Declaration Ref No: DC21-0035

# CE Declaration of Conformity

## According to Annex III of the IVD Directive 98/79/EC

We,

**Atlas Medical**
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Blankenfelde-Mahlow, Germany.
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Declare our responsibility that the following product:

**See Attached list**

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:
  **Certificate N$^{0}$**.: 36655 rev 1
  **Expiry Date**: October 8 $^{th}$.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And
Intended for In-Vitro Professional use only.

**Manufacturer**
**Atlas Medical**
**Ludwig-Erhard-Ring 3**
**Blankenfelde-Mahlow , Germany.**

Atlas Medical
Quality Diagnostic Products

| Atlas Medical | Issue date | Date of review | Management approval | MRXDO10F.10 08.02.2011 |
|---|---|---|---|---|
| | March 2021 | 09.03.2021 | | |

Digitally signed by Monastirschi Viorica
Date: 2022.10.04 10:34:43 EEST
Reason: MoldSign Signature
Location: Moldova

Atlas Medical

# CE Declaration of Conformity

## According to Annex III of the IVD Directive 98/79/EC

| Product Description |
|---|
| 8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls). |
| 8.00.00.0.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls) |
| 8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls) |
| 8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests |
| 8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex (A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide). |
| 8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control) Without card,stirring sticks. |
| 8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only). |

Atlas Medical
Quality Diagnostic Products

# CERTIFICAT
*CERTIFICATE OF REGISTRATION*
**N° 36655 rev.1**

**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, 2020 (included)**
**Valable jusqu'au** */ Expiry date :* **October 8th, 2023 (included)**
**Etabli le** */ Issued on :* **October 8th, 2020**

DocuSigned by:
Beatrice Lys
EE33BDA9BAA04A3...

GMED SAS GMED SAS GMED GROUPE LNE

**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° 36655–1
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 36655-0

GMED_SQ_plus3sites-F-V0-07-2018

**Addendum au certificat n° 36655 rev. 1** page 1/1
*Addendum of the certificate n° 36655 rev. 1*
Dossier / *File* N°P601408

**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*

**********

**William James House**
**Cowley Road,**
**Cambridge, CB OWX**
**United Kingdom**

French version:
**Contact réglementaire**
*English version*:
*Regulatory Administration*

**********

**3 sites / 3** *sites*

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

Atlas Medical CE

# RPR SYPHILIS CARD TEST

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

2°C 8°C Store at 2 to 8 °C

## 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**:Contains less than 0.1% sodium azide.
- **Positive Control** : Contains less than 0.1% sodium azide.
- **Negative control**: Contains less than 0.1% sodium azide
- **RPR test cards (Optional).**
- **Plastic sticks.**
- **Package insert**.

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

### MATERIALS NEEDED BUT NOT PROVIDED

- Rotator (100rpm).
- Timer.
- Pipettes.

## SAMPLES

Fresh serum or plasma. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

## PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Always use a fresh pipette tip for every test.
- 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.

## 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.

## 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. Place the card on a mechanical rotator and rotate at 100 r.p.m. for 8 minutes.
7. 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.

## PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** 100%.
2. **Specificity**: 100%.

## 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.

**REFERENCES**


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



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**PPI2074A01**
**Rev B (15.03.2021)**


| | | | |
|---|---|---|---|
| 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 |