PACKAGE INSERT RED CELL REAGENTS

Registration No. 2000/026390/08

Identification of the substance/preparation and company
Reagent red cells for use in ABO, RhD grouping, antibody detection (Screen cells), identification of red cell antibodies (Panel cells) and for use in the control of anti-human globulin (Sensitised cells) technique for in vitro diagnostic use only.
Product codes: 78018, 79019, 78020, 78519, 78521, 78525, 78522, 78523, 78510, 78518, 78524.

REAGENTS LABORATORY
Produced onsite at:
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Intended use:
ABO & RhD cells
These reagent red cells are intended to be used to test plasma/serum samples to determine ABO group (Reverse or serum group). It is important to determine the ABO blood group correctly in order to ensure that any subsequent transfusion is as free from risk of a red cell transfusion reaction as possible within the limits of the techniques used.
Refer to examination procedure 1.

Antibody screen cells
These reagent red cells are intended to be used to screen plasma/serum samples for the presence of red cell antibodies by serological means.
Refer to examination procedure 1, 2, 3 and 4.

Panel cells
These reagent red cells are intended to be used to test plasma/serum samples for the presence of red cell antibodies by serological means.
Refer to examination procedure 1, 2, 3 and 4.

Sensitised cells
These reagent red blood cells are intended to be used for the control of negative anti-human globulin (AHG) tests and can also be used to monitor the washing efficiency of cell washer centrifuges.
Refer to examination procedure 5.

Components
These reagent red cells are supplied as a 3%-5% suspensions to be used directly from the vial. These reagent red cells, prepared from non-remunerated donor blood, are washed and suspended in Red cell suspending fluid containing Adenine (0.002g/l), Calcium Chloride (0.00075g/l), Citric Acid (0.01375g/l), inosine (0.00875g/l), Neomycin Sulphate (0.0025g/l), Chloramphenicol (0.00825g/l), Tri-Sodium Citrate (0.147g/l), Glucose (0.25g/l).

Reagent Preparation
Mix before use.

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.
Do not use if obviously discoloured or haemolysed.
Cells must not be pooled.
The donations used in this product 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. 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. Enzyme technique method 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.

4. 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.

5. 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.