Atlas Medical

Contract No:Co2403079 **Date:09/03/2024**

Letter of Authorization

Manufacturer: Atlas Medical GmbH
Ludwig-Erhard-Ring 3,
15827Blankenfelde-Mahlow, Germany
Tel: +49 33 70 83 55 030
Email: amug@atlas-medical.com

Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK
Tel: +44 1223 858 910
Fax: +44 1223 858 524
Email: info@atlas-site.co.uk

Middle East Site: Sahab Free Zone Area
P. O. Box 204, Amman 11512, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Agent: San Medico
Republic of Moldova, city Chisina
+37368228890

Atlas Medical, hereby appoint the above mentioned agent to import, register and distribute Atlas Medical Products in Maldova

Appointment Conditions:

1. This appointment is valid for 3 year from the above mentioned date.
2. Either Party can cancel this appointment by giving the other party a 60 day notice.

On behalf of the Manufacturer
General Manager
Haya Amawi

Atlas Medical
Quality Diagnostic Products

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.2

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow GERMANY

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité */ Effective date* **October 9th, 2023 (included)**
Valable jusqu'au */ Expiry date :* **October 8th, 2026 (included)**
Etabli le */ Issued on :* **October 9th, 2023**

DocuSigned by:
Béatrice LYS
EF33BDA9BA...
GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 36655–2
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-1

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites:

French version :
Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:
Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

French version:
Siège social, responsable de la mise sur le marché
English version:
Headquarter, legal manufacturer

****

Sahab Industrial Zone Area
King Abdullah II Industrial City
Amman 11512
JORDAN

French version:
Conception, fabrication et contrôle final
English version:
Design, manufacture and final control

****

2 sites / *2 sites*

DocuSigned by:
Beatrice Lys
FF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Declaration Ref No: DC21-0194

Date: 06.09.2021

CE Declaration of Conformity

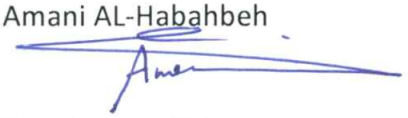
Name and address of Manufacturer	**Atlas Medical GmbH** Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com

Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.00.19.0.0050	Atlas TPHA Kit , 50 Tests	51819
8.00.19.0.0100	Atlas TPHA Kit , 100 Tests	51819
8.00.19.0.0200	Atlas TPHA Kit , 200 Tests	51819

Meets the essential requirments of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And
EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

IVD Categorization	Directive 98/79, Other IVDs (Non-annex II, non-self-test).
Conformity Assesment Route	Directive 98/79/EC , Annex III.
Name , Address and Identification number of notified body	N/A

Date of issuance:	06.September.2021
Place	Atlas Medical GmbH
Signed by: **Position :**	Amani AL-Habahbeh  Regulatory Affairs Manager

Atlas Medical GmbH
Ludwig - Erhard Ring 3
15827 Blankenfelde - Mahlow
Tel. (0049) 33708 - 355030

Atlas Medical

Declaration Ref No: DC21-0193

CE Declaration of Conformity

We,

Atlas Medical GmbH

Head office: Ludwig-Erhard-Ring 3

15827 Blankenefelde-Mahlow Germany

Tel: +49(0)33708355030

Email: info@atlas-medical.com

Middle East Site: Sahab Industrial Zone Area, King Abdullah II Industrial City

Amman 11512, Jordan

Tel.: +962 6 4026468

Fax: +962 6 4022588

Email: info@atlas-medical.com

Declare our responsibility that the following product:

Product Code	Product Name	Class	GMDN code
8.00.18.0.0005	RPR Carbon Antigen Reagent, 5 ml/vial	General-IVD	32450
8.00.18.2.1000	RPR Carbon Antigen 1000ml/bottle	General-IVD	32450
8.00.18.0.0050	RPR Carbon Antigen Kit, 50 Tests	General-IVD	32450
8.00.18.1.0050	RPR Carbon Antigen Kit, 50 Tests, White Glass Slide.	General-IVD	32450
8.00.18.2.0500	RPR Carbon Antigen Kit, 500 Tests (2ml latex, 2x0.5 ml control) Without card.	General-IVD	32450
8.00.18.3.0500	RPR Carbon Antigen Kit, 500 Tests (10ml latex, 2x0.5 ml control) Without card, stirring sticks.	General-IVD	32450
8.00.18.0.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.2.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control +White Glass slide stirring sticks)	General-IVD	32450
8.00.18.0.0025	RPR Carbon Antigen Kit, 25 Tests (0.5ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.0.0150	RPR Carbon Antigen Kit, 150 Tests	General-IVD	32450
8.00.18.0.0200	RPR Carbon Antigen Kit, 200 Tests	General-IVD	32450
8.00.18.0.0250	RPR Carbon Antigen Kit, 250 Tests	General-IVD	32450

Atlas Medical Quality Products

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	September.2021	06.09.2021		

Amin Al-Habashneh
RA Manager

Atlas Medical

Declaration Ref No: DC21-0193

8.00.18.0.0500	RPR Carbon Antigen Kit,500 Tests	General-IVD	32450
8.00.18.0.1000	RPR Carbon Antigen Kit, 1000 Tests	General-IVD	32450
8.00.18.4.0500	RPR Carbon Antigen Kit,500 Tests (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.5.0500	RPR Carbon Antigen Kit, 500 Tests, (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.8.0500	RPR Carbon Antigen 500 Test (10ml reagent) without Control's.	General-IVD	32450
8.00.18.9.0050	RPR Carbon Antigen Kit, (5x10ml Reagent,2x2ml Control) , white glass Slide, Stirring Stick.	General-IVD	32450
8.33.04.0.0001	RPR Positive control	General-IVD	32450
8.33.04.1.0001	RPR Positive control ,Bulk	General-IVD	32450
8.33.04.0.0100	RPR Positive control(100ml/vial)	General-IVD	32450
8.33.04.0.0500	RPR Positive control(500ml/bottle)	General-IVD	32450
8.33.08.0.0001	RPR Negative control	General-IVD	32450

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate:

Certificate N^0.: 36655 rev 1

Expiry Date: October 8 th.2023

and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I

And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016

EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,

EN 13612:2002, EN 13641:2002 , EN 13975:2003, ISO 13485:2016

And

Intended for In-Vitro Professional use only.

This Declaration includes the batches produced beyond this day according to the product Lot Log.

Manufacturer

Atlas Medical GmbH

Ludwig-Erhard-Ring 3

15827 Blankenefelde-Mahlow Germany.

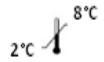
Atlas Medical
Quality Diagnostic Products

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	September.2021	06.09.2021	Amer Al-Habahbeh RA Manager	

Atlas Medical CE

RPR Carbon Antigen

IVD ***For In-Vitro diagnostic and professional use only***



Store at 2 to 8 °C

***INTENDED USE**

A manual rapid plasma reagin carbon test for the qualitative and semi-quantitative detection of non-treponemal antibodies against Syphilis in human serum and plasma to provide serological evidence of past/current Syphilis infections when preceeded by a positive treponemal test. Not to be used as a screening tool for blood or tissue donations.

INTRODUCTION

Syphilis is a disease caused by infection with the spirochete Treponema pallidum. The infection is systemic and the disease is characterized by periods of latency. These features, together with the fact that T pallidum cannot be isolated in culture, mean that serologic techniques play a major role in the diagnosis and follow-up of treatment for syphilis.

Syphilis is categorized by an early primary infection in which patients may have non-specific symptoms, and potentially, genital lesions. Patients tested by serology during the primary phase may be negative for antibodies, especially if testing is performed during the first 1 to 2 weeks after symptom onset. As the disease progresses into the secondary phase, antibodies to T pallidum reach peak titers, and may persist indefinitely regardless of the disease state or prior therapy. Therefore, detection of antibodies to nontreponemal antigens, such as cardiolipin (a lipoidal antigen released by host cells damaged by T pallidum) may help to differentiate between active and past syphilis infection. Nontreponemal antibodies are detected by the rapid plasma reagin (RPR) assay, which is typically positive during current infection and negative following treatment or during late/latent forms of syphilis.

PRINCIPLE

RPR utilises carbon particles coated with cardiolipin antigen to detect reagin antibodies present in serum or plasma of syphilitic persons.

Specimens that contain reagin cause aggregation of the carbon particles which appear as dark clumps against a white background. The aggregation can be read macroscopically. Non-reactive samples typically appear as a smooth non-aggregated pattern which may form buttons in the centre of the test area.

MATERIALS

MATERIALS PROVIDED

- **RPR carbon antigen reagent**: A particulate carbon suspension coated with lipid complexes, with 0.95 g/L sodium azide.
- **Positive Control**: Human syphilitic serum reactive with the test reagent, with 0.95 g/L Sodium azide. **(Optional).**
- **Negative control**: non-reactive phosphate buffer containing 5% BSA pH7.4, with 0.1% of Sodium azide. **(Optional).**
- **RPR test cards or white glass slide (Optional).**
- **Plastic sticks (Optional).**
- **Package insert**.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

- Rotator (100rpm).
- Timer.
- Calibrated micropipettes and tips.

PACKAGING CONTENT

REF **8.00.18.0.0100 (2mL Reagent, 1x0.5ml Positive Control, 1x0.5mL Negative Control)**

REF **8.00.18.0.0500 (10mL Reagent, 1x1ml Positive Control, 1x1mL Negative Control)**

REF **8.00.18.3.1000 (2x10ml Reagent, 1x2ml Positive Control, 1x2ml Negative Control)**

STORAGE AND STABILITY

- All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C.
- *Do Not Freeze.
- *Signs of deterioration:
  - RPR Carbon: Visible agglutination.
  - Controls: Presence of particles and turbidity.

PRECAUTIONS AND WARNINGS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- *The test is not for near-patient or self-testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all negative and positive in the manner as patient specimens .
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Components of different human origin have been tested and found to be negative for the presence of antibodies anti- HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
- *Do not touch, drink, or ingest the reagent.
- *Do not use black glass slides during testing.
- *Perform the test in a well-lit area with good visibility.
- *Failure in following the instructions may give incorrect results or face safety hazards.
- *Wash the area of contact with water immediately if contact occurs.
- *Wash of the hands and the test table top with water and soap.
- *Do not use the reagent if displaying any signs of deterioration.
- *Always use a fresh pipette tip and stirring sticks for each test.
- *Handle the used disinfectant with care.
- *Glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- *Do not use the reagents if the label is missing, damaged, or unclear.
- *Do not use leaked vials and making proper disposal of them.
- *Use forceps, scoops, or other mechanical devices for removing broken glass from the working area. A dustpan and brush should be used to clean up shards/small pieces of broken glass. Broken glass must be disposed of in a sharps container.
- *The reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide bulidup.
- *Any serious incident that occur in relation to the device shall be reported to the manufacturer and the competent authority. (Feedback@atlas-medical.com)

COLLECTION, HANDLING AND PREPARATION OF SPECIMEN

- Fresh serum or plasma. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.
- *Samples may be stored at 2-8° C for up to 7 days. For long term storage sera should be stored at -20° C up to 30 days.

REAGENT PREPARATION

RPR reagent is ready to use. No preparation is required.

PROCEDURES

QUALITATIVE PROCEDURE

- **Mix well the RPR reagent before use.**

1. Bring the reagents and samples to room temperature.
2. Dispense **50 µL of each sample** into a separate circle on the card. Use a separate tip for each sample.
3. Dispense **1 drop of each of positive and negative controls** into two additional circles.
4. Gently shake the dispensing vial and slightly press to remove air bubbles from the needle and the drop obtained is correct.

5. Dispense **1 drop (17.5 µl) of RPR antigen** to each circle next to the sample to be tested.
6. *Close the reagent vial tightly.
7. *Spread the specimen evenly over the test circle.
8. Place the card on a mechanical rotator and rotate at 100 r.p.m. for 8 minutes.
9. Observe macroscopically for agglutination within a minute after removing the card from the rotator.

SEMI-QUANTITATIVE PROCEDURE

- **Mix well the RPR reagent before use**.

1. Make doubling dilutions from Undiluted to 1:16 normal saline.
2. Place 50 µl of each dilution in to a separate circle on the test card.
3. Spread each dilution evenly over the test circle.
4. Continue as from Qualitative procedure .
   The titer of the sample is expressed as the final dilution which shows aggregation of the carbon particles.

INTERPRETATION OF TEST RESULTS

1. **Strong Reactive:** Large clumps of carbon particles with a clear background.

2. **Reactive:** Large clumps of carbon particles somewhat more disperse than Strong Reactive pattern.

3. **Weak Reactive:** Small clumps of carbon particles with light grey background.

4. **Trace Reactive:** Slight clumping of carbon particles typically seen as a button of aggregates in the centre of the test circle or dispersed around the edge of the test circle.

5. **Non-Reactive:** Typically a smooth grey pattern or a button of non-aggregated carbon particles in the centre of the test circle.

<u>*LIMITATION OF THE TEST</u>

- Pregnancy may give a false positive reaction.
- Hepatitis and Brucellosis may give a false positive reaction.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PERFORMANCE CHARACTERISTICS

Sensitivity: 100%.
Specificity: 100%.
Precision: 100%
Hook effect: no prozone effect up to the titer level studied: 1/16.
Interferences: There is no effect from Hemoglobin/Bilirubin and Rheumatoid factor on the results of RPR carbon antigen at the studied concentrations:
Bilirubin: ≤15 mg/dL.
Hemoglobin: ≤10 g/L.
Rheumatoid factor: ≤300 IU/ml.

REFERENCES

- Falcone V.H., Stout G.W. and Moore M.B. Jr., PHR 79: 491-495, 1964.

ATLAS Medical GmbH
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

PPI2280A01
Rev C (27.03.2024)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control

<u>*: Indication of the introduced modifications.</u>

Atlas Medical

TPHA TEST KIT

A passive particle agglutination assay for the qualitative and semi-quantitative detection of IgG and IgM antibodies to *Treponema pallidum*

IVD For *in vitro* diagnostic and professional use only

2°C 8°C Store at 2° to 8° C CE

INTENDED USE

TPHA test kit is designed for the detection of antibodies to *Treponema pallidum* (IgG and IgM antibodies) in human serum or plasma based on the principle of passive particle agglutination.

INTRODUCTION

Syphilis is a venereal disease caused by the spirochaete microorganism *Treponema pallidum*. As this organism cannot be cultured on artificial media the diagnosis of syphilis depends on the correlation of clinical data with the specific antibody demonstrated by serological tests. Serological screening tests for syphilis using cardiolipin and lecithin as antigens are simple to perform but biological false positive (BFP) reactions occur frequently because the tests use non-treponemal antigens.

The TPI and FTA-ABS tests utilize pathogenic *Treponema pallidum* as the antigen but these tests present some difficulties for routine serodiagnosis. The TPI test requires living pathogenic *T.Pallidum* and the FTA-ABS test requires a fluorescence microscope. Both tests require a high level of expertise.

TPHA test kit has been shown to be a convenient and specific test for the diagnosis of treponemal infection, having specificity similar to that of the TPI test and sensitivity comparable to that of the FTAABS test. It requires minimum laboratory equipment and is very simple to perform.

PRINCIPLE OF THE TEST

Atlas TPHA uses preserved avian erythrocytes coated with extracted antigens of T.pallidum (Nichols strain). Specific antibodies present in a sample of plasma or serum bind to these antigens when the sample is incubated with the particles. This causes the particles to agglutinate, then settle to form a characteristic pattern in the test well.

Non-specific reactions are eliminated by the use of absorbents. The assay can be run and interpreted manually or with an auto-analyzer using an agglutination interpretation program.

MATERIALS PROVIDED

- Test cells; avian erythrocytes coated with antigens of *T. Pallidum.*
- Control cells; avian erythrocytes.
- Sample Diluent; Saline solution containing absorbents.
- Positive control; Rabbit antiserum, titer 1/1280, **Pre-diluted.**
- Negative control; Normal Rabbit Serum, **Pre-diluted.**
- Package Insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Micropipettes capable of delivering: 10, 25, 75 and 190µl.
- U-Well microtitration plates.

PACKAGING CONTENTS

REF **8.00.19.0.0200 (2x20 ml Diluent, 2x8.5 ml Control Cell, 2x8.5 ml Test Cells, 1x1 ml Positive Control, 1x1 ml Negative Control)**

REF **8.00.19.0.0100 (20ml Diluent, 8.5ml Control Cell, 8.5ml Test Cells, 1ml Positive Control, 1ml Negative Control)**

PRECAUTIONS

- For i*n vitro* diagnostic and professional use.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- If spillage of reagent occur clean with disinfectant (disinfectant used could be irritable so handle with care).
- The test is for well-trained professional health user not for lay user.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Reagents and controls contain 0.1% sodium azide as a preservative which is toxic and can be absorbed through the skin when drained, the drains should be thoroughly washed with water.
- The reagent is considered toxic, avoid drinking, ingestion and contact with skin or mucus membrane.

REAGENTS HANDELING

- All the reagents must be allowed to equilibrate to room temperature before use.
- Do not freeze any of the reagents.

REAGENTS STORAGE

- Store bottles upright at **2–8°C**.
- **Do not freeze**
- Do not use after the expiry date.

SAMPLE PREPARATION AND HANDLING

- Use fresh serum or plasma samples free of cells and microbial contamination.
- Samples may be stored at 2-8°C for up to 7 days prior to testing.
- Samples can be frozen at -20°C or lower, these should be thawed and mixed prior to testing.

INTERFERING SUBSTANCES AND LIMITATION OF THE TEST

- Atlas TPHA test kit can be used for serum and plasma samples.
- No interfering substances have been identified.
- Atlas TPHA test kit can cross react with other treponemal infections such as *T.pertenue* and *T.carateum* so positive results should be confirmed by another method.
- In early primary syphilis, occasionally, specific antibodies may not be detected.

PROCEDURES

Bring all reagents and samples to room temperature before use.

Kit controls must be run with each assay.

Ensure Test and Control Cells are thoroughly re-suspended.

QUALITATIVE METHOD

Each sample requires 3 wells of a microtitration plate.

1. Add 190 µl of diluent to Well 1.
2. Add 10 µl sample to Well 1. (Sample dilution 1:20).
3. Using a micropipette, mix contents of Well 1 and transfer 25 µl to Wells 2 & 3.
4. Ensure that the Test and Control Cells are thoroughly suspended. Add 75 µl of control cells to Well 2. Add 75µl of Test Cells to Well 3.
5. Tap the plate gently to mix the contents thoroughly.
6. Incubate 45-60 minutes at 15-30° C. **Caution! Keep the plate away from heat, direct sunlight and any source of vibration.**
7. Read results. Results are stable if the plate is covered and the above precautions are observed.

NOTE

Kit controls must be run in parallel and are diluted and ready for use.

SEMI-QUANTITATIVE TEST

9 wells are needed for each sample.

Sample Dilution (to 1 in 20)

1. Add 190µL of sample diluent to a well.
2. Add 10µL of sample to the same well. Mix thoroughly.

Note: Kit controls are pre-diluted (i.e. diluted 1 in 20)

Titration

1. Leave the first well empty, add 25µL of diluent all other wells in the sequence.

2. Transfer 25µL from step 1 to the first well.
3. Transfer 25µL from step 1 to the second well and mix, then serially dilute along the well sequence, discard the excess 25µL from the final well.

Test

Re-suspend the Test and Control Cells thoroughly

4. Add 75µL of Test Cells to each well.

(Final sample dilution is 1 in 80 – 1 in 10,240)

5. Mix wells thoroughly.
6. Incubate at 15-30°C on a vibration-free surface for 45 - 60 minutes. Caution! Keep the plate away from heat, direct sunlight and any source of vibration.
7. Read results. Results are stable if the plate is covered and the above precautions are observed.

The titer of the sample is the reciprocal of the final positive sample dilution.

INTERPRETATION AND ASSAY VALIDATION

Assay Control

The Kit Controls must be give the correct result; Negative is Negative and Positive is Positive. When the Kit Positive is titrated the expected end point is 640 – 2560.

Positive **Equivocal Negative**

A sample where the Test Cell well is non-reactive should be considered as **negative for *T.pallidum***. Reactivity less than equivocal is considered negative.

A sample where the Test Cell well is reactive indicates antibodies to *T.pallidum* resulting from a syphilis infection. The sample should be repeated in duplicate. Where 2 or more wells are positive the sample should be considered as **positive *for T.pallidum***.

A repeatable equivocal sample should be considered positive.

Where a sample is reactive in both Test and Control Cells, if the agglutination is greater in the Test Cells, then the sample is considered positive and should be repeated as above.

Where a sample has greater or equal agglutination in the Control Cells then the sample should be absorbed using the following procedure.

Absorption of Non-specific Reactions

1. Add 10µL of sample to 190µL of re-suspended Control Cells, mix thoroughly and leave for 30 minutes.
2. Centrifuge to deposit the cells at a minimum of 1500g for 3 minutes.
3. Add 25µL of supernatant from step 2 to each of 2 wells.
4. Ensure Test and Control Cells are re-suspended.

   Add 75µL of Test Cells to the first well.
   Add 75µL of Control Cells to the second well.
5. Mix wells thoroughly and Incubate at 15-30°C on a vibration-free surface for 45 - 60 minutes
6. Read and interpret patterns as above.

PERFORMANCE CHARACTERISTICS

Specificity

A study on 300 donor serum showed 100% specificity. (95% confidence limits 98.8 – 100%).
A study on 300 donor EDTA plasma showed 100% specificity. (95% confidence limits 98.8– 100%).

Sensitivity

A study on 100 syphilis positive samples showed 100% sensitivity. (95% confidence limits 96.6 – 100%).

Analytical sensitivity

Atlas TPHA has an expected sensitivity of between 0.1 and 0.025 IU/ml against the 1st IS for human syphilitic plasma IgG and IgM NIBSC code: 05/132

REFRENCES

1. Rathlev T. - Haemagglutination tests utilizing antigens from pathogenic and apathogenic Treponema pallidum WHO/VDT/RES 1965 ; 77 : 65.
2. Tomizawa T, Kasamatsu S. - Haemagglutination tests for diagnosis of syphilis. A preliminary report. Japan. J. Med. Sci. Biol. 19, 305-308, 1966.
3. Rathlev T. - Haemagglutination test utilizing pathogenic Treponema pallidum for the serodiagnosis of syphilis. Br J Vener Dis 1967 ; 43 : 181-5
4. Tomizawa T. Kasamatsu S. Yamaya S. - Usefulness of the haemagglutination test using Treponema pallidum antigen (TPHA) for the serodiagnosis of syphilis. Jap J Med Sci Biol 1969 ; 22 : 341-50.
5. Sequeira P,J,L. Eldridge A,E. - Treponemal Haemagglutination test. Br J Vener Dis 1973 ; 49 : 242-8.
6. Larsen S.A., Hambie E.A., et coll., Specificity, sensitivity and reproducibility among the fluorescent treponemal antibody absorption test, the microhemagglutination assay for Treponema pallidum antibodies, and the hemagglutination treponemal test for syphilis. J. Clin. Microbiol., 1981; 14 : 441 – 445.
7. Wasley G.D. & Wong H.H.Y. Syphilis Serology Priciples and Practice. Oxford Medical Publications 104 - 105

ATLAS MEDICAL GmbH
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

PPI2388A01
Rev B (22.02.2024)

REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry

***: Indication of the introduced modifications.**