Declaration Ref No: DC11-0011

CE Declaration of Conformity

We,
Atlas Medical

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Declare our responsibility that the following product:

RPR Carbon Antigen

Is produced under Atlas quality system (ISO9001: 2008) and (ISO13485: 2003) supported by Lloyd's certificate and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And
EN 18113-1, -2 :2011, EN ISO 15223:2012
EN ISO 14971:2012, EN ISO 13640:2002, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002

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
William James House, Cowley Rd.
Cambridge, CB0 4WX, UK

Atlas Medical
Quality Diagnostic Products

Atlas Medical

Date: 15/Jan/2022

STATEMENT

We, ATLAS MEDICAL having a registered office at Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

On behalf of manufacturer:-

General Manager

Haya Amawi

Signature: _____

Date: 15.01.2022

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

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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

****

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
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On behalf of the President
Béatrice LYS
Technical Director

Atlas Medical CE

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

IVD *For in- vitro diagnostic use only*

2°C 8°C Store at 2 to 8 °C

INTENDED USE

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

INTRODUCTION & PRINCIPLE

Besides other antibodies, *Treponema Pallidium* 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.

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

MATERIALS NEEDED BUT NOT PROVIDED

- Saline 0.9%.
- Rotator (100rpm).
- Accurate pipette to deliver 50 µl and.
- Timer.

SAMPLES

Fresh serum or plasma. Stable 7 days at 2-8ºC or 3 months at –20ºC. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

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

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

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 (16µl) 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

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

1. Make serial two fold dilutions of the sample in 9 g/l saline solution.
2. 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.
3. 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.

4. Starting from circle 5 and onto 4, 3, 2 and 1, mix and spread the serum over the entire area of each test circle.
5. 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.

PERFORMANCE CHARACTERISTICS

1. Analytical sensitivity: Accurate titer determination of the Reference Material, under the described assay conditions (see calibration).
2. Prozone effect: No prozone effect was detected up to titers ≥ 1/128.
3. Diagnostic sensitivity: 100 %.
4. Diagnostic specificity: 100 %.

LIMITATION

- RPR carbon test is non-specific for syphilis.All Reactive samples should be retested with treponemic methods such as TPHA and FTA-Abs to confirm the results.
- A Non Reactive result by itself does not exclude a diagnosis of syphilis. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
- False positive results have been reported in diseases such as infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy and autoimmune diseases.

REFERENCES

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

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PPI1511A01
Rev A (02.09.2019)

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