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STATEMENT

We, ACON Laboratories, Inc., having a registered office at *5850 Oberlin Drive #340, San Diego, CA 92121* authorize SRL Sanmedico having a registered office at *A. Corobceanu street 7A, apt. 9, Chisinău, MD-2012, Moldova*

to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: January 3, 2023

Signature: _____

Qiyi Xie, Md, MPH
Sr. Officer, Regulatory & Clinical Affairs
ACON Laboratories, Inc.
Ph: 858-875-8011
Email: qxie@aconlabs.com

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

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

TÜV SÜD Product Service

Certificate

No. Q5 104507 0001 Rev. 03

Holder of Certificate: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture and distribution of In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets**

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 104507 0001 Rev. 03

Report No.: SH22743A01

Valid from: 2022-09-15
Valid until: 2025-09-06

Date, 2022-09-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

TÜV SÜD Product Service

Certificate

No. Q5 104507 0001 Rev. 03

Applied Standard(s):

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

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

Address holder for registration only

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Manufacture and distribution of
In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets

ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA

Storage of
In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Design and Development of
In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644
Tijuana B.C. CP, MEXICO

Manufacture of
blood glucose test strips, antigen rapid test and IgG/IgM antibody rapid test for infectious disease.

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Manufacturer: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Product Category(ies): **Blood glucose measuring systems for self testing and self-testing devices for clinical chemistry, hematology and pregnancy and ovulation**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1 104507 0003 Rev. 06

Report no.: SH22743EXT01

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

Date, 2022-05-04

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Model(s):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Cholesterol Monitoring System (CCM-111),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices,
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Strips (CCS-101),
PT/INR Monitoring System (CCM-151),
PT/INR Test Strips (CCS-151),
Hemoglobin Testing System (CCM-141),
Hemoglobin Test Strips (CCS-141),
hCG Pregnancy Rapid Test Cassette (Urine),
Pregnancy Rapid Test Midstream,
On Call Extra Mobile Blood Glucose Monitoring System (OGM-281),
On Call Sure Blood Glucose Monitoring System (OGM-211),
On Call Sure Sync Blood Glucose Monitoring System (OGM-212),
On Call Sure Blood Glucose Test Strips (OGS-211),
GIMA Blood Glucose Monitoring System,
GIMA Bluetooth Blood Glucose Monitoring System,
GIMA Blood Glucose Test Strips,
On Call GU Dual Blood Glucose & Uric Acid Monitoring

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EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

System (OGM-201),
On Call Blood Uric Acid Test Strips (OGS-201),
LH Ovulation Rapid Test Cassette (Urine),
Ovulation Rapid Test Midstream,
Ovulation & Pregnancy Test Combo Pack,
On Call Extra Voice Blood Glucose Monitoring System (OGM-291),
Early Detection Pregnancy Test,
Digital Pregnancy Test,
Go-Keto Blood Glucose & Ketone Monitoring System (OGM-161),
Go-Keto Blood Ketone Test Strips (OGS-161),
Go-Keto Blood Glucose Test Strips,
On Call Extra GM Blood Glucose Monitoring System(OGM-191),
On Call Extra GM Blood Glucose Test Strips (OGS-191),
On Call Plus GM Blood Glucose Monitoring System,
On Call Plus GM Blood Glucose Test Strips,
Go-Keto Urinalysis Reagent Strips

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644 Tijuana B.C. CP, MEXICO

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TÜV®

Mission® Urinalysis Strips and Controls

Mission® Urinalysis Reagent Strips

Simple to use

- Analytical sensitivity comparable to market leaders
- High quality color chart ensures accurate visual reading
- Compatible for visual and analyzer reading
- Over 35 different combinations available

Multiple Packaging Options

Canister Packaging

- Available in 25, 50, and 100 strips per canister
- Available in 150 strips per canister without MA/CRE Combo

Pouch Packaging

- Individually packaged strips available in kits of 3 or 6 strips for visual reading only (includes 1 color chart)
- Unique packaging maintains 2 year shelf life for all strips in the kit

Shelf Life

- 2 year shelf life for unopened canisters offers cost savings
- 3 month shelf life for strips in opened canisters

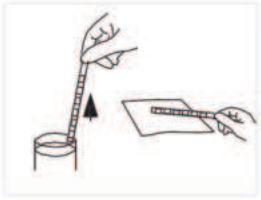
High Quality Color Chart

Large Choice of Parameter Combinations

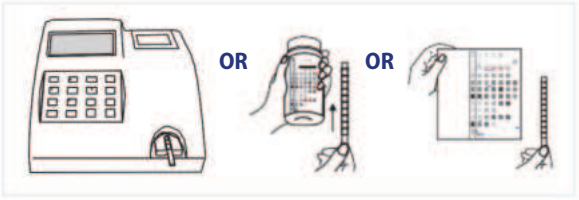
Individually Pouched Strips

Reagent Strips 3 Easy Steps

STEP 1
Immerse strip into urine



STEP 2
Remove excess urine



STEP 2
Obtain results by analyzer or visual reading

Urinalysis Reagent Strip – Combinations for Visual Reading

Catalog Number	Number of Parameters	Type of Strip	Parameter Order (First parameter is closest to strip handle)	ASC	GLU	BIL	KET	SG	BLO	PH	PRO	URO	NIT	LEU	ALB	CRE	CA
U031-141	14	14C	Ca/Blo/pH/Cre/Nit/Ket/SG/Asc/Glu/Bil/Pro/Alb/Uro/Leu	*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-131	13	13CE	Blo/pH/Cre/Nit/Ket/SG/Asc/Glu/Bil/Pro/Alb/Uro/Leu	*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-111	11	11A	Asc/Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit/Leu	*	*	*	*	*	*	*	*	*	*	*			
U031-101	10	10U	Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit/Leu		*	*	*	*	*	*	*	*	*	*			
U031-091	9	9U	Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit		*	*	*	*	*	*	*	*	*				
U031-081	8	8U	Glu/Bil/Ket/Blo/pH/Pro/Uro/Nit		*	*	*		*	*	*	*	*				
		8N	Glu/Ket/SG/Blo/pH/Pro/Nit/Leu1		*		*	*	*	*	*		*	*			
		8S	Glu/SG/Blo/pH/Pro/Uro/Nit/Leu		*			*	*	*	*	*	*	*			
		8K	pH/Glu/Bil/Pro/Uro/Nit/Leu/Ket		*	*	*			*	*	*	*	*			
U031-071	7	7N	Glu/Ket/Pro/pH/Blo/Nit/Leu		*		*		*	*	*		*	*			
U031-061	6	6N	Glu/Pro/pH/Blo/Nit/Leu		*				*	*	*		*	*			
		6U	Bil/SG/Blo/Uro/Pro/Nit			*		*	*		*	*	*				
U031-051	5	5B	Glu/Ket/Pro/pH/Blo		*		*		*	*	*						
		5N	Glu/Pro/Nit/Blo/Leu		*				*		*		*	*			
		5S	Glu/SG/Pro/pH/Blo		*			*	*	*	*						
		5U	Bil/Uro/Leu/Nit/Blo			*			*			*	*	*			
U031-041	4	4P	Glu/Pro/Nit/Leu		*						*		*	*			
		4S	Glu/SG/pH/Pro		*			*		*	*						
		4B	Glu/Pro/pH/Blo		*				*	*	*						
		4K	Glu/Ket/Pro/pH		*		*			*	*						
		4G	Pro/Glu/Leu/Blo		*				*		*			*			
		4N	Pro/Nit/Blo/Leu						*		*		*	*			
U031-031	3	3P	Glu/pH/Pro		*					*	*						
		3K	Glu/Ket/Pro		*		*				*						
		3G	Glu/Ket/pH		*		*			*							
		3N	Blo/Nit/Leu						*				*	*			
U031-021	2	2G	Glu/Pro		*						*						
		2K	Glu/Ket		*		*										
		2N	Nit/Leu										*	*			
		2B	Blo/Leu						*					*			
		2U	Bil/Uro			*						*					
		2S	SG/pH					*		*							
		2C	Alb/Cre												*	*	
U031-011	1	1B	Blo						*								
		1P	pH							*							
		1G	Glu		*												
		1K	Ket				*										
		1R	Pro								*						

TYPE OF STRIP: 1-10 Parameters – 510(k) Cleared, CLIA Waived and CE Marked for sale in the European Community; 11-13 and 14 Parameters only CE Marked for sale in the European Community

Mission® Urinalysis Strips and Controls

Mission® Urine Controls

Accurate

- Use with Mission® and Mission® Expert Urinalysis Reagent Strips and Urine Analyzers for optimum quality control
- Validate urinalysis results and prevent procedure errors

Quick Testing

- Ensures accurate results for all parameters
- Obtain quick results in any setting
- Competitively priced

Two Types of Urine Controls available

- Ready to use without dissolving in distilled water
- 24 months shelf life for unopened controls at 2 - 8 ºC
- Two Packaging Options

Dropper Tip Bottles

– Dropper tip bottles provide efficient use of the control solution
– Easily drop the control solution onto each reagent pad using the dropper tip bottle
– Controls can be used up to 30 days at room temperature
– Controls can be used until the expiration date if kept refrigerated

Diptubes

– Diptube packaging allows for QC testing in a way similar to using a urine specimen
– Simply dip the strip into the control solution and read results, or place on strip tray for analyzer reading
– Controls can be used 30 days at room temperature
– Do not dip more than 20 strips into the tube to avoid inaccurate results
– Controls can be used until the expiration date if kept refrigerated

High Quality Color Chart

Large Choice of Parameter Combinations

Dropper bottles or Dip Tubes

Mission® Urinalysis Strips and Controls

Urine Control Specifications

Features	Specifications	
Product Name	Liquid Urine Control	Liquid Diptube Urine Control
Test Parameters	LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB, CRE, CA (13)	
Solution Detection Levels	**Level 1**	**Negative:** LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB, CRE, CA
	Level 2	**Positive:** LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ALB CRE, CA and Negative ASC
Compatible Urine Strips	Mission® Urinalysis Reagent Strips and Mission® Expert Urinalysis Reagent Strips	
Reading Time/Stability	Refer to insert	Refer to insert
Storage Temperature	2 - 8 ˚C	2 - 8 ˚C
Unopened Control Shelf Life	24 months	24 months
Opened Control Stability	30 days at 15 - 30 °C or until the expiration date at 2 - 8 °C	30 days at 15 - 30 °C or until the expiration date at 2 - 8 °C
Maximum Tests per Unit	20 to 40 tests/bottle	20 tests/diptube

Ordering Information

Product Name	Product Number	Components	Kit Box Dimensions (LxWxH) & Weight	Carton Dimensions (LxWxH) & Weight	# Kits /Carton
Liquid Urine Control	**U021-011**	**Level 1:** 3 x 10 mL /bottle; Level 2: 3 x 10 mL/bottle	85 mm x 55 mm x 60 mm; 107 g	400 mm x 270 mm x 345 mm; 5.2 kg	198
		Level 1: 3 x 5 mL/bottle; Level 2: 3 x 5 mL/bottle	85 mm x 55 mm x 60 mm; 75 g	400 mm x 270 mm x 345 mm; 4.2 kg	198
		Level 1: 1 x 10 mL/bottle; Level 2: 1 x 10 mL/bottle	55 mm x 28 mm x 60 mm; 41 g	400 mm x 270 mm x 345 mm; 6.6 kg	228
		Level 1: 1 x 5 mL/bottle; Level 2: 1 x 5 mL/bottle	55 mm x 28 mm x 60 mm; 31 g	400 mm x 270 mm x 345 mm; 5.5 kg	228
Liquid Diptube Urine Control	**U021-071**	**Level 1:** 2 x 12 mL/diptube; Level 2: 2 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 101 g	385 mm x 255 mm x 320 mm; 4.7 kg	30
		Level 1: 1 x 12 mL/diptube; Level 2: 1 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 62 g	385 mm x 255 mm x 320 mm; 3.5 kg	30

All Urine Controls are 510(k) Cleared, CLIA Waived and CE Marked for sale in the European Community

aconlabs.com

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego, CA 92121, U.S.A.
Tel: 1.858.875.8000
Fax: 1.858.200.0729
Email: info@aconlabs.com

PN 2170004302 • Date 12/17

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Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Mission® Urinalysis Reagent Strips (U031-XX1)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 11 day of February, 2020
in San Diego, CA USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

Mission® Urinalysis Reagent Strips (Urine)

Package Insert

REF U031-011	REF U031-051	REF U031-091	English
REF U031-021	REF U031-061	REF U031-101	
REF U031-031	REF U031-071	REF U031-111	
REF U031-041	REF U031-081		

For rapid detection of multiple analytes in human urine.
For in vitro diagnostic use only.

INTENDED USE

The Urinalysis Reagent Strips (Urine) are firm plastic strips onto which several separate reagent areas are affixed. The test is for the qualitative and semi-quantitative detection of one or more of the following analytes in urine: Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes.

SUMMARY

Urine undergoes many changes during states of disease or body dysfunction before blood composition is altered to a significant extent. Urinalysis is a useful procedure as an indicator of health or disease, and as such, is a part of routine health screening. The Urinalysis Reagent Strips (Urine) can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.[1,2]

PRINCIPLE AND EXPECTED VALUES

Ascorbic acid: This test involves decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from blue-green to orange. Patients with adequate diet may excrete 2-10 mg/dL daily. After ingesting large amounts of ascorbic acid, levels can be around 200 mg/dL.

Glucose: This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose is first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown. Glucose should not be detected in normal urine. Small amounts of glucose may be excreted by the kidney.[3] Glucose concentrations as low as 100 mg/dL may be considered abnormal if results are consistent.

Bilirubin: This test is based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acidic medium. Varying bilirubin levels will produce a pinkish-tan color proportional to its concentration in urine. In normal urine, no bilirubin is detectable by even the most sensitive methods. Even trace amounts of bilirubin require further investigation. Atypical results (colors different from the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine specimen, and are possibly masking the bilirubin reaction.

Ketone: This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise.[4-6] In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.[7]

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration. Randomly collected urine may vary in specific gravity from 1.003-1.035.[8] Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022.[8] In cases of severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

Blood: This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue. Any green spots or green color development on the reagent area within 60 seconds is significant and the urine specimen should be examined further. Blood is often, but not invariably, found in the urine of menstruating females. The significance of a trace reading varies among patients and clinical judgment is required in these specimens.

pH: This test is based on a double indicator system which gives a broad range of colors covering the entire urinary pH range. Colors range from orange to yellow and green to blue. The expected range for normal urine specimens from newborns is pH 5-7.[9] The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.[9]

Protein: This reaction is based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results. 1-14 mg/dL of protein may be excreted by a normal kidney.[10] A color matching any block greater than trace indicates significant proteinuria. Clinical judgment is required to evaluate the significance of trace results.

Urobilinogen: This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and urobilinogen in strongly acidic medium to produce a pink color. Urobilinogen is one of the major compounds produced in heme synthesis and is a normal substance in urine. The expected range for normal urine with this test is 0.2-1.0 mg/dL (3.5-17 µmol/L).[8] A result of 2.0 mg/dL (35 µmol/L) may be of clinical significance, and the patient specimen should be further evaluated.

Nitrite: This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1 N-(1-naphthyl) ethylenediamine to produce a pink color. Nitrite is not detectable in normal urine.[9] The nitrite area will be positive in some cases of infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40% in cases where little bladder incubation occurred, to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

Leukocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color. Normal urine specimens generally yield negative results. Trace results may be of questionable clinical significance. When trace results occur, it is recommended to retest using a fresh specimen from the same patient. Repeated trace and positive results are of clinical significance.

REAGENTS AND PERFORMANCE CHARACTERISTICS

Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances. The following table below indicates read times and performance characteristics for each parameter.

Reagent	Read Time	Composition	Description
Ascorbic Acid (ASC)	30 seconds	2,6-dichlorophenolindophenol; buffer and non-reactive ingredients	Detects ascorbic acid as low as 5-10 mg/dL (0.28-0.56 mmol/L).
Glucose (GLU)	30 seconds	glucose oxidase; peroxidase; potassium iodide; buffer; non-reactive ingredients	Detects glucose as low as 50-100 mg/dL (2.5-5 mmol/L).
Bilirubin (BIL)	30 seconds	2, 4-dichloroaniline diazonium salt; buffer and non-reactive ingredients	Detects bilirubin as low as 0.4-1.0 mg/dL (6.8-17 µmol/L).
Ketone (KET)	40 seconds	sodium nitroprusside; buffer	Detects acetoacetic acid as low as 2.5-5 mg/dL (0.25-0.5 mmol/L).
Specific Gravity (SG)	45 seconds	bromthymol blue indicator; buffer and non-reactive ingredients; poly (methyl vinyl ether/maleic anhydride); sodium hydroxide	Determines urine specific gravity between 1.000 and 1.030. Results correlate with values obtained by refractive index method within ± 0.005.
Blood (BLO)	60 seconds	3,3',5,5'-tetramethylbenzidine (TMB); diisopropylbenzene dihydroperoxide; buffer and non-reactive ingredients	Detects free hemoglobin as low as 0.018-0.060 mg/dL or 5-10 Ery/µL in urine specimens with ascorbic acid content of < 50 mg/dL.
pH	60 seconds	methyl red sodium salt; bromthymol blue; non-reactive ingredients	Permits the quantitative differentiation of pH values within the range of 5-9.
Protein (PRO)	60 seconds	tetrabromophenol blue; buffer and non-reactive ingredients	Detects albumin as low as 7.5-15 mg/dL (0.075-0.15 g/L).
Urobilinogen (URO)	60 seconds	p-diethylaminobenzaldehyde; buffer and non-reactive ingredients	Detects urobilinogen as low as 0.2-1.0 mg/dL (3.5-17 µmol/L).
Nitrite (NIT)	60 seconds	p-arsanilic acid; N-(1-naphthyl) ethylenediamine; non-reactive ingredients	Detects sodium nitrite as low as 0.05-0.1 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid.
Leukocytes (LEU)	120 seconds	derivatized pyrrole amino acid ester; diazonium salt; buffer; non-reactive ingredients	Detects leukocytes as low as 9-15 white blood cells Leu/µL in clinical urine.

The performance characteristics of the Urinalysis Reagent Strips (Urine) have been determined in both laboratory and clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, this test has been developed to be specific for the parameters to be measured with the exceptions of the interferences listed. Please refer to the Limitations section in this package insert.
Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the chart corresponds to a range of analyte concentrations.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The strip should remain in the closed canister until use.
- Do not touch the reagent areas of the strip.
- Discard any discolored strips that may have deteriorated.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used strip should be discarded according to local regulations after testing.

STORAGE AND STABILITY

Store as packaged in the closed canister either at room temperature or refrigerated (2-30°C). Keep out of direct sunlight. The strip is stable through the expiration date printed on the canister label. Do not remove the desiccant. Remove only enough strips for immediate use. Replace cap immediately and tightly. **DO NOT FREEZE.** Do not use beyond the expiration date.
Note: Once the canister has been opened, the remaining strips are stable for up to 3 months. Stability may be reduced in high humidity conditions.

SPECIMEN COLLECTION AND PREPARATION

A urine specimen must be collected in a clean and dry container and tested as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.
Prolonged storage of unpreserved urine at room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose.
Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent, specific gravity and bilirubin) test results.

MATERIALS

Materials Provided

- Strips
- Package insert

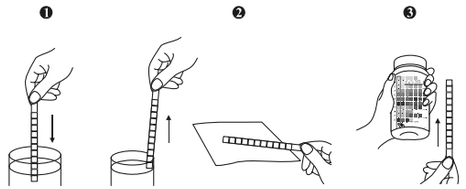
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the strip, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the strip from the closed canister and use it as soon as possible. Immediately close the canister tightly after removing the required number of strip(s). Completely immerse the reagent areas of the strip in fresh, well-mixed urine and immediately remove the strip to avoid dissolving the reagents. See illustration 1 below.
2. While removing the strip from the urine, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with urine. See illustration 2 below.
3. Compare the reagent areas to the corresponding color blocks on the canister label at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.
   Note: Results may be read up to 2 minutes after the specified times.



INTERPRETATION OF RESULTS

Results are obtained by direct comparison of the color blocks printed on the canister label. The color blocks represent nominal values; actual values will vary close to the nominal values. In the event of unexpected or questionable results, the following steps are recommended: confirm that the strips have been tested within the expiration date printed on the canister label, compare results with known positive and negative controls and repeat the test using a new strip. If the problem persists, discontinue using the strip immediately and contact your local distributor.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls whenever a new test is performed, or whenever a new canister is first opened. Each laboratory should establish its own goals for adequate standards of performance.

LIMITATIONS

Note: The Urinalysis Reagent Strips (Urine) may be affected by substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin.[8] The color development on the test pad may be masked or a color reaction may be produced that could be interpreted as false results.
Ascorbic acid: No interference is known.
Glucose: The reagent area does not react with lactose, galactose, fructose or other metabolic substances, nor with reducing metabolites of drugs (e.g. salicylates and nalidixic acid). Sensitivity may be decreased in specimens with high specific gravity (>1.025) and with ascorbic acid concentrations of ≥ 25 mg/dL. High ketone levels ≥ 100 mg/dL may cause false negative results for specimens containing a small amount of glucose (50-100 mg/dL).
Bilirubin: Bilirubin is absent in normal urine, so any positive result, including a trace positive, indicates an underlying pathological condition and requires further investigation. Reactions may occur with urine containing large doses of chlorpromazine or rifampen that might be mistaken for positive bilirubin.[9] The presence of bilirubin-derived bile pigments may mask the bilirubin reaction. This phenomenon is characterized by color development on the test patch that does not correlate with the colors on the color chart. Large concentrations of ascorbic acid may decrease sensitivity.
Ketone: The test does not react with acetone or β-hydroxybutyrate.[8] Urine specimens of high pigment, and other substances containing sulfhydryl groups may occasionally give reactions up to and including trace (±).[9]
Specific Gravity: Ketoacidosis or protein higher than 300 mg/dL may cause elevated results. Results are not affected by non-ionic urine components such as glucose. If the urine has a pH of 7 or greater, add 0.005 to the specific gravity reading indicated on the color chart.
Blood: A uniform blue color indicates the presence of myoglobin, hemoglobin or hemolyzed erythrocytes.[8] Scattered or compacted blue spots indicate intact erythrocytes. To enhance accuracy, separate color scales are provided for hemoglobin and for erythrocytes. Positive results with this test are often seen with urine from menstruating females. It has been reported that urine of high pH reduces sensitivity, while moderate to high concentration of ascorbic acid may inhibit color formation. Microbial peroxidase, associated with urinary tract infection, may cause a false positive reaction. The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.
pH: If the procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing the pH result to appear artificially low. pH readings are not affected by variations in urinary buffer concentration.
Protein: Any green color indicates the presence of protein in the urine. This test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and mucoprotein.[8] A negative result does not rule out the presence of these other proteins. False positive results may be obtained with highly buffered or alkaline urine. Contamination of urine specimens with quaternary ammonium compounds or skin cleansers containing chlorhexidine may produce false positive results.[8] The urine specimens with high specific gravity may give false negative results.
Urobilinogen: All results lower than 1 mg/dL urobilinogen should be interpreted as normal. A negative result does not at any time preclude the absence of urobilinogen. The reagent area may react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid and sulfonamides.[9] False negative results may be obtained if formalin is present. The test cannot be used to detect porphobilinogen.
Nitrite: The test is specific for nitrite and will not react with any other substance normally excreted in urine. Any degree of uniform pink to red color should be interpreted as a positive result, suggesting the presence of nitrite. Color intensity is not proportional to the number of bacteria present in the urine specimen. Pink spots or pink edges should not be interpreted as a positive result. Comparing the reacted reagent area on a white background may aid in the detection of low nitrite levels, which might otherwise be missed. Ascorbic acid above 30 mg/dL may cause false negatives in urine containing less than 0.05 mg/dL nitrite ions. The sensitivity of this test is reduced for urine specimens with highly buffered alkaline urine or with high specific gravity. A negative result does not at any time preclude the possibility of bacteruria. Negative results may occur in urinary tract infections from organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder for a sufficient length of time (at least 4 hours) for reduction of nitrate to nitrite to occur; when receiving antibiotic therapy or when dietary nitrate is absent.
Leukocytes: The result should be read between 60-120 seconds to allow for complete color development. The intensity of the color that develops is proportional to the number of leukocytes present in the urine specimen. High specific gravity or elevated glucose concentrations (≥ 2,000 mg/dL) may cause test results to be artificially low. The presence of cephalexin, cephalothin, or high concentrations of oxalic acid may also cause test results to be artificially low. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. High urinary protein may diminish the intensity of the reaction color. This test will not react with erythrocytes or bacteria common in urine.[8]

BIBLIOGRAPHY

1. Free AH, Free HM. *Urinalysis, Critical Discipline of Clinical Science*. CRC Crit. Rev. Clin. Lab. Sci. 3(4): 481-531, 1972.
2. Yoder J, Adams EC, Free, AH. *Simultaneous Screening for Urinary Occult Blood, Protein, Glucose, and pH*. Amer. J. Med Tech. 31:285, 1965.
3. Shchersten B, Fritz H. *Subnormal Levels of Glucose in Urine*. JAMA 201:129-132, 1967.
4. McGarry JD, Lilly. Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. Diabetes 28: 517-523 May, 1978.
5. Williamson DH. *Physiological Ketoses, or Why Ketone Bodies?* Postgrad. Med. J. (June Suppl.): 372-375, 1971.
6. Paterson P, et al. *Maternal and Fetal Ketone Concentrations in Plasma and Urine*. Lancet: 862-865; April 22, 1967.
7. Fraser J, et al. *Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk*. Clin. Chem. Acta II: 372-378, 1965.
8. Henry JB, et al. Clinical Diagnosis and Management by Laboratory Methods, 20th Ed. Philadelphia. Saunders. 371-372, 375, 379, 382, 385, 2001.
9. Tietz NW. Clinical Guide to Laboratory Tests. W.B. Saunders Company. 1976.
10. Burtis CA, Ashwood ER. Tietz Textbook of Clinical Chemistry 2nd Ed. 2205, 1994.

Index of Symbols

	Consult instructions for use	Σ	Tests per kit		Manufacturer
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 #
EC REP	Authorized Representative				

ACON **Laboratories, Inc.**
10125 Mesa Rim Road,
San Diego, CA 92121, USA

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150310404
Effective date: 2011-03-14

Atlas Medical

PRODUCT CATALOGUE

2022-2023

TABLE OF CONTENTS

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 diagnostic products to local, regional and international markets.

High and Consistent Quality

Satisfied Customer

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.

Continuous Improvement & Innovation

Care for the Environment & Working Conditions

Sites

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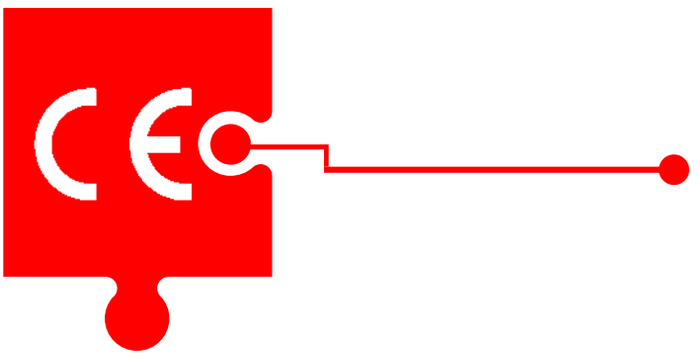
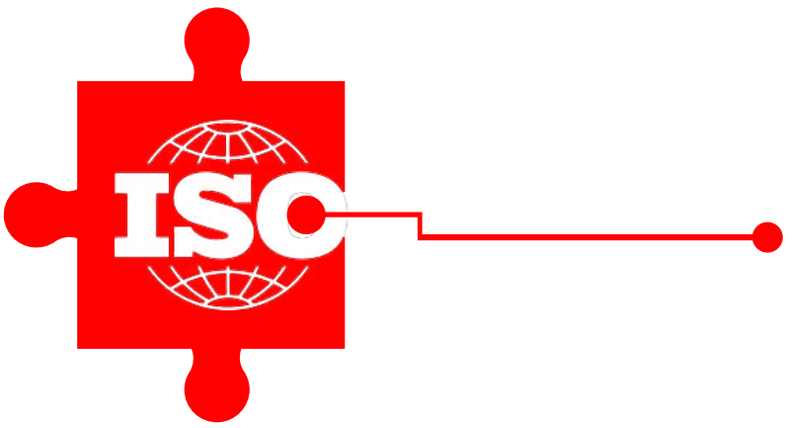
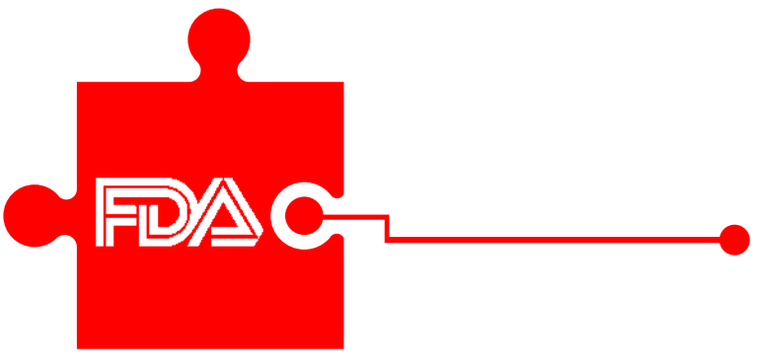
Atlas Medical enjoys a good presence in many international markets. We take pride in our export activities through our dedicated export department. We actively participate in major industry-related exhibitions seeking keen representatives around the globe to sell and distribute our products in their 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 conformity for CE marking purposes for many of our IVD products, either self-declared or through our Notified Body LNE/G-MED



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



the company also adheres to the US-FDA regulations and had already FDA-cleared few products for the US market. Our products are registered in numerous countries.

1996

Establishment of Cambridge - UK

Establishment of Manufacturing Site Amman-Jordan

2001

2003

Obtaining ISO13485 By Lloyd's Register

CE Self Testing Certificate

- Home Ovulation Test
- Home Pregnancy Test

2006

2007

CE Self Testing Certificate

- Home Menopause Test

2009

CE Self Testing Certificate
- Home Screening Tests

Kuala-Lumpur (Puchong)-Malaysia Manufacturing and Sales (SEA)

2010

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

Establishment of Istanbul - Turkey

2019

2019

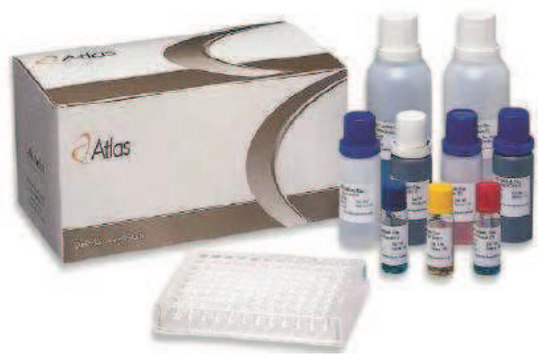
Obtaining FDA 510 K

-Drug of Abuse Tests (Cup and Panel format)

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

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

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



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

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

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

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

- Atlas Medical offers VTM that allows the safe transfer of viruses for further research, including diagnostic tests, and molecular biology techniques
- Atlas VTM can come either as a biological format “activated product (VTM) “ or in a chemical format “In Activated product (IVTM)“ .
- Atlas VTM maintain the viral structure and activity over a wide temperature range and suppress “
- Atlas viral transport medium is stable at room temperature

- Atlas VTM kits are conveniently packed in different sizes of 50 ,100 tube per kit with flocked swabs

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

Latex kits 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
8.00.16.0.0050 8.00.16.0.0100	Rota Virus Latex Kit	50 Tests 100 Tests
8.00.17.0.0050 8.00.17.0.0100	D-Dimer Latex Kit	50 Tests 100 Tests
8.00.21.0.0050 8.00.21.0.0100	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

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.

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

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 8.00.18.0.0250 8.00.18.0.0500	RPR Carbon Antigen Kit	100 Tests 250 Tests 500 Tests
8.00.19.0.0050 8.00.19.0.0100 8.00.19.0.0200	TPHA Kit	50 Tests 100 Tests 200 Tests
8.00.20.0.0250 8.00.20.0.0500 8.00.20.0.2500	VDRL Kit	250 Tests 500 Tests 2500 Tests
8.00.20.1.0250 8.00.20.1.2500	VDRL Kit with controls	250 Tests 2500 Tests

- 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 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.

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

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

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

Blood Grouping reagents 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.

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

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

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.

- 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
8.02.69.0.0005	Fibrinogen Reagent	5ml/vial
8.02.45.1.0080	APTT (PTT) Kit (Calcium Chloride reagent + Normal Control)	80 Tests
8.02.64.0.0006	Normal & Abnormal Coaggulation Control	3x1ml
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, 40x (White Plastic Bottle)	50ml/Bottle 2x50ml 6x50ml
8.02.50.0.0010 8.02.50.0.0050	Haemoglobin Standard	10ml/vial 50ml/Bottle

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	2x50ml Buffer + 2 vials of Sodium Dithionate
8.02.67.0.0100	Sickle Cell Kit, 100 Tests	4x50ml Buffer, 4 vials of Sodium Dithionate
8.02.68.0.0001 8.02.68.1.0001	Sickle Cell positive & negative control set	1ml each 0.5 ml each

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.

RAPID TESTS

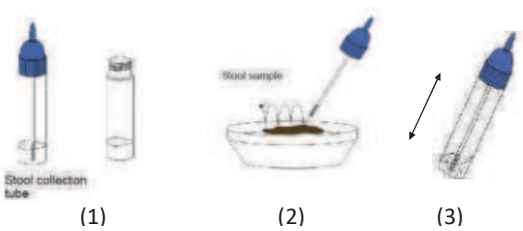
Item Code	Item Description	Sizes
8.04.27.0.0001 8.04.27.0.0020	HIV 1/2 Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.28.0.0001 8.04.28.0.0020	HIV 1/2 Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.29.0.0001 8.04.29.0.0100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

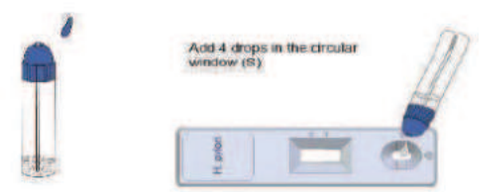
Item Code	Item Description	Sizes
8.04.20.0.0001 8.04.20.0.0020	H.pylori Antibody Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.21.0.0001 8.04.21.0.0020	H.pylori Antibody Test Cassette, Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box
8.04.22.0.0001 8.04.22.0.0100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

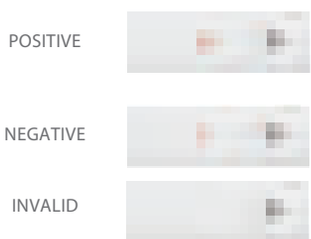
Item Code	Item Description	Sizes
8.42.47.0.0020	HAV IgM Test Cassette, Individually Pouched	20 Tests/Box
8.04.44.0.0001 8.04.44.0.0020	Dengue IgG/IgM Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box

STOOL SAMPLE

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







SWAB & NASAL SAMPLE

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

BLOOD SAMPLE

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

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

Urine Reagent Strips (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.
- Atlas Medical can also provide suitable readers to read the strip colors and document the results.

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

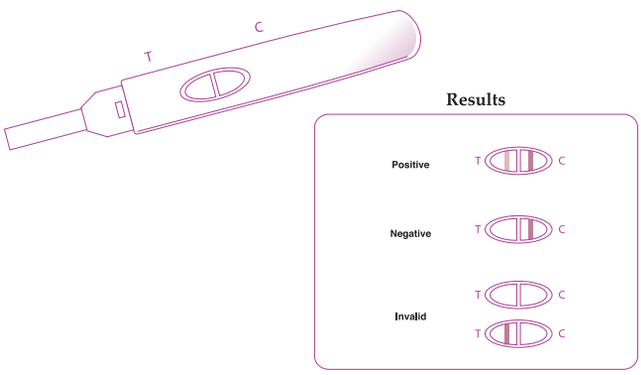
Atlas Urine Analyzer is a manual analyzer that detects Photosensitive Diode using the method of Reflectance Photometry. Test Categories include Routine, STAT and QC. Atlas Urine Analyzer has an Automatic calibration for accurate results and easy operation. It can read strips with up to 14 parameters,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

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

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

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.
- Different strip sizes are available.



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

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

Atlas Medical Microalbumin Rapid Test is a rapid visual immunoassay used for the qualitative detection of microalbumin in human urine samples. This kit is intended for use as an aid in the diagnosis of renal dysfunction.

- The test comes in cassette and Strip formats.

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

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

- 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

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).

- 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.

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

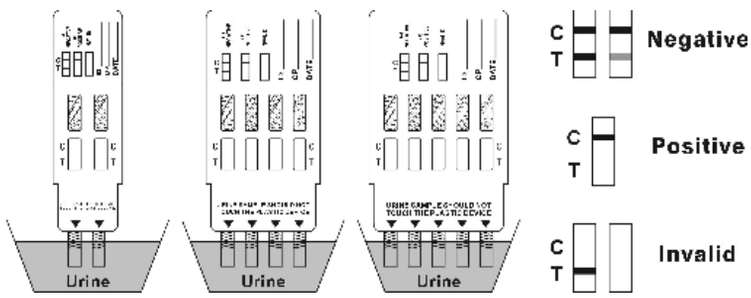
All the tests in this group are qualitative and based on lateral flow immunoassay for the detection of various Drug of Abuse .

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

STRIP AND CASSETTE FORMAT

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

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



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

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

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.

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

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

Item Code	Item Description	Sizes
8.05.16.0.0250 8.05.16.0.0500	Creatinine Jaffe Color-Kinetic	2x125ml 4x125ml
8.05.17.0.0250 8.05.17.0.0500	Glucose GOD-POD (Liquid)	2x125ml 4x125ml
8.05.18.0.0020 8.05.18.0.0040	GOT (AST) IFCC Kinetic (Tablets)	10x2ml 20x2ml
8.05.19.0.0250 8.05.19.0.0500	GOT (AST) IFCC Kinetic (Liquid)	5x50ml 5x100ml
8.05.20.0.0250 8.05.20.0.0500	GOT (AST) Reitman-Frankel Colorimetric	2x125ml 2x250ml
8.05.21.0.0020 8.05.21.0.0040	GPT (ALT) IFCC Kinetic (Tablets)	10x2ml 20x2ml
8.05.22.0.0250 8.05.22.0.0500	GPT (ALT) IFCC Kinetic (Liquid)	5x50ml 5x100ml
8.05.23.0.0200 8.05.23.0.0250	GPT (ALT) Reitman-Frankel Colorimetric	2x100ml 2x125m
8.05.24.0.0020 8.05.24.0.0040	Gamma GT Kinetic, Carboxy Substrate (Tablets)	10x2ml 20x2ml
8.05.25.0.0250 8.05.25.0.0500	Gamma GT Kinetic, Carboxy Substrate (Liquid)	5x50ml 5x100ml
8.05.26.0.0100 8.05.26.0.0200	HDL Cholesterol Precipitating Reagent	2x50ml 2x100ml
8.05.27.0.0200	Iron Ferrozine Colorimetric	4x50ml
8.05.28.0.0030 8.05.28.0.0060	LDH IFCC Kinetic (Tablets)	10x3ml 20x3ml
8.05.29.0.0250 8.05.29.0.0500	LDH Pyruvate Kinetic UV DGKC (Liquid)	5x50ml 5x100ml
8.05.30.0.0060	Lipase Kinetic (Liquid)	6x10ml
8.05.31.0.0250 8.05.31.0.0500	Magnesium Calmagite Colorimetric	2x125ml 4x125ml
8.05.32.0.0250 8.05.32.0.0500	Phosphorus Phosphomolybdate UV	2x125ml 4x125ml
8.05.33.0.0050 8.05.33.0.0100	Potassium Colorimetric	50 Tests 100 Tests
8.05.34.0.0050 8.05.34.0.0100	Sodium Colorimetric	50 Tests 100 Tests
8.05.35.0.0100	TIBC (Total Iron Binding Capacity)	100 Tests
8.05.36.0.0250 8.05.36.0.0500	Total Lipids 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

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

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

Atlas Medical supplies kits to test for alcohol in urine, saliva and breath. The urine alcohol test is based on the detection of EtG (Ethyl Glucuronide) in urine using a rapid lateral flow immunoassay. Whereas the saliva alcohol test uses a strip with dry chemistry pad that changes color to indicate the level of alcohol in the saliva. The alcohol breath test is a tube with crystals that change color as the subject blows through when alcohol level in breath exceeds a certain limit.

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

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

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.

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

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

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

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

Antibiotic sensitivity 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

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

- 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.

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

HORMONE ELISA KITS

Item Code	Item Description	Sizes
8.07.02.0.0096	PSA Elisa Kit	96 Tests
8.07.10.0.0096	Free PSA Elisa Kit	96 Tests

HORMONE ELISA KITS

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

Atlas Medical offers a range of Enzyme Linked Immunosorbent Assay (ELISA or EIA) to detect IgG and IgM antibodies against ToRCH (Toxoplasmosis, Rubella, CMV and Herpes I & II) in serum.

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

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

TORCH ELISA KITS

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

Atlas Medical offers a range of Enzyme Linked Immunosorbent Assay (ELISA or EIA) to detect a series of infection diseases such as HIV, Hepatitis (A, B, C, D and E) and H. pylori (antigens in feces).

INFECTIOUS DISEASES ELISA KITS

Item Code	Item Description	Sizes
8.14.19.1.0096	Helicobacter Pylori Antigen Elisa Kit	96 Tests

INFECTIOUS DISEASES ELISA KITS

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

OTHER ELISA KITS

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

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.

- 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 .

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

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

Fertility Kits

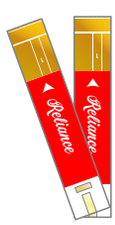
Item Code	Item Description	Sizes
70171001	Atlas Home Pregnancy Test Cassette	1 Test/Box
70172001	Atlas Home Pregnancy Test Midstream	1 Tests/Box
70174001	Atlas Home Ovulation Test Cassette	5 Tests/Box
70175001	Atlas Home Ovulation Test Midstream	3 Tests/Box
70177001	Atlas Home Menopause Test Cassette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

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



CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.1

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

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

pour les activités
for the activities

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

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

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

Voir addendum
See addendum

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

ISO 13485: 2016

Début de validité / Effective date : October 9th, 2020 (included)
Valable jusqu'au / Expiry date : October 8th, 2023 (included)
Etabli le / Issued on : October 8th, 2020

On behalf of the President
Béatrice LYS
Technical Director

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. 2
Délivrée à Paris le 19 mars 2020
Issued in Paris on March 19th, 2020

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
See addendum

GMED atteste qu'à l'examen des résultats figurant dans le rapport référence P172375, 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 P172375, the product(s) complies(s) with the requirements of the directive 98/79/EC, annex I.

Début de validité / Effective date : March 18th, 2020 (included)
Valable jusqu'au / Expiry date : October 8th, 2022 (included)

On behalf of the President
Béatrice LYS
Technical Director

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. 3
Délivrée à Paris le 08 octobre 2020
Issued in Paris on October 8th, 2020

ATTESTATION CE / EC CERTIFICATE
Appréciation du Système Complet d'Assurance Qualité / Approval (of) 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 (VD), un certificat CE de la conception est requis
For list A (VD) 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 détails sur addendum
See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référence P581488, 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 P581488, 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 : October 5th, 2020 (included)
Valable jusqu'au / Expiry date : October 8th, 2023 (included)

On behalf of the President
Béatrice LYS
Technical Director

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

Full Quality Assurance Certificate.

OTHER CERTIFICATES

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

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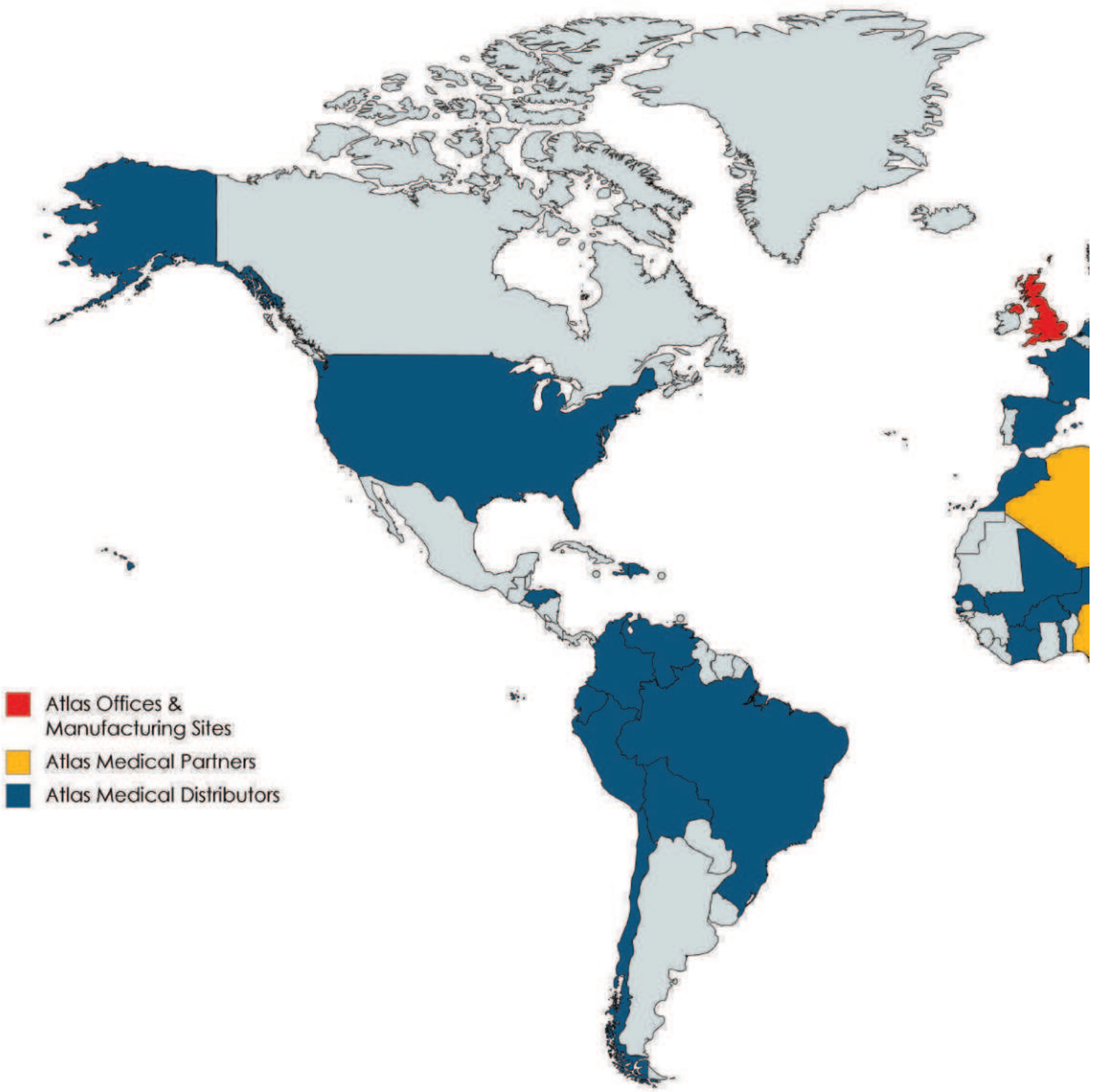
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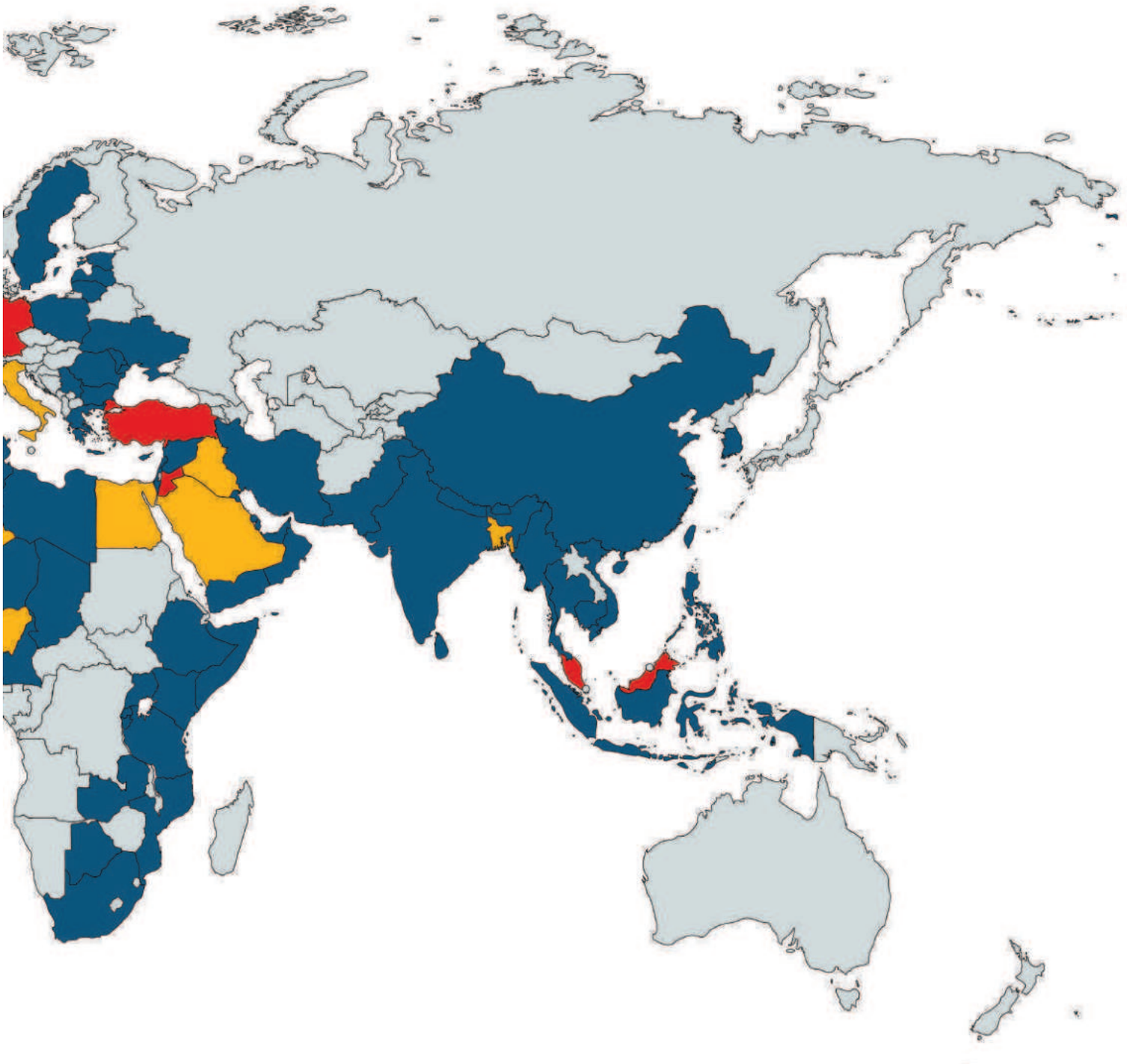

Atlas Medical CE 0459

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**

2°C 8°C **Store at 2- 8°C**

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 (D^{u}) 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 IgG/IgM 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 ºC, 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±10µl) of each reagent into a separate and appropriately marked tube.
3. Add 50 µl of red blood cell suspension prepared in step 1.
4. Shake to homogenize the mixture, then centrifuge at 500g for **1 minute.**
5. 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.
7. 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 (50µl) of the AHG reagent into the tube. Mix and centrifuge at 120g for **1 minute.**
10. 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

1. 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.
2. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
3. Add one drop (40 µl ± 10 µl) 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).
2. Using the wax pen divide the slide into appropriate numbers of divisions.
3. Using the provided dropper, place one drop (40 µl ± 10 µl) of each reagent onto its correspondent division on the slide.
4. Add 25µl of the precipitated cells next to each drop of reagents.
5. 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 **30 seconds**.
7. 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

POSITIVE: If Agglutination appears.

NEGATIVE: If no agglutination is observed.

Use the below table to determine the blood group:

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

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.
2. 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.
6. 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				
CE marked device	Lot A	Lot B	Lot C	Compliance
232	232	232	232	100%
Tube Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
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 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%

Slide Technique				
Group O				
Negative 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
241	241	241	241	100%
Tube Technique				
Group O				
Negative 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
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				
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
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.

REFERENCES

1. BCSH Blood Transfusion Task Force. Guidlines for microplate techniques in liquid-phase blood grouping and antibody screening. Clin. Lab. Haem 1990: 12, 437-460.
2. Issitt P. D. Applied Blood Group Serology, 3rd ed. Miami: Montgomery Scientific, 1985.
3. Kholer G., Milstein C. Continuous culture of fused cells secreting antibody of predefined specificity, 256, 495-497, 1975
4. Messeter L. et. al. Mouse monoclonal antibodies with anti-A, anti-B and anti-A,B specificities, some superior to human polyclonal ABO reagents, Vox Sang 46, 185-194, 1984
5. Race R.R. and Sanger R. Blood groups in man, 6th ed., Oxford: Blackwell Scientific, 1975.
6. Voak D. ET. al., Monoclonal anti-A and anti-B development as cost effective reagents. Med. Lab. Sci 39, 109-122. 1982.

7. Standards for Blood Banks d Transfusion Service. 11th Ed., Washington D.C., AABB 1984:25.
8. Widmann F.K.ed Technical Manual, 9th Ed., Wahington D.C.: AABB 1985:9.

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PPI861A01
Rev.L (19.02.2022)

CE 0459

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

Certificate of Analysis / Quality Control

Product: Anti-k, monoclonal
REF: B18908

Lot: 32514-A1 and all sub-lots (ie 32514-A2, 32514-A3, 32514-A4, etc)
Mfg.: 2023-06-09
Exp.: 2025-06-09

Results:

Preservative: < 0.1% Sodium Azide w/v

Dye: None

Sterility: Product filtered through a sterile 0.2 µm filter

Storage: 2 - 8 °C

Micro Testing: Source materials used to produce this lot were tested and found to be non-reactive for anti-HIV 1+2, anti-HCV and HBsAg.

Potency:

	Tube Test	BioVue Card	DiaMed Card
Kk Cells	1 in 16	1 in 32	1 in 16

Specificity:

Positive Phenotypes		**Negative Phenotypes**	
Kk Cells	Grade 5	**KK Cells**	Negative

This lot meets our specifications.

Rev. 1
Date: 2018-09-20

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

Anti-k, monoclonal

HUMAN BLOOD GROUPING REAGENTS

For Indirect Antiglobulin Techniques

REF Cont.

B18908 **1x 2 mL** **Anti-k, monoclonal**

For professional in vitro diagnostic use only.

SUMMARY

The k (Cellano) antigens were reported in 1949. Anti-k has been implicated in Haemolytic Transfusion Reactions and Haemolytic Disease of the Newborn.

Anti-K	Anti-k	Phenotype	Percentage
+	0	**K+k-**	0.2
+	+	**K+k+**	8.8
0	+	**K-k+**	91.0

PRINCIPLE

The reagent will cause indirect agglutination (clumping) of test red cells, that carries the corresponding specific antigen, in the antiglobulin phase of testing. No agglutination generally indicates the absence of the corresponding specific antigen (see Limitations).

REAGENTS

This Monoclonal IgG blood grouping reagent contains human monoclonal antibodies diluted in a phosphate buffer containing sodium chloride and bovine albumin. The reagent is supplied at optimal dilution for use with all the recommended techniques stated below without the need for further dilution or addition. For lot reference number and expiry date see Vial Label.

Product	Cell Line/Clone
Anti-k (Cellano)	P3A118OL67

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8ºC 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 EN23640:2011.

SAMPLE COLLECTION AND PREPARATION

Blood samples can be collected into EDTA, citrate, CPDA anticoagulants or as a clotted sample. The samples should be tested as soon as possible following collection. If a delay in testing should occur, store the samples at 2-8°C. Samples displaying gross haemolysis or microbial contamination should not be used for testing. Blood samples showing evidence of lysis may give unreliable results. It is preferable to wash all blood samples with PBS or Isotonic saline before being tested.

CONTROLS AND ADVICE

1. It is recommended a positive control (ideally heterozygous cells) 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.
2. The antiglobulin techniques can only be considered valid if all negative tests react positively with IgG sensitised red cells.
3. The reagents contain macromolecular potentiators which may cause false positive reactions with IgG sensitised cells, it is recommended that patient's cells are tested with patient's plasma to test for false positive reactions.
4. In the **Tube Technique** one volume is approximately 50 µL when using the vial dropper provided.
5. The use of the reagents and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagents are in use.
6. User must determine suitability of the reagents for use in other techniques.

REAGENTS AND MATERIALS REQUIRED

- Anti-Human Globulin (e.g. DIALAB Anti-HG polyspecific/monoclonal, REF: B05181) or anti-IgG
- Coombs cell washer
- Bio-Rad / DiaMed ID-Cards (LISS/Coombs or Coombs Anti-IgG).
- Bio-Rad / DiaMed ID-Centrifuge
- Bio-Rad / DiaMed ID-CellStab or ID-Diluent 2.
- Bio-Rad / DiaMed ID-Incubator equilibrated to 37ºC ± 2ºC
- Glass test tubes (10 x 75 mm or 12 x 75 mm)
- IgG sensitised red cells
- Ortho BioVue System Cassettes (AHG/Coombs)
- Ortho BioVue System Centrifuge
- Ortho BioVue System Heat Block equilibrated to 37°C ± 2ºC
- Ortho 0.8% Red Cell Diluent
- PBS solution (pH 6.8 – 7.2) or Isotonic saline solution (pH 6.5 – 7.5)
- Positive (ideally heterozygous) and negative control red cells
- Volumetric pipettes
- Water bath or dry heat incubator equilibrated to 37ºC ± 2ºC

RECOMMENDED TECHNIQUES

A. Indirect Antiglobulin Technique (IAT)

1. 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 incubate at 37ºC for 15 minutes.
4. Wash test red cells 4 times with PBS or Isotonic saline, taking care to decant saline between washes and resuspend each red cell button after each wash. Completely decant saline after last wash.
5. Add 2 volumes of anti-human globulin or anti-IgG to each dry cell button.
6. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
7. Gently resuspend red cell button and read macroscopically for agglutination
8. Confirm validity of all negative reactions with IgG sensitised red cells.

B. Bio-Rad/DiaMed-ID Micro Typing Technique

1. Prepare a 0.8% suspension of washed test red cells in ID-CellStab or ID-Diluent 2.
2. Remove aluminium foil from as many microtubes as needed on either LISS/Coombs or Coombs Anti-IgG ID cards.
3. Place in appropriate microtube: 50 µL of test red cell suspension and 25 µL of DIALAB Anti-k, monoclonal reagent.
4. Incubate the LISS/Coombs ID-Card(s) for 15 minutes at 37ºC.
5. Centrifuge the LISS/Coombs ID-Card(s) in a Bio-Rad/Diamed ID-Card centrifuge.
6. Read macroscopically for agglutination.

C. Ortho BioVue Typing Technique

1. Prepare a 0.8% suspension of washed test red cells in 0.8% Ortho Red Cell Diluent.
2. Remove aluminium foil from as many reaction chambers as needed on either AHG Polyspecific or AHG Anti-IgG cassettes.
3. Place in appropriate reaction chamber: 50 µL of test red cell suspension and 40 µL of DIALAB Anti-k, monoclonal reagent.
4. Incubate cassette(s) 15 minutes at 37ºC.
5. Centrifuge cassette(s) in an Ortho BioVue System Centrifuge.
6. Read macroscopically for agglutination.

INTERPRETATION OF TEST RESULTS

1. **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.
2. **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.

STABILITY OF THE REACTIONS

1. Washing steps should be completed without interruption and tests centrifuged and read immediately after addition of the reagent. Delays may result in dissociation of antigen-antibody complexes, causing false negative or weak positive results.
2. Caution should be exercised in the interpretation of results of tests at temperatures other than those **recommended**.

LIMITATIONS

1. Red cells that have a positive DAT due to a coating of IgG cannot be typed by the **Indirect Antiglobulin Technique.**
2. Suppressed or diminished expression of certain blood group antigens may conversely give rise to false negative reactions and so caution should always be exercised when assigning genotypes on the basis of test results.
3. 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

PERFORMANCE CHARACTERISTICS

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

DISCLAIMER

1. The user is responsible for the performance of the reagents by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations from the **Recommended Techniques** should be validated prior to use.

PRECAUTIONS

1. The reagents are intended for in vitro diagnostic use only.
2. If a reagent vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagents past the expiration date (see **Vial Label**).
4. Do not use the reagents if a precipitate is present.
5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
6. The reagents have been filtered through a 0.2 µm capsule to reduce the 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.

7. The reagents contain 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 water.
8. Materials used to produce the reagents were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg 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.

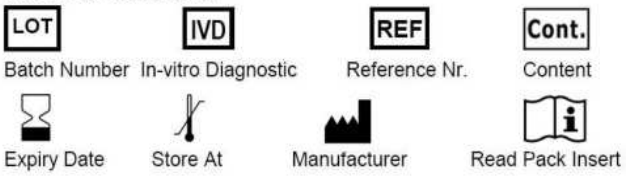
DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES

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

BIBLIOGRAPHY

1. Widman FK. Technical Manual, 9th Edition. American Association of Blood Banks, Arlington, VA, 1985; Chapter 8
2. Race RR, Sanger R. Blood Groups in Man, 6th Edition. Blackwell Scientific, Oxford 1975; Chapter 2
3. Mollison PL. Blood Transfusion in Clinical Medicine, 8th Edition. Blackwell Scientific, Oxford 1987; Chapter 7
4. Issitt PD. Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami 1985; Chapter 6
5. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
6. British Committee for Standards in Haematology, Blood Transfusion Task Force. Recommendations for evaluation, validation and implementation of new techniques for blood grouping, antibody screening and cross matching. Transfusion Medicine, 1995, 5, 145-150.

TABLE OF SYMBOLS



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One Step Multi-Drug Screen Cassette Test (Urine) Package Insert

CE

Package insert for testing of any combination of the following drugs: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, Ethyl Glucuronide, Fentanyl, Lysergic acid diethylamide, Marijuana, Methadone, EDDP (Methadone Metabolites), Ketamine, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Propoxyphene, K2 (Synthetic Cannabinoid), Tramadol and Tricyclic Antidepressants.

A rapid, one step screening test for the simultaneous, qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, Ethyl Glucuronide, Fentanyl, Lysergic acid diethylamide, Marijuana, Methadone, EDDP (Methadone Metabolites), Ketamine, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Propoxyphene, K2 (Synthetic Cannabinoid), Tramadol and Tricyclic Antidepressants and the metabolites in human urine.

For healthcare professional in vitro diagnostic use only.

INTENDED USE

Urine based Drug tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The **One Step Multi-Drug Screen Cassette Test (Urine)** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs, drug metabolites and alcohol at the following cut-off concentrations in urine:[1]

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	1,000
Amphetamine (AMP)	D-Amphetamine	500
Amphetamine (AMP)	D-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Barbiturates (BAR)	Secobarbital	200
Benzodiazepines (BZO)	Oxazepam	300
Benzodiazepines (BZO)	Oxazepam	200
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoylecgonine	300
Cocaine (COC)	Benzoylecgonine	150
Cotinine (COT)	Cotinine	200
MDMA (Ecstasy)	D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	500
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	300
Fentanyl (FEN)	Fentanyl	300
Fentanyl (FEN)	Fentanyl	200
Fentanyl (FEN)	Fentanyl	100
Fentanyl (FEN)	Norfentanyl	20
Ketamine (KET)	Ketamine	1,000
Ketamine (KET)	Ketamine	100
Lysergic acid diethylamide (LSD)	D-lysergic acid diethylamide	20
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	25
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	20
Methadone (MTD)	Methadone	300
EDDP (Methadone Metabolites)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300
EDDP (Methadone Metabolites)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	100
Methamphetamine (MET, mAMP)	D-Methamphetamine	1,000
Methamphetamine (MET, mAMP)	D-Methamphetamine	500
Methamphetamine (MET, mAMP)	D-Methamphetamine	300
Methaqualone (MQL)	Methaqualone	300
Methylenedioxypyrovalerone	3,4-Methylenedioxypyrovalerone	1,000
(MDPV)		
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
Morphine (MOP 300)	Morphine	300
Morphine (OPI, MOP 2000)	Morphine	2,000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
K2 Synthetic Cannabinoid	JWH-073/JWH-018	50
K2 Synthetic Cannabinoid	JWH-073/JWH-018	25
Tramadol (TRA)	Tramadol	200
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Alcohol (ALC)	Ethanol	>0.04% B.A.C

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

AMPHETAMINE (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days

Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception. Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.

BUPRENORPHINE (BUP)

Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex® and a Buprenorphine/Naloxone combination product, Suboxone® are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine.[1,2] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[2]

COTININE (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.[1] While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.[2] Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

MDMA (ECSTASY)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

ETHYL GLUCURONIDE (ETG)

Ethyl Glucuronide (EtG) is a direct metabolite of ethanol alcohol. The presence of EtG in the urine can be used to detect recent alcohol consumption, even after the ethanol alcohol is no longer measurable. Consequently, the presence of EtG in the urine is a definitive indicator that alcohol has been ingested. Traditional laboratory practices typically measure the amount of alcohol present in the body. Depending on the amount of alcohol that has been consumed, this method usually reveals alcohol ingestion within the past few hours.

The presence of EtG in the urine, on the other hand, demonstrates that ethanol alcohol was ingested within the past three or four days, or roughly 80 hours after the ethanol alcohol has been metabolized by the body. As a result, it can be determined that a urine alcohol test employing EtG is a more accurate indicator of the recent consumption of alcohol as opposed to simply measuring for the existence of ethanol alcohol.

FENTANYL (FEN)

Fentanyl is a synthetic opioid. It has the brand names of Sublimaze, Actiq, Durogestic, Fentora and others. The Fentanyl drug is approximately 100 times more potent than morphine, with 100 micrograms of fentanyl approximately equivalent to 10 mg. of morphine or 75 mg. of meperidine in analgesic activity. The Fentanyl drug is a potent narcotic analgesic with rapid onset and short duration of action. Historically, the fentanyl drug has been used to treat chronic breakthrough pain and is commonly used pre-procedures. Illicit use of pharmaceutical fentanyl drugs first appeared in the mid-1970s. Because the effects of the fentanyl drug last for only a very short time, it is even more addictive than heroin. Regular users may become addicted very quickly. The Fentanyl drug is much more potent than heroin, and tends to produce significantly worse respiratory depression, making it somewhat more dangerous than heroin to users. Overdose of the fentanyl drug has caused death. In the United States, the fentanyl drug is classified as a Schedule II controlled substance.

KETAMINE (KET)

Ketamine is a short-acting "dissociative" anesthetic due to its ability to separate perception from sensation. It also has hallucinogenic and painkilling qualities that seem to affect people in very different ways. Ketamine is chemically related to PCP ('Angel Dust'). Ketamine is occasionally administered to people but, more commonly, is used by vets for pet surgery. Generally street K is

most often diverted in liquid form from vets' offices or medical suppliers. Ketamine generally takes 1-5 minutes to take effect. Snorted ketamine takes a little longer at 5-15 minutes. Depending on how much and how recently one has eaten, oral ketamine can take between 5 and 30 minutes to take effect. The primary effects of ketamine last approximately a 30-45 minutes if injected, 45-60 minutes when snorted, and 1-2 hours if used orally. The Drug Enforcement Administration reports that the drug can still affect the body for up to 24 hours.

LYSERGIC ACID DIETHYLAMIDE (LSD)

D-lysergic acid diethylamide (LSD) is the most potent hallucinogenic substance known to man. Dosages of LSD are measured in micrograms, or millionths of a gram. By comparison, dosages of cocaine and heroin are measured in milligrams, or thousandths of a gram. Compared to other hallucinogenic substances, LSD is 100 times more potent than psilocybin and psilocin and 4,000 times more potent than mescaline. The dosage level that will produce a hallucinogenic effect in humans generally is considered to be 25 micrograms. Over the past several years, the potency of LSD obtained during drug law enforcement operations has ranged between 20 and 80 micrograms per dosage unit. The Drug Enforcement Administration (DEA) recognizes 50 micrograms as the standard dosage unit equivalency.

MARIJUANA (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of Morphine dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of Oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.

EDDP

EDDP is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate-dependent patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The tampering of specimens by spiking the urine with methadone can be prevented. Also, renal clearance of EDDP is not affected by urinary pH; therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone test. Methadone is an unusual drug in a sense that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure. Thus, they are very difficult to detect with immunoassays targeted to the native compound. Exacerbating this problem, there is a subsection of the population classified as "extensive metabolizers" of methadone. In these individuals, a urine specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance.

METHAMPHETAMINE (MET, mAMP)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulaDtion of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use.

METHAQUALONE (MQL)

Methaqualone (Quaalude, Sopor) is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956. It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form, and is also available in Europeon countries in combination with diphenhydramine (Mandrax). Methaqualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule. At least 12 metabolites have been identified in the urine.

METHYLENEDIOXYPYROVALERONE (MDPV)

Bath salts', a form of designer drugs, also promoted as 'plant food' or 'research chemicals', is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised a'legal'highs. The technical term for 'bath salts' is substituted cathinone. Substituted cathinone is synthetic, concentrated version of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. It has a stimulant effect on the user and can be quite dangerous. The white crystals resemble legal bathing salts, thus the name of 'bath salts'. In 2009 and 2010 there was a significant rise in the abuse of synthetic cathinone, initially in the United Kingdom and the rest of Europe, and subsequently in the US and Canada,

Established as one of the main ingredients for 'bath salts', among other synthetic stimulants like Mephedrone, Methylone, Butylone and Methedrone, MDPV started appearing around 2004 when it was popularized as a club drug, often used in combination with alcohol, GHB, cannabis and other abused drugs, for its desired effects such as euphoria, alertness, talkativeness, and sexual arousal. There are currently no prescribed used for the synthetic stimulants.

While synthetic stimulants appear to affect users in ways similar to amphetamines, ecstasy and cocaine, reports concerning aggression, tachycardia, paranoia and suicide suggest that they may be more acutely toxic. These negative effects have resulted in an increase of ER visits and hospitalizations, severe psychotic and violent episodes, self-inflicted wounds, suicide and an alarming increase in abuse-related deaths. U.S. Poison Control and National Drug Intelligence have all issued health warnings, noting nationwide emergency room visits related to these drugs. In October 2011, the DEA announced an emergency ban on MDPV, Methylone and Mephedrone, making testing for these substances more vital than ever.

6-MONOACETYLMORPHINE (6-MAM)

6-Monoacetylmorphine (6-MAM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-acetylmorphine (3-ACM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. Since 6-ACM is a unique metabolite to heroin, its presence in the urine confirms that heroin was the opioid used. This is significant because on a urine immunoassay drug screen, the test typically tests for morphine, which is a metabolite of a number of legal and illegal opiates/opioids such as codeine, morphine sulphate, and heroin. 6-MAM remains in the urine for no more than 24 hours so a urine specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day.

MORPHINE (MOP)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[4]

OXYCODONE (OXY)

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyIR®, OxyFast® (immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours).

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations. Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a mild narcotic analgesic found in various pharmaceutical preparations, usually as the hydrochloride or napsylate salt. These preparations typically also contain large amounts of acetaminophen, aspirin, or caffeine. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels. In human, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

SYNTHETIC MARIJUANA (K2)

Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness.

Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 72 hours after smoking (depending on usage/dosage).

As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclo hexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety. JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", K3" and others. These products may be smoked for their psychoactive effects.

TRAMADOL (TRA)

Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.[2] Large doses of Tramadol could develop tolerances and physiological dependency and lead to its abuse. Both Δ (d) and L forms of the isomers are controlled substances. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucoronidation or sulfation in the liver.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

ALCOHOL (ALC)

Excess or inappropriate consumption of alcohol is a common and pervasive social problem. It is a contributory factor to many accidents, injuries and medical conditions. Screening of individuals for alcohol consumption is an important method for the identification of individuals who might be at risk due to alcohol use or intoxication. Screening is also an important deterrent against inappropriate alcohol consumption. The blood alcohol concentration at which a person becomes impaired is variable dependent on the individual. Parameters specific to the individual such as physical size, weight, activity level, eating habits and alcohol tolerance all affect the level of impairment. Determination of ethyl alcohol in urine, blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. Alcohol Test is designed to detect ethyl alcohol in urine specimens.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

The Adulterant Test Strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for Oxidants, Specific Gravity, pH, Creatinine, Nitrite and Glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroying the drugs present in the urine. Dilution may also be used to produce false negative drug test results. To determine certain urinary characteristics such as specific gravity and pH, and to detect the presence of oxidants, Nitrite, Glutaraldehyde and Creatinine in urine are considered to be the best ways to test for adulteration or dilution.

- **Oxidants (OX)**: Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
- **Specific Gravity (S.G.)**: Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
- **pH:** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in

the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.

- **Nitrite (NIT)**: Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
- **Glutaraldehyde (GLU):** Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
- **Creatinine (CRE):** Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

PRINCIPLE

(1) The **One Step Multi-Drug Screen Cassette Test (Urine)** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in urine. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3CHO + H_2O_2$$

$$H_2O_2 + DH_2 \xrightarrow{\text{Peroxidase}} D + 2H_2O$$

Blue

REAGENTS

Each test line in the test panel contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

ADULTERANT TESTS (SPECIMEN VALIDITY TEST) REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OX)	0.30%	99.70%
Specific Gravity (S.G.)	0.21%	99.79%
pH	0.06%	99.94%
Nitrite (NIT)	0.06%	99.94%
Glutaraldehyde (GLU)	0.02%	99.98%
Creatinine (CRE)	0.03%	99.97%

PRECAUTIONS

- For healthcare professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- The test dip card should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test dip card should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test dip card is stable through the expiration date printed on the sealed pouch. The test dip card must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

1. 25 Sealed pouches each containing a test dip card and a desiccant
2. 1 Package insert
3. 2 Color Chart Cards for Adulterant Interpretation (when applicable)
4. 2 Color Chart Cards for Alcohol (when applicable)

Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

Allow the test dip card, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

1) Remove the test dip card from the foil pouch.
2) Remove the cap from the test dip card. Label the dip card with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic dip card.
4) Replace the cap over the absorbent tip and lay the dip card flatly on a non-absorptive clean surface.
5) Read the adulteration strip at 2 minutes by comparing the colors on the adulteration strip to the enclosed color chart. If the result indicates adulteration, do not interpret the drug test results. Either retest the urine or collect another specimen.
6) Read the alcohol strip in 4 minutes by comparing the colors on the alcohol strip to the enclosed color chart.
7) Read the drug strip results at 5 minutes. **DO NOT INTERPRET RESULT AFTER 5 MINUTES.**

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

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 using a new test panel. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

Note: There is no meaning attributed to line color intensity or width.

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by One Step Multi-Drug Screen Test Dip Card (Urine). The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial substance is present but isn't detected by One Step Multi-Drug Screen Test Dip Card (Urine). If the sample is diluted, or the sample is adulterated that may cause false negative result.

ALCOHOL/ADULTERANT INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

QUALITY CONTROL

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

LIMITATIONS

1. The One Step Multi-Drug Screen Cassette Test (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

80 clinical urine specimens were analyzed by GC-MS and by the **One Step Multi-Drug Screen Cassette Test (Urine)**. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Specimen	AMP	AMP 500	AMP 300	BAR	BAR 200	BUP	BZO
Positive	91.7%	95.8%	96.7%	95.0%	94.2%	93.3%	91.7%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	95.8%	97.9%	98.3%	97.5%	97.1%	96.7%	95.8%

Specimen	BZO 200	COC	COC 150	COT	EDDP	EDDP 100	ETG
Positive	92.5%	95.8%	95.0%	92.5%	94.2%	93.3%	95.0%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	96.3%	97.9%	97.5%	96.3%	97.1%	96.7%	97.5%

Specimen	ETG 300	FEN	FEN 200	FEN 100	FEN 20	K2	K2 25
Positive	95.8%	97.5%	95.8%	93.3%	97.5%	93.3%	95.8%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.9%	98.8%	97.9%	96.7%	98.8%	96.7%	97.9%

Specimen	KET	KET 100	LSD	MET	MET 500	MET 300	MDMA
Positive	95.8%	91.7%	91.7%	95%	95.8%	95.8%	95.0%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.9%	95.8%	95.8%	97.5%	97.9%	97.9%	97.5%

Specimen	MOP	MQL	6-MAM	MTD	OPI	OXY	PCP
Positive	96.7%	91.7%	92.5%	95.0%	88.3%	93.3%	91.7%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	98.3%	95.8%	96.3%	97.5%	94.2%	96.7%	95.8%

Specimen	PPX	THC	THC 25	THC 20	TCA	TRA	MDPV
Positive	95.0%	95.8%	94.2%	91.7%	95.0%	93.3%	94.2%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.5%	97.9%	97.1%	95.8%	97.5%	96.7%	97.1%

Analytical Sensitivity

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each dip card by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2 (Synthetic Cannabinoid), Ketamine, Methaqualone, Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, Cotinine, 6-Monoacetylmorphine, Methylenedioxypyrovalerone, Lysergic acid diethylamide, Marijuana and Benzodiazepines. The cut-off value for the dip card is verified.

Analytical Specificity

The following table lists compounds that are positively detected in urine by the **One Step Multi-Drug Screen Cassette Test (Urine)** at 5 minutes.

Drug	Concentration (ng/mL)
AMPHETAMINE (AMP)	
D-Amphetamine	1,000
D,L - Amphetamine (Amphetamine Sulfate)	1,000
Phentermine	1,250
(+/-)-4-Hydroxyamphetamine HCL	600
L-Amphetamine	20,000
3,4-Methylenedioxyamphetamine HCI (MDA)	1,500
d-Methamphetamine	>100,000 ng/mL
1-Methamphetamine	>100,000 ng/mL
ephedrine	>100,000 ng/mL
3,4-Methylenedioxyethylamphetamine (MDE)	>100,000 ng/mL
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000 ng/mL
AMPHETAMINE (AMP 500)	
D-Amphetamine	500
D,L-Amphetamine	750
L-Amphetamine	16,000
Phentermine	650
(+/-)-Methylenedioxyamphetamine (MDA)	800
d-Methamphetamine	>100,000
1-Methamphetamine	>100,000
ephedrine	>100,000
3,4-Methylenedioxyethylamphetamine (MDE)	>100,000
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000
AMPHETAMINE (AMP 300)	
D-Amphetamine	300
D,L-Amphetamine	450
L-Amphetamine	9,000
Phentermine	450
(+/-)-Methylenedioxyamphetamine (MDA)	600
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	750
Aprobarbital	250
Butabarbital	2,500
Butethal	2,500
Cyclopentobarbital	500
Pentobarbital	2,500
Phenobarbital	25,000
BARBITURATES (BAR 200)	
Secobarbital	200
Amobarbital	200
Alphenal	500
Aprobarbital	200
Butabarbital	2,000
Butethal	2,000
Butalbital	2,000
Cyclopentobarbital	300
Pentobarbital	2,000
BENZODIAZEPINES (BZO)	
Alprazolam	200
Bromazepam	1,560
Chlordiazepoxide HCL	1,560
Clobazam	100

Drug	Concentration (ng/mL)
Clonazepam	780
Clorazepate Dipotassium	200
Delorazepam	1,560
Desalkylflurazepam	400
Diazepam	200
Estazolam	2,500
Flunitrazepam	400
a-Hydroxyalprazolam	1260
(±) Lorazepam	1,560
RS-Lorazepam glucuronide	160
Midazolam	12,500
Nitrazepam	100
Norchlordiazepoxide	200
Nordiazepam	400
Oxazepam	300
Temazepam	100
Triazolam	2,500
BENZODIAZEPINES (BZO200)	
Alprazolam	200
Bromazepam	1,000
Chlordiazepoxide HCL	1,000
Clobazam	80
Clonazepam	500
Clorazepate Dipotassium	100
Delorazepam	1,000
Desalkylflurazepam	300
Diazepam	100
Estazolam	2,000
Flunitrazepam	300
a-Hydroxyalprazolam	840
(±) Lorazepam	1,000
RS-Lorazepam glucuronide	100
Midazolam	10,000
Nitrazepam	100
Norchlordiazepoxide	100
Nordiazepam	300
Oxazepam	200
Temazepam	800
Triazolam	2,000
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	20
COCAINE (COC)	
Benzoylecogonine	300
Cocaethylene	300
Cocaine HCl	300
COCAINE (COC 150)	
Benzoylecogonine	150
Cocaethylene	2,500
Cocaine	500
Ecgonine	12,500
Ecgonine methylester	50,000
COTININE (COT)	
Cotinine	200

Drug	Concentration (ng/mL)
Nicotine	6,250
MDMA (ECSTASY)	
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine HCI (MDA)	3,000
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300
d-methamphetamine	2500
d-amphetamine	>100,000
l-amphetamine	>100,000
l-methamphetamine	>100,000
ETHYL GLUCURONIDE (EtG 500)	
Ethyl-β-D-glucuronide	500
Ethyl-β-D-glucuronide-D5	500
ETHYL GLUCURONIDE (EtG 300)	
Ethyl-β-D-glucuronide	300
Ethyl-β-D-glucuronide-D5	300
FENTANYL (FEN)	
Norfentanyl	20
Fentanyl	300
FENTANYL (FEN20)	
Norfentanyl	20
Fentanyl	300
FENTANYL (FEN200)	
Norfentanyl	15
Fentanyl	200
Sufentanyl	50,000
Fenfluramine	50,000
FENTANYL (FEN 100)	
Norfentanyl	10
Fentanyl	100
Buspirone	>100,000
Sufentanyl	25,000
Fenfluramine	25,000
KETAMINE (KET)	
Ketamine	1,000
Norketamine	3,000
Methoxy-amphetamine	12,500
Promethazine	25,000
4-hydroxyphenyl cyclohexyl piperidine	50,000
KETAMINE (KET 100)	
Ketamine	100
Norketamine	100
Methoxy-amphetamine	1,250
Promethazine	2,500
4-hydroxyphenyl cyclohexyl piperidine	5,000
LYSERGIC ACID DIETHYLAMIDE (LSD)	
D-lysergic acid diethylamide	20
Fentanyl	75
Norfentanyl	300

Drug	Concentration (ng/mL)
MARIJUANA (THC)	
Delta-9-Tetrahydrocannabinol	50,000
11-nor-delta-9-THC-carboxyglucuronide	75
(-)-11-nor-9-carboxy-delta9-THC	75
11-Nor-Δ^9-Tetrahydrocannabinol	50
11-Hydroxy-Δ^9-Tetrahydrocannabinol	5,000
11-Nor-Δ^8-Tetrahydrocannabinol	50
Δ^8-THC-COOH	50,000
MARIJUANA (THC 25)	
Delta-9-Tetrahydrocannabinol	25,000
11-nor-delta-9-THC-carboxyglucuronide	37.5
(-)-11-nor-9-carboxy-delta9-THC	37.5
11-Nor-Δ^9-Tetrahydrocannabinol	25
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2,500
11-Nor-Δ^8-Tetrahydrocannabinol	25
Δ^8-THC-COOH	25,000
MARIJUANA (THC 20)	
Delta-9-Tetrahydrocannabinol	20,000
11-nor-delta-9-THC-carboxyglucuronide	30
(-)-11-nor-9-carboxy-delta9-THC	30
11-Nor-Δ^9-Tetrahydrocannabinol	20
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2,000
11-Nor-Δ^8-Tetrahydrocannabinol	20
Δ^8-THC-COOH	20,000
METHADONE (MTD)	
Methadone	300
Doxylamine	5,000
EDDP (Methadone Metabolites)	
EDDP	300
Disopyramide	50,000
Methadone	>100,000
EMDP	500
EDDP100 (Methadone Metabolites)	
EDDP	100
Disopyramide	20,000
Methadone	>100,000
EMDP	200
METHAMPHETAMINE (mAMP)	
D-Methamphetamine	1,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
Methamphetamine	1,000
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2,500
Chloroquine	50,000
Ephedrine	100,000
Fenfluramine	50,000
p-Hydroxymethamphetamine	10,000
METHAMPHETAMINE (MET 500)	
p-Hydroxymethamphetamine	15,000
l-Methamphetamine	4,000

Drug	Concentration (ng/mL)
Mephentermine	25,000
d,l-Amphetamine	75,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	75,000
d-Methamphetamine	500
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
d-Amphetamine	50,000
Chloroquine	12,500
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	50,000
Trimethobenzamide	20,000
Ranitidine (Zantac)	50,000
Fenfluramine	50,000
METHAMPHETAMINE (MET 300)	
p-Hydroxymethamphetamine	10,000
l-Methamphetamine	3,000
Mephentermine	15,000
d,l-Amphetamine	50,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	50,000
d-Methamphetamine	300
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
d-Amphetamine	30,000
Chloroquine	7,500
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	12,000
Procaine (Novocaine)	30,000
Trimethobenzamide	12,000
Ranitidine (Zantac)	30,000
Fenfluramine	30,000
METHAQUALONE (MQL)	
Methaqualone	300
METHYLENEDIOXYPYROVALERONE (MDPV)	
3,4-Methylenedioxypyrovalerone	1,000
Ethylone HCl	1,200
Methylone	50,000
Pyrovalerone	50,000
6-MONOACETYLMORPHINE (6-MAM)	
6-Moonacetylmorphine	10
Morphine	>500,000
Codeine	>600,000
Dextromethorphan	>100,000
Dihydrocodeine	>100,000
Heroin HCl	250
Hydrocodone	>100,000
Hydromorphone	>100,000
Imipramine	>100,000
Levorphanol	>10,000
NorMeperidine	>10,000
Normorphine	>100,000
Nalorphine	>100,000
Naloxone	>100,000
Naltrexone	>100,000
Norcodeine	>100,000
Oxycodone	>100,000
Oxymorphone	>100,000

Drug	Concentration (ng/mL)
MORPHINE (MOP)	
Morphine	300
O6-Acetylmorphine	400
Codeine	300
EthylMorphine	100
Heroin	600
Hydromorphone	500
Hydrocodone	50,000
Levorphanol	1,500
Oxycodone	30,000
Procaine	15,000
Thebaine	6,240
MORPHINE (OPI, MOP2000)	
Morphine	2,000
O6-Acetylmorphine	2,500
Codeine	1,000
EthylMorphine	250
Heroin	5,000
Hydromorphone	2,500
Hydrocodone	5,000
Oxycodone	75,000
Thebaine	13,000
OXYCODONE (OXY)	
Naloxone hydrochloride	10,000
Naltrexone hydrochloride	50,000
Oxycodone	100
Hydrocodone	5,000
Hydromorphone	5,000
Oxymorphone-D3	5,000
Oxymorphone	200
N-Benzylisopropylamine	2,500
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxy Phencyclidine	90
PROPOXYPHENE (PPX)	
Norpropoxyphene	300
d-Propoxyphene	300
K2 (SYNTHETIC CANNABINOID)	
JWH-018 5-Pentanoic acid metabolite	50
JWH-018 5-Hydroxypentyl metabolite	500
JWH-018 4-Hydroxypentyl metabolite	400
JWH-018 N-(4-hydroxypentyl) metabolite solution	5,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-019 6-Hydroxyhexyl	5,000
JWH-073 4-butanoic acid metabolite	50
JWH-073 4-Hydroxybutyl metabolite	500
JWH-210 5-Hydroxypentyl metabolite solution	<10,000
JWH-122 5-Hydroxypentyl metabolite solution	<10,000
Spice Cannabinoid Mix 3 solution	<10,000
JWH-122 4-Hydroxypentyl metabolite solution	<10,000
JWH-122 4-Hydroxypentyl metabolite-D5 solution	<10,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-018 N-(4-hydroxypentyl) metabolite solution	<10,000

Drug	Concentration (ng/mL)
JWH-073 N-(3-Hydroxybutyl) metabolite solution	<10,000
K2 (SYNTHETIC CANNABINOID) 25 ng/mL	
JWH-018 5-Pentanoic acid metabolite	25
JWH-018 5-Hydroxypentyl metabolite	250
JWH-018 4-Hydroxypentyl metabolite	200
JWH-018 N-(4-hydroxypentyl) metabolite solution	2,500
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-019 6-Hydroxyhexyl	2,500
JWH-073 4-butanoic acid metabolite	25
JWH-073 4-Hydroxybutyl metabolite	250
JWH-210 5-Hydroxypentyl metabolite solution	<10,000
JWH-122 5-Hydroxypentyl metabolite solution	<10,000
Spice Cannabinoid Mix 3 solution	<10,000
JWH-122 4-Hydroxypentyl metabolite solution	<10,000
JWH-122 4-Hydroxypentyl metabolite-D5 solution	<10,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-018 N-(4-hydroxypentyl) metabolite solution	<10,000
JWH-073 N-(3-Hydroxybutyl) metabolite solution	<10,000
TRAMADOL (TRA)	
Tramadol	200
N-desmethyl-tramadol	500
O-desmethyl-tramadol	20,000
Tricyclic Antidepressants (TCA)	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	50,000
Desipramine	5,000
Doxepine	10,000
Imipramine	10,000
Maprotiline	100,000
Nordoxepin	10,000
Promazine	50,000
Promethazine	2,500
Trimipramine	50,000
Cyclobenzaprine Hydrochloride	5,000
Norclomipramine	50,000

Precision

This study is performed 2 runs/day and lasts 25 days for each format with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

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 GBDOA-1X5

Drug Conc. (Cut-off range)	AMP		AMP 500		AMP 300		BAR		BAR 200		BZO		BZO 200		BUP	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	20	30	20	30	22	28	23	27	23	27	18	32	24	26	28	22
+25% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	COC		COC150		COT		EDDP		EDDP 100		ETG		ETG 300		FEN	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	41	9	44	6	42	8	50	0
Cut-off	20	30	24	26	20	30	21	29	30	20	23	27	23	27	22	28
+25% Cut-off	0	50	0	50	0	50	0	50	3	47	8	42	4	46	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	FEN 200		FEN 100		FEN 20		K2		K2 25		KET		KET 100		MET		MET 500	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	46	4	43	7	50	0	50	0	50	0	45	5	44	6	50	0	50	0
Cut-off	28	22	20	30	22	28	18	32	22	28	18	32	30	20	24	26	25	25
+25% Cut-off	5	45	2	48	0	50	0	50	0	50	6	44	3	47	0	50	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	OXY		MET 300		MDMA		MOP		MQL		6-MAM		MTD		OPI	
	-	+	-	+	-	+	-	-	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	50	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	50	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	50	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	48	50	50	0	50	0	50	0
Cut-off	24	26	25	25	24	26	22	28	24	22	22	27	28	22	22	28
+25% Cut-off	0	50	0	50	0	50	0	50	6	0	5	45	0	50	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	0	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	0	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	0	0	50	0	50	0	50

Drug Conc. (Cut-off range)	PCP		PPX		THC		THC 25		THC 20		TCA		TRA		LSD		MDPV	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	47	3	44	6	48	2
Cut-off	22	28	26	24	20	30	23	27	25	25	22	28	25	25	21	29	24	26
+25% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	1	49	5	45	7	43
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

Twelve (12) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **One Step Multi-Drug Screen Cassette Test (Urine)** was tested in duplicate using drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The **One Step Multi-Drug Screen Cassette Test (Urine)**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2(Synthetic Cannabinoid), Ketamine, Methaqualone, Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, Cotinine, 6-Monoacetylmorphine, Methylenedioxypyrovalerone, Lysergic acid diethylamide, Marijuana and Benzodiazepines positive urine. The following compounds show no cross-reactivity when tested with the **One Step Multi-Drug Screen Cassette Test (Urine)** at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Pseudoephedrine	Quinidine
N-Acetylprocainamide	Creatinine	Kynurenic Acid	Quinine
Acetylsalicylic acid	Dexamethasone	Labetalol	Salicylic acid
Amiloride	Dextromethorphan	Loperamide	Serotonin
Amoxicillin	Desipramine	Meprobamate	Sulfamethazine
Ampicillin	Diflunisal	Methoxyphenamine	Sulindac
l-Ascorbic acid	Digoxin	Methylphenidate	Tetracycline
Apomorphine	Droperidol	Nalidixic acid	Tetrahydrocortisone,
Aspartame	Ethyl-p-aminobenzoate	Naproxen	3-Acetate
Atropine	Ethopropazine	Niacinamide	Theobromine
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tolazamide
p-Aminobenzoic Acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
Beclomethasone	Furosemide	Octopamine	Thioridazine Hydrochloride
Caffeine	Gentisic acid	Oxalic acid	D/L-Tyrosine
Cannabidiol	Hemoglobin	Oxyphenbutazone	Tolbutamide
Carbamazepine	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Paclitaxel	Trimethoprim
Chlorpheniramine	α-Hydroxyhippuric acid	Perphenazine	D,L-Tryptophan
Chlorpromazine	Hydroxyprogesterone	Phenelzine	Uric acid
Cholesterol	Isoproterenol-(+/-)	Prednisone	Verapamil
Clonidine	Isoxsuprine	Prilocaine	Zomepirac

BIBLIOGRAPHY

1. *Stewart DJ, Inaba T, Lucassen M, Kalow W. Clin. Pharmacol. Ther. April 1979; 25 ed: 464, 264-8.*
2. *Ambre J. J. Anal. Toxicol. 1985; 9:241.*
3. *Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.*
4. *Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.*
5. *FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.*

INDEX OF SYMBOLS

	Consult instructions for use	Σ	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#

Revision Date: 2022-05-31
B21769-03