Atlas Medical

PRODUCT CATALOGUE

2023-2024

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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 repre - sented 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.

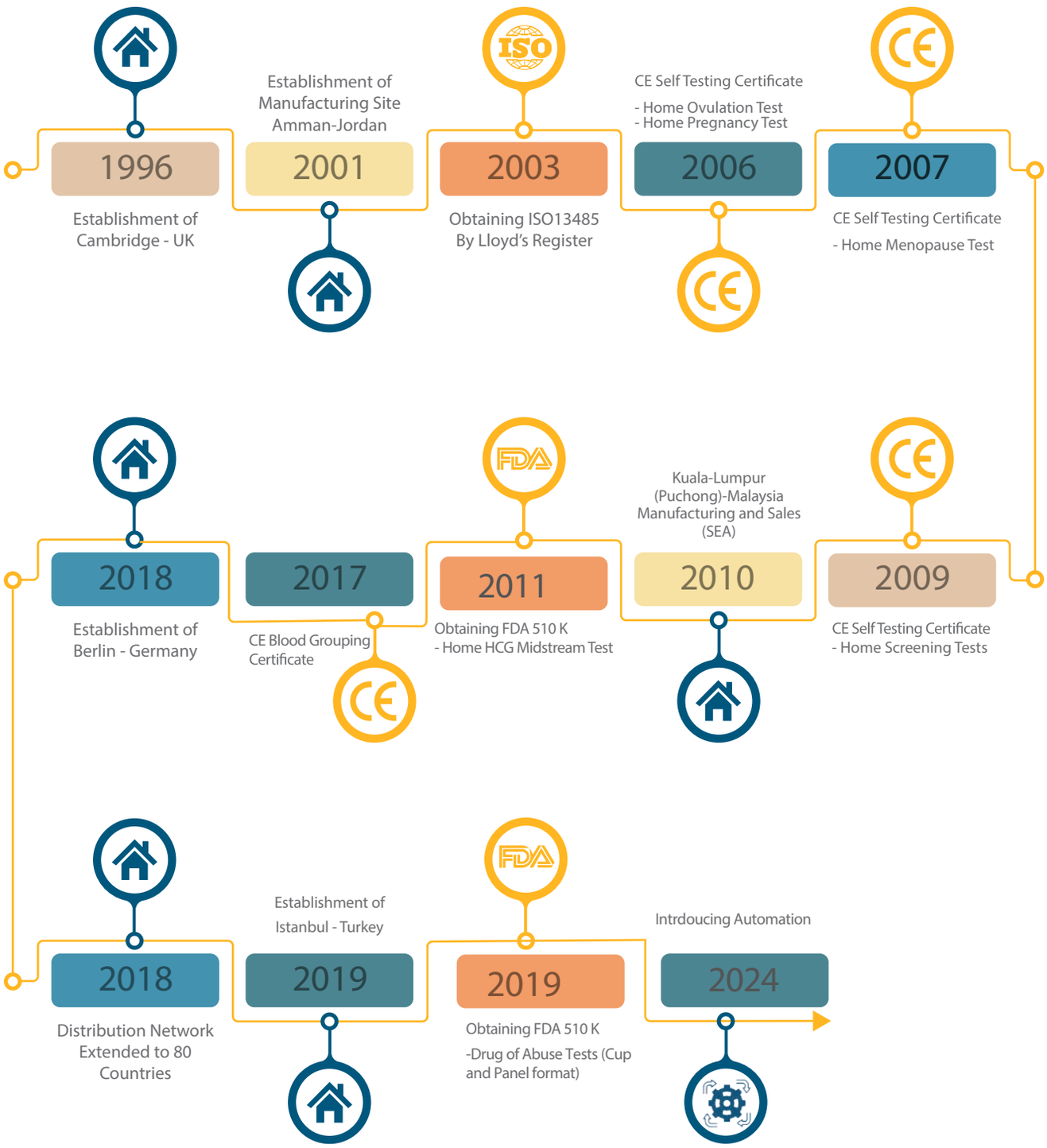
Standards

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 con
marking purposes for many of our IVD products, either self-declared or through our Notified Bod

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


1996
Establishment of Cambridge - UK
2001
Establishment of Manufacturing Site Amman-Jordan
2003
Obtaining ISO13485 By Lloyd's Register
2006
CE Self Testing Certificate
- Home Ovulation Test
- Home Pregnancy Test
2007
CE Self Testing Certificate
- Home Menopause Test
2009
CE Self Testing Certificate
- Home Screening Tests
2010
Kuala-Lumpur (Puchong)-Malaysia Manufacturing and Sales (SEA)
2011
Obtaining FDA 510 K
- Home HCG Midstream Test
2017
CE Blood Grouping Certificate
2018
Establishment of Berlin - Germany
2018
Distribution Network Extended to 80 Countries
2019
Establishment of Istanbul - Turkey
2019
Obtaining FDA 510 K
-Drug of Abuse Tests (Cup and Panel format)
2024
Intrdoucing Automation

LATEX KITS

Overview

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

Features

- They cover a selection of routine tests in serology and microbiology.
- They are conveniently packed in sizes of 50 or 100 tests and includes all the necessary reagents, controls, stirrers and slides to conduct the test.
- Affordable, easy to use, dependable and offer a clear and visible agglutination for doubt-free results.
- Some Latex Kits come with a Buffer.

Item Code	Item Description	Sizes
8.00.00.0.0050 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
8.00.17.0.0050 8.00.17.0.0100	D-Dimer Latex Kit	50 Tests 100 Tests
8.00.21.0.0050 8.00.21.0.0100	Waaler 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

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 Turbilatex products is to detect and quantify the antigen present in human serum or plasma samples.

Features

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

Item Code	Item Description	Sizes
8.44.00.0.0050	RF Turbidimetric Latex Kit	50 Tests
8.44.01.0.0050	CRP Turbidimetric Latex Kit	50 Tests
8.44.02.0.0050	ASO Turbidimetric Latex Kit	50 Tests
8.44.03.0.0050	D-Dimer Turbidimetric Latex Kit	50 Tests
8.44.04.0.0050	Microalbumine Turbidimetric Latex Kit	50 Tests
8.44.05.0.0050	Ferritin Turbidimetric Latex Kit	50 Tests
8.44.06.0.0050	Transferrin Turbidimetric Latex Kit	50 Tests
8.44.08.0.0050	HbA1C Turbidimetric Latex Kit	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 floccuation to detect reagin antibodies in serum or plasma .

Item Code	Item Description	Sizes
8.00.18.0.0100	RPR Carbon Antigen Kit	100 Tests
8.00.18.0.0500		500 Tests
8.00.19.0.0100	TPHA Kit	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
8.01.19.0.0005	Febrile Antigens Positive Control	5 ml/vial
8.01.20.0.0005	Febrile Antigen Negative Control	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	Salmonella OB Reagent	5 ml/vial
8.01.03.0.0005	Salmonella OC Reagent	5 ml/vial
8.01.04.0.0005	Salmonella OD Reagent	5 ml/vial
8.01.05.0.0005	Salmonella HA Reagent	5 ml/vial
8.01.06.0.0005	Salmonella HB Reagent	5 ml/vial
8.01.07.0.0005	Salmonella HC Reagent	5 ml/vial
8.01.08.0.0005	Salmonella HD Reagent	5 ml/vial
8.01.10.0.0005	Brucella Abortus Reagent	5 ml/vial
8.01.11.0.0005	Brucella Melitensis Reagent	5 ml/vial
8.01.12.0.0005	Proteus OX2 Reagent	5 ml/vial
8.01.13.0.0005	Proteus OX19 Reagent	5 ml/vial
8.01.14.0.0005	Proteus OXK Reagent	5 ml/vial
8.01.15.0.0010	Brucella Antigen Kit (Brucella melitensis, Brucella abortus)	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

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
8.02.16.0.0005	Anti-A1, Lectin (Dolichosbiflorus),	5 ml/vial
8.02.17.0.0005	Anti-H, Lectin (Ulexeuropaeus),	5 ml/vial
8.02.18.0.0005	Anti-C Monoclonal,	5 ml/vial
8.02.19.0.0005	Anti-c Monoclonal,	5 ml/vial
8.02.20.0.0005	Anti-E Monoclonal,	5 ml/vial
8.02.21.0.0005	Anti-e Monoclonal,	5 ml/vial
8.02.22.0.0005	Anti-C+D+E Monoclonal,	5 ml/vial
8.02.27.0.0002	Anti-Fya, Human,	2 ml/vial
8.02.28.0.0002	Anti-Fyb, Human,	2 ml/vial
8.02.29.0.0002	Anti-k, Human,	2 ml/vial
8.02.30.0.0002	Anti-Kpa, Human,	2 ml/vial
8.02.31.0.0002	Anti-Kpb, Human,	2 ml/vial
8.02.32.0.0002	Anti-Jka, Human,	2 ml/vial
8.02.36.0.0005	Anti-K Monoclonal,	5 ml/vial
8.02.54.0.0002	Anti-Cw,	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
8.02.52.0.0010	Rh-D Negative Control	10 ml/vial
8.02.63.1.0010	Antibody Enhancement Solution (LISS)	10 ml/vial
8.02.23.0.0002	Anti-M, Human,	2 ml/vial
8.02.24.0.0002	Anti-N, Lectin (Viciagraminea),	2 ml/vial
8.02.25.0.0002	Anti-S, Human,	2 ml/vial
8.02.26.0.0002	Anti-s, Human,	2 ml/vial
8.02.37.0.0002	Anti-Lea, Monoclonal,	2 ml/vial
8.02.38.0.0002	Anti-Leb, Monoclonal,	2 ml/vial
8.02.39.0.0002	Anti-P1, Monoclonal,	2 ml/vial

HEMATOLOGY TESTS

Overview

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

Features

- Some kits includes 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.

Co-aggulation 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
8.02.45.1.0080	APTT (PTT) Kit (Calcium Chloride reagent + Normal Control)	80 Tests
8.02.69.0.0100	Fibronogen Test kit KIT	100 Tests

Hemoglobin Reagents

Item Code	Item Description	Sizes
8.02.46.1.0500 8.02.46.1.1000 8.02.46.1.3000	Drabkins Reagent,	50ml/Bottle 2x50ml 6x50ml
8.02.50.0.0010	Haemoglobin Standard	10ml/vial

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:
  1. A screening test to detect sickle haemoglobin (HbS)
  2. A centrifugation test to differentiate the sickle cell trait (AS) from sickle cell anaemia (SS).

Item Code	Item Description	Sizes
8.02.67.0.0050 8.02.67.0.0100	Sickle Cell Kit, 50 Tests Sickle Cell Kit,	50 Test 100 Test
8.02.68.0.0001	Sickle Cell positive & negative control set	1ml 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.

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

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

INFECTIOUS DISEASE RAPID TESTS

ANTIGEN TESTING

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
8.66.01.0.0001 8.66.01.0.0020	**COVID-19 Antgen Test Cassette, Nasal Swab, Individually pouched**	**Bulk 20Test/ Box**
8.66.02.0.0001 8.66.02.0.0020	**COVID-19 Combo Antigen & Influenza, A+B Test , Individually pouched**	**Bulk 20Test/ Box**

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

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.

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, Leucocytes	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, Protien, 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

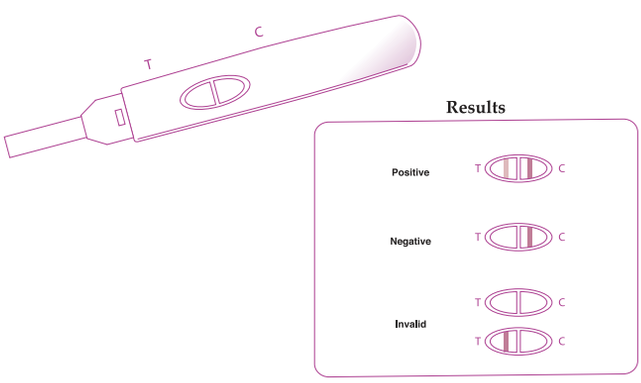
FERTILITY RAPID TESTS

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

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

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

- Can be supplied in cassette , strip, panel and cup formats.
- The kits are conveniently packed in different kitsizes 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
8.16.47.0.0001 8.16.47.0.0020	Fentanyl Test Cassette, Urine, Individually Pouched	Bulk 20 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

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	CEFACLOR (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 / SULBACTUM (75 µg + 30 µg) - CS	5x50 Discs
8.39.15.0.0250	CEFOTAXIME (30 µg) - CTX	5x50 Discs
8.39.16.0.0250	CEFPIROME (30 µg) - CE	5x50 Discs
8.39.17.0.0250	CEFPODOXIME (10 µg) – CPD	5x50 Discs
8.39.18.0.0250	CEFPROZIL (30 µg) - CPR	5x50 Discs
8.39.19.0.0250	CEFTAZIDIME (30 µg) – CAZ	5x50 Discs
8.39.20.0.0250	CEFTIZOXIME (30 µg) - CZX	5x50 Discs
8.39.21.0.0250	CEFTRIOXONE (30 µg) - CTR	5x50 Discs
8.39.22.0.0250	CEFUROXIME (30 µg) - CXM	5x50 Discs
8.39.23.0.0250	CEPHALEXIN (30 µg) - CN	5x50 Discs
8.39.24.0.0250	CEPHALORIDINE (30 µg)- CH	5x50 Discs
8.39.25.0.0250	CEPHALOTHIN (30 µg) - CEP	5x50 Discs
8.39.26.0.0250	CHLORAMPHENICOL (30 µg) - C	5x50 Discs
8.39.27.0.0250	CIPROFLOXACIN (5 µg) - CIP	5x50 Discs
8.39.28.0.0250	CLARITHROMYCIN (15 µg) - CLR	5x50 Discs
8.39.29.0.0250	CLINDAMYCIN (2 µg) - CD	5x50 Discs
8.39.30.0.0250	CLOXACILLIN (5 µg) - COX	5x50 Discs
8.39.32.0.0250	DOXYCYCLINE (30 µg) - DOX	5x50 Discs
8.39.33.0.0250	ERYTHROMYCIN (15 µg) - E	5x50 Discs
8.39.34.0.0250	FURAZOLIDONE (100 µg) - FZ	5x50 Discs
8.39.35.0.0250	GATIFLOXACIN (5 µg) - GAT	5x50 Discs
8.39.36.0.0250	GENTAMYCIN (10 µg) - GEN	5x50 Discs
8.39.38.0.0250	KANAMYCIN (30 µg) - K	5x50 Discs
8.39.39.0.0250	LEVOFOLXACIN (5 µg) - LE	5x50 Discs
8.39.40.0.0250	LINCOMYCIN (15 µg) - LN	5x50 Discs
8.39.41.0.0250	LINEZOLID (30 µg) - LZ	5x50 Discs
8.39.42.0.0250	LOMEFLOXACIN (10 µg) - LOM	5x50 Discs
8.39.43.0.0250	MEROPENEM (10 µg) - MRP	5x50 Discs
8.39.44.0.0250	MINOCYCLINE (30 µg) - MI	5x50 Discs
8.39.45.0.0250	MOXIFLOXACIN (5 µg) - MXF	5x50 Discs
8.39.46.0.0250	NALIDIXIC ACID (30 µg) - NA	5x50 Discs
8.39.47.0.0250	NITROFURANTOIN (300 µg) - NIT	5x50 Discs

ANTIBIOTIC SENSITIVITY DISCS

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

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

ELISA KITS

Features

- The kits feature high sensitivities, simple and robust methods, breakable well strips, quantitative results, ready-to use liquid reagents, and reasonable assay time.
- The assays can be used on most open ELISA manual readers and washers as well as open ELISA auto-analyzers.
- Kits are packed in sizes of 96 tests.

Overview

Atlas Medical offers a range of Enzyme Linked Immunosorbent Assay (ELISA or EIA) to detect major hormones in the fields of thyroids and fertility in serum.

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

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 .
Clincal Chemistry tests are indicated to assess systemic functions such liver function , kidney function , and endocrine and metabolic function .
Methods commonly used are colormetric and kinetic.

Features

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

Item Code	Item Description	Sizes
8.05.00.0.0250 8.05.00.0.0500	Albumin Bromocresol Green	2x125ml 4x125ml
8.05.01.0.0030 8.05.01.0.0060	Amylase	3x10ml 6x10ml
8.05.04.0.0250 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
8.05.13.0.0250 8.05.13.0.0500	CK-MB Kinetic (Liquid)	5x10ml 5x20ml
8.05.15.0.0250 8.05.15.0.0500	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
8.05.19.0.0250 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
8.05.22.0.0250 8.05.22.0.0500	GPT (ALT) IFCC Kinetic (Liquid)	5x50ml 5x100ml
8.05.23.0.0250 8.05.23.0.0500	GPT (ALT) Reitman-Frankel Colorimetric	2x100ml 2x125m
8.05.25.0.0250 8.05.25.0.0500	Gamma GT Kinetic, Carboxy Substrate (Liquid)	5x50ml 5x100ml
8.05.26.0.0250 8.05.26.0.0500	HDL Cholesterol Precipitating Reagent	2x50ml 2x100ml
8.05.27.0.0250	Iron Ferrozine Colorimetric	4x50ml
8.05.29.0.0250 8.05.29.0.0500	LDH Pyruvate Kinetic UV DGKC (Liquid)	5x50ml 5x100ml
8.05.30.0.0250	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
8.05.33.0.0250 8.05.33.0.0500	Potassium Colorimetric	50 Tests 100 Tests
8.05.34.0.0250 8.05.34.0.0500	Sodium Colorimetric	50 Tests 100 Tests
8.05.35.0.0250	TIBC (Total Iron Binding Capacity)	100 Tests
8.05.36.0.0250 8.05.36.0.0500	Total Lipids Phosphovainilline 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

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 ingredientsto ensure good quality and vivid staining.

Features

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

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
8.15.150.0250	Mayers haematoxylin	250ml/Bottle

STAIN PACKS FOR HISTOLOGY

Item Code	Item Description	Sizes
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

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

HOME TESTS

CE 0459

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 .

CE 0459

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.

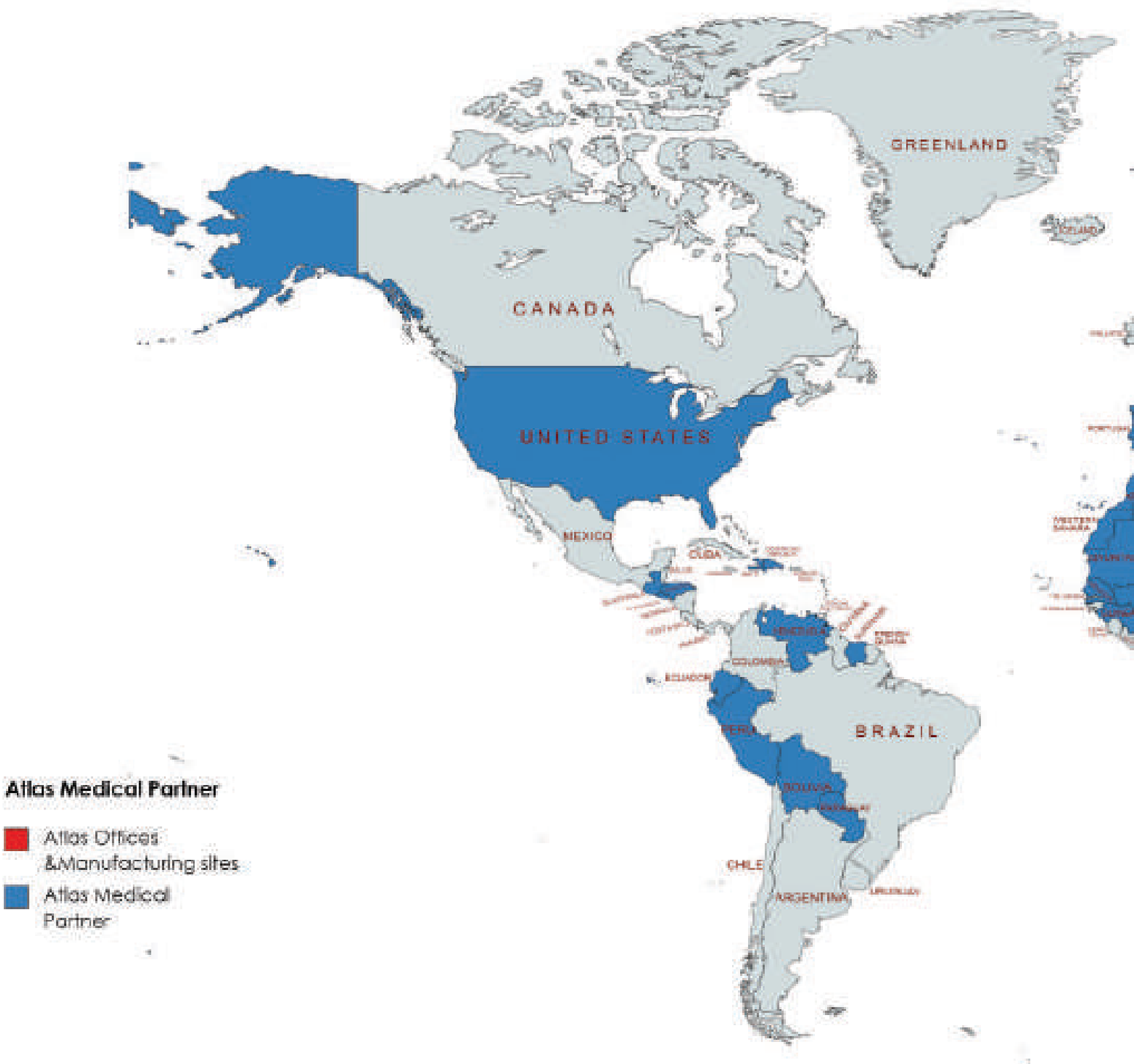
Features

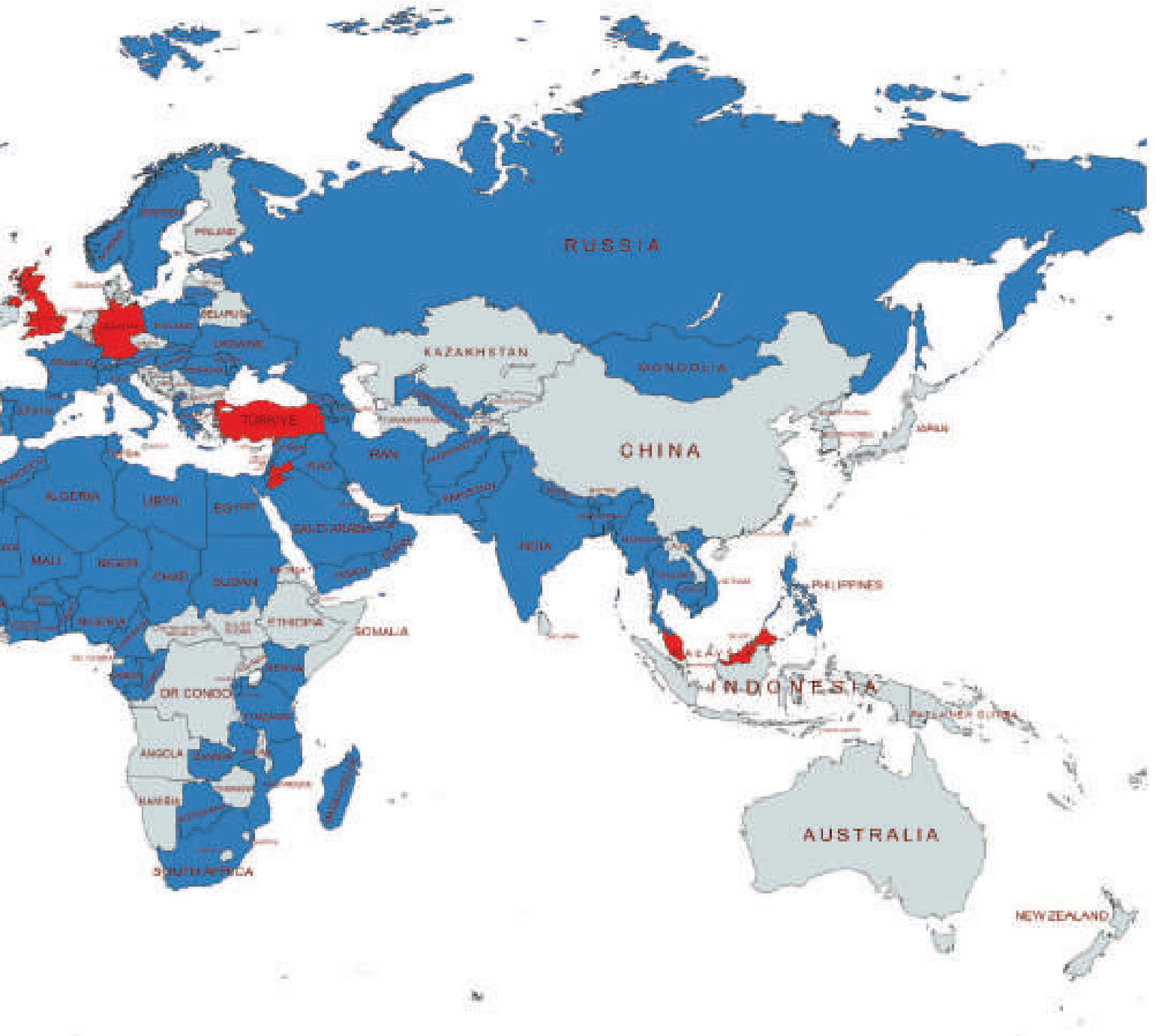
- Reliance Gold ™ by Atlas Medical, uses the latest blood glucose gold sensor technology to offer the most accurate and reliable results.
- Test time required is 5 Seconds.
- Required sample volume is 0.9µl
- Test result range is between 10 - 600 mg/dl (0.6 -33.3 mmol/L)

Reliance Gold

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

INTERNATIONAL PRESENCE




RUSSIA
KAZAKHSTAN
MONGOLIA
CHINA
INDIA
IRAN
IRAQ
TÜRKIYE
SAUDI ARABIA
EGYPT
LIBYA
ALGERIA
MALI
NIGER
CHAD
SUDAN
ETHIOPIA
SOMALIA
DR CONGO
ANGOLA
NAMIBIA
SOUTH AFRICA
PHILIPPINES
INDONESIA
AUSTRALIA
NEW ZEALAND

CERTIFICATES

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.2

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

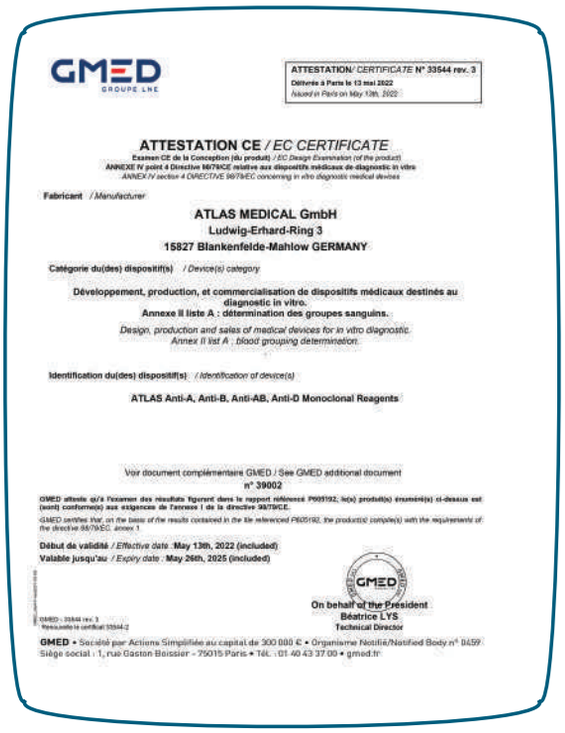
Début de validité / *Effective date* : October 9th, 2023 (included)
Valable jusqu'au / *Expiry date* : October 8th, 2026 (included)
Etabli le / *Issued on* : October 9th, 2023

On behalf of the President
Béatrice LYS
Technical Director

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
Remplace le certificat 36655-1

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

ISO 13485



ATTESTATION / *CERTIFICATE* N° 33544 rev. 3
Délivrée à Paris le 13 mai 2022
Issued in Paris on May 13th, 2022

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

Fabricant / *Manufacturer*

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

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

Développement, production, et commercialisation de dispositifs médicaux destinés au diagnostic in vitro.
Annexe II liste A : détermination des groupes sanguins.
Design, production and sales of medical devices for in vitro diagnostic.
Annex II list A : blood grouping determination.

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

ATLAS Anti-A, Anti-B, Anti-AB, Anti-D Monoclonal Reagents

Voir document complémentaire GMED / See GMED additional document
n° 39002

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P605192, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 98/79/CE.
GMED certifies that, on the basis of the results contained in the file referenced P605192, the product(s) complies with the requirements of the directive 98/79/EC, annex I.

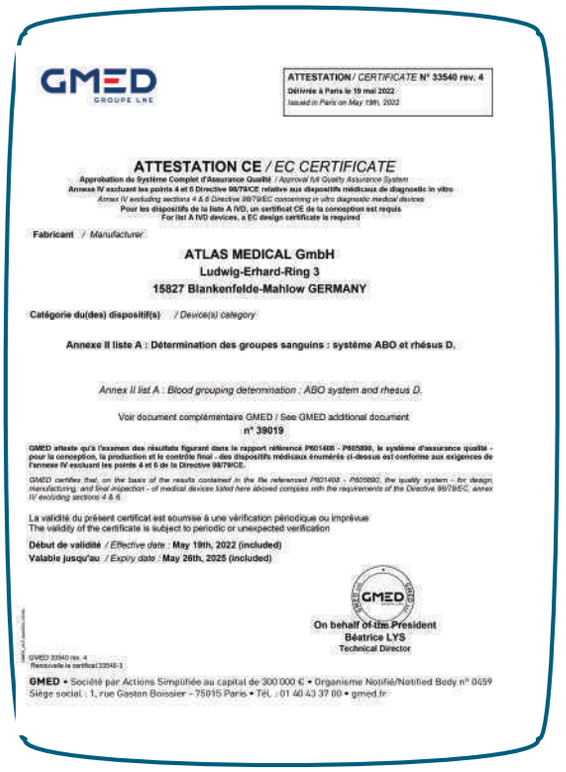
Début de validité / *Effective date* : May 13th, 2022 (included)
Valable jusqu'au / *Expiry date* : May 26th, 2025 (included)

On behalf of the President
Béatrice LYS
Technical Director

GMED - 33544 rev. 3
Remplace le certificat 33544-2

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Blood Grouping CE Certificate



ATTESTATION / *CERTIFICATE* N° 33540 rev. 4
Délivrée à Paris le 19 mai 2022
Issued in Paris on May 19th, 2022

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

Fabricant / *Manufacturer*

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

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

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

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

Voir document complémentaire GMED / See GMED additional document
n° 39019

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P601408 - P605890, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe IV excluant les points 4 et 6 de la Directive 98/79/CE.
GMED certifies that, on the basis of the results contained in the file referenced P601408 - P605890, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 98/79/EC, annex IV excluding sections 4 & 6.

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

Début de validité / *Effective date* : May 19th, 2022 (included)
Valable jusqu'au / *Expiry date* : May 26th, 2025 (included)

On behalf of the President
Béatrice LYS
Technical Director

GMED 33540 rev. 4
Remplace le certificat 33540-3

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Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

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

FIND US ON:

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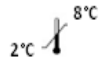
Atlas Medical CE

RPR Carbon Antigen

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



Store at 2 to 8 °C

***INTENDED USE**

A manual rapid plasma reagin carbon test for the qualitative and semi-quantitative detection of non-treponemal antibodies against Syphilis in human serum and plasma to provide serological evidence of past/current Syphilis infections when preceeded by a positive treponemal test. Not to be used as a screening tool for blood or tissue donations.

INTRODUCTION

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

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

PRINCIPLE

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

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

MATERIALS

MATERIALS PROVIDED

- **RPR carbon antigen reagent**: A particulate carbon suspension coated with lipid complexes, with 0.95 g/L sodium azide.
- **Positive Control**: Human syphilitic serum reactive with the test reagent, with 0.95 g/L Sodium azide. **(Optional).**
- **Negative control**: non-reactive phosphate buffer containing 5% BSA pH7.4, with 0.1% of Sodium azide. **(Optional).**
- **RPR test cards or white glass slide (Optional).**
- **Plastic sticks (Optional).**
- **Package insert**.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

- Rotator (100rpm).
- Timer.
- Calibrated micropipettes and tips.

PACKAGING CONTENT

REF **8.00.18.0.0100 (2mL Reagent, 1x0.5ml Positive Control, 1x0.5mL Negative Control)**

REF **8.00.18.0.0500 (10mL Reagent, 1x1ml Positive Control, 1x1mL Negative Control)**

REF **8.00.18.3.1000 (2x10ml Reagent, 1x2ml Positive Control, 1x2ml Negative Control)**

STORAGE AND STABILITY

- All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C.
- *Do Not Freeze.
- *Signs of deterioration:
  - RPR Carbon: Visible agglutination.
  - Controls: Presence of particles and turbidity.

PRECAUTIONS AND WARNINGS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- *The test is not for near-patient or self-testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all negative and positive in the manner as patient specimens .
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Components of different human origin have been tested and found to be negative for the presence of antibodies anti- HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
- *Do not touch, drink, or ingest the reagent.
- *Do not use black glass slides during testing.
- *Perform the test in a well-lit area with good visibility.
- *Failure in following the instructions may give incorrect results or face safety hazards.
- *Wash the area of contact with water immediately if contact occurs.
- *Wash of the hands and the test table top with water and soap.
- *Do not use the reagent if displaying any signs of deterioration.
- *Always use a fresh pipette tip and stirring sticks for each test.
- *Handle the used disinfectant with care.
- *Glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- *Do not use the reagents if the label is missing, damaged, or unclear.
- *Do not use leaked vials and making proper disposal of them.
- *Use forceps, scoops, or other mechanical devices for removing broken glass from the working area. A dustpan and brush should be used to clean up shards/small pieces of broken glass. Broken glass must be disposed of in a sharps container.
- *The reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide bulidup.
- *Any serious incident that occur in relation to the device shall be reported to the manufacturer and the competent authority. (Feedback@atlas-medical.com)

COLLECTION, HANDLING AND PREPARATION OF SPECIMEN

- Fresh serum or plasma. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.
- *Samples may be stored at 2-8° C for up to 7 days. For long term storage sera should be stored at -20° C up to 30 days.

REAGENT PREPARATION

RPR reagent is ready to use. No preparation is required.

PROCEDURES

QUALITATIVE PROCEDURE

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

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

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

SEMI-QUANTITATIVE PROCEDURE

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

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

INTERPRETATION OF TEST RESULTS

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

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

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

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

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

<u>*LIMITATION OF THE TEST</u>

- Pregnancy may give a false positive reaction.
- Hepatitis and Brucellosis may give a false positive reaction.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PERFORMANCE CHARACTERISTICS

Sensitivity: 100%.
Specificity: 100%.
Precision: 100%
Hook effect: no prozone effect up to the titer level studied: 1/16.
Interferences: There is no effect from Hemoglobin/Bilirubin and Rheumatoid factor on the results of RPR carbon antigen at the studied concentrations:
Bilirubin: ≤15 mg/dL.
Hemoglobin: ≤10 g/L.
Rheumatoid factor: ≤300 IU/ml.

REFERENCES

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

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Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

PPI2280A01
Rev C (27.03.2024)

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

<u>*: Indication of the introduced modifications.</u>

Atlas Medical

TPHA TEST KIT

A passive particle agglutination assay for the qualitative and semi-quantitative detection of IgG and IgM antibodies to *Treponema pallidum*

IVD For *in vitro* diagnostic and professional use only

2°C 8°C Store at 2° to 8° C CE

INTENDED USE

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

INTRODUCTION

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

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

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

PRINCIPLE OF THE TEST

Atlas TPHA uses preserved avian erythrocytes coated with extracted antigens of T.pallidum (Nichols strain). Specific antibodies present in a sample of plasma or serum bind to these antigens when the sample is incubated with the particles. This causes the particles to agglutinate, then settle to form a characteristic pattern in the test well.

Non-specific reactions are eliminated by the use of absorbents. The assay can be run and interpreted manually or with an auto-analyzer using an agglutination interpretation program.

MATERIALS PROVIDED

- Test cells; avian erythrocytes coated with antigens of *T. Pallidum.*
- Control cells; avian erythrocytes.
- Sample Diluent; Saline solution containing absorbents.
- Positive control; Rabbit antiserum, titer 1/1280, **Pre-diluted.**
- Negative control; Normal Rabbit Serum, **Pre-diluted.**
- Package Insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Micropipettes capable of delivering: 10, 25, 75 and 190µl.
- U-Well microtitration plates.

PACKAGING CONTENTS

REF **8.00.19.0.0200 (2x20 ml Diluent, 2x8.5 ml Control Cell, 2x8.5 ml Test Cells, 1x1 ml Positive Control, 1x1 ml Negative Control)**

REF **8.00.19.0.0100 (20ml Diluent, 8.5ml Control Cell, 8.5ml Test Cells, 1ml Positive Control, 1ml Negative Control)**

PRECAUTIONS

- For i*n vitro* diagnostic and professional use.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- If spillage of reagent occur clean with disinfectant (disinfectant used could be irritable so handle with care).
- The test is for well-trained professional health user not for lay user.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Reagents and controls contain 0.1% sodium azide as a preservative which is toxic and can be absorbed through the skin when drained, the drains should be thoroughly washed with water.
- The reagent is considered toxic, avoid drinking, ingestion and contact with skin or mucus membrane.

REAGENTS HANDELING

- All the reagents must be allowed to equilibrate to room temperature before use.
- Do not freeze any of the reagents.

REAGENTS STORAGE

- Store bottles upright at **2–8°C**.
- **Do not freeze**
- Do not use after the expiry date.

SAMPLE PREPARATION AND HANDLING

- Use fresh serum or plasma samples free of cells and microbial contamination.
- Samples may be stored at 2-8°C for up to 7 days prior to testing.
- Samples can be frozen at -20°C or lower, these should be thawed and mixed prior to testing.

INTERFERING SUBSTANCES AND LIMITATION OF THE TEST

- Atlas TPHA test kit can be used for serum and plasma samples.
- No interfering substances have been identified.
- Atlas TPHA test kit can cross react with other treponemal infections such as *T.pertenue* and *T.carateum* so positive results should be confirmed by another method.
- In early primary syphilis, occasionally, specific antibodies may not be detected.

PROCEDURES

Bring all reagents and samples to room temperature before use.

Kit controls must be run with each assay.

Ensure Test and Control Cells are thoroughly re-suspended.

QUALITATIVE METHOD

Each sample requires 3 wells of a microtitration plate.

1. Add 190 µl of diluent to Well 1.
2. Add 10 µl sample to Well 1. (Sample dilution 1:20).
3. Using a micropipette, mix contents of Well 1 and transfer 25 µl to Wells 2 & 3.
4. Ensure that the Test and Control Cells are thoroughly suspended. Add 75 µl of control cells to Well 2. Add 75µl of Test Cells to Well 3.
5. Tap the plate gently to mix the contents thoroughly.
6. Incubate 45-60 minutes at 15-30° C. **Caution! Keep the plate away from heat, direct sunlight and any source of vibration.**
7. Read results. Results are stable if the plate is covered and the above precautions are observed.

NOTE

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

SEMI-QUANTITATIVE TEST

9 wells are needed for each sample.

Sample Dilution (to 1 in 20)

1. Add 190µL of sample diluent to a well.
2. Add 10µL of sample to the same well. Mix thoroughly.

Note: Kit controls are pre-diluted (i.e. diluted 1 in 20)

Titration

1. Leave the first well empty, add 25µL of diluent all other wells in the sequence.

2. Transfer 25µL from step 1 to the first well.
3. Transfer 25µL from step 1 to the second well and mix, then serially dilute along the well sequence, discard the excess 25µL from the final well.

Test

Re-suspend the Test and Control Cells thoroughly

4. Add 75µL of Test Cells to each well.

(Final sample dilution is 1 in 80 – 1 in 10,240)

5. Mix wells thoroughly.
6. Incubate at 15-30°C on a vibration-free surface for 45 - 60 minutes. Caution! Keep the plate away from heat, direct sunlight and any source of vibration.
7. Read results. Results are stable if the plate is covered and the above precautions are observed.

The titer of the sample is the reciprocal of the final positive sample dilution.

INTERPRETATION AND ASSAY VALIDATION

Assay Control

The Kit Controls must be give the correct result; Negative is Negative and Positive is Positive. When the Kit Positive is titrated the expected end point is 640 – 2560.

Positive **Equivocal Negative**

A sample where the Test Cell well is non-reactive should be considered as **negative for *T.pallidum***. Reactivity less than equivocal is considered negative.

A sample where the Test Cell well is reactive indicates antibodies to *T.pallidum* resulting from a syphilis infection. The sample should be repeated in duplicate. Where 2 or more wells are positive the sample should be considered as **positive *for T.pallidum***.

A repeatable equivocal sample should be considered positive.

Where a sample is reactive in both Test and Control Cells, if the agglutination is greater in the Test Cells, then the sample is considered positive and should be repeated as above.

Where a sample has greater or equal agglutination in the Control Cells then the sample should be absorbed using the following procedure.

Absorption of Non-specific Reactions

1. Add 10µL of sample to 190µL of re-suspended Control Cells, mix thoroughly and leave for 30 minutes.
2. Centrifuge to deposit the cells at a minimum of 1500g for 3 minutes.
3. Add 25µL of supernatant from step 2 to each of 2 wells.
4. Ensure Test and Control Cells are re-suspended.

   Add 75µL of Test Cells to the first well.
   Add 75µL of Control Cells to the second well.
5. Mix wells thoroughly and Incubate at 15-30°C on a vibration-free surface for 45 - 60 minutes
6. Read and interpret patterns as above.

PERFORMANCE CHARACTERISTICS

Specificity

A study on 300 donor serum showed 100% specificity. (95% confidence limits 98.8 – 100%).
A study on 300 donor EDTA plasma showed 100% specificity. (95% confidence limits 98.8– 100%).

Sensitivity

A study on 100 syphilis positive samples showed 100% sensitivity. (95% confidence limits 96.6 – 100%).

Analytical sensitivity

Atlas TPHA has an expected sensitivity of between 0.1 and 0.025 IU/ml against the 1st IS for human syphilitic plasma IgG and IgM NIBSC code: 05/132

REFRENCES

1. Rathlev T. - Haemagglutination tests utilizing antigens from pathogenic and apathogenic Treponema pallidum WHO/VDT/RES 1965 ; 77 : 65.
2. Tomizawa T, Kasamatsu S. - Haemagglutination tests for diagnosis of syphilis. A preliminary report. Japan. J. Med. Sci. Biol. 19, 305-308, 1966.
3. Rathlev T. - Haemagglutination test utilizing pathogenic Treponema pallidum for the serodiagnosis of syphilis. Br J Vener Dis 1967 ; 43 : 181-5
4. Tomizawa T. Kasamatsu S. Yamaya S. - Usefulness of the haemagglutination test using Treponema pallidum antigen (TPHA) for the serodiagnosis of syphilis. Jap J Med Sci Biol 1969 ; 22 : 341-50.
5. Sequeira P,J,L. Eldridge A,E. - Treponemal Haemagglutination test. Br J Vener Dis 1973 ; 49 : 242-8.
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7. Wasley G.D. & Wong H.H.Y. Syphilis Serology Priciples and Practice. Oxford Medical Publications 104 - 105

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Website: www.atlas-medical.com

PPI2388A01
Rev B (22.02.2024)

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

***: Indication of the introduced modifications.**

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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ZLG-BS-245.10.07

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 092378 0009 Rev. 00

Manufacturer:

Healgen Scientific Limited Liability Company
3818 Fuqua Street
Houston TX 77047
USA

Product: **Screening test for Hepatitis C marker**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. 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:V7 092378 0009 Rev. 00

Report No.: 713234651

Valid from: 2022-04-22
Valid until: 2025-05-26

Date, 2022-04-22

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 092378 0009 Rev. 00

Model(s): **HCV Hepatitis C Virus Rapid Test**

Facility(ies):

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

Parameters:

Model Name:	Model No.:
--	
HCV Hepatitis C Virus Rapid Test (Serum / Plasma) (Cassette)	GCHCV-302a
HCV Hepatitis C Virus Rapid Test (Whole Blood /Serum / Plasma) (Cassette)	GCHCV-402a

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

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Tel: +1 713 733 8088
Fax: +1 713 733 8848
Web: www.Healgen.com
E-mail: sales@healgen.com

CE-DOC-H003
Ver.1.7

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: Healgen Scientific Limited Liability Company

Legal Manufacturer Address: *3818 Fuqua Street, Houston, TX 77047, USA.*

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

Orient Gene HCV Hepatitis C Virus Rapid Test (Serum/Plasma) (Cassette)	GCHCV-302a
Orient Gene HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma)(Cassette)	GCHCV-402a

EDMA Code: 15 70 02 02

Classification: *Annex II List A*
Conformity assessment route: *Annex IV (Full Quality Assurance)*

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body
Notified Body: TÜV SÜD Product Service GmbH
Notified Body Address: Munich Branch Ridlerstraße 65 80339 München Germany
EC Certificate No.: V1 092378 0004 Rev. 02 Valid until: 2025-05-26
EC Design-Examination Certificate No.: V7 092378 0009 Rev. 00 Valid until: 2025-05-26

It bears the mark

CE 0123

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 Name: QARAD b.v.b.a.
EC Representative Address: Cipalstraat 3, B-2440 Geel, Belgium

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

Signature:
Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President
Date: 2022.4.22

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 092305 0001 Rev. 02

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. 02

Report No.: SH2398804

Valid from: 2024-03-17
Valid until: 2027-03-16

Date, 2024-03-01

Christoph Dicks
Head of Certification/Notified Body

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 092305 0001 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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

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TÜV®

Evaluation Report for *HEALGEN/ORIENT GENE* HCV Test Device

Objective: To evaluate the diagnostic sensitivity and specificity of the *HEALGEN/ORIENT GENE* HCV Rapid Test Device

Institute	:	Biomex GmbH	Country	:	Germany
Name	:	Dr. Heike Lukhaup	Title	:	Quality control
Address	:	Siemensstraße 38 69123 Heidelberg			
Date	:	09th April 2015			

	Details of the *HEALGEN/ORIENT GENE* HCV test devices used in this study	Details of the reference test used in this study
Name	*HEALGEN/ORIENT GENE* HCV Rapid Test Device (Whole Blood/ Serum/ Plasma) (GCHCV-402a)	Abbott PRISM HCV IgG_ChLIA ROCHE 480/ COBAS Taqman HCV 2.0 Abbott HCV IgG Assay Kit Abbott RealTime HCV PCR Biorad/Sanofi
Manufacturer	*Zhejiang Orient Gene Biotech Co., LTD*	
Lot No.	S1411001	
Exp.	2016-10	

Diagnostic Sensitivity - HCV positive samples (any genotype)

#	Sample ID	Sample Matrix (Whole blood, serum or Plasma)	*HEALGEN/ORIENT GENE* HCV			Result with reference test		
			Signal of T	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
1	6937	Citrat-plasma	√	√	positive	positive		positive
2	6995	Citrat-plasma	√	√	positive	positive		positive
3	7032	Citrat-plasma	√	√	positive	positive		positive
4	7037	Citrat-plasma	√	√	positive	positive		positive
5	7075	Citrat-plasma	√	√	positive	positive		positive
6	8012	Citrat-plasma	√	√	positive	positive		positive
7	HCVGT5131126-06	CPD-Plasma	√	√	positive	17600	IU/mL	positive
8	HCVGT5131126-07	CPD-Plasma	√	√	positive	45700	IU/mL	positive
9	HCVGT5131126-08	CPD-Plasma	√	√	positive	73900	IU/mL	positive
10	HCVGT5131126-09	CPD-Plasma	√	√	positive	57800	IU/mL	positive
11	HCVGT5131126-10	CPD-Plasma	√	√	positive	146000	IU/mL	positive
12	HCVGT5131126-11	CPD-Plasma	√	√	positive	72200	IU/mL	positive
13	HCVGT5131126-12	CPD-Plasma	√	√	positive	210000	IU/mL	positive
14	HCV6140425-01	CPD-Plasma	√	√	positive	27466,00	IU/mL	positive
15	HCV6140425-03	CPD-Plasma	√	√	positive	7933,00	IU/mL	positive
16	HCV6140425-06	CPD-Plasma	√	√	positive	6933,00	IU/mL	positive
17	HCV6140425-07	CPD-Plasma	√	√	positive	1347,00	IU/mL	positive
18	HCV6140425-08	CPD-Plasma	√	√	positive	2320,00	IU/mL	positive
19	HCV6140425-10	CPD-Plasma	√	√	positive	767,00	IU/mL	positive
20	HCV6140425-15	CPD-Plasma	√	√	positive	47,00	IU/mL	positive
21	HCV6140425-17	CPD-Plasma	√	√	positive	771,00	IU/mL	positive

#	Sample ID	Sample Matrix (Whole blood, serum or Plasma)	*HEALGEN/ORIENT GENE* HCV			Result with reference test		
			Signal of T	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
22	HCV6140425-19	CPD-Plasma	√	√	positive	31200,00	IU/mL	positive
23	HCV6140425-22	CPD-Plasma	√	√	positive	25334,00	IU/mL	positive
24	HCV6140425-23	CPD-Plasma	√	√	positive	10200,00	IU/mL	positive
25	HCV6140425-24	CPD-Plasma	√	√	positive	31334,00	IU/mL	positive
26	HCV6140425-25	CPD-Plasma	√	√	positive	76801,00	IU/mL	positive
27	HCV6140425-28	CPD-Plasma	√	√	positive	40,00	IU/mL	positive
28	HCV6140619-01	CPD-Plasma	√	√	positive	30664,65	IU/mL	positive
29	HCV6140619-02	CPD-Plasma	√	√	positive	14732,97	IU/mL	positive
30	HCV6140619-03	CPD-Plasma	√	√	positive	2332,03	IU/mL	positive
31	HCV6140619-04	CPD-Plasma	√	√	positive	13995,90	IU/mL	positive
32	HCV6140619-05	CPD-Plasma	√	√	positive	7799,81	IU/mL	positive
33	HCV6140619-06	CPD-Plasma	√	√	positive	2633,27	IU/mL	positive
34	6284	Citrat-plasma	√	√	positive	10,1	s/co	positive
35	7471	Citrat-plasma	√	√	positive	12,1	s/co	positive
36	7692	Citrat-plasma	√	√	positive	positive		positive
37	13632	Plasma	√	√	positive	60000	IU/mL	positive
38	9914	Plasma	√	√	positive	330000	IU/mL	positive
39	10503	Plasma	√	√	positive	290	IU/mL	positive
40	10653	Plasma	√	√	positive	370000	IU/mL	positive
41	13507	Plasma	√	√	positive	460000	IU/mL	positive
42	13830	Plasma	√	√	positive	1500	IU/mL	positive
43	1023	Plasma	√	√	positive	22400000	IU/mL	positive
44	1136	Plasma	√	√	positive	1000000	IU/mL	positive
45	1527	Plasma	√	√	positive	2300000	IU/mL	positive
46	1674	Plasma	√	√	positive	13300000	IU/mL	positive
47	1775	Plasma	√	√	positive	910000	IU/mL	positive
48	1797	Plasma	√	√	positive	900000	IU/mL	positive
49	2403	Plasma	√	√	positive	430000	IU/mL	positive
50	2352	Plasma	√	√	positive	16000000	IU/mL	positive
51	2446	Plasma	√	√	positive	2900000	IU/mL	positive
52	2489	Plasma	√	√	positive	7100	IU/mL	positive
53	2746	Plasma	√	√	positive	18000	IU/mL	positive
54	3160	Plasma	√	√	positive	15200000	IU/mL	positive
55	3346	Plasma	√	√	positive	800000	IU/mL	positive
56	3355	Plasma	√	√	positive	2000	IU/mL	positive
57	3357	Plasma	√	√	positive	180000	IU/mL	positive
58	3375	Plasma	√	√	positive	2960000	IU/mL	positive
59	3618	Plasma	√	√	positive	3100000	IU/mL	positive

#	Sample ID	Sample Matrix (Whole blood, serum or Plasma)	*HEALGEN/ORIENT GENE* HCV			Result with reference test		
			Signal of T	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
60	3600	Plasma	√	√	positive	780000	IU/mL	positive
61	3810	Plasma	√	√	positive	3100000	IU/mL	positive
62	3930	Plasma	√	√	positive	900000	IU/mL	positive
63	4048	Plasma	√	√	positive	4780000	IU/mL	positive
64	4049	Plasma	√	√	positive	4950000	IU/mL	positive
65	4086	Plasma	√	√	positive	4360000	IU/mL	positive
66	4348	Plasma	√	√	positive	900	IU/mL	positive
67	4360	Plasma	√	√	positive	940000	IU/mL	positive
68	4646	Plasma	√	√	positive	4600	IU/mL	positive
69	4786	Plasma	√	√	positive	7300	IU/mL	positive
70	5553	Plasma	√	√	positive	25000000	IU/mL	positive
71	5690	Plasma	√	√	positive	830000	IU/mL	positive
72	6032	Plasma	√	√	positive	15000	IU/mL	positive
73	6210	Plasma	√	√	positive	2000000	IU/mL	positive
74	6366	Plasma	√	√	positive	250	IU/mL	positive
75	6598	Plasma	√	√	positive	720000	IU/mL	positive
76	6761	Plasma	√	√	positive	1100000	IU/mL	positive
77	6825	Plasma	√	√	positive	11000000	IU/mL	positive
78	7017	Plasma	√	√	positive	2000000	IU/mL	positive
79	6970	Plasma	√	√	positive	3000000	IU/mL	positive
80	7390	Plasma	√	√	positive	360000	IU/mL	positive
81	7398	Plasma	√	√	positive	3900000	IU/mL	positive
82	8091	Plasma	√	√	positive	9900	IU/mL	positive
83	8368	Plasma	√	√	positive	8700	IU/mL	positive
84	8261	Plasma	√	√	positive	460000	IU/mL	positive
85	8434	Plasma	√	√	positive	2000000	IU/mL	positive
86	8631	Plasma	√	√	positive	610000	IU/mL	positive
87	8767	Plasma	√	√	positive	154000	IU/mL	positive
88	8933	Plasma	√	√	positive	3300000	IU/mL	positive
89	8879	Plasma	√	√	positive	6600000	IU/mL	positive
90	13666	Plasma	√	√	positive	7'800'000	IU/mL	positive
91	9068	Plasma	√	√	positive	1300000	IU/mL	positive
92	9069	Plasma	√	√	positive	>100000000	IU/mL	positive
93	9400	Plasma	√	√	positive	5300000	IU/mL	positive
94	9532	Plasma	√	√	positive	1300000	IU/mL	positive
95	9595	Plasma	√	√	positive	73000	IU/mL	positive
96	9637	Plasma	√	√	positive	9900000	IU/mL	positive
97	9698	Plasma	√	√	positive	1200000	IU/mL	positive

#	Sample ID	Sample Matrix (Whole blood, serum or Plasma)	*HEALGEN/ORIENT GENE* HCV			Result with reference test		
			Signal of T	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
98	9847	Plasma	√	√	positive	2800000	IU/mL	positive
99	9918	Plasma	√	√	positive	3100000	IU/mL	positive
100	10174	Plasma	√	√	positive	51000000	IU/mL	positive
101	10752	Plasma	√	√	positive	2200000	IU/mL	positive
102	10773	Plasma	√	√	positive	290000	IU/mL	positive
103	10861	Plasma	√	√	positive	1300000	IU/mL	positive
104	10863	Plasma	√	√	positive	65000	IU/mL	positive
105	10936	Plasma	√	√	positive	5000000	IU/mL	positive
106	11027	Plasma	√	√	positive	1900000	IU/mL	positive
107	11149	Plasma	√	√	positive	370000	IU/mL	positive
108	11311	Plasma	√	√	positive	35000	IU/mL	positive
109	11455	Plasma	√	√	positive	8100000	IU/mL	positive
110	11590	Plasma	√	√	positive	2600000	IU/mL	positive
111	13323	Plasma	√	√	positive	2000000	IU/mL	positive
112	13327	Plasma	√	√	positive	48000000	IU/mL	positive
113	13353	Plasma	√	√	positive	1300000	IU/mL	positive
114	13354	Plasma	√	√	positive	680000	IU/mL	positive
115	13516	Plasma	√	√	positive	26000000	IU/mL	positive
116	13544	Plasma	√	√	positive	2100000	IU/mL	positive
117	13579	Plasma	√	√	positive	5'100'000	IU/mL	positive
118	13578	Plasma	√	√	positive	750'000	IU/mL	positive
119	13553	Plasma	√	√	positive	110	IU/mL	positive
120	13690	Plasma	√	√	positive	630000	IU/mL	positive

Diagnostic Sensitivity HCV positive samples - specified Genotypes

#	Sample ID	Sample Matrix (Whole blood, serum or Plasma)	*HEALGEN/ORIENT GENE* HCV			Result with reference test		
			Signal of T1	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
	Genotype 1							
1	5674	Citrat-plasma	√	√	positive	N/A		positive
2	5759	Serum	√	√	positive	N/A		positive
3	5902	Citrat-plasma	√	√	positive	N/A		positive
4	6059	Citrat-plasma	√	√	positive	N/A		positive
5	6553	Citrat-plasma	√	√	positive	N/A		positive
6	6586	Citrat-plasma	√	√	positive	N/A		positive
7	6587	Citrat-plasma	√	√	positive	N/A		positive
8	6656	Citrat-plasma	√	√	positive	N/A		positive
9	13522	Plasma	√	√	positive	20	IU/mL	positive
10	13517	Plasma	√	√	positive	3200000	IU/mL	positive

#	Sample ID	Sample Matrix (Whole blood, serum or Plasma)	*HEALGEN/ORIENT GENE* HCV			Result with reference test		
			Signal of T1	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
	Genotype 2							
1	65085617904	CPD-Plasma	√	√	positive	4,90	s/co	positive
2	72082519415	CPD-Plasma	√	√	positive	4,92	s/co	positive
3	31085111289	CPD-Plasma	√	√	positive	10,18	s/co	positive
4	68100838590	CPD-Plasma	√	√	positive	4,91	s/co	positive
5	66116141772	CPD-Plasma	√	√	positive	6,87	s/co	positive
6	43113013116	CPD-Plasma	√	√	positive	7,19	s/co	positive
7	72120844076	CPD-Plasma	√	√	positive	4,95	s/co	positive
8	3345	Plasma	√	√	positive	6'200'000	IU/mL	positive
9	5145	Plasma	√	√	positive	44'000	IU/mL	positive
10	5584	Plasma	√	√	positive	830'000	IU/mL	positive
	Genotype 3							
1	2568	Citrat-plasma	√	√	positive	N/A		positive
2	2948	Citrat-plasma	√	√	positive	N/A		positive
3	7702	Citrat-plasma	√	√	positive	N/A		positive
4	2216	Plasma	√	√	positive	7'260'000	IU/mL	positive
5	3796	Plasma	√	√	positive	1'200'000	IU/mL	positive
6	4517	Plasma	√	√	positive	3'600'000	IU/mL	positive
7	6105	Plasma	√	√	positive	2'600'000	IU/mL	positive
8	6123	Plasma	√	√	positive	180'000	IU/mL	positive
9	6844	Plasma	√	√	positive	15'000'000	IU/mL	positive
10	7566	Plasma	√	√	positive	370'000	IU/mL	positive
	Genotype 4							
1	67088571410	CPD-Plasma	√	√	positive	4,931	s/co	positive
2	67088199276	CPD-Plasma	√	√	positive	4,96	s/co	positive
3	1080	Plasma	√	√	positive	1'130'000	IU/mL	positive
4	2150	Plasma	√	√	positive	30	IU/mL	positive
5	3521	Plasma	√	√	positive	10	IU/mL	positive
6	10471	Plasma	√	√	positive	290	IU/mL	positive
7	HCV4150204-01	Plasma	√	√	positive	N/A		positive
8	HCV4150204-02	Plasma	√	√	positive	N/A		positive
9	HCV4150204-03	Plasma	√	√	positive	N/A		positive
10	HCV4150204-04	Plasma	√	√	positive	N/A		positive
	Genotype 4 non a							
1	HCVn4a150204-01	Plasma	√	√	positive	N/A		positive
2	HCVn4a150204-02	Plasma	√	√	positive	N/A		positive
3	HCVn4a150204-03	Plasma	√	√	positive	N/A		positive
4	HCVn4a150204-04	Plasma	√	√	positive	N/A		positive
5	HCVn4a150204-05	Plasma	√	√	positive	N/A		positive

#	Sample ID	Sample Matrix (Whole blood, serum or Plasma)	*HEALGEN/ORIENT GENE* HCV			Result with reference test		
			Signal of T1	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
6	HCVn4a150204-06	Plasma	√	√	positive	N/A		positive
7	HCVn4a150204-07	Plasma	√	√	positive	N/A		positive
8	HCVn4a150204-08	Plasma	√	√	positive	N/A		positive
9	HCVn4a150204-09	Plasma	√	√	positive	N/A		positive
10	HCVn4a150204-10	Plasma	√	√	positive	N/A		positive
	Genotype 5							
1	HCVGT5131126-01	Plasma	√	√	positive	N/A		positive
2	HCVGT5131126-02	Plasma	√	√	positive	N/A		positive
3	HCVGT5131126-03	Plasma	√	√	positive	N/A		positive
4	HCVGT5131126-04	Plasma	√	√	positive	N/A		positive
5	HCVGT5131126-05	Plasma	√	√	positive	N/A		positive

Diagnostic Specificity – Blood donor samples

No. of Negative Samples Tested	Samples Negative by *HEALGEN/ORIENT GENE* HBsAG Test
500	500
% Specificity Observed	
> 99,9%	

Diagnostic Specificity – Cross reactivity Panel

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* anti-HCV			Results of potentially cross reacting substances	
			Signal of T	Signal of Control Line	Interpretation (*,**)	Sample / Cut-Off OD Ratio	
	Rheumatoid Factor						
1	5401	Citrate plasma	-	√	negative*	45,4	IU/ml
2	5729	Citrate plasma	-	√	negative*	49,1	IU/ml
	ANA						
3	4958	Citrate plasma	-	√	negative*	1:2560	titer
4	5729	Citrate plasma	-	√	negative*	1:160	titer
	Multipara						
5	8485	Citrate plasma	-	√	negative*	n.a.	n.a.
6	5436	Citrate plasma	-	√	negative*	n.a.	n.a.
7	7452	Citrate plasma	-	√	negative*	n.a.	n.a.
8	6975	Citrate plasma	-	√	negative*	n.a.	n.a.
	anti-EBV						
9	7108	Citrate plasma	-	√	negative*	>160	s/co
10	9035	Citrate plasma	-	√	negative*	72.19	s/co
11	9055	Citrate plasma	-	√	negative*	67.72	s/co

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* anti-HCV			Results of potentially cross reacting substances	
			Signal of T	Signal of Control Line	Interpretation (*,**)	Sample / Cut-Off OD Ratio	
	anti-CMV						
12	3630	Serum	-	√	negative*	20.9	AU/ml
13	6474	Citrate plasma	-	√	negative*	10.1	AU/ml
14	1379	Citrate plasma	-	√	negative*	718	AU/ml
15	1665	Citrate plasma	-	√	negative*	831	AU/ml
	Dialysis patients						
16	C	Serum	-	√	negative**	n.a.	n.a.
17	H	Serum	-	√	negative**	n.a.	n.a.
18	G	Serum	-	√	negative**	n.a.	n.a.
19	I	Serum	-	√	negative**	n.a.	n.a.
	anti-HBV						
20	208130806096	CPD plasma	-	√	negative*	446.1	s/co
21	208130806139	CPD plasma	-	√	negative*	380.3	s/co
	HbsAg						
22	6937	Citrate plasma	-	√	negative*	446,1	s/co
23	6995	Citrate plasma	-	√	negative*	380,3	s/co
	anti-Syphillis						
24	4777	Citrate plasma	-	√	negative*	pos	
25	7467	Citrate plasma	-	√	negative*	pos	
26	22180	Citrate plasma	-	√	negative**	24.8	s/co
27	19507	Citrate plasma	-	√	negative**	42.32	s/co
	Anti-HAV IgM						
28	3319	Citrate plasma	-	√	negative*	3.4	s/co
29	3621	Citrate plasma	-	√	negative*	3.02	s/co
30	5188	Citrate plasma	-	√	negative*	5.88	s/co

* confirmed to be negative for anti-HIV, anti-HCV and HBsAg with the Abbott PRISM HIV Ag/Ab Combo ChLIA

** confirmed to be negative for anti-HIV, anti-HCV and HBsAg with the Abbott Architect HIV Ag/Ab Combo

Diagnostic Specificity – Inhibition Panel

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* anti-HCV			
			Signal of T	Signal of Control Line	Interpretation	Concentration
	Hemolytic (low)					
1	63238493	K2EDTA plasma	-	√	negative	600 mg/dl
2	63238581	K2EDTA plasma	-	√	negative	600 mg/dl
3	63238715	K2EDTA plasma	-	√	negative	600 mg/dl
	Hemolytic (medium)					
4	63238493	K2EDTA plasma	-	√	negative	1000 mg/dl
5	63238581	K2EDTA plasma	-	√	negative	1000 mg/dl
6	63238715	K2EDTA plasma	-	√	negative	1000 mg/dl

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* anti-HCV			
			Signal of T	Signal of Control Line	Interpretation	Concentration
	Hemolytic (high)					
7	63238493	K2EDTA plasma	-	√	negative	2000 mg/dl
8	63238581	K2EDTA plasma	-	√	negative	2000 mg/dl
9	63238715	K2EDTA plasma	-	√	negative	2000 mg/dl
	Lipemic (low)					
10	494141143958	CPD plasma	-	√	negative	200 mg/dl
11	141037521	Na-Citrate plasma	-	√	negative	319 mg/dl
12	141029931	Na-Citrate plasma	-	√	negative	387 mg/dl
	Lipemic (medium)					
13	494141311159	Na-Citrate plasma	-	√	negative	411 mg/dl
14	141095371	Na-Citrate plasma	-	√	negative	440 mg/dl
15	10024 57020	CPD plasma	-	√	negative	450 mg/dl
	Lipemic (high)					
16	1002458127	CPD plasma	-	√	negative	635 mg/dl
17	1410 93301	Na-Citrate plasma	-	√	negative	729 mg/dl
18	1002468323	CPD plasma	-	√	negative	1137 mg/dl
	Icteric (low)					
19	11231152	Serum	-	√	negative	10 mg/dl
20	11231153	Serum	-	√	negative	10,5 mg/dl
21	11231204	Serum	-	√	negative	10 mg/dl
	Icteric (medium)					
22	11231155	Serum	-	√	negative	15 mg/dl
23	11231205	Serum	-	√	negative	15,4 mg/dl
24	11231210	Serum	-	√	negative	15,9 mg/dl
	Icteric (high)					
25	11231150	Serum	-	√	negative	17 mg/dl
26	11231151	Serum	-	√	negative	17,9 mg/dl
27	11231156	Serum	-	√	negative	18,1 mg/dl

Overall Diagnostic Sensitivity and Specificity for all tested samples

No. of positive samples Tested	Samples positive by *HEALGEN/ORIENT GENE* HCV Test	No. of Negative Samples Tested	Samples Negative by *HEALGEN/ORIENT GENE* HCV Test
175	175	557	557
% Sensitivity Observed		% Specificity Observed	
> 99,9 %		> 99,9 %	

Result Matrix

Method		Reference Test			Total Results
	Results	Positive	Negative	Indeterminate	
HCV Rapid Test Device	Positive	175	0	0	175
	Negative	0	557	0	557
	Invalid	0	0	0	0
Total Results		175	557	0	732

Performance of the test		Excellent	Very Good	Good	Satisfactory	Not Satisfactory
Clarity with clear background	:	√				
Signal of T1 Test Line	:	√				
Signal of Control Line	:	√				
Overall Performance of the Test kit	:	√				
Time Taken for final result	:	√				
Convenience in performing test	:	√				
Quantity of Buffer	:	√				
Quality of Buffer Bottle	:	√				
Appearance	:	√				

Heidelberg, 09th April 2015

Heike Lukhaup

Dr. Heike Lukhaup, Head of Quality Control

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HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma)

INTENDED USE

The HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- Hepatitis C virus (HCV) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HCV. Any reactive specimen with the HCV Ab Rapid Cassette must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens [1, 2] . Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests [3 ,4].

HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a whole blood, serum or plasma specimen. The test utilizes a combination of recombinant antigen to selectively detect elveated levels of HCV antibodies in whole blood, serum or plasma.

PRINCIPLE

The HCV Ab Rapid Test Cassette is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing HCV antigens conjugated with colloidal gold (HCV Ag conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane cassette containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated HCV antigens, and the C band is pre-coated with goat anti-rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antibodies: either the IgG, the IgM, or the IgA, to HCV if present in the specimen will bind to the HCV Ag conjugates. The immunocomplex is then captured on the membrane by the pre-coated HCV antigens, forming a burgundy colored T band, indicating a HCV Ab positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless the presence of any antibodies to HCV. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRODUCT CONTENTS

HCV Ab Rapid Test Cassette(Whole Blood/Serum/Plasma) containing HCV antigen coated particles and HCV antigen coated on the membrane.

MATERIALS SUPPLIED

1. Test Cassette (25 sealed pouches) 2. Disposable pipette for each test 3.Desiccant 4. 1 Buffer (4 ml) 5.Package Insert 6. Sterile disposable lancet for each test 7. Alcohol swab for each test

MATERIAL REQUIRED BUT NOT PROVIDED

1.Specimen collection containers 2.Centrifuge (for plasma only) 3.Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1.For professional In Vitro diagnostic use only. Do not use after expiration date.

2.Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.

3 . Do not use it if the tube/pouch is damaged or broken.

4 .Test is for single use only. Do not re-use under any circumstances.

5.Handle all specimens as if they contain infectious agents.Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.

6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

7. Humidity and temperature can adversely affect results .

SPECIMEN COLLECTION

1.The HCV Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

2.To collect Fingerstick Whole Blood specimens:

Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.

Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger. Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site. Add the Fingerstick Whole Blood specimen to the test cassette by using a capillary tube:

Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles. Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the sample pad of the test cassette.

Add the Fingerstick Whole Blood specimen to the test cassette by using hanging drops:

Position the patient's finger so that the drop of blood is just above the sample pad of the test cassette.

Allow 2 hanging drops of fingerstick whole blood to fall into the center of sample pad of the test cassette or, move the patient's finger so that the hanging drop touches the center of the sample pad. Avoid touching the finger directly to the sample pad.

3.Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

4.Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

5.Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

6.If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing. 1.Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test device on a clean and level surface.

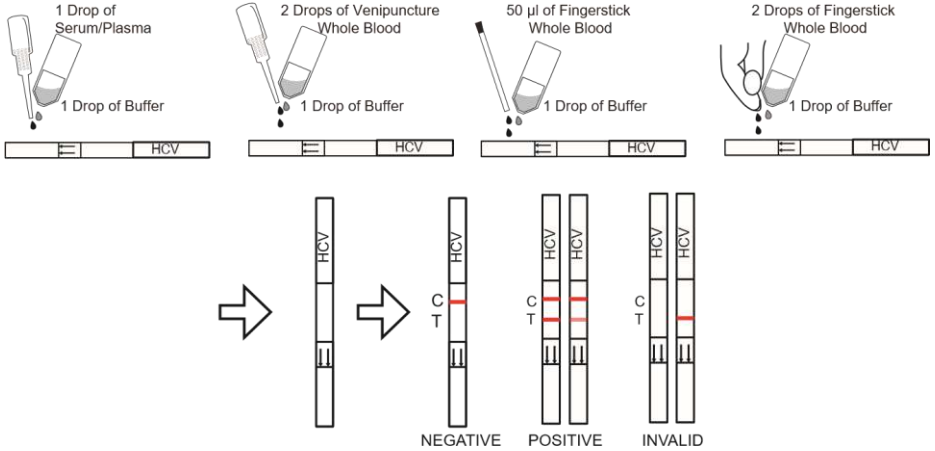
For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the sample pad of the test cassette, then add 1 drop of buffer (approximately 30 µL) and start the timer. See illustration below.

For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the sampel pad of the cassette, then add 1 drop of buffer (approximately 30 µL) and start the timer. See illustration below.

For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the sample pad on the test cassette, then add 1 drop of buffer (approximately 30 µL) and start the timer. See illustration below.

For venipuncture whole blood and plasma: K2EDTA, Sodium Heparin, Sodium citrate Sterile, and Lithium heparin should be used as the anticoagulant. Other anticoagulants have not been tested and may give incorrect results.

3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

(please refer to the illustration above)

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

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

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

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control 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 HCV Ab Rapid Test Cassette (Whole Blood/ Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HCV in whole blood, serum or plasma specimen.
2. The HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative r esult at any time does not preclude the possibility of Hepatitis C Virus infection.
5. A negative result can occur if the quantity of the antibodies to HCV present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

PERFORMANCE CHARACTERISTICS

Sensitivity: HCV Ab Rapid Test Cassette (Whole Blood/ Serum/Plasma) has passed a seroconversion panel and compared with leading commercial HCV EIA test using clinical specimens.

Specificity: The recombinant antigens used for HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) are encoded by genes for both structural (nucleocapsid) and non-structural proteins. HCV Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is highly specific for antibodies to Hepatitis C Virus compared with a leading commercial HCV EIA test.

The HCV Ab Rapid Test Cassette vs.EIA test

Method		EIA		Total Results
HCV Ab RapidTest	Results	Positive	Negative	
	Positive	105	19	124
	Negative	2	1760	1762
Total Results		107	1779	1886

Relative sensitivity: 99.9%
Relative specificity: 99.9%

REFERRENCE

1.Choo, Q.L., G.Kuo,A.J. Weiner, L.R. Overby,D.W. Bradley, andM. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome Science 189;244:359

2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiolog Virus of human non-A, non-B hepatitis. Science 1989; 244:362.

3. Van der Poel, C.L., H.T.M. Cuypers, H.W. Reesink, and P.N. Lelie .Confirmation of hepatitis C Virus infection by new four- antigen recombinant immunoblot assay. Lancet 1991;337:317

Wilber, J.C.Development and use of laboratory tests for hepatitis Cinfection: a review.J. Clin. Immunoassy 1993;16:204

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

CE

A rapid test for the semi-quantitative detection of C- Reactive Protein (CRP) in whole blood, serum or plasma specimens.
For professional in vitro diagnostic use only.

INTENDED USE

The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for semi-quantitative detection of C-Reactive Protein in whole blood, serum or plasma specimens to aid in evaluating risks of cardiovascular disease.

SUMMARY

C-Reactive Protein (CRP) is a marker of acute phase response to inflammatory disorder. CRP measurements have been used for many years in the management of a variety of clinical situations, such as bacterial infections, ischemic necrosis of tissue, and active inflammatory conditions.[1]
Recent studies suggest that CRP is a strong predictor of future coronary events in apparently healthy subjects and of prognostic value in patients with acute coronary syndromes.[2] As per the American Heart Association (AHA) and Centers for Disease Control and Prevention (CDC), CRP concentrations of 1-3 mg/L signify moderate risk and concentrations greater than 3 mg/L signify high risk for CVD. However, a CRP level above 10 mg/L does not necessarily signify cardiac risk as it can be indicative of inflammation due to other etiologies or infection. CRP concentrations below 1 mg/L signify low risk.[3].
The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/ Plasma) utilizes a combination of colloidal gold conjugate and anti-CRP antibodies to selectively detect CRP in whole blood, serum or plasma. The Minimum Detection Level (MDL) of this test is 1 mg/L (T Line) with 2 reference lines representing values of 3 mg/L (R) and 10 mg/L (C).

PRINCIPLE

The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is a semi-quantitative, membrane based immunoassay for the detection of CRP in whole blood, serum or plasma specimens. The membrane is pre-coated with anti-CRP antibodies on the test line region. During testing, specimen reacts with the particles coated with anti-CRP antibodies. The mixture migrates upward on the membrane by capillary action to react with anti-CRP antibodies on the membrane and generate a colored line. If the intensity of the test line (T) is weaker than reference line 2 (R), it indicates that the CRP level in the specimen is between 1-3 mg/L. If the intensity of the test line (T) is weaker than reference line 1(C) but stronger than reference line 2 (R), it indicates that the CRP level in the specimen is between 3-10 mg/L. If the intensity of the test line (T) is stronger than the reference line 1(C), it indicates that the CRP level is above 10 mg/L. To serve as a procedural control, reference line 1 and 2 (C and R) will always appear in reference line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains anti-CRP antibodies conjugated to colored particles and anti-CRP antibodies coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- The test must remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

- The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/ Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma specimens.
- To collect **Venipuncture Whole Blood Specimens**: Collect anti-coagulated blood sample (EDTA, Heparin, and Sodium Oxalate) following standard laboratory procedures.
- To collect **Fingerstick Whole Blood Specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

1. 25 Sealed pouches each containing a test cassette, a dropper and a desiccant
2. 1 Buffer, 4.0 mL
3. 1 Package insert

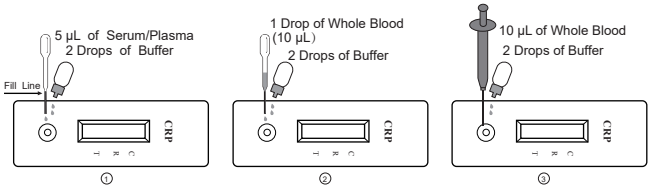
Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Lancets (for fingerstick whole blood only)
- Timer

DIRECTIONS FOR USE

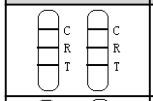
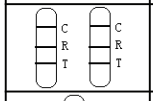
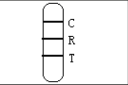
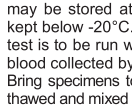
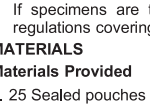
Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch and buffer to room temperature before opening it. Remove the test device from the sealed 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. Place the test device on a clean and level surface.
   For **Serum or Plasma Specimens:**
   Hold the dropper vertically, draw the specimen up to the **Fill Line** (approximately 5 µL), and transfer the specimen to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See illustration below. Avoid trapping air bubbles in the specimen well (S).
   For **Whole Blood (Venipuncture/Fingerstick) Specimens**:
   To use a dropper: Hold the dropper vertically, draw the specimen 0.5-1 cm above the **Fill Line**, and **transfer 1 drop of whole blood** (approximately 10 µL) to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 uL) and start the timer. See illustration below.
   To use a micropipette: Pipet and **dispense 10 µL of whole blood** to the specimen well (S) of the test device, then **add 2 drops of buffer** (approximately 80 µL) and start the timer. See illustration below.
3. Wait for the red line(s) to appear. * **Read the results at 10 minutes.** Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustrations in the first column of the table below)

Result	Test Line (T) Intensity	Possible Interpretation of CRP Levels
POSITIVE	Three distinct red lines appear.	
	Test Line (T) intensity is weaker than or close to R	A Test Line intensity that is weaker than or close to R could be interpreted as a CRP level of 1-3 mg/L.
	Test Line (T) intensity is darker than R, but lighter than or close to C	A Test Line intensity that is darker than R, but lighter than or close to C, could be interpreted as a CRP level of 3-10 mg/L.
	Test Line (T) intensity is stronger than C	A Test Line intensity that is stronger than C could be interpreted as a CRP level that is above 10 mg/L.
NEGATIVE	Two red lines appear in C and R regions, and no apparent red or pink line appears in the test region (T).	
	No Test Line (T)	No Test Line result could be interpreted as a CRP level that is below 1 mg/L.
INVALID		
	C or R fail(s) to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for failure of reference lines to develop. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.	

LIMITATIONS

1. The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/ Plasma) is for in vitro diagnostic use only. This test should be used for the detection of CRP in whole blood, serum or plasma specimen.
2. The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/ Plasma) will only indicate the semi-quantitative level of CRP in the specimen and should not be used as the sole criteria for evaluating cardiac risks or inflammatory conditions.
3. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
4. There is a slight possibility that some whole blood specimens with a very high viscosity or stored more than 2 days may not run properly on the test device; repeat the test with a serum or plasma specimen from the same patient using a new test device.
5. The elevated results of CRP in oral contraceptive (OC) users should be reported with caution as The American Physiological Society has recommended further studies on impact of OC use on CRP and inflammatory parameters.[4]
6. CRP values near the cut-off level (1 mg/L), reference level 1 (C: 10 mg/L), and reference level 2 (R: 3 mg/L) should be reported with caution as with all quantitative assays there exists some level of variation. Therefore, a T line with slightly higher intensity than C can also represent a value slightly below 10 mg/L. Similar observations may occur with values near 3 mg/L and 1 mg/L. A repeat test/further quantitative test is recommended in such cases.
7. High concentrations of CRP may produce a dose hook effect, resulting in incorrect interpretation of CRP levels. High dose hook effect has not been observed with this test up to 200 mg/L of CRP

EXPECTED VALUES

CRP is a non-specific marker for inflammation and a cardiac risk marker. For ruling out cardiac risks, its expected value is less than 1 mg/L as per AHA. A CRP level above 10 mg/L signifies some other source of inflammation and/or infection.

PERFORMANCE CHARACTERISTICS

Accuracy

The C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested in comparison with a leading commercial CRP EIA test using clinical specimens.

Method		EIA			
		Positive			Negative
	Ranges	1-3 mg/L	3-10 mg/L	≥10 mg/L	0-1 mg/L
CRP Rapid Test Device	0-1 mg/L	5	0	0	345
	1-3 mg/L	86	3	0	13
	3-10 mg/L	4	75	10	0
	≥10 mg/L	0	2	130	0
Total Results		95	80	140	358
% Agreement		90.5% *	93.8% *	92.8%	96.4%
		98.4%			

Relative Positive Agreement: 98.4%
Relative Negative Agreement: 96.4%
Relative Accuracy: 97.3%

Precision

Intra-Assay

Within-run precision has been determined by using replicates of 10 tests for each of three lots using CRP specimen levels at 1 mg/L, 3 mg/L, 10 mg/L and 20 mg/L. The specimens were correctly identified >98% of the time.

Inter-Assay

Between-run precision has been determined by using CRP specimen levels at 1 mg/L, 3 mg/L, 10 mg/L and 20 mg/L of CRP in 10 independent assays. Three different lots of the C-Reactive Protein Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >98% of the time.

Interfering Substances

The following substances do not interfere with the test results at the indicated concentrations: human albumin at 110 mg/mL, bilirubin at 6 mg/mL, hemoglobin at 10 mg/mL, cholesterol at 5 mg/mL and triglycerides at 15 mg/mL.

BIBLIOGRAPHY

1. Thompson D, Milford-Ward A, Whicher JT. The value of acute phase protein measurements in clinical practice. *Ann. Clin Biochem*; 29:123–31 (1992).
2. Rifai N, Ridker PM. High-Sensitivity C-reactive protein: A Novel and Promising Marker of Coronary Heart Disease. *Clinical Chemistry* 47:3 403–411 (2001).
3. Dreon DM, Slavin JL; and Phinney, SD. Oral Contraceptives Increase C-Reactive Protein, An Inflammatory Biomarker by The American Physiological Society, April 9 (2003).
4. Pearson TA, et.al. Markers of Inflammation and Cardiovascular Disease: Application to Clinical and Public Health Practice: A Statement for Healthcare Professionals From the Centers for Disease Control and Prevention and the American Heart Association, Circulation (2003); 107; 499-511.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	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

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

REF GDCRP-402a

Revision Date: 2022-03-04
B20865-03

Instruction for use
A solid-phase enzyme immunoassay kit
for the qualitative detection of IgG antibodies
to *Treponema pallidum* in human serum or plasma

Treponema pallidum IgG EIA

Catalogue number REF **K111G**

Σ 96 For 96 determinations

IVD *In vitro* diagnostic medical device

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tel.:+ 49 911 931 639 67
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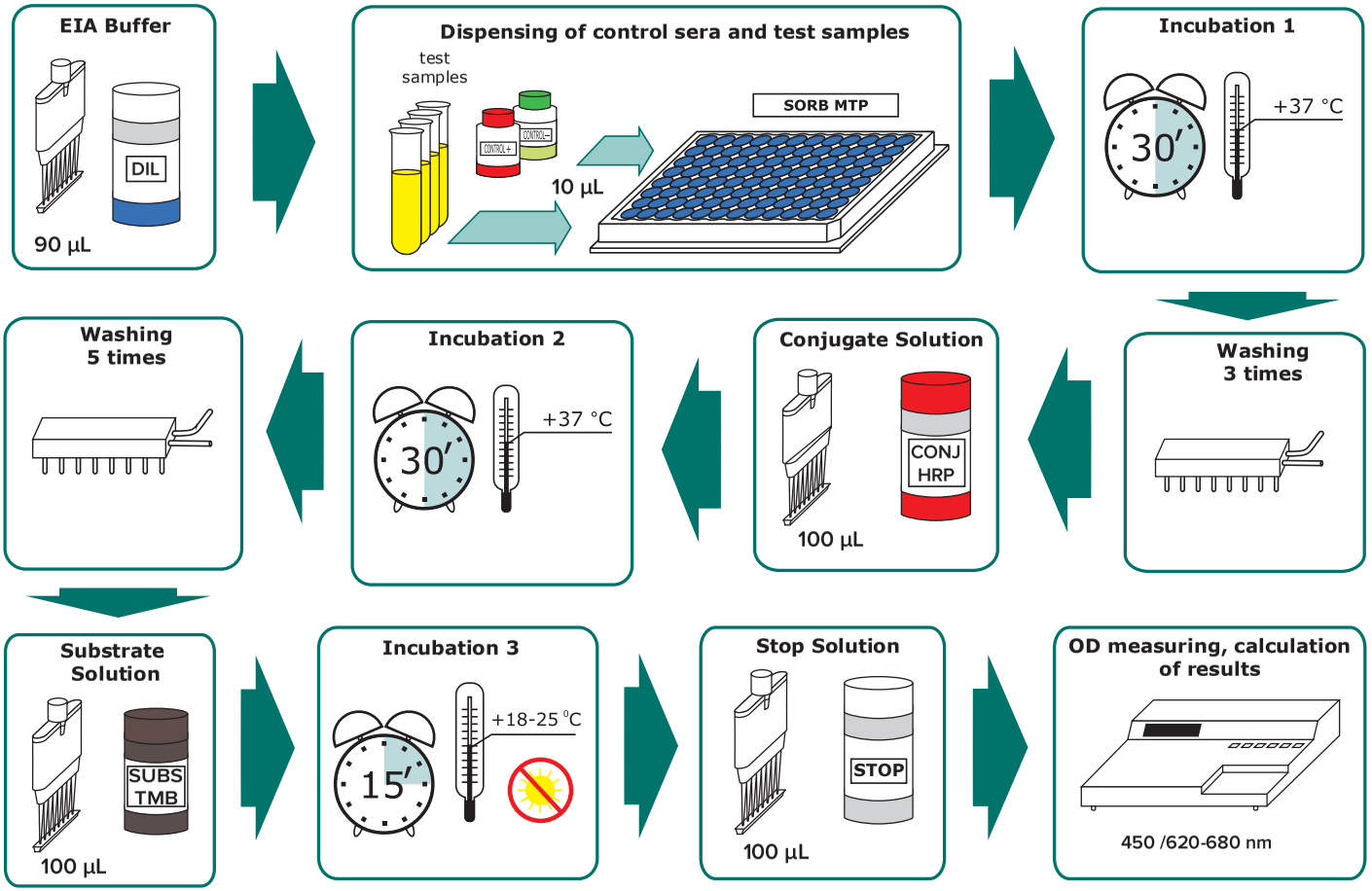
ASSAY PROCEDURE



K111G

CONTENT

Instruction for use
A solid-phase enzyme immunoassay kit for the qualitative detection of IgG antibodies to *Treponema pallidum* in human serum or plasma

Treponema pallidum IgG EIA

1. INTENDED USE

A solid-phase enzyme immunoassay for the qualitative determination of IgG antibodies to Treponema pallidum in human serum or plasma.

The field of application is clinical laboratory diagnostics.

2. GENERAL INFORMATION

Syphilis is a sexually transmitted disease caused by Treponema pallidum (Tp.) bacterium belonging to the family of Spirochaetaceae. Tp is gram negative, has a cell wall and is considered strictly anaerobe, exhibiting a characteristic mobility due to periplasmic flagella.

Clinical manifestations of syphilis may be diverse, depending upon the stage of infection and the individual response, and characterized by alternating acute and latent periods. The first anti-Tp antibodies being detected from the second week after infection, belong to IgM class, their titer reaching its maximum at weeks 6-9 and then falling down.

Tp-specific IgG antibodies are produced from week 4. A successful treatment of the disease usually leads to a drop of anti-Tp IgG titer, but in some cases they may be found during a long time and detected by sensitive serological methods. Many assays have been developed for the immunological detection of the Tp infection in the past (VDRL, TPHA, RPR), but ELISA is considered to be the most sensitive.

In this test, a mixture of recombinant antigens and synthetic analogs of Tp lipoproteins with MM of 15, 17, 41-45 and 47 kDa (p15, p17, TmpA and p47, resp.) are used.

3. TEST PRINCIPLE

The detection of IgG antibodies to *Treponema pallidum* is based the two-site sandwich enzyme immunoassay principle. On the inner surface of the microplate wells are immobilized recombinant antigens of *Treponema pallidum {p15; p17; p41 and p47}*. Murine monoclonal IgG antibodies conjugated to the horseradish peroxidase is used as enzyme conjugate. The analysis procedure includes three stages of incubation:

- during the first stage specific to *Treponema pallidum IgG* antibodies from the specimen are bound by antigens coated onto the microwell surface;
- during the second stage horseradish peroxidase-conjugated murine monoclonal IgG antibodies bind to the antigen-antibody complexes, fixed in the formed at the previous stage complexes;
- during the third stage, the complexes formed due to the reaction with the chromogen 3,3’,5,5’-tetramethylbenzidine are visualized.

After stopping the reaction with a stop solution, the intensity of the color of the microwells is measured. The optical density (OD) in the microwell is directly related to the concentration of the measured IgG antibodies to *Treponema pallidum* in test specimen.

4. KIT COMPONENTS

Code of component	Symbol	Name	Volume	Qty, pcs.	Description
P111GZ	SORB MTP	**Microplate**	-	1	96-well polystyrene strip microplate coated with recombinant antigens of *Treponema pallidum IgG*, ready to use
CN111GZ	CONTROL -	**Negative Control Serum K-**	0.2 mL	1	Solution based on human serum, free of specific antibodies to *Treponema pallidum IgG*, with preservative, ready to use (yellow liquid)
CP111GZ	CONTROL +	**Positive Control Serum K+**	0.5 mL	1	Solution based on inactivated human serum pool with a high content of specific antibodies to *Treponema pallidum IgG*, with preservative, ready to use (red liquid)
T111GZ	CONJ HPR	**Conjugate Solution**	12 mL	1	Solution of murine monocnoclonal antibodies to IgG conjugated to the horseradish peroxidase, ready to use (red liquid)
S011Z	DIL	**EIA Buffer**	12 mL	1	Buffer solution with detergent and preservative, ready to use (blue liquid)
R055Z	SUBS TMB	**Substrate Solution**	12 mL	1	Tetramethylbenzidine (TMB) substrate solution, ready to use (colourless liquid)
S008Z	BUF WASH 26X	**26x Concentrate Washing Solution**	30 mL	1	Buffer solution with detergent, 26x concentrate (colourless liquid)
R050Z	STOP	**Stop Solution**	12 mL	1	5.0% solution of sulphuric acid, ready to use (colourless liquid)
The kit also includes instruction for use, quality control data sheet and plate sealing tape (2 pcs.)					

5. EQUIPMENT AND MATERIAL REQUIRED BUT NOT PROVIDED

– microplate photometer with 450\620-680 nm wavelength;
– dry thermostat for +37°C±1°C;
– automatic plate washer (optional);
– micropipettes with variable volume, range volume 5-1000 µL;
– graduated cylinder of 1000 mL capacity;
– distilled or deionized water;
– timer;
– vortex mixer;
– disposable gloves;
– absorbent paper.

6. WARNING AND PRECAUTIONS

In order to prevent incorrect results, strictly follow the recommended order and duration of the analysis procedure.

6.1. The kit is for *in vitro* diagnostic use only. For professional laboratory use.

6.2. Follow the rules mentioned below during the kit using:

- do not use kit beyond expire date;
- do not use the kit if its packaging is damaged;
- in order to avoid contamination, use new tips to pipette samples and reagents;
- use only verified equipment;
- close each vial with its own cap, after using the reagent;
- do not use components of other kits or reagents of other manufacturers;
- do not let wells dry after completing the rinsing step; immediately proceed to the next stage;
- avoid bubbles when adding reagents.

ATTENTION! The TMB substrate solution is light sensitive. Avoid prolonged exposure of the component to light.

6.3. Some kit components, such as stop solution, substrate solution, and washing solution, may cause toxic or irritant effects. If they get on the skin or mucosa, the affected area should be washed with plenty of running water.

6.4. All human products, including patient samples, should be considered potentially infectious. Handling and disposal should be in accordance with the procedures defined by an appropriate national biohazard safety guidelines or regulations.

6.5. The Control Serum included in the kit are negative for antibodies to HIV 1,2, hepatitis C virus and HBsAg, but the reagents should be considered as potentially infectious material and handled carefully.

6.6. Specimens must not contain any azide compounds, as they inhibit activity of peroxidase.

6.7. Wear protective gloves, protective clothing, eye protection, face protection.

6.8. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.

6.9. Safety Data Sheet for this product is available upon request directly from XEMA LLC.

6.10. Serious incidents related to the kit must be reported to the manufacturer, Authorized Representative, and to the Competent Authority of the EU member state(s) where the incident has occurred.

7. SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE OF SAMPLES

7.1. Blood sampling should be carried out from the cubital vein with a disposable needle using a vacuum blood sampling system. Serum or plasma specimens should be clearly labeled and identified. Serum must be separated from the clot as early as possible to avoid hemolysis of red blood cells. If there are any visible particles in the sample, they should be removed by centrifugation at 3000-5000 rpm for 20 minutes at room temperature or by filtration.

Don't use samples with high lipidemia, hemolysis as they may give false test results.

7.2. Specimen should be stored at +2…+8°C up to 3 days. Specimen held for a longer time, should be placed in a freezer at -15°C or below, do not refreeze/thaw samples.

7.3. For the transportation of samples, it is recommended to use triple packaging. The primary package is the labeled tube containing the sample. Secondary packaging is a polyethylene bag that is hermetically closed with a zip-lock. The outer packaging is a heat-insulating container, while the secondary packaging is placed in the outer packaging for transportation in the center of the thermal container. Frozen refrigerants are placed on the bottom, along the side walls of the thermal container, and cover the samples with them.

8. TRANSPORTATION AND STORAGE TERMS OF KIT, WASTE DISPOSAL

Information about the singularity storage conditions, transportation of the kit, and disposal of waste should be taken into account by all persons who participate in these processes.

8.1. Transportation

The Treponema pallidum IgG EIA kit should be transported in the manufacturer's packaging at +2...+8°C. Single transportation at the temperature up to 25ºC for 5 days is acceptable.

8.2. Storage

The Treponema pallidum IgG EIA kit should be stored in the manufacturer's packaging at +2...+8°C. Do not freeze.

The kit contains reagents sufficient for 96 determinations including Control Serum.

Once opened test-kit is stable for 2 months when stored properly as intended by manufacturer at 2-8°C.

In case of partial use of the kit, the components should be stored in the following way:

- the remaining strips should be immediately resealed in the bag along with the silica gel, closed with the zip-lock, and stored at +2...+8°C within 2 months;
- Substrate Solution, Stop Solution, and Washing Solution concentrate after opening the vial, can be stored tightly closed at +2...+8°C until the kit's shelf life;
- Conjugate Solution and Control Serum after opening the vial, can be stored tightly closed at +2...+8°C within 2 months;
- diluted Washing Solution can be stored at room temperature (+18…+25°C) for up to 5 days or at +2…+8°C for up to 14 days.

Kits that were stored in violation of the storage condition cannot be used.

8.3. Disposal

Expired kit components, used reagents and materials, as well as residual samples must be inactivated and disposed of in accordance with legal requirements.

9. REAGENTS PREPARATION

9.1. All reagents (including microstrips) and test samples should be allowed to reach room temperature (+18…+25 °C) for at least 30 minutes before use.

9.2. Microplate preparation

Open the package with the microplate and install the required number of strips into the frame. The remaining strips should be immediately resealed in the bag along with the silica gel and closed with the zip-lock to prevent moisture from affecting the plate's strips.

9.3. Washing Solution preparation

Add the contents of the 30 mL washing solution concentrate vial to 750 mL of distilled or deionized water and mix thoroughly. In case of partial use of the kit, take the necessary amount of washing solution concentrate and dilute it 26 times with distilled or deionized water.

The spending of the components in case of partial use of the kit is given in the table:

Quantity of strips	1	2	3	4	5	6	7	8	9	10	11	12
Volume of the Washing Solution concentrate, mL	2.5	5	7.5	10	12.5	15	17.5	20	22.5	25	27.5	30
Volume of water, mL	62.5	125	187.5	250	312.5	375	437.5	500	562.5	625	687.5	750

10. ASSAY PROCEDURE

10.1. Put the desired number of strips into the frame based on the number of test samples and 4 wells for Positive and Negative Control Serum (1 well for Positive Control (CP) and 3 wells for Negative Control Serum (CN)).

10.2. Dispense **90 µL of EIA Buffer** to all wells.

10.3. Dispense **10 µL of Positive and Negative Control Serum as well as 10 µL of test serum/plasma samples** (SAMP) to the wells of the microplate according to the scheme below. The introduction of Positive and Negative Control Serum and test samples should be carried out within 5 minutes to ensure equal incubation time for the first and last samples.

NOTE: during performing several independent series of tests, Positive and Negative Control Serum should be used each time.

Scheme of introduction of samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	CP	SAMP5	SAMP13	SAMP21								
B	CN	SAMP6	SAMP14	SAMP22								
C	CN	SAMP7	SAMP15	SAMP23								
D	CN	SAMP8	SAMP16									
E	SAMP1	SAMP9	SAMP17									
F	SAMP2	SAMP10	SAMP18									
G	SAMP3	SAMP11	SAMP19									
H	SAMP4	SAMP12	SAMP20									

10.4. Carefully mix the contents of the microplate in a circular motion on a horizontal surface, cover strips with a plate sealing tape and incubate for **30 minutes at +37°C**.

10.5. At the end of the incubation period, remove and discard the plate cover. Aspirate and wash each well **3 times** using an automatic washer or an 8-channel dispenser. For each washing, add 300 µL of Washing Solution (see 9.3) to all wells, then remove the liquid by aspiration or decantation. The residual volume of the Washing Solution in the wells after each aspiration or decantation should be no more than 5µL. After washing, carefully remove the remaining liquid from the wells on the absorbent paper. For the automatic washer/analyzer, the Washing Solution volume can be increased to 350 µL.

10.6. Add **100 µL of Conjugate Solution** to all wells

10.7. Cover strips with a plate sealing tape and incubate for **30 minutes at +37°C**.

10.8. At the end of the incubation period, aspirate and wash each well **5 times** as described in 10.5.

10.9. Add **100 µL of Substrate Solution** to all wells. The introduction of the Substrate Solution into the wells must be carried out within 2-3 minutes. Incubate the microplate in the dark **at room temperature (+18...+25°C) for 15 minutes**.

10.10. Add **100 µL of Stop Solution** to all wells in the same order as the Substrate Solution. After adding the Stop Solution, the contents of the wells turn yellow.

10.11. Read the optical density (OD) of the wells at 450nm and reference light filters 620–680 nm using a microplate photometer within 5 minutes of adding the stop solution.

11. TEST VALIDITY AND CALCULATION OF RESULTS

11.1. The test results are valid only if Positive and Negative Control Serum are within the specified ranges and if all other test parameters are also within the given assay specifications, namely:

- OD of Negative Control Serum - < 0.15;
- OD of Positive Control Serum + > 1.5.
- OD(CN) x 0,5 < OD(CN) < OD(CN) x 2.

11.2. Calculate the mean OD value of the Negative Control Serum:

meanOD(CN) = (OD1(CN) + OD2(CN) + OD3(CN))/3

If one of the OD values of the Negative Control Serum differs significantly, it should be discarded and the meanOD(CN) should be calculated using the remaining OD values of the Negative Control Serum.

11.3. Calculate the Cut-off value by adding to the mean OD value of the Negative Control Serum the coeficient 0.2.

Cut-off = meanOD(CN) + 0.2

11.4. Calculate the boundary of the «gray zone» (GZ) - the OD values that are within 10% below the Cut-off value:

Cut-off x 0.9 ≤ GZ ≤ Cut-off

11.5. Alternatively, calculate Positivity Index (PI) for each sample by dividing the OD of the sample by Cut-off value:

PI = ODsample/Cut-off

12. INTERPRETATION OF THE RESULTS

Calculation of results taking into account the OD sample:

Samples with the OD > Cut off are considered **POSITIVE**,
Samples within the «gray zone» are considered **EQUIVOCAL**,
Samples with OD < the value of the «gray zone» are considered **NEGATIVE.**

Calculation of results taking into account the PI:

If PI value > 1.0 the result is **POSITIVE**,
If PI value is between 0.9 and 1.0 the result is **EQUIVOCAL**,
If PI value < 0.9 the result is **NEGATIVE**.

Positive samples should be retested again with the «Treponema pallidum IgG - EIA» reagent kit. After repeated testing, samples are considered positive if the OD of at least one of the replicates was higher than or equal to the Cut-off. If during repeated testing the OD of the sample was below the Cut-off value, such a sample should be considered negative.

If equivocal results are obtained, it is recommended to conduct a reexamination of the sample in several replicates. If the result is equivocal again, a new sample should be obtained within 5-7 days and retested. If the result remains equivocal, the sample should be considered negative.

13. PERFORMANCE CHARACTERISTICS

13.1. Analytical performance characteristics

13.1.1. Precision of Measurement

Repeatability (Intra assay repeatability) was determined by evaluation the coefficient of variation (CV) for 2 different samples during 1 day in 24 replicates on one series of ELISA kit.

No. sample	mean PI	CV, %
1	1.33	2.3
2	5.47	4.7

Reproducibility (Inter assay reproducibility) was determined by evaluating the coefficients of variation for 2 samples during 5 days in 8-replicate determinations.

No. sample	mean PI	CV, %
1	1.32	6.3
2	5.46	3.2

13.1.2. Analytical specificity

For the analysis result is not affected by the presence in the sample of bilirubin in a concentration of up to 0.21 mg/mL and hemoglobin in a concentration of up to 10 mg/mL.

13.2. Diagnostic performance characteristics

The clinical sensitivity and specificity of the assay was evaluated on a panel of 300 positive and 280 negative clinical serum samples and was found to be 100%. The positive predictive value (PPV) of the kit and the negative predictive value (NPV) were 100%. The relative sensitivity and specificity of the assay was evaluated using a panel of 360 donor sera characterized for Treponema pallidum IgG antibodies in commercial kits and was determined to be 96.8%.

14. LIMITATIONS

A positive test result indicates that the patient has IgG antibodies specific to Treponema pallidum antigens. In some cases, in the early stages of the disease, the EIA result may be negative due to the absence or ultra-low titer of antibodies below the limit of sensitivity of the test. In such cases, in the presence of symptoms of the disease, it is recommended to re-sample and analyze the sample in 7-10 days, as well as verify the result by another laboratory method, such as PCR, culture, microscopic, etc.

Both laboratory test results and clinical manifestations of the disease should be taken into account for the establishment of the diagnosis.

15. REFERENCES

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SAMPLES IDENTIFICATION PLAN

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
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LOT _____ DATE _____

SAMPLES IDENTIFICATION PLAN

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A												
B												
C												
D												
E												
F												
G												
H												

LOT _____ DATE _____

	Manufacturer
IVD	*In vitro* diagnistic medical device
REF	Catalogue number
	Use-by date
LOT	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Consult instructions for use
	Conformity Marking with technical regulations in Ukraine
EC REP	Authorized representative in the European Community/European Union
CE	CE Conformity Marking

For any issues related to operation of the kit and technical support, please contact by telefon number

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