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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.



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





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.





High and Consistent Quality



Satisfied Customer



Continuous Improvement & Innovation



Care for the Environment & Working Conditions



Atlas Medical GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany

Tel: +49 - 33708 - 3550 30

Email: amug@atlas-medical.com



Atlas Medical UK.
William James House, Cowley
Road, Cambridge, CB4 0WX, UK.

Tel.: +44 (0) 1223 858 910

Fax: +44 (0) 1223 858 524

Email: info@atlas-medical.com



Atlas Medlab

AKTARHÜSSAM MAH. 1.DEĞİRMEN SK. GÖKTAŞ
GÜNDOĞDU İŞHANI A BLOK NO: 6 İÇ KAPI NO: 8
Osmangazi / Bursa/Turkey
Tel: +90 552 366 21 71
Email:m.gholeh@atlas-medlab.com.tr

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Atlas Medical Jordan Sahab Free Zone Area,

Amman 11512 Jordan

Tel: +962 6 4026468

Fax +962 6 4022588

Email: info@atlas-medical.com



Our Markets

Atlas Medical enjoys a good presence in many international markets. We take pride in our export activities through our dedicated export department. We actively participate in major industry-related exhibitions seeking keen representatives around the globe to sell and distribute our products in their respective countries. We are internationally represented in more than 80 of countries spanning in five continents: Europe, North America, South America, Africa and Asia. Our efforts will continue to increase our representation to include most markets around the globe.





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

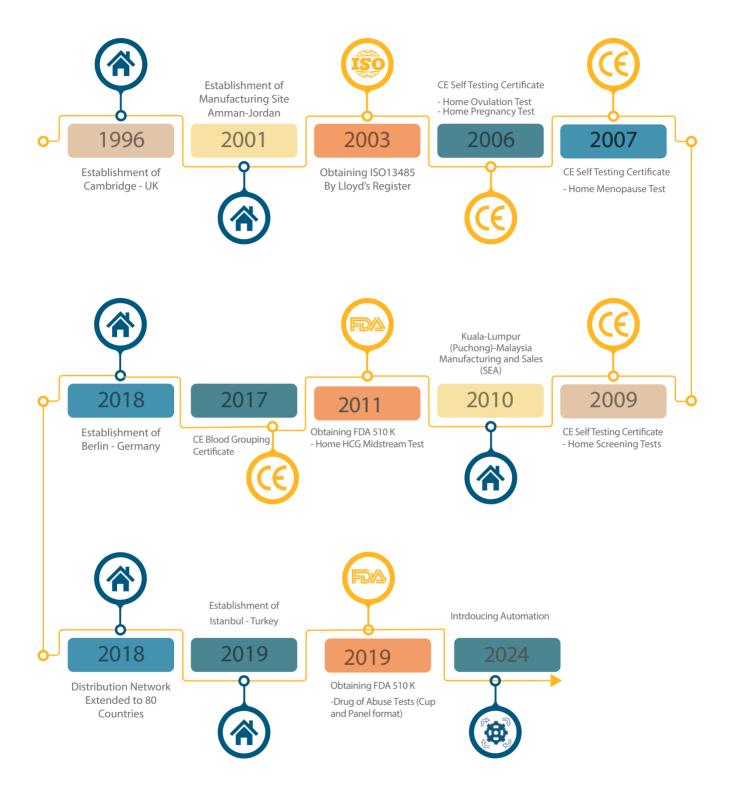


To complete the quality assurance scheme the company has put in place a robust Quality Management and Enhancement System that has concluded in the successful attainment of ISO13485: 2016 certificate



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



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.

- 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.



- ∂ 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



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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.

- 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 lgG/lgM 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 liquid formats 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.



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

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Co-aggulation		
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

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.

- 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	Sickle Cell Kit, 50 Tests	50 Test
8.02.67.0.0100	Sickle Cell Kit,	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.

- 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
	HIV 1/2 Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
	HIV 1/2 Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
	HIV 1/2 Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
	HCV Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
	HCV Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
	HCV Antibody Test Strip, Serum/Plasma, Individually Pouched	Bulk 100 Tests/Box
	HBs Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
	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
	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
	Syphilis Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
	Syphilis Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
	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
	HBsAg Test Cassette (Whole Blood/Serum/ Plasma), Individually Pouched	Bulk 20 Tests/Box
	HBsAg Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
	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.

- 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.









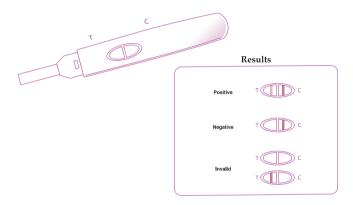
Item Code	Item Description	Sizes
8.03.00.0.0050 8.03.00.0.0100	URS 1 Parameter: Glucose	50 Strips 100 Strips
8.03.01.0.0050 8.03.01.0.0100	URS 1 Parameter: Protein	50 Strips 100 Strips
8.03.02.0.0050 8.03.02.0.0100	URS 1 Parameter: Ketone	50 Strips 100 Strips
8.03.45.0.0050	URS 1 Parameter Blood, (5mm)	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	URS 10 Parameters: Sample end: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin,	50 Strips
8.03.17.0.0100	Glucose, Ascorbic Acid	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.

- Accurate.
- Convenient.
- ₹ Easy to use (add or dip in urine).
- ← Competitively priced.
- Results are obtained in 1 to 5 minutes.
- Oifferent 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 Fecal Occult Blood Test (FOB) Test Cassette, 8.04.38.0.0020 20 Tests/Box Stool Sample, Individually Pouched Fecal Occult Blood Test (FOB) Test Strip 8.04.85.0.0050 50 Tests/Box Stool Sample, Individually Pouched 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 20 Tests/Box / Serum/ Plasma) 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	PSA Test Cassette, Whole Blood/Serum/Plasma),	Bulk
8.16.28.0.0020	Individually Pouched	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	PSA Test Strip, Serum/Plasma, Individually	Bulk
8.04.40.0.0100	Pouched	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		Bulk 20 Tests/Box

- 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 .

- ${\color{red} \bigcirc}$ 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	Morphine Test Cassette, Urine,	Bulk
8.04.49.0.0020	Individually Pouched	20 Tests/Box
8.04.50.0.0001	Morphine Test Strip, Urine,	Bulk
8.04.50.0.0100	Individually Pouched	100 Tests/Box
8.04.51.0.0001	Marijuana (THC) Test Cassette, Urine,	Bulk
8.04.51.0.0020	Individually Pouched	20 Tests/Box
8.04.52.0.0001	Marijuana (THC) Test Strip, Urine,	Bulk
8.04.52.0.0100	Individually Pouched	100 Tests/Box
8.04.53.0.0001	Amphetamine Test Cassette, Urine,	Bulk
8.04.53.0.0020	Individually Pouched	20 Tests/Box
8.04.54.0.0001	Amphetamine Test Strip, Urine,	Bulk
8.04.54.0.0100	Individually Pouched	100 Tests/Box
8.04.55.0.0001	Barbiturates Test Cassette, Urine,	Bulk
8.04.55.0.0020	Individually Pouched	20 Tests/Box
8.04.56.0.0001	Barbiturates Test Strip, Urine,	Bulk
8.04.56.0.0100	Individually Pouched	100 Tests/Box
8.04.57.0.0001	Benzodiazepines Test Cassette, Urine,	Bulk
8.04.57.0.0020	Individually Pouched	20 Tests/Box
8.04.58.0.0001	Benzodiazepines Test Strip, Urine,	Bulk
8.04.58.0.0100	Individually Pouched	100 Tests/Box
8.04.59.0.0001	Cocaine Test Cassette, Urine,	Bulk
8.04.59.0.0020	Individually Pouched	20 Tests/Box
8.04.60.0.0001	Cocaine Test Strip, Urine,	Bulk
8.04.60.0.0100	Individually Pouched	100 Tests/Box
8.04.61.0.0001	Methamphetamine Test Cassette, Urine,	Bulk
8.04.61.0.0020	Individually Pouched	20 Tests/Box
8.04.62.0.0001	Methamphetamine Test Strip, Urine,	Bulk
8.04.62.0.0100	Individually Pouched	100 Tests/Box
8.04.63.0.0001	Methadone Test Cassette, Urine,	Bulk
8.04.63.0.0020	Individually Pouched	20 Tests/Box
8.04.64.0.0001	Methadone Test Strip, Urine,	Bulk
8.04.64.0.0100	Individually Pouched	100 Tests/Box
8.04.65.0.0001	Phencyclidine Test Cassette, Urine,	Bulk
8.04.65.0.0020	Individually Pouched	20 Tests/Box
8.04.66.0.0001	Phencyclidine Test Strip, Urine,	Bulk
8.04.66.0.0100	Individually Pouched	100 Tests/Box
8.16.47.0.0001	Fentanyl Test Cassette, Urine,	Bulk
8.16.47.0.0020	Individually Pouched	20 Tests/Box





Item Description	Sizes
Tricyclic Anti-Depressants Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
Tricyclic Anti-Depressants Test Strip, Urine,	Bulk
Individually Pouched	100 Tests/Box
Buprenorphine Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
Buprenorphine Test Strip, Urine,	Bulk
Individually Pouched	100 Tests/Box
Tramadol Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
Tramadol Test Strip, Urine,	Bulk
Individually Pouched	100 Tests/Box
Methylenedioxymethamphetamine (MDMA)	Bulk
Ecstasy Test Cassette, Urine, Individually Pouched	20 Tests/Box
Methylenedioxymethamphetamine (MDMA)	Bulk
Ecstasy Test Strip, Urine,Individually Pouched	100 Tests/Box
Opiates Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
Opiates Test Strip, Urine,	Bulk
Individually Pouched	100 Tests/Box
Cotinine Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
Cotinine Test Strip, Urine,	Bulk
Individually Pouched	100 Tests/Box
Oxycodone Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
Oxycodone Test Strip, Urine,	Bulk
Individually Pouched	100 Tests/Box
Ketamine Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
Ketamine Test Strip, Urine,	Bulk
Individually Pouched	100 Tests/Box
Proxyphene Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
Proxyphene Test Strip, Urine,	Bulk
Individually Pouched	100 Tests/Box
Tramadol Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
EDDP Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
EDDP Test Strip, Urine,	Bulk
Individually Pouched	100 Tests/Box
Dolantin Test Cassette, Urine,	Bulk
Individually Pouched	20 Tests/Box
Dolantin Test Strip, Urine,	Bulk
Individually Pouched	100 Tests/Box
	Tricyclic Anti-Depressants Test Cassette, Urine, Individually Pouched Tricyclic Anti-Depressants Test Strip, Urine, Individually Pouched Buprenorphine Test Cassette, Urine, Individually Pouched Buprenorphine Test Strip, Urine, Individually Pouched Tramadol Test Cassette, Urine, Individually Pouched Tramadol Test Strip, Urine, Individually Pouched Methylenedioxymethamphetamine (MDMA) Ecstasy Test Cassette, Urine, Individually Pouched Methylenedioxymethamphetamine (MDMA) Ecstasy Test Strip, Urine, Individually Pouched Opiates Test Cassette, Urine, Individually Pouched Opiates Test Strip, Urine, Individually Pouched Cotinine Test Cassette, Urine, Individually Pouched Cotinine Test Strip, Urine, Individually Pouched Oxycodone Test Cassette, Urine, Individually Pouched Oxycodone Test Strip, Urine, Individually Pouched Ketamine Test Cassette, Urine, Individually Pouched Ketamine Test Cassette, Urine, Individually Pouched Proxyphene Test Cassette, Urine, Individually Pouched Proxyphene Test Strip, Urine, Individually Pouched Proxyphene Test Strip, Urine, Individually Pouched EDDP Test Strip, Urine, Individually Pouched EDDP Test Strip, Urine, Individually Pouched Dolantin Test Strip, Urine, Individually Pouched Dolantin Test Strip, Urine, Individually Pouched

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.

- 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
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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		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 ingredients to ensure good quality and vivid staining.

Features

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



STAIN PACKS FOR HISTOLOGY			
Item Code	Item Description	Sizes	
8.17.009.1000	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	

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 lodine	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 lodine	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





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





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

- 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.



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.





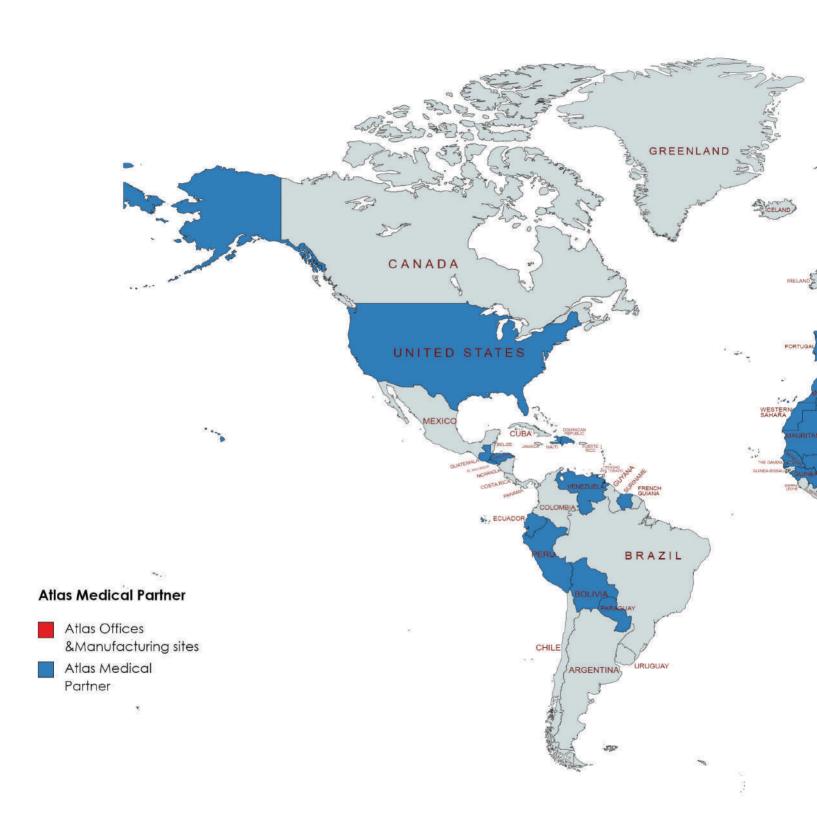
- Reliance Gold ™ by Atlas Medical, uses the latest blood glucose gold sensor technology to offer the most accurate and reliable results.
- ₹ Test time required is 5 Seconds.
- Required sample volume is 0.9μl
- Test result range is between 10 600 mg/dl (0.6 -33.3 mmol/L)

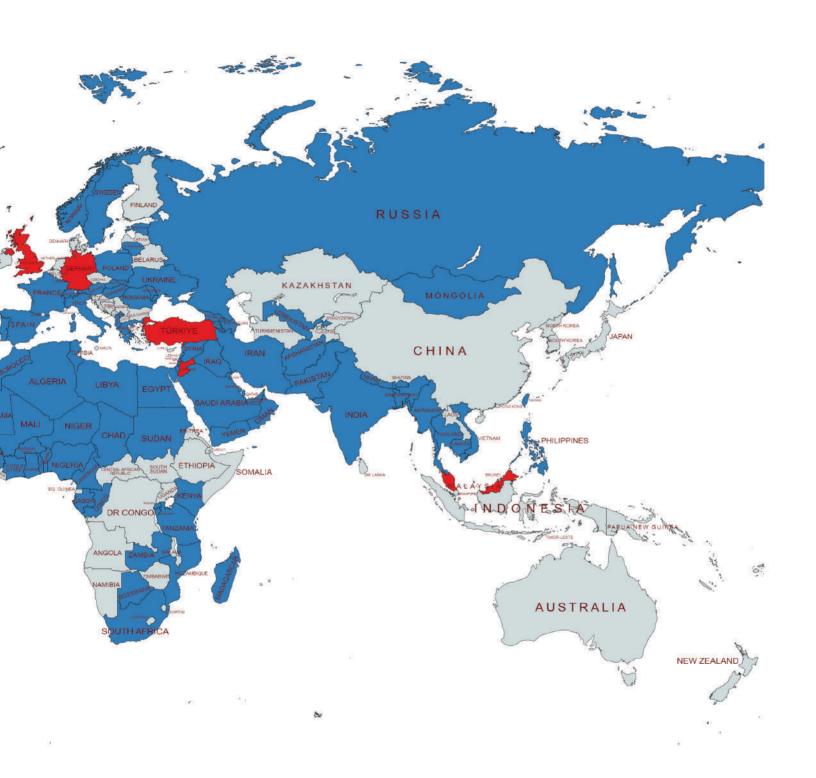
Reliance Gold		
Item Code	Item Description	Sizes
8.52.00.0.0001	Reliance Gold Glucometer Pack	1 Pack
8.52.00.0.0025 8.52.00.0.0050	Strips for Reliance Gold Glucometer	25 Strips/Bottle 50 Strips/Bottle
8.52.00.1.0001	Reliance Gold Glucometer (Divce only)	1 Divce only





INTERNATIONAL PRESENCE





CERTIFICATES



ISO 13485



Full Quality Assurance Certificate.



Blood Grouping CE Certificate

OTHER CERTIFICATES

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



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Blood Grouping Reagents:

Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent, Anti-AB Monoclonal Reagent, Anti-D IgG/IgM blend Reagent, & Their variants SLIDE AND TUBE TESTS

IVD For In-Vitro and professional use only



INTENDED USE

The blood grouping reagents are used to detect the presence or absence of A, B or Rhesus Antigens on the surface of human red blood cells based on hemaglutination using slide or tube test techniques in whole blood samples or anticoagulant blood samples collected in EDTA , citrate or heparin tubes.

INTRODUCTION & PRINCIPLES

Blood grouping reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines. The reagents are diluted with phosphate buffer containing sodium chloride, EDTA and bovine albumin to give reagents that are optimized for use in tube and slide procedures. Anti-A monoclonal reagent is colored with acid blue (patent blue) dye, Anti-B monoclonal reagent is colored with acid yellow (tartrazine) dye, and Anti-AB monoclonal reagent is not colored. The test procedure is based on hemaglutination principle, where red cells possessing the antigen agglutinate in the presence of the corresponding antibody indicating that the result is positive. The test is considered negative when no agglutination appears.

Anti-D IgG/IgM blend reagent is prepared from carefully blended human monoclonal IgM and IgG. Anti-D IgG/IgM blend reagent is suitable for slide and tube test procedures. The reagent will directly agglutinate Rh D positive cells, including majority of variants (but not D^VI) and a high proportion of weak D (Du) phenotypes. The reagent will agglutinate category D^VI and low grade weak D (Du) phenotypes by the indirect anti-globulin techniques.

Anti-D IgG/IgM blend reagent is diluted with a sodium chloride solution, sodium phosphate solution and bovine albumin (sodium caprylate free). Anti-D IgG/IgM blend reagent is not colored. The procedure is based on hemaglutination principle, where red cells' possessing the antigen agglutinates in the presence of the corresponding antibody in the reagent indicating that the result is positive. The test is considered negative when no agglutination appears.

MATERIALS

MATERIALS PROVIDED

Blood Grouping Reagents:

- Anti-A monoclonal reagent (10 ml/vial), Clone: (9113D10).
- Anti-B monoclonal reagent (10 ml/vial), Clone: (9621A8).
- Anti-AB monoclonal reagent (10ml/vial), Clone: (152D12+9113D10).
- Anti-D lgG/lgM Blend reagent (10 ml/vial), Clone: (P3X61 + P3X21223B10 + P3X290 + P3X35).

MATERIALS NEEDED BUT NOT PROVIDED

- Plastic test tube or glass.
- Isotonic saline solution (% 0.9) NaCl).
- Applicator sticks.
- Centrifuge (100-1200 (g) for tube test).
- Timer.
- Incubator
- Anti-Human Globulin Reagent (can be ordered from Atlas Medical).
- White or transparent glass slide.

PRECAUTIONS

- The reagents are intended for in vitro diagnostic use only.
- The test is for well trained professional healthy user not for lay user.
- These reagents are derived from animal and human sources, thus, appropriate care must be taken in the use and disposal of these reagents, as there are no known test methods that can guarantee absence of infectious agents.
- Do not use reagents if it is turbid or contain particles as this may indicate reagent deterioration or contamination.
- Protective clothing should be worn when handling the reagents.
- The reagents contain (0.1-0.2%) Sodium Azide and 0.02% sodium arseniate which is toxic and can be absorbed through the skin.
 When drained, the drains should be thoroughly flushed with water.
- The reagents should be used as supplied and in accordance to the procedure mentioned below. Don't use beyond expiration date.
- Avoid cross contamination of reagents or specimens.
- Visible signs of microbial growth in any reagent may indicate degradation and the use of such reagent should be discontinued.

- Don't use these reagents if the label is not available or damaged.
- Do not use dark glass slide.
- Don't 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.
- Wash hands and the test table top with water and soap once the testing is done.
- Heamolysed blood sample should not be used for testing.
- The test should be performed at room temperature in a well let area with very good visibility.
- Failure to follow the procedure in this package insert may give false results or safety hazard.
- Close the vial tightly after each test.
- The reagent is considered toxic, so don't drink or eat beside it.
- If spillage of reagent occurs clean with disinfectant (disinfectant used could be irritable so handle with care).

STORAGE CONDITIONS

- The reagents should be stored refrigerated between 2 8°C.
- Never Freeze or expose to elevated temperature.
- The reagent is stable until the expiry date stated on the product label. Do not use the reagents past the expiry date.

REAGENT PREPRATION

- The reagents are intended for use as supplied, no prior preparation or dilution of the reagent is required.
- All reagents should be brought to room temperature before use.

SPECIMEN COLLECTION AND PREPARATION

 Blood collected with or without anticoagulant (EDTA, Heparin or Citrate) can be used for Antigen typing.

Note: Blood collected without anticoagulant should be tested immediately.

- The specimens should be tested as soon as possible after collection.
 If testing is delayed, the specimens should be stored at 2- 8 °C,
 Sample must be retained to room temperature prior to analysis.
 (Testing should be carried out within five days of collections).
- Insure that there is no sign of hemolysis.
- At the time of the test, centrifuge the blood sample at 1200 RCF for 3 minutes.
- Blood collection is to be done with great care.

PROCEDURES

A. DIRECT TUBE METHOD AT ROOM TEMPERATURE

- 1. Prepare a 5% suspension of red blood cells in isotonic solution.
- 2. Using the vial dropper, transfer a drop (40±10 μ l) of each reagent into a separate and appropriately marked tube.
- 3. Add 50 μl of red blood cell suspension prepared in step 1.
- Shake to homogenize the mixture, then centrifuge at 500g for 1 minute.
- Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
- 6. Read the reaction immediately.
- For Anti-D tube, if the reaction is weak or negative, shake the tubes and incubate at 37°C for 15 minutes.
- 8. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
- 9. Add one drop (50 μ l) of the AHG reagent into the tube. Mix and centrifuge at 120g for 1 minute.
- Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
- 11. Read the reaction immediately.

B. ANTIGLOBULIN INDIRECT METHOD for ANTI-D

- After immediately centrifuging and reading as above, if the reaction is weak or negative, shake the tubes and incubate at 37°C for 15 minutes.
- Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
- 3. Add one drop (40 μ l \pm 10 μ l) of ANTI-HUMAN GLOBULIN to the tube. Mix and centrifuge at 120 (g) for 1 minute.
- 4. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
- 5. Read the reaction immediately.

C. DIRECT SLIDE METHOD AT ROOM TEMPERATURE

- 1. Bring reagents and samples to room temperature (18-25°C).
- Using the wax pen divide the slide into appropriate numbers of divisions
- 3. Using the provided dropper, place one drop (40 μ l \pm 10 μ l) of each reagent onto its correspondent division on the slide.
- 4. Add $25\mu l$ of the precipitated cells next to each drop of reagents.
- Mix the reagent and the cells using a clean stirring stick over an area with a diameter of approximately 20-40mm.
- 6. Incubate the slide at room temperature (18-25°C) without stirring for ${\bf 30}$ seconds.
- Hold the slide and gently rock the slide for 3 minutes and observe macroscopically for any agglutination.
- 8. Read the reaction immediately.

READING THE RESULT

<u>POSITIVE</u>: If Agglutination appears. <u>NEGATIVE</u>: If no agglutination is observed.

Use the below table to determine the blood group:

	Result of each reaction										
Anti-A monoclonal reagent	Anti-B monoclonal reagent	Anti-AB monoclonal reagent	Anti-D IgG/IgM blend reagent	ABO Group							
+	- +		+	A+							
+	-	+		A-							
-	+	+	+	B+							
-	+	+	1	B-							
+	+	+	+	AB+							
+	+	+		AB-							
-	-	-	+	0+							
-	-	-	-	0-							

STABILITY OF THE REACTIONS

- ABO Blood Grouping Tube tests should be read immediately following centrifugation.
- Slide tests should be interpreted within three minutes to avoid the
 possibility that a negative result may be incorrectly interpreted as
 positive due to drying of reagents.
- Delay in reading and interpreting results may result in weekly positive or falsely negative reactions. Slide tests should be interpreted at the end of the three minutes.

PROCEDURE LIMITATION

- 1. False positive/ negative results may occur due to:
 - Contamination from test materials.
 - Improper storage, cells concentration, incubation time or temperature.
 - Improper or excessive centrifugation.
 - Deviation from the recommended technique.
 - Blood samples of weak A or B subgroups may give rise to false negative results or weak reactions when tested using slide test method. It is advisable to re-test weak subgroups using tube test method.
- Weaker reactions may be observed with stored blood than with fresh blood.
- 3. ABO antigens are not fully developed at birth, weaker reactions may therefore occur with cord or neonatal red cells.
- 4. ABO blood grouping interpretation on individuals greater than 6 months old should be confirmed by testing serum or plasma of the individual against group A and group B red cells (reverse grouping). If the results obtained with the serum do not correlate with the red cell test, further investigation is required.
- 5. Return the kit to the agent if it does not function properly.
- Anti-D IgG/IgM blend Reagent tests conducted on particular weak-D phenotypes, while satisfactory, cannot ensure recognition of all weak variants, due to the variability of antigen patterns.

DIAGNOSTIC PERFORMANCE CHARACTERISTICS

The following tables compare the results in slide and tube techniques of 3 lots of Atlas Medical reagents and the results of a CE marked device.

Slide Technique									
Group A									
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control									
Compliance Compliance									
232	232 232 232			100%					
	Tube	Technique							
	G	roup A							
Positive with			-	anti-AB					
Negativ		onal reage -B and Neg	nt ative contr	ol					
CE marked device	Lot A	Lot B	Lot C	Compliance					
212	212	212	212	100%					

Slide Technique
Group B
Positive with anti-B monoclonal reagent and anti-AB
monoclonal reagent
Negative with anti-A and Negative control

CE marked device	Lot A	Lot B	Lot C	Compliance							
61	61	61	61	100%							
	Tube Technique										
	Group B										
Positive with Negativ	monoc	noclonal re lonal reage -A and Neរុ	nt								
CE marked device	Lot A	Lot B	Lot C	Compliance							
61	61	61	61	100%							

Slide Technique										
Group O										
Negative w	ith anti-A	monoclona	al reagent,	Anti-B						
monoclonal r	eagent and	d anti-AB n	nonoclonal	reagent						
N ₁	egative wit	h Negative	control							
Compliance Compliance										
241	241 241 241			100%						
	Tube	Technique	!							
	G	iroup O								
Negative w	ith anti-A	monoclona	al reagent,	Anti-B						
monoclonal r	eagent and	d anti-AB n	nonoclonal	reagent						
N	egative wit	h Negative	control							
CE marked device	Lot A	Lot B	Lot C	Compliance						
243	243	243	243	100%						

Slide Technique									
Group AB									
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control									
CE marked device	Lot A	Lot B	Lot C	Compliance					
33	33 33 33			100%					
	Tube	Technique							
	Gr	oup AB							
monoclonal r	ith anti-A n eagent and egative wit	d anti-AB n	nonoclonal						
CE marked device	Lot A Lot B		Lot C	Compliance					
24	24	24	24	100%					

No inversion in diagnosis has been shown: from a qualitative point of view we have observed 100% compliance in direct group testing in slide and tube techniques for determination of A, B, AB and O groups for the three lots of Atlas Medical.

QUALITY CONTROL

The reactivity of all blood grouping reagents should be confirmed by testing known positive and negative red blood cells on each day of use. To confirm the specificity and sensitivity, Blood grouping reagents should be tested with antigen-positive and antigen-negative red blood cells.

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Germany

Tel: +49 - 33708 - 3550 30 Email: <u>Info@atlas-medical.com</u> Website: <u>www.atlas-medical.com</u>

PPI861A01 Rev.L (19.02.2022)

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LIST OF VARIENTS:

Product Code	Product Name
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/Carton Box
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial. 10 vials / Plastic Pack
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1 /512), 10ml/vial. 18 vials / Carton Box
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, / Carton Box
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials / Plastic Pack
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials / Carton Box
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 1 vial/ Carton Box
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 10 vials/Plastic Pack
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /512), 10ml/vial, 18 vials/Carton Box
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 1 vial/ Carton Box
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 10 vials / Plastic Pack
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1 /128), 10ml/vial, 18 vials / Carton Box
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1 Vial/Carton Box
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials / Plastic Pack
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/Carton Box
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 10 vials /Plastic Pack
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1 /256), Anti-D (1/64)),3x10ml / plastic Pack
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1 /256), 2x10ml /Plastic Pack
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial, 1vial/Carton Box
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial,10 vials /Plastic Pack
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1 /256), 10ml/vial,18 vials / Carton Box
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 1Vial/ Carton Box
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1 /64), 10ml/vial, 10 vials / Plastic Pack
8.02.47.0.0030	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-D (1 /128)),3x10ml/Plastic Pack
8.02.47.1.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Carton Box.
8.02.47.3.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /64)), 3x10ml /Plastic Pack
8.02.47.5.0030	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-D (1 /128)), 3x10ml/Plastic Pack
8.02.49.0.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /64)), 4x10ml/Carton Box
8.02.49.2.0040	ABO Set (Anti-A (1 /256), Anti-B (1 /256), Anti-AB (1 /256), Anti-D (1 /128)), 4 x 10ml, 4 vials/Plastic Pack
8.02.53.0.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml/Plastic Pack
8.02.53.1.0040	ABO Set (Anti-A (1 /512), Anti-B (1 /512), Anti-AB (1 /512) Anti-D (1 /128)), 4x10ml, 4vials/Plastic Pack
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial ,1Vial/ Carton Box
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial , 1Vial/ Carton Box
8.02.85.0.0010	Anti-D IgG/IgM Blend reagent (Titer 1 /256), 10ml/vial, 1Vial/ Carton Box

REF	Catalogue Number	1	Temperature limit
IVD	In Vitro diagnostic medical device	\triangle	Caution
\sum	Contains sufficient for <n> tests and Relative size</n>		Consult instructions for use (IFU)
LOT	Batch code	-	Manufacturer
Ī	Fragile, handle with care		Use-by date
	Manufacturer fax number	8	Do not use if package is damaged
	Manufacturer telephone number	\lambda	Date of Manufacture
巻	Keep away from sunlight	+	Keep dry



Certificate of Analysis for Blood Grouping Kit

Product	Identif	fica	ntion:								
Product	Name:	A	Anti-A Moi	noclo	nal Reagent		Minimal titer accepted: (1/256)				
Catalog nu	ımber		8.02.04.0.00	10	Quantity Prod	luced	400 kit	Mfg. Date		09.02.2025	
Lot N	0		25020604		Storage Cond	ition	2-8°C	EXP.	Date	202	7.01.30
Physical	Inspec	etio	n:								
Kit Comp	ponents		Size		Color & st	atus	Acceptance Criteria (Color &status)		Qt	y. /Kit	Pass/Fail
Anti	i-A		10 ml		Blue, liq	uid	Blue,	liquid		1	Pass
Package	Insert		-		-		-			1	Pass
The oute	r label	of	the kit is o	correc	t and clear:	■Pas	s □ Fail				
Biochem	ical In	spe	ection:								
Item		S	Specificity (S	lide Me	ethod)			Sensitivity ((Tube Met	hod)	
	Rea	actio	on time				ype of Cell Titer resultension & lot no		ult	Agglutination strength	Pass/Fail
Anti-A		2	sec		+4		ell Suspension JSA250213)	1/256		+3	Pass
Anti-B											
Anti-AB											
Anti-D									-		

Conclusion:

The product had been tested by the quality control department following the related QC test method and the testing results show that it meets the specified acceptance criteria and accordingly, it is released for the next process.



QC Manager Approval: Shahd Alhawamdeh

Date: 13.02.2025



..Certificate of Analysis for Blood Grouping Kit

Product	Identif	fica	ation:								
Product	Name:	A	Anti-AB M	onocl	onal Reagent		Minimal tite	er accepted	: (1/256	6)	
Catalog nu	ımber		8.02.06.0.00	10	Quantity Prod	uced	192 Kit	Mfg.	Date	05.02.2025	
Lot N	0		25012022		Storage Cond	ition	2-8°C	EXP.	Date	202	7.02.01
Physical	Inspec	tio	n:								
Kit Comp	ponents		Size		Color & st	atus	Acceptance Criteria (Color &status)		Qty. /Kit		Pass/Fail
Anti-	·AB		10 ml		Yellowish, l	liquid	Yellowish	, liquid		1	Pass
Package	insert		-		-		-	-		1	Pass
The oute	r label	of	the kit is c	correc	ct and clear:	■Pas	s □ Fail				
Biochem	ical In	_									
Item		S	Specificity (S)	lide Me	ethod)			Sensitivity (Tube Me	thod)	
	Rea	actio	on time	A	gglutination strength		Type of Cell Titer resension & lot no		ult	Agglutination strength	Pass/Fail
Anti-A											
Anti-B											
Anti-AB		2 sec					Cell Suspension 1/2 JSAB250206)			+3	Pass
Anti-D											

Conclusion:

The product had been tested by the quality control department following the related QC test method and the testing results show that it meets the specified acceptance criteria and accordingly, it is released for the next process.



QC Manager Approval: Shahd Alhawamdeh
Date:06.02.2025



Certificate of Analysis for Blood Grouping Kit

Product	Identif	fica	tion:								
Product	Name:	A	Anti-B Moi	noclo	nal Reagent		Minimal tite	er accepted	: (1/256)	
Catalog nu	umber		8.02.05.0.00	10	Quantity Produced		390 kit	Mfg. Date		10.02.2025	
Lot N	0		25020605		Storage Cond	ition	2-8°C	EXP.	Date	2027	7.01.30
Physical	Inspec	tio	n:								
Kit Com	ponents		Size		Color & st	atus	Acceptance Criteria (Color &status)		Qt	ty. /Kit	Pass/Fail
Anti	i-B		10 ml		Yellow, lic	quid	Yellow	, liquid		1	Pass
Package	Insert		-		-		-	-		1	Pass
The oute	r label	of	the kit is o	correc	ct and clear:	■Pass	s □ Fail				
Biochem	ical In	spe	ection:								
Item		S	Specificity (S)	lide Me	ethod)			Sensitivity (Tube Met	thod)	
	Rea	actio	on time	A	gglutination strength	_		Type of Cell Titer responsion & lot no		Agglutination strength	Pass/Fail
Anti-A											
Anti-B	2 sec +4		+4			ell Suspension 1/256 USB250211)		5 +3		Pass	
Anti-AB											
Anti-D					-				-		

Conclusion:

The product had been tested by the quality control department following the related QC test method and the testing results show that it meets the specified acceptance criteria and accordingly, it is released for the next process.



QC Manager Approval: Shahd Olhawamdeh	
Date:11.02.2025	



Certificate of Analysis for Blood Grouping Kit

Product	Identi	fica	ation:									
Product N	ame: A	Anti	i-D IgG/ IgM	I Mond	oclonal Reagent		Mini	mal titer a	ccepted: (1/6	4)		
Catalog number		8.02.07.0.0010		10	Quantity Produced		9	900kit	Mfg. Date		04.01.2025	
Lot No		24123112			Storage Condition			2-8°C	EXP. Date		2026.11.07	
Physical	Inspec	etio	n:									
Kit Components		Size			Color & status			Acceptance Criteria (Color &status)		Qty. /Kit		Pass/Fail
Anti-D IgM			10 ml		Yellowish, liquid			Yellowish, liquid		1		Pass
Package Insert			-		-			-		1		Pass
The oute	r label	lof	the kit is o	correc	et and clear:	■Pas	ss 🗆	Fail			-	
Biochem	ical In	_										
Item		2	Specificity (S	lide Me	ethod)				Sensitivity (Tube Meth	nod)	
	Reacti		on time	Agglutination strength			Type of Cell Suspension & lot no		Titer res	ult	Agglutination strength	Pass/Fail
Anti-A												
Anti-B	i-B											
Anti-AB	В											
Anti-D	Anti-D 3 sec					Cell Suspension USO250106)		1/64		+3	Pass	

Conclusion:

The product had been tested by the quality control department following the related QC test method and the testing results show that it meets the specified acceptance criteria and accordingly, it is released for the next process.



QC Manager Approval:	Shahd Alhawamdeh
Date: 06.01.2025	





Anti-K, monoclonal MONOCLONAL BLOOD GROUPING REAGENT

For Tube, DiaMed-ID, Ortho BioVue, Microplate and Slide Techniques





B18908 1x 5 mL Anti-K, monoclonal

For professional in vitro diagnostic use only.

SUMMARY

The K antigen was reported in 1946. The antigen is fully developed at birth and can be strongly immunogenic. Anti-K has been implicated in Haemolytic Transfusion Reactions and Haemolytic Disease of the Newborn.

Anti- K	Anti- k	Phenotype	Caucasians %	Afro-Americans %	
+	0	K+k-	0.2	Rare	
+	+	K+k+	8.8	2.0	
0	+	K-k+	91.0	98.0	
0	0	K _o	Exceedingly Rare		

TEST PRINCIPLE

Reagent will cause direct agglutination (clumping) of cells that carry K antigen. No agglutination generally indicates absence of K antigen (see LIMITATIONS).

REAGENTS

DIALAB Anti-K, monoclonal blood grouping reagent is a low protein reagent containing the monoclonal IgM antibody, Clone MS-56, diluted in a phosphate buffer containing sodium chloride (0.9 g%), bovine albumin (6 g%) and macromolecular potentiators. The reagent is supplied at optimal dilution for use with all recommended techniques stated below without need for further dilution or addition. For lot reference number and expiry date see

STORAGE

Reagent vials should be stored at 2-8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. The reagent has undergone transportation stability studies at 37°C and -25°C as described in document EN 23640:2011.

SAMPLE COLLECTION AND PREPARATION

Blood samples drawn with or without anticoagulant may be used for antigen typing. If testing is delayed, then store specimens at 2-8°C. EDTA and citrate samples should be typed within 48 hours. Samples collected into ACD, CPD or CPDA-1 may be tested up to 35 days from the date of withdrawal. All blood samples should be washed at least twice with PBS or Isotonic saline before being tested.

CONTROLS AND ADVICE

- It is recommended a positive control (ideally heterozygous) and a negative control be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
- When typing red cells from a patient it is important that a reagent negative control is included since the macromolecular potentiators in
- the reagent may cause false positive reactions with IgG coated cells. Weak K antigens may be poorly detected by the gel card, microtitre plate and slide technique. It is recommended that weak K antigens 3.
- are tested using the tube test technique.

 In the Recommended Techniques one volume is approximately 4. 50 μL when using the vial dropper provided.
- The use of the reagents and the interpretation of results must be carried out by properly trained and qualified personnel in accordance 5 with the requirements of the country where the reagents are in use.
- The user must determine suitability of reagent for use in other techniques

REAGENTS AND MATERIALS REQUIRED

- Applicator sticks.
- Automatic plate reader.
- PBS solution (pH 6.8-7.2) or Isotonic saline solution (pH 6.5-7.5)

- DiaMed ID-Cards (Neutral).
 DiaMed ID-Centrifuge.
 DiaMed ID-Diluent: i.e. ID-CellStab.
- Glass microscope slides.
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- Microplate centrifuge.
- Ortho BioVue System Cassettes (Neutral).
 Ortho BioVue System Centrifuge.
- Ortho 0.8% Red Cell Diluent.
- Positive (ideally Kk) and negative (kk) control red cells.
- Test tube centrifuge. Validated "U" well microplates.
- Volumetric pipettes

RECOMMENDED TECHNIQUES

A. Tube Technique:

- Prepare a 2-3% suspension of washed test red cells in PBS or Isotonic saline.
- 2. Place in a labelled test tube: 1 volume of DIALAB Anti-K, monoclonal reagent and 1 volume of test red cell suspension.
- 3. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
- Gently resuspend red cell button and read macroscopically for 4 agglutination
- 5. Any tubes, which show a negative or questionable result, should be incubated for 15 minutes at room temperature.
- 6. Following incubation, repeat steps 3 and 4.

В. DiaMed-ID Micro Typing Technique (Neutral Cards):

- Prepare a 0.8% suspension of washed test red cells in an ID-Diluent.
- Remove aluminium foil from as many microtubes as needed. Place in appropriate microtube: 50 μL of test red cell suspension and 3. 25 μL of DIALAB Anti-K, monoclonal reagent.
- Centrifuge ID-Card(s) in a DiaMed ID centrifuge Read macroscopically for agglutination.
- 5.

C. Ortho BioVue Typing Technique:

- Prepare a 0.8% suspension of washed test red cells in 0.8% Ortho 1. Red Cell Diluent.
- Remove aluminium foil from as many reaction chambers as needed. 3.
- Place in appropriate reaction chamber: 50 μL of test red cell suspension and 40 μL of DIALAB Anti-K, monoclonal reagent.
- 4. Centrifuge cassette(s) for 5 minutes in an Ortho BioVue System Centrifuge
- Read macroscopically for agglutination. 5.

D. Microplate Technique, using "U" wells:

- 1. Prepare a 2-3% suspension of washed test red cells in PBS or Isotonic saline.
- Place in the appropriate well: 1 volume DIALAB Anti-K, monoclonal 2.
- reagent and 1 volume test red cell suspension.

 Mix thoroughly, preferably using a microplate shaker, taking care to avoid cross-well contamination. 3.
- Incubate at room temperature for 15 minutes (time dependant on user).
- Centrifuge the microplate for 1 minute at 140 rcf or for a suitable alternative time and force.
- 6. Resuspend the cell buttons using carefully controlled agitation on a
- Read macroscopically or with a validated automatic reader. Any weak reactions should be repeated by the tube technique.
- 8.

E.

- Slide Technique:

 Prepare a 35-45% suspension of test red cells in serum, plasma or 1.
- Place on a labelled glass slide: 1 volume of DIALAB Anti-K, monoclonal reagent and 1 volume of test red cell suspension. 2.
- Using a clean applicator stick, mix reagent and cells over an area of about 20 x 40 mm.
- Slowly tilt the slide back and forth for 30 seconds, with occasional further mixing during the 2-minute period, maintaining slide at room temperature.
- 5. Read macroscopically after 2 minutes over a diffuse light and do not mistake fibrin strands as agglutination.

 Any weak reactions should be repeated by the tube technique.
- 6.

INTERPRETATION OF TEST RESULTS

- Positive: Agglutination of the test red cells constitutes a positive test result and within accepted limitations of test procedure, indicates the
- presence of the K antigen on the test red cells. **Negative:** No agglutination of the test red cells constitutes a negative result and within the accepted limitations of the test procedure,
- indicates the absence of the K antigen on the test red cells.

 Test results of cells that are agglutinated using the reagent negative control shall be excluded, as the agglutination is most probably caused by the effect of the macromolecular potentiators in the reagent on sensitised cells.

STABILITY OF THE REACTIONS

- Read all tube and microplate tests straight after centrifugation.
- Slide tests should be interpreted within two minutes to ensure specificity and to avoid the possibility a negative result may be incorrectly interpreted as positive due to drying of the reagent.
- Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended. 3

LIMITATIONS

- Stored blood may give weaker reactions than fresh blood
- False positive or false negative results may also occur due to:
 - Contamination of test materials
 - Improper storage, cell concentration, incubation time or temperature
 - Improper or excessive centrifugation
 - Deviation from the recommended techniques

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PERFORMANCE CHARACTERISTICS

- The reagent has been characterised by all the procedures mentioned in the Recommended Techniques.
- Prior to release, each lot of DIALAB Anti-K, monoclonal is tested by 2 the **Recommended Techniques** against a panel of antigen-positive red cells to ensure suitable reactivity.
- Specificity of source monoclonal antibodies is demonstrated using a 3.
- panel of antigen-negative cells.
 The Quality Control of the reagent was performed using red cells that had been washed twice with PBS or Isotonic saline prior to use.
- 5. The reagent complies with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.

DISCLAIMER

- The user is responsible for the performance of the reagents by any method other than those mentioned in the RECOMMENDED TECHNIQUES.
- Any deviations from the RECOMMENDED TECHNIQUES should be validated prior to use.

PRECAUTIONS

- The reagent is intended for in vitro diagnostic use only.
- 2. If a reagent vial is cracked or leaking, discard the contents
- Do not use the reagent past the expiration date (see **Vial Label**). Do not use the reagent if a precipitate is present.
- 5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.

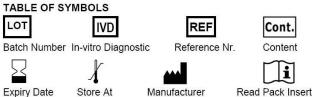
 The reagent has been filtered through a 0.2 µm capsule to reduce the
- 6. bioburden. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination. The reagent contains < 0.1% sodium azide. Sodium azide may be
- toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal, flush away with large volumes of
- Materials used to produce the reagent were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg 8. using approved microbiological tests.
- 9. No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF REAGENTS AND DEALING WITH SPILLAGES

For information on disposal of the reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

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 Mollison PL. Blood Transfusion in Clinical Medicine, 8th Edition,
- 4. Oxford, Blackwell Scientific Publications, 1987, Chapter 7.
- Guidelines for the Blood Transfusion Service in the United Kingdom. 5 H.M.S.O. Current Edition.
- British Committee for Standards in Haematology, Blood Transfusion 6. Task Force. Recommendations for evaluation, validation and implementation of new techniques for blood grouping, antibody screening and cross matching. Transfusion Medicine, 1995, 5, 145-







DIALAB Produktion und Vertrieb von chemisch - technischen Produkten und Laborinstrumenten Gesellschaft m.b.H. A – 2351 Wiener Neudorf, Austria IZ-NÖ Süd, Hondastrasse, Objekt M55 Phone: ++43 (0) 2236 660910-0 Fax: ++43 (0) 2236 660910-30 e-mail: office@dialab.at

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Certificate of Analysis / Quality Control

Product:	Anti-K,	monoclonal
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REF: B18908

Lot: 9463/760107-A5 2024-04-05 Mfg.: Exp.: 2026-04-05

Results:

Preservative: < 0.1% Sodium Azide w/v

None

Dye: Product filtered through a sterile 0.2 µm filter

2 - 8 °C

Kk Cells

Sterility: Source materials used to produce this lot were tested and found to be

non-reactive for anti-HIV 1+2, anti-HCV and HBsAg.

Storage:

Micro Testing:

Potency: **Tube Test** BioVue Card DiaMed Card Microplate

Kk Cells 1in128 1in512 1in128 1in128

Avidity: (1st sign of

agglutination)

Specificity:

Positive Phenotypes Negative Phenotypes

3 sec

Kk Cells Grade 4 kk Cells Negative

This lot meets our specifications.

Thomas 2024.10.18 Breininger 14:46:31 +02'00'

Rev.

2018-05-24 Date: