

Declaration Ref No: DC21-0035

## **CE Declaration of Conformity**

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

We,

**Atlas Medical**

Head office: Ludwig-Erhard-Ring 3  
Blankenfelde-Mahlow, Germany.  
Tel: +49 - 33708 – 3550 30  
Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.  
Tel.: +962 6 4026468  
Fax: +962 6 4022588  
Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)

Declare our responsibility that the following product:

**See Attached list**

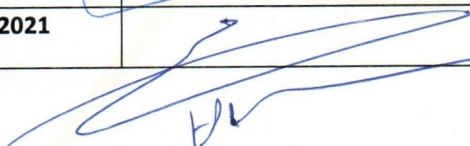
- Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:  
**Certificate N°:** 36655 rev 1  
**Expiry Date:** October 8<sup>th</sup>.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	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	March.2021	09.03.2021		

## 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).



**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**

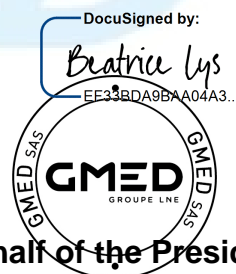


**CERTIFICATION  
DE SYSTEMES  
DE MANAGEMENT**  
Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)

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



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



**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**



## RPR SYPHILIS CARD TEST

### A qualitative and Semi- quantitative rapid card test for the detection of Non-Treponema (reagin) in serum or plasma

For *In-Vitro* and professional use only  
Store at 2 to 8 °C

#### INTENDED USE

For the qualitative and quantitative detection of Non-Treponema in serum or plasma.

#### INTRODUCTION & PRINCIPLE

Besides other antibodies, *Treponema Pallidum* produces non-Treponemal antibodies (reagin) in syphilitic persons. These antibodies can be detected by RPR antigen. ATLAS RPR card test is a macroscopic screening test for the qualitative and Semi-quantitative detection of reagin antibodies in serum or plasma. The kit contains RPR antigen which is based on the easy to use VDRL carbon antigens. In the presence of the reagin, the antigen causes flocculation of the carbon particles, which appears as black clumps. The charcoal particles contained in the antigen suspension enhances the visual appearance of the coagglutination in positive samples.

#### MATERIALS

##### MATERIALS PROVIDED

- RPR carbon antigen reagent.
- Positive and negative controls.
- RPR test cards.
- Plastic sticks.
- Dispensing Dropper.

##### MATERIALS NEEDED BUT NOT PROVIDED

- Saline 0.9%.

- Rotator (100rpm).
- Accurate pipette to deliver 50 µl and.
- Timer.

#### PRECAUTIONS

- Always use a fresh pipette tip for every test.

#### STORAGE AND STABILITY

- The reagents in this kit should be stored in an upright position and refrigerated between 2 to 8°C . Never Freeze. Test cards need not to be refrigerated and can be kept at room temperature.
- Reagents should be brought to room temperature and mixed well to obtain a uniform suspension of carbon particles.

#### PREPARING THE SPECIMEN

- ATLAS RPR kit can be used with either unheated plasma or heated serum samples.
- Serum samples can stay stable for up to 5 days if stored at 2 to 8 °C.
- Plasma samples collected with EDTA can stay stable up to 24 hours if stored at 2 to 8 °C.

#### PROCEDURES

##### QUALITATIVE PROCEDURE

1. Bring reagents to room temperature.
2. Dispense 50µl of sample onto a single circle on the test card.
3. Repeat step 2 for the positive and negative controls.
4. Spread the sample of each test specimen over the entire test circle.
5. Mix the carbon antigen suspension well.
6. Dispense one drop (20 µl ) of the carbon antigen onto each test circle containing specimen. Do not mix the antigen with the sample.
7. Using the rotator, rotate the card at 100rpm for 8 minutes.

8. Read the results in good light immediately after 8 minutes.
9. Don't read the results after more than 8 minutes.

#### READING THE QUALITATIVE RESULTS

##### POSITIVE

- If large aggregates appear in the centre or the periphery of the test circle containing the sample, then the test should be read as positive (reactive)
- If the aggregates are visible, but weak or small, then the test should be read as weak positive (weakly reactive).
- If test is positive, then results should be confirmed by the quantitative procedure mentioned below.

##### NEGATIVE

If no aggregates appear and the specimen has smooth grey appearance (non-reactive)

#### SEMI-QUANTITATIVE PROCEDURE

1. Dispense 50µl of 0.9% saline to test circles numbered 2 to 5. Saline should not be spread. Dispense 50 µl of specimen onto test circle 1.
2. Dispense 50 µl of specimen onto test circle 2. Prepare serial two-fold dilutions by drawing the mixture up and down the pipette 5-6 times ( avoid any bubble formation. Transfer 50 µl from circle 2 to 3, to 4 and to 5. Dispose 50 µl from circle 5 after mixing.
3. Starting from circle 5 and onto 4,3,2 and 1, mix and spread the serum over the entire area of each test circle.
4. Continue with steps 6-9 of the qualitative procedure.

#### READING THE SEMI-QUANTITATIVE RESULTS

The dilution of the circles are as follows:

Circle	1	2	3	4	5
Dilution	-	1:2	1:4	1:8	1:16

The titer of the sample is read as follows (P:Positive, N:Negative)

Positive 1:2	P	P	N	N	N
--------------	---	---	---	---	---

Positive 1:4	P	P	P	N	N
Positive 1:8	P	P	P	P	N
Positive 1:16	P	P	P	P	P

Positive and negative results are read as in the reading qualitative results procedure.

If the result in circle 5 is positive, then further dilution to 1:32, 1:64, 1:128 and 1:256 is required. Use steps 3 in semi-quantitative procedure and steps 6-9 in qualitative procedure to obtain the required dilutions.

**\*\*The titer** , in the semi- quantitative method , is defined as the highest dilution showing a positive results.

## LIMITATION

- This test provides a presumptive diagnosis of syphilis. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
- In positive specimens, it is recommended to confirm the result by another serological test such as the TPHA.

## REFERENCES

1. Falcone V.H., Stout G.W. and Moore M.B. Jr., PHR 79: 491-495, 1964.
2. Larsen S.A., *et. al.*, ata on file, Treponemal Research and Immunology lab, CDC.
3. McGrew B.E., Stout G.W., Falcon V.H., AM. J. Med. Techs., 34:634, 1969
4. Manual of Tests for Syphilis, PHS publication No.411, 1969.

## ATLAS MEDICAL

William James House, Cowley Rd,  
Cambridge, CB4 4WX, UK  
Tel: ++44 (0) 1223 858 910  
Fax: ++44 (0) 1223 858 524  
PPI009A01  
Rev F (08.10.2011)