



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



CE-DOC-OG080
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Influenza A & B Ag Rapid Test Strip (Swab)	GCFLU(A/B)-501a
Influenza A & B Ag Rapid Test Cassette (Swab)	GCFLU(A/B)-502a

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: *Shanghai International Holding Corp. GmbH (Europe)*

EC Representative's Address: *Eiffestrasse 80, 20537 Hamburg, Germany*

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: November 7, 2017

Name of authorized signatory: *Joyce Pang*
Position held in the company: *Vice-President*



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



CE-DOC-OG266
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Strep A Rapid Test Strip (Throat Swab)	GCSTR-501a
Strep A Rapid Test Cassette (Throat Swab)	GCSTR-502a

Classification: Other
Conformity assessment route: Annex III (EC DECLARATION OF CONFORMITY)

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: CMC Medical Devices & Drugs S.L

EC Representative's Address: C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: May 20, 2022

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President



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

Report No.: SH2198802

Valid from: 2022-04-11

Valid until: 2024-03-16

Date, 2022-04-11

Christoph Dicks

Head of Certification/Notified Body

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



[Handwritten signature in blue ink]

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Strep A Rapid Test Cassette (Throat Swab)



INTENDED USE

The Strep A Rapid Test Cassette (Throat Swab) is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

INTRODUCTION

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.¹ Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.² Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.^{3,4} The Strep A Rapid Test Cassette (Throat Swab) is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a throat swab specimen.

PRINCIPLE

The Strep A Rapid Test Cassette (Throat Swab) is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED

1. 20 Test cassettes
2. 20 Sterile swabs
3. 20 Extraction tubes and tips
4. 1 Workstation and 1 package insert
5. 1 Reagent B (0.2M acetic acid): 10.0 mL

6. 1 Reagent A (2M sodium nitrite): 10.0 mL



Harmful if swallowed.
Wash thoroughly after handling.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect results.
6. Do not use test if pouch is damaged.
7. Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
8. Do not interchange reagent bottle caps.
9. Do not interchange external control solution bottle caps.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

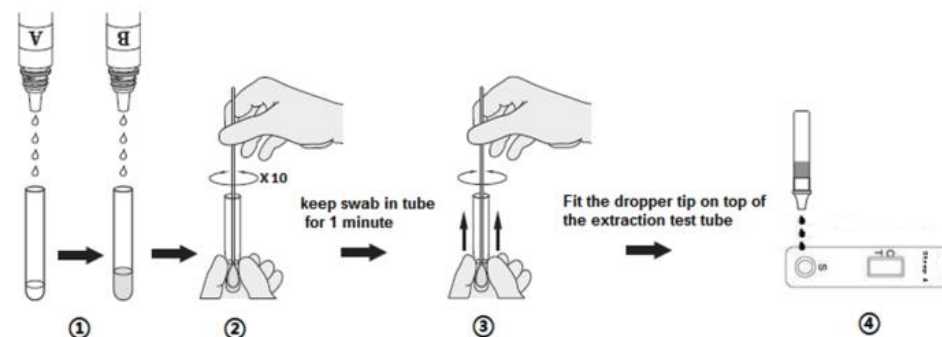
1. Only use reagents and sterile swabs provided in the kit.
2. Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.⁵

3. Testing should be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C. Transport swabs containing modified Stuart's or Amies medium can also be used with this product.
4. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Rapid Test Cassette (Throat Swab).

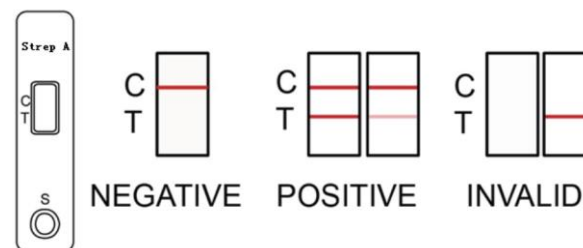
TEST PROCEDURE

Allow the test device, reagents, throat swab specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Hold the Reagent A bottle vertically and add 4 full drops of Reagent A to an extraction tube. Reagent A is red in color. Hold the Reagent B bottle vertically and add 4 full drops to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction tube. The addition of Reagent B to Reagent A changes the color of the solution from red to yellow.
3. Immediately add the throat swab to the extraction tube of yellow solution. Agitate the swab 10 times in the tube. Leave the swab in the tube for 1 minute. Then press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab.
4. Fit the dropper tip on top of the extraction tube. Place the test device on a clean and level surface. Add 3 full drops of solution to the specimen well (S) and then start the timer.
5. Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes.



INTERPRETATION OF RESULTS



Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

Negative: One coloured line appears in the control line region (C). No line appears in the test line region (T).

Invalid: Control line fails to appear.

NOTE: Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The Strep A Rapid Test Cassette (Throat Swab) is for *in vitro* diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A streptococcus bacteria.
3. A negative result must be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.
4. The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth⁵ and any bleeding areas of the mouth with the swab when collecting specimens. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity and Specificity

The Strep A Rapid Test Cassette (Throat Swab) was used to evaluate 368 throat swab specimens collected from three physician offices patients presenting with pharyngitis. The test result compared to the culture method. The below table summarizes the data.

Clinical Performance: Strep A Rapid Test vs. Culture

Strep A Rapid Test Cassette (Throat Swab) Results	Reference Culture Results		Total
	Positive	Negative	
Positive	200	1	201
Negative	6	161	167
Total	206	162	368

Sensitivity: 97.1% (200/206); 95%CI = 93.7% - 98.8%

Specificity: 99.4% (161/162); 95%CI = 96.2% - 100.0%

Clinical Performance Stratified by Age

Age	Sensitivity	Sensitivity(95%CI)	Specificity	Specificity(95%CI)
0 ~ 5	97.4% (74/76)	90.4% - 99.8%	98.1% (52/53)	89.1% - 100.0%
5+ ~ 21	96.7% (119/123)	91.7% - 99.0%	100% (88/88)	95.0% - 100.0%
21+	100% (7/7)	59.6% - 100.0%	100% (21/21)	81.8% - 100.0%
All	97.1% (200/206)	93.7% - 98.8%	99.4% (161/162)	96.2% - 100.0%

Cross-Reactivity

The following organisms were tested at 1.0×10^7 organisms per test and were all found to be negative when tested with the Strep A Rapid Test Cassette (Throat Swab). No mucoid-producing strains were tested.

Group B Streptococcus	Neisseria meningitidis	Serratia marcescens
Group F Streptococcus	Neisseria sicca	Klebsiella pneumoniae
Streptococcus pneumoniae	Branhamella catarrhalis	Bordetella pertussis
Streptococcus mutans	Group C Streptococcus	Neisseria gonorrhea
Staphylococcus aureus	Group G Streptococcus	Neisseria subflava
Corynebacterium diphtheria	Streptococcus sanguis	Hemophilus influenza
Candida albicans	Enterococcus faecalis	
Pseudomonas aeruginosa	Staphylococcus epidermidis	

Physician's Office Laboratory (POL) Studies

Three physicians' offices were used to conduct an evaluation of the Strep A Rapid Test Cassette (Throat Swab). Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (20), low positive (20), and medium positive (20) for three days. The results obtained had a 96% correlation with the expected results.

REFERENCE

1. Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C. p. 299-307.
2. Webb, KH. Does Culture Confirmation of High-sensitivity Rapid Streptococcal Tests Make Sense? A Medical Decision Analysis. Pediatrics (Feb 1998), 101: 2, 2.
3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Diagnosis and Management of Group A Streptococcal Pharyngitis. Clinical Infectious Diseases (1997), 25: 574-83.
4. Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High-sensitivity Antigen Test

on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468-3473.

5. Shea, Y.R., Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1-1.1.30, 1992.
6. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
7. Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA. Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999), 491-492.

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#

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GCSTR-502a

Swab information

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Email-info@llins-service.com

Revision Date: 2022-04-12
B20402-04

Influenza A & B Ag Rapid Test Cassette (Swab) (C)

INTENDED USE

The Influenza A & B Ag Rapid Test Cassette (Swab) is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A (including the subtype H1N1) and B nucleoprotein antigens in nasopharyngeal swabs, nasal swabs, throat swabs or nasal aspirates specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

SUMMARY AND EXPLANATION

Influenza is an acute and highly contagious viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA virus known as influenza viruses. There are three types of influenza viruses: A, B and C.

Type A Viruses are the most prevalent and are associated with most serious epidemics, while Type B infection is generally milder. Type C virus have never been associated with a large epidemic of human disease. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season and particular epidemic area. The disease is easily transmitted through coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks normally occur each year during fall and winter seasons. Rapid diagnosis of influenza infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

PRINCIPLE OF THE TEST

The Influenza A&B Ag Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in nasopharyngeal swabs, nasal swabs, throat swabs or nasal aspirates specimens. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against Influenza virus A and B; the reaction membrane contains the secondary antibodies either for virus A or for B. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If influenza A presents in the sample, a complex formed between the anti-influenza A conjugate and the virus will be captured by the specific anti-influenza A monoclonal antibodies coated on the A region (A). If the sample contains influenza B, a complex formed between the anti-influenza B conjugate and the virus will be captured by the specific anti-influenza B monoclonal antibodies coated on the B region (B).

Results appear at 10 minutes in the form of a red line that develops on the membrane. To serve as a procedural control, a red line will always appear in the control region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

MATERIALS PROVIDED

20 Test cassettes
20 Sterile swabs
20 Extraction tubes and tips
1 Workstation
2 Buffers
1 Package inset

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock, timer, or stopwatch

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. The test cassette should remain in the sealed pouch until use.
3. Do not use kit past its expiration date.
4. Swabs, tubes and test cassettes are for single use only.
5. Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
6. Do not interchange or mix components from different kit lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C).
2. Do not freeze any of the test kit components.
3. Do not use test cassette and reagents after expiration date.
4. Test cassettes that have been outside of the sealed pouch for more than 1 hour should be discarded.
5. Close the kit box and secure its contents when not in use.

SPECIMEN COLLECTION

It is applicable to the diagnosis of the influenza virus A and B from the samples of nasopharyngeal swabs, nasal swabs, throat swabs or nasal aspirates. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

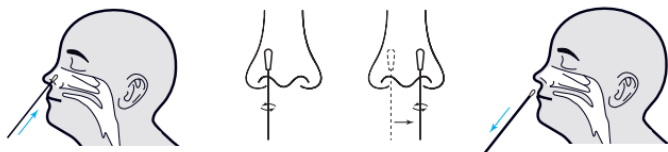
For Nasopharyngeal Swab Specimen Collection:

1. Using the sterile swab provided in the kit, carefully insert the swab in the patient's nostril.
2. Swab over the surface of the posterior nasopharynx and rotate the swab several times.
3. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer provided in the test kit.



For Nasal Swab Specimen Collection:

1. Using the sterile swab provided in the kit, carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2-4 cm until resistance is met.
2. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
3. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
4. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the Influenza A & B Ag Rapid Test Cassette (Swab).



For Throat Swab Specimen Collection:

1. Deeply insert the sterilized swab into the throat and swab several times to collect the epidermal cells of the mucus. Caution has to be paid to avoid the swab to be contaminated with saliva.
2. Withdraw the swab from the throat. The sample is now ready for processing using the Influenza A & B Ag Rapid Test Cassette (Swab).



For Nasal Aspirates Specimen Collection:

Nasal aspirator is not provided in the kit. Collect nasal aspirate fluids according to the instructions for use of the used nasal aspirator.



SAMPLE PREPARATION PROCEDURE

Insert the test extraction tube into the workstation provided in the kit. Make sure that the tube is standing upright and reaches the bottom of the workstation. Add the sample buffer to extraction tube until it reaches the lower mark (about 13-17 drops, 0.5 mL)

For nasopharyngeal, nasal or throat swabs:

Insert the swab into the extraction tube which contains 0.5 mL of the extraction buffer. After mixing, squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.

For nasal aspirate fluids:

Add 0.5 mL of the nasal aspirate fluids into the extraction tube which contains 0.5 mL of the extraction buffer, and mix well to be used as test sample.

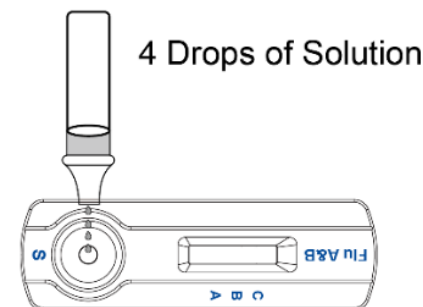
SPECIMEN TRANSPORT AND STORAGE

Specimens should be tested as soon as possible after collection. If transport of the samples is required, the following transport media are recommended and have been tested and shown not to interfere with the performance of the test: Hank's Balanced salt solution, M5 Media, or saline. Alternatively, samples may be stored refrigerated (2-8°C), or at room temperature (15-30°C), in a clean, dry, closed container for up to eight hours prior to testing. Nasal wash/aspirate specimens may also be stored frozen (-70°C or colder) for up to one month.

TEST PROCEDURE

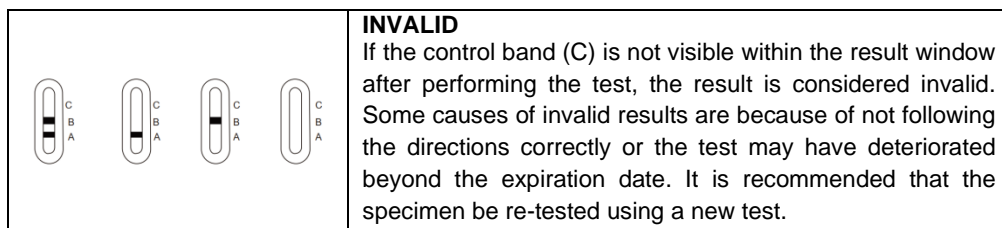
Allow the test cassette, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Just prior to testing remove the test cassette from the sealed pouch and lay it on a flat surface.
2. Push the nozzle which contains the filter onto the extraction tube. Ensure the nozzle has a tight fit.
3. Hold the extraction tube vertically and add 4 drops (approximately 100 µL) of test sample solution tube into the sample well.
4. Start the timer.
5. Read the results at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

<p>(+) (+) (+)</p> <p>Flu A+B Flu B Flu A</p>	<p>POSITIVE</p> <p>1. Flu A Positive: The presence of two lines as control line (C) and A test line within the result window indicates a positive result for Influenza A viral antigen.</p> <p>2. Flu B Positive: The presence of two lines as control line (C) and B test line within the result window indicates a positive result for Influenza B viral antigen.</p> <p>3. Flu A+B Positive: The presence of three lines as control line (C), A test line and B test line within the result window indicates a positive result for Influenza A and Influenza B viral antigen.</p>
<p>(-)</p>	<p>NEGATIVE</p> <p>The presence of only control band (C) within the result window indicates a negative result.</p>



NOTE:

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

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The Influenza A&B Ag Rapid Test Cassette (Swab) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of influenza A and/or B.
2. The etiology of respiratory infection caused by microorganisms other than influenza A or B virus will not be established with this test. The Influenza A&B Ag Rapid Test Cassette (Swab) is capable of detecting both viable and non-viable influenza particles. The performance of the Influenza A&B Ag Rapid Test depends on antigen load and may not correlate with cell culture performed on the same specimen.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of influenza A and/or B viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The validity of Influenza A&B Ag Rapid Test Cassette (Swab) has not been proven for identification or confirmation of cell culture isolates.
5. Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test result.
6. Although this test has been shown to detect cultured avian influenza viruses, including avian influenza A subtype H5N1 virus, the performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.
7. Performance characteristics for influenza A were established when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.
8. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.
9. Positive and negative predictive values are highly dependent on prevalence. False positive

test results are more likely during periods of low influenza activity when prevalence is moderate to low.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity

The minimum detection limit is 1.5×10^4 TCID₅₀/test for the Influenza A virus antigen and is 1.5×10^5 TCID₅₀/test for the Influenza B virus antigen.

2. Analytical Reactivity

The influenza A strain listed tested positive in the Influenza A&B Ag Rapid Test Cassette (Swab). Although the specific influenza strains causing infection in human can vary, all contain the conserved nucleoproteins targeted by Influenza A&B Ag Rapid Test Cassette (Swab).

Strains	Sources	Subtypes	Concentration
Flu A/Hubei/PR 8/2001	Human	H1N1	1.8×10^4 TCID ₅₀ /test
Flu A/New Kaledonia/20/99	Human	H1N1	1.8×10^4 TCID ₅₀ /test
Flu A/Yamagata/32/89	Human	H1N1	1.8×10^4 TCID ₅₀ /test
Flu A/Beijing/262/95	Human	H1N1	1.8×10^4 TCID ₅₀ /test
Flu A/Singapore/1/57	Human	H2N2	3.0×10^4 TCID ₅₀ /test
Flu A/Hubei/3/2005	Human	H3N2	3.0×10^4 TCID ₅₀ /test
Flu A/Akita/1/94	Human	H3N2	3.0×10^4 TCID ₅₀ /test
Flu A/Iowa/15/30	Swine	H1N1	3.0×10^4 TCID ₅₀ /test
Flu A/Hongkong/168/93	Swine	H1N1	3.0×10^4 TCID ₅₀ /test
Flu A/Anhui/24/2004	Swine	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Hubei/134/2000	Swine	H9N2	6.0×10^5 TCID ₅₀ /test
Flu A/Hubei/251/2001	Swine	H9N2	6.0×10^5 TCID ₅₀ /test
Flu A/Yuyao/1/2006	Chicken	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Yuyao/2/2006	Chicken	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Jiangsu/2/2004	Chicken	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Hubei/216/83	Duck	H7N8	3.0×10^5 TCID ₅₀ /test
Flu A/Hubei/118/2003	Duck	H9N2	1.5×10^5 TCID ₅₀ /test
Flu A/Hubei/155/2003	Duck	H9N2	6.0×10^5 TCID ₅₀ /test
Flu A/Hubei/137/1982	Duck	H10N4	3.0×10^5 TCID ₅₀ /test
Flu A/Singapore/3/97	Duck	H5N3	6.0×10^4 TCID ₅₀ /test
Flu A/Henan/1/2004	Tree sparrow	H5N1	6.0×10^5 TCID ₅₀ /test
Flu A/Henan/2/2004	Tree sparrow	H5N1	3.0×10^5 TCID ₅₀ /test
Flu A/Henan/4/2004	Tree sparrow	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Wisconsin/66	Turkey	H9N2	6.0×10^4 TCID ₅₀ /test
Flu A/England/1/63	Turkey	H7N3	6.0×10^4 TCID ₅₀ /test
Flu A/Singapore/1/57	Bird	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Hunan/71/2004	Bird	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Shanxi/50/2006	Bird	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Shanxi/42/2006	Bird	H5N1	6.0×10^4 TCID ₅₀ /test
Flu A/Fujian/320/2004	Bird	H5N1	3.0×10^5 TCID ₅₀ /test

Influenza A&B Ag Rapid Test Cassette (Swab) can detect all nine influenza B strains.

3. Clinical Study Data Summary

The Influenza A&B Ag Rapid Test performance vs. Cell Culture

Kind of samples	Type	Sensitivity (%)	Specificity (%)	Accuracy (%)
Nasopharyngeal/Nasal Swab	A	92.6 (25/27)	96.4 (81/84)	95.5 (106/111)
	B	90.0 (27/30)	95.8 (91/95)	94.4 (118/125)

Throat Swab	A	83.3 (20/24)	95.2 (59/62)	91.9 (79/86)
	B	82.6 (19/23)	91.8 (67/73)	89.6 (86/96)
Nasal Aspirate	A	88.9 (48/54)	93.3 (125/134)	92.0 (173/188)
	B	91.2 (52/57)	95.4 (98/103)	93.8 (150/160)

4. Analytical Specificity and Cross-reactivity

The Influenza A&B Ag Rapid Test Cassette (Swab) was evaluated with a total of 30 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration between 10^7 and 10^9 or g/mL. Viral isolates were evaluated at a concentration of at least 10^4 - 10^8 TCID₅₀/mL. Adenovirus 18 and Parainfluenza virus 3 were tested at 10^2 TCID₅₀/mL. None of the organisms or viruses listed below gave a positive result in the Influenza A&B Ag Rapid Test Cassette (Swab).

Bacterial Panel:

Acinetobacter calcoaceticus	Bacteroides fragilis
Neisseria gonorrhoeae	Neisseria meningitidis
Pseudomonas aeruginosa	Staphylococcus aureus
Streptococcus pneumoniae	Streptococcus sanguis
Proteus vulgaris	Streptococcus sp. Gp. B
Streptococcus sp. Gp. C	Streptococcus sp. Gp. G
Mycobacterium tuberculosis	Mycoplasma orale

Viral Panel:

Human Adenovirus B	Human Rhinovirus 2
Human Adenovirus C	Human Rhinovirus 14
Adenovirus type 10	Human Rhinovirus 16
Adenovirus type 18	Measles
Human Coronavirus OC43	Mumps
Human Coxsackievirus A9	Sendai virus
Coxsackievirus B5	Parainfluenza virus 2
Human herpesvirus2	Parainfluenza virus 3










5. Interfering Substances


Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the Influenza A&B Ag Rapid Test Cassette (Swab) at the levels tested: whole blood (2%); three OTC mouthwashes (25%); three OTC throat drops (25%); three OTC nasal sprays (10%); 4-Acetamidophenol (10 mg/mL); Acetylsalicylic Acid (20 mg/mL); Chlorpheniramine (5 mg/mL); Dextromethorphan (10 mg/mL); Diphenhydramine (5 mg/mL); Ephedrine (20 mg/mL); Guaiacol glyceryl ether (20 mg/mL); Oxymetazoline (10 mg/mL); Phenylephrine (100 mg/mL); and Phenylpropanolamine (20 mg/mL).


REFERENCES

1. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children: Impact on Physician Decision Making and Cost. Infect. Med. 19(3): 109-111.
2. Dowdle, W.R, Kendal, A.P., and Noble, G.R. (1980). Influenza Virus, p 836-844. Manual of Clinical Microbiology, 3rd edition, in Lennette, et. al (ed.). American Society for Microbiology, Washington, D.C.
3. "Key Facts about Avian Influenza (Bird Flu) and Avian Influenza A (H5N1) Virus" CDC Publication, May 24, 2005. <http://www.cdc.gov/flu/avian/gen-info/facts.htm>
4. "Avian Influenza Infection in Humans" CDC Publication, May 24, 2005. <http://www.cdc.gov/flu/avian/gen-info/avian-flu-humans.htm>
5. "Updated Interim Guidance for Laboratory Testing of Persons with Suspected Infection with Avian Influenza A (H5N1) Virus in the United States" CDC Health Alert, June 7, 2006. <http://www.phppo.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00246>

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

 Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffelstrasse 80, 20537 Hamburg, Germany

 GCFLU(A/B)-502a

Revision Date: 2022-11-14
B21900-03

Toxicology Urine Test



Product Description	Format	Cut-off Value	Qualification
Acetaminophen (ACE) Test	Strip/Cassette/Dip Card/Cup	5000 ng/mL	CE
Amphetamine (AMP) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Barbiturates (BAR) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/200 ng/mL	CE 510(k)
Benzodiazepines (BZO) Test	Strip/Cassette/Dip Card/Cup	600/400/300/200/100 ng/mL	CE 510(k)
Buprenorphine (BUP) Test	Strip/Cassette/Dip Card/Cup	10/5 ng/mL	CE 510(k)
Caffeine (CAF) Test	Strip/Cassette/Dip Card/Cup	6000 ng/mL	/
Carisoprodol (SOMA) Test	Strip/Cassette/Dip Card/Cup	1000 ng/mL	CE
Clonazepam (CLO) Test	Strip/Cassette/Dip Card/Cup	500/100 ng/mL	CE
Cocaine (COC) Test	Strip/Cassette/Dip Card/Cup	600/300/150/100 ng/mL	CE 510(k)
Codeine (COD) Test	Strip/Cassette/Dip Card/Cup	2000 ng/mL	CE
Cotinine (COT) Test	Strip/Cassette/Dip Card/Cup	400/300/200/100/50 ng/mL	CE
Ecstasy (MDMA) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250/150 ng/mL	CE 510(k)
Ethyl Glucuronide (EtG) Test	Strip/Cassette/Dip Card/Cup	500/300ng/mL	CE
Fentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	300/200/100/50 ng/mL	CE
Norfentanyl (FEN) Test	Strip/Cassette/Dip Card/Cup	200/50/20/10/5 ng/mL	CE
Gabapentin (GAB) Test	Strip/Cassette/Dip Card/Cup	3750/2000/1000 ng/mL	CE
Hydrocodone (HCD) Test	Strip/Cassette/Dip Card/Cup	300/10 ng/mL	CE
Hydromorphone (HMO) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
Ketamine (KET) Test	Strip/Cassette/Dip Card/Cup	3000/2000/1000/500/100 ng/mL	CE
Kratom (KRA) Test	Strip/Cassette/Dip Card/Cup	250/150/100 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Strip/Cassette/Dip Card/Cup	20 ng/mL	CE
Marijuana (THC) Test	Strip/Cassette/Dip Card/Cup	600/300/200/150/100/50/40/25/20/18/15 ng/mL	CE 510(k)
Methadone Metabolite (EDDP) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Methadone (MTD) Test	Strip/Cassette/Dip Card/Cup	1000/600/300/200/50 ng/mL	CE 510(k)
Methamphetamine (MET) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500/300/250 ng/mL	CE 510(k)
Methaqualone (MQL) Test	Strip/Cassette/Dip Card/Cup	300/1000 ng/mL	CE
Methcathinone (MTC) Test	Strip/Cassette/Dip Card/Cup	500/300 ng/mL	CE
3,4-Methylenedioxypropylvalerone (MDPV) Test	Strip/Cassette/Dip Card/Cup	1000/500/300 ng/mL	CE
Methylphenidate (MPD) Test	Strip/Cassette/Dip Card/Cup	300 ng/mL	CE
6-Monoacetylmorphine (6-MAM) Test	Strip/Cassette/Dip Card/Cup	20/10 ng/mL	CE
Morphine (MOP) Test	Strip/Cassette/Dip Card/Cup	2000/600/300/150/100 ng/mL	CE 510(k)
Opiate (OPI) Test	Strip/Cassette/Dip Card/Cup	2000/300/100 ng/mL	CE 510(k)
Oxycodone (OXY) Test	Strip/Cassette/Dip Card/Cup	300/100 ng/mL	CE 510(k)
Phencyclidine (PCP) Test	Strip/Cassette/Dip Card/Cup	50/25 ng/mL	CE 510(k)
Pinaca Ab (K3) Test	Strip/Cassette/Dip Card/Cup	10 ng/mL	CE
Pregabalin (PGB) Test	Strip/Cassette/Dip Card/Cup	2000/1000/500 ng/mL	CE
Propoxyphene (PPX) Test	Strip/Cassette/Dip Card/Cup	600/300 ng/mL	CE 510(k)
Synthetic Marijuana (K2) Test	Strip/Cassette/Dip Card/Cup	75/50/25/20/10 ng/mL	CE
Tramadol (TRA) Test	Strip/Cassette/Dip Card/Cup	200/100 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Strip/Cassette/Dip Card/Cup	1000/300 ng/mL	CE 510(k)
UR-144 Test	Strip/Cassette/Dip Card/Cup	50 ng/mL	CE
Zolpidem (ZOL) Test ^{New}	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Zopiclone (ZOP) Test ^{New}	Strip/Cassette/Dip Card/Cup	50 ng/mL	/
Alcohol (ALC) Test	Strip/Cassette/Dip Card/Cup	0.04%	CE

Toxicology Saliva Test



Product Description	Format	Cut-off Value	Qualification
7-Aminoclonazepam (ACL) Test ^{New}	Device	100 ng/mL	/
Amphetamine (AMP) Test	Device	50/40 ng/mL	CE
Barbiturates (BAR) Test	Device	300/50/30 ng/mL	CE
Benzodiazepines (BZO) Test	Device	50/20/10 ng/mL	CE
Buprenorphine (BUP) Test	Device	10/5 ng/mL	CE
Carisoprodol (SOMA) Test	Device	300 ng/mL	/
Cocaine (COC) Test	Device	50/20 ng/mL	CE
Codeine (COD) Test	Device	10 ng/mL	CE
Cotinine (COT) Test	Device	50/30/10 ng/mL	CE
Diphenhydramine (DIP) Test ^{New}	Device	150/100 ng/mL	/
Ecstasy (MDMA) Test	Device	60/50 ng/mL	CE
Ethyl Glucuronide (EtG) Test ^{New}	Device	150/100 ng/mL	/
Fentanyl (FEN) Test	Device	10 ng/mL	CE
Hydrocodone (HCD) Test ^{New}	Device	10 ng/mL	/
Hydromorphone (HMO) Test ^{New}	Device	300/150 ng/mL	/
Ketamine (KET) Test	Device	100/50 ng/mL	CE
Lysergic acid diethylamide (LSD) Test	Device	25/10 ng/mL	CE
Marijuana (THC) Test	Device	50/40/30/25/15/12/10/5/4/3 ng/mL	CE
Methadone Metabolite (EDDP) Test	Device	20 ng/mL	CE
Mephedrone (MEP) Test ^{New}	Device	50 ng/mL	/
Methadone (MTD) Test	Device	75/50/30 ng/mL	CE

Methamphetamine (MET) Test	Device	50 ng/mL	CE
Methaqualone (MQL) Test	Device	150/100 ng/mL	CE
Methcathinone (MTC) Test	Device	50 ng/mL	/
3,4-Methylenedioxypropylvalerone (MDPV) Test	Device	200/100/50 ng/mL	CE
Methylphenidate (MPD) Test	Device	50 ng/mL	/
6-Monoacetylmorphine (6-MAM) Test	Device	25/15/10/5/4 ng/mL	CE
Morphine (MOP) Test	Device	15 ng/mL	CE
Opiate (OPI) Test	Device	50/40 ng/mL	CE
Oxycodone (OXY) Test	Device	50/40/20 ng/mL	CE
Phencyclidine (PCP) Test	Device	10 ng/mL	CE
Phenytoloin (PHEN) Test ^{New}	Device	150/100 ng/mL	/
Pinaca Ab (K3) Test ^{New}	Device	10 ng/mL	/
Pregabalin (PGB) Test ^{New}	Device	100 ng/mL	/
Propoxyphene (PPX) Test	Device	50/20 ng/mL	CE
Synthetic Marijuana (K2) Test	Device	25/10/5 ng/mL	CE
Tramadol (TRA) Test	Device	100/50 ng/mL	CE
Tricyclic Antidepressants (TCA) Test	Device	100 ng/mL	CE
XLR-11 Test ^{New}	Device	100 ng/mL	/
Zolpidem (ZOL) Test ^{New}	Device	25 ng/mL	/
Zopiclone (ZOP) Test ^{New}	Device	25 ng/mL	/
Alcohol (ALC) Test	Device	0.05/0.02%	CE

Toxicology Hair Test



Product Description	Format	Label	Cut-off Value	Qualification
Amphetamine (AMP) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5 ng/mg	/
Benzodiazepines (BZO) Test	Cassette	Fluorescence	0.2 ng/mg	/
		Gold	1 ng/mg	/
Cocaine (COC) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2 ng/mg	CE
Ecstasy (MDMA) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	5 ng/mg	/
2-Fluorodeschloroketamin (FKE) Test	Cassette	Fluorescence	0.2 ng/mg	/
Ketamine (KET) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Gold	2/1/0.5 ng/mg	CE
Marijuana (THC) Test	Cassette	Fluorescence	0.05 ng/mg	CE
		Gold	2/1.5 ng/mg	CE
Methamphetamine (MET) Test	Cassette	Fluorescence	0.5/0.2 ng/mg	CE
		Gold	5/2/1 ng/mg	CE
Methcathinone (MTC) Test	Cassette	Fluorescence	0.2 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
6-Monoacetylmorphine (6-MAM) Test	Cassette	Gold	2 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
Morphine (MOP) Test	Cassette	Gold	5/2/0.5 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
Oxycodone (OXY) Test	Cassette	Gold	4 ng/mg	/
		Fluorescence	0.3 ng/mg	CE
Phencyclidine (PCP) Test	Cassette	Gold	1 ng/mg	CE
		Fluorescence	0.2 ng/mg	CE
Pinaca Ab (K3) Test	Cassette	Gold	0.5 ng/mg	/
		Fluorescence	0.2 ng/mg	CE
Synthetic Marijuana (K2) Test	Cassette	Gold	1 ng/mg	/
Tramadol (TRA) Test	Cassette	Fluorescence	0.2 ng/mg	/
UR-144 Test	Cassette	Fluorescence	0.05 ng/mg	/

Infectious Disease



Product Description	Specimen	Catalog No.	Format	Cut-off Value	Kit Size
Adenovirus Antigen Test	Swab	GCADE-502a√	Cassette	/	20 Tests/Kit
Adenovirus Test	Feces	GCADE-602a√	Cassette	/	20 Tests/Kit
Brucella Antibody Test	WB/S/P	GCBRU-402a√	Cassette	/	25 Tests/Kit
Candida albicans Test	Vaginal Secretion	GCCA-502a√	Cassette	10 ⁶ CFU/mL	20 Tests/Kit
Chagas Antibody Test	S/P	GCCHA-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHA-402a√	Cassette	/	25 Tests/Kit
Clostridium difficile GDH Test	Feces	GCDD(GDH)-602a√	Cassette	2 ng/mL	20 Tests/Kit
Clostridium difficile Toxin A/B Test	Feces	GCDD(Toxin A/B)-602a√	Cassette	Toxin A: 2 ng/mL Toxin B: 2 ng/mL	20 Tests/Kit
Clostridium difficile GDH & Toxin A/B Combo Test	Feces	GCCD-625a√	Cassette	Toxin A: 2 ng/mL Toxin B: 2 ng/mL	20 Tests/Kit
Chikungunya IgM Test	S/P	GCCHK(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCCHK(IgM)-402a√	Cassette	/	25 Tests/Kit

Chikungunya IgG/IgM Test	WB/S/P	GCCHK(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
Chlamydia Test	Swab/Urine	GCCHL-502a√	Cassette	4.8×10 ³ IFU/mL	20 Tests/Kit
CMV IgG Test	S/P	GCCMV(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCCMV(IgG)-402a	Cassette	/	25 Tests/Kit
	S/P	GCCMV(IgM)-302a	Cassette	/	25 Tests/Kit
CMV IgM Test	WB/S/P	GCCMV(IgM)-402a	Cassette	/	25 Tests/Kit
	S/P	GCCMV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
CMV IgG/IgM Test	WB/S/P	GCCMV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
COVID-19 IgM/IgG Test	WB/S/P	GCCOV-402a√	Cassette	/	25 Tests/Kit
COVID-19 Neutralizing Antibody Test	WB/S/P	GCCOV(NAB)-402b√	Cassette	/	25 Tests/Kit
		GCCOV-502a√	Cassette	/	20 Tests/Kit
	Nasopharyngeal Swab	GCCOV-502Ca√	Cassette	/	20 Tests/Kit
		GCCOV-501a√ ^{New}	Strip	/	20 Tests/Kit
	Nasal Swab	GCCOV-502a-NA√	Cassette	/	1/2/3/5/7/10/15/20 Test(s)/Kit
		GCCOV-503a√ ^{NA}	Device	/	1/2/5/10 Tests/Kit
	NA & NP Swab	GCCOV-502a-NN√	Cassette	/	20 Tests/Kit
	Oral Fluid	GCCOV-702a√	Cassette	/	20 Tests/Kit
		GCCOV-502a-Hxx√	Cassette	/	1/2/3/5/7/10/15/20 Test(s)/Kit
COVID-19 Antigen Self-Test	Nasal Swab	GCCOV-502a-HxxOGE√	Cassette	/	1/2/3/5/8/10/15/20/25 Test(s)/Kit
	Oral Fluid	GCCOV-702a-Hxx√ ^{New}	Cassette	/	1/2/3/5/7/10/15/20 Test(s)/Kit
Digital COVID-19 Antigen Test	Nasal Swab	GCCOV-D503a√ ^{New}	Reader	/	1/2/3/5/7/10/15/20 Test(s)/Kit
COVID-19 Antigen & B.1.1.7 Mutant Strain Combo Test	Nasal Swab	GCCOV(B117)-525a√	Cassette	/	20 Tests/Kit
COVID-19/Flu A&B/RSV Antigen Combo Test	Nasal Swab	GCFCR-T525a√ ^{New}	Cassette	/	20 Tests/Kit
SARS-CoV-2 Delta-series Mutant Strain Antigen Test	Nasal Swab	GCCOV(Del)-T502a√	Cassette	/	20 Tests/Kit
SARS-CoV-2 Ag Fluorescence Rapid Test	Nasal Swab	FCCOV-502a√ ^{New}	Cassette	/	20 Tests/Kit
Dengue IgG/IgM Antibody Test	WB/S/P	GCDEN(lab)-402c√	Cassette	/	25 Tests/Kit
Dengue NS 1 Antigen Test	WB/S/P	GCDEN(NS)-402c√	Cassette	/	25 Tests/Kit
Dengue NS1 & IgG/IgM Combo Test	WB/S/P	GCDEN-425a√	Cassette	/	20 Tests/Kit
EV71 IgM Test	S/P	GCEV71(IgM)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCEV71(IgM)-402a√	Cassette	/	25 Tests/Kit
Giardia lamblia Test	Feces	GCGLA-602a√	Cassette	/	20 Tests/Kit
Gonorrhoeae Test	Swab	GCGON-502b	Cassette	1.0E+7	20 Tests/Kit
HAV IgM Test	S/P	GCHAV(IgM)-302Ba√	Cassette	/	25 Tests/Kit
HAV IgG/IgM Test	WB/S/P	GCHAV(IgG/IgM)-402a√	Cassette	/	25 Tests/Kit
HAV AntigenTest	Feces	GCHAV-602a√	Cassette	/	25 Tests/Kit
	S/P	GCH8cb-302a	Cassette	2 NCU	25 Tests/Kit
HBCAb Hepatitis B Core Antibody Test	S/P	GCH8cb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCH8cb-402a	Cassette	2 NCU	25 Tests/Kit
	S/P	GCH8eb-302a	Cassette	2 NCU	25 Tests/Kit
		GCH8eb-302b	Cassette	8 NCU	25 Tests/Kit
	WB/S/P	GCH8eb-402a	Cassette	2 NCU	25 Tests/Kit
	S/P	GCH8eg-302a	Cassette	0.5 NCU	25 Tests/Kit
HBeAg Hepatitis B Envelope Antigen Test	WB/S/P	GCH8eg-402a	Cassette	0.5 NCU	25 Tests/Kit
	S/P	GCH8sb-301a	Strip	30 mIU/mL	50 Tests/Kit
		GCH8sb-302a	Cassette	30 mIU/mL	25 Tests/Kit
		GCH8sb-401a	Strip	30 mIU/mL	50 Tests/Kit
		GCH8sb-402a	Cassette	30 mIU/mL	25 Tests/Kit
		GCH8sb-402b	Cassette	20 mIU/mL	25 Tests/Kit
		GCH8sg-301a	Strip	1 ng/mL	50 Tests/Kit
	S/P	GCH8sg-302a	Cassette	1 ng/mL	25 Tests/Kit
		GCH8sg-401a	Strip	1 ng/mL	50 Tests/Kit
		GCH8sg-402a	Cassette	1 ng/mL	25 Tests/Kit
HBSAg Hepatitis B Surface Antigen Rapid Test	WB/S/P	GCHBC-402a	Cassette	/	25 Tests/Kit
	S/P	GCHBCISY-345a	Cassette	/	20 Tests/Kit
HBSAg/HCV/HIV/Syphilis Combo Test	WB/S/P	GCHBCISY-445a	Cassette	/	20 Tests/Kit
HBV HBCAb/HBeAb/HBeAg/HBsAb	S/P	GCHBV-355a	Cassette	/	20 Tests/Kit
	WB/S/P	GCHBV-455a	Cassette	/	20 Tests/Kit
	S/P	GCHCV-301a	Strip	/	50 Tests/Kit
		GCHCV-302a√	Cassette	/	25 Tests/Kit
		GCHCV-401a	Strip	/	50 Tests/Kit
HCV Hepatitis C Virus Test	WB/S/P	GCHCV-402a√	Cassette	/	25 Tests/Kit
HCV/HIV Combo Test	WB/S/P	GCHCI-402a	Cassette	/	25 Tests/Kit
HEV Hepatitis E Virus IgM Test	S/P	GCHEV-302a√	Cassette	/	25 Tests/Kit
	S/P	GCHIV-301a	Strip	/	50 Tests/Kit
		GCHIV-302a√	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Test	WB/S/P	GCHIV-401a	Strip	/	50 Tests/Kit
		GCHIV-402a√	Cassette	/	25 Tests/Kit
HIV 1/2 Antibody Tri-line Test	WB/S/P	GCHIV-GT402a	Cassette	/	25 Tests/Kit
	S/P	GCHIV-T302b	Cassette	/	25 Tests/Kit
HIV 1/2/O Antibody Test	WB/S/P	GCHIV-T402a	Cassette	/	25 Tests/Kit
HIV Antigen/Antibody Combo Test	WB/S/P	GCHIV(Ag/Ab)-402a	Cassette	/	25 Tests/Kit
	S/P	GCHSV(IgG)-302a√	Cassette	/	25 Tests/Kit
	WB/S/P	GCHSV(IgG)-402a√	Cassette	/	25 Tests/Kit
	S/P	GCHSV(IgM)-302a√	Cassette	/	25 Tests/Kit
HSV IgM Test	WB/S/P	GCHSV(IgM)-402a√	Cassette	/	25 Tests/Kit
	S/P	GCHSV(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
HSV IgG/IgM Test	WB/S/P	GCHSV(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
	S/P	GCHP-301a√	Strip	/	50 Tests/Kit
		GCHP-302a√	Cassette	/	25 Tests/Kit
		GCHP-401a√	Strip	/	50 Tests/Kit
	WB/S/P	GCHP-402a√	Cassette	/	25 Tests/Kit

H. pylori Antigen Test	Feces	GCHP-601a/	Strip	/	25 Tests/Kit
		GCHP-601Ca/	Strip	/	25 Tests/Kit
		GCHP-602a/	Cassette	/	20 Tests/Kit
		GCHP-602Ca/	Cassette	/	20 Tests/Kit
Influenza A Antigen Test	Nasal/Throat Swabs	GCFLU(A)-501a/	Strip	1.5 x 10 ⁴ TCID ₅₀	25 Tests/Kit
		GCFLU(A)-502a/	Cassette	1.5 x 10 ⁴ TCID ₅₀	20 Tests/Kit
		GCFLU(A/B)-501a/	Strip	1.5x 10 ⁴ TCID ₅₀ /1.5 x 10 ⁵ TCID ₅₀	25 Tests/Kit
Influenza A/B Antigen Test	Nasal/Throat Swabs	GCFLU(A/B)-502a/	Cassette	1.5x 10 ⁴ TCID ₅₀ /1.5 x 10 ⁵ TCID ₅₀	20 Tests/Kit
		GCFLU(A/B)-502Ca/	Cassette	1.5x 10 ⁴ TCID ₅₀ /1.5 x 10 ⁵ TCID ₅₀	20 Tests/Kit
		Nasopharyngeal Swab	GCFC-525a/	Cassette	/
Influenza & COVID-19 Antigen Combo Test	NA & NP Swab	GCFC-525a-NN/	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFC-525a-NA/	Cassette	/	20 Tests/Kit
		GCFC-525a/ ^{New}	Cassette	/	1/5/20 Tests/Kit
		GCFC-T503a/ ^{New}	Device	/	1/2/5/10 Test(s)/Kit
Flu, COVID-19, RSV & Adeno Antigen Combo Test	Nasopharyngeal Swab	GCFCRA-545a/	Cassette	/	20 Tests/Kit
	Nasal Swab	GCFCRA-T525a/ ^{New}	Cassette	/	20 Tests/Kit
	S/P	GKcal-301a	Strip	/	50 Tests/Kit
GKcal-302a		Cassette	/	25 Tests/Kit	
GKcal-401a/		Strip	/	50 Tests/Kit	
Leishmania Antibody Test	WB/S/P	GKcal-402a	Cassette	/	25 Tests/Kit
		GKcal-T402a/	Cassette	/	25 Tests/Kit
		GMAL(pan)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria Pan Antigen Test	Whole Blood	GMAL(pf)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f. Antigen Test	Whole Blood	GMAL(pf/pan)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./Pan Antigen Test	Whole Blood	GMAL(pf/pf)-402a/	Cassette	200 parasites	25 Tests/Kit
Malaria P.f./P.v. Antibody Test	S/P	GMAL(pf/pv Ab)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GMAL(pf/pv Ab)-402a/	Cassette	/	25 Tests/Kit
Monkeypox IgG/IgM Antibody Test	WB/S/P	GCMKP-402a/ ^{New}	Cassette	/	25 Tests/Kit
Monkeypox Antigen Test	WB/S/P or Throat swab	GCMKP-502a/ ^{New}	Cassette	/	25 Tests/Kit
Mononucleosis Test	S/P	GCMON-325a/	Cassette	/	25 Tests/Kit
		GCMON-402a/	Cassette	/	25 Tests/Kit
		GCMON-425a/	Cassette	/	25 Tests/Kit
M. pneumoniae IgM Test	S/P	GCMP(IgM)-302a/	Cassette	/	25 Tests/Kit
Respiratory Syncytial Virus Antigen Test	Swab	GCRSV-502a/	Cassette	/	20 Tests/Kit
Rotavirus Test	Feces	GCROA-602a/	Cassette	/	25 Tests/Kit
Rotavirus/Adenovirus Test		GCROA/ADE-602a/	Cassette	/	25 Tests/Kit
Rubella IgG Test	S/P	GCRUB(IgG)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgG)-402a	Cassette	/	25 Tests/Kit
Rubella IgM Test	S/P	GCRUB(IgM)-302a	Cassette	/	25 Tests/Kit
	WB/S/P	GCRUB(IgM)-402a	Cassette	/	25 Tests/Kit
Rubella IgG/IgM Test	WB/S/P	GCRUB(IgG/IgM)-302a	Cassette	/	25 Tests/Kit
		GCRUB(IgG/IgM)-402a	Cassette	/	25 Tests/Kit
		GCRUB(IgG/IgM)-T402a	Cassette	/	25 Tests/Kit
Strep A Test	Throat Swab	GCSTR-501a/	Strip	/	25 Tests/Kit
		GCSTR-502a/	Cassette	/	20 Tests/Kit
		GCSTR-502Ca/	Cassette	/	20 Tests/Kit
		GCSYP-301a/	Strip	/	50 Tests/Kit
Syphilis Test	S/P	GCSYP-302a/	Cassette	/	25 Tests/Kit
		GCSYP-401a/	Strip	/	50 Tests/Kit
		GCSYP-402a/	Cassette	/	25 Tests/Kit
S. typhi Antigen Test	S/P/Feces	GCSAL(ST)-602a/	Cassette	/	20 Tests/Kit
TOXO IgG Test	S/P	GCTOX(IgG)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOX(IgG)-402a	Cassette	/	25 Tests/Kit
TOXO IgM Test	S/P	GCTOXO(IgM)-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOXO(IgM)-402a	Cassette	/	25 Tests/Kit
Toxo IgG/IgM Test	S/P	GCTOX-302b	Cassette	/	25 Tests/Kit
	WB/S/P	GCTOX(IgG/IgM)-302a/	Cassette	/	20 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgG Combo Test	S/P	GCTOX-402b	Cassette	/	25 Tests/Kit
	S/P	GCTOG-345a	Cassette	/	20 Tests/Kit
ToRCH Toxo/Rubella/CMV/HSV IgM Combo Test	S/P	GCTOM-345a	Cassette	/	20 Tests/Kit
Trichomonas vaginalis Test	Vaginal Swab	GCTV-502a/	Cassette	/	20 Tests/Kit
Tuberculosis IgG/IgM Test	S/P	GCTB-302a/	Cassette	/	25 Tests/Kit
	WB/S/P	GCTB-402a/	Cassette	/	25 Tests/Kit
Typhoid IgG/IgM Test	S/P	GCTYP-301a	Strip	/	50 Tests/Kit
	WB/S/P	GCTYP-302a/	Cassette	/	25 Tests/Kit
V. cholerae O1 Antigen Test	Feces	GCVCH(O1)-602a/	Cassette	/	25 Tests/Kit
V. cholerae O1/O139 Antigen Test	Feces	GCVCH(O1/O9)-602a/	Cassette	/	25 Tests/Kit
ZIKA IgM Test	WB/S/P	GCZIK(IgM)-402a	Cassette	/	25 Tests/Kit
ZIKA IgG Test	WB/S/P	GCZIK(IgG)-402a	Cassette	/	25 Tests/Kit
ZIKA NS1 Test	WB/S/P	GCZIK(INS1)-402a	Cassette	/	25 Tests/Kit

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
LH Ovulation Test	Urine	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
		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
		GALH-103d	Midstream	30 mIU/mL	1/5 Test(s)/Kit
FSH Menopause Test	Urine	GAFSH-101a/	Strip	25 mIU/mL	100 Tests/Kit
IGFBP-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-002a/	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
CRP C-Reactive Protein Semi-Quantitative Test	WB/S/P	GDCKM-402a/	Cassette	5 ng/mL	25 Tests/Kit
	WB/S/P	GDGRP-402a/	Cassette	1-3-10 mg/L	25 Tests/Kit
D-dimer Test	WB/P	GDGDI-402b/	Cassette	10-40-80 mg/L	25 Tests/Kit
Myoglobin Test	WB/S/P	GDIMOY-402a/	Cassette	500 ng/mL	25 Tests/Kit
Procalcitonin Test	WB/S/P	GDPCIT-402a/	Cassette	50 ng/mL	25 Tests/Kit
Troponin I Test	S/P	GDTR-302a/	Cassette	0.5-2-10 ng/mL	25 Tests/Kit
	WB/S/P	GDTR-402a/	Cassette	0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDTR-402b/	Cassette	0.5 ng/mL	25 Tests/Kit
Cardiac Myoglobin/CK-MB/CK-TnI Combo Test	S/P	GDCA-335a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
	WB/S/P	GDCA-435a/	Cassette	50/5/0.5 ng/mL	25 Tests/Kit
		GDCA-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
	WB/S/P	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
	WB/S/P	GECEA-401a/	Strip	5 ng/mL	50 Tests/Kit
		GECEA-402a/	Cassette	5 ng/mL	25 Tests/Kit
FOB Fecal Occult Blood Test	Feces	GEFOB-601b/†	Strip	50 ng/mL	25 Tests/Kit
		GEFOB-601Cb/	Strip	50 ng/mL	25 Tests/Kit
		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
		GEFOB/TF-602a/	Cassette	50/10 ng/mL	20 Tests/Kit
		GENMP22-102a/ ^{New}	Cassette	10 U/mL	25 Tests/Kit
FOB/Transferrin Combo Test	Urine	GENMP22-102a/ ^{New}	Cassette	10 U/mL	25 Tests/Kit
PSA Prostate Specific Antigen Test	S/P	GEPSA-301a/	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-302a/	Cassette	4 ng/mL	25 Tests/Kit
	WB/S/P	GEPSA-401a/	Strip	4 ng/mL	50 Tests/Kit
		GEPSA-402a/	Cassette	4 ng/mL	25 Tests/Kit
PSA Prostate Specific Antigen Semi-Quantitative Test	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	GFCAV-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 IU	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	GFCDIA-532a	Cassette	Gold	/	10 Tests/Kit
Canine Influenza Virus (CIV) Antigen Test	Secretions	GFClV-502a	Cassette	Gold	/	10 Tests/Kit
Canine Parvovirus (CPV) Antigen Test	Feces	GFPCV-602a	Cassette	Gold	/	10 Tests/Kit
Canine Parvovirus (CPV) Antigen Test	WB/S/P	FFCPV-602a	Cassette	Fluorescence	10 IU	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	GFFCV-502a	Cassette	Gold	/	10 Tests/Kit
Feline Coronavirus (FCoV) Antigen Test	Feces	GFFCV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Herpes Virus (FHV) Antigen Test	Secretions	GFFHV-502a	Cassette	Gold	/	10 Tests/Kit
Feline Herpes Virus (FHV) Antigen Test	Secretions	FFFHV-502a	Cassette	Fluorescence	10 IU	10 Tests/Kit
		GFFPV-602a	Cassette	Gold	/	10 Tests/Kit
Feline Parvovirus (FPV) Antigen Test	Feces	FFFPV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) & Coronavirus (FCoV) Antigen Combo Test	Feces	FFFPV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Parvovirus (FPV) & Coronavirus (FCoV) Antigen Combo Test	Feces	GFPPV-602a	Cassette	Fluorescence	10 IU	10 Tests/Kit
Feline Serum Amyloid A (fSAA) Test	WB/S/P	FFSAA-402a	Cassette	Gold	/	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
Vaginal pH Test	Vaginal Secretion	GIHSA-102a	Cassette	20 µg/mL	25 Tests/Kit
		VPH-501a ^{New}	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	GCIGE-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.

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Rev.08/2022

PRODUCT CATALOG

Enhancing
Global Health



CE Declaration of Conformity

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

Product Code	Product Name	GMDN code
8.16.20.0.0020	Atlas RSV Test Cassette , Swab Sample Individually Pouched 20 Tests/Box	49504
8.45.00.0.0020	Atlas Strep B Test Cassette, Individually Pouched, 20 Tests/Box	51747
8.04.25.0.0020	Atlas Strep A Test Cassette, Individually Pouched , 20 Tests/Box	51707
8.16.91.0.0025	Atlas Norovirus Genogroups I & II Ag Cassette , Individually Pouched , 25 Tests/Box	47897
8.16.86.0.0025	Atlas C.Difficile Toxin A+B Test Device (Stool Sample) , Individually Pouched, 25 Test/Box	50856
8.16.81.0.0025	Atlas Clostridium difficile Antigen Test Strip ,Stool Sample, Individually Pouched , 25 Tests/Box	50831
8.16.80.0.0020	Atlas Clostridium difficile Antigen Test Cassette,Stool Sample, Individually Pouched , 20 Tests/Box	50831
8.16.85.0.0025	Atlas Salmonella paratyphi Antigen Test , Stool sample, Individually Pouched, 25 Tests/Box.	51543
8.16.82.0.0025	Atlas Salmonella typhi Antigen Test cassette, Stool sample, Individually Pouched, 25 Tests/Box.	51561
8.16.40.0.0025	Atlas E.coli Test Strip , Stool sample, Individually Pouched, 25 Tests/Box.	50921
8.16.41.0.0020	Atlas E.coli Test Cassette , Stool sample, Individually Pouched, 20 Tests/Box.	50921
8.16.32.0.0025	Atlas Crypto-Giardia Test Strip , Stool sample, Individually Pouched, 25 Tests/Box.	48235
8.16.33.0.0020	Atlas Crypto-Giardia Test Cassette , Stool sample, Individually Pouched, 20 Tests/Box.	48235
8.16.30.0.0025	Atlas Giardia Test Strip , Stool sample, Individually Pouched, 25 Tests/Box.	52249
8.16.31.0.0020	Atlas Giardia Test Cassette , Stool sample, Individually Pouched, 20 Tests/Box.	52249
8.16.02.0.0025	Atlas Cryptovirus Test Strip , Stool sample, Individually Pouched, 25 Tests/Box.	52163

Declaration Ref No: DC21-0212

Date: 06.09.2021

8.16.14.0.0020	Atlas Malaria Pf/Pv. Test Cassette , Whole Blood, Individually Pouched ,20 Tests/Box	52364
8.04.37.0.0020	Atlas Malaria Pf. Test Cassette, Whole Blood ,Individually Pouched 20 Tests/Box.	52364
8.04.73.0.0020	Atlas Rota-Adeno Antigens Combo test Cassette, Stool Sample, Individually Pouched ,20 Tests/Box	48235
8.04.72.0.0025	Atlas Adenovirus Antigen Test Strip ,Stool Sample, Individually Pouched, 25 Test/Box	49856
8.04.71.0.0020	Atlas Adenovirus Antigen Test Cassette ,Stool Sample, Individually Pouched, 20 Test/Box	49856
8.04.70.0.0025	Atlas Rotavirus Antigen Test Strip ,Stool Sample, Individually Pouched, 25 Test/Box	50245
8.04.69.0.0020	Atlas Rotavirus Antigen Test Cassette ,Stool Sample, Individually Pouched, 20 Test/Box	50245
8.16.38.0.0025	Atlas Adeno-RSV Respiratory Test Strip ,Swab Sample, Individually Pouched, 25 Test/Box	63143
8.16.38.0.0020	Atlas Adeno-RSV Respiratory Test Cassette ,Swab Sample, Individually Pouched, 20 Test/Box	63143
8.16.36.0.0025	Atlas Adeno Respiratory Antigen Test Strip, Swab Sample, Individually Pouched, 25 Test/Box	63143
8.16.37.0.0020	Atlas Adeno Respiratory Antigen Test Cassette , Swab Sample, Individually Pouched, 20 Test/Box	63143
8.16.01.0.0020	Atlas Crypto Virus Test Cassette , Stool Sample, Individually Pouched, 20 Test/Box	52163
8.66.02.0.0020	Atlas COVID-19 & Influenza A&B Antigen Combo Rapid Test Device, Individually Pouched, 20 Test/Box	63143

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

EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016

EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,

EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

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

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

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

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

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

pour les activités
for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485: 2016

Début de validité / Effective date October 9th, 2023 (included)

Valable jusqu'au / Expiry date : October 8th, 2026 (included)

Etabli le / Issued on : October 9th, 2023

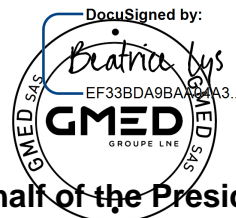


**CERTIFICATION
DE SYSTEMES
DE MANAGEMENT**
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 36655-2

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

Renouvelle le certificat 36655-1



On behalf of the President
Béatrice LYS
Technical Director

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

French version :

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

English version:

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

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

French version:

Siège social, responsable de la mise sur le marché

English version:

Headquarter, legal manufacturer

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


French version:

Conception, fabrication et contrôle final

English version:

Design, manufacture and final control

2 sites / 2 sites

DocuSigned by:
Beatrice Lys
FF33BDA98AA04A3...


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

Date: 05/Jan/2023

STATEMENT

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

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

On Behalf of Manufacturer:

General Manager

Haya Amawi

Signature: _____

Date: _____

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

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Regulatory Office: William James House, Cowley Rd, Cambridge, CB4 0WX, United Kingdom
Tel: +44 (0) 1223 858 910

Middle East Site: P.O Box 204, King Abdullah II Industrial Estate, Amman, 11512, Jordan
Tel: +962 6 4026468

E. coli Device

One Step Escherichia coli Antigen Test Device

IVD For In-Vitro diagnostic and professional use only

2-30°C
Store at 2-30°C

INTENDED USE

The *E. coli* Device test is a rapid chromatographic immunoassay for the qualitative detection of *E. coli* O157:H7 antigens in human faeces specimens to aid in the diagnosis of *E. coli* infections.

SYNTHESIS

E. coli O157:H7 is one of hundreds of strains of the bacterium Escherichia coli. Although most strains are harmless, this strain produces a powerful toxin that can cause severe illness. *E. coli* O157:H7 has been found in the intestines of healthy cattle, deer, goats, and sheep.

E. coli O157:H7 was first recognized as a cause of illness in 1982 during an outbreak of severe bloody diarrhea; the outbreak was traced to contaminated hamburgers. Since then, more infections in all over the world have been caused by eating undercooked ground beef than by any other food.

PRINCIPLE

The *E. coli* Device is a qualitative lateral flow immunoassay for the detection of Escherichia coli antigen in human faeces samples. The membrane is pre-coated with monoclonal antibodies against *E. coli* O157 antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*E. coli* O157 antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A green coloured band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

PRECATION

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.

- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

STORAGE AND STABILITY

- The tests are packaged in the sealed pouch at room temperature or refrigerated 2-30°C.
- The test cassette is stable through the expiration date printed on the sealed pouch. Do not use beyond the expiration date.
- Do not freeze

MATERIALS

MATERIALS PROVIDED

- Devices.
- Specimen Collection vial with Buffer.
- Package insert.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection Container.
- Disposable gloves.
- Timer

SPECIMEN COLLECTION AND PREPARATION

- Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8°C/36-46.4°F) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at -20°C/-4°F. In this case, the sample will be totally thawed, and brought to room temperature before testing.
- For the enrichment culture test, stool sample is inoculated into a SMAC medium and incubated overnight on a shaker at 37°C.

PROCEDURES

To process the collected stool samples (see illustration 1): Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick two times into the faecal specimen to pick up quite a lot of sample (APPROX. 125 mg). Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 125 uL into the specimen collection vial with buffer.

Test Procedure (see illustration 2)

Allow the tests, stool samples and buffer to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the *E. coli* Device from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.
3. Use a separate device for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer.
4. Read the result at 10 minutes after dispensing the sample.

Illustration 1

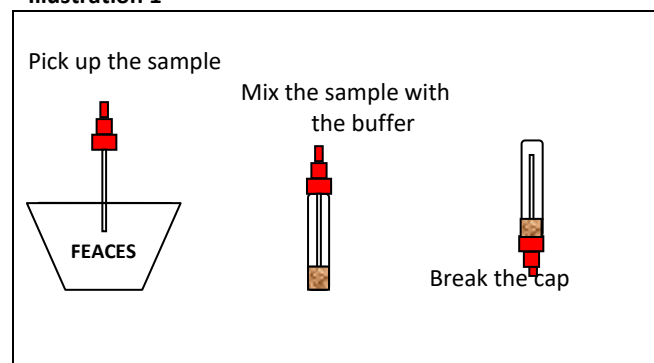
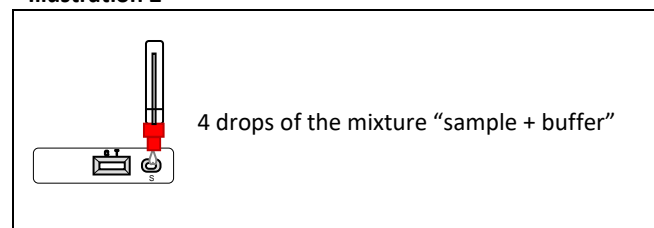
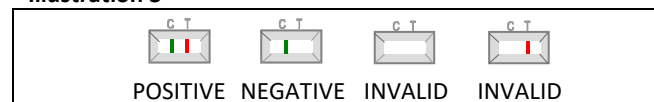


Illustration 2



INTERPRETATION OF RESULTS

Illustration 3



POSITIVE: Two lines appears across the central window in the result line region (red test line marked with the letter T) and in the control line region (green control line marked with the letter C).

NEGATIVE: Only one green band appears across the control line region marked with the letter C (control line).

INVALID: A total absence of the green control coloured band regardless the appearance or not of the red test line. Note:

Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPREATION OF RESULT

The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural controls are included in the test:

A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. E. coli Device will only indicate the presence of Escherichia coli in the specimen (qualitative detection) and should be used for the detection of E. coli O157 antigens in faeces specimens only. Neither the quantitative value nor the rate of increase in E. coli antigens concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of E. coli infection.
5. This test provides a presumptive diagnosis of E. coli. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

Escherichia coli O157:H7 is a leading cause of foodborne illness. Based on a 1999 estimate, 73,000 cases of infection and 61 deaths occur in the United States each year.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

It was performed an evaluation using E. coli Device. It was studied some stool samples and the results were confirmed by

culture E. coli Device showed >99% of sensitivity and 85% of specificity.

2. Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of E. coli Device. There is not cross reactivity with common gastrointestinal pathogens occasionally present in faeces

Campylobacter	Helicobacter pylori	Shigella
Citobacter freundii	Listeriamonocytogenes	Staphylococcus aureus
Clostridium difficile	Morganella morganii	Yersinia enterocolitica
Escherichia coli	Proteus mirabilis	
Klebsiella pneumoniae	Salmonella	

REFERENCES

1. Rangel, J. M., Sparling, P. H., Crowe, C., Griffin, P. M. & Swerdlow, D. L. 2005 Epidemiology of Escherichia coli O157:H7 outbreaks, United States, 1982–2002. Emerg. Infect. Dis. 11, 603–609.
2. Griffin, P.M. “The Epidemiology of infections caused by Escherichia coli O157:H7, other enterohemorrhagic E. coli, and the associated haemolytic uremic syndrome”. Epidemiol. Rev, 1991, 13:60-98.



ATLAS MEDICAL

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PPI1847A01

Rev A (02.09.2019)

	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
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if the package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry



PRODUCT CATALOGUE

2022-2023

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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.

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.

Objectives



High and Consistent Quality



Satisfied Customer



Continuous Improvement & Innovation



Care for the Environment & Working Conditions



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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

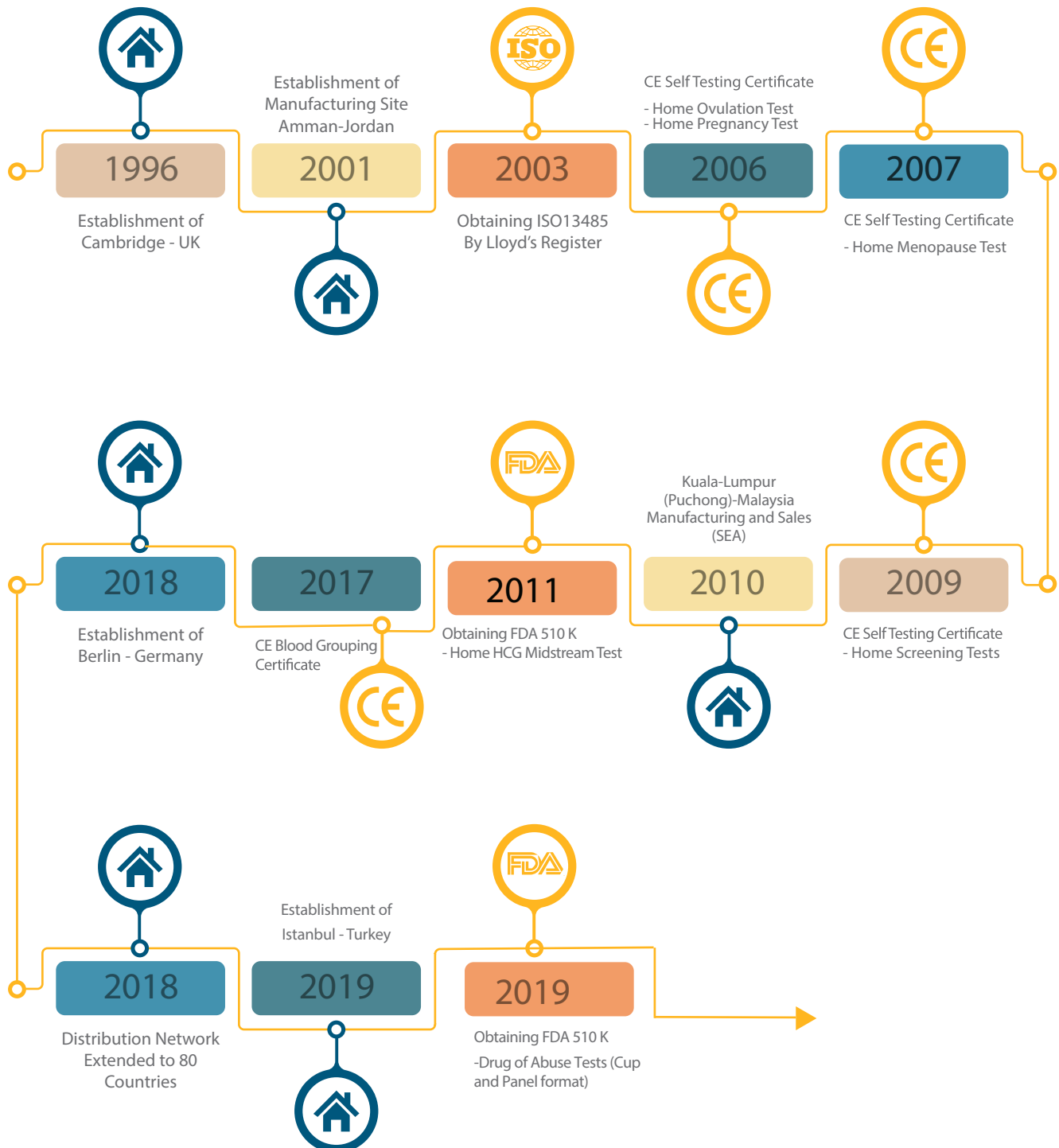


To complete the quality assurance scheme the company has put in place a robust Quality Management and Enhancement System that has concluded in the successful attainment of ISO13485: 2016 certificate



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 8.66.00.0.0020	COVID-19 IgM /IgG Test Cassette, Whole Blood/ Serum/Plasma ,Individually Pouched	Bulk 20 Tests/Box
8.66.01.0.0001 8.66.01.0.0020	COVID-19 Antigen Test Cassette, Nasal Swab, Individually Pouched	Bulk 20 Tests/Box
8.66.02.0.0001 8.66.02.0.0020	COVID-19 Combo Antigen & Influenza, A+B Test Individually Pouched	Bulk 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 8.64.02.0.0100	Viral Transport Medium (VTM) with Flocked , Swab ,Individually Pouched	50 Tube/Kit 100 Tube/Kit
8.64.03.0.0050 8.64.03.0.0100	Viral Transport Medium (In Activating) with Flocked Swab ,(3 ml /vial)	50 Tube/Kit 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.

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



- Some Latex Kits come with a Buffer.

Item Code	Item Description	Sizes
8.00.09.0.0050 8.00.09.0.0100	Toxo Latex Kit	50 Tests 100 Tests
8.00.10.0.0050 8.00.10.0.0100	Toxo Latex Kit with Buffer	50 Tests 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 Turbilateral 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 Turbilateral	50 Tests
8.44.05.0.0050	Ferritin Turbilateral	50 Tests
8.44.06.0.0050	Transferrin Turbilateral (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 8.01.19.0.0005	Febrile Antigens Positive Control	1 ml/vial 5 ml/vial
8.01.20.0.0001 8.01.20.0.0005	Febrile Antigen Negative Control	1 ml/vial 5 ml/vial



Item Code	Item Description	Sizes
8.01.00.0.0005 8.01.00.0.0050 8.01.00.0.0100	Brucella Rose Bengal Kit	5ml/vial 50 Tests 100 Tests
8.01.01.0.0005 8.01.01.1.0040 8.01.01.0.0050	Salmonella OA Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.02.0.0005 8.01.02.1.0040 8.01.02.0.0050	Salmonella OB Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.03.0.0005 8.01.03.1.0040 8.01.03.0.0050	Salmonella OC Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.04.0.0005 8.01.04.1.0040 8.01.04.0.0050	Salmonella OD Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.05.0.0005 8.01.05.1.0040 8.01.05.0.0050	Salmonella HA Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.06.0.0005 8.01.06.1.0040 8.01.06.0.0050	Salmonella HB Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.07.0.0005 8.01.07.1.0040 8.01.07.0.0050	Salmonella HC Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.08.0.0005 8.01.08.1.0040 8.01.08.0.0050	Salmonella HD Reagent	5 ml/vial 8x5 ml 10x5 ml
8.01.10.0.0005 8.01.10.1.0040	Brucella Abortus Reagent	5 ml/vial 8x5 ml
8.01.11.0.0005 8.01.11.1.0040	Brucella Melitensis Reagent	5 ml/vial 8x5 ml
8.01.12.0.0005 8.01.12.1.0040	Proteus OX2 Reagent	5 ml/vial 8x5 ml
8.01.13.0.0005 8.01.13.1.0040	Proteus OX19 Reagent	5 ml/vial 8x5 ml
8.01.14.0.0005 8.01.14.1.0040	Proteus OXK Reagent	5 ml/vial 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 8.02.00.1.0100	Anti-A Monoclonal reagent (titer: 1/512)	10 ml/vial 10x10 ml
8.02.01.0.0010 8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512)	10 ml/vial 10x10 ml
8.02.02.0.0010 8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512)	10 ml/vial 10x10 ml
8.02.03.0.0010 8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128)	10 ml/vial 10x10 ml
8.02.04.0.0010 8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256)	10 ml/vial 10x10 ml
8.02.05.0.0010 8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256)	10 ml/vial 10x10 ml
8.02.06.0.0010 8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256)	10 ml/vial 10x10 ml
8.02.07.0.0010 8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64)	10 ml/vial 10x10 ml
8.02.08.0.0010 8.02.08.1.0100	Bovine Albumin 22%	10 ml/vial 10x10 ml
8.02.09.0.0010 8.02.09.1.0100	Bovine Albumin 30%	10 ml/vial 10x10 ml
8.02.10.0.0010 8.02.10.1.0100	Anti-Human Globulin (Green) (Titer 1/512)	10 ml/vial 10x10 ml
8.02.11.0.0010 8.02.11.1.0100	Anti-Human Globulin (Green) (Titer 1/256)	10 ml/vial 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 8.02.52.0.0100	Rh-D Negative Control	10 ml/vial 10x10 ml
8.02.63.1.0010 8.02.63.0.0100	Antibody Enhancement Solution (LISS)	10 ml/vial 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 8.02.46.1.1000 8.02.46.1.3000	Drabkins Reagent, 40x (White Plastic Bottle)	50ml/Bottle 2x50ml 6x50ml
8.02.50.0.0010 8.02.50.0.0050	Haemoglobin Standard	10ml/vial 50ml/Bottle



Co-agglutination Reagents

Item Code	Item Description	Sizes
8.02.40.1.0010 8.02.40.1.0050 8.02.40.1.0100	PT Calcium Rabbit Brain Thromboplastin, Liquid	2ml (20 Tests) 5ml (50 Tests) 10ml (100 Tests)
8.02.41.1.0040 8.02.41.1.0050 8.02.41.1.0100	APTT (PTT) Micronised Silica Platelet Substitute	2ml (40 Tests) 2.5ml (50 Tests) 5ml (100 Tests)
8.02.44.0.0040 8.02.44.0.0100	PT Kit with Normal Control	2x2ml + 1ml 2x10ml + 1ml
8.02.45.0.0080 8.02.45.0.0200	APTT (PTT) Kit with Normal Control	2x2ml + 1ml 2x10ml + 1ml
8.02.48.0.0010 8.02.48.0.0100	Calcium Chloride, 25 mM	10ml/vial 10ml/vial / 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 + 2 vials of Sodium Dithionate
8.02.67.0.0100	Sickle Cell Kit, 100 Tests	4x50ml Buffer, 4 vials of Sodium Dithionate
8.02.68.0.0001 8.02.68.1.0001	Sickle Cell positive & negative control set	1ml each 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 8.04.27.0.0020	HIV 1/2 Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.28.0.0001 8.04.28.0.0020	HIV 1/2 Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.29.0.0001 8.04.29.0.0100	HIV 1/2 Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.30.0.0001 8.04.30.0.0020	HCV Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.31.0.0001 8.04.31.0.0020	HCV Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.32.0.0001 8.04.32.0.0100	HCV Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.35.0.0001 8.04.35.0.0020	HBs Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.36.0.0001 8.04.36.0.0100	HBs Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 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 8.04.20.0.0020	H.pylori Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.21.0.0001 8.04.21.0.0020	H.pylori Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.22.0.0001 8.04.22.0.0100	H.pylori Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.04.41.0.0001 8.04.41.0.0020	Syphilis Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.42.0.0001 8.04.42.0.0020	Syphilis Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.43.0.0001 8.04.43.0.0100	Syphilis Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
8.16.16.0.0001 8.16.16.0.0020	TB Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.16.16.1.0020 8.16.16.1.0025	TB Test Cassette, Whole Blood, Individually Pouched	20 Tests/Box 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 8.04.44.0.0020	Dengue IgG/IgM Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 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

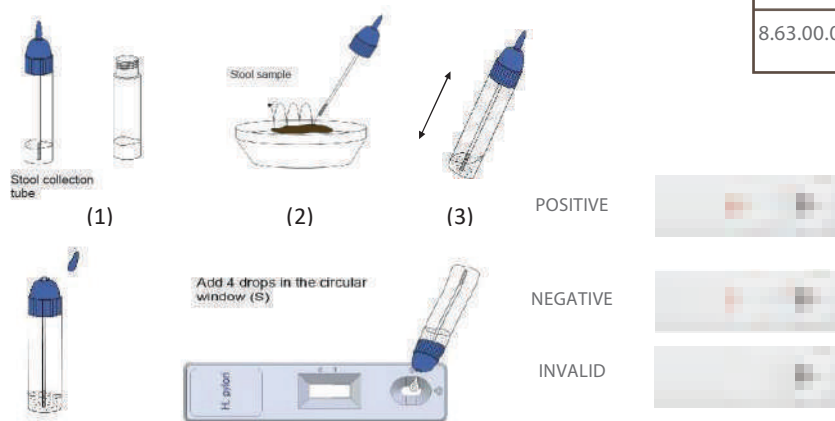
SWAB & NASAL SAMPLE		
Item Code	Item Description	Sizes
8.04.25.0.0020	Strep A Test Cassette, Swab Sample	20 Tests/Box
8.45.00.0.0020	Strep B Test Cassette, Swab Sample	20 Tests/Box
8.45.01.0.0020	Strep A+B Test Cassette, Swab Sample	20 Tests/Box
8.04.86.0.0020	Influenza A+B Test Cassette, Nasal Sample	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 8.16.24.0.0020	HBsAg Test Cassette (Whole Blood/Serum/Plasma), Individually Pouched	Bulk 20 Tests/Box
8.04.33.0.0001 8.04.33.0.0020	HBsAg Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.34.0.0001 8.04.34.0.0100	HBsAg Test Strip, Serum/Plasma, Individually Pouched	Bulk 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 8.03.00.0.0100	URS 1 Parameter: Glucose	50 Strips 100 Strips
8.03.01.0.0050 8.03.01.0.0100	URS 1 Parameter: Protein	50 Strips 100 Strips
8.03.02.0.0050 8.03.02.0.0100	URS 1 Parameter: Ketone	50 Strips 100 Strips
8.03.45.0.0050	URS 1 Parameter Blood, (5mm)	50 Strips
8.03.03.0.0050 8.03.03.0.0100	URS 2 Parameters: Glucose, Ketone	50 Strips 100 Strips
8.03.04.0.0050 8.03.04.0.0100	URS 2 Parameters: Glucose, Protein	50 Strips 100 Strips
8.03.05.0.0100	URS 2 Parameters: Sample end: Urobilinogen, Bilirubin	100 Strips
8.03.19.0.0050 8.03.19.0.0100	URS 2 Parameters(5mm): Sample End: Creatinine, pH	50 Strips 100 Strips
8.03.06.0.0050 8.03.06.0.0100	URS 3 Parameters: Protein, pH, Glucose	50 Strips 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 8.03.10.0.0100	URS 3 Parameters: Sample end:Protein, Specific Gravity, Creatinine	50 Strips 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 8.03.13.0.0100	URS 5 Parameters: Glucose, Protein, Ketone, pH, Blood	50 Strips 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 8.03.17.0.0100	URS 10 Parameters: Sample end: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid	50 Strips 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

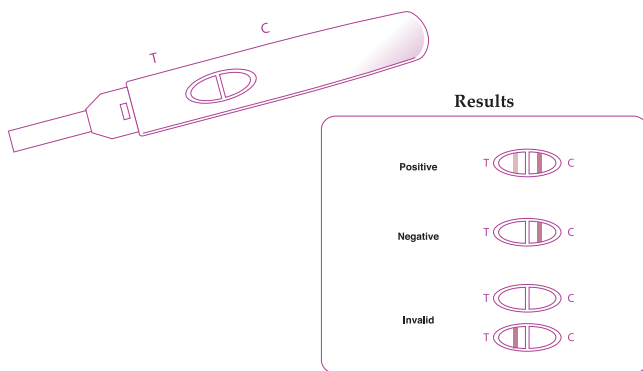
Overview

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 8.04.00.0.0020	hCG Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.01.0.0001 8.04.01.0.0020	hCG Test Cassette, Urine/Serum, Individually Pouched	Bulk 20 Tests/Box
8.04.04.0.0001 8.04.04.0.0100	hCG Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.10.0.0001 8.04.10.0.0100	hCG Test Strip, Urine/Serum, Individually Pouched	Bulk 100 Tests/Box
8.04.13.0.0001 8.04.13.0.0015	hCG Midstream Test, Individually Pouched	Bulk 15 Tests/Box
8.04.14.0.0001 8.04.14.0.0020	LH Test Cassette, Urine, Individually pouched	Bulk 20 Tests/Box
8.04.15.0.0001 8.04.15.0.0100	LH Test Strip, Urine, Individually pouched	Bulk 100 Tests/Box
8.04.16.0.0001 8.04.16.0.0015	LH Midstream Test, Individually Pouched	Bulk 15 Tests/Box
8.04.17.0.0001 8.04.17.0.0020	FSH Test Cassette, Urine, Individually pouched	Bulk 20 Tests/Box
8.04.18.0.0001 8.04.18.0.0100	FSH Test Strip, Urine, Individually pouched	Bulk 100 Tests/Box
8.04.19.0.0001 8.04.19.0.0015	FSH Midstream Test, Individually Pouched	Bulk 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 8.16.52.0.0020	Microalbumin Test Cassette ,Individually Pouched	Bulk 20 Tests/Box
8.16.53.0.0030 8.16.53.0.0100	Microalbumin Test Strip ,Individually Pouched	30 Tests/Box 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 8.16.28.0.0020	PSA Test Cassette, Whole Blood/Serum/Plasma), Individually Pouched	Bulk 20 Tests/Box
8.04.39.0.0001 8.04.39.0.0020	PSA Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.40.0.0001 8.04.40.0.0100	PSA Test Strip, Serum/Plasma, Individually Pouched	Bulk 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 8.04.45.0.0020	Troponin I Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.46.0.0001 8.04.46.0.0020	Myoglobin Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.47.0.0001 8.04.47.0.0020	CK-MB Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.48.0.0001 8.04.48.0.0020	Cardiac Triple Test Cassette (Troponin I, CK-MB, Myoglobin), Whole Blood/Serum/Plasma, Individually Pouched	Bulk 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 8.04.49.0.0020	Morphine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.50.0.0001 8.04.50.0.0100	Morphine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.51.0.0001 8.04.51.0.0020	Marijuana (THC) Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.52.0.0001 8.04.52.0.0100	Marijuana (THC) Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.53.0.0001 8.04.53.0.0020	Amphetamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.54.0.0001 8.04.54.0.0100	Amphetamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.55.0.0001 8.04.55.0.0020	Barbiturates Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.56.0.0001 8.04.56.0.0100	Barbiturates Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.57.0.0001 8.04.57.0.0020	Benzodiazepines Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.58.0.0001 8.04.58.0.0100	Benzodiazepines Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.59.0.0001 8.04.59.0.0020	Cocaine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.60.0.0001 8.04.60.0.0100	Cocaine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.61.0.0001 8.04.61.0.0020	Methamphetamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.62.0.0001 8.04.62.0.0100	Methamphetamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.63.0.0001 8.04.63.0.0020	Methadone Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.64.0.0001 8.04.64.0.0100	Methadone Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.65.0.0001 8.04.65.0.0020	Phencyclidine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.66.0.0001 8.04.66.0.0100	Phencyclidine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box

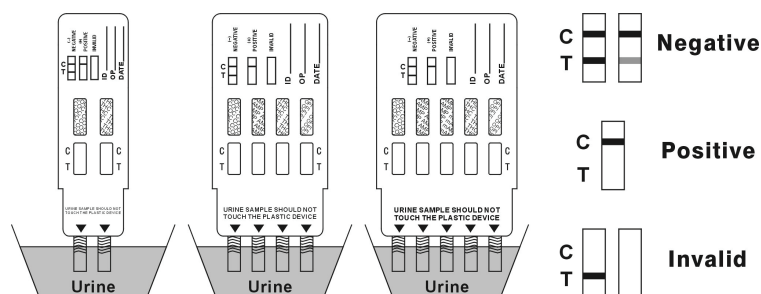


Item Code	Item Description	Sizes
8.04.67.0.0001 8.04.67.0.0020	Tricyclic Anti-Depressants Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.68.0.0001 8.04.68.0.0100	Tricyclic Anti-Depressants Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.99.0.0001 8.04.99.0.0020	Buprenorphine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

DOA RAPID TESTS



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



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



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

CLINICAL CHEMISTRY KITS



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



Item Code	Item Description	Sizes
8.05.71.0.0250 8.05.71.0.0500	Uric Acid Enzymatic Colorimetric (Mono Reagents)	2x125ml 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 8.05.73.0.0050	Electrolytes Kit (Sodium, Potassium, Chloride)	20 Tests for each 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 8.25.01.0.0025	Saliva Alcohol Test Strip, Individually Pouched	Bulk 25 Tests/Box
8.25.02.0.0001 8.25.02.0.0020	Breath Alcohol Test (0.02%), Individually Pouched	Bulk 20 Tests/Box
8.25.03.0.0001 8.25.03.0.0025	Breath Alcohol Test (0.05%), Individually Pouched	Bulk 25 Tests/Box
8.25.04.0.0001 8.25.04.0.0025	Breath Alcohol Test (0.08%), Individually Pouched	Bulk 25 Tests/Box
8.25.05.0.0001 8.25.05.0.0020	Ethyl Glucuronide (ETG) Urine Strip, Individually pouched	Bulk 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	CEFACLOX (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	CEPHELEXIN (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



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



INFECTIOUS DISEASES ELISA KITS

Item Code	Item Description	Sizes
8.14.19.1.0096	Helicobacter Pylori Antigen 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 (Divce only)	1 Divce only



CERTIFICATES



ISO 13485



Blood Grouping CE Certificate



Full Quality Assurance Certificate.

OTHER CERTIFICATES

- FDA 510k Atlas Drug of Abuse Tests (Cup & Panel Format)
- GMP Certificate
- FDA 510k Atlas Home Pregnancy Test (Midstream Format)
- FDA 510k Atlas Home Ovulation Test (Midstream Format)
- hCG Test Strip CE certificate
- hCG Test Cassette CE certificate
- hCG Midstream Test CE certificate
- Ovulation Test Midstream CE certificate
- Ovulation Test Cassette CE certificate
- Menopause Test Midstream CE certificate
- Menopause Test Cassette CE certificate
- Liver Function Test CE certificate
- Diabetes Test CE certificate
- UTI Test CE certificate
- Kidney function Test CE certificate

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