



DIAGNOSTIC AUTOMATION, INC.

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MATERIAL SAFETY DATA SHEET

Syphilis (TPA) IgM

IDENTIFICATION OF THE PREPARATION AND COMPANY NAME.

Supplier: Diagnostic Automation Inc.
21250 Califa Street, Suite 102 and 116,
Woodland Hills, CA 91367USA

Emergency Telephone number: Please contact the local hospitals.

Product Name: Treponema pallidum IgM
Catalog No: 1464-6

COMPOSITION/INFORMATION ON INGREDIENTS

Product type: Chemical kit: Enzyme linked immunosorbent assay for the qualitative presumptive detection of IgM antibodies to T. palladium in human serum. Product consisting of assay plates and preparations of different compounds.

This kit contains biological material.

Information of ingredients when in 100% concentration:

1. Human source material (in cut-off calibrators, negative and positive controls)
2. Thiomersal 5 mg/10mL (as a preservative in the controls, cut-off, conjugate, dilution buffer, wash buffer, control antigen),
CAS#: 1464Z, S-phrases: S2-13-28-36-45,R-phrases: R26/27-33 (phrases determined at 100% concentration).
3. stop solution: CAS# 1464Z, S-phrases: S 26 R-phrases: R36/R38
4. 3,3,5,5-Tetramethylbenzidine (TMB), CAS# 1464Z, S 26 R-phrases: R36/R38

Warnings : Irritant (sulphuric acid in stop solution) on user label (primary and secondary packing)

Composition of components expressed in w/w %.

Positive Control: containing inactivated plasma (< 1%) demineralised water (90-95%) saline salt (< 1%), Tween-20 (< 1%) Thiomersal (5 mg/100 mL), BSA (<1%), red dye (<1%).

Negative Control: containing inactivated plasma (<1%), demineralised water (80-90%) saline salts (< 10%), Tween-20 (< 1%) Thiomersal (5 mg/100 mL), BSA (<1%), performance protein (<10%), yellow dye (<1%).

Cut-off Control: containing inactivated plasma (<1%) demineralised water (90-95%) saline salt (< 1%), Tween-20 (< 1%) Thiomersal (5 mg/100 mL), BSA (<1%) and a green dye (<1%).

Conjugate: containing peroxidase (<1%) demineralised water (50- 40%) saline (< 1%), Tween-20 (< 1%), Thiomersal (5 mg/100 mL), BSA (< 1 %), performance protein (< 10%), Glycerol (40-50%).

Control antigen: containing inactivated protein (<1%) demineralised water (50-60%) saline (< 1%), Tween-20 (< 15%),

BSA (<1%), FCS(10%), organic (20-30%) Thiomersal (5 mg/100 mL).

Dilution Buffer: containing demineralised water (90-95%) saline salts (<1%), Tween 20 (<1%), performance protein (< 1%), and Thiomersal (5 mg/100mL) and Bromephenol Blue (<1%).

Wash buffer: containing demineralised water (80-90 %) saline salts (5-10%) Tween-20 (<1%) and Thiomersal (5 mg/100mL)*

TMB Substrate solution : containing 3,3,5,5-Tetramethylbenzidine (0-5%) in aqueous stabilizer solution (85-95%).

Stop Solution: Sulphuric acid 0.5 M. containing demineralised water (90-95%) and sulphuric acid (0-5%), pH < 1.0.

HAZARDS IDENTIFICATION

Label precautionary statements; Irritating to eyes and skin. In case of accident or if you feel unwell, seek medical advice immediately. Keep tightly closed. Sulphuric acid in low concentration is irritating to the eyes and skin.

FIRST AID MEASURES

General protective measures: No specific requirements known, skin and eye contact with the stop solution will cause irritation.

Eye contact: For eye contact with stop solution, flush with plenty of water for at least 15 minutes. For eye contact with test specimens, flush with plenty of water and seek medical attention.

Skin contact: For skin contact with reagent or test specimens, wash with soap and water.

Ingestion: For ingestion of kit reagents or any test specimens, seek immediate medical attention.

FIRE-FIGHTING MEASURES

Extinguishing media: Use standard fire fighting procedures depending on the source of the surrounding fire.

Thermal Decomposition: Packaging material will burn in a fire. No irritating fumes or toxins are released during fire. When heated to dryness TMB will form hazardous decomposition products.

ACCIDENTAL RELEASE MEASURES

After spillage: Decontaminate spill with a bleach solution or appropriate germicide prior to pick up. If material is spilled down drain, flush with a large volume of water to prevent Thiomersal build up in copper or lead-plumbing. Decontamination procedures are available on request.

Absorbent material: If stop solution spills, neutralize with soda ash, lime or a commercial available acid neutralizer.

Special measures to limit damage: No special measures.

HANDLING AND STORAGE

Handling: Read the package insert before use. Always follow good laboratory practices when using this product. Handle all test specimens as if capable of transmitting disease. Employee exposure to human source material is regulated under the Code of Federal Regulations 29 CFR 1910.1030. Refer to the Centre for Disease Control/ National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories".

Storage: The product should be stored in a closed room at a temperature of in between 2 and 8 °C. No special ventilation is necessary. Keep tightly closed.

EXPOSURE CONTROL/PERSONAL PROTECTION

Respiratory protection: protection measures may be required as laboratory conditions indicate.

Eye protection: Goggles may be required as laboratory conditions indicate

Hand protection: Barrier gloves (rubber)

Skin protection: Laboratory coat

No special ventilation is necessary, however, a bio-safety cabinet, as recommended in the CDC/NIH manual, may be necessary if there is a possibility of aerosolization of test specimens or controls.

PHYSICAL AND CHEMICAL PROPERTIES

Properties	Sulphuric acid (>5%)	TMB (<5%)*	Other compounds
<i>Physical state:</i>	Solution	Solution	Solution
<i>Colour:</i>	no colour	Light yellow	miscellaneous
<i>Odour:</i>	no odour	Organic solvent	no odour
<i>pH value:</i>	about pH1,0	about pH4,4-4,8	about pH 8,2
<i>Boiling point:</i>	about 100 °C	about 189 °C	about 100 °C
<i>Melting point:</i>	N.A.	about 8 °C	N.A.
<i>Flash point:</i>	N.A.	about 95 °C	N.A.
<i>Ignition temperature:</i>	N.A.	about 270 °C	N.A.
<i>Explosion limits:</i>	< 0,3	Not determined	N.A.
<i>Vapour pressure:</i>	1,02	< 0,5	< 0,3
<i>Density:</i>	1,1	1,1	1,02
<i>Solubility in water:</i>	very soluble	very soluble	very soluble
<i>Viscosity:</i>	N.A.	N.A.	N.A.

All components in the kit are aqueous based solutions.

STABILITY AND REACTIVITY

Incompatibilities: If disposed down a drain, the Thiomersal in this kit may react with aluminium and reducing agents. Decomposition of Thiomersal can occur when exposed to light.

Hazardous reactions: hazardous polymerization will not occur. Further this product is stable. If involved in a fire, poisonous gas may be produced by the packaging materials. The stop solution will produce oxides and sulphur or hydrogen.

TOXICOLOGICAL INFORMATION

Occupational exposure to this product is not expected to produce adverse human health effects following prudent workplace practices. The human serum components used in the preparation of this chemical kit have been tested by an FDA approved method for the presence of the antibody to HIV 1&2, Hepatitis C and Hepatitis B surface antigen and found to be negative. Because no test method can offer complete assurance that HIV, Hepatitis C, Hepatitis B virus or other infectious agents are absent, specimens and human based reagents should be handled as if capable of transmitting infectious agents. The test wells are coated with inactivated *Toxoplasma gondii* antigen. Caution is advised because of the possible presence of residual virus.

Note: The Centre for Disease Control and Centre for Devices and Radiological Health recommend that potentially infectious agents be handled at the Biosafety level 2.

The following toxicological information concerns the most potentially hazardous ingredients;

1. Sulphuric acid solution (stop solution) is a poison and causes irritation. The oral LD50 (oral rat) for sulfuric acid is 2140 mg/kg (25% solution). LC50 (inhalation rat): 510 mg/m³/2h (calculated on the basis of pure compound).
2. Thiomersal (controls and buffers <0.05% w/w); LD50 : 75 mg/ kg, oral rat, reproductive impairment is demonstrated. No evidence of carcinogenic properties.
3. 3,3,5,5-Tetramethylbenzidine (Substrate solution); The active compound may be absorbed through ingestion. May give irritation to the eyes and skin. May give irritation of the gastrointestinal tract. TMB has shown a possible mutagenic effect in experimental animals (Mice)

ECOLOGICAL INFORMATION

Water hazard class: Accordance with local regulations should be observed. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. TMB is toxic to aquatic organisms. (EC50: 1-10mg/l.). TMB is not readily biodegradable. May cause long-term adverse effects in the aquatic environment. Bio-accumulative potential of TMB: Log Kow 4. 11.

DISPOSAL CONSIDERATIONS

Dispose of through authority facilities or pass to chemical disposal company. Disposable ignitable materials must be incinerated; liquid waste and non-ignitable materials must be decontaminated with sodium hypochlorite at a final concentration of 3 % for at least half an hour. Liquid waste containing acid must be neutralized before treatment. A minimum of one hour at 121 °C is usually considered adequate, though the users must check the effectiveness of their decontamination cycle by initially validating it and routinely using indicators. TMB:EWC code: 16 05 08

REGULATORY INFORMATION

This product does not require special labelling, in accordance with the appropriate international transport regulations (in addition as described in section 14).

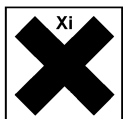
The compounds Thiomersal and 3,3,5,5-tetramethylbenzidine are in low quantities (<5%) present in the preparations. No additional information is needed on the user label according to national legislation. The LD50 value of the preparation is calculated according to section 3.6.1.7.1 of the IATA manual and considered not dangerous.

The compound sulphuric acid is known to cause irritation to the eyes and in low level quantities (1N., 0.5 M). The label "Irritant" is used on the user labels (primary and secondary packing).

Risk phrases: R36/R38: Irritating to eyes and skin

Safety Phrases: S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Symbol on the user-label (Stop solution and kit-package):



Date Adopted	2016-05-18
REF 1464-6	DA-Syphilis (TPA) IgM



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