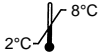




ALBAclone[®]
Anti-Human C3
BLOOD GROUPING REAGENT
Murine Monoclonal

REF Z360



IVD



INTRODUCTION

This reagent has been prepared using a murine monoclonal antibody to C3 (class IgG) pre-diluted for the optimum detection of C3b and/or C3d components of complement on the surface of red blood cells.

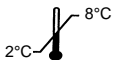
INTERPRETATION OF LABEL SYMBOLS

LOT

Batch code



Use by (YYYY-MM-DD)



Storage temperature limitation (2°C– 8°C)

IVD

In vitro diagnostic medical device



Consult instructions for use

www.quotientbd.com



Manufacturer



Product Code

INTENDED PURPOSE

This Anti-Human C3 reagent is for the *in vitro* detection of C3b and/or C3d components of complement on the surface of red blood cells by the direct antiglobulin test.

REAGENT DESCRIPTION

The monoclonal antibody to C3 has been given the clone reference number 3G8.

The reagent is diluted in phosphate buffered saline (PBS) which contains 20g/l bovine serum albumin, 1g/l sodium azide and 0.1g/l Tween 80. The reagent has been filtered to 0.2µm.

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 buildup.

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 techniques 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

- PBS pH 7.0 ± 0.2
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Complement coated red blood cells

RECOMMENDED TECHNIQUES

Direct Antiglobulin Test

- Add 1 volume of washed (x4) 2-3% NIS suspended red cells.
- Add two drops of anti-human C3 reagent to each tube.
- Mix thoroughly.
- 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

Every batch of antiglobulin tests should include a suitable positive (sensitivity) control. A method to prepare red blood cells sensitised with complement is published in the Guidelines for the Blood Transfusion Services in the United Kingdom.

PERFORMANCE LIMITATIONS

Washing is best performed with approximately four cycles of 4ml PBS per tube.

Any PBS present after the completion of the wash phase may dilute the Anti-C3 reagent beyond its optimal working concentration. It is therefore important to ensure that the

maximum amount of wash fluid is removed after each centrifugation stage.

If automated cell washers are used, the performance and cleanliness of the instrument should be checked frequently.

Direct antiglobulin tests should be performed with fresh cells collected in EDTA anticoagulant to avoid in vitro sensitisation with complement.

The sensitivity of the reaction of complement with anti-complement reagent can be increased by incubation for 5 minutes at room temperature prior to centrifugation.

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

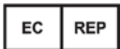
It is important to use the recommended g force during centrifugation as excessive centrifugation can lead to difficulty in resuspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

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

2023-01

For further information or advice please contact your local distributor.



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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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