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

Atlas Medical: Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Germany. Tel: +49 33 70 83 55 030

Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK. Tel: +44 1223 858 910

Middle East Site : King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box: 204, Amman 11512, Jordan

Digitally signed by Monastîrschii Viorica
Date: 2022.06.10 13:22:16 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

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		

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

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

****

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

Atlas Medical CE

Procalcitonin (PCT) Rapid Test Device (Serum/Plasma)

IVD *For in vitro diagnostic use only*

2 30°C Store at 2-30 °C

INTENDED USE

The PCT Rapid Test Device (Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of Procalcitonin in human serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of inflammation.

INTRODUCTION

Procalcitonin (PCT) is the precursor of calcitonin, and is normally produced in the C-cells of the thyroid gland.During systemic and severe infections, PCT is also produced rapidly in other tissues, and serum PCT concentrations increase to very high levels. first described PCT as an inflammation-induced protein in 1993. Since then, numerous clinical studies have demonstrated the utility of this marker. PCT is more specific for detecting bacterial infection than other inflammatory markers, such as C-reactive protein (CRP) and white blood cell counts (WBC), because viral infections, autoimmune and allergic disorders do not induce PCT.

PRINCIPLE

The PCT Rapid Test Device (Serum/Plasma) detects Procalcitonin through visual interpretation of color development on the internal strip. Anti-PCT antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-PCT antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are sufficient PCT in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually pouched test devices.
- Disposable dropper.
- Buffer.
- Package insert.

Materials Required But Not Provided

- Specimen collection container.
- Centrifuge.
- Timer.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to any testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

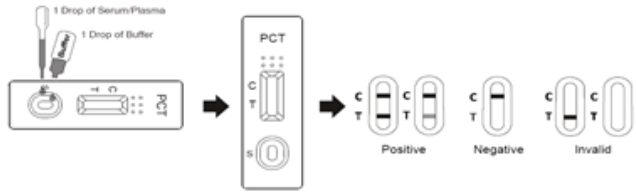
SPECIMEN COLLECTION AND PREPARATION

- The PCT Rapid Test Cassette can be performed using serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

PROCEDURE

Bring tests, specimens, buffer, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 μL) to the specimen well of test cassette, then add 1 drop of buffer (approx. 40ul) and start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line is appeared. The result should be read at 15minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of PCT antigen present in the specimen. Therefore, any shade of color in the test region (T)

should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The PCT Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of PCT in serum or plasma specimen.
2. The PCT Rapid Test Cassette (Serum/Plasma) cannot detect less than 1ng/ml of PCT in specimens.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. In some instances elevated Procalcitonin levels in due to noninfectious reasons can be observed:
   - During the first days after trauma or surgical intervention burns, release of proinflammatoric cytokines, lung cancer (oat cell carcinoma), Medullary Thyroid Carcinoma (C-Cell Carcinoma).
   - New born children, < 48hours.
   - Severe cardiogenic shock.

EXPECTED VALUES

The PCT Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial PCT EIA test. The correlation between these two systems is over 98%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The PCT Rapid Test Cassette (Serum/Plasma) has correctly identified a panel of specimens and has been compared to a leading commercial PCT EIA test using clinical specimens. The results show that the relative sensitivity of the PCT Rapid Test Cassette (Whole Blood /Serum /Plasma) is 98.7%, and the relative specificity is 98.9%.

Method		EIA		Total Results
PCT Rapid Test Cassette(Serum /Plasma)	Results	Positive	Negative	
	Positive	231	2	233
	Negative	3	180	183
Total Results		234	182	416

Relative Sensitivity: 98.7% (97.5%CI: 96.3%-99.7%)
Relative Specificity: 98.9% (95%CI: 96.1%-99.9%)
Accuracy: 98.8% (95%CI: 97.2%-99.6%)
Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens containing negative, low positive and high positive. The negative and positive values were correctly identified 99% of the time.

Inter-Assay

Between-run precision has been determined by using the same three specimens of negative, low positive and high positive of PCT in 15 independent assays. Three different lots of the PCT Rapid Test Cassette (Serum/Plasma) has been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

Cross-reactivity

The PCT Rapid Test Cassette (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity

Interfering Substances

The PCT Rapid Test Cassette (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed.

In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 1000 mg/dL Bilirubin, and 2000 mg/dL human serum Albumin.

REFERENCES

1. American College of Chest Physicians/Society of Critical Care Medicine: Crit Care Med 1992, 20: 864-874.
2. Brunkhorst F.M. et al.: Intensive Care Med. 2000, 26(suppl.2): 148-152.
3. Chiesa C. et al.: Clin Infect Dis (1998), 26: 664-672:
4. Fernandez Lopez A. et al.: Pediatr. Infect. Dis. J. 2003, 22:895-903.
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6. Harbarth S. et al.: Am. J. Resp. Crit. Care Med. 2001, 164: 396-402

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PPI1754A01
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
	Do not re-use		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