Atlas Medical

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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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 N⁰.: 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 Monastîrschii Viorica
Date: 2021.12.09 14:04:55 EET
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

DocuSign Envelope ID: E555CF41-ED58-436A-9E80-9AE16BFCED23

GMED
GROUPE LNE

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:
Béatrice Lys
EF33BDA9BAA04A3...

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 • 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

GMED
GROUPE LNE

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...

GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

Atlas Medical CE

STREPTOCOCCAL GROUPING SLIDE LATEX TEST

A qualitative latex agglutination test for the Detection of Streptococcal groups A, B, C, D, F and G

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

2°C 8°C Store at 2° to 8° C

INTENDED USE

For the qualitative detection of streptococcal groups A, B, C, D, F and G based on latex agglutination.

INTRODUCTION & PRINCIPLES

ATLAS Streptococcal test uses an enzyme extraction procedure to release Carbohydrate antigen from Streptococcal cell walls.

The antigens are detected using specific antibodies to groups A, B, C, D, F and G Lancefield. These antibodies are coated on latex particles. When the antigen extract is mixed with the latex reagent, agglutination will occur. The agglutination appears as a visible clumping and can be seen macroscopically.

MATERIALS

MATERIALS PROVIDED

- Group A, B, C, D, F and G latex reagents.
- Extraction Enzyme dried.
- Positive control.
- Test slide.
- Stirring Sticks.
- Package Insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Water bath.
- Pipette to deliver 50ul.
- Timer and test tubes.

PRECAUTIONS:

1. Prior to use, the Latex reagent should be mixed well to obtain a uniform suspension of the Latex.
2. This kit should be stored in an upright position and refrigerated between 2 to 8ºC. Never Freeze.
3. Use a fresh disposable slide and mixer for each test.
4. Always ensure an acceptable performance of the kit by performing the test on the negative and the Positive controls before using the kit.
5. The extraction procedure may not kill all organisms; therefore carefully dispose the materials into disinfectant or by autoclaving.

PREPARING THE EXTRACTION ENZYME

The Extract enzyme in this kit comes in two vials dried.Reconstitute with 10ml distilled or deionized water. Once reconstituted store at 2-8°C for a maximum of 3 months or a liquot in 0.4ml volumes and store at -20°C for up to a year.

SAMPLE PREPARATION

Cultures

Note colonial characteristics, hemolysis, and cell morphology before starting the test. Ensure that the organisms to be tested are Gram-positive and catalase-negative. Any blood agar plate culture yielding 2-6 well-separated colonies maybe used, they should have been inoculated from a pure culture of the organism.

PROCEDURES

1. Using a sterile bacteriological loop, pick no more than 6 colonies of streptococci (avoiding other types of colony on the plate) and emulsify them in 0.4 ml extraction enzyme. (If a broth culture is to be grouped, pipette 0.1ml of an overnight culture into 0.4ml extraction enzyme).
2. Incubate the mixture in a water bath at 37ºC for 10 minutes. Shake the tubes vigorously after 5 minutes incubation. Longer incubation period may lead to false positive results.
3. Re-suspend the latex reagents by gentle agitation.
4. Dispense 1 drop of each latex into the appropriate labeled circle on the test slide.
5. Using a pipette, place 50ul of the extract to each drop of latex reagent, and mix the contents of each circle with a separate mixing stick.
6. Gently rock the slide for one minute.
7. Read the result in normal light and observe for any agglutination.

READING THE RESULT

POSITIVE: If Agglutination appears within one minute.
NEGATIVE: If Agglutination does not appear within one minute.

PROCEDURE LIMITATION

- This test provides a presumptive diagnosis. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
- Faint granularity may be seen in some negative patterns, this should be disregarded.

PERFORMANCE CHARACTERISTICS

		Test reagent	
		+	-
Reference method	+	607	55
	-	0	24

Sensitivity 607/662 = 92%
Specificity 24/24 = 100%

INTERNAL QUALITY CONTROL

A positive control is provided and should be used to verify that the latex reagents are working satisfactorily under test conditions.

Periodically check the following:

1. The test reagents agglutinate with a known reference Streptococcus strain
2. The test reagents do not auto agglutinate in normal saline solution.

REFERENCES

1. Lancefield, R.c., (1938)Proc. Soc.Exp. Bio. Med. 38, 473

2. Harvey,C.L.,Mcillmurray, M.B. (1984) Eur.J. Clin. Microbiol, 3.6,526
3. Facklam,R.R., (1980) “Manual of Clinical Microbiology” 3 Edn., American Society for Microbiology, Washington, DC, pp 88-110.

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PPI082A01
Rev C (09.09.2015)

REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
Σ	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if
	Manufacturer telephone number		