



MATERIAL SAFETY DATA SHEET
ENZY-WELL TREPONEMA IgM
(According to 2001/58/CE and 1999/45/CE)

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1. IDENTIFICATION

Product name: **DIESSE ENZY-WELL TREPONEMA IgM**

Catalogue numbers: **91051**

Use of product: Immunoenzymatic capture method for the qualitative determination of IgM-class antibodies to Treponema pallidum in human serum.

Manufacturer/Supplier: DIESSE Diagnostica Senese SpA

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2. COMPOSITION/INFORMATION ABOUT THE COMPONENTS

Microplate: Microplate coated with anti-human IgM monoclonal antibodies.

Dangerous components: Does not contain hazardous substances.

**Positive Control Serum,
Cut-Off Control Serum,
Negative Control Serum:** Diluted human serum in phosphate buffer 0.01 mol/L with BSA 1% and sodium azide 0.09%.

Sample Diluent 10: PBS containing proteins 1% w/v and sodium azide 0.09%, containing methyl orange as dye

Dangerous components:

Name:	Sodium azide
CAS No:	26628-22-8
EC No:	247-852-1
EC Index No:	011-004-00-7 Very Toxic
Concentration:	0.09 %

Dangerous components:

Name:	Methyl orange
CAS No:	547-58-0
EC No:	208-925-3
EC Index No:	-
Concentration:	0.002%

Conjugate: Purified recombinant proteins of Treponema pallidum conjugated to peroxidase, in phosphate buffer with phenol 0.05% and Bronidox 0.02%.

Dangerous components:

Name:	Phenol
CAS No:	108-95-2
EC Number:	203-632-7
EC Index No:	604-001-00-2
Concentration:	0.05%

Dangerous components:

Name:	Bronidox
CAS No:	30007-47-7
EC Number:	250-001-7
EC Index No:	-
Concentration:	0.02%

Wash Buffer 10x: Phosphate buffered saline, concentrated 10 times; contains Brij 0.5%.

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Substrate: Tetramethylbenzidine and hydrogen peroxide stabilized in citrate buffer, pH 3.8.

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Stop Solution: Solution used to stop enzymatic reaction in ELISA tests; 0.3 mol/L solution of H₂SO₄.

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3. HAZARDS IDENTIFICATION

Sodium Azide is an irritant. Avoid contact with components containing azide. Do not ingest or inhale. In the concentrations present in the reagents, sodium azide is below the regulatory threshold limits according to Regulation (EC) No1272/2008

Methyl orange is toxic if swallowed. Do not ingest. This substance is not classified in the Regulation (EC) No1272/2008.

Phenol is toxic and corrosive. Do not ingest or inhale. In the concentrations present in the reagents, phenol is below the regulatory threshold limits according to the Regulation (EC) No1272/2008.

Bronidox is irritant to skin or by ingestion, slightly irritant to eyes and by inhalation. Do not ingest or inhale. This substance is not classified in the Regulation (EC) No1272/2008.

The reagents contain human serum which have been tested and confirmed negative for HBsAg and antibodies directed against HIV. Since no test method offers complete assurance that infectious agents are absent, these reagents should be treated as potentially infectious.

4. FIRST AID

General: In case of doubt or when symptoms of feeling unwell persist, seek medical attention.

Inhalation: Supply with fresh air or oxygen. Consult doctor if discomfort persists.

Skin contact: Wash skin with plenty of water. Remove contaminated clothing and shoes. Seek medical assistance.

Eye contact: Flush eyes with plenty of water for at least 15 minutes. If any irritation persists, seek medical assistance.

Ingestion: Wash out mouth with plenty of water. Give large amount of water to drink. Seek medical assistance.

5. FIRE FIGHTING MEASURES

Precautions during fire: Avoid inhalation of fumes

Suitable extinguishing media: Water spray, carbon dioxide, or fire retardant foams and powders.

Special fire-fighting procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Individual precautions: Wear Protective clothing for the prevention of skin and eye contact.

Environmental precautions: Dispose of any contaminated material in biohazardous disposal units and in accordance with established safety procedures.

Cleaning methods: Wipe up spills with absorbent paper, then clean area with a concentrated chlorine solution. Dispose contaminated material as waste following the recommendations under section 13.

7. HANDLING AND STORAGE

Handling: All clinical specimens and any infected or potentially infected material should be handled as though potentially infectious.

Storage: Store at 2 – 8°C



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Specific Use: This product is for laboratory use only.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

General protective and hygienic measures: Keep away from food and beverages. Wash hands before breaks and after finishing the work.

Breathing protection: Not required

Hands protection: Protective gloves recommended

Eyes protection: Protective goggles recommended

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: Blue (Positive Control); Light blue (Cutoff Control); Transparent (Negative control); Pinkish (Conjugate); Light orange (Sample diluent)

Physical state: Liquid

Odor: Odorless

Solubility in water: Fully miscible

10. STABILITY AND REACTIVITY

General information: Stable under the recommended handling and storage conditions (see section 7).

Dangerous reactions: No dangerous reactions known.

Hazardous decomposition products: No dangerous decomposition products known

11. TOXICOLOGICAL INFORMATION

Should not be ingested. The toxicity is low. No evidence is known of carcinogenicity, mutagenity or reproductive toxicity.

12. ECOLOGICAL INFORMATION

Water toxicity: Slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach sewage system.

13. DISPOSAL CONSIDERATIONS

Residues of test materials are generally considered as hazardous waste. All such materials should be disposed of in accordance with established safety procedures.

14. TRANSPORT INFORMATION

No specific recommendations

15. REGULATORY INFORMATION

Directive 2001/58/EC
Regulation (EC) No1272/2008.



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16. OTHER INFORMATION

Training : This product should be handled only by technically qualified individuals.
The contents of this MSDS should be known before use.

Restrictions on Use: This product is for laboratory use only.

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