

MATERIAL SAFETY DATA SHEET**Wampole Laboratories**

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Princeton, NJ 08540

Syphilis IgG

Emergency Telephone Number
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SECTION I – IDENTITY

Product Type: Diagnostic test kit.

Description: An enzyme immunoassay for the qualitative detection of IgG antibodies to *Treponema pallidum* in serum or plasma specimens.

Product Code: 31004U (96 tests), 31004T (960 tests).

Ingredients Potentially Hazardous: 1. *sodium azide* (as a preservative in the High Positive Control, Low Positive Standard, and Negative Control); CAS #: 26628-22-8; Content: 0.1% (each unit); ACGIH TLV (ceiling) - 0.29 ppm as sodium azide and 0.11ppm as hydrazoic acid vapor; NIOSH REL (ceiling) - 0.3 mg/m³ as sodium azide and 0.1 ppm as hydrazoic acid vapor. 2. *Thimerosal* (as a preservative in antibody, conjugate, and Dilution Buffer III); CAS#: 54-64-8; Content: 0.01%. 3. *3-3'-5-5'-tetramethyl-benzidine* (CAS#: 54827-17-7) Content: 2% in *dimethyl sulfoxide* (CAS#: 67-68-5) as an active ingredient in TMB Chromogen.

SECTION II – PHYSICAL/CHEMICAL CHARACTERISTICS

Chemical Characteristics: This kit contains a chemical reagent and biological material stabilized by chemical preservatives.

Appearance: Test kit consisting of microassay plates, controls, buffer, and reagent.

SECTION III – FIRE AND EXPLOSION HAZARD DATA

Condition: No fire or explosion hazards. Packaging material will burn in a fire.

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

SECTION IV – REACTIVITY DATA

Incompatibilities: If disposed down a drain, the sodium azide in this kit may react with lead and copper plumbing to form highly explosive metal azides.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Not applicable.

Hazardous Decomposition or Byproducts: This product is stable. If involved in a fire, the packaging materials may produce poisonous gas.

SECTION V – TOXICOLOGY/HEALTH EFFECTS

Occupational exposure to this product is not expected to produce adverse human health effects following prudent workplace practices. The control sera included in this kit are of human origin. They have been screened for HBsAG, HIV 1, HIV 2, and HCV antibodies and found to be negative. The *Treponema pallidum* antigen has been inactivated during the production process. Patient specimens, kit controls, and all fluid wastes and aspirates should be handled as if they contain infectious material, in accordance with national guidelines for Biosafety/Hazards Group 2 and OSHA blood borne pathogen rule.

The TMB Chromogen is stabilized in dimethyl sulfoxide, which can irritate the skin and mucous membranes.

SECTION VI – FIRST AID

Route of Entry: Accidental ingestion is possible.

Medical Conditions Generally Aggravated by Exposure: No specific information known.

Emergency and First Aid Procedures:

- For ingestion of reagents or test specimens, seek immediate medical attention.
- For eye contact with reagent or test specimens, flush with plenty of water and seek medical attention.
- For skin contact with reagent or test specimens, immediately wash with soap and water.

SECTION VII – PRECAUTIONS FOR SAFE HANDLING

General: Read the package insert. Always follow good laboratory practices when using this product. Handle all test specimens as if capable of transmitting disease. Do not pipette by mouth. Avoid sharp liquid handling devices, which may puncture the skin. Do not smoke, eat, or drink in the laboratory area and wash hands thoroughly on completion of a manipulation. Employee exposure to human source material is regulated under the Code of Federal Regulations 29 CFR 1910.1030.

Steps to Be Taken in Case Material is Spilled: If material is spilled down drain, flush with a large volume of water to prevent azide buildup on copper or lead plumbing. Decontamination procedures are available on request.

Waste Disposal Method: All containers and solution for disposal should be autoclaved at 121.5°C for 15 minutes. Liquid wastes should be mixed with sodium hypochlorite solution to a final concentration of 1.0% then left for 30 minutes for decontamination to be completed. Place material in a sealed container and dispose of in accordance with applicable environmental regulations. Liquid wastes containing acid must be neutralized with the appropriate base before mixing with sodium hypochlorite. Spillages should be wiped up immediately using absorbent paper towels, which should be subsequently, be sealed in waterproof bags, and incinerated. Residual contamination should then be scrubbed with an approved laboratory disinfectant.

SECTION VIII – CONTROL MEASURES

Personal Protective Equipment: Barrier gloves, eye protection, and laboratory coat are required as laboratory conditions indicate.

Ventilation: A biosafety cabinet, as recommended in the CDC/NIH manual, may be necessary if there is a possibility of aerosolization of test specimens.