

ATLAS ANTI-A, ANTI-B, ANTI AB and ANTI-D SLIDE AND TUBE TESTS

IVD For In-Vitro diagnostic and professional use only

2°C ↓ 8°C ↑ Store at 2- 8°C

INTENDED USE

Anti-A, Anti-B and Anti-AB reagents (here under referred to as ABO reagents) are used for qualitative in-vitro determination of human blood groups of the ABO system to determine the blood type. Anti-D reagent is used for the qualitative determination of Rhesus factor on human blood groups.

These reagents are intended to be used in slide and tube methods.

INTRODUCTION & PRINCIPLES

ATLAS ABO 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 is colored with acid blue (patent blue) dye, Anti-B is colored with acid yellow (tartrazine) dye, and Anti-AB is not colored. The test procedure is based on agglutination 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.

ATLAS Anti-D reagent is prepared from carefully blended human monoclonal IgM and IgG. Anti-D is suitable for slide and tube test procedures. The reagent will directly agglutinate Rh D positive cells, including majority of variants (but not DVI) and a high proportion of weak D (Du) phenotypes. The reagent will agglutinate category DVI and low grade weak D (Du) phenotypes by the indirect anti-globulin techniques. Anti-D reagent is diluted with a sodium chloride solution, sodium phosphate solution and bovine albumin (sodium caprylate free). Anti-D is not colored. The procedure is based on agglutination 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

- ABO grouping reagent: Anti-A (10 ml/vial), Anti-B (10 ml/vial), Anti-AB (10 ml/vial).
- Anti-D IgG/IgM Blend reagent (10 ml/vial).

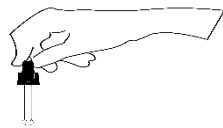
MATERIALS NEEDED BUT NOT PROVIDED

- 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% Sodium Azide 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.
- Hemolyzed 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 occur clean with disinfectant (disinfectant used could be irritable so handle with care).
- The dropper should be held in vertical position (see the illustration below), or it may lead to inaccurate volume of the reagent.



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 a 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 anticoagulant (EDTA, ACD/CPD, sodium citrate, or heparin) can be used for antigen typing.
- 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).
- Blood collection is to be done with great care.

PROCEDURES

A. DIRECT METHOD IN A TUBE AT ROOM TEMPERATURE

1. Bring reagents and samples to room temperature (18-25°C).
2. Prepare a 5% suspension of red blood cells in isotonic solution.
3. Using the vial dropper, transfer a drop (40 µl ± 10 µl) of each reagent into a separate and appropriately marked tube.
4. Add 50 µl of red blood cells suspension.
5. Shake to homogenize the mixture, then centrifuge at 500 g for 1 minute.
6. Read macroscopically while gently shaking the tubes so as to detach the red blood cell pellet.
7. Note the appearance of any agglutination.

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 (NaCl 0.9%) solution and discard the last washing liquid.
3. Add (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. SLIDE PROCEDURE

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 25 µl of the whole blood cell 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 20-40 mm.
6. Hold the slide and gently rock the slide for 1 minute and observe macroscopically for any agglutination.
7. 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	Anti-B	Anti-AB	Anti-D	
+	-	+	+	A+
+	-	+	-	A-
-	+	+	+	B+
-	+	+	-	B-
+	+	+	+	AB+
+	+	+	-	AB-
-	-	-	+	O+
-	-	-	-	O-

Stability of the reactions

- ABO Blood Grouping Tube tests should be read immediately following centrifugation.
- Delay in reading and interpreting results may lead to inaccurate results.

PROCEDURE LIMITATION

1. False positive/ negative results may occur due to:
 - Contamination from test materials.

- Improper storage, wrong cells concentration, inaccurate incubation time or temperature.
 - Improper or excessive centrifugation.
 - Deviation from the recommended technique.
2. Blood samples of weak A or B subgroups may give rise to false negative results or weak reactions.
 3. Weaker reactions may be observed with stored blood than with fresh blood.
 4. ABO antigens are not fully developed at birth, weaker reactions may therefore occur with cord or neonatal red cells.
 5. 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.
 6. Return the kit to the agent if it does not function properly.

DIAGNOSTIC PERFORMANCE CHARACTERISTICS

Atlas Blood Grouping Reagents were compared with competitive CE marked devices and the results showed:

Analytical sensitivity: 100%

Analytical specificity: 100%

Precision: 100%

Accuracy: 100%

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, ATLAS blood grouping reagents and ATLAS Anti-D should be tested with antigen-positive and antigen-negative red blood cells.

















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	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