

## Certificate of Analysis / Quality Control

**Product:** Anti-K, monoclonal

**REF:** B18908

**Lot:** 9463/760107-A5

**Mfg.:** 2024-04-05

**Exp.:** 2026-04-05

### Results:

**Preservative:** < 0.1% Sodium Azide w/v  
None

**Dye:** Product filtered through a sterile 0.2 µm filter  
2 - 8 °C

**Sterility:** Source materials used to produce this lot were tested and found to be non-reactive for anti-HIV 1+2, anti-HCV and HBsAg.

**Storage:**

### Micro Testing:

#### Potency:

|                 | Tube Test | BioVue Card | DiaMed Card | Microplate |
|-----------------|-----------|-------------|-------------|------------|
| <b>Kk Cells</b> | 1in128    | 1in128      | 1in512      | 1in128     |

**Avidity:** (1st sign of agglutination)

**Kk Cells** 3 sec

#### Specificity:

##### Positive Phenotypes

##### Negative Phenotypes

**Kk Cells** Grade 4

**kk Cells** Negative

This lot meets our specifications.

Thomas  
Breininger

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Rev. 2  
Date: 2018-05-24

# Anti-K, monoclonal

## MONOCLONAL BLOOD GROUPING REAGENT

For Tube, DiaMed-ID, Ortho BioVue, Microplate and Slide Techniques

REF

Cont.

**B18908 1x 5 mL Anti-K, monoclonal**

For professional in vitro diagnostic use only.

### SUMMARY

The K antigen was reported in 1946. The antigen is fully developed at birth and can be strongly immunogenic. Anti-K has been implicated in Haemolytic Transfusion Reactions and Haemolytic Disease of the Newborn.

| Anti-K | Anti-k | Phenotype      | Caucasians %     | Afro-Americans % |
|--------|--------|----------------|------------------|------------------|
| +      | 0      | K+k-           | 0.2              | Rare             |
| +      | +      | K+k+           | 8.8              | 2.0              |
| 0      | +      | K-k+           | 91.0             | 98.0             |
| 0      | 0      | K <sub>o</sub> | Exceedingly Rare |                  |

### TEST PRINCIPLE

Reagent will cause direct agglutination (clumping) of cells that carry K antigen. No agglutination generally indicates absence of K antigen (see LIMITATIONS).

### REAGENTS

DIALAB Anti-K, monoclonal blood grouping reagent is a low protein reagent containing the monoclonal IgM antibody, Clone MS-56, diluted in a phosphate buffer containing sodium chloride (0.9 g%), bovine albumin (6 g%) and macromolecular potentiators. The reagent is supplied at optimal dilution for use with all recommended techniques stated below without need for further dilution or addition. For lot reference number and expiry date see Vial Label.

### STORAGE

Reagent vials should be stored at 2-8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. The reagent has undergone transportation stability studies at 37°C and -25°C as described in document EN 23640:2011.

### SAMPLE COLLECTION AND PREPARATION

Blood samples drawn with or without anticoagulant may be used for antigen typing. If testing is delayed, then store specimens at 2-8°C. EDTA and citrate samples should be typed within 48 hours. Samples collected into ACD, CPD or CPDA-1 may be tested up to 35 days from the date of withdrawal. All blood samples should be washed at least twice with PBS or Isotonic saline before being tested.

### CONTROLS AND ADVICE

- It is recommended a positive control (ideally heterozygous) and a negative control be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
- When typing red cells from a patient it is important that a reagent negative control is included since the macromolecular potentiators in the reagent may cause false positive reactions with IgG coated cells.
- Weak K antigens may be poorly detected by the gel card, microtitre plate and slide technique. It is recommended that weak K antigens are tested using the tube test technique.
- In the **Recommended Techniques** one volume is approximately 50 µL when using the vial dropper provided.
- The use of the reagents and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagents are in use.
- The user must determine suitability of reagent for use in other techniques.

### REAGENTS AND MATERIALS REQUIRED

- Applicator sticks.
- Automatic plate reader.
- PBS solution (pH 6.8 – 7.2) or Isotonic saline solution (pH 6.5 – 7.5)
- DiaMed ID-Cards (Neutral).
- DiaMed ID-Centrifuge.
- DiaMed ID-Diluent: i.e. ID-CellStab.
- Glass microscope slides.
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- Microplate centrifuge.
- Ortho BioVue System Cassettes (Neutral).
- Ortho BioVue System Centrifuge.
- Ortho 0.8% Red Cell Diluent.
- Plate shaker.
- Positive (ideally Kk) and negative (kk) control red cells.
- Test tube centrifuge.
- Validated "U" well microplates.
- Volumetric pipettes.

### RECOMMENDED TECHNIQUES

#### A. Tube Technique:

- Prepare a 2-3% suspension of washed test red cells in PBS or Isotonic saline.
- Place in a labelled test tube: 1 volume of DIALAB Anti-K, monoclonal reagent and 1 volume of test red cell suspension.
- Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
- Gently resuspend red cell button and read macroscopically for agglutination
- Any tubes, which show a negative or questionable result, should be incubated for 15 minutes at room temperature.
- Following incubation, repeat steps 3 and 4.

#### B. DiaMed-ID Micro Typing Technique (Neutral Cards):

- Prepare a 0.8% suspension of washed test red cells in an ID-Diluent.
- Remove aluminium foil from as many microtubes as needed.
- Place in appropriate microtube: 50 µL of test red cell suspension and 25 µL of DIALAB Anti-K, monoclonal reagent.
- Centrifuge ID-Card(s) in a DiaMed ID centrifuge.
- Read macroscopically for agglutination.

#### C. Ortho BioVue Typing Technique:

- Prepare a 0.8% suspension of washed test red cells in 0.8% Ortho Red Cell Diluent.
- Remove aluminium foil from as many reaction chambers as needed.
- Place in appropriate reaction chamber: 50 µL of test red cell suspension and 40 µL of DIALAB Anti-K, monoclonal reagent.
- Centrifuge cassette(s) for 5 minutes in an Ortho BioVue System Centrifuge.
- Read macroscopically for agglutination.

#### D. Microplate Technique, using "U" wells:

- Prepare a 2-3% suspension of washed test red cells in PBS or Isotonic saline.
- Place in the appropriate well: 1 volume DIALAB Anti-K, monoclonal reagent and 1 volume test red cell suspension.
- Mix thoroughly, preferably using a microplate shaker, taking care to avoid cross-well contamination.
- Incubate at room temperature for 15 minutes (time dependant on user).
- Centrifuge the microplate for 1 minute at 140 rcf or for a suitable alternative time and force.
- Resuspend the cell buttons using carefully controlled agitation on a microplate shaker
- Read macroscopically or with a validated automatic reader.
- Any weak reactions should be repeated by the tube technique.

#### E. Slide Technique:

- Prepare a 35-45% suspension of test red cells in serum, plasma or PBS.
- Place on a labelled glass slide: 1 volume of DIALAB Anti-K, monoclonal reagent and 1 volume of test red cell suspension.
- Using a clean applicator stick, mix reagent and cells over an area of about 20 x 40 mm.
- Slowly tilt the slide back and forth for 30 seconds, with occasional further mixing during the 2-minute period, maintaining slide at room temperature.
- Read macroscopically after 2 minutes over a diffuse light and do not mistake fibrin strands as agglutination.
- Any weak reactions should be repeated by the tube technique.

### INTERPRETATION OF TEST RESULTS

- Positive:** Agglutination of the test red cells constitutes a positive test result and within accepted limitations of test procedure, indicates the presence of the K antigen on the test red cells.
- Negative:** No agglutination of the test red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of the K antigen on the test red cells.
- Test results of cells that are agglutinated using the reagent negative control shall be excluded, as the agglutination is most probably caused by the effect of the macromolecular potentiators in the reagent on sensitised cells.

### STABILITY OF THE REACTIONS

- Read all tube and microplate tests straight after centrifugation.
- Slide tests should be interpreted within two minutes to ensure specificity and to avoid the possibility a negative result may be incorrectly interpreted as positive due to drying of the reagent.
- Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

### LIMITATIONS

- Stored blood may give weaker reactions than fresh blood
- False positive or false negative results may also occur due to:
  - Contamination of test materials
  - Improper storage, cell concentration, incubation time or temperature
  - Improper or excessive centrifugation
  - Deviation from the recommended techniques

#### PERFORMANCE CHARACTERISTICS

1. The reagent has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of DIALAB Anti-K, monoclonal is tested by the **Recommended Techniques** against a panel of antigen-positive red cells to ensure suitable reactivity.
3. Specificity of source monoclonal antibodies is demonstrated using a panel of antigen-negative cells.
4. The Quality Control of the reagent was performed using red cells that had been washed twice with PBS or Isotonic saline prior to use.
5. The reagent complies with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.

#### DISCLAIMER

1. The user is responsible for the performance of the reagents by any method other than those mentioned in the **RECOMMENDED TECHNIQUES**.
2. Any deviations from the **RECOMMENDED TECHNIQUES** should be validated prior to use.

#### PRECAUTIONS

1. The reagent is intended for *in vitro* diagnostic use only.
2. If a reagent vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagent past the expiration date (see **Vial Label**).
4. Do not use the reagent if a precipitate is present.
5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
6. The reagent has been filtered through a 0.2 µm capsule to reduce the bioburden. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination.
7. The reagent contains < 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal, flush away with large volumes of water.
8. Materials used to produce the reagent were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg using approved microbiological tests.
9. No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

#### DISPOSAL OF REAGENTS AND DEALING WITH SPILLAGES

For information on disposal of the reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

#### LITERATURE

1. Kholer G, Milstein C. Continuous culture of fused cells secreting antibody of predefined specificity. *Nature* 1975, 256, 495-497.
2. Race RR, Sanger R. *Blood Groups in Man* 6<sup>th</sup> Edition, Oxford, Blackwell Scientific Publishers 1975, Chapter 2.
3. Issitt PD. *Applied Blood Group Serology*, 3<sup>rd</sup> Edition, Montgomery Scientific, Miami, 1985, Chapter 10.
4. Mollison PL. *Blood Transfusion in Clinical Medicine*, 8<sup>th</sup> Edition, Oxford, Blackwell Scientific Publications, 1987, Chapter 7.
5. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
6. British Committee for Standards in Haematology, Blood Transfusion Task Force. Recommendations for evaluation, validation and implementation of new techniques for blood grouping, antibody screening and cross matching. *Transfusion Medicine*, 1995, 5, 145-150.

#### TABLE OF SYMBOLS



Batch Number



In-vitro Diagnostic



Reference Nr.



Content



Expiry Date



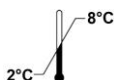
Store At



Manufacturer



Read Pack Insert



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