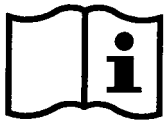
Product information

Information about other products is available at: www.ibl-america.com



Useŕs Manual

Treponema pallidum (Syphilis) IgM ELISA

REF **IB79829**

Σ **96 wells**

RUO For Research Use Only – Not for Use in Diagnostic Procedures

Manufactured For:
Immuno-Biological Laboratories, Inc. (IBL-America)
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V 17-01/23a-RUO / JL
Updated 230816

Please use only the valid version of the package insert provided with the kit.

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Introduced modifications	
The following changes have been made in comparison to the previous version:	
Detailed editorial revision. Changed wording in several chapters.	
4.4 Reagent Preparation:	Stability of wash solution changed to 1 week at 20 °C to 25 °C (before: 4 weeks at 2 °C to 8 °C)
9.1 Specificity of Antigen:	More detailed information
9.2 Sensitivity:	Updated and additional data
9.3 Method Comparison:	Addition of “Positive and Negative Percent Agreement”, previous chapters for Specificity and Sensitivity removed.
9.4.3 Between-Lot Precision:	Added
12 LITERATURE:	Updated

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1 INTRODUCTION

1.1 Intended Use

The **Treponema pallidum IgM Enzyme Immunoassay Kit** provides materials for the determination of IgM-class antibodies to Treponema pallidum in human serum or plasma (EDTA, lithium heparin or citrate plasma).

For Research Use Only – Not for Use in Diagnostic Procedures. For laboratory professional use.

2 PRINCIPLE OF THE TEST

The Treponema pallidum IgM ELISA is a solid phase enzyme-linked immunosorbent assay (ELISA). Samples are diluted with Sample Diluent and additionally incubated with IgG-RF-Sorbent to remove rheumatoid factor and potentially interfering IgG. Microtiter wells as a solid phase are coated with Treponema pallidum antigen. Pre-treated samples and ready-to-use controls are pipetted into these wells. During incubation Treponema pallidum specific antibodies of controls and positive samples are bound to the immobilized antigens. After a washing step to remove all unbound material enzyme conjugate (horseradish peroxidase conjugated anti-human IgM antibodies) is added to the wells. During the second incubation the conjugate binds to the captured analyte specific antibodies resulting in the formation of enzyme-linked immune complexes. After a second washing step to remove unbound conjugate, the solid phase is incubated with the substrate solution. The colorimetric reaction is stopped by addition of stop solution, and optical density (OD) of the resulting yellow product is measured. The intensity of this color is directly proportional to the amount of specific antibodies in the sample. Optical density at 450 nm/620 nm is read using an ELISA microtiter plate reader.

3 WARNINGS AND PRECAUTIONS

- This kit is for research use only. Not for Use in Diagnostic Procedures. For laboratory professional use only.
- Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
- Do not mix or use components from kits with different lot numbers. It is advised not to interchange wells of different plates even of the same lot. The kits may have been shipped or stored under different conditions and the binding characteristics of the plates may result slightly different.
- Do not use reagents beyond expiry date as shown on the kit labels.
- Do not reuse microtiter wells.
- Reagents of other manufacturers must not be used together with the reagents of this test kit.
- All reagents in this kit are clear liquids, substrate solution is clear and colorless. Changes in its appearance may affect the performance of the test. In that case, contact IBL-America.
- Microbial contamination of reagents or samples may give false results.
- Allow the reagents to reach room temperature (20 °C to 25 °C) before starting the test. Temperature will affect the optical density readings of the assay. However, values for the patient samples will not be affected.
- All indicated volumes must be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiter plate readers.
- Use reservoirs only for single reagents. This especially applies to the substrate reservoirs. Using a reservoir for dispensing a substrate solution that had previously been used for the conjugate solution may turn solution colored. Do not pour reagents back into original vials as reagent contamination may occur.

General Precautions

- Follow laboratory quality assurance and laboratory safety guidelines.
- Never pipet by mouth and avoid contact of reagents and samples with skin and mucous membranes.
- Do not smoke, eat, drink, or apply cosmetics in areas where samples or kit reagents are handled.
- Wear lab coats and disposable latex gloves when handling samples and reagents and where necessary safety glasses.

Biohazard Information

- All reagents of this test kit which contain human serum or plasma have been tested and confirmed negative for HIV I/II, HBsAg and HCV by FDA approved procedures. However, no known test method can offer total assurance that no infectious agent is present.
- The device contains material of animal origin, which is certified apparently free of infectious or contagious diseases and injurious parasites.
- Bovine components originate from countries where BSE (Bovine spongiform encephalopathy) has not been reported.
- All materials and samples of human or animal origin must be handled as if capable of transmitting infectious diseases.
- Handling must be done in accordance with the procedures defined by appropriate national biohazard and safety guideline or regulation. Waste must be discarded according to local rules and regulations.

Information to Chemical Hazards and Hazard Classification

- Some reagents contain preservatives in non-declarable concentrations. Nevertheless, in case of contact with eyes or skin, flush immediately with water.
- Substrate Solution contains an ingredient in non-declarable concentrations which causes serious eye irritation. In case of possible contact with eyes, rinse immediately carefully and thoroughly with eye wash or water. After contact with skin, wash with plenty of water. Take-off contaminated clothing and wash it before reuse.
- Avoid contact with Stop Solution containing < 2 % H_2SO_4. It may cause skin irritation and burns.
- Chemicals and prepared or used reagents must be treated as hazardous waste according to the national safety guideline or regulation.
- This product does not contain substances which have carcinogenic, mutagenic or toxic for reproduction (CMR) properties.

All reagents of this test kit do NOT contain hazardous substances in concentrations to be declared, a classification and labelling is not required. For detailed information, please refer to the Safety Data Sheet, which is available upon request directly from IBL-America.

4 MATERIALS

4.1 Materials Provided with the Kit

1. **SORB MT Microtiterwells**, 12 x 8 (break apart) strips, 96 wells; Wells coated with Treponema pallidum antigen.
2. **SAM DIL Sample Diluent *** 1 vial x 100 mL, ready to use; colored yellow; pH 7.2 ± 0.2.
3. **IgG-RF SORB IgG-RF-Sorbent *,** 1 vial x 6.5 mL, ready to use; colored yellow; Contains anti-human IgG-class antibody.
4. **CAL C Pos. Control ***, 1 vial x 2.0 mL, ready to use; colored yellow, red cap.
5. **CAL A Neg. Control *,** 1 vial x 2.0 mL, ready to use; colored yellow, yellow cap.
6. **CAL B Cut-off Control ***, 1 vial x 2.0 mL, ready to use; colored yellow, black cap.
7. **ENZ CONJ Enzyme Conjugate ***, 1 vial x 20 mL, ready to use; colored red, antibody to human IgM conjugated to horseradish peroxidase.
8. **SUB TMB Substrate Solution**, 1 vial x 14 mL, ready to use, Contains 3,3‘,5,5‘-tetramethylbenzidine (TMB). Keep away from direct sun light.
9. **STOP SOLN Stop Solution**, 1 vial x 14 mL, ready to use, contains <2% H_2SO_4,
   Avoid contact with the stop solution. It may cause skin irritations and burns.
10. **WASH SOLN 20x Wash Solution ***, 1 vial x 30 mL; 20X concentrate; see „Preparation of Reagents“.
11. **1 x Cover foil, 1 x Instructions for Use, 1 x Certificate of Analysis (CoA)**

* contain(s) non-mercury preservative

4.2 Material required but not provided

- A microtiter plate calibrated reader (450 nm, with reference wavelength at 620 nm to 630 nm)
- Calibrated variable precision micropipettes
- Incubator 37 °C
- Manual or automatic equipment for rinsing wells
- Vortex tube mixer
- Absorbent paper
- Freshly distilled water
- Timer

4.3 Storage Conditions and stability of the Kit

Unopened kits and reagents as well as **opened reagents** must be stored at 2 °C to 8 °C.
The microplate must always be stored in the resealable aluminum pouch containing a desiccant. Do not open the pouch until it has reached room temperature. The microtiter plate consists of 12 individual strips. Each strip can be divided into 8 individual wells. Unused wells must be immediately returned to the aluminum pouch with the desiccant and stored again tightly resealed at 2 °C to 8 °C. Once opened, reagent vials must be closed tightly again.

	Storage Temperature	Stability
Unopened kits and unopened reagents	2 °C to 8 °C	Until the expiration date printed on the label. Do not use reagents beyond this date!
Opened kit	2 °C to 8 °C	8 weeks

4.4 Reagent Preparation

Bring all reagents and required number of strips to room temperature (RT, 20 °C to 25 °C) prior to use.

Wash Solution

Add fresh and germ-free distilled water to the 20X concentrated Wash Solution.
Dilute the complete content of the vial 1 + 19 (30 mL Wash Solution + 570 mL distilled water) to a final volume of 600 mL.
If crystals have formed in the wash solution concentrate, ensure that they are completely transferred and dissolved into the solution.
This diluted wash solution must have a pH value of 7.2 ± 0.2.

Stability after dilution:	At 20 °C to 25 °C	1 week

4.5 Disposal of the Kit

The disposal of the kit and all used materials/reagents must be performed according to the national regulations. Special information for this product is given in the Safety Data Sheet, section 13.

4.6 Damaged Test Kits

In case of any severe damage to the test kit or components, IBL-America has to be informed in writing, at the latest, one week after receiving the kit. Severely damaged single components should not be used for a test run. They have to be stored until a final solution has been found. After this, they should be disposed according to the official regulations.

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5 SAMPLE COLLECTION, STORAGE AND PREPARATION

The following sample material can be used in this test:

Human serum or plasma (EDTA plasma, lithium heparin plasma or citrate plasma)

Samples containing sodium azide should not be used in the assay. In general, it should be avoided to use hemolytic, icteric, or lipemic samples. For further information refer to chapter *"Interfering Substances"*.

5.1 Sample Collection

Serum:

Collect blood by venipuncture (e.g. Sarstedt Monovette for serum), allow to clot, and separate serum by centrifugation at room temperature. Do not centrifuge before complete clotting has occurred. Samples that have encountered anticoagulant therapy may require increased clotting time.

Plasma:

Whole blood should be collected into centrifuge tubes containing anti-coagulant (e.g. Sarstedt Monovette with the appropriate plasma preparation) and centrifuged immediately after collection.

Whole blood should not be frozen before centrifugation.

5.2 Sample Storage

Samples must be stored tightly capped prior to performing the assay. If stored frozen, freeze only once. Thawed samples must be inverted several times prior to testing

Stability	At 2 °C to 8 °C	3 days
	At -20 °C (in aliquots)	Up to 18 months

5.3 Sample Preparation

Before starting the test, samples must first be diluted with Sample Diluent. Afterwards, these prediluted samples are incubated with IgG RF Sorbent to eliminate rheumatoid factors.

1. Dilute each sample **1+50** with Sample Diluent;
   e.g. 10 µL of sample + 0.5 mL of Sample Diluent. **Mix well.**
2. Mix well the IgG-RF-Sorbent before use.
3. Dilute this prediluted sample **1+1** with IgG-RF-Sorbent
   e.g. 60 µL prediluted sample + 60 µL IgG-RF-Sorbent. **Mix well.**
4. **Let stand at room temperature for at least 15 minutes, up to a maximum of 2 hours and mix well again.**

Take **100 µL** of the pre-treated sample for the ELISA. Use only fresh pre-treated samples!

Please note: Controls are ready for use and must not be diluted!

6 ASSAY PROCEDURE

6.1 Procedural Notes

- All reagents and samples must be allowed to come to room temperature (20 °C to 25 °C) before use.
- All reagents must be mixed without foaming.
- Do not interchange caps of reagent vials to avoid cross-contamination.
- Use new disposal plastic pipette tips for each standard, control, or sample in order to avoid carryover.
- To avoid cross-contamination and falsely elevated results pipette patient samples and dispense conjugate without splashing accurately to the bottom of wells.
- Mix the contents of the microtiter plate wells thoroughly to ensure good test results.
- Do not let wells dry during assay; add reagents immediately after completing the rinsing steps.
- Once the test has been started, all steps must be completed without interruption and in the same sequence for each step.
- The enzymatic reaction is linearly proportional to time and temperature.
- Optical density is a function of the incubation time and temperature. Respect the incubations times and temperatures as given in chapter "Test Procedure".

- Before starting the assay, it is recommended that all reagents are ready, caps removed, all needed wells secured in holder, etc. This will ensure equal elapsed time for each pipetting step without interruption.
- During the incubation at 37 °C cover microtiter strips with foil to avoid evaporation.

- **Important note to wash procedure:**
  Washing is critical. Improperly washed wells will give erroneous results. The sensitivity and precision of this assay is markedly influenced by the correct performance of the washing procedure!

- **Test performance using fully automated analysis devices:**
  Automated test performance using fully automated, open-system analysis devices is possible. However, the combination must be validated by the user.

6.2 Test Procedure

The controls serve as internal controls for the reliability of the test procedure. They must be assayed with each test run.
The given test procedure describes manual processing.

Before starting the assay, dilute *Wash Solution*, **prepare samples as described in section 5.3** and mix well before pipetting. For all controls and samples carefully document the distribution on the plate on the Plate Layout Sheet supplied in the kit.

Secure the desired number of microtiter wells in the frame holder.

1. Please allocate at least:
   1 well (e.g. A1) for the *Neg. Control*,
   2 wells (e.g. B1+C1) for the *Cut-off Control* and
   1 well (e.g. D1) for the *Pos. Control.*
   It is left to the user to determine controls and samples in duplicate

2. Pipette
   100 µL of *Neg. Control* into well A1
   100 µL of *Cut-off Control* into wells B1 and C1
   100 µL of *Pos. Control* into well D1 and
   100 µL of each p r e - t r e a t e d sample with new disposable tips into appropriate wells.

3. Cover wells with foil supplied in the kit. Incubate for **60 minutes at 37 °C.**

4. Wash the wells as follows:
   If the wash step is performed manually:
   Briskly shake out the content of the wells.
   Rinse the wells **5 times** with **300 µL** diluted *Wash Solution* per well.

   If an automated plate washer is used:
   Rinse the wells **5 times** with 4**00 µL** diluted *Wash Solution* per well.

   At the end of the washing step, always strike the wells sharply on absorbent paper to remove residual droplets!

5. Pipette **100 µL** Enzyme Conjugate into each well.

6. Incubate for **30 minutes at room temperature (20 °C to 25 °C).**

7. Wash as described in step 4.

8. Pipette **100 µL** of **Substrate Solution** into each well.

9. Incubate for **exactly 15 minutes at room temperature (20 °C to 25 °C) in the dark**.

10. Stop the enzymatic reaction by adding **100 µL** of **Stop Solution** to each well.
    Any blue color developed during the incubation turns into yellow.
    Note: Highly positive samples can cause dark precipitates of the chromogen!

11. Measure the optical density (OD) of the solution in each well at **450 nm (reading) and at 620 nm to 630 nm (background subtraction, recommended)** with a microtiter plate reader. It is recommended that the wells be read **within 30 minutes** after adding the *Stop Solution*.

Note: Record the OD values for each control, and sample in the Plate Layout Sheet.

7 RESULTS

7.1 Validation of the Test Run

The test run may be considered valid provided the following criteria are met:

Neg. Control in A1: OD value **lower than 0.200**
Cut-off Control in B1/C1: OD value **between 0.350 - 0.850**
Pos. Control in D1: OD value **between 0.650 - 3.000**

(OD Pos. Control > OD Cut-off Control).
If these criteria are not met, the test is not valid and must be repeated.

7.2 Results

Where applicable **calculate the mean OD** values of all duplicates.

7.2.1 Determination of Cut-off [CO]

Where applicable **calculate the mean OD** values of all duplicates.

Calculate the mean OD value of the duplicate determination of the Cut-off Control (e.g. in B1/C1).

Example: (0.44 + 0.46)/2 = 0.45 = **CO**

7.2.2 Results in Arbitrary Units [AU]

$$\frac{\text{Mean OD (sample)} \times 10}{\text{CO}} = \text{Arbitrary Units [AU]}$$

Example: $\frac{1.580 \times 10}{0.45} = 35$ AU

7.3 Interpretation

7.3.1 Interpretation of Results in Arbitrary Units [AU]

Cut-off value: 10 AU

NEGATIVE:	<9 AU
GREY ZONE:	9-11 AU
POSITIVE:	>11 AU

7.3.2 Interpretation of Qualitative Results

NEGATIVE Sample (mean) OD value more than 10% below CO
(Mean OD_{sample} <0.9 x CO)

GREY ZONE Sample (mean) OD value from 10 % above to 10% below CO
repeat test 2-4 weeks later – with new sample
(0.9 x CO ≤ Mean OD_{sample} ≤ 1.1 x CO)
Results in the second test again in the grey zone ➔ **NEGATIVE**

POSITIVE Sample (mean) OD value more than 10% above CO
(Mean OD_{sample} > 1.1 x CO)

8 QUALITY CONTROL

The use of control samples is advised to assure the day-to-day validity of results. The controls and the corresponding results of the Quality Control Laboratory are stated in the Certificate of Analyses (CoA) added to the kit. The values and ranges stated on the CoA always refer to the current kit lot and must be used for direct comparison of the results. Apply appropriate statistical methods for analyzing control values and trends. If the results of the assay do not agree with the established acceptable ranges of control materials, results should be considered invalid. In this case, please check the following technical areas: Pipetting and timing devices; photometer, expiration dates of reagents, storage and incubation conditions, aspiration and washing methods. After checking the above-mentioned items without finding any error contact your distributor or IBL-America directly.

9 PERFORMANCE CHARACTERISTICS

9.1 Specificity of Antigen

The antigen used for the Treponema pallidum IgM ELISA shows no cross-reactivity to measured samples with following interfering antigens:

Samples positive to	N	Cross-reaction
Epstein Barr Virus (VCA) IgM	16	no
Borrelia burgdorferi IgM	24	no
Mycoplasma pneumonia IgM	14	no
Toxoplasma pallidum IgM	9	no
Fasciola hepatica	9	no
Echinococcus	7	no
Strongyloides stercoralis	5	no

Samples positive to	N	Cross-reaction
Ascaris	6	no
Entamoeba histolytica	7	no
Schistosoma	5	no
Trichinella	6	no
Toxocara canis	7	no
Giardia lamblia	15	no

9.2 Sensitivity

Analytical sensitivity [Conc. Corresponding to mean OD (Neg. Control) + 2 x SD]	0.491 AU
Limit of Blank	0.433 AU
Measuring Range	0.433 AU – 60 AU
Linear Range	2.06 AU – 60 AU

9.3 Method Comparison

Positive percent agreement (PPA)	100%
Negative percent agreement (NPA)	100%

9.4 Sensitivity

9.4.1 Within-Run Precision

The within-run precision was determined by 20 measurements of each sample covering the measuring range of the ELISA.

Sample	n	Mean OD	CV (%)
1	20	0.374	8.3
2	20	0.243	9.6
3	20	0.509	8.6
4	20	0.941	6.3
5	20	0.937	7.1
6	20	0.665	6.5
7	20	1.301	3.7
8	20	1.351	3.4
9	20	1.436	3.4
10	20	1.958	2.5
11	20	2.076	2.8
12	20	1.622	4.8

9.4.2 Between-Run Precision

The between-run precision was determined in 20 independent runs with 2 replicates per run.

Sample	n	Mean OD	CV (%)
1	40	1.856	2.7
2	40	1.201	3.3
3	40	1.443	2.7

9.4.3 Between-Lot Precision

The between-lot variation was determined by 6 measurements of different samples with 3 different kit lots.

Sample	n	Mean AU	CV (%)
1	18	1.89	12.0
2	18	6.03	5.3
3	18	18.34	7.7
4	18	48.80	4.0

9.5 Linearity

Samples containing different amounts of analyte were serially diluted with Sample Diluent. The percentage recovery was calculated by comparing the expected and measured values for the analyte.

		Sample 1	Sample 2	Sample 3
Concentration (AU)		42.7	34.2	44.6
Average Recovery (%)		97.8	104.9	92.1
Range of Recovery (%)	**from**	86.6	95.1	86.0
	to	112.4	114.2	97.5

10 LIMITATIONS OF USE

Reliable and reproducible results will be obtained when the assay procedure is performed with a complete understanding of the instructions for use and with adherence to good laboratory practice. Any improper handling of samples or modification of this test might influence the results.
Bacterial contamination or repeated freeze-thaw cycles of the samples may affect the optical density values.
In immunocompromised samples serological data only have restricted value.

10.1 Interfering Substances

Hemoglobin (up to 4.0 mg/mL), bilirubin (up to 0.5 mg/mL) and triglyceride (up to 30 mg/mL have no influence on the assay results.

None of the following samples with interference factors will interfere with the ELISA: samples with rheumatoid factor, samples with pregnancy hormones, samples with tumor marker (CYFRA, CA-72-4, CA-21-1, CA-15-3), samples with HAMA, samples with ANA, and samples from elderly people with high amount of proteins.

11 LEGAL ASPECTS

11.1 Reliability of Results

The test must be performed exactly as per the manufacturer's instructions for use. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or other applicable national standards and/or laws. This is especially relevant for the use of control reagents. It is important to always include, within the test procedure, a sufficient number of controls for validating the accuracy and precision of the test. The test results are valid only if all controls are within the specified ranges and if all other test parameters are also within the given assay specifications. In case of any doubt or concern please contact IBL-America.

11.2 Liability

Any modification of the test kit and/or exchange or mixture of any components of different lots from one test kit to another could negatively affect the intended results and validity of the overall test. Such modification and/or exchanges invalidate any claim for replacement. Claims submitted due to customer misinterpretation of laboratory results subject to point 11.2 are also invalid. Regardless, in the event of any claim, the manufacturer's liability is not to exceed the value of the test kit. Any damage caused to the test kit during transportation is not subject to the liability of the manufacturer.

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SYMBOLS USED WITH IBL-AMERICA ASSAYS

Symbol	English	Deutsch	Francais	Espanol	Italiano
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conforme aux normes européennes	Conformidad europea	Conformità europea
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las Instrucciones	Consultare le istruzioni per l'uso
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Ussage Diagnostic in vitro	Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Référence	Número de catálogo	No. di Cat.
LOT	Lot. No. / Batch code	Chargen-Nr.	No. de lot	Número de lote	Lotto no
Σ	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Note warnings and precautions	Warnhinweise und Vorsichtsmaßnahmen beachten	Avertissements et mesures de précaution font attention	Tiene en cuenta advertencias y precauciones	Annoti avvisi e le precauzioni
	Storage Temperature	Lagerungstemperatur	Temperature de conservation	Temperatura de conservacion	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributtore