Atlas Medical

Contract No:Co2403079

Date:09/03/2024

Letter of Authorization

Manufacturer: Atlas Medical GmbH
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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

Digitally signed by Dolgopol Iulian
Date: 2025.07.04 11:04:11 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

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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

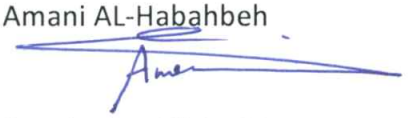
Name and address of Manufacturer	**Atlas Medical GmbH** Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com

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
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Tel. (0049) 33708 - 355030

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

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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.**

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Amendment Record

Issue Level	Date Issued	Summary of Amendment	Reviewed by
1.1	14.04.2018	General Review	Sondos Shalabi
1.2	11.01.2020	Amend the address from UK to be German address	Amani AL-Habahbeh

2. General Information.

Trade Names & Synonyms: TPHA Test Kit (Treponema Pallidum indirect Haemagglutination Test)

Chemical Family: In Vitro Diagnostics

Formula: not applicable.

Manufacturer: Atlas Medical.

Manufacturer's address: Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow Germany

Manufacturer's phone: +49(0)33708355030

Email: info@atlas-medical.com

3. Composition, Information on Active Ingredients.

Composition: TPHA Test Cells
(Preserved coated avian erythrocytes: Contains <1%Sodium Azide
TPHA Control Cells
(Preserved avian erythrocytes: Contains <1%Sodium Azide
Diluent: Contains <1%Sodium Azide
Positive and Negative Control: Contain <1%Sodium Azide

Hazardous Components: SODIUM AZIDE: <1%

4. Hazard Information.

Main hazards: These products are for in vitro diagnostic use only.
Specimen material may contain pathogenic organisms. Handle with the appropriate precautions, according to good laboratory practices.

5. Fire & Explosion Hazard Data.

Extinguishing media: Not combustible. Suitable extinguishing media for the surrounding fire should be used.

Exposure hazards: None in small quantities

6. Accidental release measures.

Personal precautions: Wear appropriate protective clothing. Refer to section 8 of MSDS for personal protection details.

Environmental precautions: Properly disinfect any spills. Do not discharge into drains or rivers. Contain large spillages using bunding.

Clean-up procedures: Absorb into dry earth or sand. Transfer to a closable, labeled salvage container for disposal by an appropriate method.

7. Handling and Storage.

Handling requirements: For in vitro diagnostic use only. Read the instructions for use. Avoid the formation of aerosols. Avoid direct contact with the substance

Storage conditions: Store in cool, well-ventilated area. Keep container tightly closed.

8. Exposure control and personal gear.

Hazardous ingredients:

SODIUM AZIDE: WEL (8 hr TWA): 0.1 mg/m^3 WEL (15 min STEL): 0.3 mg/m^3

Respiratory protection: Respiratory protection not required.

Hand protection: Protective disposable gloves.

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: Protective clothing.

9. Physical and chemical properties.

State: Liquid

Colour: Test and Control Cells: Brown/red suspension
Positive and Negative Controls: Colorless liquid
Diluent: yellow/orange liquid

Odor: Odorless
pH: Test and Control Cells: pH 6.2-7.4
Solubility: Soluble/ suspension
Flammability: Not combustable

10. Stability and Reactivity Data.

Stability: Stable under normal storage and handling conditions. Do not use after expiry date.
Materials to avoid: Strong oxidising agents. Strong acids.
Hazardous decomposition products: In combustion may emit toxic fumes.

11. Toxicological information.

Hazardous ingredients:

SODIUM AZIDE:

ORL MUS LD50 27 mg/kg
ORL RAT LD50 27 mg/kg
SKN RAT LD50 50 mg/kg

Routes of exposure: Refer to section 4 of SDS for routes of exposure and corresponding symptoms.

12. Ecological information.

Mobility: Readily absorbed into soil.
Persistence and degradability: No data available.
Bio-accumulative potential: No data available.
Other adverse effects: No data available.

13. Waste disposal information.

Waste code number: 160506 Hazardous waste.
NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

14. Transport information.

SODIUM AZIDE:ADR / RID

UN no: - Not applicable.

Shipping name: Not classified as dangerous in the meaning of transport regulations.

IMDG / IMO UN no: - **Marine pollutant:** NO

IATA / ICAO UN no: - Not applicable.

15. Regulatory information.

SODIUM AZIDE:

Hazard symbols: Harmful.
Risk phrases: R22: Harmful if swallowed.
R32: Contact with acids liberates very toxic gas.
EC classification: Xn- Harmful
Safety phrases: S29/35: Do not empty into drains; dispose of this material and its container in a safe way.
S36/37/39: Wear suitable protective clothing, gloves and eye / face protection. S46: If swallowed, seek medical advice immediately and show this container or label.

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions that complete these regulations. Refer to all applicable national, international and local regulations or provisions.

17. Other information.

Warning: Because no test method can offer complete assurance that HIV, HCV, HbsAg or other infectious agents are absent, the components of this kit should be handled accordingly.

18. Disclaimer.

The information above is believed to be accurate represents the best information currently available to us.
However we make no warranty of merchantability or any other warranty expressed or implied, with respect to such information, and we assume no liability resulting from its

use. Users should make their own investigations to determine the suitability of the information for their particular purpose. In no way shall the company be liable for any claims, losses or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.