BLOOD GROUPING REAGENT
Anti-P1
ALBAclone®
(Murine Monoclonal)
For Tube Techniques

REF **Z202U**

- **FOR *IN VITRO* DIAGNOSTIC USE**
- **Meets FDA potency requirements**
- **Discard if turbid**
- **Preservative: 0.09% (w/v) sodium azide**

CAUTIONS: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER.

INTERPRETATION OF LABELING SYMBOLS

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

INTENDED USE

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

SUMMARY AND EXPLANATION

The P1 antigen (P1PK1) was discovered by Landsteiner and Levine in 1927 in the same series of experiments which led to the description of the M and N antigens. P1 (originally P and subsequently P_1, now obsolete) is classified as part of the P1PK blood group system along with two other antigens; Pk and NOR. The antigen was given the identification P as this was the first letter after the already assigned M, N and O.
P1 antigen strength shows a very wide distribution and the presence or absence of the P1 antigen gives classification of individuals into the phenotypes P1+ (P1) and P1- (P2).
Anti-P1 is often found in the serum of P2 individuals, generally as a cold reactive antibody of the IgM class. Unless anti-P1 is demonstrable in tests at temperatures above 25 °C it is considered to be of no clinical significance.

PRINCIPLE OF THE TEST

When used by the recommended technique, this reagent will cause the agglutination (clumping) of red blood cells carrying the P1 antigen. Lack of agglutination demonstrates the absence of the P1 antigen.

REAGENT DESCRIPTION

The main component of this reagent is derived from the *in vitro* culture of the IgM mouse hybridoma:

Product Name	Product Code	Cell Line
Anti-P1	Z202U	650

The formulation also contains 0.09% (w/v) sodium azide.

NOTE: The volume delivered by the reagent bottle dropper is approximately 40 µL. Care should be taken to ensure that appropriate serum to cell ratios are maintained in all test systems.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only
Products should be used by qualified personnel
Do not use beyond the expiration date
Do not use if turbid
Do not dilute
The format of the expiration date is expressed as YYYY-MM-DD (Year-Month-Day)

This reagent contains 0.09% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive compounds. If discarded into a sink, flush with a large volume of water to prevent azide build-up.
This reagent contains material of animal origin (murine and bovine), therefore care must be taken during use and disposal as there is a potential infection risk.

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED, WAS FOUND NEGATIVE FOR INFECTIOUS AGENTS WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS.

The bovine material used in the manufacture of this reagent was collected in a USDA approved facility or obtained from a geographical region classified as negligible risk for BSE.

Monoclonal antibodies exhibit a high degree of potency, avidity and specificity. When using such antibodies, great care should be taken to avoid cross contamination.
This product has components (dropper bulbs) containing dry natural rubber.

STORAGE

The reagent should be stored at 2–8 °C.

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by a standard collection technique. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at refrigerated temperatures.

Clotted samples, or those collected in EDTA, should be tested within fourteen days from collection. Donor blood collected in ACD, CPD, CPDA -1, CP2D, CP2D with AS-3, CPD with AS-1, and CPD with AS-5 may be tested until the expiration date of the donation.

Special care should be taken if hemolyzed samples must be tested. Grossly icteric or contaminated blood specimens should not be used.

MATERIALS

Material provided
- ALBAclone® Anti-P1

Materials required but not provided
- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-P1
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Optical aid (optional)
- Centrifuge

PROCEDURE

NOTE: This reagent has been standardized for use by the technique described below and therefore its suitability for use by other techniques cannot be guaranteed. When a test is required to be incubated for a specific time period, a timer should be used.

When using supplemental testing equipment (i.e. centrifuge), follow the procedures that are contained in the operator's manual provided by the device manufacturer.

Tube Technique – Immediate Spin/5 Minute Incubation and Spin
1. Prepare a 2-4% suspension of red blood cells in isotonic saline solution (Reagent Red Blood Cells may be used directly from the vial or according to the manufacturer's instructions.)
2. Add 1 drop of blood grouping reagent to a glass test tube.
3. Add 1 drop of red blood cell suspension. Steps 2 and 3 may be performed in either order.
4. Mix the contents of the test tube and centrifuge.
   NOTES:
   - Test may be incubated up to 5 minutes at 18-24 °C prior to centrifugation.

- Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy re-suspension of antigen-negative red blood cells.

5. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.
6. Record results.

Refer to Performance Limitations section for additional guidance on the use of this product

STABILITY OF REACTION

Test results should be read, interpreted and recorded immediately after centrifugation. Delays may cause dissociation of antigen-antibody complexes resulting in weak positive or false negative reactions.

INTERPRETATION OF RESULTS

Agglutination	=	positive test result
No agglutination	=	negative test result

QUALITY CONTROL

Quality control of reagents is essential and should be performed on each day of use and in accordance with local, state and federal regulations.

P1+ red blood cells should be used as a positive control
P1- red blood cells should be used as a negative control

Other red blood cell types may be suitable but should be selected with care.

False positive test results are rarely seen with low-protein reagents. False positive agglutination may be due to a positive direct antiglobulin test (DAT), cold agglutinins, or abnormal serum proteins. If false positive results are suspected, or local regulations require, and a control test for spontaneous agglutination is desired, ALBAcheck® - BGS Monoclonal Control (Z271U) or 6-10% albumin in saline may be substituted for the blood grouping reagent in the testing procedure. A negative result would serve as an appropriate control. If the monoclonal control test gives a positive reaction, a valid interpretation of the results obtained in red blood cell testing cannot be made without further investigation.

PERFORMANCE LIMITATIONS

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

Gently re-suspend tube tests before reading. Excessive agitation may disrupt weak agglutination and produce false negative results.

Excessive centrifugation can lead to difficulty in re-suspending 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.

Suppressed or weak expression of blood group antigens may give rise to false negative reactions.

Care should be taken when testing red blood cells that have been treated with proteolytic enzymes, as these may produce false positive or false negative results.

SPECIFIC PERFORMANCE CHARACTERISTICS

Prior to release, each lot of ALBAclone® Anti-P1 is tested using FDA recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

In performance evaluation studies (data on file at Alba Bioscience Limited), blood group samples were tested with ALBAclone® Anti-P1 as follows:

Reagent	No. Samples Tested	Concordance*
ALBAclone® Anti-P1	1115	99.6%

* Concordance indicated agreement between the ALBAclone® Anti-P1 and comparator reagents only and does not indicate which reagent gave the correct results.

Repeatability and reproducibility of the trial reagent was confirmed by means of Lot to Lot and Precision studies.

Comparator Study Results

During comparator studies (data on file at Alba Bioscience Limited), blood samples were tested with ALBAclone® Anti-P1 (Monoclonal) (IgM) as follows:

Anti-P1		Comparator Reagent			One-sided 95% Exact lower confidence limit
		Positive	Negative	Total	
Trial Reagent	Positive	819	3	822	
	Negative	1	292	293	
	Total	820	295	1115	
Positive Percent Agreement*				99.88	99.42%
Negative Percent Agreement*				98.98	97.39%

** Indicates agreement between the ALBAclone® Anti-P1 and comparator reagents only and does not indicate which reagent gave the correct result(s).*

In performance evaluation studies, 1115 samples were tested with ALBAclone® Anti-P1 (Monoclonal) (IgM). The positive percent agreement at the one-sided 95% exact lower confidence limit was 99.42% for agglutination tests based on a comparison of interpreted results. The negative agreement at the one-sided 95% exact lower confidence limit was 97.39% for agglutination tests based on a comparison of interpreted results. The following factor may have had an impact on the outcome of the testing and the discrepancies observed:

- Test site investigation suggested that one discrepancy may have been due to test error.

The three remaining discrepant results were unresolved.

Results were evaluated against comparable FDA approved products using the appropriate methods for the comparators.

Precision Study Results

As part of the performance evaluation, precision and lot to lot studies were performed using multiple operators, days and runs to confirm repeatability and reproducibility of test results in the same run, day and with the same operator and between runs, days and operators. The study took account of variables such as days of the week, times of day and supplementary reagents used in the testing.
All antigen positive test outcomes generated unequivocal positive reactions and antigen negative test outcomes generated unequivocal negative reactions.

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