



浙江东方基因生物制品有限公司  
Zhejiang Orient Gene Biotech Co.,LTD

---

## Relationship between Healgen and OrientGene

Date : Aug 13<sup>th</sup> , 2020

To Whom it may concern,

This is to certify that Zhejiang Orient Gene Biotech Co.,Ltd,Located at NO.:3787# East Yangguang Avenue,Dipu Street,Anji313300,Huzhou,Zhejiang,China,and Healgen Scientific LLC,Located at 3818 Fuqua Street ,Houston,TX 77047,USA,are affiliated business divisions under the same management,Zhejiang Orient Gene Biotech Co.,Ltd is an ISO 13485 certificated medical device manufacturer.

Mr Bryan Fang

General Manger

Healgen Scientific LLC



Mr.Xiaoliang Fang

General Manager

Zhejiang OrientGene Biotech Co.,Ltd



**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**

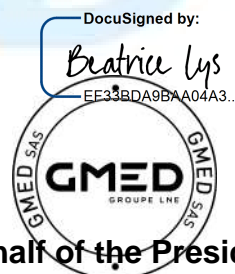


Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)

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



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

**Ce certificat couvre les activités et les sites suivants :**  
*This certificate covers the following activities and sites:*

**French version :**

**Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.**

**English version:**

*Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.*

**ATLAS MEDICAL GmbH  
Ludwig-Erhard-Ring 3  
15827 Blankenfelde-Mahlow  
GERMANY**

French version:

**Siège social, responsable de la mise sur le marché**

*English version:*

*Headquarter, legal manufacturer*

\*\*\*\*\*

**Sahab Industrial Zone Area  
King Abdullah II Industrial City  
Amman 11512  
JORDAN**

French version:

**Conception, fabrication et contrôle final**

*English version:*

*Design, manufacture and final control*

\*\*\*\*\*

**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**

## 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

2°C 8°C  
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 fluorescence 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 HANDLING

- 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 2-8° 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 10µl serum 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 75µl of 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 25µl of 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. Incubate for 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.



## 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.

**INDETERMINATE** 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.

### REFERENCES:

1. Rathlev T. - Haemagglutination tests utilizing antigens from pathogenic and apathogenic Treponema pallidum WHO/VDT/RES 1965 ; 77 : 65.
2. Tomizawa T, Kasamatsu S. - Haemagglutination tests for diagnosis of syphilis. A preliminary report. Japan. J. Med. Sci. Biol. 19, 305-308, 1966.
3. Rathlev T. - Haemagglutination test utilizing pathogenic Treponema pallidum for the serodiagnosis of syphilis. Br J Vener Dis 1967 ; 43 : 181-5.
4. Tomizawa T. Kasamatsu S. Yamaya S. - Usefulness of the haemagglutination test using Treponema pallidum antigen (TPHA) for the serodiagnosis of syphilis. Jap J Med Sci Biol 1969; 22: 341-50.
5. Sequeira P, J, L. Eldridge A, E. – Treponemal Haemagglutination test. Br J Vener Dis 1973; 49: 242-8.
6. Larsen S.A., Hambie E.A., et coll., Specificity, sensitivity and reproducibility among the fluorescent treponemal antibody absorption test, the microhemagglutination assay for Treponema pallidum antibodies, and the hemagglutination treponemal test for syphilis. J. Clin. Microbiol., 1981 ; 14 : 441 – 445.
7. Houg H. - Syphilis: new diagnostic directions. Intern. J. STD and AIDS 1992; 3: 391-413.
8. Sluis J.J. Van Der. - Laboratory Techniques in the diagnosis of syphilis: a review. Genitourin Med. 1992; 68 : 413-9.



William James House, Cowley Rd,

Cambridge, CB4 4WX, UK

Tel: ++44 (0) 1223 858 910

Fax: ++44 (0) 1223 858 524

PPI080A01

Rev F (09.06.2016)

|     |                               |  |   |
|-----|-------------------------------|--|---|
| 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 <b>damaged</b> |
|     | Manufacturer telephone number |  |   |



**RPR SYPHILIS CARD TEST**

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

2°C 8°C Store at 2 to 8 °C

**INTRODUCTION**

Syphilis is a disease caused by infection with the spirochete *Treponema pallidum*. The infection is systemic and the disease is characterized by periods of latency. These features, together with the fact that *T pallidum* cannot be isolated in culture, mean that serologic techniques play a major role in the diagnosis and follow-up of treatment for syphilis.

Syphilis is categorized by an early primary infection in which patients may have non-specific symptoms, and potentially, genital lesions. Patients tested by serology during the primary phase may be negative for antibodies, especially if testing is performed during the first 1 to 2 weeks after symptom onset. As the disease progresses into the secondary phase, antibodies to *T pallidum* reach peak titers, and may persist indefinitely regardless of the disease state or prior therapy. Therefore, detection of antibodies to nontreponemal antigens, such as cardiolipin (a lipoidal antigen released by host cells damaged by *T pallidum*) may help to differentiate between active and past syphilis infection. Nontreponemal antibodies are detected by the rapid plasma reagin (RPR) assay, which is typically positive during current infection and negative following treatment or during late/latent forms of syphilis.

**PRINCIPLE**

RPR utilises carbon particles coated with cardiolipin antigen to detect reagin antibodies present in serum or plasma of syphilitic persons.

Specimens that contain reagin cause aggregation of the carbon particles which appear as dark clumps against a white background. The aggregation can be read macroscopically. Non-reactive samples typically appear as a smooth non-aggregated pattern which may form buttons in the centre of the test area.

**MATERIALS**

**MATERIALS PROVIDED**

- **RPR carbon antigen reagent:** Contains less than 0.1% sodium azide.
- **Positive Control :** Contains less than 0.1% sodium azide.
- **Negative control:** Contains less than 0.1% sodium azide

- RPR test cards (Optional).
- Plastic sticks.
- Package insert.

**NOTE: This package insert is also used for individually**

**MATERIALS NEEDED BUT NOT PROVIDED**

- Rotator (100rpm).
- Timer.
- Pipettes.

**PACKED REAGENT**

**REF** 8.00.18.0.0100 (2ml latex, 2x0.5 ml control)

**SAMPLES**

Fresh serum or plasma. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

**PRECAUTIONS**

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Always use a fresh pipette tip for every test.
- Handle all negative and positive in the manner as patient specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Components of different human origin have been tested and found to be negative for the presence of antibodies anti- HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.

**STORAGE AND STABILITY**

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C.

**PROCEDURES**

**QUALITATIVE PROCEDURE**

- **Mix well the RPR reagent before use.**
1. Bring the reagents and samples to room temperature.
  2. Dispense 50 µl of each sample into a separate circle on the card. Use a separate tip for each sample.
  3. Dispense 1 drop of each of positive and negative controls into two additional circles.
  4. Gently shake the dispensing vial and slightly press to remove air bubbles from the needle and the drop obtained is correct.

5. Dispense 1 drop (17.5 µl) of RPR antigen to each circle next to the sample to be tested.
6. Place the card on a mechanical rotator and rotate at 100 r.p.m. for 8 minutes.
7. Observe macroscopically for agglutination within a minute after removing the card from the rotator.

**SEMI-QUANTITATIVE PROCEDURE**

- **Mix well the RPR reagent before use.**

1. Make doubling dilutions from Undiluted to 1:16 normal saline.
  2. Place 50 µl of each dilution in to a separate circle on the test card.
  3. Spread each dilution evenly over the test circle.
  4. Continue as from Qualitative procedure .
- The titer of the sample is expressed as the final dilution which shows aggregation of the carbon particles.

**PERFORMANCE CHARACTERISTICS**

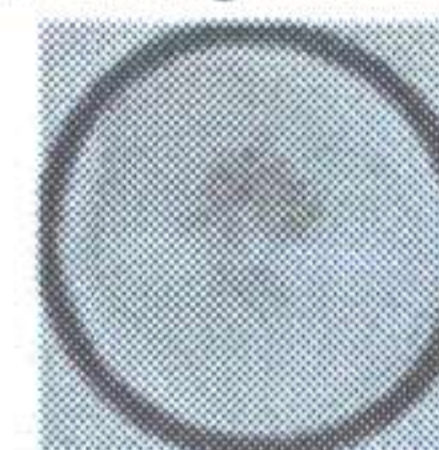
1. **Sensitivity:** 100%.
2. **Specificity:** 100%.

**INTERPRETATION OF TEST RESULTS**

1. **Strong Reactive:** Large clumps of carbon particles with a clear background.



2. **Reactive:** Large clumps of carbon particles somewhat more disperse than Strong Reactive pattern.

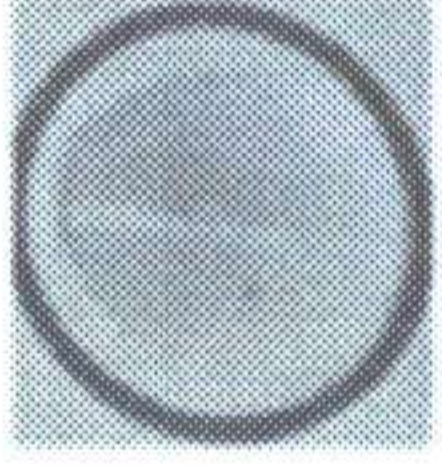


3. **Weak Reactive:** Small clumps of carbon particles with light grey background.





4. **Trace Reactive:** Slight clumping of carbon particles typically seen as a button of aggregates in the centre of the test circle or dispersed around the edge of the test circle.



5. **Non-Reactive:** Typically a smooth grey pattern or a button of non-aggregated carbon particles in the centre of the test circle.



**REFERENCES**

- Falcone V.H., Stout G.W. and Moore M.B. Jr., PHR 79: 491-495, 1964.

**ATLAS Medical GmbH**  
 Ludwig-Erhard Ring 3  
 15827 Blankenfelde-Mahlow  
 Germany  
 Tel: +49 - 33708 - 3550 30  
 Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)  
 Website: [www.atlas-medical.com](http://www.atlas-medical.com)

**PPI2280A01**  
 Rev A (10.10.2022)

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





PRODUCT  
CATALOGUE

2022-2023

# TABLE OF CONTENTS

---

|   |    |
|---|----|
| Introduction .....                        | 1  |
| Vision, Objectives, Mission .....         | 1  |
| Sites, Our Products .....                 | 2  |
| Standards, Our Markets .....              | 3  |
| MILESTONES .....                          | 4  |
| COVID-19 TESTING KITS .....               | 5  |
| VIRAL TRANSPORT MEDIUM KITS .....         | 6  |
| LATEX KITS .....                          | 7  |
| TURBIDIMETRIC LATEX KITS .....            | 8  |
| SYPHILIS KITS .....                       | 8  |
| FEBRILE ANTIGENS .....                    | 9  |
| BLOOD GROUPING REAGENTS.....              | 10 |
| HEMATOLOGY TESTS .....                    | 11 |
| SICKLE CELL KITS .....                    | 11 |
| INFECTIOUS DISEASE RAPID TESTS .....      | 12 |
| ANTIBODY TESTING .....                    | 12 |
| ANTIGEN TESTING .....                     | 13 |
| URINE REAGENT STRIPS .....                | 14 |
| FERTILITY RAPID TESTS .....               | 15 |
| KIDNEY FUNCTION RAPID TESTS .....         | 15 |
| INFLAMMATION AND CANCER MARKERS .....     | 16 |
| CARDIAC MARKERS RAPID TESTS .....         | 16 |
| DOA RAPID TESTS .....                     | 17 |
| CLINICAL CHEMISTRY KITS .....             | 19 |
| ALCOHOL TESTS .....                       | 20 |
| STAINS FOR HISTOLOGY & MICROBIOLOGY ..... | 21 |
| ANTIBIOTIC SENSITIVITY DISCS .....        | 22 |
| ELISA KITS .....                          | 23 |
| HORMONE ELISA KITS .....                  | 23 |
| TORCH ELISA KITS .....                    | 24 |
| INFECTIOUS DISEASES ELISA KITS .....      | 24 |
| OTHER ELISA KITS .....                    | 24 |
| HOME TESTS .....                          | 25 |
| BLOOD GLUCOSE MONITORING SYSTEMS .....    | 26 |
| CERTIFICATES .....                        | 27 |
| CONTACT US .....                          | 28 |
| INTERNATIONAL PRESENCE .....              | 29 |



# INTRODUCTION

Atlas Medical GmbH was established in 1996 as a manufacturer and supplier of quality Diagnostic Reagents and Kits. Our products are sold in over 80 countries worldwide.

The company is located at the Cambridge Science Park, Cambridge, UK. In addition to the UK site, the company has offices in Germany and Turkey as well as 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.

## Vision

To be a major provider of quality medical diagnostic products to local, regional and international markets.

## Objectives



*High and Consistent Quality*



*Satisfied Customer*



*Continuous Improvement & Innovation*



*Care for the Environment & Working Conditions*

## 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.



Atlas Medical GmbH  
Ludwig-Erhard-Ring 3  
15827 Blankenfelde-Mahlow,  
Berlin, Germany  
Tel: +49 - 33708 – 3550 30  
Email: amug@atlas-medical.com



Atlas Medical UK.  
William James House, Cowley  
Road, Cambridge, CB4 0WX, UK.  
Tel.: +44 (0) 1223 858 910  
Fax: +44 (0) 1223 858 524  
Email: info@atlas-medical.com



Atlas Medlab  
Aktarhüssam Mh.1. Değirmen Sk.  
Değirmen İşhane No :9, D: 405 .  
Osmangazi / Bursa/ Turkey  
Tel: +90 552 366 21 71  
Email: info@atlas-medical.com



Atlas Medical Jordan  
Sahab Free Zone Area,  
Amman 11512 Jordan  
Tel: +962 6 4026468  
Fax +962 6 4022588  
Email : info@atlas-medical.com



## 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.



## 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

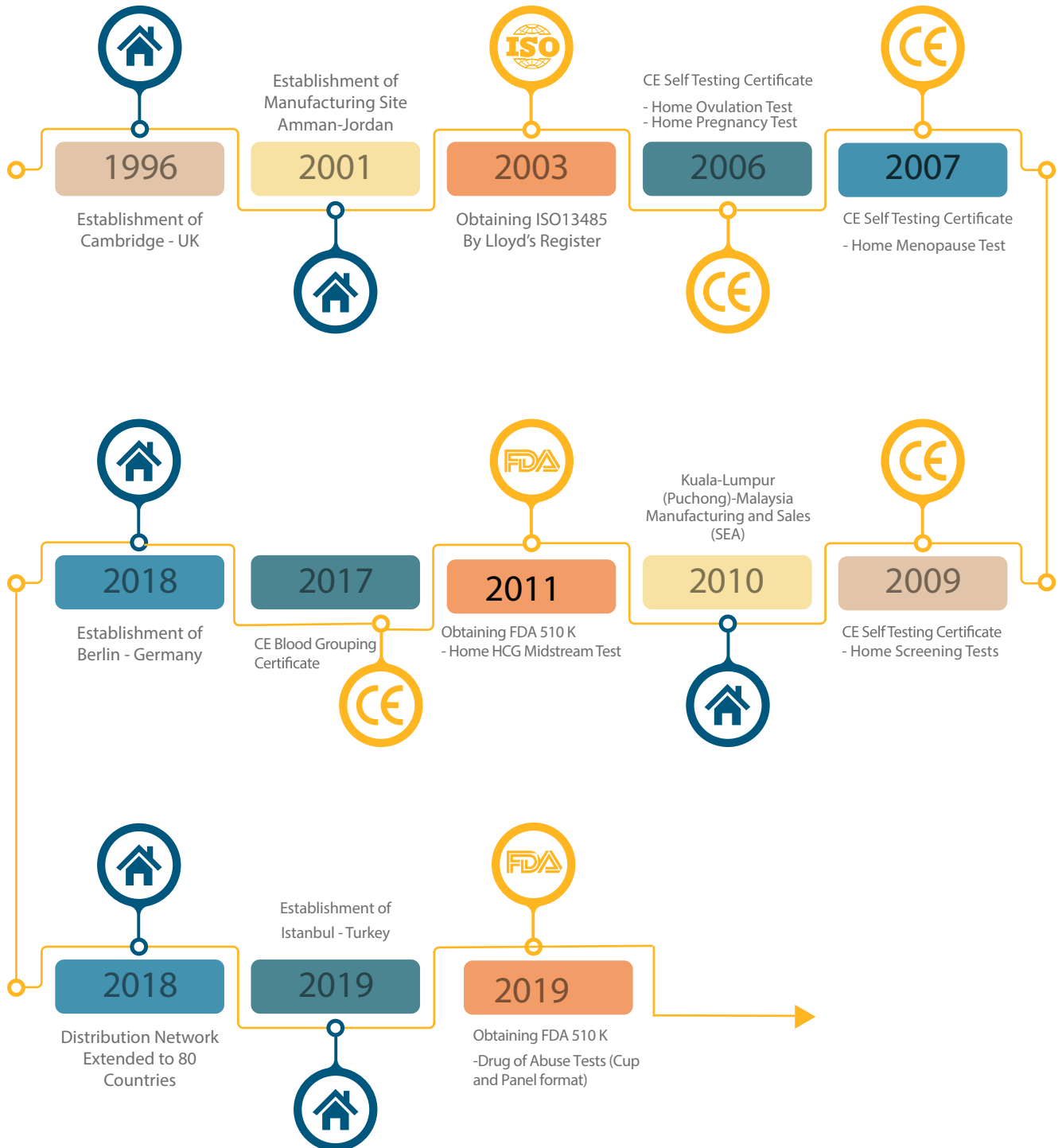


To complete the quality assurance scheme the company has put in place a robust Quality Management and Enhancement System that has concluded in the successful attainment of ISO13485: 2016 certificate



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.

# MILESTONES



# COVID-19 TESTING KITS

## Overview

Atlas medical is introducing COVID-19 Real Time RT-PCR kit for the amplification and detection of the viral genetic material in patient specimen ,In addition Atlas Medical had introduced three new kits using the ELISA technique to detect the antibody response to COVID-19 infection. Detecting antibodies to SARS-CoV-2 virus could tell if a patient has been infected with COVID-19, either currently or in the past.



| Item Code    | Item Description               | Sizes          |
|--------------|--------------------------------|----------------|
| 8.14.45.0096 | COVID-19 Real Time RT-PCR Test | 96 Tests /Kits |
| 8.14.45.0096 | COVID-19 Total Ab Elisa Kit    | 96 Tests /Kits |
| 8.14.46.0096 | COVID-19 IgM Elisa Kit         | 96 Tests /Kits |
| 8.14.47.0096 | COVID-19 S1-RBD IgG Elisa Kit  | 96 Tests /Kits |

## Features

- Reverse-Transc RT-PCR is a special version used when RNA is being detected
- Atlas RT-PCR testing kits are fairly quick, sensitive ,reliable and can detect current infections of disease.
- Atlas ELISA kits are based on a simple and high sensitive laboratory technique, results can typically be produced within 1 to 2 hours from the moment of collecting the nasal swab sample .



# COVID-19 RAPID TESTING KITS

## Overview

Atlas Medical offers COVID-19 Rapid Test as a quick screening tool for the detection of the presence of SARS-CoV-2 virus in Nasopharyngeal swabs,"COVID-19 Antigen testing kit" , in addition Atlas medical offers" COVID-19 IgG/IgM Antibody Testing kit " as a screening tool for the human body response to the infection with the virus .



| Item Code                        | Item Description  | Sizes                |
|----------------------------------|---|----------------------|
| 8.66.00.0.0001<br>8.66.00.0.0020 | COVID-19 IgM /IgG Test Cassette, Whole Blood/ Serum/Plasma ,Individually Pouched                    | Bulk<br>20 Tests/Box |
| 8.66.01.0.0001<br>8.66.01.0.0020 | COVID-19 Antigen Test Cassette, Nasal Swab, Individually Pouched                                    | Bulk<br>20 Tests/Box |
| 8.66.02.0.0001<br>8.66.02.0.0020 | COVID-19 Combo Antigen & Influenza, A+B Test Individually Pouched                                   | Bulk<br>20 Tests/Box |
| 8.66.04.0.0020                   | COVID-19 Neutralizing Antibody Rapid Test Cassette ,Whole Blood /Serum/Plasma, Individually Pouched | 20 Tests/Box         |

## Features

- COVID-19 rapid test kits are based on Lateral Flow Immuno-Chromatographic Assay.
- Reliable ,easy to use with a short testing time of 10-15 minutes per each sample.
- The kits are conveniently packed in different sizes of 20,25 or 100 tests per kit including the necessary test accessories to perform the assay .



# VIRAL TRANSPORT MEDIUM KITS

## Overview

As a result of the current worldwide crises such as the COVID-19 pandemic and other worldwide health pandemic that are caused from malaria, Influenza and chlamydia, Atlas Medical had come up with Viral transport media. The Media is used for facilitating the testing procedures by preserving the sample through the collection and transport process of the clinical samples containing viruses; including SARS-CoV-2 (COVID-19) and other viruses, in active form from collection site to the testing laboratory.

## Features

- Atlas Medical offers VTM that allows the safe transfer of viruses for further research, including diagnostic tests, and molecular biology techniques
- Atlas VTM can come either as a biological format "activated product (VTM)" or in a chemical format "In Activated product (IVTM)".
- Atlas VTM maintain the viral structure and activity over a wide temperature range and suppress "
- Atlas viral transport medium is stable at room temperature
- Atlas VTM kits are conveniently packed in different sizes of 50, 100 tube per kit with flocked swabs



| Item Code                        | Item Description   | Sizes                       |
|----------------------------------|--|-----------------------------|
| 8.64.02.0.0050<br>8.64.02.0.0100 | Viral Transport Medium (VTM) with Flocked, Swab, Individually Pouched  | 50 Tube/Kit<br>100 Tube/Kit |
| 8.64.03.0.0050<br>8.64.03.0.0100 | Viral Transport Medium (In Activating) with Flocked Swab, (3 ml /vial) | 50 Tube/Kit<br>100 Tube/Kit |



# LATEX KITS



## Overview

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.

## Features

- 🔗 They 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.
- 🔗 Affordable, easy to use, dependable and offer a clear and visible agglutination for doubt-free results.

- 🔗 Some Latex Kits come with a Buffer.

| Item Code                        | Item Description          | Sizes                 |
|----------------------------------|---------------------------|-----------------------|
| 8.00.00.0.0050<br>8.00.00.0.0100 | CRP Latex Kit             | 50 Tests<br>100 Tests |
| 8.00.01.0.0050<br>8.00.01.0.0100 | CRP Latex Kit with Buffer | 50 Tests<br>100 Tests |
| 8.00.02.0.0050<br>8.00.02.0.0100 | ASO Latex Kit             | 50 Tests<br>100 Tests |
| 8.00.03.0.0050<br>8.00.03.0.0100 | ASO Latex Kit with Buffer | 50 Tests<br>100 Tests |
| 8.00.04.0.0050<br>8.00.04.0.0100 | RF Latex Kit              | 50 Tests<br>100 Tests |
| 8.00.05.0.0050<br>8.00.05.0.0100 | RF Latex Kit with Buffer  | 50 Tests<br>100 Tests |
| 8.00.07.0.0050<br>8.00.07.0.0100 | hCG Latex Kit             | 50 Tests<br>100 Tests |
| 8.00.11.0.0050<br>8.00.11.0.0100 | SLE Latex Kit             | 50 Tests<br>100 Tests |
| 8.00.16.0.0050<br>8.00.16.0.0100 | Rota Virus Latex Kit      | 50 Tests<br>100 Tests |
| 8.00.17.0.0050<br>8.00.17.0.0100 | D-Dimer Latex Kit         | 50 Tests<br>100 Tests |
| 8.00.21.0.0050<br>8.00.21.0.0100 | Waler Rose Kit            | 50 Tests<br>100 Tests |
| 8.00.08.0.0050<br>8.00.08.0.0100 | IM Latex Kit              | 50 Tests<br>100 Tests |
| 8.00.12.0.0050<br>8.00.12.0.0100 | Staphylococcus Latex Kit  | 50 Tests<br>100 Tests |
| 8.00.13.0.0300                   | Streptococcus Latex Kit   | 50 Tests              |



| Item Code                        | Item Description           | Sizes                 |
|----------------------------------|----------------------------|-----------------------|
| 8.00.09.0.0050<br>8.00.09.0.0100 | Toxo Latex Kit             | 50 Tests<br>100 Tests |
| 8.00.10.0.0050<br>8.00.10.0.0100 | Toxo Latex Kit with Buffer | 50 Tests<br>100 Tests |
| 8.00.14.0.0100                   | Rubella Latex Kit          | 100 Tests             |

# TURBIDIMETRIC LATEX KITS

## Overview

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 serum or plasma samples.



## Features

- 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                | Sizes     |
|----------------|---------------------------------|-----------|
| 8.44.00.0.0050 | RF Turbidimetric Latex Kit      | 50 Tests  |
| 8.44.00.0.0250 |                                 | 250 Tests |
| 8.44.01.0.0050 | CRP Turbidimetric Latex Kit     | 50 Tests  |
| 8.44.01.0.0100 |                                 | 100 Tests |
| 8.44.01.0.0250 |                                 | 250 Tests |
| 8.44.02.0.0050 | ASO Turbidimetric Latex Kit     | 50 Tests  |
| 8.44.02.0.0100 |                                 | 100 Tests |
| 8.44.02.0.0250 |                                 | 250 Tests |
| 8.44.03.0.0050 | D-Dimer Turbidimetric Latex Kit | 50 Tests  |
| 8.44.03.0.0100 |                                 | 100 Tests |
| 8.44.03.0.0250 |                                 | 250 Tests |
| 8.44.04.0.0050 | Microalbumine Turbilatex        | 50 Tests  |
| 8.44.05.0.0050 | Ferritin Turbilatex             | 50 Tests  |
| 8.44.06.0.0050 | Transferrin Turbilatex ( TRF )  | 50 Tests  |

# SYPHILIS KITS

## Overview

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 or plasma using micro haemagglutination ; VDRL and RPR kits which are based on non-Treponemal flocculation to detect reagin antibodies in serum or plasma .



| Item Code      | Item Description       | Sizes      |
|----------------|------------------------|------------|
| 8.00.18.0.0100 | RPR Carbon Antigen Kit | 100 Tests  |
| 8.00.18.0.0250 |                        | 250 Tests  |
| 8.00.18.0.0500 |                        | 500 Tests  |
| 8.00.19.0.0050 | TPHA Kit               | 50 Tests   |
| 8.00.19.0.0100 |                        | 100 Tests  |
| 8.00.19.0.0200 |                        | 200 Tests  |
| 8.00.20.0.0250 | VDRL Kit               | 250 Tests  |
| 8.00.20.0.0500 |                        | 500 Tests  |
| 8.00.20.0.2500 |                        | 2500 Tests |
| 8.00.20.1.0250 | VDRL Kit with controls | 250 Tests  |
| 8.00.20.1.2500 |                        | 2500 Tests |

## Features

- Easy to use, affordable and conveniently packed in different sizes to suit all needs.
- They include all the necessary reagents/devices, controls, stirrers and slides to conduct the test



# FEBRILE ANTIGENS



## Overview

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.

## Features

- Atlas Medical Febrile Antigen kits contain various types of antigens for Brucella, Proteus, Salmonella typhi and paratyphi, and their controls as needed.
- Atlas Medical Febrile Antigen kits are competitively priced and easy to use, and give clear results within 2 minutes



| Item Code                        | Item Description   | Sizes                  |
|----------------------------------|--|------------------------|
| 8.01.17.0.0050                   | Febrile Antigen Set (10 Antigens: Salmonella OA, OB, OC, OD, HA, HB, HC, HD, Brucella abortus, melitensis)                       | 10x5 ml                |
| 8.01.17.1.0050                   | Febrile Antigen Set (10 Antigens: Salmonella OA, OB, OC, OD, HA, HB, HC, HD, Brucella abortus, melitensis) with 3x1.0ml Controls | 10x5 ml                |
| 8.01.18.0.0030                   | Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD)   | 6x5 ml                 |
| 8.01.18.1.0030                   | Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD) with 2x1.0ml Controls                                     | 6x5 ml                 |
| 8.01.19.0.0001<br>8.01.19.0.0005 | Febrile Antigens Positive Control  | 1 ml/vial<br>5 ml/vial |
| 8.01.20.0.0001<br>8.01.20.0.0005 | Febrile Antigen Negative Control   | 1 ml/vial<br>5 ml/vial |



| Item Code  | Item Description   | Sizes                             |
|--|--|-----------------------------------|
| 8.01.00.0.0005<br>8.01.00.0.0050<br>8.01.00.0.0100 | Brucella Rose Bengal Kit   | 5ml/vial<br>50 Tests<br>100 Tests |
| 8.01.01.0.0005<br>8.01.01.1.0040<br>8.01.01.0.0050 | Salmonella OA Reagent  | 5 ml/vial<br>8x5 ml<br>10x5 ml    |
| 8.01.02.0.0005<br>8.01.02.1.0040<br>8.01.02.0.0050 | Salmonella OB Reagent  | 5 ml/vial<br>8x5 ml<br>10x5 ml    |
| 8.01.03.0.0005<br>8.01.03.1.0040<br>8.01.03.0.0050 | Salmonella OC Reagent  | 5 ml/vial<br>8x5 ml<br>10x5 ml    |
| 8.01.04.0.0005<br>8.01.04.1.0040<br>8.01.04.0.0050 | Salmonella OD Reagent  | 5 ml/vial<br>8x5 ml<br>10x5 ml    |
| 8.01.05.0.0005<br>8.01.05.1.0040<br>8.01.05.0.0050 | Salmonella HA Reagent  | 5 ml/vial<br>8x5 ml<br>10x5 ml    |
| 8.01.06.0.0005<br>8.01.06.1.0040<br>8.01.06.0.0050 | Salmonella HB Reagent  | 5 ml/vial<br>8x5 ml<br>10x5 ml    |
| 8.01.07.0.0005<br>8.01.07.1.0040<br>8.01.07.0.0050 | Salmonella HC Reagent  | 5 ml/vial<br>8x5 ml<br>10x5 ml    |
| 8.01.08.0.0005<br>8.01.08.1.0040<br>8.01.08.0.0050 | Salmonella HD Reagent  | 5 ml/vial<br>8x5 ml<br>10x5 ml    |
| 8.01.10.0.0005<br>8.01.10.1.0040                   | Brucella Abortus Reagent   | 5 ml/vial<br>8x5 ml               |
| 8.01.11.0.0005<br>8.01.11.1.0040                   | Brucella Melitensis Reagent  | 5 ml/vial<br>8x5 ml               |
| 8.01.12.0.0005<br>8.01.12.1.0040                   | Proteus OX2 Reagent  | 5 ml/vial<br>8x5 ml               |
| 8.01.13.0.0005<br>8.01.13.1.0040                   | Proteus OX19 Reagent   | 5 ml/vial<br>8x5 ml               |
| 8.01.14.0.0005<br>8.01.14.1.0040                   | Proteus OXK Reagent  | 5 ml/vial<br>8x5 ml               |
| 8.01.15.0.0010                                     | Brucella Antigen Kit ( Brucella melitensis, Brucella abortus )   | 2 vials/Box                       |
| 8.01.15.1.0010                                     | Brucella Antigen Kit with Controls (Brucella melitensis, Brucella abortus, 2x1.0 ml Controls )         | 2 vials/Box                       |
| 8.01.15.2.0010                                     | Brucella Antigen Kit with Controls, (5ml Brucella melitensis, 5ml Brucella abortus, 2x0.5 ml Controls) | 2 vials/Box                       |
| 8.01.16.0.0040                                     | Salmonella Antigen Set ( 8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD )                                  | 8x5 ml                            |
| 8.01.16.1.0040                                     | Salmonella Antigen Set ( 8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD ) with 2x1.0 ml Controls           | 8x5 ml                            |
| 8.01.16.2.0040                                     | Salmonella Antigen set (8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD) with 2x0.5ml Controls              | 8x5 ml                            |

# BLOOD GROUPING REAGENTS

## Overview

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.



## Features

- 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                             | Sizes      |
|----------------|--|------------|
| 8.02.14.0.0010 | Anti-D Monoclonal (IgM), Clone 1, 10ml/vial  | 10 ml/vial |
| 8.02.15.0.0010 | Anti-D Monoclonal (IgM), Clone 2, 10ml/vial  | 10 ml/vial |
| 8.02.16.0.0005 | Anti-A1, Lectin (Dolichosbiflorus), 5ml/vial | 5 ml/vial  |
| 8.02.17.0.0005 | Anti-H, Lectin (Ulexeuropaeus), 5ml/vial     | 5 ml/vial  |
| 8.02.18.0.0005 | Anti-C Monoclonal, 5ml/vial                  | 5 ml/vial  |
| 8.02.19.0.0005 | Anti-c Monoclonal, 5ml/vial                  | 5 ml/vial  |
| 8.02.20.0.0005 | Anti-E Monoclonal, 5ml/vial                  | 5 ml/vial  |
| 8.02.21.0.0005 | Anti-e Monoclonal, 5ml/vial                  | 5 ml/vial  |
| 8.02.22.0.0005 | Anti-C+D+E Monoclonal, 5ml/vial              | 5 ml/vial  |
| 8.02.27.0.0002 | Anti-Fya, Human, 2ml/vial                    | 2 ml/vial  |
| 8.02.28.0.0002 | Anti-Fyb, Human, 2ml/vial                    | 2 ml/vial  |
| 8.02.29.0.0002 | Anti-k, Human, 2ml/vial                      | 2 ml/vial  |
| 8.02.30.0.0002 | Anti-Kpa, Human, 2ml/vial                    | 2 ml/vial  |
| 8.02.31.0.0002 | Anti-Kpb, Human, 2ml/vial                    | 2 ml/vial  |
| 8.02.32.0.0002 | Anti-Jka, Human, 2ml/vial                    | 2 ml/vial  |
| 8.02.35.0.0002 | Anti-Lub, Human, 2 ml/vial                   | 2 ml/vial  |
| 8.02.36.0.0005 | Anti-K Monoclonal, 5ml/vial                  | 5 ml/vial  |
| 8.02.54.0.0002 | Anti-Cw, 2 ml/vial                           | 2 ml/vial  |



| Item Code                        | Item Description   | Sizes                  |
|----------------------------------|--|------------------------|
| 8.02.00.0.0010<br>8.02.00.1.0100 | Anti-A Monoclonal reagent (titer: 1/512)                                 | 10 ml/vial<br>10x10 ml |
| 8.02.01.0.0010<br>8.02.01.1.0100 | Anti-B Monoclonal Reagent (Titer: 1/512)                                 | 10 ml/vial<br>10x10 ml |
| 8.02.02.0.0010<br>8.02.02.1.0100 | Anti-AB Monoclonal Reagent (Titer: 1/512)                                | 10 ml/vial<br>10x10 ml |
| 8.02.03.0.0010<br>8.02.03.1.0100 | Anti-D IgG/IgM Blend Reagent (Titer: 1/128)                              | 10 ml/vial<br>10x10 ml |
| 8.02.04.0.0010<br>8.02.04.0.0100 | Anti-A Monoclonal Reagent (Titer: 1/256)                                 | 10 ml/vial<br>10x10 ml |
| 8.02.05.0.0010<br>8.02.05.0.0100 | Anti-B Monoclonal Reagent (Titer: 1/256)                                 | 10 ml/vial<br>10x10 ml |
| 8.02.06.0.0010<br>8.02.06.1.0100 | Anti-AB Monoclonal Reagent (Titer: 1/256)                                | 10 ml/vial<br>10x10 ml |
| 8.02.07.0.0010<br>8.02.07.1.0100 | Anti-D IgG/IgM Blend Reagent (Titer: 1/64)                               | 10 ml/vial<br>10x10 ml |
| 8.02.08.0.0010<br>8.02.08.1.0100 | Bovine Albumin 22%   | 10 ml/vial<br>10x10 ml |
| 8.02.09.0.0010<br>8.02.09.1.0100 | Bovine Albumin 30%   | 10 ml/vial<br>10x10 ml |
| 8.02.10.0.0010<br>8.02.10.1.0100 | Anti-Human Globulin (Green) (Titer 1/512)                                | 10 ml/vial<br>10x10 ml |
| 8.02.11.0.0010<br>8.02.11.1.0100 | Anti-Human Globulin (Green) (Titer 1/256)                                | 10 ml/vial<br>10x10 ml |
| 8.02.47.0.0030                   | ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128))                 | 3x10 ml                |
| 8.02.47.1.0030                   | ABO Set (Anti-A (1/265), Anti-B (1/265), Anti-D (1/64))                  | 3x10 ml                |
| 8.02.49.0.0040                   | ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/64)) | 4x10 ml                |
| 8.02.53.0.0040                   | ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)) | 4x10 ml                |
| 8.02.05.6.0030                   | ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64))                  | 3x10ml                 |
| 8.02.05.7.0020                   | ABO Set: Anti-A (1/256), Anti-B (1/256)                                  | 2x10ml                 |
| 8.02.52.0.0010<br>8.02.52.0.0100 | Rh-D Negative Control  | 10 ml/vial<br>10x10 ml |
| 8.02.63.1.0010<br>8.02.63.0.0100 | Antibody Enhancement Solution (LISS)                                     | 10 ml/vial<br>10x10 ml |
| 8.02.23.0.0002                   | Anti-M, Human, 2ml/vial  | 2 ml/vial              |
| 8.02.24.0.0002                   | Anti-N, Lectin (Viciagraminea), 2ml/vial                                 | 2 ml/vial              |
| 8.02.25.0.0002                   | Anti-S, Human, 2ml/vial  | 2 ml/vial              |
| 8.02.26.0.0002                   | Anti-s, Human, 2ml/vial  | 2 ml/vial              |
| 8.02.34.0.0002                   | Anti-Lua, Human, 2ml/vial  | 2 ml/vial              |
| 8.02.37.0.0002                   | Anti-Lea, Monoclonal, 2ml/vial   | 2 ml/vial              |
| 8.02.38.0.0002                   | Anti-Leb, Monoclonal, 2ml/vial   | 2 ml/vial              |
| 8.02.39.0.0002                   | Anti-P1, Monoclonal, 2ml/vial  | 2 ml/vial              |



# HEMATOLOGY TESTS

## Overview

Atlas Medical supplies coagulation reagents. The coagulation reagents include PT, PTT and fibrinogen in liquid formats and in various sizes to suit most lab applications. The range also includes normal and abnormal coagulation controls.

## Features

- Some kits include normal and abnormal controls.
- The kit comes in sizes of 50 and 100 tests.
- Atlas Medical provides high quality coagulation reagents that are accurate, easy to use, competitively priced, and conveniently packed in different sizes and options.



### Hemoglobin Reagents

| Item Code                        | Item Description                               | Sizes                    |
|----------------------------------|--|--------------------------|
| 8.02.46.1.0500                   | Drabkins Reagent, 40x ( White Plastic Bottle ) | 50ml/Bottle              |
| 8.02.46.1.1000                   |  | 2x50ml                   |
| 8.02.46.1.3000                   |  | 6x50ml                   |
| 8.02.50.0.0010<br>8.02.50.0.0050 | Haemoglobin Standard                           | 10ml/vial<br>50ml/Bottle |



| Co-agglutination Reagents                          |  |  |   |
|--|--|--|---|
| Item Code  | Item Description   | Sizes  |   |
| 8.02.40.1.0010<br>8.02.40.1.0050<br>8.02.40.1.0100 | PT Calcium Rabbit Brain Thromboplastin, Liquid             | 2ml (20 Tests)<br>5ml (50 Tests)<br>10ml (100 Tests) |   |
| 8.02.41.1.0040<br>8.02.41.1.0050<br>8.02.41.1.0100 |  | APTT (PTT) Micronised Silica Platelet Substitute     | 2ml (40 Tests)<br>2.5ml (50 Tests)<br>5ml (100 Tests) |
| 8.02.44.0.0040<br>8.02.44.0.0100                   |  |  | PT Kit with Normal Control                            |
| 8.02.45.0.0080<br>8.02.45.0.0200                   | APTT ( PTT) Kit with Normal Control                        |  |   |
| 8.02.48.0.0010<br>8.02.48.0.0100                   |  | Calcium Chloride, 25 mM                              | 10ml/vial<br>10ml/vial /<br>10 Vials / Box            |
| 8.02.60.0.0006                                     | Normal Coagulation Control                                 |  | 6x1ml   |
| 8.02.61.0.0006                                     | Abnormal Coagulation Control                               | 6x1ml  |   |
| 8.02.69.0.0005                                     | Fibrinogen Reagent   | 5ml/vial   |   |
| 8.02.45.1.0080                                     | APTT (PTT) Kit (Calcium Chloride reagent + Normal Control) | 80 Tests   |   |
| 8.02.64.0.0006                                     | Normal & Abnormal Coagulation Control                      | 3x1ml  |   |
| 8.02.69.0.0100                                     | Fibrinogen Test kit KIT                                    | 100 Tests  |   |



# SICKLE CELL KITS

## Overview

Sickle cell disease (also called sickle cell anemia) is an inherited blood disorder that affects red blood cells. The sickle cell gene causes the body to produce abnormal hemoglobin.

## Features

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



| Item Code                        | Item Description                            | Sizes  |
|----------------------------------|---|--|
| 8.02.67.0.0050                   | Sickle Cell Kit, 50 Tests                   | 2x50ml Buffer +<br>2 vials of Sodium<br>Dithionate |
| 8.02.67.0.0100                   | Sickle Cell Kit, 100 Tests                  | 4x50ml Buffer,<br>4 vials of Sodium<br>Dithionate  |
| 8.02.68.0.0001<br>8.02.68.1.0001 | Sickle Cell positive & negative control set | 1ml each<br>0.5 ml each                            |

# INFECTIOUS DISEASE RAPID TESTS

## ANTIBODY TESTING

### Overview

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.



### Features

- 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, 25, 30, 40, 50 and 100 tests per kit and include the necessary test accessories to perform the assay.

RAPID TESTS



| Item Code                        | Item Description  | Sizes                 |
|----------------------------------|---|-----------------------|
| 8.04.27.0.0001<br>8.04.27.0.0020 | HIV 1/2 Antibody Test Cassette,<br>Whole Blood/Serum/Plasma, Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.28.0.0001<br>8.04.28.0.0020 | HIV 1/2 Antibody Test Cassette,<br>Serum/Plasma, Individually Pouched             | Bulk<br>20 Tests/Box  |
| 8.04.29.0.0001<br>8.04.29.0.0100 | HIV 1/2 Antibody Test Strip,<br>Serum/Plasma, Individually Pouched                | Bulk<br>100 Tests/Box |
| 8.04.30.0.0001<br>8.04.30.0.0020 | HCV Antibody Test Cassette,<br>Whole Blood/Serum/Plasma, Individually Pouched     | Bulk<br>20 Tests/Box  |
| 8.04.31.0.0001<br>8.04.31.0.0020 | HCV Antibody Test Cassette,<br>Serum/Plasma, Individually Pouched                 | Bulk<br>20 Tests/Box  |
| 8.04.32.0.0001<br>8.04.32.0.0100 | HCV Antibody Test Strip,<br>Serum/Plasma, Individually Pouched                    | Bulk<br>100 Tests/Box |
| 8.04.35.0.0001<br>8.04.35.0.0020 | HBs Antibody Test Cassette,<br>Serum/Plasma, Individually Pouched                 | Bulk<br>20 Tests/Box  |
| 8.04.36.0.0001<br>8.04.36.0.0100 | HBs Antibody Test Strip,<br>Serum/Plasma, Individually Pouched                    | Bulk<br>100 Tests/Box |
| 8.04.107.0.0040                  | Toxo IgG test cassette individually packed  | 40 Tests/Box          |



| Item Code                        | Item Description   | Sizes                        |
|----------------------------------|--|------------------------------|
| 8.04.20.0.0001<br>8.04.20.0.0020 | H.pylori Antibody Test Cassette,<br>Whole Blood/Serum/Plasma, Individually Pouched | Bulk<br>20 Tests/Box         |
| 8.04.21.0.0001<br>8.04.21.0.0020 | H.pylori Antibody Test Cassette,<br>Serum/Plasma, Individually Pouched             | Bulk<br>20 Tests/Box         |
| 8.04.22.0.0001<br>8.04.22.0.0100 | H.pylori Antibody Test Strip,<br>Serum/Plasma, Individually Pouched                | Bulk<br>100 Tests/Box        |
| 8.04.41.0.0001<br>8.04.41.0.0020 | Syphilis Antibody Test Cassette,<br>Whole Blood/Serum/Plasma, Individually Pouched | Bulk<br>20 Tests/Box         |
| 8.04.42.0.0001<br>8.04.42.0.0020 | Syphilis Antibody Test Cassette,<br>Serum/Plasma, Individually Pouched             | Bulk<br>20 Tests/Box         |
| 8.04.43.0.0001<br>8.04.43.0.0100 | Syphilis Antibody Test Strip,<br>Serum/Plasma, Individually Pouched                | Bulk<br>100 Tests/Box        |
| 8.16.16.0.0001<br>8.16.16.0.0020 | TB Test Cassette,<br>Serum/Plasma, Individually Pouched                            | Bulk<br>20 Tests/Box         |
| 8.16.16.1.0020<br>8.16.16.1.0025 | TB Test Cassette,<br>Whole Blood, Individually Pouched                             | 20 Tests/Box<br>25 Tests/Box |



| Item Code                        | Item Description  | Sizes                |
|----------------------------------|---|----------------------|
| 8.42.47.0.0020                   | HAV IgM Test Cassette, Individually Pouched                                     | 20 Tests/Box         |
| 8.04.44.0.0001<br>8.04.44.0.0020 | Dengue IgG/IgM Test Cassette,<br>Whole Blood/Serum/Plasma, Individually Pouched | Bulk<br>20 Tests/Box |

# INFECTIOUS DISEASE RAPID TESTS

## ANTIGEN TESTING



| STOOL SAMPLE   |   |              |
|----------------|---|--------------|
| Item Code      | Item Description  | Sizes        |
| 8.04.23.1.0020 | H.pylori Antigen Test Cassette, Stool Sample, Individually Pouched                | 20 Tests/Box |
| 8.04.24.1.0025 | H.pylori Antigen Test Strip, Stool Sample, Individually Pouched                   | 25 Tests/Box |
| 8.04.69.0.0020 | Rotavirus Antigen Test Cassette, Stool Sample, Individually Pouched               | 20 Tests/Box |
| 8.04.70.0.0025 | Rotavirus Antigen Test Strip, Stool Sample, Individually Pouched                  | 25 Tests/Box |
| 8.04.71.0.0020 | Adenovirus Antigen Test Cassette, Stool Sample, Individually Pouched              | 20 Tests/Box |
| 8.04.72.0.0025 | Adenovirus Antigen Test Strip, Stool Sample, Individually Pouched                 | 25 Tests/Box |
| 8.04.73.0.0020 | Rota-Adeno Antigens Combo test Cassette, Stool Sample, Individually Pouched       | 20 Tests/Box |
| 8.04.74.0.0025 | Rota-Adeno Antigens Combo test Strip, Stool Sample, Individually Pouched          | 25 Tests/Box |
| 8.16.01.0.0020 | Crypto Virus Test Cassette, Stool Sample, Individually Pouched                    | 20 Tests/Box |
| 8.16.02.0.0025 | Crypto Virus Test Strip, Stool Sample, Individually Pouched                       | 25 Tests/Box |
| 8.16.31.0.0020 | Giardia Test Cassette, Stool Sample, Individually Pouched                         | 20 Tests/Box |
| 8.16.30.0.0025 | Giardia Test Strip, Stool Sample, Individually Pouched                            | 25 Tests/Box |
| 8.16.33.0.0020 | Crypto-Giardia Test Cassette, Stool Sample, Individually Pouched                  | 20 Tests/Box |
| 8.16.32.0.0025 | Crypto-Giardia Test Strip, Stool Sample, Individually Pouched                     | 25 Tests/Box |
| 8.16.41.0.0020 | E.coli Test Cassette, Stool Sample, Individually Pouched                          | 20 Tests/Box |
| 8.16.40.0.0025 | E.coli Test Strip, Stool Sample, Individually Pouched                             | 25 Tests/Box |
| 8.16.82.0.0025 | Salmonella typhi Antigen Test Cassette, Stool Sample, Individually Pouched        | 25 Tests/Box |
| 8.16.85.0.0025 | Salmonella paratyphi Antigen Test Cassette, Stool Sample, Individually Pouched    | 25 Tests/Box |
| 8.16.80.0.0020 | Clostridium difficile Antigen Test Cassette, Stool Sample, Individually Pouched   | 20 Tests/Box |
| 8.16.81.0.0025 | Clostridium difficile Antigen Test Strip, Stool Sample, Individually Pouched      | 25 Tests/Box |
| 8.16.86.0.0025 | C.Difficile Toxin A+B, Test Cassette, Stool Sample, Individually Pouched          | 25 Tests/Box |
| 8.16.91.0.0025 | Norovirus Genogroups I & II Ag, Test Cassette, Stool Sample, Individually Pouched | 25 Tests/Box |

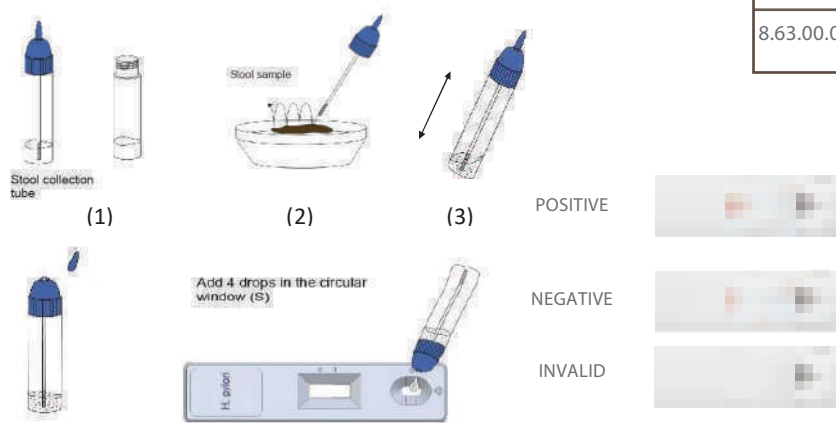
| SWAB & NASAL SAMPLE |  |              |
|---------------------|--|--------------|
| Item Code           | Item Description                                     | Sizes        |
| 8.04.25.0.0020      | Strep A Test Cassette, Swab Sample                   | 20 Tests/Box |
| 8.45.00.0.0020      | Strep B Test Cassette, Swab Sample                   | 20 Tests/Box |
| 8.45.01.0.0020      | Strep A+B Test Cassette, Swab Sample                 | 20 Tests/Box |
| 8.04.86.0.0020      | Influenza A+B Test Cassette, Nasal Sample            | 20 Tests/Box |
| 8.04.96.0.0025      | Influenza A+B Test Strip, Nasal Sample               | 25 Tests/Box |
| 8.16.20.0.0020      | RSV Test Cassette, Swab Sample                       | 20 Tests/Box |
| 8.16.22.0.0025      | RSV Test Strip, Swab Sample                          | 25 Tests/Box |
| 8.16.37.0.0020      | Adeno Respiratory Antigen Test Cassette, Swab Sample | 20 Tests/Box |
| 8.16.36.0.0025      | Adeno Respiratory Antigen Test Strip, Swab Sample    | 25 Tests/Box |
| 8.16.39.0.0020      | Adeno - RSV Respiratory Test Cassette, Swab Sample   | 20 Tests/Box |
| 8.16.38.0.0025      | Adeno - RSV Respiratory Test Strip, Swab Sample      | 25 Tests/Box |



| BLOOD SAMPLE   |   |              |
|----------------|---|--------------|
| Item Code      | Item Description  | Sizes        |
| 8.04.37.0.0020 | Malaria Pf. Test Cassette, Whole Blood, Individually Pouched    | 20 Tests/Box |
| 8.16.14.0.0020 | Malaria Pf/Pv. Test Cassette, Whole Blood, Individually Pouched | 20 Tests/Box |



| Item Code                        | Item Description  | Sizes                 |
|----------------------------------|---|-----------------------|
| 8.16.24.0.0001<br>8.16.24.0.0020 | HBsAg Test Cassette ( Whole Blood/Serum/Plasma), Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.33.0.0001<br>8.04.33.0.0020 | HBsAg Test Cassette, Serum/Plasma, Individually Pouched               | Bulk<br>20 Tests/Box  |
| 8.04.34.0.0001<br>8.04.34.0.0100 | HBsAg Test Strip, Serum/Plasma, Individually Pouched                  | Bulk<br>100 Tests/Box |
| 8.04.26.0.0020                   | Chlamydia Test Cassette, Urine or Swab                                | 20 Tests/Box          |
| 8.63.00.0.0025                   | Chlamydia + Gonorrhea Rapid Test Cassette (Cervical/Urethral swab)    | 25 Tests/Box          |



# URINE REAGENT STRIPS

## Overview

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.



## Features

- Atlas Medical Urine Reagent Strips can be used to detect up to 14 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.

## URINE ANALYZER

Atlas Urine Analyzer is a manual analyzer that detects Photosensitive Diode using the method of Reflectance Photometry. Test Categories include Routine, STAT and QC. Atlas Urine Analyzer has an Automatic calibration for accurate results and easy operation. It can read strips with up to 14 parameters, including Microalbumin/Creatinine/Calcium. It has an option to print results for quick and simple record management.

- Accurate.
- Reliable.
- Convenient.
- Easy Data Management.



| Item Code  | Item Description                   | Sizes  |
|------------|------------------------------------|--------|
| 8.001.U120 | Urine Analyzer For Clinics, U120   | 1 Unit |
| 8.002.U500 | Urine Analyzer For Hospitals, U500 | 1 Unit |



| Item Code                        | Item Description  | Sizes                   |
|----------------------------------|---|-------------------------|
| 8.03.00.0.0050<br>8.03.00.0.0100 | URS 1 Parameter: Glucose  | 50 Strips<br>100 Strips |
| 8.03.01.0.0050<br>8.03.01.0.0100 | URS 1 Parameter: Protein  | 50 Strips<br>100 Strips |
| 8.03.02.0.0050<br>8.03.02.0.0100 | URS 1 Parameter: Ketone   | 50 Strips<br>100 Strips |
| 8.03.45.0.0050                   | URS 1 Parameter Blood, (5mm)  | 50 Strips               |
| 8.03.03.0.0050<br>8.03.03.0.0100 | URS 2 Parameters: Glucose, Ketone   | 50 Strips<br>100 Strips |
| 8.03.04.0.0050<br>8.03.04.0.0100 | URS 2 Parameters: Glucose, Protein  | 50 Strips<br>100 Strips |
| 8.03.05.0.0100                   | URS 2 Parameters: Sample end: Urobilinogen, Bilirubin   | 100 Strips              |
| 8.03.19.0.0050<br>8.03.19.0.0100 | URS 2 Parameters(5mm): Sample End: Creatinine, pH   | 50 Strips<br>100 Strips |
| 8.03.06.0.0050<br>8.03.06.0.0100 | URS 3 Parameters: Protein, pH, Glucose  | 50 Strips<br>100 Strips |
| 8.03.07.0.0100                   | URS 3 Parameters: Glucose, Protein, Ketone  | 100 Strips              |
| 8.03.08.0.0100                   | URS 3 Parameters: Sample end:pH, Ketone, Glucose  | 100 Strips              |
| 8.03.09.0.0100                   | URS 3 Parameters: Sample end:Leukocytes, Nitrite, Blood   | 100 Strips              |
| 8.03.10.0.0050<br>8.03.10.0.0100 | URS 3 Parameters: Sample end:Protein, Specific Gravity, Creatinine  | 50 Strips<br>100 Strips |
| 8.03.11.0.0100                   | URS 4 Parameters: Protein, pH, Specific Gravity, Glucose  | 100 Strips              |
| 8.03.12.0.0100                   | URS 4 Parameters: Protein, pH, Blood, Glucose   | 100 Strips              |
| 8.03.13.0.0050<br>8.03.13.0.0100 | URS 5 Parameters: Glucose, Protein, Ketone, pH, Blood   | 50 Strips<br>100 Strips |
| 8.03.25.0.0100                   | URS 5 Parameters(5mm): Blood, Glucose, Protein, Nitrite, Leukocytes   | 100 Strips              |
| 8.03.14.0.0100                   | URS 6 Parameters: Leukocytes, Nitrite, Protein, pH, Blood, Glucose  | 100 Strips              |
| 8.03.44.0.0100                   | URS 7 Parameter: Glucose, Ketone, Protein, PH, Blood, Bilirubin, Urobilinogen   | 100 Strips              |
| 8.03.23.0.0100                   | URS 8 Parameters: Glucose, Protein, pH, Ketone, Urobilinogen, Bilirubin, Blood, Nitrite   | 100 Strips              |
| 8.03.15.0.0100                   | URS 9 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose                             | 100 Strips              |
| 8.03.16.0.0100                   | URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose                | 100 Strips              |
| 8.03.17.0.0050<br>8.03.17.0.0100 | URS 10 Parameters: Sample end: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid | 50 Strips<br>100 Strips |
| 8.03.18.0.0100                   | URS 11 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid | 100 Strips              |
| 8.03.47.0.0100                   | URS 14 Parameters (ASC, GLU, BIL, KET, SG, BLO, PH, PRO, URO, NIT, LEU, ALB, CRE, CA)   | 100 Strips              |

# FERTILITY RAPID TESTS

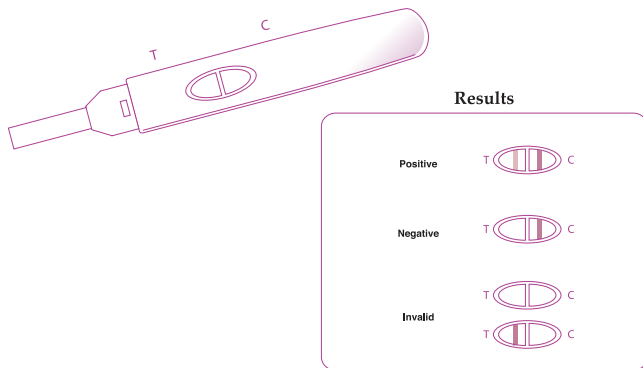
## Overview

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.



## Features

- 🔄 Accurate.
- 🔄 Convenient.
- 🔄 Easy to use (add or dip in urine).
- 🔄 Competitively priced.
- 🔄 Results are obtained in 1 to 5 minutes.
- 🔄 Different strip sizes are available.



| Item Code                        | Item Description                                     | Sizes                 |
|----------------------------------|--|-----------------------|
| 8.04.00.0.0001<br>8.04.00.0.0020 | hCG Test Cassette, Urine, Individually Pouched       | Bulk<br>20 Tests/Box  |
| 8.04.01.0.0001<br>8.04.01.0.0020 | hCG Test Cassette, Urine/Serum, Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.04.0.0001<br>8.04.04.0.0100 | hCG Test Strip, Urine, Individually Pouched          | Bulk<br>100 Tests/Box |
| 8.04.10.0.0001<br>8.04.10.0.0100 | hCG Test Strip, Urine/Serum, Individually Pouched    | Bulk<br>100 Tests/Box |
| 8.04.13.0.0001<br>8.04.13.0.0015 | hCG Midstream Test, Individually Pouched             | Bulk<br>15 Tests/Box  |
| 8.04.14.0.0001<br>8.04.14.0.0020 | LH Test Cassette, Urine, Individually pouched        | Bulk<br>20 Tests/Box  |
| 8.04.15.0.0001<br>8.04.15.0.0100 | LH Test Strip, Urine, Individually pouched           | Bulk<br>100 Tests/Box |
| 8.04.16.0.0001<br>8.04.16.0.0015 | LH Midstream Test, Individually Pouched              | Bulk<br>15 Tests/Box  |
| 8.04.17.0.0001<br>8.04.17.0.0020 | FSH Test Cassette, Urine, Individually pouched       | Bulk<br>20 Tests/Box  |
| 8.04.18.0.0001<br>8.04.18.0.0100 | FSH Test Strip, Urine, Individually pouched          | Bulk<br>100 Tests/Box |
| 8.04.19.0.0001<br>8.04.19.0.0015 | FSH Midstream Test, Individually Pouched             | Bulk<br>15 Tests/Box  |

| Item Code      | Item Description                                     | Sizes |
|----------------|--|-------|
| 8.59.00.0.0001 | Vaginal PH strips with handle , Individually Pouched | Bulk  |

# KIDNEY FUNCTION RAPID TESTS

## Overview

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.

## Features

- 🔄 The test comes in cassette and Strip formats.



| Item Code                        | Item Description                                 | Sizes                         |
|----------------------------------|--|-------------------------------|
| 8.16.52.0.0001<br>8.16.52.0.0020 | Microalbumin Test Cassette ,Individually Pouched | Bulk<br>20 Tests/Box          |
| 8.16.53.0.0030<br>8.16.53.0.0100 | Microalbumin Test Strip ,Individually Pouched    | 30 Tests/Box<br>100 Tests/Box |



# INFLAMMATION AND CANCER MARKERS



## Overview

All the tests in this group are qualitative and based on lateral flow immunoassay for the detection of various inflammation and cancer markers.

| Item Code       | Item Description  | Sizes        |
|-----------------|---|--------------|
| 8.04.38.0.0020  | Fecal Occult Blood Test (FOB) Test Cassette, Stool Sample, Individually Pouched | 20 Tests/Box |
| 8.04.85.0.0050  | Fecal Occult Blood Test (FOB) Test Strip Stool Sample, Individually Pouched     | 50 Tests/Box |
| 8.04.109.0.0020 | Procalcitonin Test Cassette (PCT), (Serum/Plasma)                               | 20 Tests/Box |
| 8.48.00.0.0020  | Procalcitonin Test Cassette (PCT), ( Whole Blood / Serum/ Plasma)               | 20 Tests/Box |
| 8.16.78.0.0025  | Calprotectin Test Cassette  | 25 Tests/Box |

## Features

- 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, 25, 30 and 100 tests per kit.



| Item Code                        | Item Description   | Sizes                 |
|----------------------------------|--|-----------------------|
| 8.16.28.0.0001<br>8.16.28.0.0020 | PSA Test Cassette, Whole Blood/Serum/Plasma), Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.39.0.0001<br>8.04.39.0.0020 | PSA Test Cassette, Serum/Plasma, Individually Pouched              | Bulk<br>20 Tests/Box  |
| 8.04.40.0.0001<br>8.04.40.0.0100 | PSA Test Strip, Serum/Plasma, Individually Pouched                 | Bulk<br>100 Tests/Box |

# CARDIAC MARKERS RAPID TESTS

## Overview

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).



| Item Code                        | Item Description  | Sizes                |
|----------------------------------|---|----------------------|
| 8.04.45.0.0001<br>8.04.45.0.0020 | Troponin I Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched                                    | Bulk<br>20 Tests/Box |
| 8.04.46.0.0001<br>8.04.46.0.0020 | Myoglobin Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched                                     | Bulk<br>20 Tests/Box |
| 8.04.47.0.0001<br>8.04.47.0.0020 | CK-MB Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched   | Bulk<br>20 Tests/Box |
| 8.04.48.0.0001<br>8.04.48.0.0020 | Cardiac Triple Test Cassette (Troponin I, CK-MB, Myoglobin), Whole Blood/Serum/Plasma, Individually Pouched | Bulk<br>20 Tests/Box |

## Features

- 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.
- The kits are conveniently packed in different kit sizes of 20, 25, 30 tests per kit.

# DOA RAPID TESTS

## Overview

All the tests in this group are qualitative and based on lateral flow immunoassay for the detection of various Drug of Abuse .



## Features

- Atlas Medical DOA rapid tests are supplied in cassette , strip, panel and cup formats.
- The kits are conveniently packed in different kit sizes of 20, 25, 30, 50 and 100 tests per kit.



### STRIP AND CASSETTE FORMAT

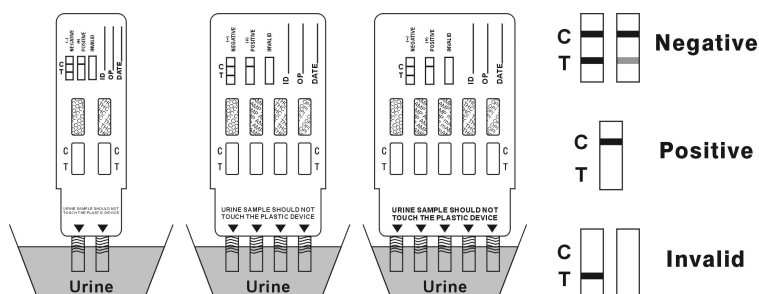
| Item Code                        | Item Description   | Sizes                 |
|----------------------------------|--|-----------------------|
| 8.04.49.0.0001<br>8.04.49.0.0020 | Morphine Test Cassette, Urine, Individually Pouched        | Bulk<br>20 Tests/Box  |
| 8.04.50.0.0001<br>8.04.50.0.0100 | Morphine Test Strip, Urine, Individually Pouched           | Bulk<br>100 Tests/Box |
| 8.04.51.0.0001<br>8.04.51.0.0020 | Marijuana (THC) Test Cassette, Urine, Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.52.0.0001<br>8.04.52.0.0100 | Marijuana (THC) Test Strip, Urine, Individually Pouched    | Bulk<br>100 Tests/Box |
| 8.04.53.0.0001<br>8.04.53.0.0020 | Amphetamine Test Cassette, Urine, Individually Pouched     | Bulk<br>20 Tests/Box  |
| 8.04.54.0.0001<br>8.04.54.0.0100 | Amphetamine Test Strip, Urine, Individually Pouched        | Bulk<br>100 Tests/Box |
| 8.04.55.0.0001<br>8.04.55.0.0020 | Barbiturates Test Cassette, Urine, Individually Pouched    | Bulk<br>20 Tests/Box  |
| 8.04.56.0.0001<br>8.04.56.0.0100 | Barbiturates Test Strip, Urine, Individually Pouched       | Bulk<br>100 Tests/Box |
| 8.04.57.0.0001<br>8.04.57.0.0020 | Benzodiazepines Test Cassette, Urine, Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.58.0.0001<br>8.04.58.0.0100 | Benzodiazepines Test Strip, Urine, Individually Pouched    | Bulk<br>100 Tests/Box |
| 8.04.59.0.0001<br>8.04.59.0.0020 | Cocaine Test Cassette, Urine, Individually Pouched         | Bulk<br>20 Tests/Box  |
| 8.04.60.0.0001<br>8.04.60.0.0100 | Cocaine Test Strip, Urine, Individually Pouched            | Bulk<br>100 Tests/Box |
| 8.04.61.0.0001<br>8.04.61.0.0020 | Methamphetamine Test Cassette, Urine, Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.62.0.0001<br>8.04.62.0.0100 | Methamphetamine Test Strip, Urine, Individually Pouched    | Bulk<br>100 Tests/Box |
| 8.04.63.0.0001<br>8.04.63.0.0020 | Methadone Test Cassette, Urine, Individually Pouched       | Bulk<br>20 Tests/Box  |
| 8.04.64.0.0001<br>8.04.64.0.0100 | Methadone Test Strip, Urine, Individually Pouched          | Bulk<br>100 Tests/Box |
| 8.04.65.0.0001<br>8.04.65.0.0020 | Phencyclidine Test Cassette, Urine, Individually Pouched   | Bulk<br>20 Tests/Box  |
| 8.04.66.0.0001<br>8.04.66.0.0100 | Phencyclidine Test Strip, Urine, Individually Pouched      | Bulk<br>100 Tests/Box |

| Item Code                        | Item Description  | Sizes                 |
|----------------------------------|---|-----------------------|
| 8.04.67.0.0001<br>8.04.67.0.0020 | Tricyclic Anti-Depressants Test Cassette, Urine, Individually Pouched             | Bulk<br>20 Tests/Box  |
| 8.04.68.0.0001<br>8.04.68.0.0100 | Tricyclic Anti-Depressants Test Strip, Urine, Individually Pouched                | Bulk<br>100 Tests/Box |
| 8.04.99.0.0001<br>8.04.99.0.0020 | Buprenorphine Test Cassette, Urine, Individually Pouched                          | Bulk<br>20 Tests/Box  |
| 8.16.23.0.0001<br>8.16.23.0.0100 | Buprenorphine Test Strip, Urine, Individually Pouched                             | Bulk<br>100 Tests/Box |
| 8.16.68.0.0001<br>8.16.68.0.0020 | Tramadol Test Cassette, Urine, Individually Pouched                               | Bulk<br>20 Tests/Box  |
| 8.16.44.0.0001<br>8.16.44.0.0100 | Tramadol Test Strip, Urine, Individually Pouched                                  | Bulk<br>100 Tests/Box |
| 8.16.15.0.0001<br>8.16.15.0.0020 | Methylenedioxyamphetamine (MDMA) Ecstasy Test Cassette,Urine,Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.16.05.0.0001<br>8.16.05.0.0100 | Methylenedioxyamphetamine (MDMA) Ecstasy Test Strip, Urine,Individually Pouched   | Bulk<br>100 Tests/Box |
| 8.16.06.0.0001<br>8.16.06.0.0020 | Opiates Test Cassette, Urine, Individually Pouched                                | Bulk<br>20 Tests/Box  |
| 8.16.07.0.0001<br>8.16.07.0.0100 | Opiates Test Strip, Urine, Individually Pouched                                   | Bulk<br>100 Tests/Box |
| 8.16.58.0.0001<br>8.16.58.0.0020 | Cotinine Test Cassette, Urine, Individually Pouched                               | Bulk<br>20 Tests/Box  |
| 8.16.59.0.0001<br>8.16.59.0.0100 | Cotinine Test Strip, Urine, Individually Pouched                                  | Bulk<br>100 Tests/Box |
| 8.16.62.0.0001<br>8.16.62.0.0020 | Oxycodone Test Cassette, Urine, Individually Pouched                              | Bulk<br>20 Tests/Box  |
| 8.16.63.0.0001<br>8.16.63.0.0100 | Oxycodone Test Strip, Urine, Individually Pouched                                 | Bulk<br>100 Tests/Box |
| 8.16.64.0.0001<br>8.16.64.0.0020 | Ketamine Test Cassette, Urine, Individually Pouched                               | Bulk<br>20 Tests/Box  |
| 8.16.65.0.0001<br>8.16.65.0.0100 | Ketamine Test Strip, Urine, Individually Pouched                                  | Bulk<br>100 Tests/Box |
| 8.16.66.0.0001<br>8.16.66.0.0020 | Proxyphene Test Cassette, Urine, Individually Pouched                             | Bulk<br>20 Tests/Box  |
| 8.16.67.0.0001<br>8.16.67.0.0100 | Proxyphene Test Strip, Urine, Individually Pouched                                | Bulk<br>100 Tests/Box |
| 8.16.68.0.0001<br>8.16.68.0.0020 | Tramadol Test Cassette, Urine, Individually Pouched                               | Bulk<br>20 Tests/Box  |
| 8.16.69.0.0001<br>8.16.69.0.0020 | EDDP Test Cassette, Urine, Individually Pouched                                   | Bulk<br>20 Tests/Box  |
| 8.16.70.0.0001<br>8.16.70.0.0100 | EDDP Test Strip, Urine, Individually Pouched                                      | Bulk<br>100 Tests/Box |
| 8.16.60.0.0001<br>8.16.60.0.0020 | Dolantin Test Cassette, Urine, Individually Pouched                               | Bulk<br>20 Tests/Box  |
| 8.16.61.0.0001<br>8.16.61.0.0100 | Dolantin Test Strip, Urine, Individually Pouched                                  | Bulk<br>100 Tests/Box |

# DOA RAPID TESTS



| Item Code                        | Item Description   | Sizes                |
|----------------------------------|--|----------------------|
| 8.04.93.0.0001<br>8.04.93.0.0025 | DOA Panel: 2 Drugs (Combination of any 2 drugs) Urine, Individually Pouched    | Bulk<br>25 Tests/Box |
| 8.04.94.0.0001<br>8.04.94.0.0025 | DOA Panel: 3 Drugs (Combination of any 3 drugs) Urine, Individually Pouched    | Bulk<br>25 Tests/Box |
| 8.04.95.0.0001<br>8.04.95.0.0025 | DOA Panel: 4 Drugs (Combination of any 4 drugs) Urine, Individually Pouched    | Bulk<br>25 Tests/Box |
| 8.04.79.0.0001<br>8.04.79.0.0025 | DOA Panel: 5 Drugs (Combination of any 5 drugs) Urine, Individually Pouched    | Bulk<br>25 Tests/Box |
| 8.04.80.0.0001<br>8.04.80.0.0025 | DOA Panel: 6 Drugs (Combination of any 6 drugs) Urine, Individually Pouched    | Bulk<br>25 Tests/Box |
| 8.04.81.0.0001<br>8.04.81.0.0025 | DOA Panel: 7 Drugs (Combination of any 7 drugs) Urine, Individually Pouched    | Bulk<br>25 Tests/Box |
| 8.04.82.0.0001<br>8.04.82.0.0025 | DOA Panel: 8 Drugs (Combination of any 8 drugs) Urine, Individually Pouched    | Bulk<br>25 Tests/Box |
| 8.04.83.0.0001                   | DOA Panel: 9 Drugs (Combination of any 9 drugs) Urine, Individually Pouched    | Bulk                 |
| 8.04.84.0.0001<br>8.04.84.0.0025 | DOA Panel: 10 Drugs (Combination of any 10 drugs), Urine, Individually Pouched | Bulk<br>25 Tests/Box |
| 8.16.03.0.0001<br>8.16.03.0.0025 | DOA Panel: 11 Drugs (Combination of any 11 drugs), Urine, Individually Pouched | Bulk<br>25 Tests/Box |
| 8.16.04.0.0001<br>8.16.04.0.0025 | DOA Panel: 12 Drugs (Combination of any 12 drugs), Urine, Individually Pouched | Bulk<br>25 Tests/Box |



| Item Code      | Item Description  | Sizes |
|----------------|---|-------|
| 8.42.43.0.0001 | Drug Of Abuse Cup, 7 parameters (Combination of any 7 drugs), Urine, Individually Pouched   | Bulk  |
| 8.42.50.0.0001 | Drug Of Abuse Cup, 8 parameters (Combination of any 8 drugs), Urine, Individually Pouched   | Bulk  |
| 8.16.71.0.0001 | Drug Of Abuse Cup, 10 parameters (Combination of any 10 drugs), Urine, Individually Pouched | Bulk  |



| Item Code      | Item Description  | Sizes |
|----------------|---|-------|
| 8.16.87.0.0001 | DOA Multiscreen Cassette: 3 Drugs (Combination of any 3 drugs), Urine, Individually Pouched | Bulk  |
| 8.16.88.0.0001 | DOA Multiscreen Panel 7 Drugs (Combination of any 7 drugs), Urine, Individually Pouched     | Bulk  |
| 8.16.89.0.0001 | DOA Multiscreen Cassette: 8 Drugs (Combination of any 8 drugs), Urine, Individually Pouched | Bulk  |

# CLINICAL CHEMISTRY KITS

## Overview

Kits in this group measure concentrations of electrolytes , hormones, proteins, and other metabolic products in human blood , serum,plasma, CSF and urine .

Clinical Chemistry tests are indicated to assess systemic functions such liver function , kidney function , and endocrine and metabolic function .

Methods commonly used are colormetric and kinetic.



## Features

- The kits are conveniently packed in different kit sizes of 20, 30, 60, 75, 100, 150, 200, 250, 500, and 1000 tests per kit.



| Item Code                        | Item Description                                    | Sizes                |
|----------------------------------|---|----------------------|
| 8.05.00.0.0250<br>8.05.00.0.0500 | Albumin Bromocresol Green                           | 2x125ml<br>4x125ml   |
| 8.05.01.0.0030<br>8.05.01.0.0060 | Amylase   | 3x10ml<br>6x10ml     |
| 8.05.02.0.0020<br>8.05.02.0.0040 | Acid Phosphatase Kinetic, Hilmann Method (Tablets)  | 10x2ml<br>20x2ml     |
| 8.05.03.0.0030<br>8.05.03.0.0060 | Alkaline Phosphatase Kinetic, DGKC Method (Tablets) | 10x3ml<br>20x3ml     |
| 8.05.04.0.0250<br>8.05.04.0.0500 | Alkaline Phosphatase Kinetic, DGKC Method (Liquid)  | 5x50ml<br>5x100ml    |
| 8.05.05.0.0250<br>8.05.05.0.0500 | Bilirubin Total (DMSO Method)                       | 2x125ml<br>4x125ml   |
| 8.05.06.0.0250<br>8.05.06.0.0500 | Bilirubin Direct (DMSO Method)                      | 2x125ml<br>4x125ml   |
| 8.05.07.0.0250<br>8.05.07.0.0500 | Bilirubin Total & Direct (DMSO Method)              | 2x125ml<br>4x125ml   |
| 8.05.08.0.0250<br>8.05.08.0.0500 | Calcium Arsenazo III                                | 2x125ml<br>4x125ml   |
| 8.05.09.0.0250<br>8.05.09.0.0500 | Calcium O-Cresolphthalein                           | 2x125ml<br>4x125ml   |
| 8.05.10.0.0250<br>8.05.10.0.0500 | Chloride Thiocyanate Colorimetric                   | 2x125ml<br>4x125ml   |
| 8.05.11.0.0250<br>8.05.11.0.0500 | Cholesterol Liquid (CHOD-POD)                       | 2x125ml<br>4x125ml   |
| 8.05.12.0.0025<br>8.05.12.0.0050 | CK-MB Kinetic (Tablets)                             | 10x2.5ml<br>20x2.5ml |
| 8.05.13.0.0050<br>8.05.13.0.0100 | CK-MB Kinetic (Liquid)                              | 5x10ml<br>5x20ml     |
| 8.05.14.0.0025<br>8.05.14.0.0050 | CK-NAC Kinetic (Tablets)                            | 10x2.5ml<br>20x2.5ml |
| 8.05.15.0.0050<br>8.05.15.0.0100 | CK-NAC Kinetic (Liquid)                             | 5x10ml<br>5x20ml     |



| Item Code                        | Item Description                              | Sizes                 |
|----------------------------------|---|-----------------------|
| 8.05.16.0.0250<br>8.05.16.0.0500 | Creatinine Jaffe Color-Kinetic                | 2x125ml<br>4x125ml    |
| 8.05.17.0.0250<br>8.05.17.0.0500 | Glucose GOD-POD (Liquid)                      | 2x125ml<br>4x125ml    |
| 8.05.18.0.0020<br>8.05.18.0.0040 | GOT (AST) IFCC Kinetic (Tablets)              | 10x2ml<br>20x2ml      |
| 8.05.19.0.0250<br>8.05.19.0.0500 | GOT (AST) IFCC Kinetic (Liquid)               | 5x50ml<br>5x100ml     |
| 8.05.20.0.0250<br>8.05.20.0.0500 | GOT (AST) Reitman-Frankel Colorimetric        | 2x125ml<br>2x250ml    |
| 8.05.21.0.0020<br>8.05.21.0.0040 | GPT (ALT) IFCC Kinetic (Tablets)              | 10x2ml<br>20x2ml      |
| 8.05.22.0.0250<br>8.05.22.0.0500 | GPT (ALT) IFCC Kinetic (Liquid)               | 5x50ml<br>5x100ml     |
| 8.05.23.0.0200<br>8.05.23.0.0250 | GPT (ALT) Reitman-Frankel Colorimetric        | 2x100ml<br>2x125ml    |
| 8.05.24.0.0020<br>8.05.24.0.0040 | Gamma GT Kinetic, Carboxy Substrate (Tablets) | 10x2ml<br>20x2ml      |
| 8.05.25.0.0250<br>8.05.25.0.0500 | Gamma GT Kinetic, Carboxy Substrate (Liquid)  | 5x50ml<br>5x100ml     |
| 8.05.26.0.0100<br>8.05.26.0.0200 | HDL Cholesterol Precipitating Reagent         | 2x50ml<br>2x100ml     |
| 8.05.27.0.0200                   | Iron Ferrozine Colorimetric                   | 4x50ml                |
| 8.05.28.0.0030<br>8.05.28.0.0060 | LDH IFCC Kinetic (Tablets)                    | 10x3ml<br>20x3ml      |
| 8.05.29.0.0250<br>8.05.29.0.0500 | LDH Pyruvate Kinetic UV DGKC (Liquid)         | 5x50ml<br>5x100ml     |
| 8.05.30.0.0060                   | Lipase Kinetic (Liquid)                       | 6x10ml                |
| 8.05.31.0.0250<br>8.05.31.0.0500 | Magnesium Calmagite Colorimetric              | 2x125ml<br>4x125ml    |
| 8.05.32.0.0250<br>8.05.32.0.0500 | Phosphorus Phosphomolybdate UV                | 2x125ml<br>4x125ml    |
| 8.05.33.0.0050<br>8.05.33.0.0100 | Potassium Colorimetric                        | 50 Tests<br>100 Tests |
| 8.05.34.0.0050<br>8.05.34.0.0100 | Sodium Colorimetric                           | 50 Tests<br>100 Tests |
| 8.05.35.0.0100                   | TIBC (Total Iron Binding Capacity)            | 100 Tests             |
| 8.05.36.0.0250<br>8.05.36.0.0500 | Total Lipids Phosphovanilline Colorimetric    | 2x125ml<br>4x125ml    |
| 8.05.37.0.0250<br>8.05.37.0.0500 | Total Protein Biuret Colorimetric             | 2x125ml<br>4x125ml    |
| 8.05.38.0.0250<br>8.05.38.0.0500 | Total Protein in CSF                          | 2x125ml<br>4x125ml    |

# CLINICAL CHEMISTRY KITS



| Item Code                        | Item Description                                      | Sizes                  |
|----------------------------------|---|------------------------|
| 8.05.39.0.0250<br>8.05.39.0.0500 | Triglycerides GPO-POD Colorimetric                    | 2x125ml<br>4x125ml     |
| 8.05.40.0.0250<br>8.05.40.0.0500 | Urea Urease-GLDH Kinetic (UV)                         | 5x50ml<br>5x100ml      |
| 8.05.41.0.0250<br>8.05.41.0.0500 | Urea Berthelot Colorimetric                           | 2x125ml<br>4x125ml     |
| 8.05.42.0.0250<br>8.05.42.0.0500 | Uric Acid Uricase-PAP Colorimetric (Two Reagents)     | 2x125ml<br>4x125ml     |
| 8.05.45.0.0250<br>8.05.45.0.0500 | G6PD Deficiency Qualitative Kit                       | 250 Tests<br>500 Tests |
| 8.05.45.1.0250<br>8.05.45.1.0500 | G6PD Deficiency Qualitative Kit, (with Filter Cards)  | 250 Tests<br>500 Tests |
| 8.05.46.0.0075<br>8.05.46.0.0150 | G6PD Deficiency Quantitative Kit                      | 75 Tests<br>150 Tests  |
| 8.05.46.1.0075<br>8.05.46.1.0150 | G6PD Deficiency Quantitative Kit, (with Filter Cards) | 75 Tests<br>150 Tests  |



| Item Code                        | Item Description   | Sizes                                  |
|----------------------------------|--|--|
| 8.05.71.0.0250<br>8.05.71.0.0500 | Uric Acid Enzymatic Colorimetric (Mono Reagents)                       | 2x125ml<br>4x125ml                     |
| 8.05.43.1.0005                   | Pathological Control for Clinical Chemistry, Lyophilized, Human Source | 5ml/vial                               |
| 8.05.44.1.0005                   | Normal Control for Clinical Chemistry, Lyophilized, Human Source       | 5ml/vial                               |
| 8.05.47.0.0003                   | G6PD Control, Normal Level, (Lyophilized)                              | 6x0.5ml                                |
| 8.05.51.0.0100                   | HDL Cholesterol, Enzymatic Colorimetric Direct Method                  | 100 Tests                              |
| 8.05.52.0.0100                   | LDL Cholesterol, Enzymatic Colorimetric Direct Method                  | 100 Tests                              |
| 8.40.00.1.0100                   | HbA1c Direct Enzymatic Colorimetric Kit                                | 100 Tests                              |
| 8.05.73.0.0020<br>8.05.73.0.0050 | Electrolytes Kit (Sodium, Potassium, Chloride)                         | 20 Tests for each<br>50 Tests for each |

# ALCOHOL TESTS

## Overview

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   | Sizes                |
|----------------------------------|--|----------------------|
| 8.25.01.0.0001<br>8.25.01.0.0025 | Saliva Alcohol Test Strip, Individually Pouched            | Bulk<br>25 Tests/Box |
| 8.25.02.0.0001<br>8.25.02.0.0020 | Breath Alcohol Test (0.02%), Individually Pouched          | Bulk<br>20 Tests/Box |
| 8.25.03.0.0001<br>8.25.03.0.0025 | Breath Alcohol Test (0.05%), Individually Pouched          | Bulk<br>25 Tests/Box |
| 8.25.04.0.0001<br>8.25.04.0.0025 | Breath Alcohol Test (0.08%), Individually Pouched          | Bulk<br>25 Tests/Box |
| 8.25.05.0.0001<br>8.25.05.0.0020 | Ethyl Glucuronide (ETG ) Urine Strip, Individually pouched | Bulk<br>20 Tests/Box |

## Features

- The kits are conveniently packed in different kit sizes of 20, 25, 50 and 100 tests per kit.





# STAINS FOR HISTOLOGY & MICROBIOLOGY



## Overview

Atlas Medical is well known for its range of lab stains for histology and microbiology applications. Atlas Medical stains are made of the highest quality ingredients to ensure good quality and vivid staining.

## Features

- The stains come in convenient sizes, but custom sizes are also available.



### STAIN PACKS FOR HISTOLOGY

| Item Code     | Item Description                                | Sizes   |
|---------------|---|---------|
| 8.17.003.0300 | Periodic Acid Schiff (PAS) Stain Kit            | 3x100ml |
| 8.17.004.0300 | Iron Stain Kit - Perl                           | 3x100ml |
| 8.17.009.1000 | Gram Stain Pack                                 | 4x250ml |
| 8.17.010.0750 | Cold ZN - Kinyoun Stain Pack                    | 3x250ml |
| 8.17.011.0750 | ZN Pack Standard                                | 3x250ml |
| 8.17.015.0500 | Diff-3 Stain Pack                               | 4x125ml |
| 8.17.016.1000 | Papanicolaou Stain Pack (EA35, EA50, EA65, OG6) | 4X250ml |

### STAINS FOR HISTOLOGY

| Item Code     | Item Description  | Sizes        |
|---------------|---|--------------|
| 8.15.017.0250 | Carbol Fuchsin (Gram)   | 250ml/Bottle |
| 8.15.019.0250 | Carbol Fuchsin (Ziehl-Neelsen)                                      | 250ml/Bottle |
| 8.15.032.0250 | Crystal Violet (for Gram Stain)                                     | 250ml/Bottle |
| 8.15.037.0250 | Eosin Y (1% Aqueous)  | 250ml/Bottle |
| 8.15.038.0250 | Eosin Y (5% Aqueous)  | 250ml/Bottle |
| 8.15.039.0250 | Eosin Stain (diff 3)  | 250ml/Bottle |
| 8.15.041.0250 | Field Stain (Solution A)  | 250ml/Bottle |
| 8.15.042.0250 | Field Stain (Solution B)  | 250ml/Bottle |
| 8.15.043.0750 | Field Stain ( Fixing Reagent, Eosin Reagent, Methylene Blue Reagent | 3x250ml      |
| 8.15.044.0500 | Field Stain (Solution A+B)  | 2x250ml      |
| 8.15.047.0250 | Giemsa Stain (Modified-Glycerol/Methanol)                           | 250ml/Bottle |
| 8.15.049.0250 | Gram's Iodine   | 250ml/Bottle |
| 8.15.051.0250 | Gram's Decolouriser   | 250ml/Bottle |
| 8.15.059.0250 | Haematoxylin Harris (no Acetic Acid)                                | 250ml/Bottle |
| 8.15.069.0250 | Leishman Stain  | 250ml/Bottle |
| 8.15.074.0250 | Lugol's Iodine  | 250ml/Bottle |
| 8.15.076.0250 | Malachite Green (Aqueous)   | 250ml/Bottle |
| 8.15.078.0250 | May Grunwald Stain (Modified)                                       | 250ml/Bottle |
| 8.15.105.0250 | New Methylene Blue for Reticulocytes                                | 250ml/Bottle |
| 8.15.110.0250 | Papanicolaou Stain EA35   | 250ml/Bottle |
| 8.15.111.0250 | Papanicolaou Stain EA36   | 250ml/Bottle |
| 8.15.112.0250 | Papanicolaou Stain EA65   | 250ml/Bottle |
| 8.15.114.0250 | Papanicolaou Stain EA50   | 250ml/Bottle |
| 8.15.115.0250 | Papanicolaou Stain OG6  | 250ml/Bottle |
| 8.15.126.0250 | Safranin (1% Aqueous)   | 250ml/Bottle |
| 8.15.143.0250 | Wright's Stain (Modified)   | 250ml/Bottle |
| 8.15.144.0250 | ZN Decolouriser   | 250ml/Bottle |
| 8.15.146.0100 | Immersion Oil   | 100ml/Bottle |
| 8.15.150.1000 | Mayers haematoxylin   | 1 L/Bottle   |
| 8.15.152.0500 | Field Stain (Solution B)+Methanol                                   | 2X250 ml     |



### MICROBIOLOGY

| Item Code      | Item Description   | Sizes        |
|----------------|--|--------------|
| 8.38.00.0.0025 | Blood Culture Bottles, Pediatric Size                                  | 25ml/Bottle  |
| 8.38.00.0.0050 | Blood Culture Bottles, Adult Size                                      | 50ml/Bottle  |
| 8.36.00.0.0020 | Mycoplasma Culture, Identification, Enumeration and Susceptibility Kit | 20 Tests/Box |



# ANTIBIOTIC SENSITIVITY DISCS



## Overview

Antibiotic sensitivity is a term used to describe the susceptibility of bacteria to antibiotics. Antibiotic susceptibility testing (AST) is usually carried out to determine which antibiotic will be most successful in treating a bacterial infection in vivo.

Small discs containing antibiotics are placed onto a plate upon which bacteria are growing. If the bacteria are sensitive to the antibiotic, a clear ring, or zone of inhibition, is seen around the disc indicating poor growth.

## Features

- Atlas Medical offers a wide range of antibiotics discs at competitive prices.
- Easy to use.
- The kit comes with a Cartridge Applicator.
- Reliable quality.
- Comprehensive range of antibiotics at different concentrations.



| Item Code      | Item Description                                 | Sizes      |
|----------------|--|------------|
| 8.39.48.0.0250 | NORFLOXACIN (10 µg) - NX                         | 5x50 Discs |
| 8.39.49.0.0250 | OFLOXACIN (5 µg) - OF                            | 5x50 Discs |
| 8.39.50.0.0250 | PEFLOXACIN (5 µg) - PF                           | 5x50 Discs |
| 8.39.51.0.0250 | PENICILLIN -G (10 IU) - P                        | 5x50 Discs |
| 8.39.52.0.0250 | PIPERACILLIN (100 µg) - PI                       | 5x50 Discs |
| 8.39.53.0.0250 | PIPERACILLIN / TAZOBACTAM (100 µg + 10 µg) - PTZ | 5x50 Discs |
| 8.39.54.0.0250 | RIFAMPIN (5 µg) - RIF                            | 5x50 Discs |
| 8.39.55.0.0250 | ROXITHROMYCIN (30 µg) - RO                       | 5x50 Discs |

| Item Code      | Item Description                                | Sizes      |
|----------------|---|------------|
| 8.39.01.0.0250 | AMIKACIN (30 µg) - AK                           | 5x50 Discs |
| 8.39.02.0.0250 | AMOXICILLIN (10 µg) - AX                        | 5x50 Discs |
| 8.39.03.0.0250 | AMOXICILLIN / CLAVULANATE (20 µg + 10 µg) - AMC | 5x50 Discs |
| 8.39.04.0.0250 | AMPICILLIN (10 µg) - AMP                        | 5x50 Discs |
| 8.39.05.0.0250 | AMPICILLIN / SULBACTAM (10 µg - 10 µg) - AS     | 5x50 Discs |
| 8.39.06.0.0250 | AZITHROMYCIN (15 µg) - AZM                      | 5x50 Discs |
| 8.39.07.0.0250 | AZTREONAM (30 µg) - AT                          | 5x50 Discs |
| 8.39.08.0.0250 | CEFACTOR (30 µg) - CF                           | 5x50 Discs |
| 8.39.09.0.0250 | CEFADROXIL (30 µg) - CD                         | 5x50 Discs |
| 8.39.10.0.0250 | CEFAZOLIN (30 µg) - CZ                          | 5x50 Discs |
| 8.39.11.0.0250 | CEFDINIR (5µg) - CDR                            | 5x50 Discs |
| 8.39.12.0.0250 | CEFIXIME (5 µg) - CFM                           | 5x50 Discs |
| 8.39.13.0.0250 | CEFOPERAZONE (75 µg) - CPZ                      | 5x50 Discs |
| 8.39.14.0.0250 | CEFOPERAZONE / SULBACTAM (75 µg + 30 µg) - CS   | 5x50 Discs |
| 8.39.15.0.0250 | CEFOTAXIME (30 µg) - CTX                        | 5x50 Discs |
| 8.39.16.0.0250 | CEFPIROME (30 µg) - CE                          | 5x50 Discs |
| 8.39.17.0.0250 | CEFPODOXIME (10 µg) - CPD                       | 5x50 Discs |
| 8.39.18.0.0250 | CEFPROZIL (30 µg) - CPR                         | 5x50 Discs |
| 8.39.19.0.0250 | CEFTAZIDIME (30 µg) - CAZ                       | 5x50 Discs |
| 8.39.20.0.0250 | CEFTIZOXIME (30 µg) - CZX                       | 5x50 Discs |
| 8.39.21.0.0250 | CEFTRIOXONE (30 µg) - CTR                       | 5x50 Discs |
| 8.39.22.0.0250 | CEFUROXIME (30 µg) - CXM                        | 5x50 Discs |
| 8.39.23.0.0250 | CEPHALEXIN (30 µg) - CN                         | 5x50 Discs |
| 8.39.24.0.0250 | CEPHALORIDINE (30 µg) - CH                      | 5x50 Discs |
| 8.39.25.0.0250 | CEPHALOTHIN (30 µg) - CEP                       | 5x50 Discs |
| 8.39.26.0.0250 | CHLORAMPHENICOL (30 µg) - C                     | 5x50 Discs |
| 8.39.27.0.0250 | CIPROFLOXACIN (5 µg) - CIP                      | 5x50 Discs |
| 8.39.28.0.0250 | CLARITHROMYCIN (15 µg) - CLR                    | 5x50 Discs |
| 8.39.29.0.0250 | CLINDAMYCIN (2 µg) - CD                         | 5x50 Discs |
| 8.39.30.0.0250 | CLOXACILLIN (5 µg) - COX                        | 5x50 Discs |
| 8.39.32.0.0250 | DOXYCYCLINE (30 µg) - DOX                       | 5x50 Discs |
| 8.39.33.0.0250 | ERYTHROMYCIN (15 µg) - E                        | 5x50 Discs |
| 8.39.34.0.0250 | FURAZOLIDONE (100 µg) - FZ                      | 5x50 Discs |
| 8.39.35.0.0250 | GATIFLOXACIN (5 µg) - GAT                       | 5x50 Discs |
| 8.39.36.0.0250 | GENTAMYCIN (10 µg) - GEN                        | 5x50 Discs |
| 8.39.38.0.0250 | KANAMYCIN (30 µg) - K                           | 5x50 Discs |
| 8.39.39.0.0250 | LEVOFOLXACIN (5 µg) - LE                        | 5x50 Discs |
| 8.39.40.0.0250 | LINCOMYCIN (15 µg) - LN                         | 5x50 Discs |
| 8.39.41.0.0250 | LINEZOLID (30 µg) - LZ                          | 5x50 Discs |
| 8.39.42.0.0250 | LOMEFLOXACIN (10 µg) - LOM                      | 5x50 Discs |
| 8.39.43.0.0250 | MEROPENEM (10 µg) - MRP                         | 5x50 Discs |
| 8.39.44.0.0250 | MINOCYCLINE (30 µg) - MI                        | 5x50 Discs |
| 8.39.45.0.0250 | MOXIFLOXACIN (5 µg) - MXF                       | 5x50 Discs |
| 8.39.46.0.0250 | NALIDIXIC ACID (30 µg) - NA                     | 5x50 Discs |
| 8.39.47.0.0250 | NITROFURANTOIN (300 µg) - NIT                   | 5x50 Discs |



# ANTIBIOTIC SENSITIVITY DISCS



| Item Code      | Item Description                              | Sizes      |
|----------------|---|------------|
| 8.39.56.0.0250 | SPARFLOXACIN (5 µg) – SPX                     | 5x50 Discs |
| 8.39.57.0.0250 | STREPTOMYCIN (10 µg) – S                      | 5x50 Discs |
| 8.39.58.0.0250 | SULFADIAZINE (300 µg) - SD                    | 5x50 Discs |
| 8.39.59.0.0250 | TEICOPLANIN (30 µg) – TEI                     | 5x50 Discs |
| 8.39.60.0.0250 | TETRACYCLINE (30 µg) – TE                     | 5x50 Discs |
| 8.39.61.0.0250 | TICARCILLIN / CLAVULANATE (75 µg + 10 µg)-TCC | 5x50 Discs |
| 8.39.62.0.0250 | TOBRAMYCIN (10 µg) – TOB                      | 5x50 Discs |
| 8.39.63.0.0250 | TRIMETHOPRIM (5 µg) – TR                      | 5x50 Discs |
| 8.39.64.0.0250 | VANCOMYCIN (30 µg) – VA                       | 5x50 Discs |
| 8.39.65.0.0250 | POLYMYXIN-B (300 UNITS) -PB                   | 5x50 Discs |
| 8.39.66.0.0050 | CEFOXITIN (30 µg) - CX                        | 1x50 Discs |
| 8.39.67.0.0250 | CEFEPIME (30 µg) - CPM                        | 5x50 Discs |
| 8.39.69.0.0050 | NOVOBIOCIN (5 µg) -NV                         | 1x50 Discs |



| Item Code      | Item Description            | Sizes       |
|----------------|-----------------------------|-------------|
| 8.39.70.0.0050 | CARBENICILLIN (100 µg) - CB | 1x50 Discs  |
| 8.39.71.0.0050 | BACITRACIN - B (10 Unit)    | 1x50 Discs  |
| 8.39.72.0.0050 | CEFOXITIN (30 µg) - CX      | 20x50 Discs |
| 8.39.76.0.0250 | COLISTIN -CL (10 µg)        | 5x50 Discs  |
| 8.39.77.0.0250 | IMIPENEM-IPM (10 µg)        | 5x50 Discs  |
| 8.39.78.0.0250 | OXACILLIN -OX (1 µg)        | 5x50 Discs  |



## ELISA KITS

### Features

- 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.



### Overview

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.



| HORMONE ELISA KITS |                    |          |
|--------------------|--------------------|----------|
| Item Code          | Item Description   | Sizes    |
| 8.07.02.0.0096     | PSA Elisa Kit      | 96 Tests |
| 8.07.10.0.0096     | Free PSA Elisa Kit | 96 Tests |



| HORMONE ELISA KITS |                        |          |
|--------------------|------------------------|----------|
| Item Code          | Item Description       | Sizes    |
| 8.10.01.0.0096     | hCG Elisa Kit          | 96 Tests |
| 8.10.03.0.0096     | FSH Elisa Kit          | 96 Tests |
| 8.10.04.0.0096     | LH Elisa Kit           | 96 Tests |
| 8.10.05.0.0096     | Prolactin Elisa Kit    | 96 Tests |
| 8.12.00.0.0096     | T3 Elisa Kit           | 96 Tests |
| 8.12.01.0.0096     | T4 Elisa Kit           | 96 Tests |
| 8.12.02.0.0096     | TSH Elisa Kit          | 96 Tests |
| 8.12.03.0.0096     | Free T4 Elisa Kit      | 96 Tests |
| 8.12.04.0.0096     | Free T3 Elisa Kit      | 96 Tests |
| 8.11.03.0.0096     | Progesterone Elisa kit | 96 Tests |
| 8.11.04.0.0096     | Testosterone Elisa Kit | 96 Tests |

# ELISA KITS

## Overview

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.

- \* Different Packaging sizes.
- \* Easy to Use
- \* High Quality



| Item Code      | Item Description                              | Sizes    |
|----------------|---|----------|
| 8.13.10.0.0096 | Herpes Simplex 2 IgM (HSV2 IgM) Elisa Kit     | 96 Tests |
| 8.13.11.0.0096 | Herpes Simplex 1,2 IgG (HSV1,2 IgG) Elisa Kit | 96 Tests |
| 8.13.12.0.0096 | Herpes Simplex 1,2 IgM (HSV1,2 IgM) Elisa Kit | 96 Tests |



| TORCH ELISA KITS |   |          |
|------------------|---|----------|
| Item Code        | Item Description                            | Sizes    |
| 8.13.00.0.0096   | Toxo Plasma Gondii IgG (Toxo IgG) Elisa kit | 96 Tests |
| 8.13.01.0.0096   | Toxoplasma gondii IgM (Toxo IgM) Elisa kit  | 96 Tests |
| 8.13.02.0.0096   | Rubella IgG Elisa Kit                       | 96 Tests |
| 8.13.03.0.0096   | Rubella IgM Elisa Kit                       | 96 Tests |
| 8.13.05.0.0096   | Cytomegalovirus IgG (CMV IgG) Elisa Kit     | 96 Tests |
| 8.13.06.0.0096   | Cytomegalovirus IgM (CMV IgM) Elisa Kit     | 96 Tests |
| 8.13.07.0.0096   | Herpes Simplex 1 IgG (HSV1 IgG) Elisa Kit   | 96 Tests |
| 8.13.08.0.0096   | Herpes Simplex 1 IgM (HSV1 IgM) Elisa Kit   | 96 Tests |
| 8.13.09.0.0096   | Herpes Simplex 2 IgG (HSV2 IgG) Elisa Kit   | 96 Tests |

## Overview

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).



| INFECTIOUS DISEASES ELISA KITS |                                       |          |
|--------------------------------|---------------------------------------|----------|
| Item Code                      | Item Description                      | Sizes    |
| 8.14.19.1.0096                 | Helicobacter Pylori Antigen Elisa Kit | 96 Tests |



| INFECTIOUS DISEASES ELISA KITS |   |          |
|--------------------------------|---|----------|
| Item Code                      | Item Description                                | Sizes    |
| 8.14.28.0.0096                 | HBsAg Elisa Kit                                 | 96 Tests |
| 8.14.29.0.0096                 | HBsAb Elisa Kit                                 | 96 Tests |
| 8.14.30.0.0096                 | HBcAb Elisa Kit                                 | 96 Tests |
| 8.14.31.0.0096                 | HBeAg Elisa Kit                                 | 96 Tests |
| 8.14.32.0.0096                 | HBeAb Elisa Kit                                 | 96 Tests |
| 8.14.35.0.0096                 | HEV IgM Elisa Kit                               | 96 Tests |
| 8.14.38.0.0096                 | HCV Ab Elisa Kit                                | 96 Tests |
| 8.14.39.0.0096                 | HAV IgM Elisa Kit                               | 96 Tests |
| 8.14.40.0.0096                 | HIV 1,2 Antibody Elisa Kit                      | 96 Tests |
| 8.14.43.0.0096                 | Syphilis Antibody total (IgG,IgA,IgM) Elisa Kit | 96 Tests |
| 8.14.44.0.0096                 | HIV Ag/Ab Elisa Kit                             | 96 Tests |



| OTHER ELISA KITS |                                    |          |
|------------------|------------------------------------|----------|
| Item Code        | Item Description                   | Sizes    |
| 8.07.03.0.0096   | Alpha Feto Protein (AFP) Elisa Kit | 96 Tests |
| 8.07.08.0.0096   | Ferritin Elisa Kit                 | 96 Tests |
| 8.08.00.0.0096   | Troponin I Elisa Kit               | 96 Tests |
| 8.09.00.0.0096   | IgE Elisa Kit                      | 96 Tests |
| 8.51.00.0.0096   | 25-OH Vitamin D Elisa Kit          | 96 Tests |
| 8.57.00.0.0096   | Vitamin B12 Elisa Kit              | 96 Tests |
| 8.58.00.0.0096   | Folic Acid Elisa Kit               | 96 Tests |
| 8.06.32.0.0096   | Anti-CRA Elisa Kit                 | 96 Tests |

# HOME TESTS



## Overview

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). 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.

### Screening Kits

| Item Code | Item Description                        | Sizes       |
|-----------|---|-------------|
| 70004001  | Atlas Home Diabetes Test                | 2 Tests/Box |
| 70021001  | Atlas Home Urinary Tract Infection Test | 2 Tests/Box |
| 70022001  | Atlas Home Kidney Function Test         | 2 Tests/Box |
| 70023001  | Atlas Home Liver Function Test          | 2 Tests/Box |

## Features

- These tests come in cassette, midstream and strip formats.
- The screening kits come 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.
- Screening bundle including (UTI, Kidney, Liver, Diabetes) is available , Family planning kit (Pregnancy and Ovulation) is also available .



- Simply dip the test strip in urine for one second.
- Wait for 30 - 60 seconds.
- Compare the colors on the strip to the color chart on the box.



### Fertility Kits

| Item Code | Item Description                              | Sizes       |
|-----------|---|-------------|
| 70171001  | Atlas Home Pregnancy Test Cassette            | 1 Test/Box  |
| 70172001  | Atlas Home Pregnancy Test Midstream           | 1 Tests/Box |
| 70174001  | Atlas Home Ovulation Test Cassette            | 5 Tests/Box |
| 70175001  | Atlas Home Ovulation Test Midstream           | 3 Tests/Box |
| 70177001  | Atlas Home Menopause Test Cassette            | 1 Test/Box  |
| 70178001  | Atlas Home Menopause Test Midstream           | 1 Test/Box  |
| 70180001  | Atlas Home Pregnancy Test Strip (With Handle) | 1 Test/Box  |
| 70170001  | Atlas Home Pregnancy Test Strip               | 1 Test/Box  |

# BLOOD GLUCOSE MONITORING SYSTEMS

## Overview

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 strips which includes Gold Electrodes.



## Features

- ⌚ Reliance Gold™ by Atlas Medical, uses the latest blood glucose gold sensor technology to offer the most accurate and reliable results.
- ⌚ Test time required is 5 Seconds.
- ⌚ Required sample volume is 0.9µl
- ⌚ Test result range is between 10 - 600 mg/dl (0.6 -33.3 mmol/L)

| Reliance Gold  |                                       |                  |
|----------------|---------------------------------------|------------------|
| Item Code      | Item Description                      | Sizes            |
| 8.52.00.0.0001 | Reliance Gold Glucometer Pack         | 1 Pack           |
| 8.52.00.0.0025 | Strips for Reliance Gold Glucometer   | 25 Strips/Bottle |
| 8.52.00.0.0050 |                                       | 50 Strips/Bottle |
| 8.52.00.1.0001 | Reliance Gold Glucometer (Divec only) | 1 Divec only     |







# CONTACT US

---



## FIND US ON:

---



@Atlas.Medical.GmbH



linkedin.com/company/atlas-medical-co



@AtlasMedic



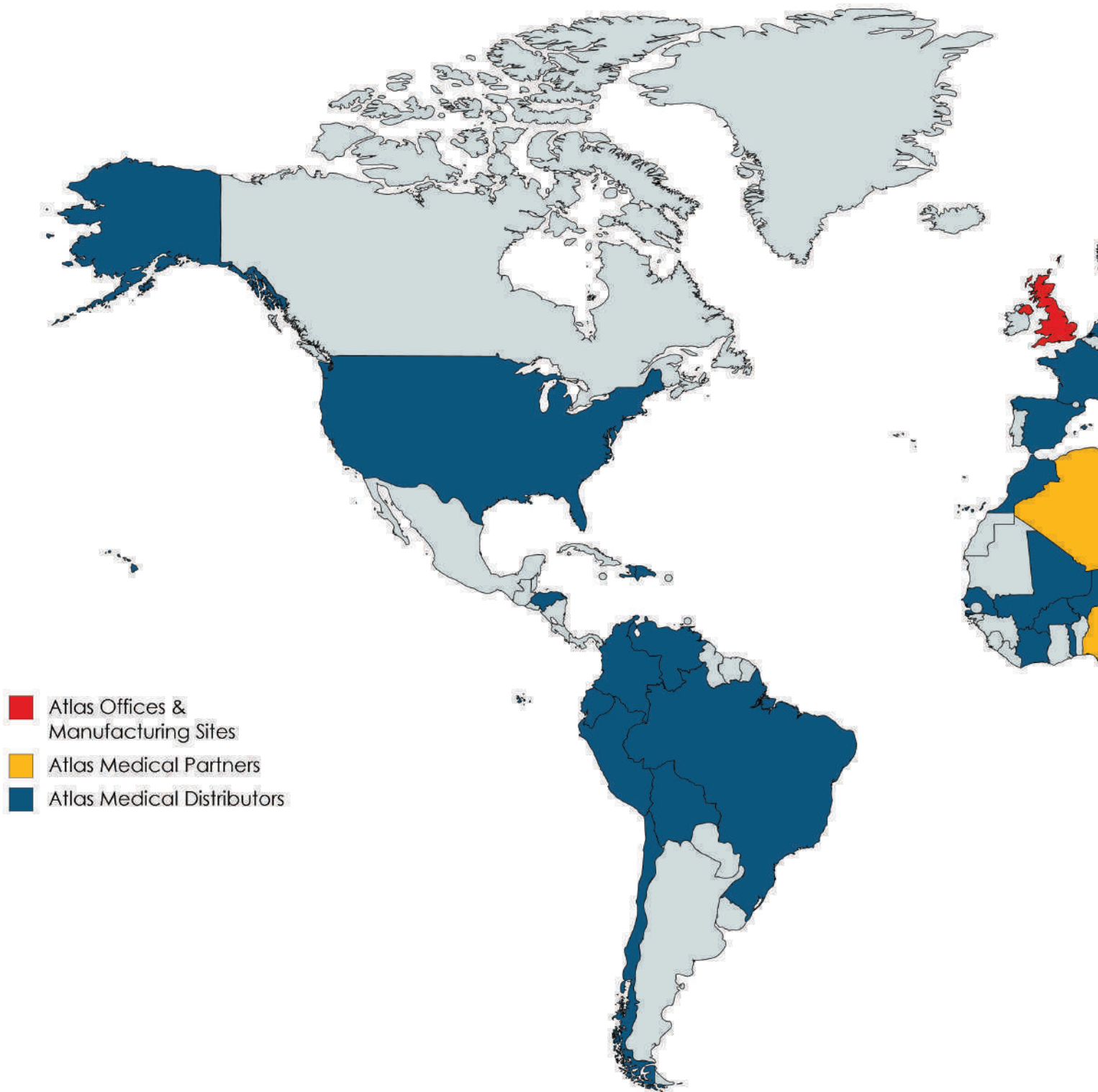
Amazon.co.uk/Atlas Medical

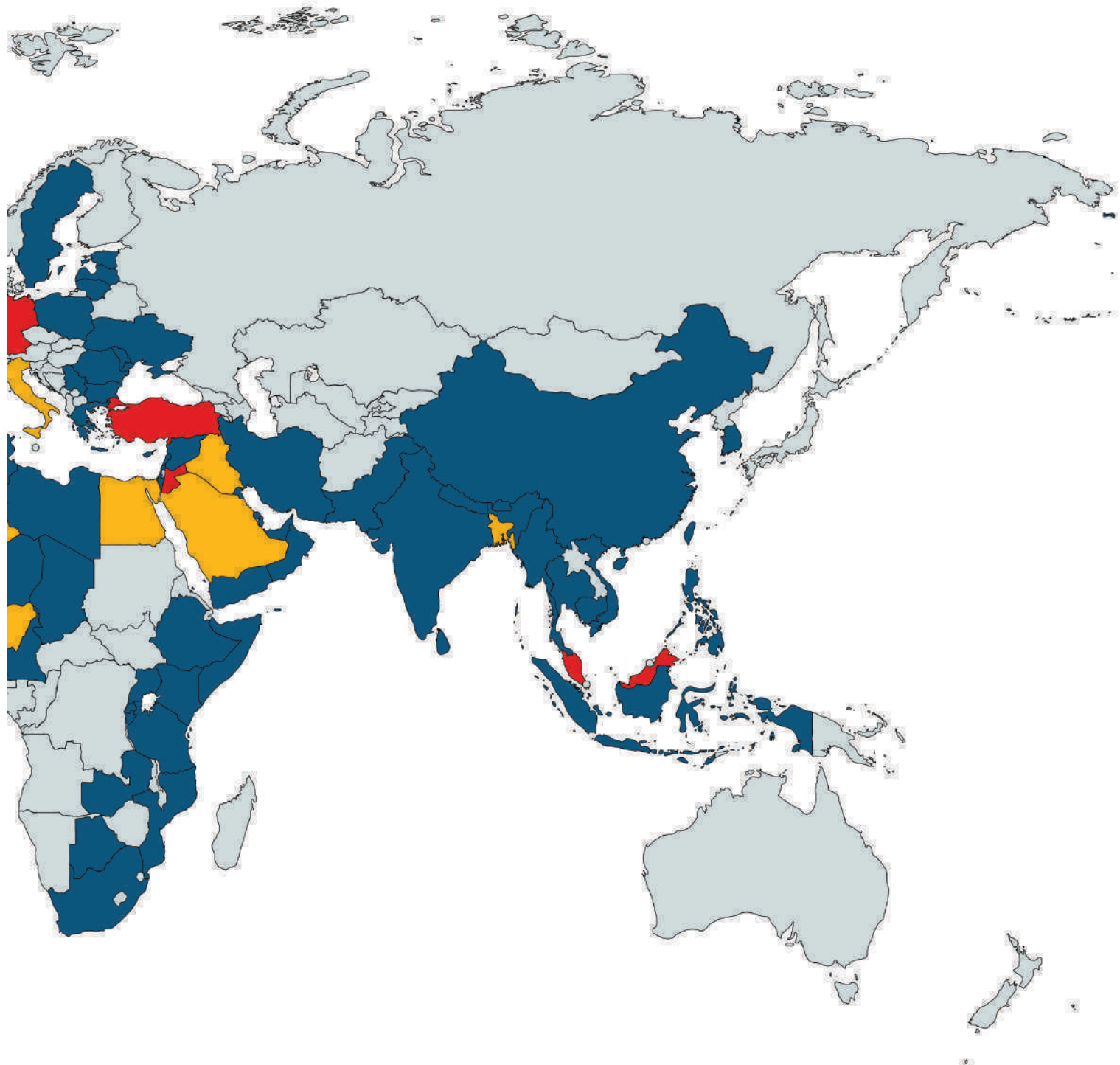
Email: [Info@atlas-medical.com](mailto:Info@atlas-medical.com)



# INTERNATIONAL PRESENCE

---









# Certificate

No. Q5 092305 0001 Rev. 01

**Holder of Certificate:** **Zhejiang Orient Gene Biotech Co., Ltd.**  
3787#, East Yangguang Avenue, Dipu Street Anji  
313300 Huzhou, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_092305_0001_Rev.01)

**Report No.:** SH2198802

**Valid from:** 2022-04-11

**Valid until:** 2024-03-16

**Date,** 2022-04-11



Christoph Dicks

Head of Certification/Notified Body



Product Service

# Certificate

No. Q5 092305 0001 Rev. 01

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Zhejiang Orient Gene Biotech Co., Ltd.  
3787#, East Yangguang Avenue, Dipu Street Anji, 313300  
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



浙江东方基因生物制品股份有限公司  
Zhejiang Orient Gene Biotech Co.,LTD

---

## STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product 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.

This Statement letter will be valid from Feb.21th,2023 to Feb.20th, 2024.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21



---

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号  
Add: 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China  
电话 Tel:+86-572-5226111 传真 Fax: +86-572-5226222 邮编 P.C.:313300



# C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma)



For professional *in vitro* diagnostic use only.

## INTENDED USE

The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is used for semi-quantitative determination and monitoring of CRP concentrations in whole blood/serum/plasma specimens.

## SUMMARY

C-Reactive Protein (CRP) in patient's sera has been found in association with acute infections, necrotic conditions and a variety of inflammatory disorders. There is a strong correlation between serum levels of CRP and the onset of the inflammatory process. Monitoring the levels of CRP in patient's sera indicates the effectiveness of treatment and the assessment of patient recovery. It is used in particular to differentiate bacterial infections from virus infections.

The C-Reactive Protein Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that semi-qualitatively detects the presence of CRP in whole blood, plasma or serum specimens at the sensitivity of 10mg/L, 40 mg/L and 80mg/L. The test utilizes a combination of monoclonal antibodies to selectively detect elevated levels of CRP in whole blood, plasma or serum. At the level of claimed sensitivity, the C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) shows no cross-reactivity interference from the related CRP or others at high physiological levels.

## PRINCIPLE

The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is an immunochromatographic test, based on two specific antibodies against human CRP. The concentration-dependent formation of test lines allows a rapid semi-quantitative determination of CRP in whole blood samples, plasma and serum.

The diluted sample is added into the sample well of the device. The sample now moves through the test strip from bottom to top. If the test sample contains CRP, it attaches to the first anti-CRP antibody which is conjugated with a red gold colloidal for color marking. The red CRP antibody-gold complex, together with the sample liquid, diffuses through the membrane that is pre dispensed with lines of different amounts of the second anti-CRP antibody. The CRP-antibody-gold complex is immobilized by the antibodies coated on the membrane leading to the formation of red lines. The number of lines depends on the CRP concentration in the sample. The more CRP is contained in the sample, the redder lines become visible.

The control line serves as a procedural control and indicates that sufficient volume of specimen has been added and membrane wicking has occurred.

## REAGENT

The test contains anti- CRP particles and anti- CRP coated on the membrane.

## MATERIALS PROVIDED

- 20 Test cassettes
- 20 Droppers
- 20 Extraction tubes with buffer
- 1 Package insert

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container
2. Timer
3. Centrifuge

## PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to any testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing

such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

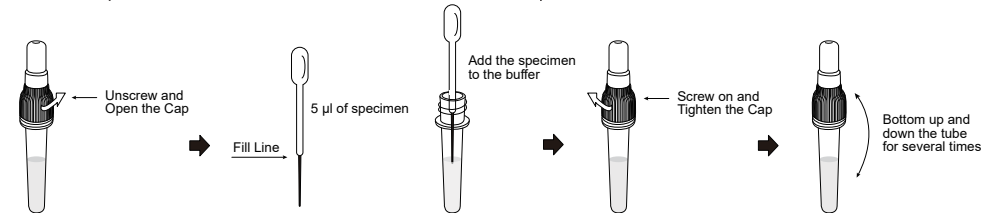
## STORAGE AND STABILITY

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

## SPECIMEN COLLECTION AND PREPARATION

- The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

1. Use a disposable pipette to transfer 5 µL of the specimens and add to the dilution tube with buffer.
2. Bottom up and down the tube for several time to mix the specimens well.

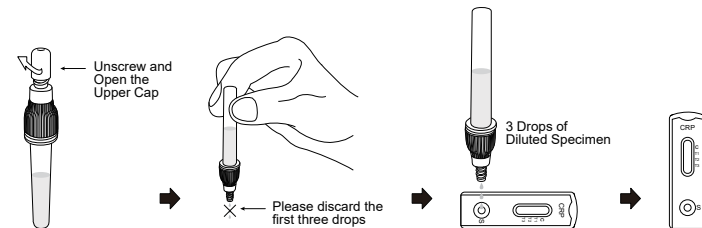


The diluted sample can be kept at room temperature for at least 8 hours. EDTA, citrate or heparin blood can also be used as a sample.

## PROCEDURE

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

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. To ensure accuracy, discard the first three drops from the bottle.
3. Add 3 drops of diluted specimen above to the specimen well and start the timer.
4. Wait for the colored bands to appear. The result should be **read at 5 minutes**. Do not interpret the result after 8 minutes.



## INTERPRETATION OF RESULTS

### POSITIVE RESULT: Possible Interpretation of CRP Levels



A Control band (C) and a test band (T3) appears indicates a CRP level 10 mg/L at least.



A Control band (C) and two test bands (T3 and T2) appear indicates a CRP level 40 mg/L at least.



A Control band (C) and three test bands (T1, T2 and T3) appears indicates a CRP level 80 mg/L at least.

### NEGATIVE RESULT:



Only a Control band (C) appears and no colored band appears in the test region (T) indicates a CRP level is lower than 10 mg/L.

### INVALID RESULT:



No Control band appears. Results from any test which has not produced Control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

### NOTE:

- The intensity of the color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Please note that this is a semi-quantitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

## QUALITY CONTROL

- Internal procedural controls are included in the test. Control band appearing in the control regions is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS OF THE TEST

The C-Reactive Protein Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should only be used for the semi-quantitative detection of C-reactive protein.

- The C-Reactive Protein Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the semi-quantitative level of CRP in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.
- Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- High concentrations of CRP may produce a dose hook effect, resulting in incorrect interpretation of CRP levels. High dose hook effect has not been observed with this test up to 2000 mg/L of CRP.

## EXPECTED VALUES

The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial CRP EIA test, demonstrating an overall accuracy of 98.9%.

## PERFORMANCE CHARACTERISTICS

### Sensitivity and Specificity

The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial CRP EIA test using clinical specimens. The results show that the sensitivity of the C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is 98.1% and the specificity is 99.2% relative to the leading EIA test.

C-Reactive Protein Semi-Quantitative Rapid Test Cassette vs. EIA

| Semi-Quantitative Rapid Test Cassette | Method   | EIA Test |          | Total Results |
|---------------------------------------|----------|----------|----------|---------------|
|                                       | Results  | Positive | Negative |               |
|                                       |          | Positive | 104      | 2             |
|                                       | Negative | 2        | 256      | 258           |
| Total Results                         |          | 106      | 258      | 364           |

Relative Sensitivity: 98.1%(93.3%-99.8%)\*

Relative Specificity: 99.2%(97.3%-99.9%)\*

Accuracy: 98.9%(97.2%-99.7%)\*

\*95% Confidence Interval

## LITERATURE REFERENCES

- Morley JJ, Kushner (1982) Serum C-reactive protein levels in disease. In: Kushner I, Volanakis JE, Gewurz H, eds. C-reactive protein and the plasma protein response to tissue injury. Ann. NY Acad. Sci. 389: 406-417.
- Peltola HO (1982) C-reactive protein for rapid monitoring of infections of the central nervous system. Lancet: 980-983.
- Macy EM, Hayes TE and Tracy RP (1997) Variability in the measurement of C-reactive protein in healthy subjects: implications for reference intervals and epidemiological applications. Clin. Chem. 43, 52-58.

## INDEX OF SYMBOLS

|  |   |  |               |  |                           |
|--|---|--|---------------|--|---------------------------|
|  | Consult instructions for use            |  | Tests per kit |  | Authorized Representative |
|  | For <i>in vitro</i> diagnostic use only |  | Use by        |  | Do not reuse              |
|  | Store between 2~30°C                    |  | Lot Number    |  | Catalog#                  |

Zhejiang Orient Gene Biotech Co.,Ltd  
 Address: 3787#, East Yangguang Avenue, Dipu Street,  
 Anji 313300, Huzhou, Zhejiang, China  
 Tel: +86-572-5226111 Fax: +86-572-5226222  
 Website: www.orientgene.com

CMC Medical Devices & Drugs S.L  
 C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain  
 Tel: +34951214054 Fax: +34952330100  
 Email: info@cmcmmedicaldevices.com

GDCRP-T402b

Revision Date: 2022-06-15  
B22574-02



Toxicology Urine Test



Table listing Toxicology Urine Test products. Columns: Product Description, Format, Cut-off Value, Qualification. Includes tests like Acetaminophen (ACE), Amphetamine (AMP), Cocaine (COC), etc.

Toxicology Saliva Test



Table listing Toxicology Saliva Test products. Columns: Product Description, Format, Cut-off Value, Qualification. Includes tests like 7-Aminoclozapem (ACL), Amphetamine (AMP), Cocaine (COC), etc.

Table listing Toxicology Urine Test products. Columns: Product Description, Format, Label, Cut-off Value, Qualification. Includes tests like Methamphetamine (MET), Methaqualone (MQL), Cocaine (COC), etc.

Toxicology Hair Test



Table listing Toxicology Hair Test products. Columns: Product Description, Format, Label, Cut-off Value, Qualification. Includes tests like Amphetamine (AMP), Benzodiazepines (BZO), Cocaine (COC), etc.

Infectious Disease



Table listing Infectious Disease products. Columns: Product Description, Specimen, Catalog No., Format, Cut-off Value, Kit Size. Includes tests like Adenovirus Antigen Test, HIV 1/2 Antibody Test, etc.

Table listing Infectious Disease products. Columns: Product Description, Specimen, Catalog No., Format, Cut-off Value, Kit Size. Includes tests like Chikungunya IgG/IgM Test, HIV 1/2 Antibody Test, etc.

Table listing Infectious Disease products. Columns: Product Description, Specimen, Catalog No., Format, Cut-off Value, Kit Size. Includes tests like H. pylori Antigen Test, Influenza A Antigen Test, etc.

√CE Marked †Cleared for US 510(k) In Specimen column: WB: Whole Blood S: Serum P: Plasma



## Fertility

| Product Description    | Specimen           | Catalog No.   | Format        | Cut-off Value | Kit Size        |
|------------------------|--------------------|---------------|---------------|---------------|-----------------|
| hCG Pregnancy Test     | Urine              | GAHCG-101a/†  | Strip         | 25 mIU/mL     | 100 Tests/Kit   |
|                        |                    | GAHCG-101b/†  | Strip         | 10 mIU/mL     | 100 Tests/Kit   |
|                        |                    | GAHCG-101d/†  | Strip         | 20 mIU/mL     | 100 Tests/Kit   |
|                        |                    | GAHCG-102a/†  | Cassette      | 25 mIU/mL     | 25 Tests/Kit    |
|                        |                    | GAHCG-102b/†  | Cassette      | 10 mIU/mL     | 25 Tests/Kit    |
|                        |                    | GAHCG-102d/†  | Cassette      | 20 mIU/mL     | 25 Tests/Kit    |
|                        |                    | GAHCG-103a/†  | Midstream     | 25 mIU/mL     | 1/2 Test(s)/Kit |
|                        |                    | GAHCG-103b/†  | Midstream     | 10 mIU/mL     | 1/2 Test(s)/Kit |
|                        |                    | GAHCG-103d/†  | Midstream     | 20 mIU/mL     | 1/2 Test(s)/Kit |
|                        |                    | GAHCG-105a    | Panel         | 25 mIU/mL     | 25 Tests/Kit    |
| Urine/Serum            |                    | GAHCG-201a/†  | Strip         | 25 mIU/mL     | 100 Tests/Kit   |
|                        |                    | GAHCG-201b/†  | Strip         | 10 mIU/mL     | 100 Tests/Kit   |
|                        |                    | GAHCG-202a/†  | Cassette      | 25 mIU/mL     | 25 Tests/Kit    |
|                        |                    | GAHCG-202b/†  | Cassette      | 10 mIU/mL     | 25 Tests/Kit    |
| Digital Pregnancy Test | Urine              | GAHCG-D103a/† | Midstream     | 25 mIU/mL     | 1/2 Test(s)/Kit |
|                        |                    | GALH-101a/†   | Strip         | 25 mIU/mL     | 100 Tests/Kit   |
|                        |                    | GALH-101b/†   | Strip         | 40 mIU/mL     | 100 Tests/Kit   |
|                        |                    | GALH-101d     | Strip         | 30 mIU/mL     | 100 Tests/Kit   |
| LH Ovulation Test      | Urine              | GALH-102a/†   | Cassette      | 25 mIU/mL     | 25 Tests/Kit    |
|                        |                    | GALH-102b/†   | Cassette      | 40 mIU/mL     | 25 Tests/Kit    |
|                        |                    | GALH-103a/†   | Midstream     | 25 mIU/mL     | 1/5 Test(s)/Kit |
|                        |                    | GALH-103b/†   | Midstream     | 40 mIU/mL     | 1/5 Test(s)/Kit |
| FSH Menopause Test     | Urine              | GAHCG-103d    | Midstream     | 30 mIU/mL     | 100 Tests/Kit   |
|                        |                    | GAHCG-103d    | Midstream     | 30 mIU/mL     | 100 Tests/Kit   |
| GAFSH-101a/†           | Strip              | 25 mIU/mL     | 100 Tests/Kit |               |                 |
| GAFSH-102a/†           | Cassette           | 25 mIU/mL     | 25 Tests/Kit  |               |                 |
| IGAIF-1 PROM Test      | Cervical Secretion | GAIGF1-501a/† | Strip         | 25 ng/mL      | 25 Tests/Kit    |
|                        |                    | GAIGF1-502a/† | Cassette      | 25 ng/mL      | 20 Tests/Kit    |
| Male Fertility Test    | Semen              | GASPE-902a/†  | Cassette      | 15M/mL        | 1 Test/Kit      |

## Cardiac Marker

| Product Description                           | Specimen | Catalog No.   | Format   | Cut-off Value  | Kit Size     |
|---|----------|---------------|----------|----------------|--------------|
| CK-MB Test                                    | S/P      | GDCKM-302a/†  | Cassette | 5 ng/mL        | 25 Tests/Kit |
|   | WB/S/P   | GDCKM-402a/†  | Cassette | 5 ng/mL        | 25 Tests/Kit |
| CRP C-Reactive Protein Semi-Quantitative Test | WB/S/P   | GDGRP-402a/†  | Cassette | 1-3-10 mg/L    | 25 Tests/Kit |
| D-dimer Test                                  | WB/S/P   | GDDBI-402b/†  | Cassette | 10-40-80 ng/mL | 25 Tests/Kit |
| Myoglobin Test                                | WB/S/P   | GDMYO-402a/†  | Cassette | 500 ng/mL      | 25 Tests/Kit |
| Procalcitonin Test                            | WB/S/P   | GDPCIT-402a/† | Cassette | 0.5-2-10 ng/mL | 25 Tests/Kit |
| Troponin I Test                               | S/P      | GDTR0-302a/†  | Cassette | 0.5 ng/mL      | 25 Tests/Kit |
|   | WB/S/P   | GDTR0-402a/†  | Cassette | 0.5 ng/mL      | 25 Tests/Kit |
|   | WB/S/P   | GDTR0-402b/†  | Cassette | 0.5 ng/mL      | 25 Tests/Kit |
| Cardiac Myoglobin/CK-MB/cTnI Combo Test       | S/P      | GDGAR-335a/†  | Cassette | 50/5/0.5 ng/mL | 25 Tests/Kit |
|   | WB/S/P   | GDGAR-435a/†  | Cassette | 50/5/0.5 ng/mL | 25 Tests/Kit |
|   | WB/S/P   | GDGAR-W435a/† | Cassette | 50/5/0.5 ng/mL | 20 Tests/Kit |

## Urinalysis

| Product Description                | Specimen | Format | Cut-off Value                         | Kit Size           |
|------------------------------------|----------|--------|---------------------------------------|--------------------|
| Ascorbate/†                        | Urine    | Strip  | 0.5-0.6 mmol/L                        | 100 Tests/Canister |
| Bilirubin/†                        | Urine    | Strip  | 8.6-17 µmol/L                         | 100 Tests/Canister |
| Blood/†                            | Urine    | Strip  | 5-15 Ery/µL                           | 100 Tests/Canister |
| Ca/                                | Urine    | Strip  | 2.5 mmol/L                            | 100 Tests/Canister |
| Creatinine/                        | Urine    | Strip  | 50 mg/dL                              | 100 Tests/Canister |
| Glucose/†                          | Urine    | Strip  | 2.8-5.5 mmol/L                        | 100 Tests/Canister |
| Ketone/†                           | Urine    | Strip  | 0.5-1.0 mmol/L                        | 100 Tests/Canister |
| Leukocytes/†                       | Urine    | Strip  | 5-15 Leuko/µL                         | 100 Tests/Canister |
| Micro Albumin/                     | Urine    | Strip  | 0.08-0.15 mg/dL                       | 100 Tests/Canister |
| Nitrite/†                          | Urine    | Strip  | 13-22 µmol/L                          | 100 Tests/Canister |
| pH/†                               | Urine    | Strip  | 0.5                                   | 100 Tests/Canister |
| Protein/†                          | Urine    | Strip  | 0.15-0.3 g/L                          | 100 Tests/Canister |
| Specific Gravity/†                 | Urine    | Strip  | 0.005                                 | 100 Tests/Canister |
| Urobilinogen/†                     | Urine    | Strip  | 3.3-16 µmol/L                         | 100 Tests/Canister |
| Urinary Tract Infection Test Strip | Urine    | Strip  | LEU: 10-15 Leuko/µL NIT: 13-22 µmol/L | 3 Tests/Kit        |

## Tumor Marker

| Product Description                                  | Specimen | Catalog No.     | Format   | Cut-off Value     | Kit Size     |
|--|----------|-----------------|----------|-------------------|--------------|
| AFP Alpha Fetal Protein Test                         | S/P      | GEAFP-301a      | Strip    | 20 ng/mL          | 50 Tests/Kit |
|  |          | GEAFP-302a/†    | Cassette | 20 ng/mL          | 25 Tests/Kit |
|  |          | GEAFP-401a/†    | Strip    | 20 ng/mL          | 50 Tests/Kit |
|  |          | GEAFP-402a/†    | Cassette | 20 ng/mL          | 25 Tests/Kit |
| CEA Carcinoembryonic Antigen Test                    | S/P      | GECEA-301a      | Strip    | 5 ng/mL           | 50 Tests/Kit |
|  |          | GECEA-302a      | Cassette | 5 ng/mL           | 25 Tests/Kit |
|  |          | GECEA-401a/†    | Strip    | 5 ng/mL           | 50 Tests/Kit |
|  |          | GECEA-402a/†    | Cassette | 5 ng/mL           | 25 Tests/Kit |
|  |          | GEFOB-601b/†    | Strip    | 50 ng/mL          | 25 Tests/Kit |
|  |          | GEFOB-601Cb/†   | Strip    | 50 ng/mL          | 25 Tests/Kit |
| FOB Fecal Occult Blood Test                          | Feces    | GEFOB-601c/†    | Strip    | 100 ng/mL         | 25 Tests/Kit |
|  |          | GEFOB-601d      | Strip    | 200 ng/mL         | 25 Tests/Kit |
|  |          | GEFOB-602b/†    | Cassette | 50 ng/mL          | 20 Tests/Kit |
|  |          | GEFOB-602Cb/†   | Cassette | 50 ng/mL          | 20 Tests/Kit |
|  |          | GEFOB-602c/†    | Cassette | 100 ng/mL         | 20 Tests/Kit |
|  |          | GEFOB-602d      | Cassette | 200 ng/mL         | 20 Tests/Kit |
|  |          | GEFOB-602h      | Cassette | 150 ng/mL         | 20 Tests/Kit |
|  |          | GEFOB-602j/†    | Cassette | 10 ng/mL          | 20 Tests/Kit |
| FOB/Transferrin Combo Test                           | Feces    | GEFOB/TF-602a/† | Cassette | 50/10 ng/mL       | 20 Tests/Kit |
| Nuclear Matrix Protein 22 Test                       | Urine    | GENMP22-102a/†  | Cassette | 10 U/mL           | 25 Tests/Kit |
| PSA Prostate Specific Antigen Test                   | S/P      | GEPSA-301a/†    | Strip    | 4 ng/mL           | 50 Tests/Kit |
|  | WB/S/P   | GEPSA-302a/†    | Cassette | 4 ng/mL           | 25 Tests/Kit |
| PSA Prostate Specific Antigen Semi-Quantitative Test | S/P      | GEPSA-401a/†    | Strip    | 4 ng/mL           | 50 Tests/Kit |
|  | WB/S/P   | GEPSA-402a/†    | Cassette | 4 ng/mL           | 25 Tests/Kit |
| PSA Prostate Specific Antigen                        | S/P      | GEPSA-302b      | Cassette | 4 ng/mL, 10 ng/mL | 25 Tests/Kit |
|  | WB/S/P   | GEPSA-402b      | Cassette | 4 ng/mL, 10 ng/mL | 25 Tests/Kit |
| Transferrin Test                                     | Feces    | GETF-601a/†     | Strip    | 10 ng/mL          | 25 Tests/Kit |
|  |          | GETF-602a/†     | Cassette | 10 ng/mL          | 20 Tests/Kit |

## Veterinary

| Product Description   | Specimen   | Catalog No. | Format   | Label        | Cut-off Value | Kit Size     |
|---|------------|-------------|----------|--------------|---------------|--------------|
| Canine Adenovirus (CAV) Antigen Test  | Secretions | GFCV-502a   | Cassette | Gold         | /             | 10 Tests/Kit |
| Canine Coronavirus (CCV) Antigen Test   | Feces      | GFCCV-602a  | Cassette | Gold         | /             | 10 Tests/Kit |
|   |            | FFCCV-602a  | Cassette | Fluorescence | 10 IU         | 10 Tests/Kit |
| Canine Coronavirus (CCV) & Parvovirus (CPV) Antigen Combo Test                            | Feces      | GFCCP-T602a | Cassette | Gold         | /             | 10 Tests/Kit |
| Canine C-Reactive Protein (cCRP) Test   | WB/S/P     | FFCCR-402a  | Cassette | Fluorescence | 10 mg/L       | 10 Tests/Kit |
| Canine Distemper Virus (CDV) Antigen Test   | Secretions | GFCDV-502a  | Cassette | Gold         | /             | 10 Tests/Kit |
|   |            | FFCDV-502a  | Cassette | Fluorescence | 10 IU         | 10 Tests/Kit |
| Canine Distemper Virus (CDV), Influenza Virus (CIV) & Adenovirus (CAV) Antigen Combo Test | Secretions | GFCVIA-532a | Cassette | Gold         | /             | 10 Tests/Kit |
| Canine Influenza Virus (CIV) Antigen Test   | Secretions | GFCIV-502a  | Cassette | Gold         | /             | 10 Tests/Kit |
| Canine Parvovirus (CPV) Antigen Test  | Feces      | GFPCV-602a  | Cassette | Gold         | /             | 10 Tests/Kit |
| Canine Progesterone (cProg) Test  | WB/S/P     | FFCPR-402a  | Cassette | Fluorescence | 15 ng/mL      | 10 Tests/Kit |
| Feline Calicivirus (FCV) Antigen Test   | Secretions | GFCCV-502a  | Cassette | Gold         | /             | 10 Tests/Kit |
| Feline Coronavirus (FCoV) Antigen Test  | Feces      | GFCCO-602a  | Cassette | Gold         | /             | 10 Tests/Kit |
| Feline Herpes Virus (FHV) Antigen Test  | Secretions | GFFHV-502a  | Cassette | Gold         | /             | 10 Tests/Kit |
|   |            | FFFHV-502a  | Cassette | Fluorescence | 10 IU         | 10 Tests/Kit |
|   |            | FFFHV-602a  | Cassette | Gold         | /             | 10 Tests/Kit |
|   |            | FFFHV-602a  | Cassette | Fluorescence | 10 IU         | 10 Tests/Kit |
| Feline Parvovirus (FPV) Antigen Test  | Feces      | FFFPV-602a  | Cassette | Gold         | /             | 10 Tests/Kit |
|   |            | FFFPV-602a  | Cassette | Fluorescence | 10 IU         | 10 Tests/Kit |
| Feline Parvovirus (FPV) & Coronavirus (FCoV) Antigen Combo Test                           | Feces      | GFPPV-622a  | Cassette | Gold         | /             | 10 Tests/Kit |
| Feline Serum Amyloid A (fSAA) Test  | WB/S/P     | FFSAA-402a  | Cassette | Fluorescence | 5 mg/L        | 10 Tests/Kit |
| Toxoplasma (Toxo) IgG/IgM Test  | WB/S/P     | GFTOX-402a  | Cassette | Gold         | /             | 10 Tests/Kit |

## Non-Infectious Disease

| Product Description | Specimen          | Catalog No.             | Format   | Cut-off Value | Kit Size           |
|---------------------|-------------------|-------------------------|----------|---------------|--------------------|
| Micro-Albumin Test  | Urine             | GIHSA-101a/†            | Strip    | 20 µg/mL      | 100 Tests/Kit      |
|                     |                   | GIHSA-102a              | Cassette | 20 µg/mL      | 25 Tests/Kit       |
| Vaginal pH Test     | Vaginal Secretion | VPH-501a <sup>new</sup> | Strip    | 3.8-4.4       | 100 Tests/Canister |

## Autoimmunity

| Product Description        | Specimen | Catalog No.    | Format   | Kit Size     |
|----------------------------|----------|----------------|----------|--------------|
| Rheumatoid Factor IgM Test | S/P      | GCRF(IgM)-302a | Cassette | 25 Tests/Kit |
| Total IgE Test             | S/P      | GGIGE-302a     | Cassette | 25 Tests/Kit |

## Instrument

| Product Description                          | Model         |
|--|---------------|
| Urine Analyzer                               | Healgen 500/† |
| Urine Analyzer                               | Healgen 501/† |
| Colloidal Gold Test Reader                   | OG-D180       |
| Handheld Oral Fluid Drug Test Reader         | OG-D200       |
| Multi-Function Colloidal Gold Test Reader    | OG-D600       |
| Fluorescence Immunoassay Analyzer            | OG-G200       |
| Handheld Fluorescence Immunoassay Analyzer   | OG-G300       |
| Mini Immunofluorescence Analyzer             | OG-H100/†     |
| Veterinary Fluorescence Immunoassay Analyzer | OG-V100       |

†CE Marked †Cleared for US 510(k) In Specimen column: WB: Whole Blood S: Serum P: Plasma



Zhejiang Orient Gene Biotech Co., Ltd was founded in December 2005 and listed on the SEE STAR Market on February 5, 2020 (securities code: 688298). Orient Gene specializes in R&D, production and sales of in vitro diagnostic products, mainly covering infectious diseases (including COVID-19 test series), toxicology, tumor markers, cardiac markers and fertility testing, etc. Through 16 years of technology accumulation and continuous investment in R&D, the Company has independently developed hundreds of products. The company own more than 200 authorized patents, and has obtained more than 500 product medical device certifications at home and abroad. The Company's sales network covers more than 100 countries, products are mainly sold to Europe, America and other developed countries.

Healgen Scientific LLC, a wholly owned subsidiary of Zhejiang Orient Gene Biotech Co., Ltd develops, manufactures and commercializes in vitro diagnostic test systems worldwide. Our product portfolio spans multiple testing categories and analytes to meet various clinical and laboratory needs.

Healgen Scientific Limited Liability Company  
 Add: 3818 Fuqua Street, Houston, TX77047, USA.  
 Tel: +1 713-733-8088  
 Toll free: 866 982 3818  
 Fax: +1 713-733-8848

E-mail: [Healgensales@healgen.us](mailto:Healgensales@healgen.us) (For South America and North America)  
 Web: <http://www.healgen.com>

Zhejiang Orient Gene Biotech Co., Ltd  
 Add: 3787#, East Yangguang Avenue, Dipu Street,  
 Anji, Huzhou, Zhejiang, China.  
 P.C.: 313300  
 Tel: +86-572-5303755/5303756  
 Fax: +86-572-5226222  
 E-mail: [sales@orientgene.com](mailto:sales@orientgene.com) (For rest of world)  
 Web: <http://www.orientgene.com>

Rev.08/2022

# PRODUCT CATALOG

Enhancing  
Global Health

