ANTI-A1 (ABO4)

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INTRODUCTION
A1 antigen is a subgroup of A and was discovered in 1910. Anti-A1 is usually non-reactive at 37ºC, however examples reactive at 37ºC and predominately IgM can cause in vivo red blood cell destruction. About 78% of group A people are A1 and 22% are A2, similar proportions apply among AB people.

PRINCIPLE
The reagent will cause agglutination (clumping) of test red cells, that carry the A1 antigen, after centrifugation. No agglutination generally indicates the absence of the A1 antigen (see Limitations).

COMPOSITION
ANTI-A1 (ABO4) blood grouping reagent is prepared from an extract of *Dolichos biflorus* seeds, diluted with a sodium chloride solution containing bovine albumin and sodium azid (<0,1%). The reagent is supplied at optimal dilution for use with the recommended technique stated below without the need for further dilution or addition.

	Vial Size	Catalogue Number
ANTI-A1 (ABO4)	5 ml	71025

PRECAUTIONS
It is advisable to wear gloves and safety spectacles, and handle samples of human origin with caution. All substrates that have come into contact with the samples are to be handled as potentially infectious products. Special protective measures and conditions for disposal and disinfection should be implemented in accordance with local regulations. Do not use damaged or leaking reagents.

1. The reagent is intended for in vitro diagnostic use only.
2. If a reagent vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagent past the expiration date (see Vial Label).
4. Do not use the reagent if a precipitate is present.
5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
6. The reagent has been filtered through a 0.2 µm capsule to reduce the bio-burden. 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 reagent contains < 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
8. 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.

STORAGE
The reagent is to be stored between +2 °C…+8 °C. Its performance is guaranteed in the recommended method from first use to the expiry date indicated on the label. The reagent must not be used after the expiry date. It is advisable to minimize its time outside the refrigerator and to avoid leaving it at room temperature between use. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

REAGENTS AND MATERIALS NECESSARY
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- PBS solution (pH 6.8–7.2) or Isotonic saline solution (pH 6.5–7.5).
- Positive (group A1B) and negative (group A2) control red cells.
- Test tube centrifuge.
- Volumetric pipettes.

SAMPLES – CONTROLS

Blood samples drawn with or without anticoagulant may be used for antigen typing. If testing is delayed then store specimens at 2-8ºC. EDTA and citrate samples should be typed within 7 days of collection. Samples collected into ACD, CPD or CPDA-1 may be tested up to 35 days from the date of withdrawal. All blood samples should be washed at least twice with PBS or Isotonic saline before being tested.

1. It is recommended a positive control (ideally group A1B cells) and a negative control (group A2 cells) be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. One volume is approximately 50µl when using the vial dropper provided.
3. The use of the reagent 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 reagent is in use.
4. User must determine suitability of the reagent for use in other techniques.

PROCEDURE

Tube Technique

1. Prepare a 2-3% suspension of washed test red cells in PBS or Isotonic saline.
2. Place in a labelled test tube: 1 volume ANTI-A1 (ABO4) reagent and 1 volume test red cell suspension.
3. Mix thoroughly and then centrifuge all the tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
4. Gently resuspend red blood cells pellet and read macroscopically for agglutination.

INTERPRETATION

1. Positive: Agglutination of test red cells constitutes a positive test result and within the accepted limitations of the test procedure, indicates the presence of A1 antigen on the test red cell.
2. Negative: No agglutination of test red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of A1 antigen on the test red cells.
3. Discrepancies: If the results obtained with plasma test don't correlate with globular test, further investigation is required.

STABILITY OF THE REACTIONS

1. Tube tests must be read immediately after centrifugation. Delays may cause dissociation of antigen-antibody complexes leading to false negative, or weak positive reactions.
2. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

LIMITATIONS OF THE METHOD

1. ANTI-A1 (ABO4) may react with Tn-polyagglutinable or Cad-positive cells
2. Cord blood and specimens from infants cannot be accurately typed using Anti-A1 (ABO4) since the A1 antigen is not fully developed on red blood cells until the age of six months.
3. Individuals older than six months should have their ABO blood-grouping results confirmed by testing their serum or plasma against known group A1 and B cells before their ABO blood group can be confirmed.
4. Stored blood may give weaker reactions than fresh blood.
5. 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

1. The reagent has been characterised by the procedure mentioned in the procedure.
2. Prior to release, each lot of ANTI-A1 (ABO4) reagent is tested by the Recommended Technique against a panel of antigen-positive red cells to ensure suitable reactivity.
3. The Quality Control of the reagent was performed using red cells that had been washed twice with PBS or Isotonic saline prior to use.
4. The reagent complies with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.

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