QUOTIENT

ALBAclone®
Anti-P1
BLOOD GROUPING REAGENT
Mouse Monoclonal / Direct Agglutinin

REF Z202

2°C – 8°C IVD CE

INTRODUCTION

The P blood group system was discovered in 1927 by Landsteiner and Levine in the same series of rabbit immunisation experiments which led to the description of the M and N antigens. The rabbit antibodies produced by Landsteiner and Levine's experiments, anti-P1, were soon found in humans and permit the classification of individuals into the phenotypes P1+ (P_1) and P1- (P_2). The P1 gene is located on the long arm of chromosome 22. P1 antigen strength shows a very wide distribution.
Anti-P1 is often found in the serum of P_2 individuals, generally as a cold reactive antibody of the IgM class. Unless anti-P1 is demonstrable in tests at 37°C it is considered to be of no clinical significance.
The antigen P is of high frequency and is absent from the red cells of rare individuals who express the antigen P^k (P^k1 or P^k2) and extremely rare individuals of the p phenotype. p red cells (formerly Tj(a-) also lack P and P^k antigens. Serum from P^k individuals contains anti-P whilst serum from p individuals contains anti-$PP1P^k$ (formerly anti-Tj^a). Auto anti-P is the Donath-Landsteiner antibody most often associated with Paroxysmal Cold Haemoglobinuria (P.C.H.).

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-P1 reagent is for the *in vitro* detection and identification of human P1 positive red blood cells by direct agglutination.

REAGENT DESCRIPTION

The main component of this reagent is derived from the *in vitro* culture of the IgM immunoglobulin secreting mouse hybridoma 650. The formulation also contains <0.1% 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

This reagent has been standardised for use by the techniques 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
- LISS
- Reagent red cells suitable for the control of Anti-P1
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge

RECOMMENDED TECHNIQUES

Tube Technique - NIS/LISS Spin

- Add 1 volume of blood grouping reagent to a 12 x 75mm glass test tube.
- Add 1 volume of washed red cells suspended to 2-3% in PBS pH 7.0 ± 0.2 or 1.5 - 2% in LISS.
- Mix thoroughly by gentle agitation.
- Centrifuge at 100-125g (about 1000rpm) for 1 minute.
- 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. As a minimum a positive and a negative control should be used.
It is recommended that red cells which are weakly P1+ are used as a positive control. P1 negative red cells should be used as a negative control.

PERFORMANCE LIMITATIONS

The P1 antigen is not fully developed at birth and therefore particular care should be exercised when determining the P1 status of cord and neonatal samples.

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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INSTRUCTIONS FOR USE
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