

MATERIAL SAFETY DATA SHEET

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

Product Name: CHLAMYDIA MICROPLATE EIA

Product Number: Catalog 31189 (192 tests)

Intended Use: The Chlamydia Microplate EIA is a qualitative enzyme immunoassay (EIA) for the direct detection of chlamydia antigen in adult male urethral and female endocervical specimens. Provided are a standard assay procedure and a shortened assay procedure, utilizing a qualified Shaker-Incubator (refer to the Package Insert for specifics). For *in vitro* diagnostic use.

Supplier's Name: Bio-Rad Laboratories, Inc.

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

Phone Number: 1-800-2-BIORAD (1-800-224-6723); or (425) 881-8300 (daytime PST)

Emergency Phone Number: This MSDS is listed with CHEMTREC (800) 424-9300. Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

COMPOSITION / INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS (2):

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

Component	Contents
R1: Specimen Treatment Solution 1, 2 X 100 mL	- 0.1N (0.5% v/v NaOH) sodium hydroxide (0.5% NaOH), EINECS/ELINCS No: 215-185-5, CAS# 1310-73-2 [pH > 11] dilution below EU regulated labeling levels (1999/45/EC). - Surfactant, chelator, pH indicator.
R2: Specimen Treatment Solution 2, 2 X 10 mL	- Citrate buffer, reducing agent [pH ~4]. - Contains 1% glutaraldehyde solution [EINECS/ELINCS No: 203-856-5, CAS# 111-30-8 with ≤ 0.1% methanol, EINECS/ELINCS No: 200-659-6, CAS# 67-56-1; Harmful (Xn); R 36/37/38-42/43, S 24/25-28-35-36 (1999/45/EC – dilution < 2% but ≥ 1%)].
R3: Specimen Treatment Solution 3, 2 X 10 mL	- Diluted (≤ 3%) hydrogen peroxide [H ₂ O ₂], EINECS/ELINCS No: 231-765-0, CAS# 7722-84-1 [(S 25-36) ≥ 1% but < 5% dilution not subject to EU labeling according to EU Directives] in a Trizma buffered solution containing: - 2N hydrochloric acid (17% HCl), EINECS/ELINCS No: 231-595-7, CAS#: 7647-01-0 [pH ≤ 3]; Corrosive (C); R 21/22-35-41; S 24/25-26-28-36/37/39-60 (1999/45/EC).
R4: Chlamydia Microplate, 2	- 8-well strip microplate coated with murine monoclonal antibody to chlamydia (in a frame).
R5: Wash Buffer Concentrate (10X), 2 X 100 mL	- A concentrated solution (10X) of 0.03M MOPS - 2M NaCl buffer, 1% Tween 20, Preserved with 0.1% ProClin [®] 300, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9; (0.003% active ingredient), Xi: Irritant; R 43; S 24-35-37.
R6: Polyclonal Antibody, 10 mL	- Rabbit polyclonal antibody directed against chlamydia in buffered saline with bovine serum. - Diluted (0.05%) 8-hydroxyquinoline hemisulfate [C ₁₈ H ₁₄ N ₂ O ₂ • H ₂ SO ₄], EINECS/ELINCS No: 205-137-1, CAS# 134-31-6 [1999/45/EC - dilution < 25%]. - Preserved ≤ 0.4% ProClin [®] 300, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9; Xi: Irritant; R 43; S 24-35-37.
R7: HRP-Conjugate, 10 mL	- Horseradish peroxidase-conjugated (goat anti-rabbit) polyclonal antibody in buffered saline with bovine serum. - Diluted (0.05%) 8-hydroxyquinoline hemisulfate [C ₁₈ H ₁₄ N ₂ O ₂ • H ₂ SO ₄], EINECS/ELINCS No: 205-137-1, CAS# 134-31-6 [1999/45/EC - dilution < 25%]. - Preserved ≤ 0.4% ProClin [®] 300, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9; Xi: Irritant; R 43; S 24-35-37.

R8: OPD Tablets, 12	- o-phenylenediamine dihydrochloride tablets [C ₆ H ₈ N ₂ – solid], EINECS/ELINCS No: 210-418-7, CAS# 615-28-1; Toxic (T), Environmental Danger (N); R 20/21-25-36-40-43-50/53-68, S 28-36/37-45-60-61 (1999/45/EC).
R9: Substrate Buffer, 120 mL	- Citrate buffer (pH 5.6), 0.03% hydrogen peroxide. - Preserved with 0.01% thimerosal [C ₉ H ₉ HgNaO ₂ S], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R 43-61; S 24/25-28-36-53-60-61 (1999/45/EC – dilution < 0.05%).
R10: Stopping Solution, 22 mL	- 4N H ₂ SO ₄ (20% sulfuric acid w/w), EINECS/ELINCS No: 231-639-5, CAS# 7664-93-9 [pH ≤ 2]; Corrosive (C); R 35-41; S 24/25-26-28-36/37/39-60 (1999/45/EC).
C0: Negative Control, 3 mL	- Phosphate buffered saline (PBS). - Preserved with 0.1% ProClin [®] 300, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9; (0.003% active ingredient), Xi: Irritant; R 43; S 24-35-37.
C1: Positive Control, 3 mL	- Inactivated chlamydia in buffered saline with bovine serum albumin. - Contains 1% formalin [0.4% formaldehyde, EINECS/ELINCS No: 200-001-8, CAS#: 50-00-0 with 0.1% methanol, EINECS/ELINCS No: 200-659-6, CAS# 67-56-1; R 43-68; S 24/25-28-35-36 (1999/45/EC – dilution < 1%)] buffered solution.
Microplate cover, 1	- Plate sealers - Clear plastic sealers.

HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (3):

The following information is furnished for those kit hazardous constituents that require regulatory control or disclosure at the concentration found in the kit. Note that the information here is often based on data from the chemical raw material (LD50, exposure limits, etc.). The kit contains a significantly diluted concentration in an aqueous solution; thus, the assessment below has taken hazard reduction processing into consideration when possible. The EU classification was made according to the latest editions of the EU lists and expanded upon from company and literature data.

Component	Content
Formalin Solution, C1 [≤ 0.4% (v/v) non-gaseous formaldehyde in an ~0.1% (v/v) methanol / water solution]	Hazardous ingredient concentration in raw material: Formaldehyde, 4% v/v; Methanol: 1-1.5% v/v + CAS#: 50-00-0 (100% formaldehyde), 67-56-1 (100% methanol) + RTECS#: LP8925000 (100% formaldehyde), PC1400000 (100% methanol) + LD50 (oral-rat): > 100 mg/kg (100% formaldehyde), 5,628 mg/kg (100% methanol) + LC50 (inhalation-rat): 1000 mg/m ³ (30 min.) (100% formaldehyde), 64,000ppm/4H (100% methanol) + PEL/TLV: 0.75 ppm (100% formaldehyde), 200 ppm (100% methanol) + Listed Carcinogen: TLV A2, NTP 2, IARC 2A (100% formaldehyde) + CA Proposition 65: Chemical known to the State of California to cause cancer; this designation is for formaldehyde gas, not formaldehyde containing solutions (100% formaldehyde) + Flash Point: 185°F / 85°C (10% formalin solution), 52°F / 11°C (100% methanol) + IATA/DOT ID: UN3082 (10% formalin solution) UN1230 (100% methanol) + RCRA Code: U122 (100% formaldehyde), U154, D001 (100% methanol) + HMIS Codes: H=2, F=0, R=1 ++ EINECS/ELINCS No: 200-001-8 (100% formaldehyde), 200-659-6 (100% methanol) + EU Classification: None (due to dilution, < 1%); R 43-68; S 24/25-28-35-36 ++ Formalin solutions (diluted non-gaseous formaldehyde) are significant sensitizers; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. Formalin solutions may reasonably be anticipated to be carcinogenic and reproductive toxins. May be detrimental if in contact with skin or ingested (generally quantities above those found in the kit). After contact with skin, wash with copious water. This material and its container must be disposed of in a safe way and in accordance with local, regional and national regulations. The potential for these adverse health effects is unknown for the highly diluted, small volume of formaldehyde in this kit, but unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions.

<p>Glutaric Dialdehyde, R2 [1% v/v Glutaraldehyde in a 0.001% v/v methanol / water solution]</p>	<p>Hazardous ingredient concentration in raw material: Glutaraldehyde, 4% v/v; Methanol, 1-1.5% v/v + CAS#: 111-30-8 (glutaraldehyde), 67-56-1(100% methanol) + RTECS#: MA2450000 (glutaraldehyde), PC1400000 (100% methanol) + LD50 (oral-rat): 468 and 600 mg/kg (25% glutaric dialdehyde solution) + LC50: NE (25% glutaric dialdehyde solution) + PEL/TLV: 0.2 ppm (ceiling) (25% glutaric dialdehyde solution) + Flash Point: NE (25% glutaric dialdehyde solution) + IATA/DOT ID: NE RCRA Code: Non-RCRA (glutaraldehyde), U154 (100% methanol) + HMIS Codes: H=2, F=0, R=1 ++ EINECS/ELINCS No: 203-856-5 (glutaraldehyde), 200-659-6 (100% methanol) + EU Classification: Harmful (Xn); R 36/37/38-42/43, S 24/25-28-35-36 (< 2% and ≥ 1% glutaraldehyde) ++</p> <p>1%-2% glutaric dialdehyde solutions are harmful if swallowed or upon contact; it is destructive to tissue of the mucous membranes and skin and may cause permanent eye injury, depending on duration of exposure. May cause sensitization by inhalation or skin contact; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals, including triggering asthma. After contact with skin, wash with copious water. Incompatible with strong oxidizers (can react violently) and bases and acids (generates heat). This material and its container must be disposed of in a safe way and in accordance with local, regional and national regulations. The potential for these adverse health effects is unknown for the highly diluted, small volume of glutaric dialdehyde in this kit, but unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions.</p>
<p>Hydrochloric Acid [2N (17% v/v HCl) in R3]</p>	<p>CAS#: 7647-01-0 (100%) + LD50 (oral-rat): NE TLV and PEL: 5 ppm (ceiling) (100%) + RCRA Code: D002 (if not neutralized) ++ HMIS Codes: H=2, F=0, R=1 ++ EU Classification: Corrosive (C); R 21/22-35-41; S 24/25-26-28-36/37/39-60 ++</p> <p>RTECS#: MW4025000 (100%) + LC50 (inhalation-rat): 3124 ppm/2H (100%) + Flash Point: NE IATA/DOT ID: UN1789 (100%) + EINECS/ELINCS No: 231-595-7 (100%) +</p> <p>Relatively concentrated hydrochloric acid solutions are Corrosive; can cause severe burns of the mucous membranes, eyes and skin. Harmful if swallowed or in contact with skin or eyes; can cause permanent eye damage or blindness. In case of contact with eyes, immediately rinse with copious water and seek medical attention. After contact with skin, rinse immediately with plenty of water. Keep away from strong bases and reducing agents. This material and/or its container must be disposed of as hazardous acidic waste. It may be neutralized to pH 5-8 for disposal if trained and equipped to do so; however, always dispose of acidic solutions as required by local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices.</p>
<p>Hydrogen Peroxide [≤ 3% H₂O₂, v/v in R3]</p>	<p>CAS#: 7722-84-1 (Concentrate 30%) + LD50 (oral-rat): 1518 mg/kg (Concentrate 30%) + TLV and PEL: 1 ppm (Concentrate 30%) + RCRA Code: D001, D002 (Concentrate 30%) + HMIS Codes: H=1, F=0, R=1 ++ EU Classification: None (due to dilution, < 5% and ≥ 1% hydrogen peroxide); S 25-36 ++</p> <p>RTECS#: MX0899000 (Concentrate 30%) + LC50: NE Flash Point: NE IATA/DOT ID: UN2014 (Concentrate 30%) + EINECS/ELINCS No: 231-765-0 (Concentrate 30%) +</p> <p>Dilute (3%) hydrogen peroxide solutions can break down to provide oxygen to feed a fire; thus, keep away from flames. 3% hydrogen peroxide may cause slight irritation by all routes of entry, but this potential is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional and national regulations.</p>
<p>8-Hydroxyquinoline, Hemisulfate Salt [C₁₈H₁₄N₂O₂ · H₂O₄S 0.05 % w/v in R6 and R7]</p>	<p>CAS#: 134-31-6 (100%) + LD50 (oral-rat): 1,200 mg/kg (100%) + PEL/TLV: NE RCRA Code: NE HMIS Codes: H=1, F=0, R=0 ++ EU Classification: None (due to dilution, < 20%); S 36 ++</p> <p>RTECS#: VC8260000 (100%) + LC50 (inhalation-rat): > 2,320 (100%) + Flash Point: NE IATA/DOT ID: NE EINECS/ELINCS No: 205-137-1 (100%) +</p> <p>8-hydroxyquinoline, hemisulfate salt may be detrimental by contact and if enough is ingested (quantities above those found in the kit). It is a Suspected reproductive toxin (mutagen) based on limited animal evidence and targets the central nervous system (CNS). The potential for these adverse health effects is unknown for the highly diluted, small volume of 8-hydroxyquinoline, hemisulfate salt in this kit, but unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional and national regulations.</p>

<p>Ortho-phenylene-diamine Dihydrochloride [OPD, solid tablet, C₆H₈N₂ in R8]</p>	<p>CAS#: 615-28-1 (100%) + LD50 (ipr-rat): 290 mg/kg (100%) + PEL/TLV: NE RCRA Code: Non-RCRA HMIS Codes: H=3, F=0, R=0 + EU Classification: Toxic (T), Environmental Danger (N); R 20/21-25-36-40-43-50/53-68, S 28-36/37-45-60-61+</p> <p>O-phenylenediamine dihydrochloride (OPD tablet) is a toxic sensitizer that is highly suspected to be a human carcinogen (CA Proposition 65 listed Carcinogen under the classification o-Phenylenediamine and its salts); risk depends on level and duration of exposure. Prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals, including triggering asthma. Causes irritation of the upper respiratory tract, mucous membranes, eyes and skin. Harmful if inhaled, swallowed or in contact with skin. After contact with skin, rinse immediately with plenty of water. Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment. Spent o-phenylenediamine dihydrochloride is considered a toxic RCRA hazardous waste; therefore, this material and its container must be disposed of as hazardous waste and in accordance with local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices.</p>
<p>ProClin® 300 [0.1% v/v in R5 and C0 and 0.4% v/v in R6 and R7]</p>	<p>Hazardous ingredient concentration in raw material: According to the manufacturer, Supelco, the concentrated preservative is a mixture of 4 ingredients: 2.1-2.9% 5-chlor-2-methyl-4-isothiazolin-3-one (C₄H₄CINOS; CAS# 26172-55-4), 0.6-1.1% 2-methyl-4-isothiazolin-3-one (C₄H₅NOS; CAS# 2682-20-4), 91-94% glycol and 2.1-2.9% modified alkyl carboxylate (no CAS# or formula given for last two). Note that this ratio of active ingredients is listed in 2001/59/EC under Index No: 613-167-00-5 with the CAS# 55965-84-9.</p> <p>RTECS#: NE LD50 (oral-rat): 3600 mg/kg (100%) + PEL/TLV: NE HMIS Codes: H=2, F=0, R=0 ++ EU Classification: Irritant (Xi), R 43; S 24-35-37 (≤ 0.06% and > 0.0015 % Active Ingredient per 2001/59/EC) ++</p> <p>The chemical, physical and toxicological properties have not been thoroughly investigated. At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit). ProClin® 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. This material and its container must be disposed of in a safe way and in accordance with local, regional and national regulations. The potential for these adverse health effects is unknown for the highly diluted, small volume of ProClin® in this kit, but unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions.</p>
<p>Sodium Hydroxide [0.1M (0.5% v/v) NaOH in R1]</p>	<p>CAS#: 1310-73-2 (100%) + LD50 (ipr-mouse): 40 mg/kg (100%) + PEL/TLV: 2mg/m³ (ceiling)(100%) + RCRA Code: D002 (if not neutralized) ++ HMIS Codes: H=1, F=0, R=1 ++ EU Classification: None (due to dilution, < 1%); S 24/25-36 ++</p> <p>Dilute (0.1M) sodium hydroxide alkaline solutions may be detrimental if swallowed and upon contact, particularly to eyes. Keep away from strong acids. Wastes can typically be neutralized to pH 5-8 for disposal; however, always dispose of dilute alkaline solutions in accordance with local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices.</p>
<p>Sulfuric Acid [4N (~20% w/w) H₂SO₄ in R10]</p>	<p>CAS#: 7664-93-9 (Conc. sulfuric acid 100%) + LD50 (oral-rat): 2,140 mg/kg (100%) + PEL/TLV: 1 mg/m³ (100%); STEL: 3 mg/m³ (100%)+ IATA/DOT ID: 2796 (< 51% sulfuric acid solutions) + HMIS Codes: H=2, F=0, R=1 ++ EU Classification: Corrosive (C); R 35-41; S 24/25-26-28-36/37/39-60 ++</p> <p>RTECS#: WS5600000 (100%) + LC50 (inhalation-rat): 510 mg/m³/2H (100%) + Flash Point: NE RCRA Code: D002 (if not neutralized) ++ EINECS/ELINCS No: 231-639-5 (100%) +</p> <p>Relatively concentrated 4N sulfuric acid solutions are CORrosive; can cause severe burns of the mucous membranes, eyes and skin. Harmful if swallowed or in contact with skin; can cause eye permanent damage or blindness. In case of contact with eyes, immediately rinse with copious water and seek medical attention. After contact with skin, rinse immediately with plenty of water. Keep away from strong bases and reducing agents. This material and/or its container must be disposed of as hazardous acidic waste. It may be neutralized to pH 5-8 for disposal if trained and equipped to do so; however, always dispose of acidic solutions as required by local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices.</p>

<p>Thimerosal [Merthiolate Sodium, C₉H₉HgNaO₂S 0.01% w/v in R9]</p>	<p>CAS#: 54-64-8 (Thimerosal powder, 100%) + RTECS#: OV8400000 (100%) + LD50 (oral-rat): 75 mg/kg (100%) + PEL/TLV: 0.01 mg Hg/m³ TWA (skin) (100%) + CA Proposition 65: Chemical known to the State of California to cause reproductive toxicity ++ HMIS Codes: H=2, F=0, R=0 ++ EINECS/ELINCS No: 200-210-4 (100%) + Flash Point: NE LC50: NE IATA/DOT ID: UN2025 (100%) + RCRA Code: D009 (to 0.2 mg/L - USA) ++ EU Classification: Dilution below 1999/45/EC labeling requirement (< 0.05%); R 43-61; S 24/25-28-36-53-60-61 ++</p> <p>Thimerosal (merthiolate sodium) is an organo-mercury biocidal preservative which may be detrimental if enough is ingested, targets the central nervous system (CNS) and is a significant sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. There are ample cases of sensitization resulting from exposure to dilute thimerosal solutions. The chemical, physical and toxicological properties have not been thoroughly investigated. Thimerosal, classified under the generic class of mercury compounds, is known to the State of California to cause developmental toxicity. Avoid exposure. After contact with skin, wash immediately with plenty of water. Mercury compounds are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. Danger of cumulative effects. Avoid release to the environment. Spent mercury-containing solutions with a concentration greater than 0.2 ppm are considered RCRA hazardous waste (D009). This material and its container must be disposed of as hazardous waste and in accordance with local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. (Note: Mercury (Hg) makes up 49.55% of the thimerosal molecule; thus, a component with 0.01% thimerosal contains ~0.005% (50 ppm) mercury w/v).</p>
<p>Chlamydia Positive Control [C1]</p>	<p>Inactivated chlamydia in buffered saline with bovine serum albumin, which has been inactivated and is not considered infectious, should be handled as if capable of transmitting infectious disease, with Universal Precautions in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH <i>Biosafety in Microbiological and Biomedical Laboratories</i>. Employ aseptic technique for personal protection and to avoid product contamination; use of a biosafety cabinet (BSC) may be warranted or desired in certain situations. Avoid splashing, spills and the generation of aerosols. Secure in secondary containment with proper biohazard labeling. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures with appropriate decon agent 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% 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 and national regulations. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions.</p>

+ The Kit Concentration was not tested; the values refer to the solution concentration as tested, designated by percentage within parentheses.
 ++ The Kit Concentration was tested or the values given were estimated for the general diagnostic laboratory usage of the kit reagent dilution.
 NE: Not Established or Unknown (unable to locate data).
 Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity

General Kit Composite Health Hazards:

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

Chemical Constituent Details	Component
Inactivated chlamydia in buffered saline with bovine serum albumin.	C1
Rabbit polyclonal antibody directed against chlamydia in buffered saline with bovine serum.	R6
Horseradish peroxidase-conjugated (goat anti-rabbit) polyclonal antibody in buffered saline with bovine serum.	R7
8-well strip microplate coated with murine monoclonal antibody to chlamydia (in a frame).	R4
0.03M MOPS free acid buffer [3-[N-Morpholino]propanesulfonic acid; C ₄ H ₈ O ₃ N-(C ₂ H ₅) ₃ S-O ₃ H], EINECS/ELINCS No: 214-478-5, CAS# 1132-61-2 [< 20% dilution not subject to EU labeling according to EU Directives].	R5
Diluted (2M) sodium chloride [NaCl], EINECS/ELINCS No: 231-598-3, CAS# 7647-14-5.	R5
Diluted (≤ 1%) Tween [®] 20 [C ₅₈ H ₁₁₄ O ₂₆], EINECS/ELINCS No 585-580-06-X, CAS# 9005-64-5.	R5

- No significant adverse health effects are expected by any route for the Phosphate Buffered Saline (PBS), 2M NaCl, citrate buffer, 0.03% hydrogen peroxide, reducing agent, surfactant, chelator, pH indicator, miscellaneous salts, buffers, antibodies, conjugates, water, dyes, catalytic or other non-reactive ingredients, in the kit volumes and/or concentrations present.

- ◆ According to the concept of Universal Precautions (29 CFR 1910.1030), all human blood and certain human body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens. No known test method can offer complete assurance that products derived from human blood will not transmit infection; thus, they should be handled as though they contain an infectious agent. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.

EMERGENCY FIRST AID MEASURES (4):

Health Effects:	Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Skin contact may result in dermatitis. Causes burns. Risk of serious damage to eyes. May cause allergic skin reaction upon repeated exposure. May be toxic to developing fetus, generally at concentrations and volumes that greatly exceed that of this kit.
Eye Contact:	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
Skin Contact:	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
Inhalation:	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively.
If Swallowed:	If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
Notes to Physician:	According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered hepatitis B vaccination prior to working with human source material.

FIREFIGHTING MEASURES (5):

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

ACCIDENTAL RELEASE MEASURES (6):

- ◆ Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.
- ◆ In the event of a hazardous material spill, contain the spill if it is safe to do so and immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.
- ◆ 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.
- ◆ Wear appropriate PPE. Immediately, and on-site if possible:
 - Decontaminate biohazard/human source material spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon agent/disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% ethanol or isopropanol, an iodophor (such as Wescodyne Plus) or a phenolic, etc.).

- Neutralize corrosive acidic spills with the appropriate *acid adsorbent* product.
- Neutralize corrosive alkaline spills with the appropriate *base adsorbent* product.
- Absorb thimerosal-containing reagents; handle and dispose of as RCRA hazardous waste.
- ◆ Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows, acid absorbent pads, etc.) which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all local, regional and national regulations.

HANDLING AND STORAGE INFORMATION (7):

- Handling:** This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper Good Laboratory Practices and safety guidelines for handling chemical, biological and laboratory hazards. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per Universal Precautions. Refer to Section 8 for more specifics. Consult with your Environmental Health & Safety Office for assistance.
- Storage:** Store according to product label instructions (generally at 2-8°C).
- Read and follow all the Precautions and Warnings in the kit product instructions (e.g. *PREPARATION AND STORAGE OF REAGENTS, WARNINGS FOR USERS, PRECAUTIONS FOR USERS*).

EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):

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

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

PHYSICAL AND CHEMICAL PROPERTIES (9):

Appearance:	Variable, generally aqueous liquids. Exceptions are the solid microtiter plate and related materials. Exception: The OPD tablets are a white to off-white solid.
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.
Flash Point:	Not applicable.
Auto Igniting:	Product is not known to be self-igniting.
Danger of Explosion:	Product is not known to present an explosion hazard.
Boiling Point:	Not applicable.
Melting Point:	Not applicable.
Solubility:	The liquid chemical components are soluble in water. The acidic solutions may release heat. The alkali solutions may release heat.
pH:	Most of the liquid chemical components are between pH 5 and 9. Exceptions are the following acidic solutions: Specimen Treatment Solution 2 at pH ~4 Specimen Treatment Solution 3 at pH ~3 Stopping solution at pH ≤ 2 Exceptions are the following alkali solutions: Specimen Treatment Solution 1 between pH 10 and 12
Specific Gravity:	Approximately 1

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

STABILITY AND REACTIVITY INFORMATION (10):

Stability:	Stable under ordinary conditions of use and storage.
Conditions to Avoid:	None known when used as intended.
Materials to Avoid:	Do not allow the acidic solutions to come in contact with strong bases, oxidizing agents and metals.
Hazardous Decomposition Products:	May release toxic oxides of carbon, nitrogen and sulfur or toxic hydrogen chloride gas.
Hazardous Polymerization:	Has not been reported to occur.

TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):

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

Acute Health Effects

Toxicity: Harmful in contact with skin. Harmful to eyes upon contact; in case of contact with eyes, immediately rinse with copious water and seek medical attention. Harmful if enough is ingested (generally quantities above those found in the kit). Toxic by inhalation, in contact with skin and if swallowed. May cause injury, blindness or death.

Primary Irritant Effect: A skin and severe eye irritant; prolonged contact may cause eye injury.

Corrosivity: Corrosive, able to cause severe burns of the mucous membranes, skin and eyes; can cause permanent eye damage or blindness. Harmful or lethal if swallowed.

Other Acute Health Effects: Targets the central nervous system (CNS), lungs, gastrointestinal tract, liver, kidneys and blood (large or prolonged dosages). Risk of serious damage to eyes.

Biohazard Potential

Inactivated chlamydia, though non-infectious, should be handled with Universal Precautions, 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*. Patient blood samples tested with this kit represent an unknown, heightened hazard. Employ Universal Precautions; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.

Chronic Toxicity

Sensitization: **Glutaric dialdehyde** and **ortho-phenylene-diamine dihydrochloride** (OPD) may cause sensitization by inhalation or skin contact. **Thimerosal** (organo-mercury compound) is a significant sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. There are ample cases of sensitization resulting from exposure to dilute thimerosal solutions. Contains a small volume of a very dilute, sensitizing preservative (**ProClin® 300**); though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly. Sensitization possible through skin contact; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.

Carcinogenicity: IARC designates **formalin** solution (non-gaseous formaldehyde (~4% in a methanol/water solution) CAS#: 50-00-0 in the carcinogen Group 2A, which specifies, "*The agent is PROBABLY Carcinogenic to Humans.*" Though **ortho-phenylene-diamine dihydrochloride** (OPD), CAS# 615-28-1 (classified under o-Phenylenediamine (CAS# 95-54-5) and its salts) is listed as containing a Chemical(s) Known to the state of California to cause cancer, it is not classifiable as to its carcinogenicity to humans based on its IARC, ACGIH, NTP classification.

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

Additional Toxicological Information

Mercury compounds such as thimerosal (merthiolate sodium), an organo-mercury biocidal preservative, are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities.

Danger of cumulative effects; avoid release to the environment.

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

ECOLOGICAL INFORMATION (12):

Various Harmful Effects:

The ecological information for the dilute organo-mercury preservative, thimerosal (**Substrate Buffer, R9**), has not been thoroughly investigated; however, mercury and its compounds are expected to significantly bioaccumulate. United States regulation considers mercury hazardous to the environment to 0.2 ppm mercury (0.01% thimerosal contains ~50 ppm mercury, which makes up ~50% of the molecule); at or above this level, any waste must be handled as dangerous waste.

The Specimen Treatment Solution 1, Specimen Treatment Solution 3 and Stopping Solution corrosive components are hazardous for drinking water and toxic to aquatic organisms by pH modification if not neutralized.

Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

DISPOSAL CONSIDERATIONS (13):

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional and national regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the kit components may change waste management requirements and options. Contact your Environmental Health & Safety Office for your specific disposal procedures.

Recommended Product Disposal:

Waste containing **thimerosal**, an organo-mercury compound, is a regulated hazardous waste if the final concentration is ≥ 0.2 mg/L = ≥ 0.2 ppm. The components in this kit that contain 0.01% thimerosal equate to 0.005% = 50 mg/L = 50 ppm mercury w/v. If the thimerosal-containing waste has a final concentration that is ≥ 0.2 mg/L = ≥ 0.2 ppm mercury, it requires disposal as a toxic environmental pollutant material in an RCRA approved waste facility (or equivalent); the US RCRA Waste Disposal Code for this waste is D009; check your 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 national, regional and local ordinances accordingly.

Dilute Basic Waste Specimen Treatment Solution 1 pH > 11 may need to be neutralized to pH 5-8 for safe sewer disposal in many areas; check your local and regional ordinances accordingly.

Dilute Acidic Waste Specimen Treatment Solution 2 pH ~4 may need to be neutralized to pH 5-8 for safe sewer disposal in many areas; check your local and regional ordinances accordingly.

Acidic Waste Specimen Treatment Solution 3 pH ≤ 3 & Stopping Solution pH ≤ 2 should be neutralized to pH 5-8 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 national and regional ordinances accordingly.

Spent o-phenylenediamine dihydrochloride is considered a toxic RCRA hazardous waste; therefore, this material and its container must be disposed of as hazardous waste and in accordance with local, regional and national regulations.

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

TRANSPORT INFORMATION (14):

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

Recommended air and land transportation information for discarded kit components and waste from this product when used as intended is:

Acidic Component **Stopping Solutions** in this kit contain **4N sulfuric acid**; thus, any unneutralized discarded kit component or waste generated from its use resulting in a corrosive liquid (pH ≤ 2 or a pH ≥ 12.5 per Method 9040 (USEPA Publication SW-846) or which corrodes steel (NACE Standard TM-01-69) must be transported as follows:

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

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

Acidic Component **Specimen Treatment Solution 3** in this kit contains **2N Hydrochloric acid** (17% v/v HCl); thus, any unneutralized discarded kit component or waste generated from its use resulting in a corrosive liquid (pH ≤ 2 or a pH ≥ 12.5 per Method 9040 (USEPA Publication SW-846) or which corrodes steel (NACE Standard TM-01-69) must be transported as follows:

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

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

Component **Substrate Buffer** in this kit contains approximately 0.005% = 50 mg/L = 50 ppm mercury (w/v) from the 0.01% **thimerosal** preservative. Therefore, any discarded kit components and waste generated from their use which results in a final concentration that is greater than or equal to 0.2 mg/L (ppm) must be transported as follows:

Proper Shipping Name: **Hazardous Waste Liquid n.o.s.**

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

Toxic Component **OPD tablets** (R8) in this kit contain ortho-phenylene-diamine dihydrochloride (OPD), CAS# 615-28-1 and must be transported as follows:

Proper Shipping Name: **Toxic Solid, Organic, n.o.s.**

DOT Class: **6.1** Packing group **III** DOT ID Number: **UN 2811**

REGULATORY INFORMATION (15):

Composite HMIS Rating: Health: 2-3* Flammability: 0 Reactivity: 0-1
 * Health: 3 = OPD Tablets (R8)

California Proposition 65:

WARNING: THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER.

WARNING: THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE REPRODUCTIVE TOXICITY.

Ortho-phenylene-diamine dihydrochloride (OPD), CAS# 615-28-1; classified under o-phenylenediamine (CAS# 95-54-5) and its salts.

Formalin solution (non-gaseous ~4% formaldehyde in a methanol/water solution) CAS#: 50-00-0; classified under formaldehyde gas (CAS# 50-00-0).

Chemicals known to cause reproductive toxicity: Thimerosal (merthiolate sodium), CAS# 54-64-8; classified under the generic class of mercury compounds.

Carcinogenicity Categories:

IARC (International Agency for Research on Cancer): IARC Group 2A, the agent is PROBABLY Carcinogenic to Humans: Formalin solution (non-gaseous formaldehyde ~4% in a methanol/water solution) CAS#: 50-00-0.

NTP (National Toxicity Program): NTP listed as Reasonably Anticipated to be a Human Carcinogen: Formalin solution (non-gaseous formaldehyde ~4% in a methanol/water solution), CAS# 50-00-0.

ACGIH TLV-CAR (Threshold Limit Value established by American Conference of Governmental Industrial Hygienists): ACGIH-TLV Group A2, Suspected Human Carcinogen: Formalin solution (non-gaseous formaldehyde ~4% in a methanol/water solution) CAS#: 50-00-0.

OSHA Subpart Z (Occupational Health and Safety Administration, U.S. Department of Labor): OSHA Regulated Carcinogen: ≤ 0.4% formaldehyde, CAS# 50-00-0.

WHMIS Classification: This MSDS contains the required information in accordance with the WHMIS hazard classification criteria for this product.

Composite WHMIS Hazard Class: Class D1B - Materials causing immediate and serious toxic effects (toxic material).
 Class D2B - Materials causing other toxic effects (toxic material).
 Class E - Corrosive material.

Markings According to European Guidelines: This product has been classified and labeled in accordance with applicable European Community (EC) Directives (refer to 1999/45/EC, 2001/59/EC and 2001/60/EC).

Hazard Designation of Composite Product:

TOXIC (T); CORROSIVE (C); HARMFUL (Xn); IRRITANT (Xi); DANGEROUS FOR THE ENVIRONMENT (N).



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

≤ 1% **Formalin** buffered solution - ≤ 0.4% formaldehyde, EINECS/ELINCS No: 200-001-8, CAS# 50-00-0 with ≤ 0.1% methanol, EINECS/ELINCS No: 200-659-6, CAS# 67-56-1 [R 43-68; S 24/25-28-35-36].

1% **Glutaraldehyde** (< 2% but ≥ 1%) solution - EINECS/ELINCS No: 203-856-5, CAS# 111-30-8 with ≤ 0.1% methanol, EINECS/ELINCS No: 200-659-6, CAS# 67-56-1 [Xn: Harmful; R 36/37/38-42/43; S 24/25-28-35-36].

2N **Hydrochloric acid** (17% HCl), EINECS/ELINCS No: 231-595-7; CAS# 7647-01-0, [C: Corrosive; R 21/22-35-41; S 24/25-26-28-36/37/39-60 (1999/45/EC and 2001/60/EC)].

O-phenylenediamine dihydrochloride tablets, EINECS/ELINCS No: 210-418-7, CAS# 615-28-1; [T: Toxic, N: Dangerous for the environment; R 20/21-25-36-40-43-50/53-68: S 28-36/37-45-60-61].

0.4% / 0.1% **ProClin® 300**, per 2001/59/EC: Index No: 613-167-00-5 with CAS# 55965-84-9 [Xi: Irritant; R 43; S 24-35-37 ($\leq 0.06\%$ and $> 0.0015\%$ active ingredient)].

0.4N **Sodium hydroxide** (2% NaOH), EINECS/ELINCS No: 215-185-5; CAS# 1310-73-2, [Xi: Irritant; R 36/38; S 24/25-26-35-36 (1999/45/EC and 2001/60/EC)].

4N **Sulfuric acid** (20% H₂SO₄ w/w), EINECS/ELINCS No: 231-639-5; CAS# 7664-93-9, [C: Corrosive; R 35-41; S 24/25-26-28-36/37/39-60 (1999/45/EC and 2001/60/EC)].

0.01% **Thimerosal** ($< 0.05\%$), EINECS/ELINCS No: 200-210-4, CAS# 54-64-8 [R 43-61; S 24/25-28-36-53-60-61].

Risk Phrases:

R 20/21	Harmful by inhalation and in contact with skin.
R 21/22	Harmful in contact with skin and if swallowed.
R 25	Toxic if swallowed.
R 35	Causes severe burns.
R 36	Irritating to eyes.
R 36/38	Irritating to eyes and skin.
R 36/37/38	Irritating to eyes, respiratory system and skin.
R 40	Limited evidence of a carcinogenic effect.
R 41	Risk of serious damage to eyes.
R 42/43	May cause sensitisation by inhalation and skin contact.
R 43	May cause sensitisation by skin contact.
R 45	May cause cancer.
R 50/53	Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.
R 53	May cause long-term adverse effects in the aquatic environment.
R 61	May cause harm to unborn child. (Designation is for concentrated thimerosal (mercury compounds), which is diluted to 0.01% in kit components).
R 68	Possible risk of irreversible effects.
Caution	Contains human source material. Handle as if capable of transmitting potentially infectious agents (Universal Precautions).

Safety Phrases:

S 24	Avoid contact with skin.
S 24/25	Avoid contact with skin and eyes.
S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 28	After contact with skin, wash immediately with plenty of soap and water.
S 35	This material and its container must be disposed of in a safe way.
S 36	Wear suitable protective clothing.
S 37	Wear suitable gloves.
S 36/37	Wear suitable protective clothing and gloves.
S 36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S 45	In case of accident or if you feel unwell, seek medical advice immediately.
S 53	Avoid exposure – obtain special instructions before use.
S 60	This material and its container must be disposed of as hazardous waste.
S 61	Avoid release to the environment. Refer to special instructions/safety data sheet.



OTHER INFORMATION (16):

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.

This Revision: Updated existing information.

Contact for general information: Bio-Rad Laboratories, Redmond Operations
Environmental Health & Safety
6565 185th Ave. NE
Redmond, WA 98052
Phone: 425-881-8300 (8 am to 5 pm PST)
www.bio-rad.com

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