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

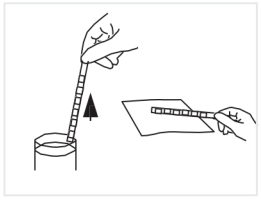
Shelf Life

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

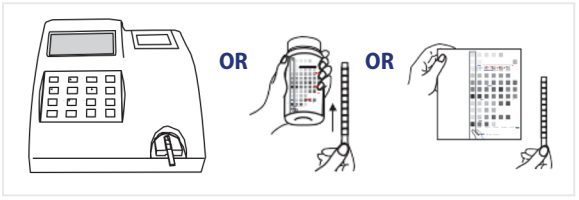
High Quality Color Chart | **Large Choice** of Parameter Combinations | **Individually Pouched Strips**

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

Digitally signed by Monastîrschii Viorica
Date: 2023.12.06 10:25:20 EET
Reason: MoldSign Signature
Location: Moldova

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

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PN 2170004302 • Date 12/17

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

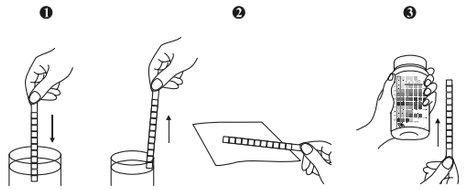
Materials Required But Not Provided

- 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]

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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.
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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

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

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

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

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

TÜV®

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

CE Declaration of Conformity

We,

Atlas Medical GmbH
Head office: Ludwig-Erhard-Ring 3
15827 Blankenefelde-Mahlow Germany
Tel: +49(0)33708355030
Email: info@atlas-site.com

Middle East Site: : Sahab Industrial Zone Area, King Abdullah II Industrial City
Amman 11512, Jordan
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

Blood Grouping Reagents:

(Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent , Anti-AB Monoclonal Reagent and Anti-D IgG/IgG blend Reagent)

see the attached list of variants

That are classified as Annex II, list A

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC

And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,
EN 13612:2002, EN 13641:2002 , EN 13975:2003,
EN ISO 13485:2016, EN 62366-1:2020

And

Intended for In-Vitro Professional use only.

Conformity Assessment Route:

Annex IV.3 –Approval full Quality Assurance System.
Annex IV.4-EC Design Examination (of the product)

Notified Body:

G-MED	CE	0459

GMED, Laboratoire national de métrologie et d'essais
1 rue Gaston Boissier 75015 Paris
Tél. : 01 40 43 37 00 , TVA:FR 28 839 022 522

EC Certificates No.:

- **CE Certificate of Approval full Quality Assurance System: 33540 rev4.**
- **CE Certificate Of EC Design Examination: 33544 rev3.**

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)	Amani	

Atlas Medical

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

Product Code	Product Name	GMDN Code
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/Carton Box	52532
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 10 vials / Plastic Pack	52532
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 18 vials / Carton Box	52532
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, / Carton Box	52538
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials / Plastic Pack	52538
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials / Carton Box	52538
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/ Carton Box	46442
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials/Plastic Pack	46442
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials/Carton Box	46442
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 1 vial/ Carton Box	52647
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 10 vials / Plastic Pack	52647
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 18 vials / Carton Box	52647
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1 Vial/Carton Box	52532
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials / Plastic Pack	52532
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	52538
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials /Plastic Pack	52538
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)),3x10ml / plastic Pack	45308
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1/256), 2x10ml /Plastic Pack	52695
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	46442
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,10 vials /Plastic Pack	46442
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,18 vials / Carton Box	45308
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 1Vial/ Carton Box	52647
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 10 vials / Plastic Pack	52647

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)		

Atlas Medical
Quality Diagnostic Products

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

8.02.47.0.0030	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128)),3x10ml/Plastic Pack	45308
8.02.47.1.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Carton Box.	45308
8.02.47.3.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Plastic Pack	45308
8.02.47.5.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/128)), 3x10ml/Plastic Pack	45308
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	45308
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	45308
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	45308
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	45308
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box	52532
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1/1024) , 10 ml/vial ,1Vial/ Carton Box	52538
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1/1024) , 10 ml/vial , 1Vial/ Carton Box	45308
8.02.85.0.0010	Anti-D IgG/IgM Blend Reagent , Titer 1/256, 10ml/vial, 1Vial/ Carton Box	52647

Atlas Medical
Quality Diagnostic Products

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)		

Atlas Medical

Declaration Ref No: DC21-0249

Date: 15.10.2021

CE Declaration of Conformity

Name and address of Manufacturer	**Atlas Medical GmbH** Ludwig-Erhard-Ring 3, 15827 Blankenefelde-Mahlow Germany . Tel: +49(0)33708355030 Email: info@atlas-medical.com

Atlas Medical GmbH declared our his own responsibility that the following IVD medical devices:

Product Code	Product Name	GMDN code
8.17.003.0300	Atlas Periodic Acid Schiff (PAS) Stain Kit, 3x100ml	43587
8.17.004.0300	Atlas Iron Stain Kit, 3x100ml	43587
8.17.009.1000	Atlas Gram Stain Kit	43733
8.17.010.0750	Atlas ZN (Kinyoun) stain pack , 3x250ml	43587
8.15.144.0250	Atlas ZN Decolouriser, 250 ml /Bottle	43587
8.17.015.0500	Atlas Diff-3 Stain.	43587
8.17.016.1000	Atlas Papanicolau Stain Pack.	43587
8.17.110.0250	Atlas Papanicolau Stain EA35, 250 ml /Bottle.	43587
8.17.111.0250	Atlas Papanicolau Stain EA36, 250 ml /Bottle	43587
8.17.112.0250	Atlas Papanicolau Stain EA65, 250 ml /Bottle.	43587
8.17.114.0250	Atlas Papanicolau Stain EA50, 250 ml /Bottle.	43587
8.17.115.0250	Atlas Papanicolau Stain OG6, 250 ml /Bottle.	43587
8.17.014.1000	Atlas Reticulocytes stain (Methylene Blue) , 1000 ml /Bottle	43587
8.15.037.0250	Atlas Eosin Y (1%) Stain, 250 ml/Bottle	43587
8.15.038.0250	Atlas Eosin Y (5%) Stain, 250 ml/Bottle.	43587
8.15.041.0250	Atlas Field Stain (Solution A), 250ml/Bottle	43587
8.15.042.0250	Atlas Field Stain (Solution B), 250ml/Bottle	43587
8.15.043.0750	Atlas Field Stain Kit 3x250ml (250ml Fixing Reagent , 250ml Eosin Reagent, 250ml Methylene Blue Reagent).	43587
8.15.047.0250	Atlas Giemsa Stain, 250 ml/Bottle.	43587
8.15.059.0250	Atlas Haematoxylin Harris Stain , 250 ml/Bottle	43587
8.15.069.0250	Atlas Leishman Stain , 250 ml/Bottle.	43587
8.15.069.1000	Atlas Leishman Stain , 1000 ml/Bottle.	43587
8.15.074.0250	Atlas Lugol's Iodine, 250 ml/Bottle.	43587
8.15.078.0250	Atlas May Grunwald Stain, 250 ml/Bottle.	43587
8.15.105.0250	Atlas New Methylene Blue for Reticulocytes, 250 ml/Bottle.	43587
8.15.143.0250	Atlas Wright's Stain, 250 ml/Bottle.	43587
8.15.146.0100	Atlas Immersion oil, 100 Bottle/Box	43587

Atlas Medical

Declaration Ref No: DC21-0249

Date: 15.10.2021

Meets the essential requirments of In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
And
EN ISO 13485 :2016 , EN 18113-1, -2,:2011, EN ISO 15223:2016
EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,
EN ISO 13612:2002, EN ISO 13641:2002 , EN ISO 62366-1+A1:2020.

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

Date of issuance:	15. October.2021
Place	Atlas Medical GmbH
Signed by: **Position :**	Amani AL-Habahbeh Regulatory Affairs Manager

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

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**

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.

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2. Issitt P. D. Applied Blood Group Serology, 3rd ed. Miami: Montgomery Scientific, 1985.
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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
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7. Standards for Blood Banks d Transfusion Service. 11th Ed., Washington D.C., AABB 1984:25.
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Website: www.atlas-medical.com

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

ATLAS ANTI-A, ANTI-B, ANTI AB și ANTI-D
SLIDE-URI (LAME) ȘI TUBURI
Numai pentru diagnostic *in vitro* și uz profesional

UTILIZAREA PRECONIZATĂ
Reactivii Anti-A, Anti-B și Anti-AB (denumiti în continuare reactivi ABO) sunt utilizați pentru determinarea calitativă in vitro a grupelor de sânge umane ale sistemului ABO pentru a determina tipul de sânge. Reactivul anti-D este utilizat pentru determinarea calitativă a factorului Rhesus pe grupele sanguine umane.
Acești reactivi sunt destinați a fi utilizați în metodele cu lame și tuburi.

INTRODUCERE ȘI PRINCIPII
Reactivii ATLAS ABO sunt preparați din supernatanți de cultură in vitro ai liniilor celulare hibridizate de șoarece secretoare de imunoglobulină. Reactivii sunt diluați cu tampon fosfat care conține clorură de sodiu, EDTA și albumină bovină pentru a da reactivi care sunt optimizați pentru utilizare în procedurile de tuburi și lame. Anti-A este colorat cu colorant albastru acid (albastru patentat), Anti-B este colorat cu colorant galben acid (tartrazină), iar Anti-AB nu este colorat. Procedura de testare se bazează pe principiul aglutinarii, în care celulele roșii care posedă antigenul se aglutinează în prezența anticorpului corespunzător, indicând faptul că rezultatul este pozitiv. Testul este considerat negativ atunci când nu apare nicio aglutinare.

Reactivul ATLAS Anti-D este preparat din IgM și IgG monoclonale umane amestecate cu grijă. Anti-D este potrivit pentru procedurile de testare pe lame și tuburi. Reactivul va aglutina direct celulele Rh D pozitive, inclusiv majoritatea variantelor (dar nu DVI) și o proporție mare de fenotipuri D (Du) slabe. Reactivul va aglutina fenotipurile de categoria DVI și D slab de grad scăzut (Du) prin tehnicile indirecte anti-globuline. Reactivul anti-D se diluează cu o soluție de clorură de sodiu, soluție de fosfat de sodiu și albumină bovină (fără caprilat de sodiu). Anti-D nu este colorat. Procedura se bazează pe principiul aglutinarii, în care celulele roșii care posedă antigenul aglutinează în prezența anticorpului corespunzător din reactiv, ceea ce indică faptul că rezultatul este pozitiv. Testul este considerat negativ atunci când nu apare nicio aglutinare.

MATERIALE
MATERIALE OFERITE

- Reactiv de grupare ABO: Anti-A (10 ml/flacon), Anti-B (10 ml/flacon), Anti-AB (10 ml/flacon).
- Reactiv Anti-D IgG/IgM AMESTEC(10 ml/flacon).

MATERIALE NECESARE, NEINCLUSE ÎN SET
• Eprubetă din plastic sau sticlă.
• Soluție salină izotonică (0,9%) NaCl).
• Bastoane aplicatoare.
• Centrifuga (100-1200 g pentru test pe tub).
• Temporizator.
• Incubator
• Reactiv anti-globulină umană (poate fi comandat de la Atlas Medical).
• Lamă de sticlă albă sau transparentă.

AVERTIZĂRI
• Reactivii sunt destinați numai pentru diagnostic in vitro.
• Testul este pentru utilizator profesionist sănătos bine instruit, nu pentru utilizator neprofesionist.
• Acești reactivi sunt derivați din surse animale și umane, prin urmare, trebuie avută grijă corespunzătoare în utilizarea și eliminarea acestor reactivi, deoarece nu există metode de testare cunoscute care să garanteze absența agenților infecțioși.
• Nu utilizați reactivi dacă este tulbure sau conține particule, deoarece acest lucru poate indica deteriorarea sau contaminarea reactivului.
• La manipularea reactivilor trebuie purtate îmbrăcăminte de protecție.
• Reactivii conțin 0,1% azidă de sodiu care este toxică și poate fi absorbită prin piele. Când sunt scurse, scurgerile trebuie spălate bine cu apă.
• Reactivii trebuie utilizați așa cum sunt furnizați și în conformitate cu procedura menționată mai jos. Nu utilizați după data de expirare.
• Evitați contaminarea încrucișată a reactivilor sau a probelor.
• Semne vizibile de creștere microbiană în orice reactiv pot indica degradarea și utilizarea unui astfel de reactiv trebuie întreruptă.
• Nu utilizați acești reactivi dacă eticheta nu este disponibilă sau este deteriorată.
• Nu utilizați lamă de sticlă închisă la culoare.
• Nu utilizați trusa dacă este deteriorată sau flacoanele de sticlă sunt sparte sau scurgerea și aruncați imediat conținutul.
• Materialele de testare și mostrele trebuie aruncate în mod corespunzător într-un container pentru risc biologic.
• Spălați-vă mâinile și blatul mesei de testare cu apă și săpun o dată se face testarea.
• Proba de sânge hemolizată nu trebuie utilizată pentru testare.
• Testul trebuie efectuat la temperatura camerei în a zona bine luminata cu vizibilitate foarte buna.
• Nerespectarea procedurii din acest prospect poate da rezultate false sau pericol pentru siguranță.
• Închideți ermetic flaconul după fiecare test.
• Reactivul este considerat toxic, așa că nu beți și nu mâncați alături aceasta.
• Dacă se scurge reactiv, curățați cu dezinfectant (dezinfectantul folosit ar putea fi iritabil, așa că manipulați-vă cu grijă).

CONDIȚIILE DE PĂSTRARE
• Reactivii trebuie păstrați la frigider între 2 - 8°C.
• Nu înghețați și nu expuneți niciodată la temperaturi ridicate.
• Reactivul este stabil până la data de expirare înscrisă pe eticheta produsului. Nu utilizați reactivii după data de expirare.

PREGĂTIREA REAGENTULUI
• Reactivii sunt destinați folosirii ca și sunt, fără prepararea sau diluarea reactivului prealabilă
• Toți reactivii trebuie aduși la temperatura camerei înainte utilizare.

COLECTAREA ȘI PREGĂTIREA SPECIMENELOR

• Sângele recoltat cu sau fără anticoagulant poate fi utilizat pentru tipizarea antigenului.
• Probele trebuie testate cât mai curând posibil după colectare. Dacă testarea este întârziată, probele trebuie păstrate la 2-8 ºC, Proba trebuie menținută la temperatura camerei înainte de analiză. (Testarea trebuie efectuată în termen de cinci zile de la colectare).
• Asigurați-vă că nu există semne de hemoliză.
• La momentul testului, centrifugați proba de sânge la 1200 g timp de 3 minute.
• Recoltarea sângelui se face cu mare grijă.

PROCEDURI

A. METODA DIRECTĂ ÎN TUB LA TEMPERATURA CAMERE

1. Aduceți reactivii și probele la temperatura camerei (18-25°C).
2. Se prepară o suspensie 5% de globule roșii în soluție isotonică.
3. Folosind picurătorul flaconului, transferați o picătură (40 µl ± 10 µl) din fiecare reactiv într-un tub separat și marcat corespunzător.
4. Adăugați 50 µl de suspensie de globule roșii.
5. Se agită pentru a omogeniza amestecul, apoi se centrifughează la 500 g timp de 1 minut.
6. Citiți macroscopic în timp ce scuturați ușor tuburile astfel încât desprindeți paletul de celule roșii din sânge.
7. Observați aspectul oricărei aglutinări.

B. METODA INDIRECTA ANTIGLOBULINĂ pentru ANTI-D

1. După centrifugare imediată și citire ca mai sus, dacă reacția este slabă sau negativă, se agită tuburile și se incubează la 37°C timp de 15 minute.
2. Spălați celulele roșii din sânge de două ori cu soluție salină izotonică (NaCl 0,9%) și aruncați ultimul lichid de spălare.
3. Adăugați (40 µl ± 10 µl) de GLOBULINĂ ANTIUMANĂ în tub. Se amestecă și se centrifughează la 120 g timp de 1 minut.
4. Agitați ușor tubul în așa fel încât să se desprindă peleta celulară și observați macroscopic pentru orice posibilă aglutinare.
5. Citiți imediat reacția

C. PROCEDURA CU SLIDE (LAME)

1. Aduceți reactivii și probele la temperatura camerei (18-25°C).
2. Folosind stiloul cu ceară, împărțiți diapozitivul în corespunzătoare numere de diviziuni.
3. Folosind picuratorul furnizat, puneți o picătură (40 µl ± 10 µl) de fiecare reactiv pe diviziunea corespunzătoare de pe lamă.
4. Adăugați 50 µl de celule precipitate lângă fiecare picătură de reactivi.
5. Amestecați reactivul și celulele folosind un amestecător curat pe o zonă cu diametrul de aproximativ 20-40 mm.
6. Țineți diapozitivul și balansați ușor toboganul timp de 1 minut și observați macroscopic pentru orice aglutinare.
7. Citiți imediat reacția.

CITIREA REZULTATULUI

POZITIV: Dacă apare aglutinarea
NEGATIV: Dacă nu se observă nici o aglutinare.
Utilizați tabelul de mai jos pentru determinarea grupei sangvine

Result of each reaction				ABO
Anti-A	Anti-B	Anti-AB	Anti-D	Group
+	-	+	+	A+
+	-	+	-	A-
-	+	+	+	B+
-	+	+	-	B-
+	+	+	+	AB+
+	+	+	-	AB-
-	-	-	+	O+
-	-	-	-	O-

Stabilitatea reacțiilor

• Testele ABO de grupare a sângelui trebuie citite imediat după centrifugare.
• Întârzierea citirii și interpretării rezultatelor poate duce la reacții pozitive sau fals negative. Testele cu diapozitive ar trebui interpretate la sfârșitul unui minut.

LIMITAREA PROCEDURILOR

1. Pot apărea rezultate fals pozitive/negative din cauza:
• Contaminare din materialele de testare.
• Depozitare necorespunzătoare, concentrarea celulelor, timpul de incubare sau temperatura.
• Centrifugare necorespunzătoare sau excesivă.
• Abatere de la tehnica recomandată.
• Probele de sânge din subgrupele slabe A sau B pot da naștere la rezultate fals negative sau reacții slabe.
2. Cu sângele stocat pot fi observate reacții mai slabe decât cu sânge proaspăt.
3. Antigenele ABO nu sunt complet dezvoltate la naștere, mai slabe pot apărea, prin urmare, reacții cu cordonul sau cu celule roșii neonatale.
4. Interpretarea grupei sanguine ABO la indivizi cu vârsta mai mare de 6 luni ar trebui confirmată prin testarea serului sau plasmei individului împotriva eritrocitelor din grupul A și grupul B (grupare inversă). Dacă rezultatele obținute cu serul nu se corelează cu testul eritrocitar, este necesară o investigație suplimentară.

CARACTERISTICI DE PERFORMANȚĂ DIAGNOSTICE

Următoarele tabele compară rezultatele în tehnicile cu lame (slide-uri) și tuburi a 3 loturi de reactivi Atlas Medical și rezultatele unui dispozitiv marcat CE.

Nu s-a evidențiat nicio inversiune în diagnostic: din punct de vedere calitativ am observat o conformitate de 100% în testarea directă de grup în tehnicile cu lame și tuburi pentru determinarea grupelor A, B, AB și O pentru cele trei loturi de Atlas Medical.

Slide Technique				
Group A				
Positive with anti-A and anti-AB 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 and anti-AB 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 and anti-AB 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 and anti-AB 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, Anti-B and anti-AB 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, Anti-B and anti-AB Negative with Negative control

CONTROLUL CALITĂȚII

Reactivitatea tuturor reactivilor de grupare a sângelui trebuie confirmată prin testarea celulelor roșii pozitive și negative cunoscute în fiecare zi de utilizare.

Pentru a confirma specificitatea și sensibilitatea, reactivii ATLAS de grupare a sângelui și ATLAS Anti-D trebuie testați cu eritrocite antigen pozitive și antigen negative.

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.

Vision

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

Mission

Our mission is to develop, produce and provide our customers with high quality products and excellent customer services through deep understanding of customers' needs and perception, recruitment of high caliber professionals & technicians, adopting strict quality assurance and control procedures and embracing new scientific advancements in the medical lab diagnostic field.

Objectives

- *High and Consistent Quality*
- *Satisfied Customer*
- *Continuous Improvement & Innovation*
- *Care for the Environment & Working Conditions*

Sites

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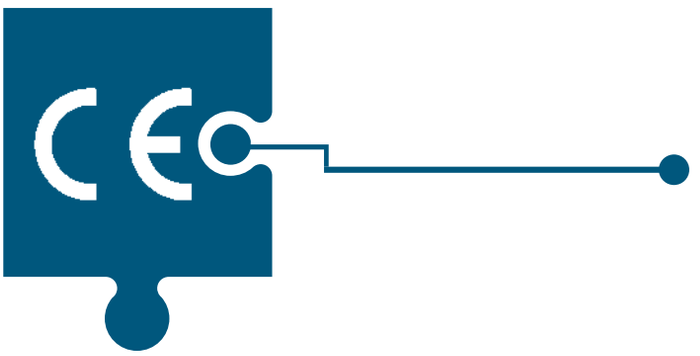
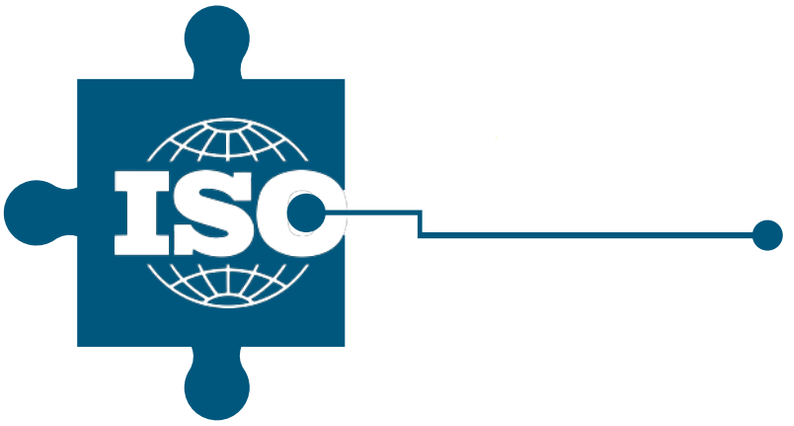
Our Markets

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

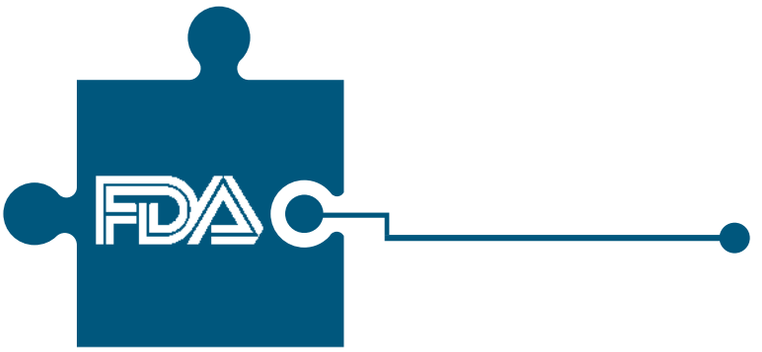
Standards



Our products are manufactured in accordance to the standards as set in the European In-Vitro Diagnostic Directive 98/79/EC. This has led to the successful attainment of Annex IV Full Quality Assurance Certification and the declaration of conformity for CE marking purposes for many of our IVD products, either self-declared or through our Notified Body LNE/G-MED

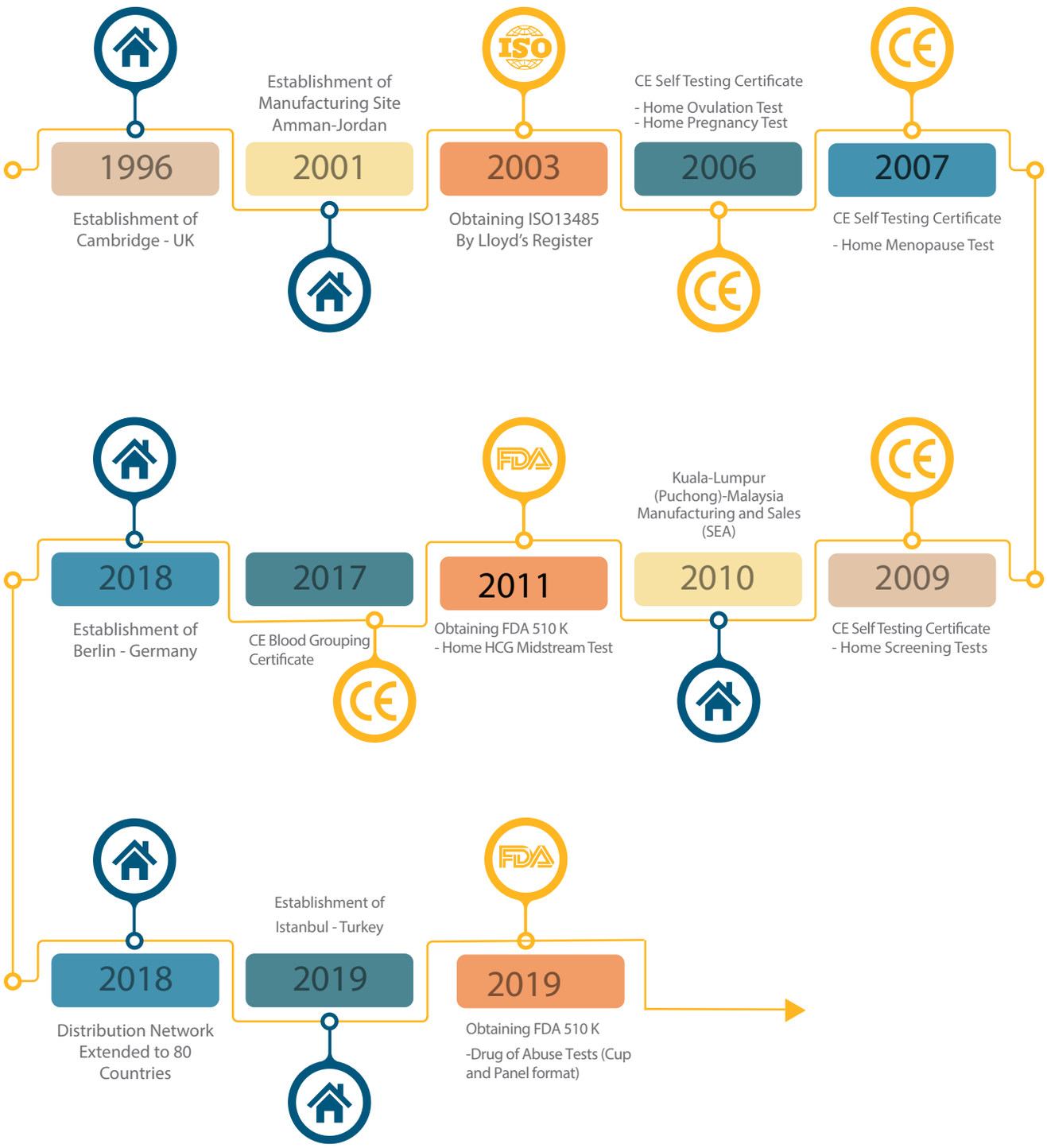


To complete the quality assurance scheme the company has put in place a robust Quality Management and Enhancement System that has concluded in the successful attainment of ISO13485: 2016 certificate



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

MILESTONES


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

COVID-19 TESTING KITS

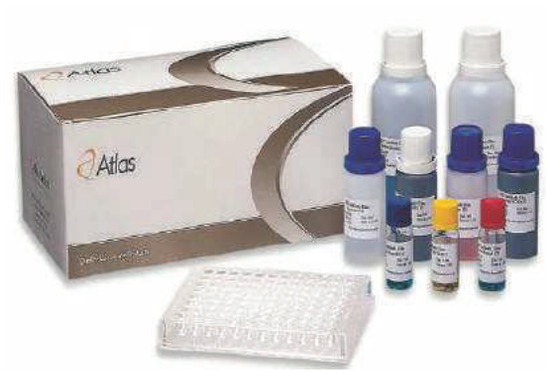
Overview

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

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

Features

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



COVID-19 RAPID TESTING KITS

Overview

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

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

Features

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

VIRAL TRANSPORT MEDIUM KITS

Overview

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

Features

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

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

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

LATEX KITS

Overview

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

Features

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

TURBIDIMETRIC LATEX KITS

Overview

The turbidimetric assay is based on the agglutination reaction between latex particles coated with antibody and the antigen in solution. The intended use for Turbilatex products is to detect and quantify the antigen present in human serum or plasma samples.

Features

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

Item Code	Item Description	Sizes
8.44.00.0.0050 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

SYPHILIS KITS

Overview

Atlas Medical offers a number of assays to detect Syphilis that include: TPHA kits which are used for the detection of antibodies to Treponema pallidum in human Serum or plasma using micro haemagglutination ; VDRL and RPR kits which are based on non-Treponemal floccuation to detect reagin antibodies in serum or plasma .

Item Code	Item Description	Sizes
8.00.18.0.0100 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

Features

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

FEBRILE ANTIGENS

Overview

Febrile antigen kits are based on bacterial suspensions that agglutinate in the presence of antibodies formed in human infection by certain fever-causing microbial agents. In positive samples, the agglutination is macroscopically visible at certain antibody levels in serum. These antigen reagents are used for the qualitative and semi quantitative febrile screening purposes.

Features

- Atlas Medical Febrile Antigen kits contain various types of antigens for Brucella, Proteus, Salmonella typhi and paratyphi, and their controls as needed.

- Atlas Medical Febrile Antigen kits are competitively priced and easy to use, and give clear results within 2 minutes

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

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

BLOOD GROUPING REAGENTS

Overview

Blood Grouping reagents are used for the identification of blood types. The test procedure is based on the agglutination principle, where red cells possessing the typing antigen agglutinate in the presence of the corresponding antibody in the testing reagent indicating the presence of the tested antigen. No agglutination indicates the absence of the tested antigen.

Features

- Atlas Medical ABO reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines.
- The reagents are formulated and optimized for use in tube and slide methods.
- Atlas Medical provides high quality blood grouping reagents that are accurate, easy to use, competitively priced, and conveniently packed in different sizes and options.

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

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

HEMATOLOGY TESTS

Overview

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

Features

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

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 KITS

Overview

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

Features

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

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

INFECTIOUS DISEASE RAPID TESTS

ANTIBODY TESTING

Overview

Atlas Medical offers an extensive range of lateral flow immunoassay tests for the rapid detection of antibodies and antigens in human samples (blood, serum, plasma, urine, oral swabs, nasal swabs, and feces). This range includes tests to detect a wide variety of viruses, microorganisms and parasites.

Features

- Atlas Medical infectious disease rapid tests are reliable, accurate and supplied in both cassette and strip formats.
- The kits are conveniently packed in different sizes of 20, 25, 30, 40, 50 and 100 tests per kit and include the necessary test accessories to perform the assay.

RAPID TESTS

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

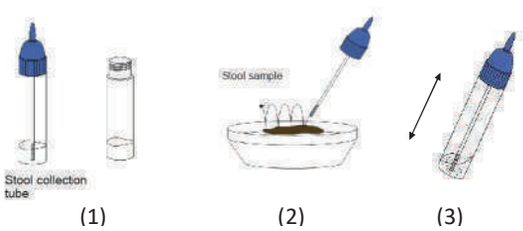
Item Code	Item Description	Sizes
8.42.47.0.0020	HAV IgM Test Cassette, Individually Pouched	20 Tests/Box
8.04.44.0.0001 8.04.44.0.0020	Dengue IgG/IgM Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched	Bulk 20 Tests/Box

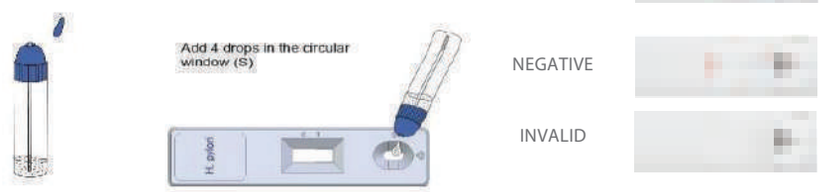
INFECTIOUS DISEASE RAPID TESTS

ANTIGEN TESTING

STOOL SAMPLE

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

Overview

Urine Reagent Strips (URS) are widely used in Urinalysis to determine pathological changes in urine. The strips contain dry-chemistry pads that, when dipped in urine, change their colors. The color change allows for the semi-quantitative measurement of various urine parameters. The strips are suitable for lab, point-of-care and even home use.

Features

- Atlas Medical Urine Reagent Strips can be used to detect up to 14 urine parameters.
- They are simple to use and the results are visually read within a minute.
- The strips are packed in desiccated bottles of 50 or 100 strips.
- Atlas Medical can also provide suitable readers to read the strip colors and document the results.

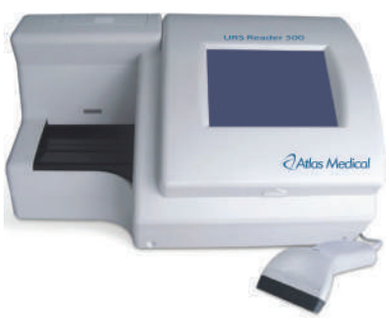
Item Code	Item Description	Sizes
8.03.00.0.0050 8.03.00.0.0100	URS 1 Parameter: Glucose	50 Strips 100 Strips
8.03.01.0.0050 8.03.01.0.0100	URS 1 Parameter: Protein	50 Strips 100 Strips
8.03.02.0.0050 8.03.02.0.0100	URS 1 Parameter: Ketone	50 Strips 100 Strips
8.03.45.0.0050	URS 1 Parameter Blood, (5mm)	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

URINE ANALYZER

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



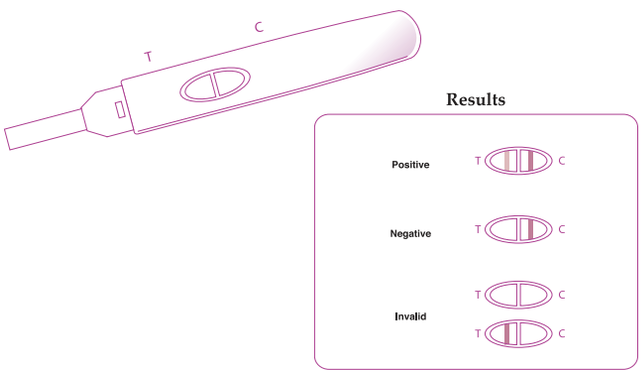
FERTILITY RAPID TESTS

Overview

Atlas Medical Fertility Rapid Tests are based on lateral flow immunoassay for the detection of human chorionic gonadotropin (hCG), Ovulation (LH), and Human Follicular Stimulating Hormone (FSH) in urine. Each of the three tests comes in strip, cassette, or midstream formats and are conveniently packed in sizes to suit lab, point-of-care and home uses.

Features

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



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

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

KIDNEY FUNCTION RAPID TESTS

Overview

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

Features

- The test comes in cassette and Strip formats.

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

INFLAMMATION AND CANCER MARKERS

Overview

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

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

Features

- Atlas Medical inflammation and cancer markers rapid tests are supplied in both cassette and strip formats.
- The kits are conveniently packed in different kit sizes of 20, 25, 30 and 100 tests per kit.

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

CARDIAC MARKERS RAPID TESTS

Overview

Atlas Medical offers lateral flow immunoassay rapid tests to detect the three major cardiac markers namely: Troponin I, Myoglobin and CK-MB, as an aid in the diagnosis of myocardial infarction (MI).

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

Features

- They can be used on whole blood (in addition to serum/plasma) making them ideal for emergency rooms.
- They come in single test or triple combo test cassette formats.
- The kits are conveniently packed in different kit sizes of 20, 25, 30 tests per kit.

DOA RAPID TESTS

Overview

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

Features

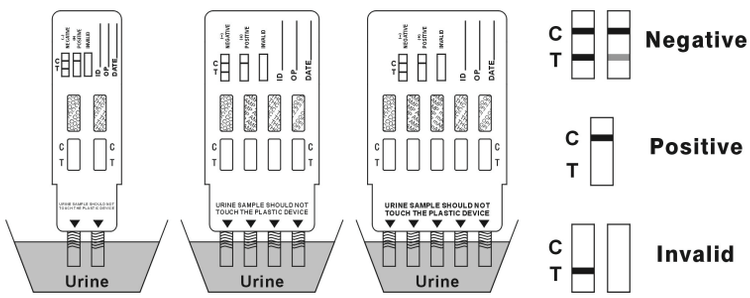
- Atlas Medical DOA rapid tests are supplied in cassette , strip, panel and cup formats.
- The kits are conveniently packed in different kit sizes of 20, 25, 30, 50 and 100 tests per kit.

STRIP AND CASSETTE FORMAT

Item Code	Item Description	Sizes
8.04.49.0.0001 8.04.49.0.0020	Morphine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.50.0.0001 8.04.50.0.0100	Morphine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.51.0.0001 8.04.51.0.0020	Marijuana (THC) Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.52.0.0001 8.04.52.0.0100	Marijuana (THC) Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.53.0.0001 8.04.53.0.0020	Amphetamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.54.0.0001 8.04.54.0.0100	Amphetamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.55.0.0001 8.04.55.0.0020	Barbiturates Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.56.0.0001 8.04.56.0.0100	Barbiturates Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.57.0.0001 8.04.57.0.0020	Benzodiazepines Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.58.0.0001 8.04.58.0.0100	Benzodiazepines Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.59.0.0001 8.04.59.0.0020	Cocaine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.60.0.0001 8.04.60.0.0100	Cocaine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.61.0.0001 8.04.61.0.0020	Methamphetamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.62.0.0001 8.04.62.0.0100	Methamphetamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.63.0.0001 8.04.63.0.0020	Methadone Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.64.0.0001 8.04.64.0.0100	Methadone Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.65.0.0001 8.04.65.0.0020	Phencyclidine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.66.0.0001 8.04.66.0.0100	Phencyclidine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.67.0.0001 8.04.67.0.0020	Tricyclic Anti-Depressants Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.04.68.0.0001 8.04.68.0.0100	Tricyclic Anti-Depressants Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.04.99.0.0001 8.04.99.0.0020	Buprenorphine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.23.0.0001 8.16.23.0.0100	Buprenorphine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.68.0.0001 8.16.68.0.0020	Tramadol Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.44.0.0001 8.16.44.0.0100	Tramadol Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.15.0.0001 8.16.15.0.0020	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Cassette,Urine,Individually Pouched	Bulk 20 Tests/Box
8.16.05.0.0001 8.16.05.0.0100	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Strip, Urine,Individually Pouched	Bulk 100 Tests/Box
8.16.06.0.0001 8.16.06.0.0020	Opiates Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.07.0.0001 8.16.07.0.0100	Opiates Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.58.0.0001 8.16.58.0.0020	Cotinine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.59.0.0001 8.16.59.0.0100	Cotinine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.62.0.0001 8.16.62.0.0020	Oxycodone Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.63.0.0001 8.16.63.0.0100	Oxycodone Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.64.0.0001 8.16.64.0.0020	Ketamine Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.65.0.0001 8.16.65.0.0100	Ketamine Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.66.0.0001 8.16.66.0.0020	Proxyphene Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.67.0.0001 8.16.67.0.0100	Proxyphene Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.68.0.0001 8.16.68.0.0020	Tramadol Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.69.0.0001 8.16.69.0.0020	EDDP Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.70.0.0001 8.16.70.0.0100	EDDP Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box
8.16.60.0.0001 8.16.60.0.0020	Dolantin Test Cassette, Urine, Individually Pouched	Bulk 20 Tests/Box
8.16.61.0.0001 8.16.61.0.0100	Dolantin Test Strip, Urine, Individually Pouched	Bulk 100 Tests/Box

DOA RAPID TESTS

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



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

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

CLINICAL CHEMISTRY KITS

Overview

Kits in this group measure concentrations of electrolytes , hormones, proteins, and other metabolic products in human blood , serum,plasma, CSF and urine .
Clincal Chemistry tests are indicated to assess systemic functions such liver function , kidney function , and endocrine and metabolic function .
Methods commonly used are colormetric and kinetic.

Features

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

Item Code	Item Description	Sizes
8.05.00.0.0250 8.05.00.0.0500	Albumin Bromocresol Green	2x125ml 4x125ml
8.05.01.0.0030 8.05.01.0.0060	Amylase	3x10ml 6x10ml
8.05.02.0.0020 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

CLINICAL CHEMISTRY KITS

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

Item Code	Item Description	Sizes
8.05.71.0.0250 8.05.71.0.0500	Uric Acid Enzymatic Colorimetric (Mono Reagents)	2x125ml 4x125ml
8.05.43.1.0005	Pathological Control for Clinical Chemistry, Lyophilized, Human Source	5ml/vial
8.05.44.1.0005	Normal Control for Clinical Chemistry, Lyophilized, Human Source	5ml/vial
8.05.47.0.0003	G6PD Control, Normal Level, (Lyophilized)	6x0.5ml
8.05.51.0.0100	HDL 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

ALCOHOL TESTS

Overview

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

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

Features

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

STAINS FOR HISTOLOGY & MICROBIOLOGY

Overview

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

Features

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

STAIN PACKS FOR HISTOLOGY

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

STAINS FOR HISTOLOGY

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

MICROBIOLOGY

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

ANTIBIOTIC SENSITIVITY DISCS

Overview

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

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

Features

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

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

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

ANTIBIOTIC SENSITIVITY DISCS

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

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

ELISA KITS

Features

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

Overview

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

HORMONE ELISA KITS

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

HORMONE ELISA KITS

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

ELISA KITS

Overview

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

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

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

TORCH ELISA KITS

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

Overview

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

INFECTIOUS DISEASES ELISA KITS

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

INFECTIOUS DISEASES ELISA KITS

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

OTHER ELISA KITS

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

HOME TESTS

CE 0459

Overview

Atlas Medical provides a range of home tests that have been specifically CE marked for OTC use. The range includes fertility tests (Pregnancy, Ovulation and Menopause). The home tests range also includes other medical conditions such as liver function, kidney function, diabetes and urine tract infection. These tests are based on urine reagent strips.

Screening Kits

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

Features

- These tests come in cassette, midstream and strip formats.
- The screening kits come with 2 individually pouched strips and easy to read instructions for use.
- All kits are packed in attractively designed boxes with various languages.
- Atlas Medical also supplies these kits under OEM arrangements.
- Screening bundle including (UTI, Kidney, Liver, Diabetes) is available , Family planning kit (Pregnancy and Ovulation) is also available .

- 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.

CE 0459

Fertility Kits

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

BLOOD GLUCOSE MONITORING SYSTEMS

Overview

Testing your blood glucose regularly helps you better manage your diabetes. Reliance ™ by Atlas Medical, uses the latest blood glucose sensor technologies to offer you the most accurate and reliable results for the peace of mind you need. Atlas Medical offers these systems in strips which includes Gold Electrodes.

Features

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

Reliance Gold

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

CERTIFICATES

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

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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
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ISO 13485

ATTESTATION/ *CERTIFICATE* N° 33544 rev. 2
Délivrée à Paris le 19 mars 2026
Issued in Paris on March 19th, 2026

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 référencé 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*
Approbation 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 IVD, un certificat CE de la conception est requis
For list A IVD devices, a EC design certificate is required

Fabricant / *Manufacturer*

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

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

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

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

Voir détails sur addendum
See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P501408, 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 P501408, 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 9th, 2020 (included)
Valable jusqu'au / *Expiry date* : October 8th, 2023 (included)

On behalf of the President
Béatrice LYS
Technical Director

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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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