

Contract No:Co2403079

Date:09/03/2024

Letter of Authorization

Manufacturer: Atlas Medical GmbH
Ludwig-Erhard-Ring 3,
15827Blankenfelde-Mahlow, Germany
Tel: +49 33 70 83 55 030
Email: amug@atlas-medical.com

Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK
Tel: +44 1223 858 910
Fax: +44 1223 858 524
Email: info@atlas-site.co.uk

Middle East Site: Sahab Free Zone Area
P. O. Box 204, Amman 11512, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

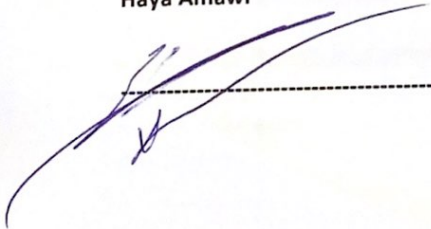
Agent: San Medico
Republic of Moldova, city Chisina
+37368228890

Atlas Medical, hereby appoint the above mentioned agent to import, register and distribute Atlas Medical Products in Maldova

Appointment Conditions:

1. This appointment is valid for 3 year from the above mentioned date.
2. Either Party can cancel this appointment by giving the other party a 60 day notice.

On behalf of the Manufacturer
General Manager
Haya Amawi



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

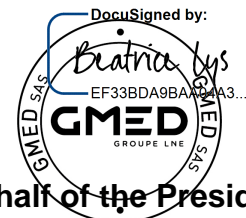


CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 36655-2

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

Renouvelle le certificat 36655-1



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

2 sites / 2 sites

DocuSigned by:
Beatrice Lys
FF33BDA8...AA04A3...


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

CE Declaration of Conformity

Name and address of Manufacturer	Atlas Medical GmbH Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com
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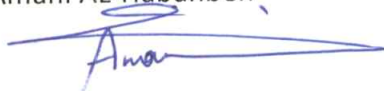
Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.00.00.0.0050	Atlas CRP Latex kit, 50 Tests (2 ml latex, 2x0.5ml positive and negative controls, 1 glass slide, 1 stirring sticks)/Box.	53707
8.00.00.0.0100	Atlas CRP Latex kit, 100 Tests (4 ml CRP latex, 2x1 ml positive and negative controls, 1 glass slide, 2 Stirring sticks)/Box.	53707
8.00.00.1.0100	Atlas CRP Latex kit, 100 Tests (4 ml CRP latex, 2x0.5 ml positive and negative controls, 1 glass slide, 2 Stirring sticks)/Box.	53707
8.00.01.0.0050	Atlas CRP Latex kit, 50 Tests (2 ml latex, 2x0.5ml positive and negative controls, 1x10 ml buffer, 1 glass slide, 1 stirring sticks)/Box.	53707
8.00.01.0.0100	Atlas CRP Latex kit, 100 Tests (4 ml CRP latex, 2x1 ml positive and negative controls, 1x10 ml Buffer, 1 glass slide, 2 Stirring sticks)/Box.	53707
8.00.00.0.0004	Atlas CRP latex, 4 ml/vial, 1 Vial/Box.	53707

Meets the essential requirments of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
 And

EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016
 EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
 EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

IVD Categorization	Directive 98/79, Other IVDs (Non-annex II, non-self-test).
Conformity Assesment Route	Directive 98/79/EC , Annex III.
Name , Address and Identification number of notified body	N/A

Date of issuance:	06. September.2021
Place	Atlas Medical GmbH
Signed by:	Amani AL-Habahbeh 
Position :	Regulatory Affairs Manager

Atlas Medical GmbH
 Ludwig - Erhard Ring 3
 15827 Blankenfelde - Mahlow
 Tel. (0049) 33708 - 355030

CRP LATEX KIT

IVD For *in-vitro* diagnostic and professional use only

2-8°C Store at 2-8°C.



INTENDED USE

CRP Latex kit is used to measure the CRP in human serum qualitatively and semi-quantitatively.

INTRODUCTION

C-reactive protein (CRP), the classic acute-phase of human serum, is synthesized by hepatocytes. Normally, it is present only in trace amounts in serum, but it can increase as much as 1,000-fold in response to injury or infection. The clinical measurement of CRP in serum therefore appears to be a valuable screening test for organic disease and a sensitive index of disease activity in inflammatory, infective and ischemic conditions. MacLeod and Avery found that antibody produced against purified CRP provided a more sensitive test than the C-polysaccharide assay. Since that time a number of immunological assays have been devised to measure CRP such as capillary precipitation, double immunodiffusion and radical immunodiffusion.

The CRP reagent kit is based on the principle of the latex agglutination assay described by Singer and Plotz. The major advantage of this method is the rapid two (2) minute reaction time.

PRINCIPLE

The CRP reagent kit is based on an immunological reaction between CRP Antiserum bound to biologically inert latex particles and CRP in the test specimen. When serum CRP equal or greater than the Reagent sensitivity (indicated on the label of the latex vial) the visible agglutination occurs.

MATERIALS

MATERIALS PROVIDED

- CRP Latex Reagent: Latex particles coated with goat IgG anti-human CRP (approximately 1%), pH 8.2 MIX WELL BEFORE USE.
- CRP Positive Control Serum (Red Cap): A stabilized pre-diluted human serum containing >20mg/L CRP.
- CRP Negative Control Serum (Blue Cap): A stabilized pre-diluted animal serum.
- Glass Slides.
- Stirring Sticks.
- Package insert.

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

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipettes 50 µL.
- Glycine Buffer 20X (1000 mmol/L): add one part to nineteen parts of distilled water before use.

PACKAGING CONTENTS

REF 8.00.00.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)

PRECAUTIONS

- All reagents contain 0.1 % (w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For *In Vitro* diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40µl). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

REAGENT PREPARATION:

The CRP Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2 - 8°C).
- DO NOT FREEZE.**
- The CRP latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- Reagents deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- Do not use plasma.

PROCEDURE

A. QUALITATIVE TEST:

- Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
- Place (40 µL) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
- Mix the CRP-latex reagent vigorously or on a vortex mixer before using and add one drop (40 µL) next to the samples to be tested.
- Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
- Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

B. SEMI-QUANTITATIVE TEST:

- Make serial two-fold dilutions of the sample in 9 g/L saline solution.

- Proceed for each dilution as in the qualitative method.

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.

The presence of agglutination indicates a CRP concentration equal or greater than the reagent sensitivity (mg/L CRP) (indicated on the label of the latex vial).

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

CALCULATIONS

The approximate CRP concentration in the patient sample is calculated as follows:

Sensitivity (indicated on the label of the latex vial)
x CRP Titer = mg/L

INTERFERENCES

NONE INTERFERING SUBSTANCES:

- Hemoglobin (10 g/dl)
- Bilirubin (20 mg/dl)
- Lipids (10 g/L)
- Other substances interfere, such as RF (100IU/ml).

NOTE

- High CRP concentration samples may give negative results. Retest the sample again using a drop of 20µl.
- The strength of agglutination is not indicative of the CRP concentration in the samples tested.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds two (2) minutes, drying of the reaction mixture may cause false positive results.
- Freezing the CRP Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative CRP concentration; therefore, screening reactions should not be graded.

- A false negative can be attributed to a prozone phenomenon (antigen excess). It is recommended, therefore, to check all negative sera by retesting at a 1:10 dilution with glycine buffer.

REFERENCE VALUES

Up to the reagent sensitivity (indicated on the label of the latex vial). Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

- Sensitivity:** Refer to vial label.
- Prozone effect:** No prozone effect was detected up to 1600 mg/L
- Diagnostic sensitivity:** 95.6 %.
- Diagnostic specificity:** 96.2 %.

REFERENCES

- Pepys, M.B.. Lancet 1:653 (1981).
- Werner, M.. Clin.Chem. Acta 25:299 (1969).
- MacLeod, C.M., et. al.. J. Exp. Med 73:191 (1941).
- Wood, H.F., et. al.. J. Clin. Invest. 30: 616 (1951).
- Mancini, G., et. al. Immunochemistry 2:235 (1965).
- Singer, J.M., et. al.. Am. J. Med 21: 888 (1956).
- Fischer, C.L., Gill, C.W.. In Serum Protein Abnormalities. Boston, Little, Brown and Co., (1975).

ATLAS Medical GmbH

Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany

Tel: +49 - 33708 - 3550 30

Email: info@atlas-medical.com

Website: www.atlas-medical.com

PPI2327A01

Rev A (05.01.2023)

	Catalogue Number		Temperature limit
	<i>In Vitro</i> diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	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
	Positive control		Negative control