

# Anti-k, monoclonal

## HUMAN BLOOD GROUPING REAGENTS

### For Indirect Antiglobulin Techniques

**REF**

B18908

**Cont.**

1x 2 mL

Anti-k, monoclonal

For professional in vitro diagnostic use only.

### SUMMARY

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

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

### PRINCIPLE

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

### REAGENTS

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

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

### STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. The reagent has undergone transportation stability studies at 37°C and -25°C as described in EN23640:2011.

### SAMPLE COLLECTION AND PREPARATION

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

### CONTROLS AND ADVICE

- It is recommended a positive control (ideally heterozygous cells) and a negative control be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
- The antiglobulin techniques can only be considered valid if all negative tests react positively with IgG sensitised red cells.
- The reagents contain macromolecular potentiators which may cause false positive reactions with IgG sensitised cells, it is recommended that patient's cells are tested with patient's plasma to test for false positive reactions.
- In the **Tube Technique** one volume is approximately 50 µL when using the vial dropper provided.
- The use of the reagents and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagents are in use.
- User must determine suitability of the reagents for use in other techniques.

### REAGENTS AND MATERIALS REQUIRED

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

### RECOMMENDED TECHNIQUES

#### A. Indirect Antiglobulin Technique (IAT)

- Prepare a 2-3% suspension of washed test red cells in PBS or Isotonic Saline.

- Place in a labelled test tube: 1 volume of DIALAB Anti-k, monoclonal reagent and 1 volume of test red cell suspension.
- Mix thoroughly and incubate at 37°C for 15 minutes.
- Wash test red cells 4 times with PBS or Isotonic saline, taking care to decant saline between washes and resuspend each red cell button after each wash. Completely decant saline after last wash.
- Add 2 volumes of anti-human globulin or anti-IgG to each dry cell button. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
- Gently resuspend red cell button and read macroscopically for agglutination
- Confirm validity of all negative reactions with IgG sensitised red cells.

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

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

#### C. Ortho BioVue Typing Technique

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

### INTERPRETATION OF TEST RESULTS

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

### STABILITY OF THE REACTIONS

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

### LIMITATIONS

- Red cells that have a positive DAT due to a coating of IgG cannot be typed by the **Indirect Antiglobulin Technique**.
- Suppressed or diminished expression of certain blood group antigens may conversely give rise to false negative reactions and so caution should always be exercised when assigning genotypes on the basis of test results.
- False positive or false negative results may also occur due to:
  - Contamination of test materials
  - Improper storage, cell concentration, incubation time or temperature
  - Improper or excessive centrifugation
  - Deviation from the recommended techniques

### PERFORMANCE CHARACTERISTICS

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

### DISCLAIMER

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

### PRECAUTIONS

- The reagents are intended for in vitro diagnostic use only.
- If a reagent vial is cracked or leaking, discard the contents immediately.
- Do not use the reagents past the expiration date (see **Vial Label**).
- Do not use the reagents if a precipitate is present.
- Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
- The reagents have been filtered through a 0.2 µm capsule to reduce the biohazard. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination.

7. The reagents contain 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal, flush away with large volumes of water.
8. Materials used to produce the reagents were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg using approved microbiological tests.
9. No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

#### DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES

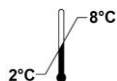
For information on disposal of the reagents and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

#### BIBLIOGRAPHY

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

#### TABLE OF SYMBOLS

|                                                                                    |                                                                                    |                                                                                    |                                                                                    |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
|   |   |   |   |
| Batch Number                                                                       | In-vitro Diagnostic                                                                | Reference Nr.                                                                      | Content                                                                            |
|  |  |  |  |
| Expiry Date                                                                        | Store At                                                                           | Manufacturer                                                                       | Read Pack Insert                                                                   |



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## Blood Grouping Reagents:

### Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent, Anti-AB Monoclonal Reagent, Anti-D IgG/IgM blend Reagent, & Their variants

#### SLIDE AND TUBE TESTS

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

2°C  8°C  
Store at 2- 8°C

#### INTENDED USE

The blood grouping reagents are used to detect the presence or absence of A, B or Rhesus Antigens on the surface of human red blood cells based on hemagglutination 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 hemagglutination 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<sup>vi</sup>) and a high proportion of weak D (Du) phenotypes. The reagent will agglutinate category D<sup>vi</sup> and low grade weak D (D<sup>u</sup>) 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 hemagglutination 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.
- Hemolysed blood sample should not be used for testing.
- The test should be performed at room temperature in a well lit 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 PREPARATION

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

#### SPECIMEN COLLECTION AND PREPARATION

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

**Note:** Blood collected without anticoagulant should be tested immediately.

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

#### PROCEDURES

##### A. DIRECT TUBE METHOD AT ROOM TEMPERATURE

1. Prepare a 5% suspension of red blood cells in isotonic solution.
2. Using the vial dropper, transfer a drop (40±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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>Negative with Negative control |       |       |       |            |
| CE marked device                                                                                                                    | Lot A | Lot B | Lot C | Compliance |
| 24                                                                                                                                  | 24    | 24    | 24    | 100%       |

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

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

**REFERENCES**

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LIST OF VARIANTS:

| 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                                    |

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

# Certificate of Analysis for Blood Grouping Kit

## 1- Product Identification:

|                                                  |                                                     |                              |                                      |
|--------------------------------------------------|-----------------------------------------------------|------------------------------|--------------------------------------|
| <b>Product Name : Anti- A Monoclonal Reagent</b> | <b>Catalog No. (Variant Code ) : 8.02.04.0.0010</b> | <b>Item Dispense #: 473</b>  | <b>Minimal Titer Accepted: 1/256</b> |
| <b>Lot #: 24020311</b>                           | <b>Mfg. Date: NA</b>                                | <b>Exp. Date: 2025/11/09</b> |                                      |

## 2- Sampling Plan:

| Date       | QC Test Method Used | Inspection level                   | AQL            | Determine the following by referring to Sampling Plan Sheet |                        |          |          |
|------------|---------------------|------------------------------------|----------------|-------------------------------------------------------------|------------------------|----------|----------|
|            |                     |                                    |                | Sample Size Code Letter                                     | Sample Size (Test QTY) | Accepted | Rejected |
| 08.02.2024 | <b>F13D</b>         | Physical Inspection: S-I           | 1.0            | <b>B</b>                                                    | <b>3</b>               | <b>0</b> | <b>1</b> |
| 07.02.2024 | <b>F13D</b>         | Biochemical Inspection: One sample | Not Applicable |                                                             |                        |          |          |

## 3- Physical Check:

| Applicable Test Type                                                          | Inspected Item and/or Criteria                                     | Inspection Results |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------|--------------------|
| ➤ Kit Assembly:                                                               | All components of the kit are present according to the outer label | ■ Pass □ Fail      |
| ➤ Item Color & Status:                                                        | Anti-A: Blue – Liquid                                              | ■ Pass □ Fail      |
|                                                                               | Anti-B: Yellow – Liquid NA                                         | □ Pass □ Fail      |
|                                                                               | Anti-D: Yellowish – Liquid NA                                      | □ Pass □ Fail      |
|                                                                               | Anti-AB: Yellowish – Liquid NA                                     | □ Pass □ Fail      |
| ➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense: | Anti-A 10 ml                                                       | ■ Pass □ Fail      |
|                                                                               | Anti-B NA                                                          | □ Pass □ Fail      |
|                                                                               | Anti-D NA                                                          | □ Pass □ Fail      |
|                                                                               | Anti-AB NA                                                         | □ Pass □ Fail      |
| ➤ Labels:                                                                     | Correct label orientation                                          | ■ Pass □ Fail      |
|                                                                               | Correct label position                                             | ■ Pass □ Fail      |
|                                                                               | Clear printing                                                     | ■ Pass □ Fail      |
| ➤ Package Insert:                                                             | Clear printing and correct folding                                 | ■ Pass □ Fail      |
|                                                                               | Correct code, version and brand as mentioned in Item Dispense      | ■ Pass □ Fail      |
|                                                                               | Address as mentioned on box design                                 | ■ Pass □ Fail      |
| ➤ Closing Cap:                                                                | No leakage and closed well                                         | ■ Pass □ Fail      |
| ➤ Dropper Coloring / Titer (CE Blood Grouping):                               | Anti A (High titer (1/512): Blue cap with black bulb NA            | □ Pass □ Fail      |
|                                                                               | Anti A (Low titer (1/256): Blue cap with grey bulb NA              | □ Pass □ Fail      |
|                                                                               | Anti B (High titer (1/512): Yellow cap with black bulb NA          | □ Pass □ Fail      |
|                                                                               | Anti B (Low titer (1/256): Yellow cap with grey bulb NA            | □ Pass □ Fail      |

|                                                                           |                                                                                              |                                          |                               |
|---------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|------------------------------------------|-------------------------------|
|                                                                           | Anti AB (High titer (1/512): Grey cap with black bulb NA                                     | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti AB (Low titer (1/256): Grey cap with grey bulb NA                                       | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti D (High titer (1/128): Black cap with black bulb NA                                     | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti D (Low titer (1/64): Black cap with grey bulb NA                                        | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
| ➤ Dropper Coloring / Titer<br>(None CE Blood Grouping):                   | Anti A (High titer (1/512): White cap with black bulb NA                                     | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti A (Low titer (1/256): White cap with white bulb                                         | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                           | Anti B (High titer (1/512): White cap with black bulb NA                                     | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti B (Low titer (1/256): White cap with white bulb NA                                      | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti AB (High titer (1/512): White cap with black bulb NA                                    | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti AB (Low titer (1/256): White cap with white bulb NA                                     | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti D (High titer (1/128): Black cap with white bulb NA                                     | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti D (Low titer (1/64): Gray cap with white bulb NA                                        | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti D (IgM) (Low titer (1/64)): Grey cap with Black bulb NA                                 | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti D (IgM) (High titer (1/128)): Black cap with black bulb NA                              | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti D (IgG) (Low titer (1/64)): Grey cap with black bulb NA                                 | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti D (IgG) (High titer (1/128)): Black cap with black bulb NA                              | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
| ➤ Dropper Coloring / Titer<br>(Real Titer (256) / Non CE Blood Grouping): | Anti A (White cap with white bulb) NA                                                        | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti B (White cap with white bulb) NA                                                        | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                           | Anti AB (White cap with white bulb) NA                                                       | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
| ➤ Dropper Function:                                                       | Able to withdraw the reagent                                                                 | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Quantity/Kit:                                                           | Compatible with the quantity mentioned in the outer label<br>• Record the QTY/Kit: (2/1)     | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Final Result:                                                           | <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....NA..... |                                          |                               |
| Done by QC Officer/Supervisor (Sign.): <i>rayan</i>                       |                                                                                              | Date: 08.02.2024                         | Time: 09:40                   |

#### 4- Biochemical Check:

##### A. Direct Slide Method: Interpret the results by referring to Table (01)

|                                                    |                        |                                                                                              |                        |                         |                        |                 |                        |
|----------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------|------------------------|-------------------------|------------------------|-----------------|------------------------|
| Pipette #:157                                      |                        |                                                                                              |                        | Pipette Code: E21PiQ157 |                        |                 |                        |
| Anti A                                             |                        | Anti -B                                                                                      |                        | Anti-AB                 |                        | Anti-D          |                        |
| A (lot No: Fresh sample )                          |                        | B ( Lot no: NA )                                                                             |                        | AB (Lot no: NA )        |                        | O+(Lot no: NA ) |                        |
| Reaction time                                      | Agglutination strength | Reaction time                                                                                | Agglutination strength | Reaction time           | Agglutination strength | Reaction time   | Agglutination strength |
| 2 Sec                                              | +4                     | NA                                                                                           | NA                     | NA                      | NA                     | NA              | NA                     |
| ➤ Final Result:                                    |                        | <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....NA..... |                        |                         |                        |                 |                        |
| Done by QC Officer/Supervisor (Sign.): <i>Toga</i> |                        |                                                                                              |                        | Date: 07.02.2024        |                        | Time: 15:53     |                        |

##### B. Sensitivity test

|                |                  |                         |                      |                         |                                   |                   |  |
|----------------|------------------|-------------------------|----------------------|-------------------------|-----------------------------------|-------------------|--|
| Pipette #: 157 |                  |                         |                      | Pipette Code: E21PiQ157 |                                   |                   |  |
| Type of Test   |                  |                         | Anti-A               | Anti-B                  | Anti-AB                           | Anti-D            |  |
| Sensitivity    | Tube Test Method | Type of Cell Suspension | A (Lot no: AC240207) | B ( Lot no: NA )        | A (Lot no: NA )<br>B (Lot no NA ) | O+<br>(Lot no NA) |  |

|                                                                                 |  |                                     |        |     |        |    |        |    |       |    |
|---------------------------------------------------------------------------------|--|-------------------------------------|--------|-----|--------|----|--------|----|-------|----|
|                                                                                 |  | Result                              | 1:2    | +4  | 1:2    | NA | 1:2    | NA | 1:2   | NA |
|                                                                                 |  |                                     | 1:4    | +3  | 1:4    | NA | 1:4    | NA | 1:4   | NA |
|                                                                                 |  |                                     | 1:8    | +3  | 1:8    | NA | 1:8    | NA | 1:8   | NA |
|                                                                                 |  |                                     | 1:16   | +2  | 1:16   | NA | 1:16   | NA | 1:16  | NA |
|                                                                                 |  |                                     | 1:32   | +2  | 1:32   | NA | 1:32   | NA | 1:32  | NA |
|                                                                                 |  |                                     | 1:64   | +2  | 1:64   | NA | 1:64   | NA | 1:64  | NA |
|                                                                                 |  |                                     | 1:128  | +1  | 1:128  | NA | 1:128  | NA | 1:128 | NA |
|                                                                                 |  |                                     | 1:256  | +1  | 1:256  | NA | 1:256  | NA | 1:256 | NA |
|                                                                                 |  |                                     | 1:512  | -ve | 1:512  | NA | 1:512  | NA | 1:512 | NA |
|                                                                                 |  |                                     | 1:1024 | -ve | 1:1024 | NA | 1:1024 | NA |       |    |
| ➤ Final Result:                                                                 |  | ■ Pass □ Fail; justify .....NA..... |        |     |        |    |        |    |       |    |
| Done by QC Officer/Supervisor (Sign.): <i>Toga</i> Date: 07.02.2024 Time: 15:55 |  |                                     |        |     |        |    |        |    |       |    |

| Table (01)              |                    |                |                        |
|-------------------------|--------------------|----------------|------------------------|
| Blood Grouping Reagents | Control Cell       | Reaction Time  | Agglutination Strength |
| Anti-A                  | A - Cell           | Up to 3 second | +4                     |
| Anti-B                  | B-Cell             | Up to 3 second | +4                     |
| Anti-AB                 | A B-Cell           | Up to 3 second | +3/+4                  |
| Anti -D                 | O RH positive cell | Up to 5 second | +3                     |

|                                                            |                         |
|------------------------------------------------------------|-------------------------|
| <b>Final Conclusion:</b> ■ Pass □ Fail                     |                         |
| <b>Final QC Manager Approval (Signature):</b> <i>Marwa</i> | <b>Date:</b> 08.02.2024 |

**QC Release Stamp:**



# Certificate of Analysis for Blood Grouping Kit

## 1- Product Identification:

|                                                  |                                                     |                              |                                      |
|--------------------------------------------------|-----------------------------------------------------|------------------------------|--------------------------------------|
| <b>Product Name : Anti-AB monoclonal Reagent</b> | <b>Catalog No. (Variant Code ) : 8.02.06.0.0010</b> | <b>Item Dispense #: 895</b>  | <b>Minimal Titer Accepted: 1/256</b> |
| <b>Lot #: 24030917</b>                           | <b>Mfg. Date: NA</b>                                | <b>Exp. Date: 2026/01/04</b> |                                      |

## 2- Sampling Plan:

| Date       | QC Test Method Used | Inspection level                   | AQL            | Determine the following by referring to Sampling Plan Sheet |                        |          |          |
|------------|---------------------|------------------------------------|----------------|-------------------------------------------------------------|------------------------|----------|----------|
|            |                     |                                    |                | Sample Size Code Letter                                     | Sample Size (Test QTY) | Accepted | Rejected |
| 12.03.2024 | <b>F13D</b>         | Physical Inspection: S-I           | 1.0            | <b>B</b>                                                    | <b>3</b>               | <b>0</b> | <b>1</b> |
| 12.03.2024 | <b>F13D</b>         | Biochemical Inspection: One sample | Not Applicable |                                                             |                        |          |          |

## 3- Physical Check:

| Applicable Test Type                                                          | Inspected Item and/or Criteria                                     | Inspection Results                       |                               |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------------------------------|-------------------------------|
| ➤ Kit Assembly:                                                               | All components of the kit are present according to the outer label | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Item Color & Status:                                                        | Anti-A: Blue – Liquid NA                                           | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                               | Anti-B: Yellow – Liquid NA                                         | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                               | Anti-D: Yellowish – Liquid NA                                      | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                               | Anti-AB: Yellowish – Liquid                                        | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense: | Anti-A NA                                                          | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                               | Anti-B NA                                                          | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                               | Anti-D NA                                                          | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                               | Anti-AB 10 ml                                                      | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Labels:                                                                     | Correct label orientation                                          | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                               | Correct label position                                             | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                               | Clear printing                                                     | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Package Insert:                                                             | Clear printing and correct folding                                 | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                               | Correct code, version and brand as mentioned in Item Dispense      | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                               | Address as mentioned on box design                                 | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Closing Cap:                                                                | No leakage and closed well                                         | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Dropper Coloring / Titer (CE Blood Grouping):                               | Anti A (High titer (1/512): Blue cap with black bulb NA            | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                               | Anti A (Low titer (1/256): Blue cap with grey bulb NA              | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                               | Anti B (High titer (1/512): Yellow cap with black bulb NA          | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                               | Anti B (Low titer (1/256): Yellow cap with grey bulb NA            | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |

|                                                                                 |                                                                                                                                     |                                          |                               |
|---------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|-------------------------------|
|                                                                                 | Anti AB (High titer (1/512): Grey cap with black bulb NA                                                                            | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti AB (Low titer (1/256): Grey cap with grey bulb NA                                                                              | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti D (High titer (1/128): Black cap with black bulb NA                                                                            | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti D (Low titer (1/64): Black cap with grey bulb NA                                                                               | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
| ➤ Dropper Coloring / Titer<br>(None CE Blood Grouping):                         | Anti A (High titer (1/512): White cap with black bulb NA                                                                            | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti A (Low titer (1/256): White cap with white bulb NA                                                                             | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti B (High titer (1/512): White cap with black bulb NA                                                                            | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti B (Low titer (1/256): White cap with white bulb NA                                                                             | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti AB (High titer (1/512): White cap with black bulb NA                                                                           | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti AB (Low titer (1/256): White cap with white bulb                                                                               | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                 | Anti D (High titer (1/128): Black cap with white bulb NA                                                                            | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti D (Low titer (1/64): Gray cap with white bulb NA                                                                               | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti D (IgM) (Low titer (1/64)): Grey cap with Black bulb NA                                                                        | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti D (IgM) (High titer (1/128)): Black cap with black bulb NA                                                                     | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti D (IgG) (Low titer (1/64)): Grey cap with black bulb NA                                                                        | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti D (IgG) (High titer (1/128)): Black cap with black bulb NA                                                                     | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
| ➤ Dropper Coloring / Titer<br>(Real Titer (256) / Non CE Blood Grouping):       | Anti A (White cap with white bulb) NA                                                                                               | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti B (White cap with white bulb) NA                                                                                               | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
|                                                                                 | Anti AB (White cap with white bulb) NA                                                                                              | <input type="checkbox"/> Pass            | <input type="checkbox"/> Fail |
| ➤ Dropper Function:                                                             | Able to withdraw the reagent                                                                                                        | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Quantity/Kit:                                                                 | Compatible with the quantity mentioned in the outer label <ul style="list-style-type: none"><li>Record the QTY/Kit: (2/1)</li></ul> | <input checked="" type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Final Result:                                                                 | <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail; justify .....NA.....                                        |                                          |                               |
| Done by QC Officer/Supervisor (Sign.): <i>Toga</i> Date: 12.03.2024 Time: 12:20 |                                                                                                                                     |                                          |                               |

#### 4- Biochemical Check:

##### A. Direct Slide Method: Interpret the results by referring to Table (01)

|                                                                          |                        |                                     |                        |                         |                        |               |                        |
|--------------------------------------------------------------------------|------------------------|-------------------------------------|------------------------|-------------------------|------------------------|---------------|------------------------|
| Pipette #:157                                                            |                        |                                     |                        | Pipette Code: E21PiQ157 |                        |               |                        |
| Anti A                                                                   |                        | Anti –B                             |                        | Anti-AB                 |                        | Anti-D        |                        |
| A (lot No: )                                                             |                        | B ( Lot no: )                       |                        | AB (Lot no: 942402)     |                        | O+(Lot no: )  |                        |
| Reaction time                                                            | Agglutination strength | Reaction time                       | Agglutination strength | Reaction time           | Agglutination Strength | Reaction time | Agglutination strength |
| NA                                                                       | NA                     | NA                                  | NA                     | 2 Sec                   | +4                     | NA            | NA                     |
| ➤ Final Result:                                                          |                        | ■ Pass □ Fail; justify .....NA..... |                        |                         |                        |               |                        |
| Done by QC Officer/Supervisor (Sign.): Toga Date: 12.03.2024 Time: 11:32 |                        |                                     |                        |                         |                        |               |                        |

##### B. Sensitivity test

|                |                  |                         |                 |                         |                                    |              |  |
|----------------|------------------|-------------------------|-----------------|-------------------------|------------------------------------|--------------|--|
| Pipette #: 157 |                  |                         |                 | Pipette Code: E21PiQ157 |                                    |              |  |
| Type of Test   |                  |                         | Anti-A          | Anti-B                  | Anti-AB                            | Anti-D       |  |
| Sensitivity    | Tube Test Method | Type of Cell Suspension | A (Lot no: NA ) | B ( Lot no: NA )        | A (Lot no: 772404 )<br>B (Lot no ) | O+ (Lot no ) |  |

|                                                                                 |  |                                     |        |    |        |    |        |     |       |    |
|---------------------------------------------------------------------------------|--|-------------------------------------|--------|----|--------|----|--------|-----|-------|----|
|                                                                                 |  | Result                              | 1:2    | NA | 1:2    | NA | 1:2    | +4  | 1:2   | NA |
|                                                                                 |  |                                     | 1:4    | NA | 1:4    | NA | 1:4    | +3  | 1:4   | NA |
|                                                                                 |  |                                     | 1:8    | NA | 1:8    | NA | 1:8    | +3  | 1:8   | NA |
|                                                                                 |  |                                     | 1:16   | NA | 1:16   | NA | 1:16   | +2  | 1:16  | NA |
|                                                                                 |  |                                     | 1:32   | NA | 1:32   | NA | 1:32   | +2  | 1:32  | NA |
|                                                                                 |  |                                     | 1:64   | NA | 1:64   | NA | 1:64   | +2  | 1:64  | NA |
|                                                                                 |  |                                     | 1:128  | NA | 1:128  | NA | 1:128  | +1  | 1:128 | NA |
|                                                                                 |  |                                     | 1:256  | NA | 1:256  | NA | 1:256  | +1  | 1:256 | NA |
|                                                                                 |  |                                     | 1:512  | NA | 1:512  | NA | 1:512  | -ve | 1:512 | NA |
|                                                                                 |  |                                     | 1:1024 | NA | 1:1024 | NA | 1:1024 | -ve |       |    |
| ➤ Final Result:                                                                 |  | ■ Pass □ Fail; justify .....NA..... |        |    |        |    |        |     |       |    |
| Done by QC Officer/Supervisor (Sign.): <i>Toga</i> Date: 12.03.2024 Time: 11:35 |  |                                     |        |    |        |    |        |     |       |    |

| Table (01)              |                    |                |                        |
|-------------------------|--------------------|----------------|------------------------|
| Blood Grouping Reagents | Control Cell       | Reaction Time  | Agglutination Strength |
| Anti-A                  | A - Cell           | Up to 3 second | +4                     |
| Anti-B                  | B-Cell             | Up to 3 second | +4                     |
| Anti-AB                 | A B-Cell           | Up to 3 second | +3/+4                  |
| Anti -D                 | O RH positive cell | Up to 5 second | +3                     |

|                                                     |                  |
|-----------------------------------------------------|------------------|
| Final Conclusion: ■ Pass □ Fail                     |                  |
| Final QC Manager Approval (Signature): <i>Marwa</i> | Date: 12.03.2024 |

QC Release Stamp:



# Certificate of Analysis for Blood Grouping Kit

## 1- Product Identification:

|                                                 |                                                     |                              |                                      |
|-------------------------------------------------|-----------------------------------------------------|------------------------------|--------------------------------------|
| <b>Product Name : Anti-B monoclonal Reagent</b> | <b>Catalog No. (Variant Code ) : 8.02.05.0.0010</b> | <b>Item Dispense #: 481</b>  | <b>Minimal Titer Accepted: 1/256</b> |
| <b>Lot #: 24020316</b>                          | <b>Mfg. Date: NA</b>                                | <b>Exp. Date: 2025/11/28</b> |                                      |

## 2- Sampling Plan:

| Date       | QC Test Method Used | Inspection level                   | AQL            | Determine the following by referring to Sampling Plan Sheet |                        |          |          |
|------------|---------------------|------------------------------------|----------------|-------------------------------------------------------------|------------------------|----------|----------|
|            |                     |                                    |                | Sample Size Code Letter                                     | Sample Size (Test QTY) | Accepted | Rejected |
| 11.02.2024 | <b>F13D</b>         | Physical Inspection: S-I           | 1.0            | <b>B</b>                                                    | <b>3</b>               | <b>0</b> | <b>1</b> |
| 11.02.2024 | <b>F13D</b>         | Biochemical Inspection: One sample | Not Applicable |                                                             |                        |          |          |

## 3- Physical Check:

| Applicable Test Type                                                          | Inspected Item and/or Criteria                                                         | Inspection Results |
|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|--------------------|
| ➤ Kit Assembly:                                                               | All components of the kit are present according to the outer label                     | ■ Pass □ Fail      |
| ➤ Item Color & Status:                                                        | Anti-A: Blue – Liquid NA                                                               | □ Pass □ Fail      |
|                                                                               | Anti-B: Yellow – Liquid                                                                | ■ Pass □ Fail      |
|                                                                               | Anti-D: Yellowish – Liquid NA                                                          | □ Pass □ Fail      |
|                                                                               | Anti-AB: Yellowish – Liquid NA                                                         | □ Pass □ Fail      |
| ➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense: | Anti-A NA                                                                              | □ Pass □ Fail      |
|                                                                               | Anti-B 10 ml                                                                           | ■ Pass □ Fail      |
|                                                                               | Anti-D NA                                                                              | □ Pass □ Fail      |
|                                                                               | Anti-AB NA                                                                             | □ Pass □ Fail      |
| ➤ Labels:                                                                     | Correct label orientation                                                              | ■ Pass □ Fail      |
|                                                                               | Correct label position                                                                 | ■ Pass □ Fail      |
|                                                                               | Clear printing                                                                         | ■ Pass □ Fail      |
| ➤ Package Insert:                                                             | Clear printing and correct folding                                                     | ■ Pass □ Fail      |
|                                                                               | Correct code, version and brand as mentioned in Item Dispense                          | ■ Pass □ Fail      |
|                                                                               | Address as mentioned on box design                                                     | ■ Pass □ Fail      |
| ➤ Closing Cap:                                                                | No leakage and closed well                                                             | ■ Pass □ Fail      |
| ➤ Dropper Function:                                                           | Able to withdraw the reagent                                                           | ■ Pass □ Fail      |
| ➤ Quantity/Kit:                                                               | Compatible with the quantity mentioned in the outer label<br>• Record the QTY/Kit: 2/1 | ■ Pass □ Fail      |
| ➤ Final Result:                                                               | ■ Pass □ Fail; justify .....NA.....                                                    |                    |

|                                                    |                  |             |
|----------------------------------------------------|------------------|-------------|
| Done by QC Officer/Supervisor (Sign.): <i>Toga</i> | Date: 11.02.2024 | Time: 11:20 |
|----------------------------------------------------|------------------|-------------|

#### 4- Biochemical Check:

**A. Direct Slide Method:** Interpret the results by referring to Table (01)

|                                                    |                        |                                     |                        |                         |                        |                 |                        |
|----------------------------------------------------|------------------------|-------------------------------------|------------------------|-------------------------|------------------------|-----------------|------------------------|
| Pipette #:157                                      |                        |                                     |                        | Pipette Code: E21PiQ157 |                        |                 |                        |
| <b>Anti A</b>                                      |                        | <b>Anti -B</b>                      |                        | <b>Anti-AB</b>          |                        | <b>Anti-D</b>   |                        |
| A (lot No: NA)                                     |                        | B ( Lot no: fresh sample)           |                        | AB (Lot no: NA )        |                        | O+(Lot no: NA ) |                        |
| Reaction time                                      | Agglutination strength | Reaction time                       | Agglutination strength | Reaction time           | Agglutination strength | Reaction time   | Agglutination strength |
| NA                                                 | NA                     | 2 Sec                               | +4                     | NA                      | NA                     | NA              | NA                     |
| ➤ Final Result:                                    |                        | ■ Pass □ Fail; justify .....NA..... |                        |                         |                        |                 |                        |
| Done by QC Officer/Supervisor (Sign.): <i>Toga</i> |                        |                                     |                        | Date: 11.02.2024        |                        | Time: 08:32     |                        |

#### B. Sensitivity test

|                                             |                  |                                     |                 |        |                         |        |                                   |    |                |    |
|---------------------------------------------|------------------|-------------------------------------|-----------------|--------|-------------------------|--------|-----------------------------------|----|----------------|----|
| Pipette #: 157                              |                  |                                     |                 |        | Pipette Code: E21PiQ157 |        |                                   |    |                |    |
| Type of Test                                |                  |                                     | Anti-A          |        | Anti-B                  |        | Anti-AB                           |    | Anti-D         |    |
| Sensitivity                                 | Tube Test Method | Type of Cell Suspension             | A (Lot no: NA ) |        | B ( Lot no: BC240211)   |        | A (Lot no: NA )<br>B (Lot no NA ) |    | O+ (Lot noNA ) |    |
|                                             |                  | Result                              | 1:2             | NA     | 1:2                     | +4     | 1:2                               | NA | 1:2            | NA |
|                                             |                  |                                     | 1:4             | NA     | 1:4                     | +3     | 1:4                               | NA | 1:4            | NA |
|                                             |                  |                                     | 1:8             | NA     | 1:8                     | +3     | 1:8                               | NA | 1:8            | NA |
|                                             |                  |                                     | 1:16            | NA     | 1:16                    | +2     | 1:16                              | NA | 1:16           | NA |
|                                             |                  |                                     | 1:32            | NA     | 1:32                    | +2     | 1:32                              | NA | 1:32           | NA |
|                                             |                  |                                     | 1:64            | NA     | 1:64                    | +2     | 1:64                              | NA | 1:64           | NA |
|                                             |                  |                                     | 1:128           | NA     | 1:128                   | +1     | 1:128                             | NA | 1:128          | NA |
|                                             |                  |                                     | 1:256           | NA     | 1:256                   | +1     | 1:256                             | NA | 1:256          | NA |
|                                             |                  |                                     | 1:512           | NA     | 1:512                   | -ve    | 1:512                             | NA | 1:512          | NA |
|                                             |                  | 1:1024                              | NA              | 1:1024 | -ve                     | 1:1024 | NA                                |    |                |    |
| ➤ Final Result:                             |                  | ■ Pass □ Fail; justify .....NA..... |                 |        |                         |        |                                   |    |                |    |
| Done by QC Officer/Supervisor (Sign.): Toga |                  |                                     |                 |        | Date: 11.02.2024        |        | Time: 08:35                       |    |                |    |

| Table (01)              |                    |                |                        |
|-------------------------|--------------------|----------------|------------------------|
| Blood Grouping Reagents | Control Cell       | Reaction Time  | Agglutination Strength |
| Anti-A                  | A - Cell           | Up to 3 second | +4                     |
| Anti-B                  | B-Cell             | Up to 3 second | +4                     |
| Anti-AB                 | A B-Cell           | Up to 3 second | +3/+4                  |
| Anti -D                 | O RH positive cell | Up to 5 second | +3                     |

**Final Conclusion:** ☒ Pass ☐ Fail

**Final QC Manager Approval (Signature):** *Marwa*

**Date:** 11.02.2024

**QC Release Stamp:**



# Certificate of Analysis for Blood Grouping Kit

## 1- Product Identification:

|                                                    |                                                     |                              |                                     |
|----------------------------------------------------|-----------------------------------------------------|------------------------------|-------------------------------------|
| <b>Product Name : Anti-D IgG/IgM Blend Reagent</b> | <b>Catalog No. (Variant Code ) : 8.02.07.0.0010</b> | <b>Item Dispense #: 617</b>  | <b>Minimal Titer Accepted: 1/64</b> |
| <b>Lot #: 24021223</b>                             | <b>Mfg. Date: NA</b>                                | <b>Exp. Date: 2025/12/06</b> |                                     |

## 2- Sampling Plan:

| Date       | QC Test Method Used | Inspection level                   | AQL            | Determine the following by referring to Sampling Plan Sheet |                        |          |          |
|------------|---------------------|------------------------------------|----------------|-------------------------------------------------------------|------------------------|----------|----------|
|            |                     |                                    |                | Sample Size Code Letter                                     | Sample Size (Test QTY) | Accepted | Rejected |
| 19.02.2024 | <b>F13D</b>         | Physical Inspection: S-I           | 1.0            | <b>B</b>                                                    | <b>3</b>               | <b>0</b> | <b>1</b> |
| 19.02.2024 | <b>F13D</b>         | Biochemical Inspection: One sample | Not Applicable |                                                             |                        |          |          |

## 3- Physical Check:

| Applicable Test Type                                                          | Inspected Item and/or Criteria                                     | Inspection Results |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------|--------------------|
| ➤ Kit Assembly:                                                               | All components of the kit are present according to the outer label | ■ Pass □ Fail      |
| ➤ Item Color & Status:                                                        | Anti-A: Blue – Liquid NA                                           | □ Pass □ Fail      |
|                                                                               | Anti-B: Yellow – Liquid NA                                         | □ Pass □ Fail      |
|                                                                               | Anti-D: Yellowish – Liquid                                         | ■ Pass □ Fail      |
|                                                                               | Anti-AB: Yellowish – Liquid NA                                     | □ Pass □ Fail      |
| ➤ Item Size/ Reagent Size is compatible with that requested in Item Dispense: | Anti-A NA                                                          | □ Pass □ Fail      |
|                                                                               | Anti-B NA                                                          | □ Pass □ Fail      |
|                                                                               | Anti-D 10 ml                                                       | ■ Pass □ Fail      |
|                                                                               | Anti-AB NA                                                         | □ Pass □ Fail      |
| ➤ Labels:                                                                     | Correct label orientation                                          | ■ Pass □ Fail      |
|                                                                               | Correct label position                                             | ■ Pass □ Fail      |
|                                                                               | Clear printing                                                     | ■ Pass □ Fail      |
| ➤ Package Insert:                                                             | Clear printing and correct folding                                 | ■ Pass □ Fail      |
|                                                                               | Correct code, version and brand as mentioned in Item Dispense      | ■ Pass □ Fail      |
|                                                                               | Address as mentioned on box design                                 | ■ Pass □ Fail      |
| ➤ Closing Cap:                                                                | No leakage and closed well                                         | ■ Pass □ Fail      |
| ➤ Dropper Coloring / Titer (CE Blood Grouping):                               | Anti A (High titer (1/512): Blue cap with black bulb NA            | □ Pass □ Fail      |
|                                                                               | Anti A (Low titer (1/256): Blue cap with grey bulb NA              | □ Pass □ Fail      |
|                                                                               | Anti B (High titer (1/512): Yellow cap with black bulb NA          | □ Pass □ Fail      |
|                                                                               | Anti B (Low titer (1/256): Yellow cap with grey bulb NA            | □ Pass □ Fail      |

|                                                                                  |                                                                                          |                               |                               |
|----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-------------------------------|-------------------------------|
|                                                                                  | Anti AB (High titer (1/512): Grey cap with black bulb NA                                 | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti AB (Low titer (1/256): Grey cap with grey bulb NA                                   | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti D (High titer (1/128): Black cap with black bulb NA                                 | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti D (Low titer (1/64): Black cap with grey bulb NA                                    | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Dropper Coloring / Titer<br>(None CE Blood Grouping):                          | Anti A (High titer (1/512): White cap with black bulb NA                                 | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti A (Low titer (1/256): White cap with white bulb NA                                  | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti B (High titer (1/512): White cap with black bulb NA                                 | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti B (Low titer (1/256): White cap with white bulb NA                                  | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti AB (High titer (1/512): White cap with black bulb NA                                | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti AB (Low titer (1/256): White cap with white bulb NA                                 | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti D (High titer (1/128): Black cap with white bulb NA                                 | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti D (Low titer (1/64): Gray cap with white bulb                                       | ■Pass                         | <input type="checkbox"/> Fail |
|                                                                                  | Anti D (IgM) (Low titer (1/64)): Grey cap with Black bulb NA                             | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti D (IgM) (High titer (1/128)): Black cap with black bulb NA                          | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti D (IgG) (Low titer (1/64)): Grey cap with black bulb NA                             | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti D (IgG) (High titer (1/128)): Black cap with black bulb NA                          | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Dropper Coloring / Titer<br>(Real Titer (256) / Non CE Blood Grouping):        | Anti A (White cap with white bulb) NA                                                    | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti B (White cap with white bulb) NA                                                    | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
|                                                                                  | Anti AB (White cap with white bulb) NA                                                   | <input type="checkbox"/> Pass | <input type="checkbox"/> Fail |
| ➤ Dropper Function:                                                              | Able to withdraw the reagent                                                             | ■ Pass                        | <input type="checkbox"/> Fail |
| ➤ Quantity/Kit:                                                                  | Compatible with the quantity mentioned in the outer label<br>• Record the QTY/Kit: (2/1) | ■Pass                         | <input type="checkbox"/> Fail |
| ➤ Final Result:                                                                  | ■Pass <input type="checkbox"/> Fail; justify .....NA.....                                |                               |                               |
| Done by QC Officer/Supervisor (Sign.): <i>rayan</i> Date: 19.02.2024 Time: 11:30 |                                                                                          |                               |                               |

#### 4- Biochemical Check:

##### A. Direct Slide Method: Interpret the results by referring to Table (01)

|                                                                                       |                        |                                     |                        |                         |                        |                           |                        |
|---------------------------------------------------------------------------------------|------------------------|-------------------------------------|------------------------|-------------------------|------------------------|---------------------------|------------------------|
| Pipette #:157                                                                         |                        |                                     |                        | Pipette Code: E21PiQ157 |                        |                           |                        |
| Anti A                                                                                |                        | Anti –B                             |                        | Anti-AB                 |                        | Anti-D                    |                        |
| A (lot No: )                                                                          |                        | B ( Lot no: )                       |                        | AB (Lot no: )           |                        | O+(Lot no: fresh sample ) |                        |
| Reaction time                                                                         | Agglutination strength | Reaction time                       | Agglutination strength | Reaction time           | Agglutination strength | Reaction time             | Agglutination strength |
| NA                                                                                    | NA                     | NA                                  | NA                     | NA                      | NA                     | 2 Sec                     | +3                     |
| ➤ Final Result:                                                                       |                        | ■ Pass □ Fail; justify .....NA..... |                        |                         |                        |                           |                        |
| Done by QC Officer/Supervisor (Sign.): <i>rayan</i> Date: 19.02.2024      Time: 10:40 |                        |                                     |                        |                         |                        |                           |                        |

##### B. Sensitivity test

|                |                  |                         |                 |                         |                             |                          |  |
|----------------|------------------|-------------------------|-----------------|-------------------------|-----------------------------|--------------------------|--|
| Pipette #: 157 |                  |                         |                 | Pipette Code: E21PiQ157 |                             |                          |  |
| Type of Test   |                  |                         | Anti-A          | Anti-B                  | Anti-AB                     | Anti-D                   |  |
| Sensitivity    | Tube Test Method | Type of Cell Suspension | A (Lot no: NA ) | B ( Lot no: NA )        | A (Lot no: )<br>B (Lot no ) | O+<br>(Lot no :OC240219) |  |

|                                                                                       |  |                                     |        |    |        |    |        |    |       |     |
|---------------------------------------------------------------------------------------|--|-------------------------------------|--------|----|--------|----|--------|----|-------|-----|
|                                                                                       |  | Result                              | 1:2    | NA | 1:2    | NA | 1:2    | NA | 1:2   | +3  |
|                                                                                       |  |                                     | 1:4    | NA | 1:4    | NA | 1:4    | NA | 1:4   | +2  |
|                                                                                       |  |                                     | 1:8    | NA | 1:8    | NA | 1:8    | NA | 1:8   | +2  |
|                                                                                       |  |                                     | 1:16   | NA | 1:16   | NA | 1:16   | NA | 1:16  | +2  |
|                                                                                       |  |                                     | 1:32   | NA | 1:32   | NA | 1:32   | NA | 1:32  | +1  |
|                                                                                       |  |                                     | 1:64   | NA | 1:64   | NA | 1:64   | NA | 1:64  | +1  |
|                                                                                       |  |                                     | 1:128  | NA | 1:128  | NA | 1:128  | NA | 1:128 | +/- |
|                                                                                       |  |                                     | 1:256  | NA | 1:256  | NA | 1:256  | NA | 1:256 | -ve |
|                                                                                       |  |                                     | 1:512  | NA | 1:512  | NA | 1:512  | NA | 1:512 | -ve |
|                                                                                       |  |                                     | 1:1024 | NA | 1:1024 | NA | 1:1024 | NA |       |     |
| ➤ Final Result:                                                                       |  | ■ Pass □ Fail; justify .....NA..... |        |    |        |    |        |    |       |     |
| Done by QC Officer/Supervisor (Sign.): <i>rayan</i> Date: 19.02.2024      Time: 10:42 |  |                                     |        |    |        |    |        |    |       |     |

| Table (01)              |                    |                |                        |
|-------------------------|--------------------|----------------|------------------------|
| Blood Grouping Reagents | Control Cell       | Reaction Time  | Agglutination Strength |
| Anti-A                  | A - Cell           | Up to 3 second | +4                     |
| Anti-B                  | B-Cell             | Up to 3 second | +4                     |
| Anti-AB                 | A B-Cell           | Up to 3 second | +3/+4                  |
| Anti -D                 | O RH positive cell | Up to 5 second | +3                     |

|                                                     |                  |
|-----------------------------------------------------|------------------|
| Final Conclusion: ■ Pass □ Fail                     |                  |
| Final QC Manager Approval (Signature): <i>Marwa</i> | Date: 19.02.2024 |

QC Release Stamp:





# PRODUCT CATALOGUE

2023-2024

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# INTRODUCTION

Atlas Medical GmbH was established in 1996 as a manufacturer and supplier of quality Diagnostic Reagents and Kits. Our products are sold in over 80 countries worldwide.

The company is located at the Cambridge Science Park, Cambridge, UK. In addition to the UK site, the company has offices in Germany and Turkey as well as two purpose-built modern facilities in both Jordan and Malaysia. We take quality assurance very seriously and strive to produce goods to the highest standards known in the industry, including, ISO13485 & CE mark and US FDA standards. Our R&D team constantly develops and innovates novel products that significantly contribute to the advancement of the Diagnostic Industry.

## Vision

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

## Mission

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

## Objectives



*High and Consistent Quality*



*Satisfied Customer*



*Continuous Improvement & Innovation*



*Care for the Environment & Working Conditions*



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Email : info@atlas-medical.com



## Our Markets

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



## Standards



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

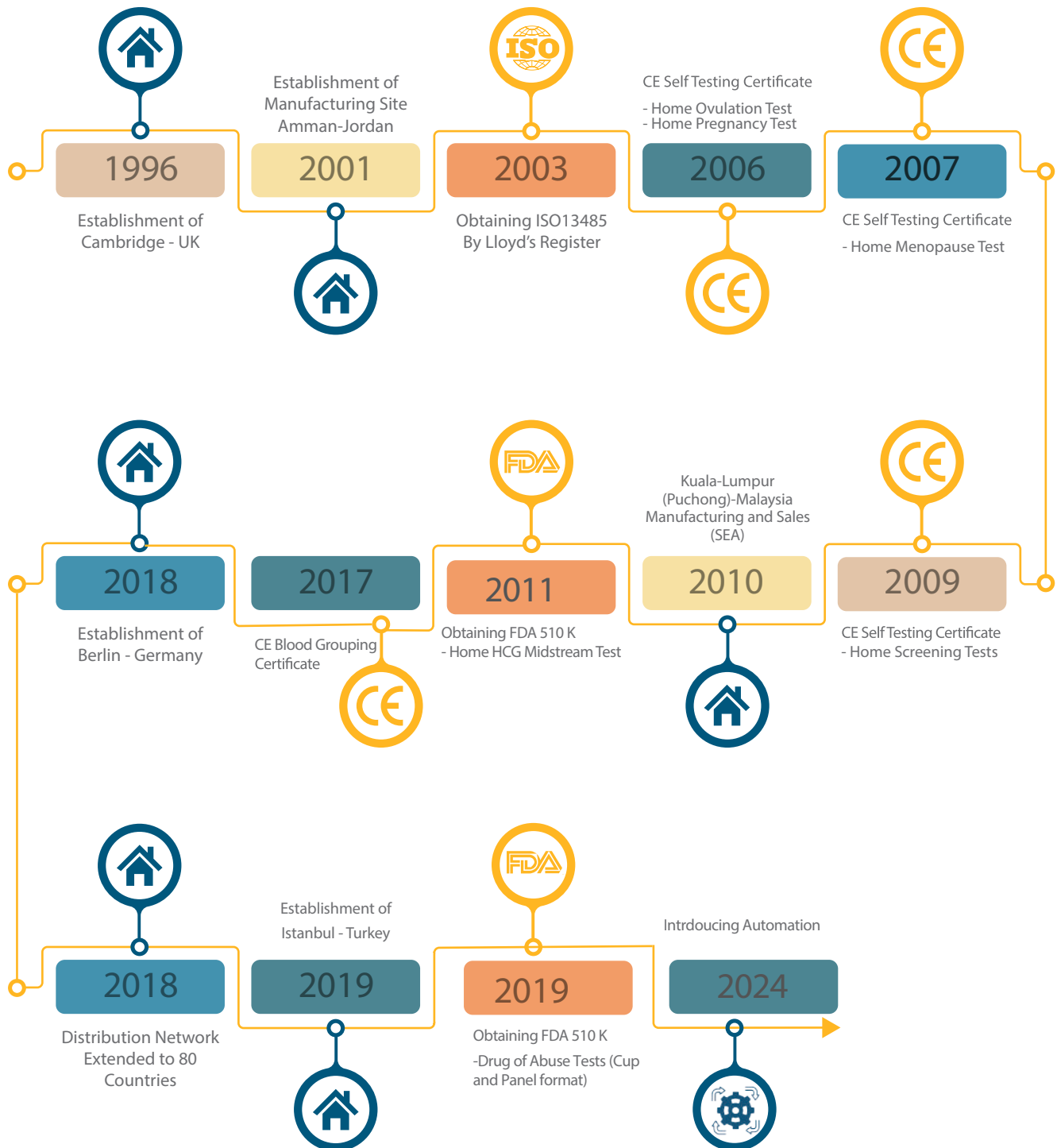


To complete the quality assurance scheme the company has put in place a robust Quality Management and Enhancement System that has concluded in the successful attainment of ISO13485: 2016 certificate



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

# MILESTONES



# 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<br>8.00.00.0.0100 | CRP Latex Kit             | 50 Tests<br>100 Tests |
| 8.00.01.0.0050<br>8.00.01.0.0100 | CRP Latex Kit with Buffer | 50 Tests<br>100 Tests |
| 8.00.02.0.0050<br>8.00.02.0.0100 | ASO Latex Kit             | 50 Tests<br>100 Tests |
| 8.00.03.0.0050<br>8.00.03.0.0100 | ASO Latex Kit with Buffer | 50 Tests<br>100 Tests |
| 8.00.04.0.0050<br>8.00.04.0.0100 | RF Latex Kit              | 50 Tests<br>100 Tests |
| 8.00.05.0.0050<br>8.00.05.0.0100 | RF Latex Kit with Buffer  | 50 Tests<br>100 Tests |
| 8.00.07.0.0050<br>8.00.07.0.0100 | hCG Latex Kit             | 50 Tests<br>100 Tests |
| 8.00.11.0.0050<br>8.00.11.0.0100 | SLE Latex Kit             | 50 Tests<br>100 Tests |
| 8.00.17.0.0050<br>8.00.17.0.0100 | D-Dimer Latex Kit         | 50 Tests<br>100 Tests |
| 8.00.21.0.0050<br>8.00.21.0.0100 | Waler Rose Kit            | 50 Tests<br>100 Tests |
| 8.00.08.0.0050<br>8.00.08.0.0100 | IM Latex Kit              | 50 Tests<br>100 Tests |
| 8.00.12.0.0050<br>8.00.12.0.0100 | Staphylococcus Latex Kit  | 50 Tests<br>100 Tests |
| 8.00.13.0.0300                   | Streptococcus Latex Kit   | 50 Tests              |



| Item Code                        | Item Description           | Sizes                 |
|----------------------------------|----------------------------|-----------------------|
| 8.00.09.0.0050<br>8.00.09.0.0100 | Toxo Latex Kit             | 50 Tests<br>100 Tests |
| 8.00.10.0.0050<br>8.00.10.0.0100 | Toxo Latex Kit with Buffer | 50 Tests<br>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.



| Item Code      | Item Description                      | Sizes    |
|----------------|---------------------------------------|----------|
| 8.44.00.0.0050 | RF Turbidimetric Latex Kit            | 50 Tests |
| 8.44.01.0.0050 | CRP Turbidimetric Latex Kit           | 50 Tests |
| 8.44.02.0.0050 | ASO Turbidimetric Latex Kit           | 50 Tests |
| 8.44.03.0.0050 | D-Dimer Turbidimetric Latex Kit       | 50 Tests |
| 8.44.04.0.0050 | Microalbumine Turbidimetric Latex Kit | 50 Tests |
| 8.44.05.0.0050 | Ferritin Turbidimetric Latex Kit      | 50 Tests |
| 8.44.06.0.0050 | Transferrin Turbidimetric Latex Kit   | 50 Tests |
| 8.44.08.0.0050 | HbA1C Turbidimetric Latex Kit         | 50 Tests |

## 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.

# SYPHILIS KITS

## Overview



| Item Code      | Item Description       | Sizes      |
|----------------|------------------------|------------|
| 8.00.18.0.0100 | RPR Carbon Antigen Kit | 100 Tests  |
| 8.00.18.0.0500 |                        | 500 Tests  |
| 8.00.19.0.0100 | TPHA Kit               | 100 Tests  |
| 8.00.19.0.0200 |                        | 200 Tests  |
| 8.00.20.0.0250 | VDRL Kit               | 250 Tests  |
| 8.00.20.0.0500 |                        | 500 Tests  |
| 8.00.20.0.2500 |                        | 2500 Tests |
| 8.00.20.1.0250 | VDRL Kit with controls | 250 Tests  |
| 8.00.20.1.2500 |                        | 2500 Tests |

## Features

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



# FEBRILE ANTIGENS



## Overview

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

## Features

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

| Item Code      | Item Description                                                                                       | Sizes       |
|----------------|--------------------------------------------------------------------------------------------------------|-------------|
| 8.01.00.0.0005 | Brucella Rose Bengal Kit                                                                               | 5ml/vial    |
| 8.01.00.0.0050 |                                                                                                        | 50 Tests    |
| 8.01.00.0.0100 |                                                                                                        | 100 Tests   |
| 8.01.01.0.0005 | Salmonella OA Reagent                                                                                  | 5 ml/vial   |
| 8.01.01.1.0040 |                                                                                                        | 8x5 ml      |
| 8.01.01.0.0050 |                                                                                                        | 10x5 ml     |
| 8.01.02.0.0005 | Salmonella OB Reagent                                                                                  | 5 ml/vial   |
| 8.01.03.0.0005 | Salmonella OC Reagent                                                                                  | 5 ml/vial   |
| 8.01.04.0.0005 | Salmonella OD Reagent                                                                                  | 5 ml/vial   |
| 8.01.05.0.0005 | Salmonella HA Reagent                                                                                  | 5 ml/vial   |
| 8.01.06.0.0005 | Salmonella HB Reagent                                                                                  | 5 ml/vial   |
| 8.01.07.0.0005 | Salmonella HC Reagent                                                                                  | 5 ml/vial   |
| 8.01.08.0.0005 | Salmonella HD Reagent                                                                                  | 5 ml/vial   |
| 8.01.10.0.0005 | Brucella Abortus Reagent                                                                               | 5 ml/vial   |
| 8.01.11.0.0005 | Brucella Melitensis Reagent                                                                            | 5 ml/vial   |
| 8.01.12.0.0005 | Proteus OX2 Reagent                                                                                    | 5 ml/vial   |
| 8.01.13.0.0005 | Proteus OX19 Reagent                                                                                   | 5 ml/vial   |
| 8.01.14.0.0005 | Proteus OXK Reagent                                                                                    | 5 ml/vial   |
| 8.01.15.0.0010 | Brucella Antigen Kit ( Brucella melitensis, Brucella abortus )                                         | 2 vials/Box |
| 8.01.15.2.0010 | Brucella Antigen Kit with Controls, (5ml Brucella melitensis, 5ml Brucella abortus, 2x0.5 ml Controls) | 2 vials/Box |
| 8.01.16.0.0040 | Salmonella Antigen Set ( 8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD )                                  | 8x5 ml      |
| 8.01.16.1.0040 | Salmonella Antigen Set ( 8 Antigens: OA, OB, OC, OD, HA, HB, HC, HD ) with 2x1.0 ml Controls           | 8x5 ml      |

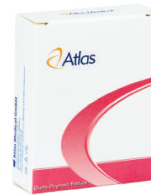
| Item Code      | Item Description                                                                                                                 | Sizes     |
|----------------|----------------------------------------------------------------------------------------------------------------------------------|-----------|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



# BLOOD GROUPING REAGENTS

## Overview

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



## Features

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



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



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

# HEMATOLOGY TESTS

## Overview

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

## Features

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



### Hemoglobin Reagents

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



### Co-aggulation Reagents

| Item Code                                          | Item Description                                           | Sizes                                                 |
|----------------------------------------------------|------------------------------------------------------------|-------------------------------------------------------|
| 8.02.40.1.0010<br>8.02.40.1.0050<br>8.02.40.1.0100 | PT Calcium Rabbit Brain Thromboplastin, Liquid             | 2ml (20 Tests)<br>5ml (50 Tests)<br>10ml (100 Tests)  |
| 8.02.41.1.0040<br>8.02.41.1.0050<br>8.02.41.1.0100 | APTT (PTT) Micronised Silica Platelet Substitute           | 2ml (40 Tests)<br>2.5ml (50 Tests)<br>5ml (100 Tests) |
| 8.02.44.0.0040<br>8.02.44.0.0100                   | PT Kit with Normal Control                                 | 2x2ml + 1ml<br>2x10ml + 1ml                           |
| 8.02.45.0.0080<br>8.02.45.0.0200                   | APTT (PTT) Kit with Normal Control                         | 2x2ml + 1ml<br>2x10ml + 1ml                           |
| 8.02.48.0.0010<br>8.02.48.0.0100                   | Calcium Chloride, 25 mM                                    | 10ml/vial<br>10ml/vial /<br>10 Vials / Box            |
| 8.02.60.0.0006                                     | Normal Coagulation Control                                 | 6x1ml                                                 |
| 8.02.61.0.0006                                     | Abnormal Coagulation Control                               | 6x1ml                                                 |
| 8.02.45.1.0080                                     | APTT (PTT) Kit (Calcium Chloride reagent + Normal Control) | 80 Tests                                              |
| 8.02.69.0.0100                                     | Fibrinogen Test kit KIT                                    | 100 Tests                                             |

# SICKLE CELL KITS

## Overview

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

## Features

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



| Item Code                        | Item Description                              | Sizes               |
|----------------------------------|-----------------------------------------------|---------------------|
| 8.02.67.0.0050<br>8.02.67.0.0100 | Sickle Cell Kit, 50 Tests<br>Sickle Cell Kit, | 50 Test<br>100 Test |
| 8.02.68.0.0001                   | Sickle Cell positive & negative control set   | 1ml each            |

# INFECTIOUS DISEASE RAPID TESTS

## ANTIBODY TESTING

### Overview

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

### Features

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



| Item Code                        | Item Description                                                                   | Sizes                 |
|----------------------------------|------------------------------------------------------------------------------------|-----------------------|
| 8.04.20.0.0001<br>8.04.20.0.0020 | H.pylori Antibody Test Cassette,<br>Whole Blood/Serum/Plasma, Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.21.0.0001<br>8.04.21.0.0020 | H.pylori Antibody Test Cassette,<br>Serum/Plasma, Individually Pouched             | Bulk<br>20 Tests/Box  |
| 8.04.22.0.0001<br>8.04.22.0.0100 | H.pylori Antibody Test Strip,<br>Serum/Plasma, Individually Pouched                | Bulk<br>100 Tests/Box |
| 8.04.41.0.0001<br>8.04.41.0.0020 | Syphilis Antibody Test Cassette,<br>Whole Blood/Serum/Plasma, Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.42.0.0001<br>8.04.42.0.0020 | Syphilis Antibody Test Cassette,<br>Serum/Plasma, Individually Pouched             | Bulk<br>20 Tests/Box  |
| 8.04.43.0.0001<br>8.04.43.0.0100 | Syphilis Antibody Test Strip,<br>Serum/Plasma, Individually Pouched                | Bulk<br>100 Tests/Box |



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

# INFECTIOUS DISEASE RAPID TESTS

## ANTIGEN TESTING



| Item Code                        | Item Description                                                            | Sizes               |
|----------------------------------|-----------------------------------------------------------------------------|---------------------|
| 8.04.23.1.0020                   | H.pylori Antigen Test Cassette, Stool Sample, Individually Pouched          | 20 Tests/Box        |
| 8.04.24.1.0025                   | H.pylori Antigen Test Strip, Stool Sample, Individually Pouched             | 25 Tests/Box        |
| 8.04.69.0.0020                   | Rotavirus Antigen Test Cassette, Stool Sample, Individually Pouched         | 20 Tests/Box        |
| 8.04.70.0.0025                   | Rotavirus Antigen Test Strip, Stool Sample, Individually Pouched            | 25 Tests/Box        |
| 8.04.71.0.0020                   | Adenovirus Antigen Test Cassette, Stool Sample, Individually Pouched        | 20 Tests/Box        |
| 8.04.72.0.0025                   | Adenovirus Antigen Test Strip, Stool Sample, Individually Pouched           | 25 Tests/Box        |
| 8.04.73.0.0020                   | Rota-Adeno Antigens Combo test Cassette, Stool Sample, Individually Pouched | 20 Tests/Box        |
| 8.04.74.0.0025                   | Rota-Adeno Antigens Combo test Strip, Stool Sample, Individually Pouched    | 25 Tests/Box        |
| 8.16.01.0.0020                   | Crypto Virus Test Cassette, Stool Sample, Individually Pouched              | 20 Tests/Box        |
| 8.16.02.0.0025                   | Crypto Virus Test Strip, Stool Sample, Individually Pouched                 | 25 Tests/Box        |
| 8.16.31.0.0020                   | Giardia Test Cassette, Stool Sample, Individually Pouched                   | 20 Tests/Box        |
| 8.16.30.0.0025                   | Giardia Test Strip, Stool Sample, Individually Pouched                      | 25 Tests/Box        |
| 8.16.33.0.0020                   | Crypto-Giardia Test Cassette, Stool Sample, Individually Pouched            | 20 Tests/Box        |
| 8.16.32.0.0025                   | Crypto-Giardia Test Strip, Stool Sample, Individually Pouched               | 25 Tests/Box        |
| 8.16.41.0.0020                   | E.coli Test Cassette, Stool Sample, Individually Pouched                    | 20 Tests/Box        |
| 8.16.40.0.0025                   | E.coli Test Strip, Stool Sample, Individually Pouched                       | 25 Tests/Box        |
| 8.66.01.0.0001<br>8.66.01.0.0020 | COVID-19 Antgen Test Cassette, Nasal Swab, Individually pouched             | Bulk<br>20Test/ Box |
| 8.66.02.0.0001<br>8.66.02.0.0020 | COVID-19 Combo Antigen & Influenza, A+B Test , Individually pouched         | Bulk<br>20Test/ Box |

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



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



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

# URINE REAGENT STRIPS

## Overview

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

## Features

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



| Item Code                        | Item Description                                                                                                                      | Sizes                   |
|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| 8.03.00.0.0050<br>8.03.00.0.0100 | URS 1 Parameter: Glucose                                                                                                              | 50 Strips<br>100 Strips |
| 8.03.01.0.0050<br>8.03.01.0.0100 | URS 1 Parameter: Protein                                                                                                              | 50 Strips<br>100 Strips |
| 8.03.02.0.0050<br>8.03.02.0.0100 | URS 1 Parameter: Ketone                                                                                                               | 50 Strips<br>100 Strips |
| 8.03.45.0.0050                   | URS 1 Parameter Blood, (5mm)                                                                                                          | 50 Strips               |
| 8.03.03.0.0050<br>8.03.03.0.0100 | URS 2 Parameters: Glucose, Ketone                                                                                                     | 50 Strips<br>100 Strips |
| 8.03.04.0.0050<br>8.03.04.0.0100 | URS 2 Parameters: Glucose, Protein                                                                                                    | 50 Strips<br>100 Strips |
| 8.03.05.0.0100                   | URS 2 Parameters: Sample end: Urobilinogen, Bilirubin                                                                                 | 100 Strips              |
| 8.03.19.0.0050<br>8.03.19.0.0100 | URS 2 Parameters(5mm): Sample End: Creatinine, pH                                                                                     | 50 Strips<br>100 Strips |
| 8.03.06.0.0050<br>8.03.06.0.0100 | URS 3 Parameters: Protein, pH, Glucose                                                                                                | 50 Strips<br>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<br>8.03.10.0.0100 | URS 3 Parameters: Sample end:Protein, Specific Gravity, Creatinine                                                                    | 50 Strips<br>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<br>8.03.13.0.0100 | URS 5 Parameters: Glucose, Protein, Ketone, pH, Blood                                                                                 | 50 Strips<br>100 Strips |
| 8.03.25.0.0100                   | URS 5 Parameters(5mm): Blood, Glucose, Protein, Nitrite, Leukocytes                                                                   | 100 Strips              |
| 8.03.14.0.0100                   | URS 6 Parameters: Leukocytes, Nitrite, Protein, pH, Blood, Glucose                                                                    | 100 Strips              |
| 8.03.44.0.0100                   | URS 7 Parameter: Glucose, Ketone, Protein, pH, Blood, Bilirubin, Urobilinogen                                                         | 100 Strips              |
| 8.03.23.0.0100                   | URS 8 Parameters: Glucose, Protein, pH, Ketone, Urobilinogen, Bilirubin, Blood, Nitrite                                               | 100 Strips              |
| 8.03.15.0.0100                   | URS 9 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose                             | 100 Strips              |
| 8.03.16.0.0100                   | URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose                | 100 Strips              |
| 8.03.17.0.0050<br>8.03.17.0.0100 | URS 10 Parameters: Sample end: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid | 50 Strips<br>100 Strips |
| 8.03.18.0.0100                   | URS 11 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid | 100 Strips              |
| 8.03.47.0.0100                   | URS 14 Parameters (ASC, GLU, BIL, KET, SG, BLO, PH, PRO, URO, NIT, LEU, ALB, CRE, CA)                                                 | 100 Strips              |

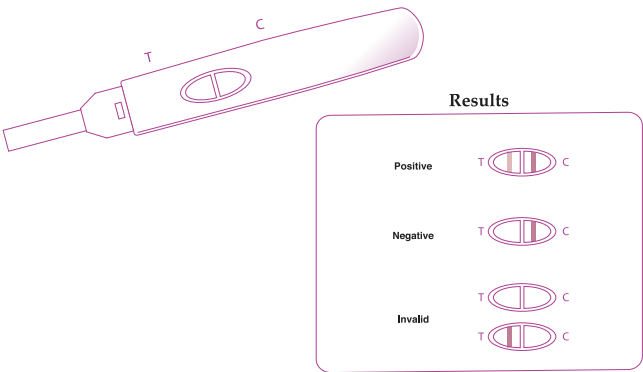
# FERTILITY RAPID TESTS

## Overview

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

## Features

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



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

# INFLAMMATION AND CANCER MARKERS



## Overview

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

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

## Features

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



| Item Code                        | Item Description                                                   | Sizes                 |
|----------------------------------|--------------------------------------------------------------------|-----------------------|
| 8.16.28.0.0001<br>8.16.28.0.0020 | PSA Test Cassette, Whole Blood/Serum/Plasma), Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.39.0.0001<br>8.04.39.0.0020 | PSA Test Cassette, Serum/Plasma, Individually Pouched              | Bulk<br>20 Tests/Box  |
| 8.04.40.0.0001<br>8.04.40.0.0100 | PSA Test Strip, Serum/Plasma, Individually Pouched                 | Bulk<br>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<br>8.04.45.0.0020 | Troponin I Test Cassette, Whole Blood/Serum/Plasma, Individually Pouched | Bulk<br>20 Tests/Box |

## Features

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

# DOA RAPID TESTS

## Overview

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

## Features

Can be supplied in cassette , strip, panel and cup formats.

The kits are conveniently packed in different kitsizes of 20,25,30,50 and 100 tests per kit.



### STRIP AND CASSETTE FORMAT

| Item Code                        | Item Description                                           | Sizes                 |
|----------------------------------|------------------------------------------------------------|-----------------------|
| 8.04.49.0.0001<br>8.04.49.0.0020 | Morphine Test Cassette, Urine, Individually Pouched        | Bulk<br>20 Tests/Box  |
| 8.04.50.0.0001<br>8.04.50.0.0100 | Morphine Test Strip, Urine, Individually Pouched           | Bulk<br>100 Tests/Box |
| 8.04.51.0.0001<br>8.04.51.0.0020 | Marijuana (THC) Test Cassette, Urine, Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.52.0.0001<br>8.04.52.0.0100 | Marijuana (THC) Test Strip, Urine, Individually Pouched    | Bulk<br>100 Tests/Box |
| 8.04.53.0.0001<br>8.04.53.0.0020 | Amphetamine Test Cassette, Urine, Individually Pouched     | Bulk<br>20 Tests/Box  |
| 8.04.54.0.0001<br>8.04.54.0.0100 | Amphetamine Test Strip, Urine, Individually Pouched        | Bulk<br>100 Tests/Box |
| 8.04.55.0.0001<br>8.04.55.0.0020 | Barbiturates Test Cassette, Urine, Individually Pouched    | Bulk<br>20 Tests/Box  |
| 8.04.56.0.0001<br>8.04.56.0.0100 | Barbiturates Test Strip, Urine, Individually Pouched       | Bulk<br>100 Tests/Box |
| 8.04.57.0.0001<br>8.04.57.0.0020 | Benzodiazepines Test Cassette, Urine, Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.58.0.0001<br>8.04.58.0.0100 | Benzodiazepines Test Strip, Urine, Individually Pouched    | Bulk<br>100 Tests/Box |
| 8.04.59.0.0001<br>8.04.59.0.0020 | Cocaine Test Cassette, Urine, Individually Pouched         | Bulk<br>20 Tests/Box  |
| 8.04.60.0.0001<br>8.04.60.0.0100 | Cocaine Test Strip, Urine, Individually Pouched            | Bulk<br>100 Tests/Box |
| 8.04.61.0.0001<br>8.04.61.0.0020 | Methamphetamine Test Cassette, Urine, Individually Pouched | Bulk<br>20 Tests/Box  |
| 8.04.62.0.0001<br>8.04.62.0.0100 | Methamphetamine Test Strip, Urine, Individually Pouched    | Bulk<br>100 Tests/Box |
| 8.04.63.0.0001<br>8.04.63.0.0020 | Methadone Test Cassette, Urine, Individually Pouched       | Bulk<br>20 Tests/Box  |
| 8.04.64.0.0001<br>8.04.64.0.0100 | Methadone Test Strip, Urine, Individually Pouched          | Bulk<br>100 Tests/Box |
| 8.04.65.0.0001<br>8.04.65.0.0020 | Phencyclidine Test Cassette, Urine, Individually Pouched   | Bulk<br>20 Tests/Box  |
| 8.04.66.0.0001<br>8.04.66.0.0100 | Phencyclidine Test Strip, Urine, Individually Pouched      | Bulk<br>100 Tests/Box |
| 8.16.47.0.0001<br>8.16.47.0.0020 | Fentanyl Test Cassette, Urine, Individually Pouched        | Bulk<br>20 Tests/Box  |

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

# ANTIBIOTIC SENSITIVITY DISCS



## Overview

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

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

## Features

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



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

| Item Code      | Item Description                                | Sizes      |
|----------------|-------------------------------------------------|------------|
| 8.39.01.0.0250 | AMIKACIN (30 µg) - AK                           | 5x50 Discs |
| 8.39.02.0.0250 | AMOXICILLIN (10 µg) - AX                        | 5x50 Discs |
| 8.39.03.0.0250 | AMOXICILLIN / CLAVULANATE (20 µg + 10 µg) - AMC | 5x50 Discs |
| 8.39.04.0.0250 | AMPICILLIN (10 µg) - AMP                        | 5x50 Discs |
| 8.39.05.0.0250 | AMPICILLIN / SULBACTAM (10 µg - 10 µg) - AS     | 5x50 Discs |
| 8.39.06.0.0250 | AZITHROMYCIN (15 µg) - AZM                      | 5x50 Discs |
| 8.39.07.0.0250 | AZTREONAM (30 µg) - AT                          | 5x50 Discs |
| 8.39.08.0.0250 | CEFACLOX (30 µg) - CF                           | 5x50 Discs |
| 8.39.09.0.0250 | CEFADROXIL (30 µg) - CD                         | 5x50 Discs |
| 8.39.10.0.0250 | CEFAZOLIN (30 µg) - CZ                          | 5x50 Discs |
| 8.39.11.0.0250 | CEFDINIR (5µg) - CDR                            | 5x50 Discs |
| 8.39.12.0.0250 | CEFIXIME (5 µg) - CFM                           | 5x50 Discs |
| 8.39.13.0.0250 | CEFOPERAZONE (75 µg) - CPZ                      | 5x50 Discs |
| 8.39.14.0.0250 | CEFOPERAZONE / SULBACTAM (75 µg + 30 µg) - CS   | 5x50 Discs |
| 8.39.15.0.0250 | CEFOTAXIME (30 µg) - CTX                        | 5x50 Discs |
| 8.39.16.0.0250 | CEFPIROME (30 µg) - CE                          | 5x50 Discs |
| 8.39.17.0.0250 | CEFPODOXIME (10 µg) - CPD                       | 5x50 Discs |
| 8.39.18.0.0250 | CEFPROZIL (30 µg) - CPR                         | 5x50 Discs |
| 8.39.19.0.0250 | CEFTAZIDIME (30 µg) - CAZ                       | 5x50 Discs |
| 8.39.20.0.0250 | CEFTIZOXIME (30 µg) - CZX                       | 5x50 Discs |
| 8.39.21.0.0250 | CEFTRIOXONE (30 µg) - CTR                       | 5x50 Discs |
| 8.39.22.0.0250 | CEFUROXIME (30 µg) - CXM                        | 5x50 Discs |
| 8.39.23.0.0250 | 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 | LEVOFLOXACIN (5 µg) - LE                        | 5x50 Discs |
| 8.39.40.0.0250 | LINCOMYCIN (15 µg) - LN                         | 5x50 Discs |
| 8.39.41.0.0250 | LINEZOLID (30 µg) - LZ                          | 5x50 Discs |
| 8.39.42.0.0250 | LOMEFLOXACIN (10 µg) - LOM                      | 5x50 Discs |
| 8.39.43.0.0250 | MEROPENEM (10 µg) - MRP                         | 5x50 Discs |
| 8.39.44.0.0250 | MINOCYCLINE (30 µg) - MI                        | 5x50 Discs |
| 8.39.45.0.0250 | MOXIFLOXACIN (5 µg) - MXF                       | 5x50 Discs |
| 8.39.46.0.0250 | NALIDIXIC ACID (30 µg) - NA                     | 5x50 Discs |
| 8.39.47.0.0250 | NITROFURANTOIN (300 µg) - NIT                   | 5x50 Discs |

# ANTIBIOTIC SENSITIVITY DISCS



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



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

# ELISA KITS

## Features

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



## Overview

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



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

# CLINICAL CHEMISTRY KITS

## Overview

Kits in this group measure concentrations of electrolytes , hormones, proteins, and other metabolic products in human blood , serum,plasma, CSF and urine .

Clinical Chemistry tests are indicated to assess systemic functions such liver function , kidney function , and endocrine and metabolic function .

Methods commonly used are colorimetric and kinetic.



## Features

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



| Item Code                        | Item Description                                   | Sizes              |
|----------------------------------|----------------------------------------------------|--------------------|
| 8.05.00.0.0250<br>8.05.00.0.0500 | Albumin Bromocresol Green                          | 2x125ml<br>4x125ml |
| 8.05.01.0.0030<br>8.05.01.0.0060 | Amylase                                            | 3x10ml<br>6x10ml   |
| 8.05.04.0.0250<br>8.05.04.0.0500 | Alkaline Phosphatase Kinetic, DGKC Method (Liquid) | 5x50ml<br>5x100ml  |
| 8.05.05.0.0250<br>8.05.05.0.0500 | Bilirubin Total (DMSO Method)                      | 2x125ml<br>4x125ml |
| 8.05.06.0.0250<br>8.05.06.0.0500 | Bilirubin Direct (DMSO Method)                     | 2x125ml<br>4x125ml |
| 8.05.07.0.0250<br>8.05.07.0.0500 | Bilirubin Total & Direct (DMSO Method)             | 2x125ml<br>4x125ml |
| 8.05.08.0.0250<br>8.05.08.0.0500 | Calcium Arsenazo III                               | 2x125ml<br>4x125ml |
| 8.05.09.0.0250<br>8.05.09.0.0500 | Calcium O-Cresolphthalein                          | 2x125ml<br>4x125ml |
| 8.05.10.0.0250<br>8.05.10.0.0500 | Chloride Thiocyanate Colorimetric                  | 2x125ml<br>4x125ml |
| 8.05.11.0.0250<br>8.05.11.0.0500 | Cholesterol Liquid (CHOD-POD)                      | 2x125ml<br>4x125ml |
| 8.05.13.0.0250<br>8.05.13.0.0500 | CK-MB Kinetic (Liquid)                             | 5x10ml<br>5x20ml   |
| 8.05.15.0.0250<br>8.05.15.0.0500 | CK-NAC Kinetic (Liquid)                            | 5x10ml<br>5x20ml   |



| Item Code                        | Item Description                             | Sizes                 |
|----------------------------------|----------------------------------------------|-----------------------|
| 8.05.16.0.0250<br>8.05.16.0.0500 | Creatinine Jaffe Color-Kinetic               | 2x125ml<br>4x125ml    |
| 8.05.17.0.0250<br>8.05.17.0.0500 | Glucose GOD-POD (Liquid)                     | 2x125ml<br>4x125ml    |
| 8.05.19.0.0250<br>8.05.19.0.0500 | GOT (AST) IFCC Kinetic (Liquid)              | 5x50ml<br>5x100ml     |
| 8.05.20.0.0250<br>8.05.20.0.0500 | GOT (AST) Reitman-Frankel Colorimetric       | 2x125ml<br>2x250ml    |
| 8.05.22.0.0250<br>8.05.22.0.0500 | GPT (ALT) IFCC Kinetic (Liquid)              | 5x50ml<br>5x100ml     |
| 8.05.23.0.0250<br>8.05.23.0.0500 | GPT (ALT) Reitman-Frankel Colorimetric       | 2x100ml<br>2x125ml    |
| 8.05.25.0.0250<br>8.05.25.0.0500 | Gamma GT Kinetic, Carboxy Substrate (Liquid) | 5x50ml<br>5x100ml     |
| 8.05.26.0.0250<br>8.05.26.0.0500 | HDL Cholesterol Precipitating Reagent        | 2x50ml<br>2x100ml     |
| 8.05.27.0.0250                   | Iron Ferrozine Colorimetric                  | 4x50ml                |
| 8.05.29.0.0250<br>8.05.29.0.0500 | LDH Pyruvate Kinetic UV DGKC (Liquid)        | 5x50ml<br>5x100ml     |
| 8.05.30.0.0250                   | Lipase Kinetic (Liquid)                      | 6x10ml                |
| 8.05.31.0.0250<br>8.05.31.0.0500 | Magnesium Calmagite Colorimetric             | 2x125ml<br>4x125ml    |
| 8.05.32.0.0250<br>8.05.32.0.0500 | Phosphorus Phosphomolybdate UV               | 2x125ml<br>4x125ml    |
| 8.05.33.0.0250<br>8.05.33.0.0500 | Potassium Colorimetric                       | 50 Tests<br>100 Tests |
| 8.05.34.0.0250<br>8.05.34.0.0500 | Sodium Colorimetric                          | 50 Tests<br>100 Tests |
| 8.05.35.0.0250                   | TIBC (Total Iron Binding Capacity)           | 100 Tests             |
| 8.05.36.0.0250<br>8.05.36.0.0500 | Total Lipids Phosphovanilline Colorimetric   | 2x125ml<br>4x125ml    |
| 8.05.37.0.0250<br>8.05.37.0.0500 | Total Protein Biuret Colorimetric            | 2x125ml<br>4x125ml    |
| 8.05.38.0.0250<br>8.05.38.0.0500 | Total Protein in CSF                         | 2x125ml<br>4x125ml    |

# STAINS FOR HISTOLOGY & MICROBIOLOGY



## Overview

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

## Features

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

### STAINS FOR HISTOLOGY

| Item Code     | Item Description                                                    | Sizes        |
|---------------|---------------------------------------------------------------------|--------------|
| 8.15.017.0250 | Carbol Fuchsin (Gram)                                               | 250ml/Bottle |
| 8.15.019.0250 | Carbol Fuchsin (Ziehl-Neelsen)                                      | 250ml/Bottle |
| 8.15.032.0250 | Crystal Violet (for Gram Stain)                                     | 250ml/Bottle |
| 8.15.037.0250 | Eosin Y (1% Aqueous)                                                | 250ml/Bottle |
| 8.15.038.0250 | Eosin Y (5% Aqueous)                                                | 250ml/Bottle |
| 8.15.039.0250 | Eosin Stain (diff 3)                                                | 250ml/Bottle |
| 8.15.041.0250 | Field Stain (Solution A)                                            | 250ml/Bottle |
| 8.15.042.0250 | Field Stain (Solution B)                                            | 250ml/Bottle |
| 8.15.043.0750 | Field Stain ( Fixing Reagent, Eosin Reagent, Methylene Blue Reagent | 3x250ml      |
| 8.15.044.0500 | Field Stain (Solution A+B)                                          | 2x250ml      |
| 8.15.047.0250 | Giemsa Stain (Modified-Glycerol/Methanol)                           | 250ml/Bottle |
| 8.15.049.0250 | Gram's Iodine                                                       | 250ml/Bottle |
| 8.15.051.0250 | Gram's Decolouriser                                                 | 250ml/Bottle |
| 8.15.059.0250 | Haematoxylin Harris (no Acetic Acid)                                | 250ml/Bottle |
| 8.15.069.0250 | Leishman Stain                                                      | 250ml/Bottle |
| 8.15.074.0250 | Lugol's Iodine                                                      | 250ml/Bottle |
| 8.15.076.0250 | Malachite Green (Aqueous)                                           | 250ml/Bottle |
| 8.15.078.0250 | May Grunwald Stain (Modified)                                       | 250ml/Bottle |
| 8.15.105.0250 | New Methylene Blue for Reticulocytes                                | 250ml/Bottle |
| 8.15.110.0250 | Papanicolaou Stain EA35                                             | 250ml/Bottle |
| 8.15.111.0250 | Papanicolaou Stain EA36                                             | 250ml/Bottle |
| 8.15.112.0250 | Papanicolaou Stain EA65                                             | 250ml/Bottle |
| 8.15.114.0250 | Papanicolaou Stain EA50                                             | 250ml/Bottle |
| 8.15.115.0250 | Papanicolaou Stain OG6                                              | 250ml/Bottle |
| 8.15.126.0250 | Safranin (1% Aqueous)                                               | 250ml/Bottle |
| 8.15.143.0250 | Wright's Stain (Modified)                                           | 250ml/Bottle |
| 8.15.144.0250 | ZN Decolouriser                                                     | 250ml/Bottle |
| 8.15.146.0100 | Immersion Oil                                                       | 100ml/Bottle |
| 8.15.150.0250 | Mayers haematoxylin                                                 | 250ml/Bottle |

### STAIN PACKS FOR HISTOLOGY

| Item Code     | Item Description             | Sizes   |
|---------------|------------------------------|---------|
| 8.17.009.1000 | Gram Stain Pack              | 4x250ml |
| 8.17.010.0750 | Cold ZN - Kinyoun Stain Pack | 3x250ml |
| 8.17.011.0750 | ZN Pack Standard             | 3x250ml |
| 8.17.015.0500 | Diff-3 Stain Pack            | 4x125ml |



### MICROBIOLOGY

| Item Code      | Item Description                      | Sizes       |
|----------------|---------------------------------------|-------------|
| 8.38.00.0.0025 | Blood Culture Bottles, Pediatric Size | 25ml/Bottle |
| 8.38.00.0.0050 | Blood Culture Bottles, Adult Size     | 50ml/Bottle |

# HOME TESTS



## 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 .



### Fertility Kits

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

# BLOOD GLUCOSE MONITORING SYSTEMS

## Overview

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



## Features

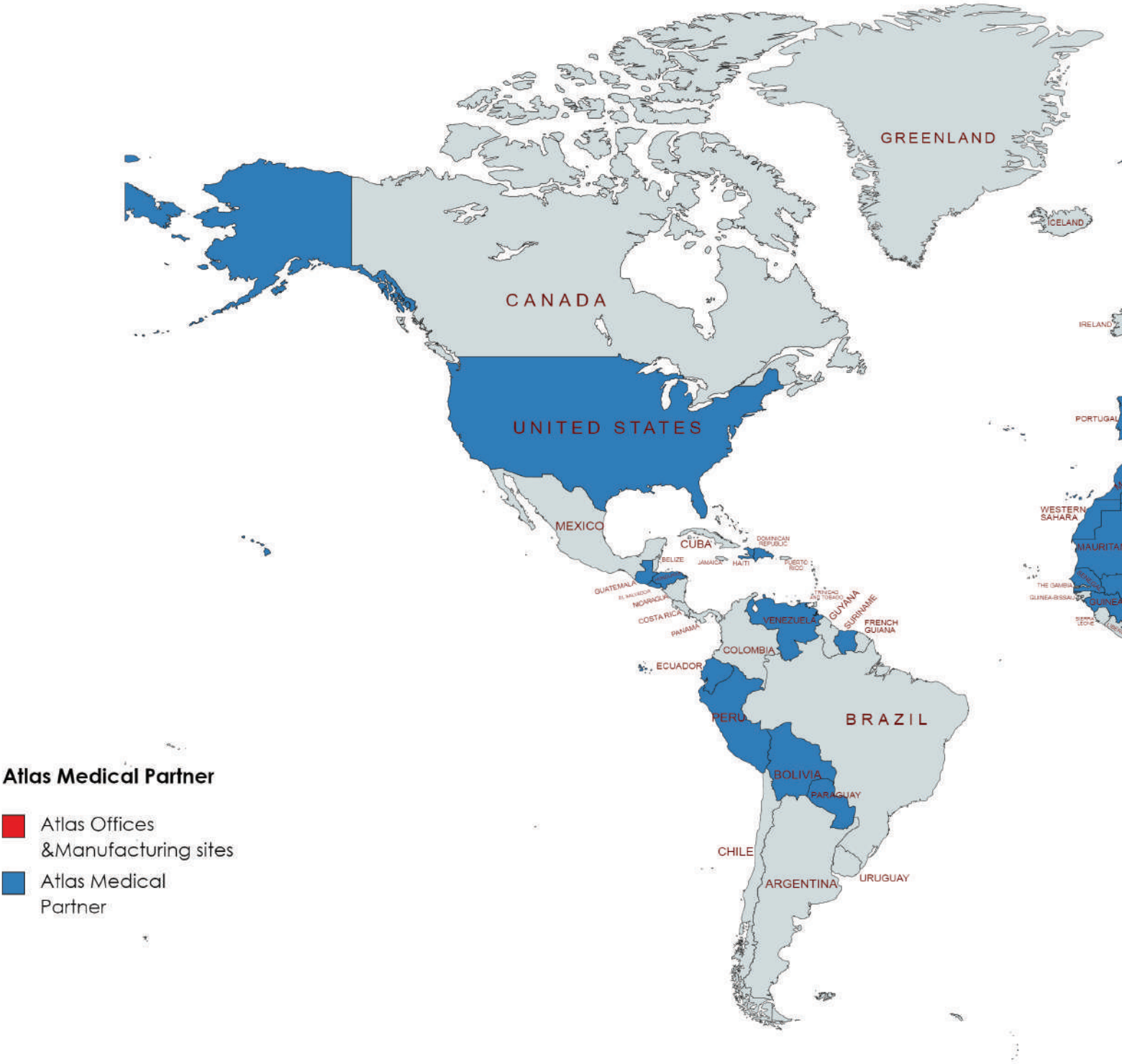
- Reliance Gold™ by Atlas Medical, uses the latest blood glucose gold sensor technology to offer the most accurate and reliable results.
- Test time required is 5 Seconds.
- Required sample volume is 0.9µl
- Test result range is between 10 - 600 mg/dl (0.6 -33.3 mmol/L)

### Reliance Gold

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



# INTERNATIONAL PRESENCE





# CERTIFICATES



ISO 13485



Blood Grouping CE Certificate



Full Quality Assurance Certificate.

## OTHER CERTIFICATES

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

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