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 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		

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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

Atlas Medical

STREPTOCOCCAL GROUPING SLIDE TEST

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

2°C 8°C Store at 2° to 8° C

CE

INTENDED USE:

ATLAS Streptococcus Latex Kit is used for qualitative detection and identification of the Lancefield group of Streptococci. Reagents are provided for groups A, B, C, D, F and G.

INTRODUCTION

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.

PRINCIPLE

Some well isolated colonies are mixed with chemical extraction reagents to liberate the group antigen. This antigen is spread on different circles of the testing glass slide.

Then latex sensitized with antibodies specific for each group, is added. If the correspondent antigen is present in the sample, the antigen-antibody reaction will cause a visible agglutination (clumping). If a sample shows negative reaction with latex of groups A, B, C, F, and G, select other colonies morphologically similar to the proceeding and threat them with the reagent for enzymatic extraction. Test the obtained antigen with latex for group D. A polyvalent extract of streptococci of the above-mentioned groups is supplied as a control for the reliability of the latex reagents.

MATERIALS

MATERIALS PROVIDED

- **Extracting Reagent 1**: Sodium nitrite solution, ready to use.
- **Extracting Reagent 2:** Acetic acid solution, ready to use.
- **Extracting Reagent 3**: Ammonium carbonate solution, ready to use. Contains sodium azide 0.9 g/L as preservative.
- **Extracting Reagent E:** lyophilized lisozyme in Tris buffer pH 8.2 + 0.2. Contains non-reactive stabilizer and sodium azide 0.9 g/L as preservative. Before use, dissolve with 2.0 mL of sterile distilled water.
- **Latex A: sensitized with antibodies (from rabbit) to streptococci of group A. Ready to use. Contains sodium azide 0.9 g/L as preservative.**
- **Latex B**: sensitized with antibodies (from rabbit) to streptococci of group B. Ready to use. Contains sodium azide 0.9 g/L as preservative.
- **Latex C**: sensitized with antibodies (from rabbit) to streptococci of group C. Ready to use. Contains sodium azide 0.9 g/L as preservative.
- **Latex D**: sensitized with antibodies (from rabbit) to streptococci of group D. Ready to use. Contains sodium azide 0.9 g/L as preservative.
- **Latex F:** sensitized with antibodies (from rabbit) to streptococci of group F. Ready to use. Contains sodium azide 0.9 g/L as preservative.
- **Latex G:** sensitized with antibodies (from rabbit) to streptococci of group G. Ready to use. Contains sodium azide 0.9 g/L as preservative.
- **Positive Control**: Lyophilized. Streptococci antigens of groups A, B, C, D, F and G in physiological saline. Contains non-reactive stabilizer and sodium azide 0.9 g/L as preservative. Before use, dissolve with 1.0 mL of sterile distilled water.
- **Test slide.**
- **Stirring Sticks.**
- **Package Insert.**

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

MATERIALS NEEDED BUT NOT PROVIDED

- Water bath.
- Test tube.
- Pipettes.
- Sterile loop.

PACKAGING CONTENT

REF **8.00.13.0.0300 (5x1.5 mL Latex (A, B, C, G, F) ,1x3.0 mL Latex (D), 1x1.0 mL Positive Control, 1x 1.5 mL Extraction Reagent 1 , 1x1.5 mL Extraction Reagent 2 , 2x2.5 mL Extraction Reagent 3, 1x2 mL Extraction Reagent E, Glass Slide, plastic stirring sticks).**

STORAGE CONDITIONS

- The reagents should be stored refrigerated between 2 - 8°C avoiding direct light.
- Never Freeze or expose to elevated temperature.
- The reagent is stable until the expiry date stated on the product label. Do not use the reagents past the expiry date.

PRECAUTIONS

1. The reagents are intended *for in vitro diagnostic and professional* use only.
2. Do not pipette by mouth.
3. Always ensure an acceptable performance of the kit by performing the test on the Positive controls before using the kit.
4. Wear protective clothing and disposable gloves when dealing with samples and reagents. Wash hands after operations.
5. Test materials and samples should be discarded properly in a biohazard container.
6. Wash hands and the test table top with water and soap once the testing is done.
7. Test specimens may contain pathogenic organisms and must be handled with appropriate precautions.
8. When used in accordance with the principles of Good Laboratory Practice, good standards of occupational hygiene and the instructions in these Instructions for Use, the reagents supplied are not considered to present a hazard to health.
9. Do not use the kit if the kit label is not available or damaged.
10. Don't use the kit if damaged or the vials are leaking and discard the contents immediately.
11. The test should be performed at room temperature in a well let area with very good visibility.
12. Do not use the reagent if it contains particles as this may indicate reagent deterioration or contamination.
13. The Latex Suspensions and Positive Control contain 0.9g/l sodium azide . Azides can react with copper and lead used in some plumbing systems to form explosive salts. The quantities used in this kit are small; nevertheless when disposing of azide-containing materials they should be flushed away with large volumes of water.
14. In accordance with the principles of Good Laboratory Practice it is strongly recommended that extracts at any stage of testing should be treated as potentially infectious and handled with all necessary precautions.
15. Extraction Reagents 2 and 3 contain a weak acid and a mild irritant respectively. Avoid direct contact by wearing suitable protective equipment. If the material comes into contact with the skin, mucous membranes or eyes immediately wash the area by rinsing with plenty of water.

REAGENT PREPARITION

Latex reagents and extracting reagents 1, 2, and 3 and are ready to use. Bring the reagents to room temperature before use, shake the latex reagents gently to obtain a homogenous suspension of particles. After opening, the reagents are stable until the expiry date if kept as indicated in "STORAGE CONDITIONS". Extracting Reagent E and Positive control are lyophilized and must be re-suspended in sterile distilled water before use. If stored at 2-8 ° C and preserved from contamination, reagents are stable for 3 months.

SPECIMEN AND SAMPLE PREPARATION

For a correct identification it is important that the colonies (which must be well isolated on blood agar) are picked up fresh.

Before serological analysis, it is advisable to observe the hemolytic activity and set up a slide with Gram stain to ensure the purity of the strain to be tested.

PROCEDURES

Allow all reagents and samples to reach room temperature (18-30°C) before use.

A. Technique with Chemical Extraction

1. Transfer **30 µL (one drop) of Extracting Reagent 1** into a labelled test tube.
2. Pick up 5-6 colonies with a stirring stick, being careful not to pick up part of the culture medium. Add colonies into the test tube and mix to obtain a homogeneous suspension.
3. Transfer **30 µL (one drop) of Extracting Reagent 2**.
4. Let stand for at least **5 minutes at room temperature**. Do not exceed 10 minutes. A prolonged extraction time decreases the sensitivity of the test.
5. Transfer **60 µL (two drops) of Extracting Reagent 3** and mix. Use within 15 minutes.
6. Re-suspend the latex reagent to be used (i.e. A, B, C, F, and/or G) by shaking the vial.
7. Holding the dropper vertically, add 1 free-falling drop of latex in one circle of the glass slide. Repeat this operation for each latex to be used.
8. Transfer **15 µL of antigenic extract** in each circle.
9. Using a clean stirring stick, mix and spread the reaction mixture carefully. Discard the used stirring stick.
10. Tilt and rotate the glass slide. After one minute, observe each circle for evidence of agglutination (clumping). Later agglutinations should be considered as nonspecific.
    NOTE: If all results are negative, proceed with the technique for identification of Group D Streptococci.

B. Direct Technique

(This procedure is able to identify about 70% of Group D strains).

1. Transfer **30 µL (a drop) of Extracting Reagent 3** in a circle of the slide.
2. Pick up 2-3 colonies with a clean stirring stick, being careful not to pick up part of the culture medium, and carefully mix them in the same circle of the slide.
3. Add a drop of Latex D.
4. Tilt the slide for 1 minute. At the end observe each circle for the presence or absence of agglutination. Later agglutinations should be considered as nonspecific.
   NOTE: If negative results are obtained continues with enzymatic extraction technique.

C. Technique with Enzymatic Extraction

(This procedure is able to identify more than 95% of group D strains)

1. Distribute, after reconstitution, **60 µL (two drops) of Extracting Reagent E** into a labelled test tube.
2. Pick up 2-3 colonies with a clean stirring stick, being careful not to pick up part of the culture medium. Insert colonies into the test tube and mix to obtain a homogeneous suspension.
3. Incubate at **37° C for 10 minutes.**
4. Holding the dropper vertically, add **1 free-falling drop of Latex D** in one circle of the glass slide.
5. Add **15 µL of antigenic extract** in one circle.
6. Using a clean stirring stick, mix and spread the reaction mixture carefully. Discard the used stirring stick.
7. Tilt and rotate the glass slide. After one minute, observe each circle for evidence of agglutination (clumping). Later agglutinations should be considered as nonspecific.

Quality Control

Use the positive control and saline as if they were extracted from a sample. The absence of reactions (respectively positive or negative) is index of alteration of the reagents and / or controls .

READING THE RESULT

A. Technique with Chemical Extraction

Positive: If Agglutination appears in the test circle with latex A, B, C, F or G respectively.
Negative: Fine particles appear in the test circle with latex A, B, C, F or G respectively with **no agglutination or clumping**.

B. Direct Technique

Positive: If Agglutination appears in the test circle with latex D.
Negative: Fine particles appear in the test circle with latex D with **no agglutination or clumping**.

C. Technique with Enzymatic Extraction

Positive: If Agglutination appears in the test circle with latex D.
Negative: Fine particles appear in the test circle with latex D with **no agglutination or clumping**.
NOTE: An insufficient amount of bacterial culture used can cause false negative results.

PERFORMANCE CHARACTERISTICS

Sensitivity

The identification with chemical extraction technique of groups A, B, C, F and G streptococci, performed both on lyophilized collection strains and on clinical isolations, has showed a sensitivity of 98%.
The identification of group D with direct technique has showed a sensitivity of 74.3%.
The identification of group D with enzymatic extraction has showed a sensitivity of 92%.

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PPI1415A01
Rev G (18.10.2023)

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
CONTROL +	Positive control	CONTROL -	Negative control

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
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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.

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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

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2 sites / *2 sites*

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Beatrice Lys
FF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director