INTENDED PURPOSE
The Anti-M reagent is for the in vitro detection and identification of human M positive red blood cells by direct agglutination.

REAGENT DESCRIPTION
The main component of this reagent is derived from the in vitro culture of the immunoglobulin secreting mouse hybridoma LM1. The formulation consists of culture supernatant in EPPS buffer, pH 8.5 and also contains 1g/L sodium azide.

The volume delivered by the reagent dropper bottle is approximately 40µL; bearing this in mind, care should be taken to ensure that appropriate serum: cell ratios are maintained in all test systems.

This reagent complies with the requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and the recommendations contained in the Guidelines for Blood Transfusion Services in the United Kingdom.

STORAGE CONDITIONS
The reagent should be stored at 2°C - 8°C. Do not use if turbid. Do not dilute. The reagent is stable until the expiry date stated on the product label.

PRECAUTIONS FOR USE AND DISPOSAL
This reagent contains 0.1% sodium azide. Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into sink, flush with a large volume of water to prevent azide build-up. Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.

As this reagent is of animal origin care must be taken during use and disposal as there is a potential infection risk. This reagent is for in vitro professional use only.

SPECIMEN COLLECTION AND PREPARATION
Specimens should be collected by aseptic technique with or without an anticoagulant. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at 2°C - 8°C. Blood specimens exhibiting gross haemolysis or contamination should not be used. Clotted samples or those collected in EDTA should be tested within seven days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiry date of the donation.

TEST PROCEDURES
General Information
This reagent has been standardised for use by the technique described below and therefore its suitability for use in other techniques cannot be guaranteed. Users are advised to carefully confirm reagent suitability before using alternative techniques.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED
- Unbuffered Saline (9g/L NaCl)
- Reagent red cells suitable for the control of Anti-M
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge

RECOMMENDED TECHNIQUES
Tube Technique - NIS 5 Min 20°C Spin
- Prepare a 2-3% suspension of washed red cells in unbuffered isotonic saline (9g/L NaCl).
- Add 1 volume of blood grouping reagent to a 12 x 75mm glass test tube.
- Add 1 volume of red cells suspended to 2-3% in unbuffered saline.
- Mix thoroughly and incubate for 5mins at 20°C.
- Following incubation, centrifuge at 1000g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

INTERPRETATION OF RESULTS
Agglutination = positive test result
No agglutination = negative test result

QUALITY CONTROL
Quality control of reagents is essential and should be performed with each series of groups and with single groups. Anti-M should be controlled with known M+N-, M+N+, M-N+. cells.

PERFORMANCE LIMITATIONS
As this reagent reacts optimally at pH 8.5 and is extremely sensitive to pH, test red cells should be suspended in unbuffered medium. Cells suspended in buffered medium e.g. Alsever’s solution, should be washed and re-suspended in unbuffered saline prior to use.
Incubation at temperatures above that recommended may result in weaker reactions.

Cells modified by proteolytic enzymes must not be used, as M antigens may be destroyed.

Do not examine tests microscopically.

Tests should be read by a ‘tip and roll’ procedure. Excessive agitation may disrupt weak agglutination and produce false negative results.

It is important to use the recommended g force during centrifugation as excessive centrifugation can lead to difficulty in resuspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

The expression of certain red cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents and certain disease states.

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For further information or advice please contact your local distributor.

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