Bluegill/Sunfish – 282 mg/l – 48 h
Chemical Formula: HCl (concentrate solution)	
Molecular weight: 36.46 g/mol (concentrate solution)	pH value: highly acidic (30-50% concentrated solution)
Synonyms/Trade Names: Acide chlorhydrique; Acido cloridrico; Anhydrous hydrochloric acid; Chloorwaterstof; Chlorohydric acid; Chlorowodor; Chlorwasserstoff; Hydrochloride; Hydrogen chloride; Hydrogen chloride; Muriatic acid; Spirits of salt	
LC ₅₀ (male rat): 1405 ppm (4-hour exposure; head-only); cited as 2810 ppm (1-hour exposure; head-only) (30-50% solution)	
LC ₅₀ (male rat): 1562 ppm (4-hour exposure; whole-body); cited as 3124 ppm (1-hour exposure; whole-body) (30-50% solution)	
Skin corrosion/irritation: Skin - rabbit - Causes burns. (30-50% solution)	
Serious eye damage/eye irritation: Eyes - rabbit - Corrosive to eyes (30-50% solution)	
IARC: Group 3: Not classifiable as to its carcinogenicity to humans (30-50% solution)	

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

DANGER!

Skin Corr. Cat. 1B, Eye Damage Cat. 1, STOT SE Cat. 3, Met. Corr. Cat. 1
H290, H314, H335
P234, P261, P264, P271, P280, P301 + P330 + P331, P303 + P361 + P353, P304 + P340,
P305 + P351 + P338, P310, P363, P390, P403 + P233, P405, P406, P501



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

Chemical Ingredient: 3,3',5,5'-Tetramethylbenzidine, Dihydrochloride

Chemical concentrations found in this product: **≤ 0.3% w/v in R9**

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

CAS#: 207738-08-7 (54827-17-7 Free base) (100%)	LD ₅₀ (ipr-mouse): 135 mg/kg (100%)
EC No: 264-769-6 (100%)	LD ₅₀ (oral-rat): NE
RTECS#: DV2300000 (100%)	LC ₅₀ (inhalation-rat): NE
Chemical Formula: C ₁₆ H ₂₀ N ₂ •2HCl (100%)	LD ₅₀ (skin-rabbit): NE
Molecular weight: 313.27 g/mol (100%)	LC ₅₀ (96 hr-fish): NE (100%)
Synonyms/Trade Names: TMB	

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 Data / Information

Chemical Ingredient: ProClin 950

Chemical concentrations found in this product: **≤ 0.16% in C0 and C2**

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

Hazardous ingredient concentration in raw material: the concentrated preservative contains:

5-10% of 2-methyl-4-isothiazolin-3-one (active ingredient).

CAS#: 2682-20-4 (active ingredient)

EC No: 220-239-6 (active ingredient)

RTECS#: NE

Chemical Formula: C₄H₅NOS (active ingredient)

LD₅₀ (oral-rat): No data available (concentrated solution)

LC₅₀ (inhalation-rat): No data available (concentrated solution)

LD₅₀ (skin-rabbit): No data available (concentrated solution)

pH value: 3.0-6.0 (concentrated solution)

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

DANGER!

Acute Tox. -- inhl. Cat. 3, Skin Corr. Cat. 1B, Eye Damage Cat. 1,

Skin Sens. Cat. 1, Aquatic Acute Cat. 1, Aquatic Chronic Cat. 1

H314, H317, H331, H410

P261, P264, P271, P272, P273, P280, P301 + P330 + P331, P303 + P361 + P353,
P305 + P351 + P338, P310, P403 + P233, P405, P501

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



Chemical Ingredient: ProClin 300

Chemical concentrations found in this product: **0.1% in R4 prior Lyophilization; 0.5% in R3 R5; and C1; potential residue dried on plates, R1**

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** (C₄H₄ClNOS; 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: Gentamicin sulfate in C0, C1

Chemical concentrations found in this product: **< 0.01% from a 50 mg/ml Solution in C0, C1, C2, R3 and R4**

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

CAS#: 1405-41-0 (100%)	LD ₅₀ (oral-rat): > 5000 mg/kg (100%, 50 mg/ml)
EC No: 215-778-9 (100%)	LC ₅₀ (inhalation-rat): NE
RTECS#: LY2625000 (100%)	LD ₅₀ (skin-rabbit): NE
Synonyms/Trade Names: Gentamicin sulfate salt; Garamycin; Gentiomycin C	

Raw Material GHS / US HCS / EC CLP Classification (10%):

DANGER!


Resp. Sens., Cat. 1, Skin Sens., Cat. 1

H317, H334

P261, P272, P280, P285, P302 + P352, P304 + P341, P333 + P313, P342 + P311, P363, P501



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

Biological Ingredient	Data / Information
<p>Human Serum [reactive and non-reactive in C0, C1 and C2]</p> 	<p>The human source material used in the preparation of the Negative Control (C0) and Cutoff Calibrator (C2) contains normal human serum/plasma that tested non-reactive for detectable hepatitis B surface antigen (HBsAg) and antibodies to hepatitis B core antigen (HBc), hepatitis C Virus (HCV), human immunodeficiency viruses (HIV-1 and HIV-2) and HBs. The human source material used in the preparation of the Positive Control (C1) contains human serum/plasma from infectious material reactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis B core antigen, which has been treated to reduce the potential for HBV infectivity. It tested non-reactive for detectable antibodies to hepatitis C virus (HCV) and human immunodeficiency viruses (HIV-1 HIV-2).</p> <p>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 <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> and 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 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.</p>
<p>Animal proteins [C1, R1, R3, R4, R5]</p>	<p>This material is of animal origin (goat, bovine, etc.) and may be a potential contact irritant. Hazard Unknown. Handle as potentially infectious. The chemical, physical and toxicological properties have not been thoroughly investigated. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional, national and international regulations.</p>

NA: Not Applicable

NE = Not Established or Unknown (unable to locate data); typically for concentrated 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 miscellaneous **Tween 20** [C₅₈H₁₁₄O₂₆, CAS #9005-64-5], **hydrogen peroxide** [H₂O₂, CAS# 7722-84-1, ≤ 0.1% v/v in R8] salts, sugars, buffers, water, animal sera (bovine, goat, rabbit, monkey, porcine, avian, murine, equine, burro, etc.), and other chemicals found in the HRP conjugate, buffers with protein stabilizers, dyes, and sodium acetate solution, in the kit volumes and/or concentrations present [chemical or dilution is not subject to GHS, US HCS, EC CLP or other GHS-based hazard labeling].

- ◆ **Anti-HBc IgM EIA Microwell Strip Plate** component (R1) contains < 0.1% of Cobalt (II) Chloride [CAS# 7646-79-9, EC No. 231-589-4], which is classified as an IARC Group 2B (possible human carcinogen) and EU Category 2 carcinogen, and silica quartz [CAS# 14808-60-7, EC No. 238-87-4], which in dust form is classified as an ACGIH Class A2 (suspected human carcinogen) and IARC Group 1 (carcinogenic to humans). This material is in a pelletized desiccant sealed packet within the plate pouch, which is unlikely to generate significant dust under normal conditions of use and is thus not typically considered a health hazard. However, health hazards could result from dusts generated if the packet is cut, split or otherwise compromised and a significant number of pellets were crushed to a powder form. Keep the desiccant packet intact as received in the microwell plate component package.
- ◆ According to the concept of *Universal Precautions* (29 CFR 1910.1030), all human blood and certain human body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens. No known test method can offer complete assurance that products derived from human blood will not transmit infection; thus, they should be handled as though they contain infectious agents. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.
- ◆ Do not eat, drink or smoke when using this product.
- ◆ Wear protective gloves/protective clothing/eye protection/face protection. Take off contaminated clothing and wash before reuse.

SECTION 4: EMERGENCY FIRST AID MEASURES

Health Effects:	Symptoms of overexposure may include headache, congestion and dizziness. Skin contact may result in dermatitis and may cause allergic skin reaction upon repeated exposure. Causes severe skin burns and eye damage. Severely irritating or corrosive to eyes; greater exposures can cause eye damage, including permanent impairment of vision. Risk of serious damage to eyes. May cause ingestion corrosive effects, including burning throat, mouth and stomach. May be toxic to developing fetus, generally at concentrations and volumes greatly exceeding 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. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present. Treat symptomatically and supportively.
If Swallowed:	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Rinse mouth. Do NOT induce vomiting. 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 taking immunosuppressant drugs may be more susceptible to infectious pathogens. Persons handling human blood 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: dry chemical, foam, carbon dioxide or water. Water spray may be used to cool fire and/or protect response personnel.
Hazardous Decomposition Products:	May release toxic oxides of carbon, nitrogen and sulfur or toxic hydrogen chloride gas.
Special Firefighting Procedures:	Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

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, 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.
- ◆ Prevent material from entering sewers, waterways or confined spaces.
- ◆ 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 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 acid spills immediately with an *acid neutralization / adsorbent* product.
- ◆ Clean the spill area with water and wipe dry. Spills can also be absorbed with appropriate inert materials (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 chemicals and biologicals and/or 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 or equivalent and eye/face protection.</p> <p>Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all human source materials, specimens and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per <i>Standard</i> and <i>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 and Safety Office for assistance.</p>
Storage:	Store according to product and label instructions (generally at 2-8°C).
<p>Caution, consult accompanying documents. Refer to the <i>Instructions For Use, Package Insert</i> for additional product information. Read and follow all the precautions and warnings in the MONOLISA™ Anti-HBc IgM EIA kit product instructions.</p>	
<p>For <i>in vitro</i> diagnostic use.</p>	

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.

Chemical	CAS-No.	Value	Control parameter	Update	Basis
Sulfuric acid	7664-93-9	TWA – TLV	0.2 mg/m ³ (thoracic fraction)	2004-01-01	USA. ACGIH Threshold Limit Values (TLV)
		TWA – PEL	1 mg/m ³ *	1993-06-30	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		REL IDLH	1 mg/m ³ 15 mg/m ³	2005-149 [SEP-2007]	USA. National Institute for Occupational Safety and Health (NIOSH)
* The value in mg/m ³ is approximate Remarks: TLV CARCINOGENICITY DESIGNATION A2 – Suspected Human Carcinogen: Substance is carcinogenic in laboratory animals under conditions that are considered relevant to worker exposure. Available human studies are conflicting or insufficient to confirm an increased risk of cancer in exposed humans. Worker exposure to an A2 carcinogen should be controlled to levels as low as reasonably achievable below the TLV. The A2 Carcinogenicity Designation refers to sulfuric acid contained in strong inorganic acid mists.					
Hydrochloric acid	7647-01-0	TLV – C	2 ppm	2007-01-01	USA. ACGIH Threshold Limit Values (TLV)
		PEL – C	7 mg/m ³ * 5 ppm	2006-02-28	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		REL – C IDLH	7 mg/m ³ 5 ppm 50 ppm	2005-149 [SEP-2007]	USA. National Institute for Occupational Safety and Health (NIOSH)
* The value in mg/m ³ is approximate. Ceiling limit is to be determined from breathing-zone air samples. Remarks: TLV CARCINOGENICITY DESIGNATION A4 – Not Classifiable as a Human Carcinogen: Inadequate data on which to classify the substance as a human and/or animal carcinogen.					
Hydrogen peroxide	7722-84-1	TWA – TLV	1 ppm	2007-01-01	USA. ACGIH Threshold Limit Values (TLV)
		TWA – PEL	1.4 mg/m ³ * 1 ppm	1997-08-04	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		REL IDLH	1.4 mg/m ³ 1 ppm 75 ppm	2005-149 [SEP-2007]	USA. National Institute for Occupational Safety and Health (NIOSH)
* The value in mg/m ³ is approximate Remarks: TLV CARCINOGENICITY DESIGNATION A3 – Animal Carcinogen: Substance is carcinogenic in laboratory animals under conditions that are not considered relevant to worker exposure. Available human studies and evidence suggest that the substance is not likely to cause cancer in humans except under unusual or unlikely routes or levels of exposure. Worker exposure to an A3 carcinogen should be controlled to levels as low as reasonably achievable below the TLV.					
Dimethyl sulfoxide	67-68-5	TWA-WEEL	250 ppm	2014	USA: Workplace Environmental Exposure Levels
		MAK	50 ppm (160 mg/m ³)	2011	GERMANY:
Source: RTECS September 2013 Update and Raw Material Vendor Safety Data Sheet					

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

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

Ventilation:	Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material/patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.
Eye/ Face Protection	Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.

Protective Gloves:	Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves such as nitrile, neoprene and vinyl are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never be reused. Wash hands thoroughly after removing gloves. Guidelines for <i>Sulfuric Acid</i> , less than 30%: RECOMMENDED (resistance to breakthrough longer than 8 hours): Butyl rubber, natural rubber, neoprene, polyethylene, polyvinyl chloride, Viton®, Viton®/Butyl rubber, Barrier (PE/PA/PE), Silver Shield/4H™ (polyethylene/ethylene vinyl alcohol), Trelchem® HPS, Trelchem® VPS, Tychem® SL (Saranex®), Tychem® CPF 3, Tychem® F, Tychem® BR/LV, Tychem® Responder™, Tychem® TK. RECOMMENDED (resistance to breakthrough longer than 4 hours): Nitrile rubber. NOT RECOMMENDED for use (resistance to breakthrough less than 1 hour): Polyvinyl alcohol. <i>Source: CHEMINFO 12-2013</i>
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 lyophilized conjugate, microtiter plate and related materials.		
Odor/odour:	No applicable information was found.	Odor/dour Threshold:	Not Established.
pH:	Most of the liquid chemical components are between pH 5 and 9; exceptions are the acidic solutions: Substrate Buffer at pH ~4, the Chromogen at pH ~1.5 and the Stopping Solution 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 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.		
Vapor/vapour pressure:	No applicable information was found.		
Vapor/vapour density:	No applicable information was found.		
Relative density	Variable, approximately 1.		
Solubility:	The liquid chemical components are soluble in water. The acidic solutions may release heat		
Partition coefficient (n-octanol/water):	No applicable information was found.		
Auto igniting:	Product is not known to be self-igniting.		

Decomposition temperature:	No applicable information was found.
Viscosity:	No applicable information was found.
Danger of explosion:	Generally, the product is not known to present an explosion hazard; however, the small amount of glycerol in component R3 should be kept away from strong oxidizing agents, including sodium hypochlorite (bleach) and potassium permanganate, as these could potentially form explosive mixtures.
No other standard characteristics 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:	Components are stable with no known inherent significant reactivity, except the acidic solutions, which may have an exothermic reaction with certain chemicals, particularly strong bases and reducing agents.
Conditions to Avoid:	None known when used as intended.
Materials to Avoid:	Do not allow the acidic Stop Solution to come in contact with strong bases or reducing agents (may lead to a violent exothermic reaction). 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 or toxic hydrogen chloride gas.
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 detrimental in contact with skin, if swallowed, and to eyes upon contact; in case of contact with eyes, immediately rinse with copious water and seek medical attention.
Primary Irritant Effect:	Irritating to skin and severely irritating or corrosive to eyes, and with greater exposures can cause eye damage, including permanent impairment of vision or blindness.
Skin Corrosivity / Metal Corrosion:	Causes severe skin burns and eye damage. The Stopping Solution (R10) is Corrosive, able to cause severe burns of the mucous membranes, skin and eyes. Destructive to tissue of the skin, respiratory tract, mucous membranes, and eyes; may cause permanent injury. May cause ingestion corrosive effects, including burning throat, mouth and stomach.
Serious Eye Damage / Irritation:	Causes severe eye damage. The Stopping Solution (R10) is severely corrosive to eyes; contact can cause eye damage, including permanent impairment of vision or blindness. The Stopping Solution poses a risk of serious damage to eyes. Harmful to eyes upon contact; in case of contact with eyes, immediately rinse with copious water and seek medical attention.
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 human source material used in the preparation of the **Negative Control (C0)** and **Cutoff Calibrator (C2)** contains normal human serum that tested non-reactive for detectable hepatitis B surface antigen (HBsAg) and antibodies to human immunodeficiency viruses (HIV-1 and HIV-2), hepatitis C Virus (HCV), hepatitis B core antigen (HBc) and HBs. The human source material used in the preparation of the **Positive Control (C1)** contains human serum from infectious material reactive for anti-HBc and anti-HBs, which has been treated to reduce the potential for HBV infectivity. It tested non-reactive for detectable hepatitis B surface antigen (HBsAg) and antibodies to human immunodeficiency viruses (HIV-1 and HIV-2) and hepatitis C virus (HCV). No known test method can offer complete assurance that HIV, hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Employ *Standard and Universal Precautions*; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, WHO *Laboratory Biosafety Manual* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Respiratory or Skin Sensitization:	May cause an allergic skin reaction. Contains a small volume of very dilute, potentially skin-contact sensitizing preservatives, ProClin and Gentamicin sulfate (an antimicrobial biocide that is also a photosensitizer); prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus handle accordingly.
Carcinogenicity:	Component R1 contains < 0.1% Cobalt (II) chloride (CAS# 7646-79-9, IARC Group 2B and EU Category 2 carcinogen) and silica quartz (CAS# 14808-60-7, ACGIH class A2 and IARC Group 1 carcinogen) sealed in a pelletized desiccant packet. Keep the desiccant packet intact as received in the microwell plate component package. Component R10 contains 1N Sulfuric Acid , CAS# 7664-93-9: IARC Group 1, The agent is Carcinogenic to Humans, NTP listed as Known to be a Human Carcinogen and ACGIH-TLV Group A2, Suspected Human Carcinogen. <i>Note: The IARC Group and ACGIH A2 Iclassifications refers specifically to sulfuric acid contained in strong inorganic acid mists are and does not apply to sulfuric acid or sulfuric acid solutions.</i>
Germ Cell Mutagenicity:	No applicable information was found.

Reproductive hazard:	Reasonably anticipated to be a reproductive toxin. May cause harm to unborn child. Gentamicin sulfate is known to the State of California to cause developmental toxicity (teratogen), classified under the generic class of aminoglycosides. (Designation is for concentrated gentamicin sulfate, which is diluted to 0.005% in kit components.)
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>Concentrated Sulfuric acid [CAS# 7664-93-9] *: Fish LC₅₀ - Gambusia affinis (Mosquito fish) – 42 mg/l - 96 h</p> <p>Concentrated Hydrochloric acid [CAS# 7647-01-0] *: Fish LC₅₀ - Bluegill/Sunfish – 282 mg/l - 48 h</p> <p>Concentrated 2-methyl-4-isothiazolin [CAS# 2682-20-4] **: Fish LC₅₀ – Lepomis macrochirus (Bluegill) – 300 µg/l [min. 240 µg/l max. 320 µg/l] - 96 h Fish LC₅₀ - Oncorhynchus mykiss (rainbow trout) – 190 µg/l [min. 130 µg/l max. 310 µg/l] - 96 h Fish LC₅₀ - Oncorhynchus mykiss (rainbow trout) – 70 µg/l [min. 60 µg/l max. 90 µg/l] - 96 h</p> <p>Concentrated Citric acid [CAS#: 77-92-9]*: Toxicity to fish mortality LC₅₀ - Leuciscus idus melanotus - 440 mg/l - 48 h Method: OECD Test Guideline 203 Toxicity to daphnia and other aquatic invertebrates: static test - Daphnia magna (Water flea) - 1,535 mg/l - 24 h *Source: Raw Material Vendor Safety Data Sheet, RTECS and/or CCOHS ** Source: PAN Pesticides Database – Chemical Studies on Aquatic Organisms [obtained 3/7/2012]</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:	The acidic corrosive Components R8 (pH 4), R9 (pH 1.5) and R10 (pH ≤2) are hazardous for drinking water and toxic to aquatic organisms by pH modification if not neutralized. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Avoid release to the environment.

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:

- ♦ **Acidic Stopping Solution** (sulfuric acid, pH ≤ 2), **Chromogen** (pH ~1.5), and **Substrate Buffer** (pH ~4.0) wastes should be neutralized to pH 6-8 for safe sewer disposal; check your applicable ordinances accordingly. In addition, if the final pH measures ≤ 2, it requires disposal as a corrosive material in an RCRA approved dangerous waste facility (or equivalent). The US RCRA Waste Disposal Code for this waste, if not neutralized, is D002; check your applicable international, national, regional and local ordinances accordingly.

- ◆ All *human source and other potentially infectious material* must be appropriately decontaminated or disposed of as infectious material; check your applicable ordinances accordingly.

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

Recommended Unclean Packaging Disposal: Dispose of 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 Unused Product Multi-Modal Transportation: According to US DOT, IATA and UN “Model Regulations,” the **STOPPING SOLUTION** in the kit must be transported as follows:

The acidic component **Stopping Solution** in this kit contains *IN sulfuric acid*; thus, any un-neutralized discarded kit component or waste generated from its use resulting in a corrosive liquid (pH ≤ 2 or an pH ≥ 12.5 per Method 9040 [USEPA Publication SW-846] or Corrodes Steel [NACE Standard TM-01-69]) must be transported as follows:

- Proper Shipping name: **Sulphuric acid [with not more than 51% acid]**
- Hazard Class or Division: **8**
- UN ID Number: **UN 2796**
- Packing group **II**



The **EIA Chromogen (11X)** solution in this product 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.

Recommended Used Product Hazardous Waste Disposal Transportation: Potential air and land transportation information for discarded kit components and waste from this product when used as intended is:

The acidic **Chromogen** is at pH ~1.5 and the *IN sulfuric acid Stopping Solution* is at pH ≤ 2; thus, any un-neutralized discarded kit component or waste generated from their use resulting in a corrosive liquid (pH ≤ 2 per Method 9040 [USEPA Publication SW-846] or Corrodes Steel [NACE Standard TM-01-69]), must be transported as follows:

- Proper Shipping name: **Waste Corrosive Liquid n.o.s.**
- Hazard Class or Division: **8**
- UN ID Number: **UN 1760**
- Packing group **III**



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: 1

Carcinogenicity Categories:

Component R1 contains < 0.1% *Cobalt (II) chloride* (CAS# 7646-79-9, IARC Group 2B and EU Category 2 carcinogen) and *silica quartz* (CAS# 14808-60-7, in dust form is an ACGIH class A2 and IARC Group 1 carcinogen) in a pelletized desiccant sealed packet. Keep the desiccant packet intact as received in the microwell plate component package.

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

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)
 - Subclass 8.2 Category B (skin corrosive, GHS 1B)
 - Subclass 8.3 Category A (eye corrosive)
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 Corrosion
 - Serious Eye Damage
 - 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

<u>Country(s) or region Inventory name</u>	<u>In Compliance (yes/no)*</u>
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

Hydrogen peroxide, CAS# 7722-84-1; Revision Date: 1993-04-24

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 (California Safe Drinking Water and Toxic Enforcement Act of 1986): WARNING: This Product Contains a Chemical(s) Known to the State of California to Cause Reproductive Toxicity.

Chemicals known to cause reproductive Toxicity: **Gentamicin Sulfate** CAS# 1405-41-0; classified under the generic class of Aminoglycosides. (Listed October 1, 1992)

SECTION 16: OTHER INFORMATION

Hazard statement abbreviation(s):

Acute Tox. – oral.	Acute toxicity – ingested (swallowed)
Acute Tox. – skn.	Acute toxicity – skin contact
Acute Tox. – inhl.	Acute toxicity - inhaled
Resp. Sens.	Respiratory sensitization
Skin Sens.	Skin sensitisation
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
Eye Damage.	Serious eye damage
Eye Irrit.	Eye irritation
STOT SE	Specific target organ toxicity - single exposure
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Met. Corr	Corrosive to Metals
Fla. Liq.	Flammable liquid
Cat.	Category
H227	Combustible liquid.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H313	May be harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H316	Causes mild skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
P210	Keep away from heat.
P234	Keep only in original container.
P261	Avoid breathing mist / vapors/vapours / spray.
P264	Wash skin thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
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.
P285	In case of inadequate ventilation wear respiratory 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 + P352	IF ON SKIN: 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.
P304 + P341	IF INHALED: If breathing is difficult, 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.
P308 + P313	If exposed or concerned: Get medical advice/ attention.
P310	Immediately call a POISON CENTER or doctor/ physician.
P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313	If eye irritation persists: Get medical advice/ attention.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.
P363	Wash contaminated clothing before reuse.
P370 + P378	In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.
P390	Absorb spillage to prevent material damage.
P391	Collect spillage.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P403 + P235	Store in a well-ventilated place. Keep cool.
P405	Store locked up.
P406	Store in corrosive resistant stainless steel container with a resistant inner liner.
P501	Dispose of contents and container in accordance to local, regional, national and international regulations.
P501	Dispose of this material and its container to hazardous or special waste collection point.

Caution: Contains human source material. Handle as if capable of transmitting potentially infectious agents (*Standard and Universal Precautions*).

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. 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 US HCS, EC CLP 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 if available and summaries]
 European Community (EC) 2008/1272/EC, 2010/453/EC, 2006/1907/EC Regulations
 Australian Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals (Section 274 of the Work Health and Safety Act)
 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*
 PAN Pesticides Database – Chemical Studies on Aquatic Organisms
 Australian Inventory of Chemical Substances (ACIS) Listing
 California Proposition 65

Key / legend to abbreviations and acronyms used in the safety data sheet:

ACGIH – American Conference of Governmental Industrial Hygienists
 ACIS – Australian Inventory of Chemical Substances
 ANSI – American National Standards Institute
 CAS – Chemical Abstracts Service
 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, Canada
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.

Bio-Rad Laboratories

Department issuing SDS: Environmental Health and Safety.

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

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

Contact 24/7/365: 1-800-424-9300

Contact Local Bio-Rad Agents for general information:

Australia , Bio-Rad Laboratories Pty. Ltd., Level 5, 446 Victoria Road, Gladesville NSW 2111 • Phone 61-2-9914-2800 • Telefax 61-2-9914-2888 • 24h/365d: 61-2-9914-2800
Austria , Bio-Rad Laboratories Ges.m.b.H., Hummelgasse 88/3-6, A-1130 Vienna • Phone 43-1-877-8901 • Telefax 43-1-876-5629 • 24h/365d: 43-1-877-89 01
Belgium , Bio-Rad S.A.-N.V. Begoniastraat 5, B-9810 Nazareth Eke • Phone 32-9-385-5511 • Telefax 32-9-385-6554 • 24h/365d: 09-385-5511
Brazil , Bio-Rad Laboratórios Brasil Ltda, Rua Alfredo Albano da Costa, 100, sl 1, 2 e 3, Lagoa Santa, CEP: 33.400-000 • Phone +55 (31)3689-6600 • Telefax +55 (31)3689-6611 • 24h/365d: (11) 99118 7957
Canada , Bio-Rad Laboratories, Ltd., 2403 Guénette Street, Montréal, Québec H4R 2E9 • Phone 1-514-334-4372 • Telefax 1-514-334-4415 • 24h/365d: 514-334-4372
China , Bio-Rad Laboratories Shanghai Ltd. 3rd Floor, #18 Dong Fang Road, Bldg E, Poly Plaza, Pudong, Shanghai, PRC 200120 • Phone 86-21-61698500 • Telefax 86-21-61698599 • 24h/365d: 86-21-63052255
Czech Republic , Bio-Rad spol. s r.o., Nad ostrovem 1119/7, 147 00 Prague 4 • Phone 420-241-430-532 • Telefax 420-241-431-642 • 24h/365d: 224 919 293
Denmark , Bio-Rad Laboratories, Symbion Science Park, Fruebjergvej 3, DK-2100 Copenhagen East • Phone +45-4452-1000 • Telefax +45-4452-1001 • 24h/365d: +45 4452 1000
Finland , Bio-Rad Laboratories, Linnanherrankuja 16, FIN-00950 Helsinki • Phone 358-9-804-22-00 • Telefax 358-9-7597-5010 • 24h/365d: +358 9 804 2200
France , Bio-Rad, 3 boulevard Raymond Poincaré, 92430 Marnes-la-Coquette • Phone 33-1-47-95-60-00 • Telefax 33-1-47-41-91-33 • 24h/365d: +33 (0)1 47 95 60 00
Germany , Bio-Rad Laboratories GmbH, Heidemannstrasse 164, D-80939 Munich • Phone +49-(0)89-318-840 • Telefax +49-(0)89-318-84100 • 24h/365d: 0049-89-31884-0
Greece , Bio-Rad Laboratories M.E.P.E., 2-4 Mesogeion Street, Fourth Floor 115 27 Athens • Phone 30-210-7774396 • Telefax 30-210-7774376
Hong Kong , Bio-Rad Pacific Ltd., Unit 1101, 11/F DCH Commercial Centre, 25 Westlands Road, Quarry Bay • Phone 852-2789-3300 • Telefax 852-2789-1290 • 24h/365d: 852-2789-3300
Hungary , Bio-Rad Hungary Ltd., H-1082 Budapest, Futo Street 47-53, Hungary • Phone +36-1-459-6100 • Telefax +36-1-459-6101 • 24h/365d: 36 1 459 6100
India , Bio-Rad Laboratories (India) Pvt. Ltd., Bio-Rad House, 86-87, Udyog Vihar, Phase IV, Gurgaon, Haryana 122 015 • Phone 1-800-180-1224 • Telefax 91-124-2398115 • 24h/365d: 91-124-2398112/113/114
Israel , Bio-Rad Laboratories Ltd., 14 Homa Street, New Industrial Area, Rishon Le Zion 75655 • Phone 972-3-9636050 • Telefax 972-3-9514129 • 24h/365d: 972-3-951-4127
Italy , Bio-Rad Laboratories S.r.l., Via Cellini 18/A, 20090 Segrate, Milan • Phone +39-02-216091 • Telefax +39-02-21609553 • 24h/365d: 02-216091
Japan , Bio-Rad Laboratories K.K., Tennoz Central Tower 20F, 2-2-24 Higashi-Shinagawa, Shinagawa-ku, Tokyo 140-0002 • Phone 81-3-6361-7070
Korea , Bio-Rad Korea Ltd., 10th Floor, Hyunjuk Building, 832-41, Gangnam-gu, Seoul 135-080 • Phone 82-2-3473-4460 • Telefax 82-2-3472-7003 • 24h/365d: 852-2789-3300
Mexico , Bio-Rad, S.A., Avenida Eugenia 197, Piso 10-A, Col. Narvarte, C.P. 03020 Mexico, D.F. • Phone +52 (55) 54 88 76 70 • Telefax +52 (55) 1107-7246 • 24h/365d: + 52 1 (55) 20 46 47 77
The Netherlands , Bio-Rad Laboratories B.V., Fokkerstraat 2-8, 3905 KV Veenendaal • Phone +31-318-540666 • Telefax +31-318-542216 • 24h/365d: 31-318-540666
New Zealand , Bio-Rad New Zealand, 189 Bush Road Unit B, Albany, Auckland • Phone 64-9-415-2280 • Telefax 64-9-415-2284 • 24h/365d: 64-9-415-2280
Norway , Bio-Rad Laboratories, Nydalsveien 33, 0484 Oslo • Phone +47-23-38-41-30 • Telefax +46(0)8-5551-2780 • 24h/365d: 47 23 38 41 30
Poland , Bio-Rad Polska Sp. z o.o., Nakielska Str. 3, 01-106 Warsaw • Phone 48-22-3319999 • Telefax 48-22-3319988 • 24h/365d: 48 (22) 331 99 85
Portugal , Bio-Rad Laboratories, Lda., Edificio Prime, Ave. Quinta Grande, 53 – Fração 3B Alfragide 26114-521 Amadora • Phone 351-21-472-7700 • Telefax 351-21-472-7777 • 24h/365d: 351-21-472-7700
Russia , Bio-Rad Laboratorii, Russian Federation, Moscow, Varshavskoe sh., 9, Bldg., 1B • Phone: +7-495-721-1404 • Telefax +7-495-721-1412
Singapore , Bio-Rad Laboratories (Singapore) Pte. Ltd., 27 International Business Park, #01-02 iQuest @IBP, Singapore 609924 • Phone 65-6415-3170 • Telefax 65-6415-3189 • 24/7/365: 65-6415-3188 • 24h/365d: 65-6415-3188
South Africa , Bio-Rad Laboratories (Pty) Ltd., 34 Bolton Road, Parkwood, Johannesburg 2193 • Phone 27-11-442-85-08 • Telefax 27-11-442-85-25

Spain, Bio-Rad Laboratories, S.A., C/ Caléndula, 95, Edificio M. Miniparc II, El Soto de la Moraleja, 28109 Madrid • Phone 34-91-590-5200 •
Telefax 34-91-590-5211 • **24h/365d**: 34-91-590-5200

Sweden, Bio-Rad Laboratories A.B., Box 1097, Solna Strandväg 3, SE-171 54, Solna • Phone +46-8-555-127-00 • Telefax +46-8-555-127-80 •
24h/365d: 46-8-55 51 27 00

Switzerland, Bio-Rad Laboratories AG, Pra Rond 23 CH-1785 Cressier • Phone +41 (0)26-674-55-05/06 • Telefax +41 (0)26-674-52-19 •
Email: swiss@bio-rad.com • **24h/365d**: 41-61-7179555

Taiwan, Bio-Rad Laboratories Taiwan Ltd., 14F-B, No. 126 Nan-King East Road, Sec. 4, Taipei, Taiwan 10546 R.O.C. • Phone 886-2-2578-7189 •
Telefax 886-2-2578-6890

Thailand, Bio-Rad Laboratories Ltd., 1st & 2nd Floor, Lumpini I Bldg., 239/2 Rajdamri Rd., Lumpini, Pathumwan, Bangkok 10330 • Phone 662-651-8311 •
Telefax 662-651-8312

United Kingdom, Bio-Rad Laboratories Ltd., Bio-Rad House, Maxted Road, Hemel Hempstead, Herts HP2 7DX • Phone +44 (0)20-8328-2000 •
Telefax +44 (0)20-8328-2550 • **24h/365d**: 020-8328-2000

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