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 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

Digitally signed by Monastîrschii Viorica
Date: 2022.03.04 10:45:24 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

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

Contract No: CO17029001

Date: 05/08/2017

LETTER OF AGREEMENT

Manufacturer: Atlas Medical
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Atlas Medical, hereby appoint the above mentioned agent to import, register and distribute Atlas Medical products in Moldova.

Appointment conditions:
1. This appointment is valid for 1 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
Suzan Shebli

Atlas Medical
Quality Diagnostic Products

Atlas Medical

ANTISTREPTOLYSIN-O (ASO) LATEX SLIDE TEST

For the qualitative and quantitative measurement of antibodies to Antistreptolysin-O in human serum.

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

Store at 2-8°C

INTENDED USE

ATLAS ANTISTREPTOLYSIN-O (ASO) latex slide Test is used for the qualitative and quantitative measurement of antibodies to Antistreptolysin-O in human serum.

INTRODUCTION

The group A ß-hemolytic streptococci produces various toxins that can act as antigens. One of these exotoxins streptolysin-O, was discovered by Todd in 1932.

A person infected with group A -hemolytic streptococci produces specific antibodies against these exotoxins, one of which is antistreptolysin-O. The quantity of this antibody in a patient's serum will establish the degree of infection due to the -hemolytic streptococcal.

The usual procedure for the determination of the antistreptolysin titer is based on the inhibitory effect that the patient's serum produces on the hemolytic power of a pre-titrated and reduced streptolysin-O. However, the antigen-antibody reaction occurs independently of the hemolytic activity of streptolysin-O. This property enables the establishment of a qualitative and quantitative test for the determination of the antistreptolysin-O by agglutination of latex particles on slide.

PRINCIPLE

ASO test method is based on an immunologic reaction between streptococcal exotoxins bound to biologically inert latex particles and streptococcal antibodies in the test sample. Visible agglutination occurs when increased antibody level, are present in the test specimen.

MATERIALS

MATERIALS PROVIDED

- ASO Latex Reagent: Latex particles coated with streptolysin O, pH, 8,2. Preservative
- ASO Positive Control(Red cap): Human serum with an ASO concentration > 200 IU/mL.Preservative
- ASO Negative Control (Blue cap) Animal serum. Preservative
- Reaction Slide.
- Stirring Sticks.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer.
- Test Tubes 12x75mm.
- Test Tube Rack.
- Serological pipettes.
- High intensity light.
- Saline Solution, 0.9% NaCL.

PRECAUTIONS

- All reagents contain 0.1% (w/v) sodium azide as a preservative. Store all reagents at 2-8°C. **DO NOT FREEZE.**
- 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 build-up.
- For In Vitro diagnostic use.
- Positive and negative controls prepared using human serum found negative for hepatitis B surface antigen (HBsAg) and HIV-III by FDA required test; however, handle controls as if potentially infectious.

REAGENT STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C).
- **DO NOT FREEZE.**
- The ASO 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.

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.
- For longer periods the sample must be frozen.
- As in all serological tests, hemolytic or contaminated serum must not be used.
- **DO NOT USE PLASMA.**

PROCEDURE

Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. 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.

Semi-quantitative method

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

QUALITY CONTROL

Positive and Negative Controls should be included in each test batch.

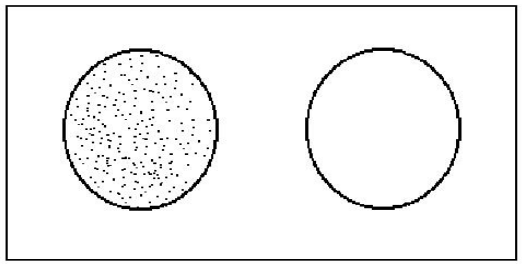
Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the ASO Negative Control and agglutination with large aggregates is observed with the ASO Positive Control.

RESULTS

A.QUALITATIVE TEST:

A negative reaction is indicated by a uniform milky suspension with no agglutination as observed with the ASO Negative Control.

A positive reaction is indicated by any observable agglutination in the reaction mixture. The specimen reaction should be compared to the ASO Negative Control (Fig. 1).



Positive Negative

Figure 1

B.QUANTITATIVE TEST

A positive reaction is indicated by any observable agglutination in the reaction mixture. Record the last dilution showing a positive reaction. Concentration of ASO can be determined by multiplying the last positive dilution factor of the sample with the concentration of the positive control (200 IU/ml).

The titer of the serum is the reciprocal of the highest dilution which exhibits a positive reaction.

IU/ml of sample = conc. of positive control (200) x specimen titer

DILUTION	IU/ml
1:1	200
1:2	400
1:4	800
1:8	1600
Etc.	

REFERENCE VALUES

Up to 200 IU/mL(adults) and 100 IU/mL (children < 5 years old)[6]. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity:

200 (±50) IU/ml.

PROZONE EFFECT

No prozone effect was detected up to 1500IU/ml.

SENSITIVITY

98%.

SPECIFICITY

97%.

INTERFERENCES

NON INTERFERING SUBSTANCES:

- Hemoglobin (10g/dl)
- Bilirubin(20mg/dl)
- Lipemia(10g/dl)

Other substances may interfere

REFERENCES

1. Haffejee . Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.
2. Ahmed Samir et al. Pediatric Annals 1992; 21: 835-842.
3. Spaun J et al. Bull Wld Hlth Org 1961; 24: 271-279.
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5. Picard B et al. La Presse Medicale 1983; 23: 2-6.
6. Klein GC. Applied Microbiology 1971; 21: 999-1001.
7. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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PPI003A01
Rev H (09.09.2017)

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 package is **damaged**
	Manufacturer telephone		

Atlas Medical CE

ATLAS C-REACTIVE PROTEIN (CRP) LATEX KIT

For the qualitative and semi-quantitative measurement of C-reactive protein (CRP) in human serum.

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

Store at 2-8°C

INTENDED USE

Atlas C-Reactive Protein (CRP) 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 Antisera bound to biologically inert latex particles and CRP in the test specimen. When serum containing greater than 6 mg/L CRP is mixed with the latex reagent, visible agglutination occurs.

MATERIALS

MATERIALS PROVIDED

- CRP Latex Reagent:Latex particles coated with goat IgG anti-human CRP, pH 8.2 **MIX WELL BEFORE USE.**
- CRP Positive Control Serum: A stabilized pre-diluted human serum containing >20mg/L CRP.
- CRP Negative Control Serum: A stabilized pre-diluted animal serum.
- Glass Slides.
- Stirring Sticks.

MATERIALS REQUIRED BUT NOT PROVIDED

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

PRECAUTIONS

- 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.
- Positive and negative controls prepared using human serum found negative for hepatitis B surface antigen (HBsAg) 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 provided with the latex and hold perpendicularly when dispensing.
- Glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.

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.

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.
- For longer periods the sample must be frozen.
- As in all serological tests, hemolytic or contaminated serum must not be used.
- Do not use plasma.

PROCEDURE

A.QUALITATIVE TEST:

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 40 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. 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.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. 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:

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

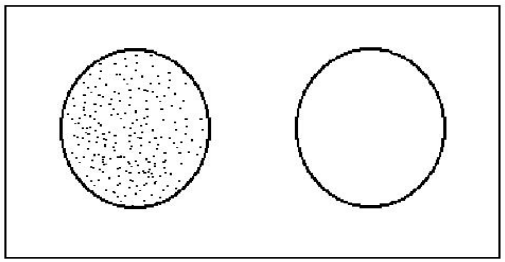
All result different from the negative control result, will be considered as a positive.

INTERPRETATION OF RESULTS

A.QUALITATIVE TEST:

A **negative** reaction is indicated by a uniform milky suspension with no agglutination as observed with the CRP Negative Control.

A **positive** reaction is indicated by any observable agglutination in the reaction mixture. The specimen reaction should be compared to the CRP Negative Control (Fig. 1).



Positive **Negative**

Figure 1

B. Semi-QUANTITATIVE TEST:

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

6×CRP titer = ---- mg/L

INTERFERENCES

NONE INTERFERING SUBSTANCES:

- Hemoglobin (10g/dl)
- Bilirubin(20mg/dl)
- Lipemia(10g/dl)
- 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

1. Reaction time is critical. If reaction time exceeds two (2) minutes, drying of the reaction mixture may cause false positive results.
2. Freezing the CRP Latex Reagent will result in spontaneous agglutination.
3. Intensity of agglutination is not necessarily indicative of relative CRP concentration; therefore, screening reactions should not be graded.
4. 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 6 mg/L. Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

- **Sensitivity:** 6(5-10) mg/L
- **Prozone effect:** No prozone effect was detected up to 1600 mg/L
- **Diagnostic sensitivity:** 95.6 %.
- **Diagnostic specificity:** 96.2 %.

REFERENCES

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

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PPI005A01
Rev H (06.06.2017)

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 package is **damaged**
	Manufacturer telephone number		

Atlas Medical CE

Atlas D-Dimer Latex Kit

IVD *For In Vitro Diagnostic Use Only.*

Store at 2°C to 8ºC.

INTENDED USE

Atlas D-Dimer Latex Test is intended for the rapid qualitative or semi-quantitative evaluation of circulating derivatives of cross-linked fibrin degradation products (XL-FDP) in human plasma.

INTRODUCTION

During blood coagulation, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerize to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by thrombin activated Factor XIII to form an insoluble fibrin clot. Production of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Fibrinogen and fibrin are both cleaved by the fibrinolytic enzyme plasmin to yield degradation products, but only degradation products from cross-linked fibrin contain D-Dimer. Therefore, cross-linked fibrin degradation products (XL-FDP) are a specific marker of fibrinolysis.

PRINCIPLE

Atlas D-Dimer Latex is a rapid agglutination assay utilizing latex beads coupled with a highly specific D-Dimer monoclonal antibody. XL-FDP present in a plasma sample bind to the coated latex beads, which results in visible agglutination occurring when the concentration of D-Dimer is above the threshold of detection of the assay.

MATERIALS

MATERIALS PROVIDED

- D-Dimer Latex Reagent: a 0.83% suspension of latex particles coated with murine anti-D-Dimer monoclonal antibody, 10mg/mL BSA and 0.1% sodium azide.
- D-Dimer Positive Control: a solution containing purified human D-Dimer fragment, 5mg/mL BSA and 0.1% sodium azide.
- D-Dimer Negative Control: a buffer solution containing 5mg/mL BSA and 0.1% sodium azide.
- Dilution Buffer
- Reaction slide
- Stirring Sticks
- Instructions for Use

MATERIALS NEEDED BUT NOT PROVIDED

- Precision pipettes and tips - 20 µL and 100 µL
- Plastic test tubes and rack
- Stopwatch or timing device
- Disposable gloves
- Tissue (for wiping dropper bottle tips)

PRECAUTIONS

- For In Vitro Diagnostic Use Only.
- Harmful if swallowed. Avoid contact with skin and eyes. Do not empty into drains.
- Wear suitable protective clothing.
- CAUTION: All reagents in Atlas D-Dimer Latex Kit contain sodium azide (0.1%) as preservative. Do not ingest or allow to contact skin or mucous membranes. Sodium azide may form explosive azides in metal plumbing. Use proper disposal procedures.
- CAUTION: The Positive Control in Atlas D-Dimer Latex Kit contains components of human origin. Each individual blood donation intended for the production of this reagent is tested for HBsAg, anti-HCV, anti-HIV1 and anti-HIV2. Only donations with negative findings are employed. As complete absence of infectious agents can never be assured, all materials derived from human blood should be treated as potentially infectious and handled with due care following the precautions recommended for biohazardous material.

STORAGE AND STABILITY

- Store at 2°C to 8ºC.
- DO NOT FREEZE.
- Stability: Refer to outer package and vial labels for expiration date.
- Indication of Reagent Deterioration
  Reagent deterioration is indicated by failure of the Latex Reagent to agglutinate with the Positive Control, agglutination with the Negative Control, or evidence of microbial contamination.

SPECIMEN COLLECTION AND PREPARATION

Plasma prepared from whole blood anticoagulated with sodium citrate is recommended. The use of EDTA and heparin will result in an increased level of false positive reactions. After separation of the plasma by centrifugation (1500g for 15 minutes at 4°C - 10°C), specimens may be tested directly for the presence of XL-FDP. Defibrination of the plasma is not recommended.
Plasma storage/stability: - 20ºC: 2 weeks
Thaw frozen specimens rapidly at 37ºC and centrifuge before testing.

PROCEDURE

- Equilibrate reagents to room temperature (20°C to 25°C) before use.
- Latex Reagent should be mixed by inversion immediately prior to use.

Qualitative Method

1. Bring reagents and specimens to room temperature before use.
2. Place 20 µL of the reagent within a well on a reaction slide. **AVOID** touching the surface of the Reaction slide
3. Accurately pipette 20 µL of undiluted plasma or of control solution inside the same well next to the drop of Latex Reagent.
4. Mix the Latex Reagent and sample with a stirrer until the Latex is uniformly distributed.
5. Rock the reaction slide gently by hand for exactly 3 minutes.
6. At exactly 3 minutes, check for agglutination under a strong light source.

NOTE

If test reading is delayed beyond 3 minutes, the latex suspension may dry out **giving a false agglutination pattern. If this is suspected, the specimen must be retested.**

Semi quantitative Method

1. Prepare serial dilutions of the test plasma with Buffer as follows:
1:2 dilution 100 µL plasma plus 100 µL Buffer solution
1:4 dilution 100 µL 1:2 dilution plus 100 µL Buffer solution
1:8 dilution 100 µL 1:4 dilution plus 100 µL Buffer solution
2. Test each dilution as described in the qualitative method.

QUALITY CONTROL

- It is recommended that both Positive and Negative Controls be included in each batch of tests to ensure proper functioning of the system. Control solutions should be tested by the same procedures as patient samples.
- D-Dimer Positive Control consists of a solution of human D-Dimer at a level of approximately ≥ 0.80 mg/L (≥ 800ng/mL).

RESULTS

A. Qualitative Assay

For the qualitative assay protocol, the following pattern of results should be obtained:
Undiluted Plasma D-Dimer (XL-FDP) concentration
Negative Less than 0.20 mg/L (200ng/mL)
Positive Greater than 0.20 mg/L (200ng/mL)
Note: All values in mg/L (ng/mL) are approximate

B. Semiquantitative Assay

Approximate levels of XL-FDP, containing the D-Dimer domain, for specimen dilutions are shown in Table 1. As with all semiquantitative tests, some variability in dose-response can be expected.

Approximate Range of D-Dimer (XL-FDP) mg/L (ng/ml)	Sample Dilution			
	Undil.	1:2	1:4	1:8
< 0.2 (< 200)	-	-	-	-
0.2 – 0.4 (200 – 400)	+	-	-	-
0.4 – 0.8 (400 – 800)	+	+	-	-
0.8 – 1.6 (800 – 1600)	+	+	+	-
1.6 – 3.2* (1600 – 3200*)	+	+	+	+

"+" = agglutination, "-" = no agglutination
* Levels of XL-FDP greater than 3.20 mg/L (3200 ng/mL) can be estimated by further dilutions beyond 1:8.

EXPECTED VALUES

A positive result, indicating active fibrinolysis, should be obtained with D-Dimer Latex Test when XL-FDP (D-Dimer) levels are at or

greater than approximately 0.20 mg/L (200ng/mL). Plasma specimens from normal subjects are expected to give negative results because their plasma XL-FDP concentrations are typically less than 0.20 mg/L (200ng/mL). Due to many variables that may affect results, each laboratory should establish its own normal range.

Elevated levels of XL-FDP (containing the D-Dimer domain) have been demonstrated in patients by a combination of immunoprecipitation and gel electrophoresis techniques. Monoclonal antibodies allow the specific detection of the D-Dimer domain. Monoclonal antibody based D-Dimer assay is of diagnostic value in disseminated intravascular coagulation (DIC) and acute vascular diseases, including pulmonary embolism (PE) and deep venous thrombosis (DVT), conditions that are difficult to detect reliably by clinical examination.

The amount of XL-FDP detected in a specimen will depend on several interrelated factors in vivo, such as the severity of the thrombotic episode, the rate of cross linked fibrin formation, and the time elapsed after the thrombotic event until blood is drawn from the patient.

Elevated levels of XL-FDP as an indication of reactive fibrinolysis have also been reported in surgery, trauma, sickle cell disease, liver disease, severe infection, sepsis, inflammation, and malignancy. D-Dimer levels also rise during normal pregnancy but very high levels are associated with complications.

LIMITATIONS

Clinical diagnosis should not be based on the result of D-Dimer Latex alone. Clinical signs and other relevant test information should be included in the diagnostic decision.

SPECIFIC PERFORMANCE CHARACTERISTICS

- Plasma from one hundred and seventy (170) apparently healthy, voluntary blood donors was tested using Atlas D-Dimer Latex. A negative result was obtained for one hundred and sixty-two (162) of the samples. This equates to a specificity of 95.3% (162/170).
- One hundred and forty-five (145) plasma samples from patients judged to be suffering from, or having a high probability for thrombotic episode, were tested by Atlas D-Dimer Latex and another agglutination reference method. The correlation coefficient was r=0.94 and the regression equation was y=1.19x.
- Intra-assay (within run) reproducibility was determined for 10 replicates of 3 plasma samples that contained different levels of XL-FDP. The results were equivalent for all replicates.
- Inter-assay (run-to-run) reproducibility was determined using 10 plasma samples with XL-FDP titers ranging from 1 to 16. In 10 runs, the replicates of these specimens did not vary by more than one titer.
- In an anticoagulant study of 50 parallel citrated, EDTA and heparin plasma samples, the correlation between the titers obtained with Atlas D-Dimer Latex and the expected titers (based on ELISA XL-FDP values) was r = 0.91 for citrated samples, r = 0.73 for EDTA samples and r = 0.78 for heparin samples. Citrate is the anticoagulant of choice.
- Atlas D-Dimer Latex does not cross-react with fibrinogen, factor XIIIa cross-linked fibrinogen, or fibrinogen degradation products.
- The interference due to presence of rheumatoid factor (RF): in a study of samples from patients with rheumatoid arthritis ,17 were found to agglutinate with D-Dimer latex. In all 17 sample ,the agglutination could be inhibited by the addition of the D-Dimer specific monoclonal antibody DD3B6/22, but not with a non - specific monoclonal antibody of the same subgroup ,IgG3K. This suggests that D-Dimer latex is insensitive to rheumatoid factor disturbances.
- No assay interference was demonstrated with Atlas D-Dimer Latex with spiked specimens containing potential interfering substances at the following concentrations:
- Bilirubin 0.2 mg/mL
- Hemoglobin 5.0 mg/mL
- Lipids (triglycerides) 30 mg/mL
- Protein (gamma globulin) 0.06 g/mL

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PPI139A01
Rev E (03.03.2016)

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 package is **damaged**
	Manufacturer telephone number		

Atlas Medical CE

ATLAS RHEUMATOID FACTOR (RF) LATEX KIT

latex slide test for the qualitative and semi-quantitative measurement of RF in human serum.

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

Store at 2-8°C

INTENDED USE

A latex slide test for the qualitative and semi-quantitative measurement of RF in human serum.

INTRODUCTION

Rheumatoid factors (RF) are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG . Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease.

One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized sheep red cells, as observed by Waaler and Rose. A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz. The RF kit is based on the principle of the latex agglutination assay of Singer and Plotz .The major advantage of this method is rapid performance (2 minute reaction time) and lack of heterophile antibody interference.

PRINCIPLE

The RF reagent is based on an immunological reaction between human IgG bound to biologically inert latex particles and rheumatoid factors in the test specimen. When serum containing rheumatoid factors is mixed with the latex reagent, visible agglutination occurs.

MATERIALS

MATERIALS PR0VIDED

- RF Latex Reagent: Latex particles coated with human gamma-globulin, pH, 8,2. Preservative. Contains N, N-dimethylformamide .
- RF Positive Control Serum: Human serum with a RF concentration > 30 IU/mL.Preservative.
- RF Negative Control Serum:Animal serum. Preservative.
- Reaction Slide
- Stirring sticks

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Test Tubes (for dilution)
- Serological pipettes (for sample addition and for dilution)
- Rotator (optional)
- Glycine Buffer (20x): add one part to nineteen parts of distilled water before use.

PRECAUTIONS

- All reagents contain 0.1 %(w/v) sodium azide as a preservative.
- 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.
- Positive and negative controls prepared using human serum found negative for hepatitis B surface antigen (HBsAg) 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.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C).
- Do not freeze.
- The RF 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.

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.
- As in all serological tests, hemolytic or contaminated serum must not be used.
- Do not use PLASMA.

PROCEDURE

Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the RF-latex reagent rigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. 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.

Semi-quantitative method

1. Make serial two fold dilutions of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

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 RF concentration equal or greater than 8 IU/mL (Note 1).

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

CALCULATIONS

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

8 x RF Titer = IU/mL

INTERFERENCES

NON INTERFERING SUBSTANCES:

- Hemoglobin (10g/dl)
- Bilirubin(20mg/dl)
- Lipemia(10g/dl)

Other substances may interfere.

QUALITY CONTROL

1. RF Positive and Negative Control should be included in each test batch.
2. Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the RF Negative Control and agglutination with large aggregates is observed with the RF Positive Control.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

8(6-16) IU/ml, under the described assay conditions.

PROZONE EFFECT

No prozone effect was detected up to 1500 IU/ml.

DIAGNOSTIC SENSITIVITY

100%.

DIAGNOSTIC SPECIFICITY

100%.

The diagnostic sensitivity and specificity have been obtained using 118 samples compared with the same method of a computer.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the RF Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative RF concentration; therefore, screening reactions should not be graded.
- Increased levels of RF may be found in some diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcodosis, lupus erythrematosus, Sjogren's syndrome.
- Certain patients with rheumatoid arthritis will not have the RF present in their serum.
- The incidence of false positive results is about 3-5 %.Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.
- Diagnosis should not be solely based on the results of latex method but also should be complemented with a Waaler Rose test along with the clinical examination.

REFERENCE VALUES

Up to 8 IU/mL. Each laboratory should establish its own reference range.

NOTES

1. Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

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PPI008A01, Rev H (17.06.2017)

REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
	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 package is **damaged**
	Manufacturer telephone number		

Atlas Medical

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

For *In-Vitro* and professional use only
Store at 2 to 8 C

INTENDED USE
For the qualitative and 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.

MATERIALS NEEDED BUT NOT PROVIDED
- Saline 0.9%.
- Rotator (100rpm).
- Accurate pipette to deliver 50 µl and.
- Timer.

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

LIMITATION

- This test provides a presumptive diagnosis of syphilis. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
- In positive specimens, it is recommended to confirm the result by another serological test such as the TPHA.

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PPI009A01
Rev F (08.10.2011)

Atlas Medical

CE

TPHA TEST KIT

For the detection of antibodies to T.pallidum in human Serum using micro haemagglutination.

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

Store at 2° to 8° C

INTENDED USE

TPHA test kit is designed for the detection of antibodies to *Treponema pallidum* (IgG and IgM antibodies) in human serum or plasma based on the principle of passive haemagglutination.

INTRODUCTION

Syphilis is a venereal disease caused by the spirochaete micro-organism *Treponema pallidum*. As this organism cannot be cultured on artificial media the diagnosis of syphilis depends on the correlation of clinical data with the specific antibody demonstrated by serological tests. Serological screening tests for syphilis using cardiolipin and lecithin as antigens are simple to perform but biological false positive (BFP) reactions occur frequently because the tests use non-treponemal antigens.

The TPI and FTA-ABS tests utilize pathogenic *Treponema pallidum* as the antigen but these tests present some difficulties for routine serodiagnosis. The TPI test requires living pathogenic *T.Pallidum* and the FTA-ABS test requires a flourescence microscope. Both tests require a high level of expertise.

TPHA test kit has been shown to be a convenient and specific test for the diagnosis of treponemal infection, having specificity similar to that of the TPI test and sensitivity comparable to that of the FTA-ABS test. It requires minimum laboratory equipment and is very simple to perform.

TPHA reagents are used to detect human serum antibody to *T.pallidum* by means of an indirect haemagglutination (IHA) method. Preserved avian erythrocytes are coated with antigenic components of pathogenic *T.pallidum* (Nichol's strain). These Test Cells agglutinate in the presence of specific antibodies to *T.pallidum,* and show characteristic patterns in microtitration plates.

Any non-specific reactions occurring are detected using the Control Cells, which are avian erythrocytes not coated with *T.pallidum* antigens. Non-specific reactions may also be absorbed out using these Control Cells.

Antibodies to non-pathogenic treponemes are absorbed by an extract of Reiter's treponemes, included in the cell suspension. Test results are obtained in 45-60 minutes and the cell agglutination patterns are both easily read and long lasting.

The test sample is diluted in absorbing diluent to remove possible cross-reacting heterophile antibody and to remove, block, or absorb potentially cross-reacting. Nonpathogenic treponemal antibodies.

MATERIALS

MATERIALS PROVIDED

- Test cells; preserved avian erythrocytes sensitised with T.pallidum antigen.
- Control cells; preserved avian erythrocyte.
- Diluent.
- Positive control serum; (prediluted 1:20), Use neat. This will give an equivalent titer of 1/640:/2560 in the quantitative test.
- Negative control serum; (prediluted 1:20), Use neat.
- Package Insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Accurate pipettes for delivering 10:25:75 and 190 microlitres.
- U-Well microtitration plates.

PRECAUTIONS

The reagents and controls contain 0.1% sodium azide as a preservative. Avoid ingestion and contact with skin or mucus membrane. Normal laboratory precautions should be maintained while handling test reagents.

REAGENTS HANDELING

- All the reagents must be allowed to reach room temperature before use.
- Do not freeze any of the reagents.
- Do not use heamolysed, contaminated or lipaemic serum or plasma for testing as this will adversely affect the results.

REAGENTS STORAGE

- The kit should be stored at 2-8º C in an upright position at all times.
- Under these conditions, kit performance characteristics will be maintained for at least 15 or 18 months from date of manufacture. See expiry date on kit label.
- Reagents should be discarded if they become contaminated or do not demonstrate correct activity with the controls.
- The reagents in each kit have been standardized to produce the proper reaction and reagents should not be interchanged with those from other batches.

SAMPLE PREPARATION

- The test is designed for use with serum only.
- Plasma samples should not be used.
- The samples should be free from haemolysis and contamination.
- Serum samples may be stored at 2-8° C if a preservative is added prior to storage.
- For long term storage sera should be stored at -20° C Strictly avoid contaminating any of the reagents or serum dilutions with saliva. This will cause confusing patterns similar to positive results with specimens which should be negative.

PROCEDURES

QUALITATIVE METHOD

Each sample requires 3 wells of a microtitration plate.

1. Add 190µl of diluent to Well 1.
2. Add 10µlserum to Well 1. (Sample dilution 1:20).
3. Using a micropipette, mix contents of Well 1 and transfer 25µl to Wells 2 & 3.
4. Ensure that the Test and Control Cells are thoroughly resuspended. Add 75µlof control cells to Well 2. Add 75µl of Test Cells to Well 3.
5. Tap the plate gently to mix the contents thoroughly.
6. Incubate 45-60 minutes at room temperature.
7. Caution! Keep the plate away from heat, direct sunlight and any source of vibration.
8. Read results. Results are stable for 24hrs if the plate is covered and the above precautions are observed.

NOTE

Kit controls can be run in parallel and are diluted and ready for use.

QUANTITATIVE TEST

Each sample requires 8 Wells of a microtitration plate, Labeled A through to H.

1. Add 25µl of diluent to Wells B to H inclusive.
2. Transfer 25µlof 1:20 serum dilution from screening test to Wells A and B.
3. Take 25µl of diluted serum from Well B and serially dilute from Wells B to H inclusive in 25µl aliquots, discarding 25µl of diluted serum from Well H.
4. Ensure that the Test Cells are thoroughly resuspended. Add 75µl of Test cells to wells A to H inclusive. This will give a dilution of serum of 1/ 80 in well A through 1/ 10240 Well H.
5. Shake the plate gently to mix the contents thoroughly.
6. Incubatefor45-60 minutes at room temperature.
7. Caution! Keep the plate away from heat, direct sunlight and any source of vibration.
8. Read results. Results are stable for 24hrs. if the plate is covered and the above precautions are observed.

RESULTS

RESULTS	TEST CELLS	CONTROL CELLS
Strong Positive	Full cell pattern covering the bottom of the well.	No agglutination tight button
Weak Positive	Cell pattern covers approx. 1/3 of well bottom	No agglutination tight button
Indeterminate	Cell pattern shows a distinctly open center	No agglutination tight button
Negative	Cells settled to a compact bottom, typically with a small clear center.	No agglutination tight button
Non-specific *	Positive reaction	Positive reaction

Non-specific absorption *

1. Add 10µl to a small tube then add 190µl of Control Cells. Mix well and stand for 30 minutes.
2. Centrifuge for 15 minutes at 1000 rpm and test the supernatant by the qualitative method.

Note:

If the result is repeatedly non-specific the sample should be tested by another method eg. Reagin or FTA-ABS.

Although TPHA test is highly specific, **false positive results** have been known to occur in patients suffering from leprosy, infectious mononucleosis and connective tissue disorders. For confirmation FTA-ABS test should be used.

INTERPRETATION OF RESULTS.

Strong positive reactions may show some folding at the edge of the cell mat.

When the Test well is positive, the Control well should be observed.

The Control cells should settle to a compact button. They should not be used as a comparison for Non-Reactive serum patterns since the Control Cells will give a more compact pattern than the Test Cells.

Weak positive may show partially not full cell pattern cover the well bottom

INVALID may show Agglutination in the Control well indicates the presence of non-specific agglutinins in the sample. A serum that gives this result may be absorbed using the Control Cells as detailed under Non-specific absorption.

INDETERMINATEA may show a doubtful reaction with Test Cells This result may indicate a low level of antibody in early primary syphilis or yaws. This sample should be first retested in the qualitative test then a further sample should be tested at a later date to determine whether or not there is a rising titer. It is also advisable to perform a regain test and/or another confirmation test (FTA-ABS) to complete the profile of the test serum.

Negative may show cells settled as a dot at the bottom of the well

PERFORMANCE

SENSITIVITY

With clinical samples when compared to FTA-ABS and/or clinical diagnosis was 99.7% (298/299)

SPECIFICITY

With clinical samples was 99.3% (301/303).

CROSS REACTIVITY

Reactive results may indicate an active or successfully treated infection. The following have all been shown not to interfere with the test results (10 clinical samples of each)

- Rheumatoid Factor.
- Post Hepatitis B vaccination.
- Genital Herpes.
- Leptospirosis.
- EBV Infection.
- SLE.
- Lyme's Disease.

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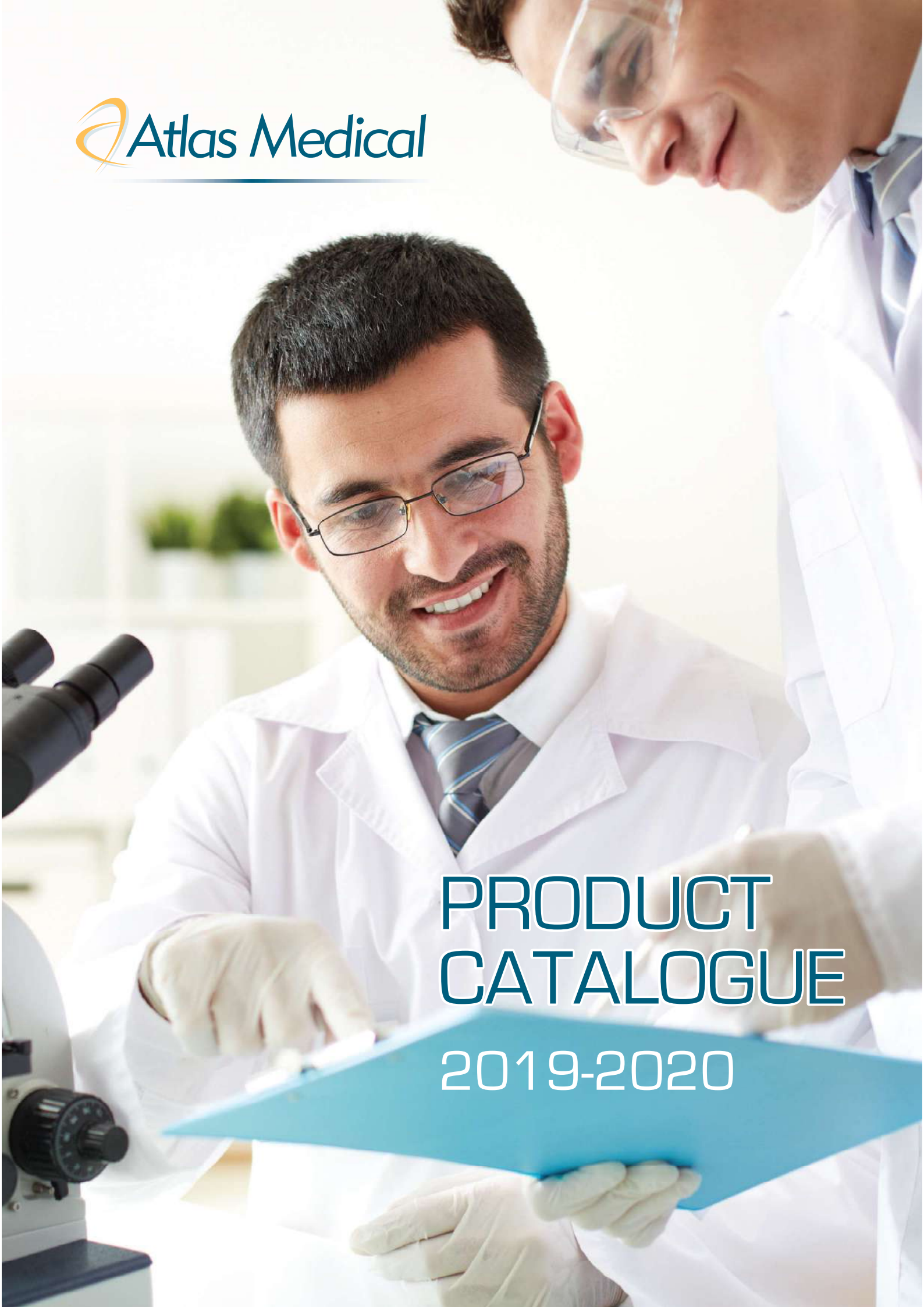
PPI080A01

Rev F (09.06.2016)

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 package is **damaged**
	Manufacturer telephone number		

Atlas Medical



PRODUCT CATALOGUE

2019-2020

Introduction

Atlas Medical is a UK-based company established in 1996 as a manufacturer and supplier of quality Diagnostic Reagents and Kits. Our products are sold in over 80 countries worldwide. Our product range comprises a comprehensive list of quality diagnostic products in the fields of serology, hematology, microbiology, immunology, histopathology and biochemistry. We have good experience in certain technologies used in manufacturing diagnostic products such as clinical chemistry, nano-beads serology, immunoassays including ELISA and lateral flow rapid test.

The company is located at the Cambridge Science Park, Cambridge, UK, just on the outskirt of Cambridge City. In addition to the UK site, the company has two purpose-built modern facilities in both Jordan and Malaysia. We take quality assurance very seriously and strive to produce goods to the highest standards known in the industry, including, ISO13485 & CE mark and US FDA standards. Our R&D team constantly develops and innovates novel products that significantly contribute to the advancement of the Diagnostic Industry.

Our Mission:

Our mission is to develop, produce and provide our customers with high quality products and excellent customer services through deep understanding of customers' needs and perception, recruitment of high caliber professionals & technicians, adopting strict quality assurance and control procedures and embracing new scientific advancements in the medical lab diagnostic field.

Our Objectives:

- High and Consistent Quality:

We have assigned and adopted high standards of performance for our products to ensure that batch after batch our products are produced at consistently high quality.

- Satisfied Customers:

We strive to supply our customers with quality products and services that will meet or exceed their expectations.

- Continuous Improvement & Innovation:

We are committed to continuously develop and innovate new products and play an active role in the advancement of medical diagnostic reagents and assays.

- Care for the environment and working conditions:

We take environmental issues very seriously and seek to provide a motivating & comfortable working atmosphere that creates team spirit to ensure increased efficiency, performance and productivity.

Our Standards:

Our products are manufactured in accordance to the standards as set in the European In-Vitro Diagnostic Directive 98/79/EC. This has led to the successful attainment of Annex IV Full Quality Assurance Certification and the declaration of conformity for CE marking purposes for many of our IVD products, either self-declared or through our Notified Body LNE/G-MED in France. To complete the quality assurance scheme the company has put in place a robust Quality Management and Enhancement System that has concluded in the successful attainment of ISO13485: 2003 certificate by Lloyd's Register. The company also offers a number of OTC products that have been certified by LNE/G-MED to Annex III.6 of the CE IVD directive for home use. Furthermore, the company also adheres to the US-FDA regulations and had already FDA-cleared few products for the US market. Our products are registered in numerous countries. Our regulatory team is experienced to provide all the supporting documents to register our products in more countries.

Our Markets:

Atlas Medical enjoys a good presence in many international markets. We take pride in our export activities through our dedicated export department. We actively participate in major industry-related exhibitions seeking keen representatives around the globe to sell and distribute our products in their respective countries. We are internationally represented in

more than 80 of countries spanning in five continents: Europe, North America, South America, Africa and Asia. Our efforts will continue to increase our representation to include most markets around the globe.

Our Products and Services:

We are specialized in the field of Medical Diagnostic Reagents and Kits for use in medical labs, clinics and hospitals. We supply an extensive range that includes:

- Latex related kits, indirect hemo-agglutination, carbon antigens (serology)
- Blood grouping and rare sera (blood banking)
- Coagulation and D-Dimer reagents (hematology)
- Stained bacterial antigens, blood culture bottles (febrile antigens - microbiology).
- Rapid tests and urine reagent strips (lateral flow immunoassay and dry chemistry).
- Stains for microbiology and histopathology
- ELISA kits (infectious diseases, hormones, torch and Vitamins)
- Clinical chemistry (biochemistry)
- Drug-of-Abuse and alcohol tests (Toxicology)
- Home (OTC) Tests: Fertility Home Tests & General Health Screening Tests.

Many of these items fulfill the day-to-day requirements of most medical labs. The OTC range is directed towards the pharmacies and chemists market and intended for home use. Detailed listing of standard production items is available in our product list.

In addition to our standard product list, we are capable of offering OEM, private labeling and R&D services to customers according to their needs.
Our Contact Details:

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MILESTONES

1996
Establishment of
Cambridge - UK

2001
Establishment of
Mnaufacturing Site Amman - Jordan

2003
Obtaining ISO13485
By Lloyd's Register

2006
Obtaining Self-Testing CE
Atlas Home Ovulation Test

2007
Obtaining Self-Testing CE
Atlas Home Menopause Test

2009
Obtaining Self-Testing CE
Atlas Home Screening Tests

2010
Kuala-Lumpur (Puchong)- Malaysia
Manufacturing and Sales (SEA)

2011
Obtaining FDA 510k
Atlas Home HCG Midstream Test
Obtaining Self - Testing CE
Atlas Home Pregnancy test

2017
Kuala-Lumpur (TPM) – Malaysia
Manufacturing

2018
Establishment of
Berlin – Germany
Distribution network extended to 80 countries

LATEX KITS

Latex kits offer a quick and simple assay to diagnose a range of pathogens and medical conditions. The assay is based on an immunological reaction between the detected analyte in the sample and its corresponding antibody or antigen already coated on latex particles

Atlas Medical latex kits cover a selection of routine tests in serology and microbiology. They are conveniently packed in sizes of 50 or 100 tests and includes all the necessary reagents, controls, stirrers and slides to conduct the test. Atlas Medical Latex kits are affordable, easy to use, dependable and offer a clear and visible agglutination for doubt-free results within 2 minutes.

Item Code	Item Description	Available sizes	CE-Status
8.00.00.0.0050 8.00.00.0.0100	CRP Latex Kit	50 Tests 100 Tests	CE-Professional
8.00.01.0.0050 8.00.01.0.0100	CRP Latex Kit with Buffer	50 Tests 100 Tests	CE-Professional
8.00.02.0.0050 8.00.02.0.0100	ASO Latex Kit	50 Tests 100 Tests	CE-Professional
8.00.03.0.0050 8.00.03.0.0100	ASO Latex Kit with Buffer	50 Tests 100 Tests	CE-Professional
8.00.04.0.0050 8.00.04.0.0100	RF Latex Kit	50 Tests 100 Tests	CE-Professional
8.00.05.0.0050 8.00.05.0.0100	RF Latex Kit with Buffer	50 Tests 100 Tests	CE-Professional
8.00.07.0.0050 8.00.07.0.0100	hCG Latex Kit	50 Tests 100 Tests	CE-Professional
8.00.09.0.0050 8.00.09.0.0100	Toxo Latex Kit	50 Tests 100 Tests	Not CE-Marked
8.00.10.0.0050 8.00.10.0.0100	Toxo Latex Kit with Buffer	50 Tests 100 Tests	Not CE-Marked
8.00.11.0.0050 8.00.11.0.0100	SLE Latex Kit	50 Tests 100 Tests	CE-Professional
8.00.12.0.0050 8.00.12.0.0100	Staphylococcus Latex Kit	50 Tests 100 Tests	CE-Professional
8.00.13.0.0300	Streptococcus Latex Kit	300 Tests	CE-Professional
8.00.14.0.0100	Rubella Latex Kit	100 Tests	Not CE-Marked
8.00.15.0.0050 8.00.15.0.0100	E.coli Latex Kit	50 Tests 100 Tests	CE-Professional
8.00.16.0.0050 8.00.16.0.0100	Rota Virus Latex Kit	50 Tests 100 Tests	CE-Professional
8.00.17.0.0050 8.00.17.0.0100	D-Dimer Latex Kit	50 Tests 100 Tests	CE-Professional
8.00.21.0.0050 8.00.21.0.0100	Waaler Rose Kit	50 Tests 100 Tests	CE-Professional
8.00.31.0.0050 8.00.31.0.0100	IM Latex Kit	50 Tests 100 Tests	CE-Professional

TURBIDIMETRIC LATEX KITS

The turbidimetric assay is based on the agglutination reaction between
latex particles coated with antibody and the antigen in solution.
The intended use for Turbilatex products is to detect and quantify the antigen present in human stool samples.

Atlas Medical offers a dynamic range of Turbidimetric Latex Kits which are conveniently packed in sizes of 50, 100 and 250 tests and include all the necessary accessories.

Item Code	Item Description	Available sizes	CE-Status
8.44.00.0.0050 8.44.00.0.0100 8.44.00.0.0250	RF Turbidimetric Latex Kit	50 Tests 100 Tests 250 Tests	CE-Professional
8.44.01.0.0050 8.44.01.0.0100 8.44.01.0.0250	CRP Turbidimetric Latex Kit	50 Tests 100 Tests 250 Tests	CE-Professional
8.44.02.0.0050 8.44.02.0.0100 8.44.02.0.0100	ASO Turbidimetric Latex Kit	50 Tests 100 Tests 250 Tests	CE-Professional
8.44.02.0.0050	D-Dimer Turbidimetric Latex Kit	50 Tests	CE-Professional

FEBRILE ANTIGENS

Febrile antigen kits are based on bacterial suspensions that agglutinate in the presence of antibodies formed in human infection by certain fever-causing microbial agents. In positive samples, the agglutination is macroscopically visible at certain antibody levels in serum. These antigen reagents are used for the qualitative and semi quantitative febrile screening purposes.

Item Code	Item Description	Available sizes	CE-Status
8.01.00.0.0005 8.01.00.0.0050 8.01.00.0.0100	Brucella Rose Bengal Kit	5ml/vial 50 Tests 100 Tests	CE-Professional
8.01.01.0.0005 8.01.01.1.0040	Salmonella OA Reagent	5ml/vial 5X8 ml	CE-Professional

Item Code	Item Description	Available sizes	CE-Status
8.01.02.0.0005 8.01.02.1.0040	Salmonella OB Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.03.0.0005 8.01.03.1.0040	Salmonella OC Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.04.0.0005 8.01.04.1.0040	Salmonella OD Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.05.0.0005 8.01.05.1.0040	Salmonella HA Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.06.0.0005 8.01.06.1.0040	Salmonella HB Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.07.0.0005 8.01.07.1.0040	Salmonella HC Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.08.0.0005 8.01.08.1.0040	Salmonella HD Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.10.0.0005 8.01.10.1.0040	Brucella abortus Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.11.0.0005 8.01.11.1.0040	Brucella melitensis Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.12.0.0005 8.01.12.1.0040	Proteus OX2 Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.13.0.0005 8.01.13.1.0040	Proteus OX19 Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.14.0.0005 8.01.14.1.0040	Proteus OXK Reagent	5ml/vial 5X8 ml	CE-Professional
8.01.15.0.0010	Brucella Antigen Kit, (Brucella melitensis, Brucella abortus)	5ml/vial	CE-Professional
8.01.15.1.0010	Brucella Antigen Kit with Controls, (Brucella melitensis, Brucella abortus, 2x1.0 ml Controls)	5ml/vial	CE-Professional
8.01.16.0.0040	Salmonella Antigen Set (8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD)	5X8 ml	CE-Professional
8.01.16.1.0040	Salmonella Antigen Set (8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD) with 2x1.0ml Controls	5X8 ml	CE-Professional
8.01.17.1.0050	Febrile Antigen Set (10 Antigens: Salmonella OA, OB, OC, OD, HA, HB, HC, HD, Brucella abortus, melitensis) with 2x1.0ml Controls	5X10 ml	CE-Professional
8.01.18.0.0030	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD)	5X6 ml	CE-Professional
8.01.18.1.0030	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD) with 2x1.0ml Controls	5X6 ml	CE-Professional
8.01.19.0.0001 8.01.19.0.0005	Febrile Antigens Positive Control	1ml/Vial 5ml/Vial	CE-Professional
8.01.20.0.0001 8.01.20.0.0005	Febrile Antigen Negative Control	1ml/Vial 5ml/Vial	CE-Professional

SYPHILIS KITS

Atlas Medical offers a number of assays to detect Syphilis that include: TPHA kits which are used for the detection of antibodies to Treponema pallidum in human Serum using micro haemagglutination; VDRL and RPR kits which are based on non-Treponemal flocculation to detect reagin antibodies in serum or plasma; and rapid lateral flow immunoassay tests to detect Syphilis antibodies in serum, plasma or whole blood.

Atlas Medical Syphilis kits are easy to use, affordable and conveniently packed in different sizes to suit all needs. The kits include all the necessary reagents/devices, controls, stirrers and slides to conduct the test (depending on the assay).

Item Code	Item Description	Available sizes	CE-Status
8.00.18.0.0100 8.00.18.0.0500	RPR Carbon Antigen Kit	100 tests/kit 500 tests/kit	CE-Professional
8.00.19.0.0100 8.00.19.0.0200	TPHA Kit, 100 Tests	100 tests/kit 500 tests/kit	CE-Professional
8.00.20.0.2500	VDRL Kit, 5ml+55ml Buffer	2500 tests/kit	CE-Professional

BLOOD GROUPING REAGENTS

Blood Grouping reagents are used for the identification of blood types. The test procedure is based on the agglutination principle, where red cells possessing the typing antigen agglutinate in the presence of the corresponding antibody in the testing reagent indicating the presence of the tested antigen. No agglutination indicates the absence of the tested antigen.

Atlas Medical ABO reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines. The reagents are formulated and optimized for use in tube and slide methods. Atlas Medical provides high quality blood grouping reagents that are accurate, easy to use, competitively priced, and conveniently packed in different sizes and options.

Item Code	Item Description	Available sizes	CE-Status
8.02.00.0.0010 8.02.00.1.0100	Anti-A Monoclonal reagent (titer: 1/512)	10ml/vial 10X10 ml	CE-Annex II List A
8.02.01.0.0010 8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512)	10ml/vial 10X10 ml	CE-Annex II List A
8.02.02.0.0010 8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512)	10ml/vial 10X10 ml	CE-Annex II List A
8.02.03.0.0010 8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128)	10ml/vial 10X10 ml	CE-Annex II List A
8.02.04.0.0010 8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256	10ml/vial 10X10 ml	CE-Annex II List A
8.02.05.0.0010 8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256)	10ml/vial 10X10 ml	CE-Annex II List A
8.02.06.0.0010 8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256)	10ml/vial 10X10 ml	CE-Annex II List A
8.02.07.0.0010 8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64)	10ml/vial 10X10 ml	CE-Annex II List A
8.02.08.0.0010 8.02.08.1.0100	Bovine Albumin 22%	10ml/vial 10X10 ml	CE-Professional
8.02.09.0.0010 8.02.09.1.0100	Bovine Albumin 30%	10ml/vial 10X10 ml	CE-Professional
8.02.10.0.0010 8.02.10.1.0100	Anti-Human Globulin (Green) (Titer 1/512)	10ml/vial 10X10 ml	CE-Professional
8.02.11.0.0010 8.02.11.1.0100	Anti-Human Globulin (Green) (Titer 1/256)	10ml/vial 10X10 ml	CE-Professional

Item Code	Item Description	Available sizes	CE-Status
8.02.47.0.0030	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128))	3x10ml	CE-Annex II List A
8.02.47.1.0030	ABO Set (Anti-A (1/265), Anti-B (1/265), Anti-D (1/64)),	3x10ml	CE-Annex II List A
8.02.49.0.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/64))	4x10ml	CE-Annex II List A
8.02.53.0.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128))	4x10ml	CE-Annex II List A
8.02.52.0.0010 8.02.52.0.0100	Rh-D Negative Control	10ml/vial 10X10 ml	CE-Professional
8.02.63.1.0010 8.02.63.1.0100	Antibody Enhancement Solution (LISS)	10ml/vial 10X10 ml	CE-Professional
8.02.14.0.0010	Anti-D Monoclonal (IgM), Clone 1, 10ml/vial	10ml/vial	Not CE-Marked
8.02.15.0.0010	Anti-D Monoclonal (IgM), Clone 2, 10ml/vial	10ml/vial	Not CE-Marked
8.02.16.0.0005	Anti-A1, Lectin (Dolichosbiflorus), 5ml/vial	5 ml/vial	Not CE-Marked
8.02.17.0.0002	Anti-H, Lectin (Ulexeuropaeus), 2ml/vial	2 ml/vial	Not CE-Marked
8.02.18.0.0005	Anti-C Monoclonal, 5ml/vial	5 ml/vial	Not CE-Marked
8.02.19.0.0005	Anti-c Monoclonal, 5ml/vial	5 ml/vial	Not CE-Marked
8.02.20.0.0005	Anti-E Monoclonal, 5ml/vial	5 ml/vial	Not CE-Marked
8.02.21.0.0005	Anti-e Monoclonal, 5ml/vial	5 ml/vial	Not CE-Marked
8.02.22.0.0005	Anti-C+D+E Monoclonal, 5ml/vial	5 ml/vial	Not CE-Marked
8.02.23.0.0002	Anti-M, Human, 2ml/vial	2 ml/vial	CE-Professional
8.02.24.0.0002	Anti-N, Lectin (Viciagraminea), 2ml/vial	2 ml/vial	CE-Professional
8.02.25.0.0002	Anti-S, Human, 2ml/vial	2 ml/vial	CE-Professional
8.02.26.0.0002	Anti-s, Human, 2ml/vial	2 ml/vial	CE-Professional
8.02.27.0.0002	Anti-Fya, Human, 2ml/vial	2 ml/vial	Not CE-Marked
8.02.28.0.0002	Anti-Fyb, Human, 2ml/vial	2 ml/vial	Not CE-Marked
8.02.29.0.0002	Anti-k, Human, 2ml/vial	2 ml/vial	Not CE-Marked
8.02.30.0.0002	Anti-Kpa, Human, 2ml/vial	2 ml/vial	Not CE-Marked
8.02.31.0.0002	Anti-Kpb, Human, 2ml/vial	2 ml/vial	Not CE-Marked
8.02.32.0.0002	Anti-Jka, Human, 2ml/vial	2 ml/vial	Not CE-Marked
8.02.34.0.0002	Anti-Lua, Human, 2ml/vial	2 ml/vial	CE-Professional
8.02.36.0.0005	Anti-K Monoclonal, 5ml/vial	5 ml/vial	Not CE-Marked
8.02.37.0.0002	Anti-Lea, Monoclonal, 2ml/vial	2 ml/vial	CE-Professional
8.02.38.0.0002	Anti-Leb, Monoclonal, 2ml/vial	2 ml/vial	CE-Professional
8.02.39.0.0002	Anti-P1, Monoclonal, 2ml/vial	2 ml/vial	CE-Professional

HEMATOLOGY TESTS

Atlas Medical supplies coagulation reagents and D-Dimer tests. The coagulation regents include PT and PTT in liquid formats and in various sizes to suit most lab applications. The range also includes normal and abnormal coagulation controls. Atlas Medical D-Dimer test is based on latex agglutination and is perceived as one of the highest quality. The kit includes positive & negative controls and assay accessories. It comes in sizes of 50 and 100 tests.

Co-aggulation Reagents

Item Code	Item Description	Available sizes	CE-Status
8.02.40.1.0010 8.02.40.1.0050 8.02.40.1.0100	PT Calcium Rabbit Brain Thromboplastin, Liquid	2ml (20 Tests) 5ml (50 Tests) 10ml (100 Tests)	CE-Professional

Item Code	Item Description	Available sizes	CE-Status
8.02.41.1.0040 8.02.41.1.0100 8.02.41.1.0200	APTT (PTT) Micronised Silica Platelet Substitute	Liquid, 2ml (40 Tests) 5ml (100 Tests) 10ml (200 Tests)	CE-Professional
8.02.44.0.0040 8.02.44.0.0100	PT Kit with Normal Control	2x2ml + 1ml 2x5ml + 1ml	CE-Professional
8.02.45.0.0080 8.02.45.0.0200	APTT (PTT) Kit with Normal Control	2x2ml + 1ml 2x5ml + 1ml	CE-Professional
8.02.48.0.0010	Calcium Chloride, 25 mM	10ml/vial	CE-Professional
8.02.60.0.0006	Normal Coagulation Control	6x1ml	CE-Professional
8.02.61.0.0006	Abnormal Coagulation Control	6x1ml	CE-Professional
8.02.69.0.0005	Fibrinogen Reagent	5ml/vial	CE-Professional

Hemoglobin Reagents

Item Code	Item Description	Available sizes	CE-Status
8.02.46.1.0500 8.02.46.1.1000 8.02.46.1.3000	Drabkins Reagent (White Plastic Bottle)	40x, 50ml/vial 40x, 2x50ml 40x, 6x50ml	CE-Professional
8.02.50.0.0010 8.02.50.1.0100	Hemoglobin Standard, 15g/dL, Ready to use	10ml/vial 10mlx10 vials/box	CE-Professional

Sickle Cell Kits

Atlas Sickle Cell Kits is a qualitative solubility test for Sickle Haemoglobin The test can be performed in two ways:
1. A screening test to detect sickle haemoglobin (HbS)
2. A centrifugation test to differentiate the sickle cell trait (AS) from sickle cell anaemia (SS).

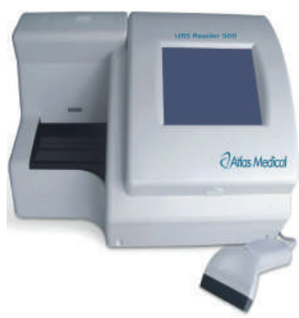
Item Code	Item Description	Available sizes	CE-Status
8.02.67.0.0100	Sickle Cell Kit, 100 Tests	4x50ml Buffer + 4 vials of Sodium Dithionate	CE-Professional
8.02.68.0.0001	Sickle Cell positive & negative control set	1ml each	CE-Professional

URINE REAGENT STRIPS

Urine Reagent Strips (URS) are widely used in Urinalysis to determine pathological changes in urine. The strips contain dry-chemistry pads that, when dipped in urine, change their colors. The color change allows for the semi-quantitative measurement of various urine parameters. The strips are suitable for lab, point-of-care and even home use.

Atlas Medical urine reagent strips can be used to detect up to 11 urine parameters. They are simple to use and the results are visually read within a minute. The strips are packed in desiccated bottles of 50 or 100 strips. Atlas Medical can also provide suitable readers to read the strip colors and document the results.

Item Code	Item Description	Available sizes	CE-Status
8.03.00.0.0100	URS 1 Parameter: Glucose	100 Strips	CE-Professional
8.03.01.0.0100	URS 1 Parameter: Protein	100 Strips	CE-Professional
8.03.02.0.0100	URS 1 Parameter: Ketone	100 Strips	CE-Professional
8.03.03.0.0100	URS 2 Parameters: Glucose, Ketone	100 Strips	CE-Professional
8.03.04.0.0100	URS 2 Parameters: Glucose, Protein	100 Strips	CE-Professional
8.03.06.0.0100	URS 3 Parameters: Protein, pH, Glucose	100 Strips	CE-Professional
8.03.07.0.0100	URS 3 Parameters: Glucose, Protein, Ketone	100 Strips	CE-Professional
8.03.11.0.0100	URS 4 Parameters: Protein, pH, Specific Gravity, Glucose	100 Strips	CE-Professional
8.03.12.0.0100	URS 4 Parameters: Protein, pH, Blood, Glucose	100 Strips	CE-Professional
8.03.13.0.0100	URS 5 Parameters: Glucose, Protein, Ketone, pH, Blood	100 Strips	CE-Professional
8.03.15.0.0100	URS 9 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose	100 Strips	CE-Professional
8.03.16.0.0100	URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, 100 Strips/Bottle.	100 Strips	CE-Professional
8.03.18.0.0100	URS 11 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid, 100 Strips/Bottle.	100 Strips	CE-Professional
8.001.U120	Urine Analyzer For Clinics, U120	1 Unit	CE-Professional
8.002.U500	Urine Analyzer For Hospitals, U500	1 Unit	CE-Professional



FERTILITY RAPID TESTS

Atlas Medical Fertility Rapid Tests are based on lateral flow immunoassay for the detection of human chorionic gonadotropin (hCG), Ovulation (LH), and Human Follicular Stimulating Hormone (FSH) in urine. Each of the three tests comes in strip, cassette, or midstream formats and are conveniently packed in sizes to suit lab, point-of-care and home uses. The tests are accurate, reliable, easy to use (add or dip in urine), competitively priced, and results are obtained in 1 to 5 minutes.

Item Code	Item Description	Available sizes	CE-Status
8.04.00.0.0001	hCG Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.00.0.0020		20 Tests/Box	
8.04.00.0.0030		30 Tests/Box	
8.04.01.0.0001	hCG Test Cassette, Urine/Serum, Individually Pouched	Bulk	CE-Professional
8.04.01.0.0020		20 Tests/Box	
8.04.01.0.0030		30 Tests/Box	

Item Code	Item Description	Available sizes	CE-Status
8.04.04.0.0001 8.04.04.0.0050 8.04.04.0.0100	hCG Test Strip,,Urine, Individually Pouched *Different strip sizes are available*	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.04.10.0.0001 8.04.10.0.0050 8.04.10.0.0100	hCG Test Strip, Urine/Serum, Individually Pouched *Different strip sizes are available*	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.04.13.0.0001 8.04.13.0.0015	hCG Midstream Test, Individually Pouched	Bulk 15 Tests/Box	CE-Professional
8.04.14.0.0001 8.04.14.0.0020 8.04.14.0.0030	LH Test Cassette, Urine, Individually pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.04.15.0.0001 8.04.15.0.0050 8.04.15.0.0100	LH Test Strip, Urine, Individually pouched *Different strip sizes are available*	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.04.16.0.0001 8.04.16.0.0015	LH Midstream Test, Individually Pouched	Bulk 15 Tests/Box	CE-Professional
8.04.17.0.0001 8.04.17.0.0020 8.04.17.0.0030	FSH Test Cassette, Urine, Individually pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.04.18.0.0001 8.04.18.0.0050 8.04.18.0.0100	FSH Test Strip, Urine, Individually pouched *Different strip sizes are available*	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.04.19.0.0001 8.04.19.0.0015	FSH Midstream Test, Individually Pouched	Bulk 15 Tests/Box	CE-Professional

KIDNEY FUNCTION RAPID TESTS

Atlas Medical Microalbumin Rapid Test is a rapid visual immunoassay used for the qualitative detection of microalbumin in human urine samples. This kit is intended for use as an aid in the diagnosis of renal dysfunction. The test comes in cassette format, but strip format can also be supplied.

Item Code	Item Description	Available sizes	CE-Status
8.16.52.0.0001 8.16.52.0.0020	Microalbumin Test Cassette ,Individually Pouched	Bulk 20 Test/Box	CE-Professional

INFECTIOUS DISEASE RAPID TESTS

Atlas Medical offers an extensive range of lateral flow immunoassay tests for the rapid detection of antibodies and antigens in human samples (blood, serum, plasma, urine, oral swabs, nasal swabs, and feces). This range includes tests to detect a wide variety of viruses, microorganisms and parasites.

Atlas Medical infectious disease rapid tests are reliable, accurate and supplied in both cassette and strip formats. The kits are conveniently packed in different sizes of 20, 30, 40, 50 and 100 tests per kit and include the necessary test accessories to perform the assay.

ANTIBODY TESTING

Item Code	Item Description	Available sizes	CE-Status
8.04.20.0.0001 8.04.20.0.0020 8.04.20.0.0030	H.pylori Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20test /box 30 Tests/Box	CE-Professional
8.04.21.0.0001 8.04.21.0.0020 8.04.21.0.0030	H.pylori Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20test /box 30 Tests/Box	CE-Professional
8.04.22.0.0001 8.04.22.0.0050 8.04.22.0.0100	H.pylori Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 50 Test/Box 100 Tests/Box	CE-Professional
8.04.27.0.0001 8.04.27.0.0020 8.04.27.0.0030	HIV 1/2 Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	Not CE-Marked
8.04.28.0.0001 8.04.28.0.0020 8.04.28.0.0030	HIV 1/2 Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	Not CE-Marked
8.04.29.0.0001 8.04.29.0.0050 8.04.29.0.0100	HIV 1/2 Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 50 Test/Box 100 Tests/Box	Not CE-Marked
8.04.30.0.0001 8.04.30.0.0020 8.04.30.0.0030	HCV Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	Not CE-Marked
8.04.31.0.0001 8.04.31.0.0020 8.04.31.0.0030	HCV Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	Not CE-Marked
8.04.32.0.0001 8.04.32.0.0050 8.04.32.0.0100	HCV Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 50 Test/Box 100 Tests/Box	Not CE-Marked
8.04.35.0.0001 8.04.35.0.0020 8.04.35.0.0030	HBsAb Test Cassette, Serum/Plasma, Individually Pouched,	Bulk 20 Tests/Box 30 Tests/Box	Not CE-Marked
8.04.36.0.0001 8.04.36.0.0050 8.04.36.0.0100	HBsAb Test Strip, Serum/Plasma, Individually Pouched	Bulk 50 Test/Box 100 Tests/Box	Not CE-Marked
8.04.41.0.0001 8.04.41.0.0020 8.04.41.0.0030	Syphilis Antibody Test Cassette, Whole Blood/Serum/ Plasma, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.04.42.0.0001 8.04.42.0.0020 8.04.42.0.0030	Syphilis Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.04.43.0.0001 8.04.43.0.0050 8.04.43.0.0100	Syphilis Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 50 Test/Box 100 Tests/Box	CE-Professional
8.16.16.0.0020	TB Test Cassette, Serum/Plasma, Individually Pouched	20 Tests/Box	CE-Professional

ANTIGEN TESTING

Item Code	Item Description	Available sizes	CE-Status
8.04.23.1.0020	H.pylori Antigen Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.04.24.1.0025	H.pylori Antigen Test Strip, 3.5mm, Stool Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.04.25.0.0020	Strep A Test Cassette, Swab Sample	20 Tests/Box	CE-Professional
8.45.00.0.0020	Strep B Test Cassette, Swab Sample	20 Tests/Box	CE-Professional
8.45.00.0.0020	Strep A+B Test Cassette, Swab Sample	20 Tests/Box	CE-Professional
8.04.26.0.0020	Chlamydia Test Cassette, Urine or Swab	20 Tests/Box	Not CE-Marked
8.04.33.0.0001 8.04.33.0.0020 8.04.33.0.0030	HBsAg Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	Not CE-Marked

Item Code	Item Description	Available sizes	CE-Status
8.04.34.0.0001		Bulk	
8.04.34.0.0050	HBsAg Test Strip, Serum/Plasma, Individually Pouched	50 Test/Box	Not CE-Marked
8.04.34.0.0100		100 Tests/Box	
8.04.37.0.0020	Malaria Pf. Test Cassette, Whole Blood, Individually Pouched	20 Tests/Box	CE-Professional
8.04.69.0.0020	Rotavirus Antigen Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.04.70.0.0025	Rotavirus Antigen Test Strip, 3.5mm, Stool Sample, Individually Pouched	25 Test/Box	CE-Professional
8.04.71.0.0020	Adenovirus Antigen Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.04.72.0.0025	Adenovirus Antigen Test Strip, 3.5mm, Stool Sample, Individually Pouched	25 Test/Box	CE-Professional
8.04.73.0.0020	Rota-Adeno Antigens Combo test Cassette, Stool Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.04.74.0.0025	Rota-Adeno Antigens Combo test Strip, 3.5mm, Stool Sample, Individually Pouched	25 Test/Box	CE-Professional
8.04.86.0.0020	Influenza A+B Test Cassette, Nasal Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.04.96.0.0025	Influenza A+B Test Strip, 3.5mm, Nasal Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.04.97.0.0020	Astro Virus Test Cassette, Nasal Sample, Individually Pouched	20 Tests/box	CE-Professional
8.04.98.0.0025	Astro VirusTest Strip, 3.5mm, Stool Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.16.01.0.0020	Crypto Virus Test Cassette, Stool Sample, Individually Pouched	20 Tests/box	CE-Professional
8.16.02.0.0025	Crypto Virus Test Strip, 3.5mm, Stool Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.16.14.0.0020	Malaria Pf/Pv. Test Cassette, Whole Blood, Individually Pouched	20 Tests/Box	CE-Professional
8.16.20.0.0020	RSV Test Cassette, Swab Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.16.22.0.0025	RSV Test Strip, Swab Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.16.24.0.0001		Bulk	
8.16.24.0.0020	HBsAg Test Cassette (Whole Blood/Serum/Plasma), Individually Pouched	20 Tests/Box	Not CE-Marked
8.16.24.0.0030		30 Tests/Box	
8.16.30.0.0025	Giardia Test Strip, Stool Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.16.31.0.0020	Giardia Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.16.32.0.0025	Crypto-Giardia Test Strip, Stool Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.16.33.0.0020	Crypto-Giardia Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.16.36.0.0025	Adeno Respiratory Antigen Test Strip, Swab Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.16.37.0.0020	Adeno Respiratory Antigen Test Cassette, Swab Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.16.38.0.0025	Adeno - RSV Respiratory Test Strip, Swab Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.16.39.0.0020	Adeno - RSV Respiratory Test Cassette, Swab Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.16.40.0.0025	E.coli Test Strip, Stool Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.16.41.0.0020	E.coli Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box	CE-Professional
8.16.82.0.0025	Salmonella typhi Antigen Test Cassette, Stool Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.16.85.0.0025	Salmonella paratyphi Antigen Test, Stool Sample, Individually Pouched	25 Tests/Box	CE-Professional
8.16.81.0.0025	Clostridium difficile Antigen Test Strip, Stool Sample, Individually Pouched	25 Tests / Box	CE-Professional
8.16.91.0.0025	Norovirus Genogroups I & II Ag, Test Cassette, Stool Sample, Individually Pouched	25Test/Box	CE-Professional
8.16.42.0.0001	Rota Virus Positive Control for Rapid Test	1ml/vial	CE-Professional
8.16.43.0.0001	Adeno Virus Positive Control for Rapid Test	1ml/vial	CE-Professional

INFLAMMATION AND CANCER MARKERS RAPID TESTS

All the tests in this group are qualitative and based on lateral flow immunoassay for the detection of various inflammation and cancer markers. Some of these tests can be read by Atlas Medical rapid test reader "Quantas" to obtain quantitative results in less than 15 minutes.

Atlas Medical inflammation and cancer markers rapid tests are supplied in both cassette and strip formats. The kits are conveniently packed in different kit sizes of 20, 30 and 100 tests per kit.

Item Code	Item Description	Available sizes	CE-Status
8.04.38.0.0020	Fecal Occult Blood Test (FOB) Test Cassette, Stool Sample, Individually Pouched	20 Tests/Box	CE-Professional

Item Code	Item Description	Available sizes	CE-Status
8.04.85.0.0050	Fecal Occult Blood Test (FOB) Test Strip, 3.5mm, Individually Pouched	50 Strips/Box	CE-Professional
8.04.39.0.0001	PSA Test Cassette, Serum/Plasma, Individually Pouched	Bulk	Not CE-Marked
8.04.39.0.0020		20 Tests/Box	
8.04.39.0.0030		30 Tests/Box	
8.04.40.0.0001	PSA Test Strip, Serum/Plasma, Individually Pouched	Bulk	Not CE-Marked
8.04.40.0.0050		50 Test/Box	
8.04.40.0.0100		100 Tests/Box	
8.16.28.0.0001	PSA Test Cassette (WB/S/P), Individually Pouched	Bulk	Not CE-Marked
8.16.28.0.0020		20 Tests/Box	
8.16.28.0.0030		30 Tests/Box	
8.04.109.0.0020	Procalcitonin test(PCT)	20 test/box	CE-Professional
8.16.78.0.0025	Calprotectin Test Cassette	25Test/Box	CE-Professional

CARDIAC MARKERS RAPID TESTS

Atlas Medical offers lateral flow immunoassay rapid tests to detect the three major cardiac markers namely: Troponin I, Myoglobin and CK-MB, as an aid in the diagnosis of myocardial infarction (MI). They can be used on whole blood (in addition to serum/plasma) making them ideal for emergency rooms. They come in single test or triple combo test cassette formats.

Item Code	Item Description	Available sizes	CE-Status
8.04.45.0.0001	Troponin I Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk	CE-Professional
8.04.45.0.0020		20 Tests/Box	
8.04.45.0.0030		30 Tests/Box	
8.04.46.0.0001	Myoglobin Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk	CE-Professional
8.04.46.0.0020		20 Tests/Box	
8.04.46.0.0030		30 Tests/Box	
8.04.47.0.0001	CK-MB Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk	CE-Professional
8.04.47.0.0020		20 Tests/Box	
8.04.47.0.0030		30 Tests/Box	
8.04.48.0.0001	Cardiac Triple Test Cassette (Troponin I, CK-MB, Myoglobin), Whole Blood/Serum/Plasma, Individually Pouched	Bulk	CE-Professional
8.04.48.0.0020		20 Tests/Box	
8.04.48.0.0030		30 Tests/Box	

ALCOHOL TESTS

In this category, Atlas Medical supplies kits to test for alcohol in urine, saliva and breath. The urine alcohol test is based on the detection of EtG (Ethyl Glucuronide) in urine using a rapid lateral flow immunoassay. Whereas the saliva alcohol test uses a strip with dry chemistry pad that changes color to indicate the level of alcohol in the saliva. The alcohol breath test is a tube with crystals that change color as the subject blows through when alcohol level in breath exceeds a certain limit.

Item Code	Item Description	Available sizes	CE-Status
8.25.01.0.0001	Saliva Alcohol Test Strip, Individually Pouched	Bulk	CE-Professional
8.25.01.0.0050		50 Tests/Box	
8.25.01.0.0100		100 Tests/Box	
8.25.02.0.0001	Breath Alcohol Test (0.02%), Individually Pouched	Bulk	CE-Professional
8.25.02.0.0025		25 Tests/Box	
8.25.03.0.0001	Breath Alcohol Test (0.05%), Individually Pouched	Bulk	CE-Professional
8.25.03.0.0025		25 Tests/Box	
8.25.04.0.0001	Breath Alcohol Test (0.08%), Individually Pouched	Bulk	CE-Professional
8.25.04.0.0025		25 Tests/Box	
8.25.05.0.0001	Ethyl glucuronide (EtG) Test Strip, Individually Pouched	Bulk	CE-Professional
8.25.05.0.0025		25 Tests/Box	

DOA RAPID TESTS

Atlas Medical Drug of Abuse (DOA) Rapid Tests can detect an extensive range of drugs in both urine and saliva samples. The tests are based on lateral flow immunoassay rapid tests and come in strip, cassette, multi-dip, multi-cassette, and multi-drug cup formats suitable for professional, forensic and work-screening use. Besides the standard selection of multi-drug tests, Atlas Medical can offer custom assortments of drugs to suit customers' applications. Atlas Medical DOA kits are easy to use and offer clear, accurate, and reliable results.

Item Code	Item Description	Available sizes	CE-Status
8.04.49.0.0001	Morphine Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.49.0.0020		20 Tests/Box	
8.04.49.0.0030		30 Tests/Box	
8.04.50.0.0001	Morphine Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.04.50.0.0050		50 Tests/Box	
8.04.50.0.0100		100 Tests/Box	
8.04.51.0.0001	Marijuana (THC) Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.51.0.0020		20 Tests/Box	
8.04.51.0.0030		30 Tests/Box	
8.04.52.0.0001	Marijuana (THC) Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.04.52.0.0050		50 Tests/Box	
8.04.52.0.0100		100 Tests/Box	
8.04.53.0.0001	Amphetamine Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.53.0.0020		20 Tests/Box	
8.04.53.0.0030		30 Tests/Box	
8.04.54.0.0001	Amphetamine Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.04.54.0.0050		50 Tests/Box	
8.04.54.0.0100		100 Tests/Box	
8.04.55.0.0001	Barbiturates Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.55.0.0020		20 Tests/Box	
8.04.55.0.0030		30 Tests/Box	

Item Code	Item Description	Available sizes	CE-Status
8.04.56.0.0001	Barbiturates Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.04.56.0.0050		50 Tests/Box	
8.04.56.0.0100		100 Tests/Box	
8.04.57.0.0001	Benzodiazepines Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.57.0.0020		20 Tests/Box	
8.04.57.0.0030		30 Tests/Box	
8.04.58.0.0001	Benzodiazepines Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.04.58.0.0050		50 Tests/Box	
8.04.58.0.0100		100 Tests/Box	
8.04.59.0.0001	Cocaine Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.59.0.0020		20 Tests/Box	
8.04.59.0.0030		30 Tests/Box	
8.04.60.0.0001	Cocaine Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.04.60.0.0050		50 Tests/Box	
8.04.60.0.0100		100 Tests/Box	
8.04.61.0.0001	Methamphetamine Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.61.0.0020		20 Tests/Box	
8.04.61.0.0030		30 Tests/Box	
8.04.62.0.0001	Methamphetamine Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.04.62.0.0050		50 Tests/Box	
8.04.62.0.0100		100 Tests/Box	
8.04.63.0.0001	Methadone Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.63.0.0020		20 Tests/Box	
8.04.63.0.0030		30 Tests/Box	
8.04.64.0.0001	Methadone Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.04.64.0.0050		50 Tests/Box	
8.04.64.0.0100		100 Tests/Box	
8.04.65.0.0001	Phencyclidine Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.65.0.0020		20 Tests/Box	
8.04.65.0.0030		30 Tests/Box	
8.04.66.0.0001	Phencyclidine Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.04.66.0.0050		50 Tests/Box	
8.04.66.0.0100		100 Tests/Box	
8.04.67.0.0001	Tricyclic Anti-Depressants Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.67.0.0020		20 Tests/Box	
8.04.67.0.0030		30 Tests/Box	
8.04.68.0.0001	Tricyclic Anti-Depressants Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.04.68.0.0050		50 Tests/Box	
8.04.68.0.0100		100 Tests/Box	
8.04.99.0.0001	Buprenorphine Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.04.99.0.0020		20 Tests/Box	
8.04.99.0.0030		30 Tests/Box	
8.16.23.0.0001	Buprenorphine Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.16.23.0.0050		50 Tests/Box	
8.16.23.0.0100		100 Tests/Box	
8.16.68.0.0001	Tramadol Test Cassette, Urine, Individually Pouched	Bulk	CE-Professional
8.16.68.0.0020		20 Tests/Box	
8.16.68.0.0030		30 Tests/Box	
8.16.44.0.0001	Tramadol Test Strip, Urine, Individually Pouched	Bulk	CE-Professional
8.16.44.0.0050		50 Tests/Box	
8.16.44.0.0100		100 Tests/Box	
8.16.15.0.0001	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Cassette, Urine,Individually Pouched	Bulk	CE-Professional
8.16.15.0.0020		20 Tests/Box	
8.16.15.0.0030		30 Tests/Box	
8.16.05.0.0001	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Strip, Urine,Individually Pouched	Bulk	CE-Professional
8.16.05.0.0050		50 Tests/Box	
8.16.05.0.0100		100 Tests/Box	

Item Code	Item Description	Available sizes	CE-Status
8.16.06.0.0001 8.16.06.0.0020 8.16.06.0.0030	Opiates Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.16.07.0.0001 8.16.07.0.0050 8.16.07.0.0100	Opiates Test Strip, Urine, Individually Pouched	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.16.58.0.0001 8.16.58.0.0020 8.16.58.0.0030	Cotinine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.16.59.0.0001 8.16.59.0.0050 8.16.59.0.0100	Cotinine Test Strip, Urine, Individually Pouched	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.16.60.0.0001 8.16.60.0.0020 8.16.60.0.0030	Dolantin Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.16.61.0.0001 8.16.61.0.0050 8.16.61.0.0100	Dolantin Test Strip, Urine, Individually Pouched	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.16.62.0.0001 8.16.62.0.0020 8.16.62.0.0030	Oxycodone Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.16.63.0.0001 8.16.63.0.0050 8.16.63.0.0100	Oxycodone Test Strip, Urine, Individually Pouched	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.16.64.0.0001 8.16.64.0.0020 8.16.64.0.0030	Ketamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.16.65.0.0001 8.16.65.0.0050 8.16.65.0.0100	Ketamine Test Strip, Urine, Individually Pouched	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.16.66.0.0001 8.16.66.0.0020 8.16.66.0.0030	Proxyphene Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.16.67.0.0001 8.16.67.0.0050 8.16.67.0.0100	Proxyphene Test Strip, Urine, Individually Pouched	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.16.69.0.0001 8.16.69.0.0020 8.16.69.0.0030	EDDP Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box 30 Tests/Box	CE-Professional
8.16.70.0.0001 8.16.70.0.0050 8.16.70.0.0100	EDDP Test Strip, Urine, Individually Pouched	Bulk 50 Tests/Box 100 Tests/Box	CE-Professional
8.04.93.0.0001 8.04.93.0.0025	DOA Panel: 2 Drugs (Combination of any 2 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	CE-Professional
8.04.94.0.0001 8.04.94.0.0025	DOA Panel: 3 Drugs (Combination of any 3 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	CE-Professional
8.04.95.0.0001 8.04.95.0.0025	DOA Panel: 4 Drugs (Combination of any 4 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	CE-Professional
8.04.79.0.0001 8.04.79.0.0025	DOA Panel: 5 Drugs (Combination of any 5 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	CE-Professional
8.04.80.0.0001 8.04.80.0.0025	DOA Panel: 6 Drugs (Combination of any 6 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	CE-Professional
8.04.81.0.0001 8.04.81.0.0025	DOA Panel: 7 Drugs (Combination of any 7 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	CE-Professional
8.04.82.0.0001 8.04.82.0.0025	DOA Panel: 8 Drugs (Combination of any 8 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	CE-Professional
8.04.83.0.0001 8.04.83.0.0025	DOA Panel: 9 Drugs (Combination of any 9 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	

Item Code	Item Description	Available sizes	CE-Status
8.04.84.0.0001 8.04.84.0.0025	DOA Panel: 10 Drugs (Combination of any 10 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	CE-Professional
8.16.03.0.0001 8.16.03.0.0025	DOA Panel: 11 Drugs (Combination of any 11 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	CE-Professional
8.16.04.0.0001 8.16.04.0.0025	DOA Panel: 12 Drugs (Combination of any 12 drugs), Urine, Individually Pouched	Bulk 25 Tests/Box	CE-Professional
8.16.9.x.0001	Drug Of Abuse Cup, 7 parameters (any combination of the above)	Bulk	CE-Professional
8.16.73.x.0001	Drug Of Abuse Cup, 8 parameters (any combination of the above)	Bulk	CE-Professional
8.16.71.x.0001	Drug Of Abuse Cup, 10 parameters (any combination of the above)	Bulk	CE-Professional

ELISA KITS

Atlas Medical offers a range of Enzyme Linked Immunosorbent Assay (ELISA or EIA) to detect major hormones in the fields of thyroids and fertility in serum. The kits feature high sensitivities, simple and robust methods, breakable well strips, quantitative results, ready-to use liquid reagents, and reasonable assay time. The assays can be used on most open ELISA manual readers and washers as well as open ELISA auto-analyzers. Kits are packed in sizes of 96 tests.

HORMONE ELISA KITS

Item Code	Item Description	Available sizes	CE-Status
8.10.01.0.0096	hCG Elisa Kit	96 Test	CE-Professional
8.10.03.0.0096	FSH Elisa Kit	96 Tests	CE-Professional
8.10.04.0.0096	LH Elisa Kit	96 Tests	CE-Professional
8.10.05.0.0096	Prolactin Elisa Kit	96 Tests	CE-Professional
8.12.00.0.0096	T3 Elisa Kit	96 Tests	CE-Professional
8.12.01.0.0096	T4 Elisa Kit	96 Tests	CE-Professional
8.12.02.0.0096	TSH Elisa Kit	96 Tests	CE-Professional
8.12.03.0.0096	Free T4 Elisa Kit	96 Tests	CE-Professional
8.12.04.0.0096	Free T3 Elisa Kit	96 Tests	CE-Professional
8.07.09.0.0096	Free β-hCG elisa kit	96 Tests	CE-Professional
8.07.09.1.0096	Beta hCG Elisa Kit	96 Tests	CE-Professional
8.07.10.0.0096	Free PSA Elisa	96 Tests	Not CE-Marked
8.11.03.0.0096	Progesterone Elisa kit	96 Tests	CE-Professional
8.11.04.0.0096	Testosterone Elisa Kit	96 Tests	CE-Professional
8.07.02.0.0096	PSA Elisa Kit	96 Tests	Not CE-Marked

TORCH ELISA KITS

Atlas Medical offers a range of Enzyme Linked Immunosorbent Assay (ELISA or EIA) to detect IgG and IgM antibodies against ToRCH (Toxoplasmosis, Rubella, CMV and Herpes I & II) in serum. The kits feature high sensitivities, simple and robust methods, breakable well strips, qualitative results, ready-to use liquid reagents, and reasonable assay time. The assays can be used on most open ELISA manual readers and washers as well as open ELISA auto-analyzers. Kits are packed in sizes of 96 tests.

Item Code	Item Description	Available sizes	CE-Status
8.13.00.0.0096	Toxo Plasma Gondii IgG (Toxo IgG), Elisa kit	96 Tests	Not CE-Marked
8.13.01.0.0096	Toxoplasma gondii IgM (Toxo IgM), Elisa kit	96 Tests	Not CE-Marked
8.13.02.0.0096	Rubella IgG Elisa Kit	96 Tests	Not CE-Marked
8.13.03.0.0096	Rubella IgM Elisa Kit	96 Tests	Not CE-Marked
8.13.05.0.0096	Cytomegalovirus IgG (CMV IgG) Elisa Kit	96 Tests	Not CE-Marked
8.13.06.0.0096	Cytomegalovirus IgM (CMV IgM) Elisa Kit	96 Tests	Not CE-Marked
8.13.07.0.0096	Herpes Simplex 1 IgG (HSV1 IgG) Elisa Kit	96 Tests	Not CE-Marked
8.13.08.0.0096	Herpes Simplex 1 IgM (HSV1 IgM) Elisa Kit	96 Tests	Not CE-Marked
8.13.09.0.0096	Herpes Simplex 2 IgG (HSV2 IgG) Elisa Kit	96 Tests	Not CE-Marked
8.13.10.0.0096	Herpes Simplex 2 IgM (HSV2 IgM) Elisa Kit	96 Tests	Not CE-Marked
8.13.11.0.0096	Herpes Simplex 1,2 IgG (HSV1,2 IgG) Elisa Kit	96 Tests	Not CE-Marked
8.13.12.0.0096	Herpes Simplex 1,2 IgM (HSV1,2 IgM) Elisa Kit	96 Tests	Not CE-Marked

INFECTIOUS DISEASES ELISA KITS

Atlas Medical offers a range of Enzyme Linked Immunosorbent Assay (ELISA or EIA) to detect a series of infection diseases such as HIV, Hepatitis (A, B, C, D and E) and H. pylori (antigens in feces). The kits feature high sensitivities, simple and robust methods, breakable well strips, ready-to use liquid reagents, and reasonable assay time. The assays can be used on most open ELISA manual readers and washers as well as open ELISA auto-analyzers. Kits are packed in sizes of 96 tests.

Item Code	Item Description	Available sizes	CE-Status
8.14.28.0.0096	HBsAg Elisa Kit	96 Tests	Not CE-Marked
8.14.29.0.0096	HBsAb Elisa Kit	96 Tests	Not CE-Marked
8.14.30.0.0096	HBcAb Elisa Kit	96 Tests	Not CE-Marked
8.14.31.0.0096	HBeAg Elisa Kit	96 Tests	Not CE-Marked
8.14.32.0.0096	HBeAb Elisa Kit	96 Tests	Not CE-Marked
8.14.33.0.0096	HDV Ab Elisa Kit	96 Tests	Not CE-Marked
8.14.34.0.0096	HDV Ag Elisa Kit	96 Tests	Not CE-Marked
8.14.35.0.0096	HEV IgM Elisa Kit	96 Tests	Not CE-Marked
8.14.36.0.0096	HEV Ab Elisa Kit	96 Tests	Not CE-Marked
8.14.37.0.0096	HGV Ab Elisa Kit	96 Tests	Not CE-Marked
8.14.38.0.0096	HCV Ab Elisa Kit	96 Tests	Not CE-Marked
8.14.39.0.0096	HAV IgM Elisa Kit	96 Tests	Not CE-Marked
8.14.40.0.0096	HIV 1,2 Antibody Elisa Kit	96 Tests	Not CE-Marked
8.14.19.1.0096 8.14.19.1.0048	Helicobacter pylori Antigen ELISA	96Test/kit 48 Test/kit	CE-Professional

OTHER ELISA KITS

Item Code	Item Description	Available sizes	CE-Status
8.07.03.0.0096	Alpha Feto Protein (AFP) Elisa Kit	96 Tests	CE-Professional
8.07.08.0.0096	Ferritin Elisa Kit	96 Tests	CE-Professional
8.08.00.0.0096	Troponin I Elisa Kit	96 Tests	CE-Professional
8.09.00.0.0096	IgE Elisa Kit	96 Tests	CE-Professional
8.51.00.0.0096	25-OH VITAMIN D Elisa Kit	96 Tests	CE-Professional
8.57.00.0.0096	Vitamin B12 Elisa Kit	96 Tests	CE-Professional
8.58.00.0.0096	Folic Acid Elisa Kit	96 Tests	CE-Professional
8.06.32.0.0096	Anti-CRA Elisa Kit	96 Tests	CE-Professional

CLINICAL CHEMISTRY KITS

Atlas Medical offers an extensive range of colorimetric and kinetic clinical chemistry kits that suit most manual and semi-automated analyzers. Application sheets for some automated analyzers are also available. The range focuses on single liquid reagent as much as possible, but lyophilized reagents are also supplied for some parameters. The kits come in various sizes to suit every application. Custom sizes are also available upon request.

Item Code	Item Description	Available sizes	CE-Status
8.05.00.0.0250 8.05.00.0.0500 8.05.00.0.1000	Albumin Bromocresol Green	2x125ml 4x125ml 4x250ml	CE-Professional
8.05.01.0.0030 8.05.01.0.0060	Amylase	3x10ml 6x10ml	CE-Professional
8.05.02.0.0020 8.05.02.0.0040 8.05.02.1.0090	Acid Phosphatase Kinetic, Hilmann Method (Tablets)	10x2ml 20x2ml 6x15ml	CE-Professional
8.05.03.0.0030 8.05.03.0.0060 8.05.03.1.0090	Alkaline Phosphatase Kinetic, DGKC Method (Tablets)	10x3ml 20x3ml 6x15ml	CE-Professional
8.05.04.0.0250 8.05.04.0.0500	Alkaline Phosphatase Kinetic, DGKC Method (Liquid)	5x50ml 5x100ml	CE-Professional
8.05.05.0.0250 8.05.05.0.0500	Bilirubin Total (DMSO Method)	2x125ml 4x125ml	CE-Professional
8.05.06.0.0250 8.05.06.0.0500	Bilirubin Direct (DMSO Method)	2x125ml 4x125ml	CE-Professional
8.05.07.0.0250 8.05.07.0.0500	Bilirubin Total & Direct (DMSO Method)	2x125ml 4x125ml	CE-Professional
8.05.08.0.0250 8.05.08.0.0500	Calcium Arsenazo III	2x125ml 4x125ml	CE-Professional
8.05.09.0.0250 8.05.09.0.0500	Calcium O-Cresolphthalein	2x125ml 4x125ml	CE-Professional
8.05.10.0.0250 8.05.10.0.0500	Chloride Thiocyanate Colorimetric	2x125ml 4x125ml	CE-Professional
8.05.11.0.0250 8.05.11.0.0500	Cholesterol Liquid (CHOD-POD)	2x125ml 4x125ml	CE-Professional
8.05.12.0.0025 8.05.12.0.0050	CK-MB Kinetic (Tablets)	10x2.5ml 20x2.5ml	CE-Professional
8.05.13.0.0050 8.05.13.0.0100	CK-MB Kinetic (Liquid)	5x10ml 5x20ml	CE-Professional
8.05.14.0.0025 8.05.14.0.0050	CK-NAC Kinetic (Tablets)	10x2.5ml 20x2.5ml	CE-Professional
8.05.15.0.0050 8.05.15.0.0100	CK-NAC Kinetic (Liquid)	5x10ml 5x20ml	CE-Professional
8.05.16.0.0250 8.05.16.0.0500	Creatinine Jaffe Color-Kinetic	2x125ml 4x125ml	CE-Professional
8.05.17.0.0250 8.05.17.0.0500	Glucose GOD-POD (Liquid)	2x125ml 4x125ml	CE-Professional
8.05.18.0.0020 8.05.18.0.0040 8.05.18.1.0090	GOT (AST) IFCC Kinetic (Tablets)	10x2ml 20x2ml 6x15ml	CE-Professional
8.05.19.0.0250 8.05.19.0.0500	GOT (AST) IFCC Kinetic (Liquid)	5x50ml 5x100ml	CE-Professional

Item Code	Item Description	Available sizes	CE-Status
8.05.21.0.0020	GPT (ALT) IFCC Kinetic (Tablets)	10x2ml	CE-Professional
8.05.21.0.0040		20x2ml	
8.05.21.1.0090		6x15ml	
8.05.22.0.0250	GPT (ALT) IFCC Kinetic (Liquid)	5x50ml	CE-Professional
8.05.22.0.0500		5x100ml	
8.05.24.0.0020	Gamma GT Kinetic, Carboxy Substrate (Tablets)	10x2ml	CE-Professional
8.05.24.0.0040		20x2ml	
8.05.24.1.0090		6x15ml	
8.05.25.0.0250	Gamma GT Kinetic, Carboxy Substrate (Liquid)	5x50ml	CE-Professional
8.05.25.0.0500		5x100ml	
8.05.26.0.0100	HDL Cholesterol Precipitating Reagent	2x50ml	CE-Professional
8.05.26.0.0200		2x100ml	
8.05.27.0.0250	Iron Ferrozine Colorimetric	2x125ml	CE-Professional
8.05.27.0.0500		4x125ml	
8.05.28.0.0030	LDH IFCC Kinetic (Tablets)	10x3ml	CE-Professional
8.05.28.0.0060		20x3ml	
8.05.28.1.0090		6x15ml	
8.05.29.0.0250	LDH IFCC Kinetic (Liquid)	5x50ml	CE-Professional
8.05.29.0.0500		5x100ml	
8.05.30.0.0060	Lipase Kinetic (Liquid)	6x10ml	CE-Professional
8.05.31.0.0250	Magnesium Calmagite Colorimetric	2x125ml	CE-Professional
8.05.31.0.0500		4x125ml	
8.05.32.0.0250	Phosphorus Phosphomolybdate UV	2x125	CE-Professional
8.05.32.0.0500		4x125	
8.05.33.0.0050	Potassium Colorimetric	50 Tests	CE-Professional
8.05.33.0.0100		100 Tests	
8.05.34.0.0050	Sodium Colorimetric	50 Tests	CE-Professional
8.05.34.0.0100		100 Tests	
8.05.35.0.0100	TIBC (Total Iron Binding Capacity)	100 Tests	CE-Professional
8.05.36.0.0250	Total Lipids Phosphovainilline Colorimetric	2x125ml	CE-Professional
8.05.36.0.0500		4x125ml	
8.05.37.0.0250	Total Protein Biuret Colorimetric	2x125ml	CE-Professional
8.05.37.0.0500		4x125ml	
8.05.38.0.0250	Total Protein in CSF	2x125ml	CE-Professional
8.05.38.0.0500		4x125ml	
8.05.39.0.0250	Triglycerides GPO-POD Colorimetric	2x125ml	CE-Professional
8.05.39.0.0500		4x125ml	
8.05.40.0.0250	Urea Urease-GLDH Kinetic (UV)	5x50ml	CE-Professional
8.05.40.0.0500		5x100ml	
8.05.41.0.0250	Urea Berthelot Colorimetric	2x125ml	CE-Professional
8.05.41.0.0500		4x125m	
8.05.42.0.0250	Uric Acid Uricase-PAP Colorimetric (Two Reagents)	2x125ml	CE-Professional
8.05.42.0.0500		4x125ml	
8.05.43.0.0005	Pathological Control for Clinical Chemistry, Lyophilized, Bovine Source	5ml/vial	CE-Professional
8.05.43.1.0005	Pathological Control for Clinical Chemistry, Lyophilized, Human Source	5ml/vial	CE-Professional
8.05.44.0.0005	Normal Control for Clinical Chemistry, Lyophilized, Bovine Source	5ml/vial	CE-Professional
8.05.44.1.0005	Normal Control for Clinical Chemistry, Lyophilized, Human Source	5ml/vial	CE-Professional
8.05.45.0.0250	G6PD Deficiency Qualitative Kit	250 Test	CE-Professional
8.05.45.0.0500		500 Test	
8.05.45.0.0750		750 Test	
8.05.45.1.0250	G6PD Deficiency Qualitative Kit, (with Filter Cards)	250 Test	CE-Professional
8.05.45.1.0500		500 Test	
8.05.45.1.0750		750 Test	
8.05.46.0.0075	G6PD Deficiency Quantitative Kit	75 Test	CE-Professional
8.05.46.0.0150		150 Test	
8.05.46.1.0075	G6PD Deficiency Quantitative Kit, (with Filter Cards)	75 Test	CE-Professional
8.05.46.1.0150		150 Test	
8.05.47.0.0003	G6PD Control, Normal Level, (Lyophilized)	6x0.5ml	CE-Professional
8.05.51.0.0100	HDL Choelsterol, Enzymatic Colorimetric Direct Method	100 Tests	CE-Professional

Item Code	Item Description	Available sizes	CE-Status
8.05.52.0.0100	LDL Cholesterol, Enzymatic Colorimetric Direct Method	100 Tests	CE-Professional
8.05.71.0.0250 8.05.71.0.0500	Uric Acid Uricase-PAP Colorimetric (Mono Reagents)	2x125ml 4x125ml	CE-Professional
8.05.72.0.0250	Alkaline Phosphatase Colorimetric Method	5x50ml	CE-Professional
8.40.00.0.0050 8.40.00.0.0100	HbA1c Direct Enzymatic Colorimetric Kit	50 Tests 100 Tests	CE-Professional

STAINS FOR HISTOLOGY & MICROBIOLOGY

STAINS FOR HISTOLOGY

Atlas Medical is well known for its range of lab stains for histology and microbiology applications. The stains come in convenient sizes, but custom sizes are also available. Atlas Medical stains are made of the highest quality ingredients to ensure good quality and vivid staining.

Item Code	Item Description	Available sizes	CE-Status
8.15.017.0250	Carbol Fuchsin (Gram)	250ml/Bottle	CE-Professional
8.15.019.0250	Carbol Fuchsin (Ziehl-Neelsen)	250ml/Bottle	CE-Professional
8.15.032.0250	Crystal Violet (for Gram Stain)	250ml/Bottle	CE-Professional
8.15.037.0250	Eosin Y (1% Aqueous)	250ml/Bottle	CE-Professional
8.15.038.0250	Eosin Y (5% Aqueous)	250ml/Bottle	CE-Professional
8.15.039.0250	Eosin Y (1% Alcoholic)	250ml/Bottle	CE-Professional
8.15.041.0250	Field Stain (Solution A)	250ml/Bottle	CE-Professional
8.15.042.0250	Field Stain (Solution B)	250ml/Bottle	CE-Professional
8.15.047.0250	Giemsa Stain (Modified-Glycerol/Methanol)	250ml/Bottle	CE-Professional
8.15.049.0250	Gram's Iodine	250ml/Bottle	CE-Professional
8.15.051.0250	Gram's Decolouriser	250ml/Bottle	CE-Professional
8.15.059.0250	Haematoxylin Harris (no Acetic Acid)	250ml/Bottle	CE-Professional
8.15.060.0250	Haematoxylin Harris (with Acetic Acid)	250ml/Bottle	CE-Professional
8.15.069.0250	Leishman Stain	250ml/Bottle	CE-Professional
8.15.074.0250	Lugol's Iodine	250ml/Bottle	CE-Professional
8.15.076.0250	Malachite Green (Aqueous)	250ml/Bottle	CE-Professional
8.15.078.0250	May Grunwald Stain (Modified)	250ml/Bottle	CE-Professional
8.15.105.0250	New Methylene Blue for Reticulocytes	250ml/Bottle	CE-Professional
8.15.110.0250	Papanicolaou Stain EA35	250ml/Bottle	CE-Professional
8.15.111.0250	Papanicolaou Stain EA36	250ml/Bottle	CE-Professional
8.15.112.0250	Papanicolaou Stain EA65	250ml/Bottle	CE-Professional
8.15.114.0250	Papanicolaou Stain EA50	250ml/Bottle	CE-Professional
8.15.115.0250	Papanicolaou Stain OG6	250ml/Bottle	CE-Professional
8.15.126.0250	Safranin (1% Aqueous)	250ml/Bottle	CE-Professional
8.15.143.0250	Wright's Stain (Modified)	250ml/Bottle	CE-Professional
8.15.144.0250	ZN Decolouriser	250ml/Bottle	CE-Professional
8.17.003.0300	Periodic Acid Schiff (PAS) Stain Kit	3x100ml	CE-Professional
8.17.004.0300	Iron Stain Kit - Perl	3x100ml	CE-Professional
8.17.009.1000	Gram Stain Pack	4x250ml	CE-Professional
8.17.010.0750	Cold ZN - Kinyoun Stain Pack	3x250ml	CE-Professional
8.17.011.0750	ZN Pack Standard	3x250ml	CE-Professional
8.17.015.0500	Diff-3 Stain Pack	4x125ml	CE-Professional
8.17.016.1000	Papanicolaou Stain Pack (EA35, EA50, EA65, OG6)	4X250ml	CE-Professional

MICROBIOLOGY

Item Code	Item Description	Available sizes	CE-Status
8.38.00.0.0025 8.38.00.0.0050	Blood Culture Bottles	Pediatric Size Adult Size	CE-Professional
8.36.00.0.0020	Mycoplasma IES Infection Test	20 Tests/Box	CE-Professional
8.36.01.0.0030	Mycoplasma IES Plus Infection Test	30 Tests/Box	CE-Professional

ANTIBIOTIC SENSITIVITY DISCS

Item Code	Item Description	Available sizes	CE-Status
8.39.01.0.0250	AMIKACIN (30 µg) – AK	5x50 Discs	CE-Professional
8.39.02.0.0250	AMOXICILLIN (10 µg) – AX	5x50 Discs	CE-Professional
8.39.03.0.0250	AMOXICILLIN / CLAVULANIC ACID (20 µg + 10 µg) - AC	5x50 Discs	CE-Professional
8.39.04.0.0250	AMPICILLIN (10 µg) – AP	5x50 Discs	CE-Professional
8.39.05.0.0250	AMPICILLIN / SULBACTAM (10 µg - 10 µg) – AS	5x50 Discs	CE-Professional
8.39.06.0.0250	AZITHROMYCIN (15 µg) – AZ	5x50 Discs	CE-Professional
8.39.07.0.0250	AZTREONAM (30 µg) – AT	5x50 Discs	CE-Professional
8.39.08.0.0250	CEFACLOR (30 µg) - CG	5x50 Discs	CE-Professional
8.39.09.0.0250	CEFADROXIL (30 µg) - CD	5x50 Discs	CE-Professional
8.39.10.0.0250	CEFAZOLIN (30 µg) - CF	5x50 Discs	CE-Professional
8.39.11.0.0250	CEFDINIR (5µg) - CN	5x50 Discs	CE-Professional
8.39.12.0.0250	CEFIXIME (5 µg) - FX	5x50 Discs	CE-Professional
8.39.13.0.0250	CEFOPERAZONE (75 µg) - PZ	5x50 Discs	CE-Professional
8.39.14.0.0250	CEFOPERAZONE / SULBACTUM (75 µg + 30 µg) - CS	5x50 Discs	CE-Professional
8.39.15.0.0250	CEFOTAXIME (30 µg) - CX	5x50 Discs	CE-Professional
8.39.16.0.0250	CEFPIROME (30 µg) - CE	5x50 Discs	CE-Professional
8.39.17.0.0250	CEFPODOXIME (10 µg) – CO	5x50 Discs	CE-Professional
8.39.18.0.0250	CEFPROZIL (30 µg) - FP	5x50 Discs	CE-Professional
8.39.19.0.0250	CEFTAZIDIME (30 µg) – CZ	5x50 Discs	CE-Professional
8.39.20.0.0250	CEFTIZOXIME (30 µg) - FO	5x50 Discs	CE-Professional
8.39.21.0.0250	CEFTRIOXONE (30 µg) - FR	5x50 Discs	CE-Professional
8.39.22.0.0250	CEFUROXIME (30 µg) - CR	5x50 Discs	CE-Professional
8.39.23.0.0250	CEPHALEXIN (30 µg) - CP	5x50 Discs	CE-Professional
8.39.24.0.0250	CEPHALORIDINE (30 µg) - CH	5x50 Discs	CE-Professional
8.39.25.0.0250	CEPHALOTHIN (30 µg) - CA	5x50 Discs	CE-Professional
8.39.26.0.0250	CHLORAMPHENICOL (30 µg) - CK	5x50 Discs	CE-Professional
8.39.27.0.0250	CIPROFLOXACIN (5 µg) - CL	5x50 Discs	CE-Professional
8.39.28.0.0250	CLARITHROMYCIN (15 µg) - CL	5x50 Discs	CE-Professional
8.39.29.0.0250	CLINDAMYCIN (2 µg) - CM	5x50 Discs	CE-Professional
8.39.30.0.0250	CLOXACILLIN (5 µg) - CV	5x50 Discs	CE-Professional
8.39.31.0.0250	CO-TRIMOXAZOLE (25 µg) - CT	5x50 Discs	CE-Professional
8.39.32.0.0250	DOXYCYCLINE (30 µg) - DO	5x50 Discs	CE-Professional
8.39.33.0.0250	ERYTHROMYCIN (15 µg) - ER	5x50 Discs	CE-Professional
8.39.34.0.0250	FURAZOLIDONE (100 µg) - FZ	5x50 Discs	CE-Professional
8.39.35.0.0250	GATIFLOXACIN (5 µg) - GF	5x50 Discs	CE-Professional
8.39.36.0.0250	GENTAMYCIN (10 µg) - GM	5x50 Discs	CE-Professional
8.39.37.0.0250	IMIPENEM / CILASTATIN (10 µg + 10 µg) - IS	5x50 Discs	CE-Professional
8.39.38.0.0250	KANAMYCIN (30 µg) - KA	5x50 Discs	CE-Professional
8.39.39.0.0250	LEVOFOLXACIN (5 µg) - LV	5x50 Discs	CE-Professional
8.39.40.0.0250	LINCOMYCIN (15 µg) - LN	5x50 Discs	CE-Professional
8.39.41.0.0250	LINEZOLID (30 µg) - LI	5x50 Discs	CE-Professional
8.39.42.0.0250	LOMEFLOXACIN (10 µg) - LF	5x50 Discs	CE-Professional
8.39.43.0.0250	MEROPENEM (10 µg) - MR	5x50 Discs	CE-Professional
8.39.44.0.0250	MINOCYCLINE (30 µg) - MN	5x50 Discs	CE-Professional
8.39.45.0.0250	MOXIFLOXACIN (5 µg) - MF	5x50 Discs	CE-Professional
8.39.46.0.0250	NALIDIXIC ACID (30 µg) - NA	5x50 Discs	CE-Professional
8.39.47.0.0250	NITROFURANTOIN (300 µg) - FU	5x50 Discs	CE-Professional
8.39.48.0.0250	NORFLOXACIN (10 µg) - NF	5x50 Discs	CE-Professional
8.39.49.0.0250	OFLOXACIN (5 µg) - OF	5x50 Discs	CE-Professional
8.39.50.0.0250	PEFLOXACIN (5 µg) – PF	5x50 Discs	CE-Professional

Item Code	Item Description	Available sizes	CE-Status
8.39.51.0.0250	PENICILLIN –G (10 IU) – PG	5x50 Discs	CE-Professional
8.39.52.0.0250	PIPERACILLIN (100 µg) – PC	5x50 Discs	CE-Professional
8.39.53.0.0250	PIPERACILLIN / TAZOBACTAM (100 µg + 10 µg) - PT	5x50 Discs	CE-Professional
8.39.54.0.0250	RIFAMPIN (5 µg) – RN	5x50 Discs	CE-Professional
8.39.55.0.0250	ROXITHROMYCIN (30 µg) – RO	5x50 Discs	CE-Professional
8.39.56.0.0250	SPARFLOXACIN (5 µg) – SP	5x50 Discs	CE-Professional
8.39.57.0.0250	STREPTOMYCIN (10 µg) – ST	5x50 Discs	CE-Professional
8.39.58.0.0250	SULPHADIAZINE (300 µg) – SD	5x50 Discs	CE-Professional
8.39.59.0.0250	TEICOPLANIN (30 µg) – TC	5x50 Discs	CE-Professional
8.39.60.0.0250	TETRACYCLINE (30 µg) – TE	5x50 Discs	CE-Professional
8.39.61.0.0250	TICARCILLIN / CLAVULANIC ACID (75 µg + 2.5 µg)-TC	5x50 Discs	CE-Professional
8.39.62.0.0250	TOBRAMYCIN (10 µg) – TO	5x50 Discs	CE-Professional
8.39.63.0.0250	TRIMETHOPRIM (5 µg) – TR	5x50 Discs	CE-Professional
8.39.64.0.0250	VANCOMYCIN (30 µg) – VM	5x50 Discs	CE-Professional

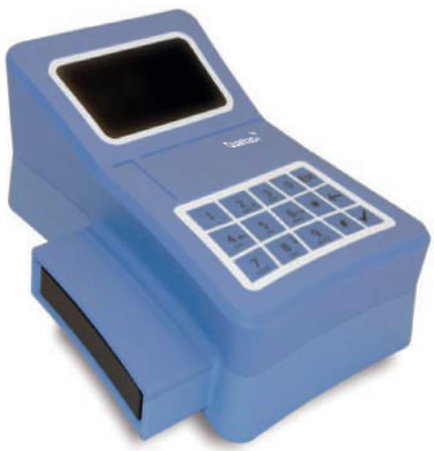
HOME TESTS

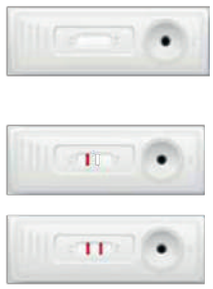
Atlas Medical provides a range of home tests that have been specifically CE marked for OTC use. The range includes fertility tests (Pregnancy, Ovulation and Menopause). These tests come in cassette and midstream formats, but strip format can also be supplied. The home tests range also includes other medical conditions such as liver function, kidney function, diabetes and urine tract infection. These tests are based on urine reagent strips. Each kit comes with 2 individually pouched strips and easy to read instructions for use. All kits are packed in attractively designed boxes with various languages. Atlas Medical also supplies these kits under OEM arrangements.

Item Code	Item Description	Available sizes	CE-Status
70004001	Atlas Home Diabetes Test	2 Tests/Box	CE Self Testing
70021001	Atlas Home Urinary Tract Infection Test	2 Tests/Box	CE Self Testing
70022001	Atlas Home Kidney Function Test	2 Tests/Box	CE Self Testing
70023001	Atlas Home Liver Function Test	2 Tests/Box	CE Self Testing
70171001	Atlas Home Pregnancy Test Cassette	1 Test/Box	CE Self Testing
70172001	Atlas Home Pregnancy Test Midstream	1 Test/Box	CE Self Testing
70174001	Atlas Home Ovulation Test Cassette	5 Tests/Box	CE Self Testing
70175001	Atlas Home Ovulation Test Midstream	3 Tests/Box	CE Self Testing
70177001	Atlas Home Menopause Test Cassette	1 Test/Box	CE Self Testing
70178001	Atlas Home Menopause Test Midstream	1 Test/Box	CE Self Testing
70180001	Atlas Home Pregnancy Test Strip (With Handle)	1 Test/Box	CE Self Testing
70170001	Atlas Home Pregnancy Test Strip	1 Test/Box	CE Self Testing

QUANTAS LATERAL-FLOW TESTS READER

Quantas+ Reader





Quantas Reader

Item Code	Item Description	Available sizes	CE-Status
8.04.109.0.0020	Procalcitonin Test (PCT)	20 Test/box	CE-Professional
8.16.78.0.0025	Calprotectin Test Cassette	25 Test/box	CE-Professional
8.16.96.0.0020	CRP Test Cassette	20 Test/box	CE-Professional
8.04.86.0.0020	influenza A+B Test Cassette	20 Test/box	CE-Professional
8.44.00.0.0020	D-Dimer Test Cassette	20 Test/box	CE-Professional
8.46.00.0.0020	Hs-CRP Test Cassette	20 Test/box	CE-Professional
	Drugs Of Abuse (DOA) Single and Multi Tests		CE-Professional

BLOOD GLUCOSE MONITORING SYSTEMS

Testing your blood glucose regularly helps you better manage your diabetes. Reliance ™ by Atlas Medical, uses the latest blood glucose sensor technologies to offer you the most accurate and reliable results for the peace of mind you need. Atlas Medical offers these systems in different Electrode strips types which includes Gold, Silver and Graphite Electrodes.

Reliance Gold

Item Code	Item Description	Available sizes	CE-Status
8.52.00.0.0001	Reliance Gold Glucometer Pack	1 Pack	Pending
8.52.00.0.0050	Strips for Reliance Gold Glucometer	50 Strips/Bottle	Pending

Reliance Silver

Item Code	Item Description	Available sizes	CE-Status
8.53.00.0.0001	Reliance Silver Glucometer Pack	1 Pack	Pending
8.53.00.0.0050	Strips for Reliance Silver Glucometer	50 Strips/Bottle	Pending

Reliance Graphite

Item Code	Item Description	Available sizes	CE-Status
8.54.00.0.0001	Reliance Graphite Glucometer Pack	1 Pack	Pending
8.54.00.0.0050	Strips for Reliance Graphite Glucometer	50 Strips/Bottle	Pending

Lloyd's Register LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

Atlas Medical
Street No. 19, Sahab Free Zone
King Abdullah II industrial Estate
Amman
Jordan

has been approved by Lloyd's Register Quality Assurance to the following Quality Management System Standards:

ISO 13485:2003

The Quality Management System is applicable to:

Design Manufacturing and Supply of Medical Diagnostic Reagents and Kits

Approval Certificate No: MEA2105234/A

Original Approval: 28 February 2009
Current Certificate: 30 March 2015
Certificate Expiry: 27 February 2018

Issued by: Lloyd's Register EMEA - Jordan for and on behalf of: Lloyd's Register Quality Assurance Limited

ISO 13485

LNE

ATTESTATION/ CERTIFICATE N° 33544 rev. 0
Délivrée à Paris le 09 octobre 2017
Issued in Paris on October 9th, 2017

Notified Body N° 0459

ATTESTATION CE / EC CERTIFICATE
Examen CE de la Conception (du produit) / EC Design Examination (of the product)
ANNEXE IV point 4 Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro
ANNEX IV section 4 DIRECTIVE 98/79/EC concerning in vitro diagnostic medical devices

Fabricant / Manufacturer

ATLAS MEDICAL
William James House, Cowley Road
CAMBRIDGE, CB 0WX UNITED KINGDOM

Catégorie du(des) dispositif(s) / Device(s) category

Annexe II liste A : détermination des groupes sanguins.

Annex II list A : blood grouping determination.

Identification du(des) dispositif(s) / Identification of device(s)

ATLAS Anti-A, Anti-B, Anti-AB, Anti-D Monoclonal Reagents
(GMDN 30597-30598)
See addendum

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P146763, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 98/79/CE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P146763, the product(s) complies with the requirements of the directive 98/79/EC, annex I.

Début de validité / Effective date : October 9th, 2017 (included)
Valable jusqu'au / Expiry date : October 8th, 2022 (included)

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

Laboratoire national de métrologie et d'essais - Etablissement public à caractère industriel et commercial
LNE/G-MED - Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 - Tél. : 01 40 43 37 00 - Fax : 01 40 43 37 37 - www.lne.fr - www.gmed.fr

Blood Grouping CE Certificate

LNE

ATTESTATION/ CERTIFICATE N° 33540 rev. 0
Délivrée à Paris le 09 octobre 2017
Issued in Paris on October 9th, 2017

Notified Body N° 0459

ATTESTATION CE / EC CERTIFICATE
Approbation du Système Complet d'Assurance Qualité / Approval of Quality Assurance System
Annexe IV excluant les points 4 et 6 Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro
Annex IV excluding sections 4 & 6 Directive 98/79/EC concerning in vitro diagnostic medical devices
Pour les dispositifs de la liste A IVD, un certificat CE de la conception est requis
For list A IVD devices, a EC design certificate is required

Fabricant / Manufacturer

ATLAS MEDICAL
William James House, Cowley Road
CAMBRIDGE, CB 0WX UNITED KINGDOM

Catégorie du(des) dispositif(s) / Device(s) category

Annexe II liste A : Détermination des groupes sanguins : système ABO et rhésus D.

Annex II list A : Blood grouping determination : ABO system and rhesus D.

Voir détails sur addendum
See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P172375, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe IV excluant les points 4 et 6 de la Directive 98/79/CE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P172375, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 98/79/EC, annex IV excluding sections 4 & 6.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : October 9th, 2017 (included)
Valable jusqu'au / Expiry date : October 8th, 2020 (included)

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

Laboratoire national de métrologie et d'essais - Etablissement public à caractère industriel et commercial
LNE/G-MED - Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 - Tél. : 01 40 43 37 00 - Fax : 01 40 43 37 37 - www.lne.fr - www.gmed.fr

Full Quality Assurance Certificate.

OTHER CERTIFICATES

- GMP Certificate
- FDA 510k Atlas Home Pregnancy Test (Midstream Format)
- hCG Test Strip CE certificate
- hCG Test Cassette CE certificate
- hCG Midstream Test CE certificate
- Ovulation Test Midstream CE certificate
- Ovulation Test Cassette CE certificate
- Menopause Test Midstream CE certificate
- Menopause Test Cassette CE certificate
- Liver Function Test CE certificate
- Diabetes Test CE certificate
- UTI Test CE certificate
- Kidney function Test CE certificate

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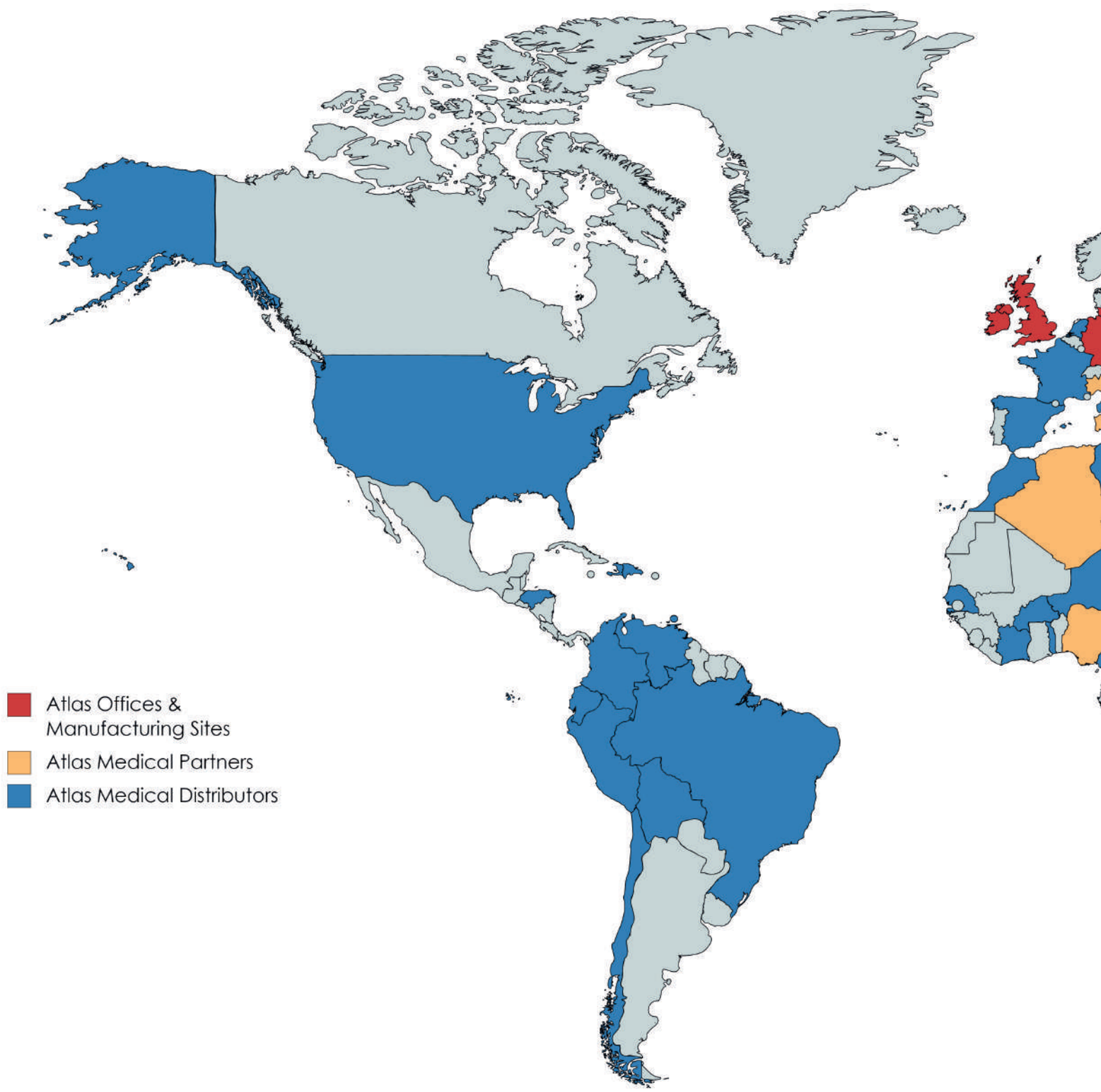
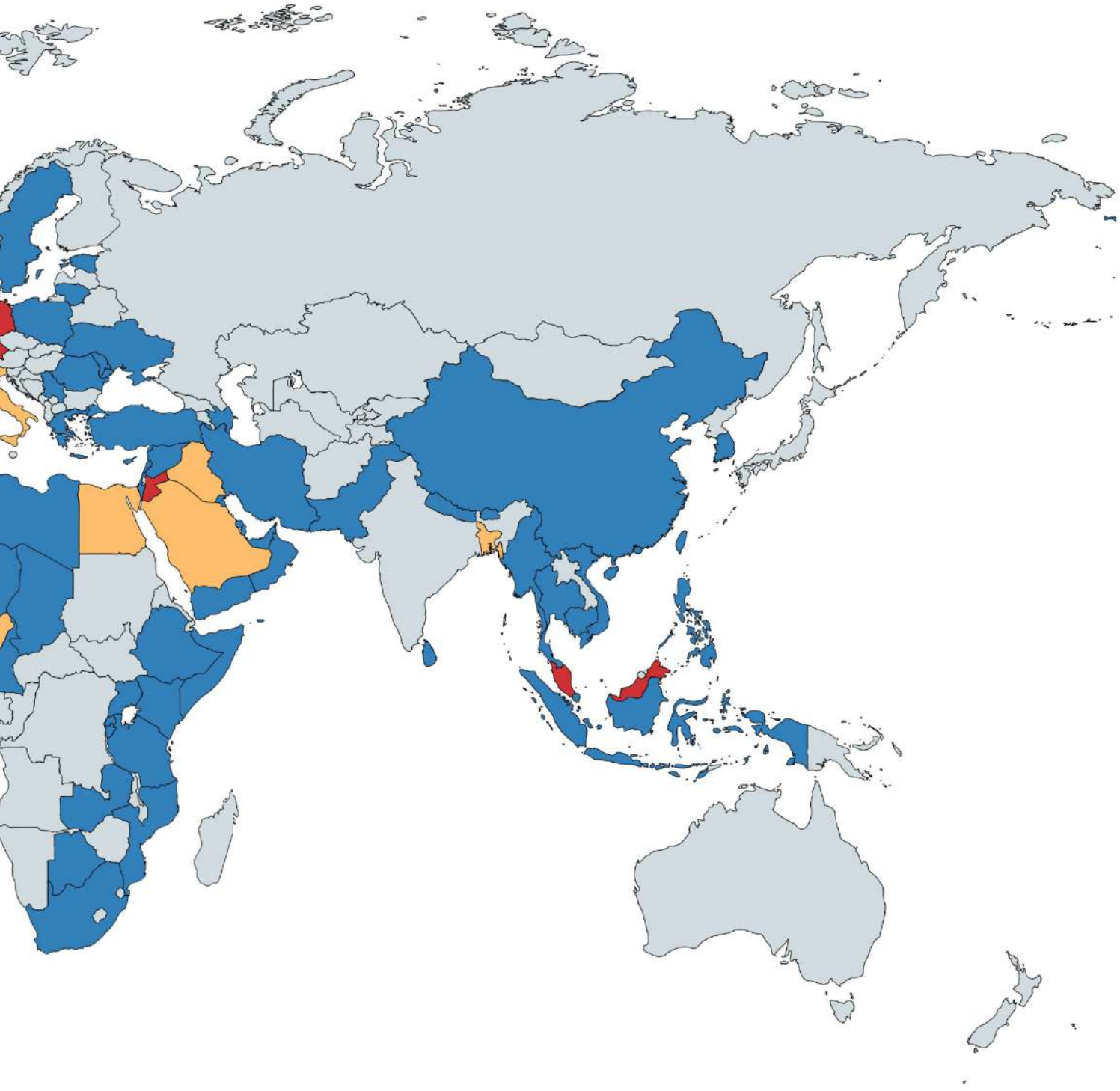
INTERNATIONAL PRESENCE





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