PACKAGE INSERT NON-RED CELL REAGENTS

Registration No. 2000/026390/08

Identification of the substance/preparation and company
Lyophilized Bromelain.
Low Ionic Reagent.
AB Serum.
Antibody Positive control serum.
Anti-D Monoclonal IgM + IgG Blend.
ABO grouping Reagents.
Anti-Human Globulin Reagent (Broad Spectrum).
Anti-T.

REAGENTS LABORATORY
Produced and or bottled onsite at:
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Intended use:

Lyophilized Bromelain
Bromelain Solution may be used in one stage or two stage tests. In one-stage tests, a drop of Bromelain solution is added to a drop of cell suspension and a drop of antisera. Incubation may be for 15 minutes to 45 minutes, at 10°C, room temperature or 37°C, depending on the blood group system being tested. In two-stage tests, the red cells are treated with Bromelain before antisera is added. This treatment results in the enhancement of agglutination and / or haemolysis with some blood group systems. This enhancement is due in part, to removal of negatively charged sialic acid-bearing glycoproteins from red cells.
Refer to examination procedure 4.

Low Ionic Reagent
Low Ionic Reagent (LIR). LIR is a reagent that greatly increases the speed of antibody sensitization of red cells (AABB Technical Manual and Standards for Blood Banks and Transfusion Services). LIR is used in laboratories for performing blood banking procedures that require enhancement of agglutination to detect the presence of antibodies or antigens in a patient's blood sample. LIR is used to reduce the minimum incubation time of the Indirect Antiglobulin Technique from 30 minutes to 10 minutes.
Refer to examination procedure 3.

AB Serum
This reagent is used as a diluent and as a red blood cell (RBC) typing control and RBC antibody negative control.
Refer to appropriate examination procedures 1 – 4, as per the test required.

Antibody Positive control serum
Antibody positive control serum has a definite anti-D antibody present. Additional antibodies may also be present. This product is used as a positive control for irregular antibody screen and identification tests.
Refer to appropriate examination procedures 1 – 4, as per the test required.

Anti-D Monoclonal IgM + IgG Blend
This reagent is used for typing red cells for the Rh D antigen. The IgM component of this reagent will directly agglutinate D positive red cells and the most examples of Rh type Weak D. When used by the indirect anti-human globulin technique, the IgG component of this reagent will detect the majority of low-grade weak D phenotypes. Control Rh positive and Rh-negative cells must be used with each batch of tests performed.
Refer to examination procedures 1-2.

ABO grouping reagent
An ABO type is usually determined by the agglutination reaction of red cells with anti-A, Anti-B and anti-A, B.
Refer to examination procedure 1.

Anti-T Lectin
Peanut Lectin Reagents is used for the detection of T-antigen activation on the red cell membrane.
Refer to examination procedure 5.

Anti-Human Globulin (AHG)
Anti-Human globulin is a broad spectrum, polyspecific murine monoclonal reagent, standardized to react with red blood cells sensitized with red cell antibodies (gamma globulins) or with components of complement. Cells that have globulins or complement absorbed to their surface are said to be sensitized.
Refer to examination procedure 2, 3 and 6.

Components
Lyophilized Bromelain
A reagent prepared by dissolving Bromelain powder in Sorenson's Buffer pH 5.5. the final product is lyophilised.

Low Ionic Reagent (LIR)
A reagent prepared from multiple chemicals dissolved in reverse osmosis water. The reagent contains approximately 20% Bovine Serum Albumin.

Plasma Reagents
Prepared from donated human plasma. The reagent is prepared by pooling, viral negative recalcified plasma, filtered and inactivated at 56°C.
The plasma contains Sodium Azide (1g/l) and Thiomersal (0.2g/l).

ABO grouping reagent
Reagents are prepared from monoclonal antibodies secreted by murine hybridoma cell lines grown in tissue culture. They therefore have the advantage of consistent performance and reliable specificity and supply associated with monoclonal reagents.
These reagents are prepared from non-human source and the risk of transmission of blood disease such as hepatitis or AIDS is practically excluded.

Bromelain Preparation
Mix before use.
Reconstitute the Bromelain powder by adding 5ml reverse osmosis water. Allocate a 7-day expiry to the product.
Do not use the Bromelain reagent if there is any moisture present in the vial.

Storage and expiry
Store at 2°C–6°C.
Do not freeze.
Do not use beyond the notified expiry date.

Warning and precautions
For professional use only.
The recommended conditions of storage and use must be rigidly applied.
The donations used in these products have been tested as source and found negative for mandatory Microbiology/Virology requirements.
All blood grouping reagents should be treated as potentially infectious. The donations used in these products are not sterilized; capable of transmitting any biological agent that has not been detected by routine screening at the time of manufacture. No known test method can offer assurance that products derived from human blood will not transmit infectious disease. Appropriate care should be taken in the use and disposal of this product.

Centrifugation
The standard centrifugation speed is 3000 rpm for 1 minute.

Examination procedure

1. Immediate spin technique
- Add cells to rest serum/plasma in 1:1 ratio.
- Mix then centrifuge.
- Read macroscopically and record the results.

2. Indirect Antiglobulin Test (IAT) technique
- Add 2 volumes of test serum to the labelled tubes.
- Add 1 volume of supplied product cells.
- Mix thoroughly and incubate at 37°C for 30 minutes.
- Wash the cells three times.
- Add 1 drop of anti-human globulin reagent.
- Centrifuge and observe for agglutination.
- Read macroscopically and record the results.

3. Low Ionic Reagent (LIR) Additive technique:
- Add 2 drops of the serum / plasma to the pre-marked tubes.
- Add 1 drop of the cells under test (suspended in saline or RCSF) to the pre-marked tubes.
- Add 2 drops of the LIR to the pre-marked tubes.
- Mix and incubate 37°C for not less than 10 minutes. Tests may be incubated for longer, but must be read within two hours of being set up.
- Examine the tubes for saline agglutination prior to washing.
- Wash the tests 3 times with saline.
- After the last wash, add 1 drop of the Anti-Human Globulin reagent. Mix the tubes well.
- Centrifuge the tubes.
- Read macroscopically and / or microscopically. Record the results onto the worksheets and interpret the results.

4. Enzyme technique for screen and panel cells
- Add cells to plasma/serum in 1:1 ratio.
- Add 1 drop of Bromelain solution.
- Mix well and incubate at RT for 15-45 minutes.
- Centrifuge and observe for agglutination.
- Read macroscopically and record the results.

5. Lectin technique
- Add one volume of Anti-T lectin to one volume of red cells.
- Incubate at room temperature for 15 minutes.
- Centrifuge and observe for agglutination.
- Read macroscopically and record the results.

6. Direct Antiglobulin technique:
- Make a 3% - 5% RCSF red cell suspension (in saline or RCSF) of the test sample.
- Add 1 drop of AB serum to the test tube.
- Add 1 drop of cell suspension to a 12mm x 75mm test tube.
- Wash 3 times in saline.
- Add 1 drop of AHG.
- Centrifuge the tubes.
- Read macroscopically and / or microscopically.

Control procedure
Each batch of tests should be controlled with suitable positive and negative controls.

Interpretation of results
The presence of agglutination indicates a positive result and the absence of agglutination indicates a negative result.

Limitations of the examination procedure

If controls set up with the batch of tests fail to give the required results then all tests must be repeated. Deviations from these recommended methods must be validated by the user. If these reagents are used in a proprietary system, the manufacturer's recommended methods must be followed.

Revision Summary

VERSION NUMBER	REVISION DETAILS
1	• Added centrifugation speed.