# BLOOD GROUPING REAGENT
# Anti-K
## ALBAclone®
## (Monoclonal)
## For Tube Techniques

REF **Z132U**

- **FOR *IN VITRO* DIAGNOSTIC USE**
- **Meets FDA potency requirements**
- **Discard if turbid**
- **Preservative: 0.1% (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-K reagent is for the *in vitro* detection and identification of the human K blood group antigen by direct agglutination.

**SUMMARY AND EXPLANATION**
Since the description of the antigen K (KEL1) in 1946 by Coombs et al and its allele k in 1949 by Levine *et al*, the Kell blood group system has been shown to be increasingly complex and over 20 antigens are now known to be associated with the system.
The antigens of the Kell blood group system are of further interest in that they tend to occur either very frequently (e.g. k 99.8%) or relatively infrequently (e.g. K 8%). The antigens require the presence of disulfide bonds for full expression and are destroyed by treatment with dithiothreitol (DTT), 2-aminoethylisithiouronium bromide (AET), or a mixture of trypsin and α-chymotrypsin. Kell system antibodies are capable of causing hemolytic transfusion reactions and hemolytic disease of the fetus and newborn.

**PRINCIPLE OF THE TEST**
When used by the recommended technique, this reagent will cause the agglutination (clumping) of red blood cells carrying the K antigen. Lack of agglutination demonstrates the absence of the K antigen.

**REAGENT DESCRIPTION**
The main component of this reagent is derived from the *in vitro* culture of the IgM secreting human/mouse heterohybridoma:

| Product Name | Product Code | Cell Line |
|---|---|---|
| Anti-K | Z132U | MS-56 |

The formulation also contains bovine material, and 0.1% (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 0.1% (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-K

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

**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 – 5-15 Minute Incubation/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 incubate at 37 °C ± 1 °C for 5-15 minutes.
5. Centrifuge the test tube.
   NOTE: 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.

6. 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.
7. 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.

K+k+ red blood cells should be used as a positive control
K-k+ 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

Kell antigen expression may be dramatically weakened in some cases of Chronic Granulomatous Disease.

Heating blocks and waterbaths promote better heat transfer and are recommended for 37 °C tests, particularly where the incubation period is 30 minutes or less.

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

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

| Reagent | No. Samples Tested | Concordance* |
|---|---|---|
| ALBAclone® Anti-K | 1132 | 99.8% |

* Concordance indicated agreement between the ALBAclone® Anti-K 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.

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

### Comparator Study Results

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

| Anti-K | | Comparator Reagent | | | One-sided 95% Exact lower confidence limit |
|---|---|---|---|---|---|
| | | Positive | Negative | Total | |
| Trial Reagent | Positive | 308 | 0 | 308 | |
| | Negative | 2 | 891 | 893 | |
| | Total | 310 | 891 | 1201 | |
| Positive Percent Agreement* | | | | 99.35 | 97.98% |
| Negative Percent Agreement* | | | | 100 | 99.66% |

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

In performance evaluation studies, 1201 samples were tested with ALBAclone® Anti-K (Monoclonal) (IgM). The positive percent agreement at the one-sided 95% exact lower confidence limit was 97.98% for agglutination tests based on a comparison of interpreted results. The negative agreement at the one-sided 95% exact lower confidence limit was 99.66% for agglutination tests based on a comparison of interpreted results. The following factors may have had an impact on the outcome of the testing and the discrepancies observed:

- DAT positive determined during investigation. Comparator and Resolver utilize IAT method and would therefore be expected to react by IAT methods
- Test site investigation suggested that the discrepancy may have been due to test error.

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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