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
Head office: Ludwig-Erhard-Ring 3
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Tel: +49 - 33708 – 3550 30
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Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
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Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:
  Certificate N^0.: 36655 rev 1
  Expiry Date: October 8 th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And
Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
Blankenfelde-Mahlow , Germany.

Atlas Medical
Quality Diagnostic Products

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	March 2021	09.08.2021		

Digitally signed by Monastîrschii Viorica
Date: 2022.12.06 12:08:10 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

Declaration Ref No: DC22-0017

CE Declaration of Conformity

We,

Atlas Medical GmbH

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Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

Referance number	Product Name	GMDN code
8.14.19.0.0096	Atlas H.pylori Antigen Elisa Kit	50994

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate:

ISO Certificate N^{0}.: 36655 rev 1

Expiry Date: October 8 th.2023

In Vitro Diagnostic Medical Devices Directive 98/79/EC

And

EN 18113-1, -2,-4:2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002.

And

Intended for In-Vitro Professional use only.

This Declaration includes the batches produced beyond this day according to the product Lot Log.

Manufacturer
Atlas Medical GmbH
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow Germany.

Atlas Medical
Quality Diagnostic Products

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	January - 2008	21.02.2022		

Amani Al Habahbeh
RA Manager

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

Date: 15/Jan/2022

STATEMENT

We, ATLAS MEDICAL having a registered office at Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

On behalf of manufacturer:-

General Manager

Haya Amawi

Signature: _____

Date: 15.01.2022

Atlas Medical
Quality Diagnostic Products

Atlas Medical

H. pylori Antigen ELISA Test Kit

An enzyme immunoassay (ELISA) for the qualitative and quantitative detection of Helicobacter pylori (*H. pylori*) Antigen in human stool

IVD For *in vitro* diagnostic and professional use only

2°C 8°C Store at (2° to 8°C)

Σ **96 Tests**

CE

INTENDED USE

The *H. pylori* Antigen ELISA Test Kit is an enzyme immunoassay for the qualitative and quantitative detection of *H. pylori* antigen in human stool. It is intended as an aid in the diagnosis of possible *H. pylori* infection and in the follow-up of patients undergoing antimicrobial therapy.

INTRODUCTION

Helicobater pylori are Gram-negative spiral-shaped bacteria that have adapted to living in the harsh acidic conditions of the stomach. These bacteria can alter their surrounding micro-environment by reducing its acidity so they can survive .Their spherical shape facilitates penetration of the epithelial lining, where the bacteria are protected by mucus against cells of the immune system.

Infections with *H.pylori,* though harmless during childhood*, manifest* as peptic ulcers of the stomach, duodenum and of small intestine, active and chronic gastritis, as well as non-ulcer dyspepsia, in about 60% of the global adult population. The mechanism of bacterial transmission is still unknown, but is thought to be oral and/or fecal borne.

The *H. pylori* Antigen ELISA Test Kit is an immunoassay for the qualitative and quantitative detection of *H. pylori* Antigen in human stool. The test utilizes antibodies to *H. pylori* to selectively detect *H. pylori* Antigen in human stool.

PRINCIPLE OF THE TEST

The *H. pylori* Antigen ELISA Test Kit is a solid phase enzyme immunoassay based on sandwich principle for the qualitative and quantitative detection of *H. pylori* antigen in human stool. The microwell plate is coated with anti-*H. pylori* antibodies. During testing, the antigens are extracted from the specimen with extraction solution and added onto the antibodies coated microwell plate along with the enzyme- conjugated antibodies to *H. pylori*, and then incubated. If specimens contain *H. pylori* antigens, it will bind to the antibodies coated on the microwell plate and simultaneously bind to the conjugate to form immobilized antibody-H. pylori antigen-conjugate complexes. If specimens do not contain *H.pylori* antigens, the complexes will not be formed. After initial incubation, the microwell plate is washed to remove unbound materials. Substrate A and substrate B are added and then incubated to produce a blue color indicating the amount of *H. pylori* antigens present in the specimens. Sulfuric acid solution is added to the microwell plate to stop the reaction producing a color change from blue to yellow. The color intensity, which corresponds to the amount of *H. pylori* antigens present in the specimens, is measured with a microplate reader at 450/630-700 nm or 450 nm.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Follow the instructions for use carefully. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.
- Wear protective clothing and disposable gloves when dealing with samples and reagents. Wash hands after operations.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different batch codes.
- It is important to calibrate all the equipment e.g. micropipettes, and/or the automated instruments used with this device, and to perform routine preventative maintenance.
- Ensure that the bottom of the plate is clean and dry and that no bubbles are present on the surface of the liquid before reading the plate.
- Never eat, drink, smoke, or apply cosmetics in the assay laboratory. Never pipette solutions by mouth.
- Avoid cross contamination between reagents to ensure valid test results.
- Follow the wash procedure to ensure optimum assay performance.
- Use Plate Sealer to cover microwell plate during incubation to minimize evaporation.
- Use a new pipette tip for each specimen assayed.
- Do not touch or splash the rim of the well. Do not blow out from micropipettes.
- Do not allow sodium hypochlorite fumes from chlorine bleach or other sources to contact the microwell plate during the assay as the color reaction may be inhibited.

HEALTH AND SAFETY INFORMATION

- Collect samples in accordance with correct medical practices.
- Some reagents may cause toxicity, irritation, burns or have a carcinogenic effect as raw materials. Contact with the skin and the mucosa should be avoided but not limited to the following reagents: Stop solution, the Conjugate, and the Wash buffer, Extraction solution, Substrate.
- The Stop solution 0.5M H2SO4 is an acid. Use it with appropriate care. Wipe up spills immediately and wash with water if it comes into contact with the skin or eyes.
- ProClinTM 300 0.1% is used as a preservative; it can cause irritation of the skin. Wipe up spills immediately or wash with water if it comes into contact with the skin or eyes.
- Pipette tips, vials, strips and specimen containers should be collected and autoclaved for not less than 2 hours at 121°C before any further steps of disposal. Solutions containing sodium hypochlorite should NEVER be autoclaved.
- All specimens and materials should be considered as potentially infectious. Strict adherence to GLP (Good Laboratory Practice) regulations can ensure personal safety.
- Chemicals should be handled and disposed of only in accordance with the current GLP (Good Laboratory Practices) and the local or national regulations.
- Neutralized acids and other liquids should be decontaminated by adding sufficient volume of sodium hypochlorite to obtain a final concentration of at least 1.0%. A 30 minute exposure to 1.0% sodium hypochlorite may be necessary to ensure effective decontamination.

STORAGE AND STABILITY

- Components of the kit will remain stable through the expiration date indicated on the label and package when stored between 2-8°C, Once opened; all reagents are stable for up to 3 months after the first opening date if stored between 2-8°C. Return reagents to 2-8°C immediately after use.
- Place unused wells in the zip-lock aluminum foiled pouch and return to 2-8 °C, under which conditions the wells will remain stable for 3 months from the opening date.
- Concentrated Wash Buffer may be stored at room temperature to avoid crystallization. If crystals are present, warm up the solution at 37°C. Working Wash Buffer is stable for 2 weeks at room temperature.
- Do not expose reagents especially the Substrate to strong light or hypochlorite fumes during storage or incubation steps.
- Do not store Stop Solution in a shallow dish or return it to the original bottle after use.

SPECIMEN COLLECTION AND PREPARATION

- This *H. pylori* Antigen ELISA Test can be performed using only human stool.
- Stool samples should be collected in clean containers. Samples can be stored in the refrigerator (2-8 °C) for 1-2 days prior to testing. For longer storage, the specimen must be kept frozen at -20ºC. In this case, the sample should be totally thawed and brought to room temperature before testing.
- The patient has to be asked to collect the specimen avoiding any possible contact with urine or water.
- The patient submitted to the test should not be under antibiotic or anti-bacterial treatments as this pharmaceutical therapy is known to affect *H. pylori* up to a certain extent, depending on the antibiotic used, giving rise to false interpretation.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

MATERIALS PROVIDED

1. ***H.Pylori* Antigen Microwell Plate:** Microwell plate coated with anti-*H. Pylori* antibodies. **(1 plate: 96 wells/plate).**
2. ***H.pylori* Antigen Conjugate:** One red cap vial containing antibodies to *H. pylori* bound to peroxidase; Preservative: 0.1% ProClin™ 300. **(1 x 8 mL).**
3. **Concentrated Wash Buffer (25x):** One white cap bottle containing Tris-HCl buffer containing 0.1% Tween 20; Preservative: 0.1% ProClin™ 300. **(1 x 40 mL).**
4. **Extraction Solution:** One white cap bottle containing 0.9% NaCl buffer containing EDTA; Preservative: 0.1% ProClin™ 300. **(1 x100 mL).**
5. **Substrate A:** One white cap vial containing Citrate-phosphate buffer containing hydrogen peroxide; Preservative: 0.1% ProClin™ 300. **(1 x 8 mL).**
6. **Substrate B:** One blue cap vial containing Buffer containing tetramethylbenzidine (TMB); Preservative: 0.1% ProClin™ 300. **(1 x 8 mL).**
7. **Stop Solution:** One yellow cap vial containing 0.5M Sulfuric acid. **(1 x 8 mL).**

8. ***H.pylori* Antigen Calibrator 1:** One white cap vial containing Buffer non-reactive for *H. pylori* Antigen; Preservative: 0.1% ProClin™ 300. **(1 x 1 mL).**
9. ***H.pylori* Antigen Calibrator 2:** One white cap vial containing Buffer containing 0.1 µg/mL *H. pylori* Antigen; Preservative: 0.1% ProClin™ 300. **(1 x 1 mL).**
10. ***H.pylori* Antigen Calibrator 3:** One white cap vial containing Buffer containing 0.5 µg/mL *H. pylori* Antigen; Preservative: 0.1% ProClin™ 300. **(1 x 1 mL).**
11. ***H.pylori* Antigen Calibrator 4:** One white cap vial containing Buffer containing 1.0 µg/mL *H. pylori* Antigen; Preservative: 0.1% ProClin™ 300. **(1 x 1 mL).**
12. **Plate Sealers (2 pieces).**
13. **Package Insert (1 copy).**

MATERIALS REQUIRED BUT NOT PROVIDED

- Freshly distilled or deionized water.
- Sodium hypochlorite solution for decontamination.
- Absorbent paper or paper towel.
- Water bath or incubator capable of maintaining 15°C to 30°C.
- Calibrated automatic or manual microwell plate washer capable of aspirating and dispensing 350 µL/well.
- Disposable gloves.
- Automated processor (optional).
- Calibrated micropipettes with disposable tips capable of dispensing 50 and 100 µL.
- Graduated cylinders for wash buffer dilution.
- Vortex mixer for specimen mixing (optional).
- Disposable reagent reservoirs.
- Calibrated microplate reader capable of reading at 450 nm with a 630-700 nm reference filter, or reading at 450 nm without a reference filter.
- Timer.

DIRECTIONS FOR USE

1. Remove unused strips from the microwell plate, and store in the original resealable pouch at 2-8°C.
2. Allow reagents and specimens to reach room temperature (15-30°C) prior to testing.

WASH PROCEDURE

a. The wash procedure is critical. Insufficient washing will Result in a poor precision and falsely elevated absorbance readings.

b. Prepare working wash buffer by adding content of wash buffer bottle provided with the kit to distilled or deionized water to reach a final volume of 1 liter. The working wash buffer is stable for 2 weeks at 15-30°C.

3. Dispense 1 mL of Extraction Solution into Specimen Extraction Tube.

For Solid Stool Specimens:

i. Take out the cap of the Specimen Extraction Tube
ii. Randomly stab the specimen collection stick into the stool specimen in at least 3 different sites to collect approximately 30 mg of specimen (equivalent to 1/4 of a pea). Do not scoop the stool specimen.
iii. Transfer into Specimen Extraction Tube.

For Liquid Stool Specimens:

i. Hold the Liquid Specimen Dropper vertically.
ii. Aspirate stool specimens and then dispense 2 drops (approximately 50 µL) into the Specimen Extraction Tube containing the Extraction Solution.
iii. Screw on and tighten the cap onto the Specimen Extraction Tube.
iv. Shake the Specimen Extraction Tube vigorously to mix the specimen and the Extraction Solution.

4. Leave A1 as Blank well.
5. Dispense 50 µL of Calibrator 1 in wells B1 and C1. (Light Yellow Reagent)
6. Dispense 50 µL of Calibrator 2 in wells D1 and E1. (Green Blue Reagent)
7. Dispense 50 µL of Calibrator 3 in wells F1 and G1. (Light Blue Reagent)
8. Dispense 50 µL of Calibrator 4 in wells H1 and A2. (Dark Blue Reagent)
9. Hold the Specimen Extraction Tube upright and break off the tip of the tube. Invert the Specimen Extraction Tube and dispense 2 drops of the specimen Extraction Solution (approx. 50 µL) to assigned wells starting at B2. (Yellow Reagent)
10. Dispense 50 µL of Conjugate to each well except for the Blank well. (Red Reagent)
11. Mix gently by swirling the microwell plate on a flat bench for 30 seconds.
12. Cover the microwell plate with the Plate Sealer and incubate at room temperature (15-30°C) in a room, a water bath, or an incubator for 60 minutes ± 5 minutes.
13. Remove the Plate Sealer.
14. Wash each well 5 times with 350 µL of Working Wash Buffer per well, and then remove the liquid.
15. Turn the microwell plate upside down on absorbent tissue for a few seconds. Ensure that all wells have been completely washed and dried.
    Note: Improper washing may cause false positive results.
16. Dispense 50 µL of Substrate A to each well. (Clear Reagent)
17. Dispense 50 µL of Substrate B to each well. (Clear Reagent) Then a blue color should develop in wells containing Positive specimens.
18. Mix gently then cover microwell plate with Plate Sealer and incubate at room temperature (15-30°C) in a room, a water bath, or an incubator for 10 minutes ± 1 minute.
19. Remove the Plate Sealer.
20. Dispense 50 µL of Stop Solution to each well. (Clear Reagent) Then a yellow color should develop in wells containing Positive specimens.
21. Read at 450/630-700 nm within 30 minutes.
22. Note: Microwell plate can also be read at 450 nm, but it is strongly recommended to read it at 450/630-700 nm for better results.

VALIDATION REQUIREMENT AND QUALITY CONTROL

1. Calculate the Mean Absorbance of Calibrators 1-4 by referring to the table below.

Example of Calibrator 2 Calculation

Item	Absorbent
Calibrator 2: Well D1	0.469
Calibrator 2: Well E1	0.507
Total Absorbance of Calibrator 2	0.976
Mean Absorbance of Calibrator 2	0.488

2. Check the validation requirements below to determine if the test results are valid.

Item	Validation Requirements
Blank Well	Blank Absorbance should be < 0.050 if read at 450/630-700 nm Note: It should be < 0.100 if read at 450 nm
Calibrator 1	Mean Absorbance after subtraction of Blank Absorbance should be < 0.100
Calibrator 2	Mean Absorbance after subtraction of Blank Absorbance should be > 0.150
Calibrator 3	Mean Absorbance after subtraction of Blank Absorbance should be > 0.500
Calibrator 4	Mean Absorbance after subtraction of Blank Absorbance should be > 1.000

NOTE: The test results are considered invalid if the above validation requirements are not met. Repeat the test or contact your local distributor.

INTERPRETATION OF RESULTS

Qualitative

Calculate the Index Value to obtain qualitative specimen results.

1. If the test is valid, obtain Cut-Off Value by subtracting the Blank Absorbance from the Mean Absorbance of 1/2× (Calibrator 2+Calibrator 1). See an example of Cut-Off Value calculation below.

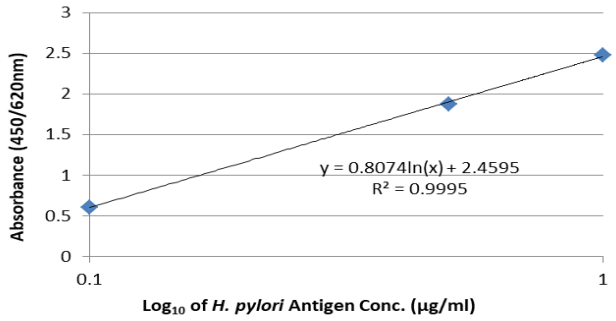
Item	Absorbent
Blank Absorbance: Well A1	0.011
Cut-Off Value: 1/2× (Mean Absorbance of Calibrator 2+ Mean Absorbance of Calibrator 1) – Blank Absorbance	1/2× (0.488+0.012)-0.011=0.239

2. Calculate the Index Value by dividing the Specimen Absorbance by the Cut-Off Value, and then read the results by referring to the Interpretation of Results table below.

Item	Absorbent
Specimen: Well F2	0.968
Blank Absorbance: Well A1	0.011
Cut-Off Value	0.239
Index Value: Specimen/Cut-Off Value	(0.968-0.011)/0.239=4.0

Quantitative

Draw the calibration curve and obtain quantitative specimen results.



1. Subtract the Blank Absorbance from the Mean Absorbance of each Calibrator, and then plot them on the Y-axis against their Log_{10} of the corresponding concentration in µg/mL on the X-axis on a linear graph paper and draw the calibration curve. Draw the best fitted line through data points to obtain a standard curve. Refer to an example of the calibration curve at right.

   NOTE: Do not use the calibration curve at right to make any calculation. A calibration curve must be performed for each run.
2. Obtain quantitative specimen results from their absorbance by using the calibration curve.

   NOTE: Specimens that have absorbance above Calibrator 4 should be pre-diluted using Extraction Solution and retested. The concentration must be multiplied by the dilution factor. Automated reading and calculation may also be performed using linear regression function on suitable computer programs.

Interpretation of Results - Qualitative and Quantitative

Results	Qualitative	Quantitative
	Index Value	Concentration
Negative	< 0.9	< 0.045 µg/mL
Positive	> 1.1	> 0.055 µg /mL
Equivocal*	≥ 0.9 and ≤ 1.1	0.045 – 0.055 µg/mL

***NOTE:** For Equivocal results, the specimen should be retested. Specimens that are repeatedly Equivocal after retest should be confirmed using an alternate method. If the results remain Equivocal, collect a new specimen in two weeks. If the new specimen is Positive, the specimen is presumed to be Positive.

LIMITATIONS

1. The *H. pylori* Antigen ELISA Test Kit is used for the detection of *H. pylori* antigen in human stool. Diagnosis of an infectious disease should not be established based on a single test result. Further testing, including confirmatory testing, should be performed before a specimen is considered positive. A negative test result does not exclude the possibility of exposure. Specimens containing precipitate may give inconsistent test results.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. As with other sensitive immunoassays, a false positive result may arise due to inadequate washing from the initial test. The results may be affected due to procedural or instrument error.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The *H. pylori* Antigen ELISA Test Kit has been compared to a leading commercial *H. Pylori* Antigen ELISA test using clinical specimens. The results show that the clinical sensitivity of the *H. pylori* Antigen ELISA Test Kit is 98.6%, and the clinical specificity is 95.4%.

***H. pylori* Antigen ELISA vs. Other ELISA**

Method		Other ELISA		Total Results
H. pylori Antigen ELISA	Results	Positive	Negative	
	Positive	70	6	76
	Negative	1	125	126
Total Results		71	131	202

Clinical Sensitivity: 98.6% (92.4-100.0%) *
Clinical Specificity: 95.4% (90.3-98.3%)*
Overall Agreement: 96.5% (93.0-98.6%)*
***95% Confidence Interval**

Reproducibility

Intra-Assay: Within-run precision has been determined by using 10 replicates of two specimens: a low positive and a high positive.

Inter-Assay: Between-run precision has been determined by using 10 replicates on the same two specimens: a low positive and a high positive. Three different lots of the *H. pylori* Antigen ELISA Test Kit have been tested using these specimens.

Specimen	Intra-Assay			Inter-Assay		
	Mean Absorbance/ Cut-Off	Standard Deviation	Coefficient of Variation (%)	Mean Absorbance/ Cut-Off	Standard Deviation	Coefficient of Variation (%)
1	1.741	0.156	8.96	1.723	0.133	7.72
2	4.726	0.252	5.33	4.861	0.252	5.18

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3. Ansorg, R, Von Recklinghausen, G, Pomarius, R and Schmid, EN. Evaluation of techniques for isolation, subcultivation and preservation of *Helicobacter pylori*. J. Clin. Micro. (1991), 29:51-53.
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5. Megraud, F, Bassens-Rabbe, MP, Denis, F, Belbouri, A and Hoa, DQ. Seroepidemiology of *Campylobacter pylori* infection in various populations. J. Clin. Micro. (1989), 27: 1870-3.

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Website: www.atlas-medical.com

PPI1532A01
Rev B (21.10.2021)

REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry

Atlas Medical CE

STREPTOCOCCAL GROUPING SLIDE
LATEX TEST

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

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

Store at 2° to 8° C

INTENDED USE

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

INTRODUCTION & PRINCIPLES

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

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

MATERIALS

MATERIALS PROVIDED

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

MATERIALS NEEDED BUT NOT PROVIDED

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

PRECAUTIONS:

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

PREPARING THE EXTRACTION ENZYME

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

SAMPLE PREPARATION

Cultures

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

PROCEDURES

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

READING THE RESULT

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

PROCEDURE LIMITATION

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

PERFORMANCE CHARACTERISTICS

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

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

INTERNAL QUALITY CONTROL

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

Periodically check the following:

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

REFERENCES

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

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

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

Certificate of Analysis for ELISA Kit

1- Product Identification:

Lot No	22030905
Product Name	H. Pylori Ag Elisa Kit
QC Method No	F28D
Batch Size	6
EXP. Date	03.2023
Mfg. Date (if applicable)	N.A

2- Physical Inspection:

Inspection level	AQL	Sample size code letter	Inspected quantity	Accepted	Rejected
N.A	N.A	N.A	1	N.A	N.A

Applicable test type	Inspected item / criteria	Acceptance criteria	Inspection results
➢ Kit Assembly:	All components of the kit are present according to the outer label		■ Pass □ Fail
➢ Item Color & Status Based Color & Status are compatible with the specifications mentioned in the Product Specifications List (QRXQU07L):	Stop solution :	Colorless, liquid	■ Pass □ Fail
	Wash Buffer :	Colorless, liquid	■ Pass □ Fail
	Enzyme Conjugate :	Red,liquid	■ Pass □ Fail
	Substrate Solution A :	Colorless, liquid	■ Pass □ Fail
	Calibrator 1 :	Yellowish,liquid	■ Pass □ Fail
	Calibrator 2 :	Greenish, liquid	■ Pass □ Fail
	Calibrator 3 :	Faint Blue , liquid	■ Pass □ Fail
	Calibrator 4 :	Dark Blue , liquid	■ Pass □ Fail
	Substrate Solution B:	Colorless, liquid	■ Pass □ Fail
	Extraction Solution :	Colorless, liquid	■ Pass □ Fail
			□ Pass □ Fail
			□ Pass □ Fail
			□ Pass □ Fail
			□ Pass □ Fail
			□ Pass □ Fail
			□ Pass □ Fail
➢ Item Size/ Reagent Size is compatible with that requested in Item Dispense:	Stop solution :	8 ml	■ Pass □ Fail
	Wash Buffer :	40 ml	■ Pass □ Fail
	Enzyme Conjugate :	8 ml	■ Pass □ Fail
	Substrate Solution A :	8 ml	■ Pass □ Fail
	Calibrator 1 :	1 ml	■ Pass □ Fail
	Calibrator 2 :	1 ml	■ Pass □ Fail
	Calibrator 3 :	1 ml	■ Pass □ Fail
	Calibrator 4 :	1 ml	■ Pass □ Fail
	Substrate Solution B:	8 ml	■ Pass □ Fail
	Extraction Solution :	100 ml	■ Pass □ Fail
			□ Pass □ Fail
			□ Pass □ Fail
			□ Pass □ Fail
			□ Pass □ Fail
			□ Pass □ Fail

Applicable test type	Inspected item / criteria	Acceptance criteria	Inspection results
➢ Labels:	Correct label orientation		■ Pass □ Fail
	Correct label position		■ Pass □ Fail
	Clear printing		■ Pass □ Fail
➢ Package Insert:	Clear printing and correct folding		■ Pass □ Fail
	Correct code, version and brand as mentioned in item dispense		■ Pass □ Fail
	Address as mentioned on box design		■ Pass □ Fail
➢ Closing Cap:	No leakage and closed well		■ Pass □ Fail
➢ ELISA Microplate Pouch:	Printing ELISA name on pouch is compatible with printed label		■ Pass □ Fail
	Clear printing		■ Pass □ Fail
	Closed well without any defects		■ Pass □ Fail
➢ Quantity/Kit:	Compatible with the quantity mentioned in the outer label. • Record the QTY/Kit: 14/1		■ Pass □ Fail
➢ Final Result:	■ Pass □ Fail, justify: …….		
Done by (Signature): …razan…… Date: 25.06.2022…… Time: 12:00….. QC Officer/Supervisor			

3- Biochemical Inspection Results:

Item	Acceptance criteria	Absorbance	Result (Pass / Fail)
Blank	0.007	< 0.050	■ Pass □ Fail
Calibrator 1	0.0197	< 0.100	■ Pass □ Fail
Calibrator 2	0.403	> 0.150	■ Pass □ Fail
Calibrator 3	1.193	> 0.500	■ Pass □ Fail
Calibrator 4	2.29	> 1.00	■ Pass □ Fail
Other materials used			
Materials name		**RN./LOT**	
NA		NA	
Done by (Signature): ….razan…… Date: 25.06.2022…… Time: 11:40….. QC Officer/Supervisor			

Final Conclusion: ■ **Pass** □ **Fail**	
Final QC Manager Approval (Signature): Tasneem	**Date:** 25.06.2022

QC Release Stamp: