QUOTIENT

ALBAclone®
Anti-N
BLOOD GROUPING REAGENT
Mouse Monoclonal / Direct Agglutinin

REF Z176

2°C – 8°C IVD CE

INTRODUCTION

The MN status of red blood cells is defined by the amino acid sequence of the major red cell sialoglycoprotein, glycophorin A. Anti-M and Anti-N react with their respective antigens on glycophorin A, causing agglutination of the red cells and classifying these cells into three distinct phenotypes: M+N-, M+N+ and M-N+. Additionally, irrespective of the MN status of their major glycoprotein, almost all human red cells carry N-antigen on a minor red cell sialoglycoprotein, glycophorin B.

INTERPRETATION OF LABEL SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
2°C – 8°C	Storage temperature limitation (2°C– 8°C)
IVD	*In vitro* diagnostic medical device
www.quotientbd.com	Consult instructions for use
	Manufacturer
REF	Product Code

INTENDED PURPOSE

The Anti-N reagent is for the *in vitro* detection and identification of human N 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 LN3. The formulation consists of culture supernatant containing 1 g/L sodium azide.
The volume delivered by the reagent dropper bottle is approximately 40 µL; 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 2-8 °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 2-8 °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

This reagent has been standardised for use by the technique described below and therefore its suitability for use in other techniques cannot be guaranteed.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- PBS pH 7.0 ± 0.2
- Reagent red cells suitable for the control of Anti-N
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge

RECOMMENDED TECHNIQUE

Tube Technique - NIS 5 Min/Spin

- 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 PBS pH 7.0 ± 0.2.
- Mix thoroughly and incubate for 5 minutes at room temperature.
- 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 batch of tests and with single tests.

Anti-N should be controlled with known M+N-, M+N+, M-N+ cells.

PERFORMANCE LIMITATIONS

Cells modified by proteolytic enzymes must not be used, as N 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.

DATE OF ISSUE

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For further information or advice please contact your local distributor.

EC REP

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 Z176PI/09

INSTRUCTIONS FOR USE
Instructions for Use are available on Quotient website at www.quotientbd.com or can be requested from your Local Distributor, by providing the relevant Product Code stated on product labels and Instructions for Use supplied with the product.

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