Blood Grouping Reagent

Anti-K (KEL1)

Seraclone® Human Monoclonal
(MS56)

FOR IN VITRO DIAGNOSTIC USE
For Tube Testing
MEETS FDA POTENCY REQUIREMENTS
U.S. License Number: 1845
Rx only

PACKAGE SIZE

[REF] 808090100 [VOL] 5 mL Seraclone® Anti-K (KEL1)

INTENDED USE

For the determination of the Kell (KEL1) antigen of red blood cells using the tube test.

SUMMARY

The Kell (KEL1) antigen was first identified in 1946 when the corresponding antibody was found to cause hemolytic disease of the fetus and newborn (HDFN). Anti-K antibody has also been shown to cause hemolytic transfusion reactions (HTR). Although in low density on the red cell membrane the Kell antigen is strongly immunogenic[1].

Since the description of the antigen K in 1946 by Coombs *et al* and its allele Þ 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. These are probably controlled from a series of closely linked loci so that Kell antigens, like CDE in the Rh system, are inherited as haplotype.

The antigens of the Kell blood group system are of further interest in that they tend to occur either very frequently (e.g. Þ 99.8%) or relatively infrequently (e.g. K 8%) and show considerable ethnic variation.

Kell system antibodies are capable of causing hemolytic transfusion reactions (HTR) and hemolytic disease of the fetus and newborn (HDFN) and are optimally detected by the indirect antiglobulin technique[1].

The frequencies of the common phenotypes are shown in the table.

Phenotypes and Frequencies in the Kell System[1]

Phenotype	Whites	Blacks
K+k-	0.2	Rare
K+k+	8.8	2
K-k+	91.0	98
Kp (a+b-)	Rare	0
Kp (a+b+)	2.3	Rare
Kp (a-b+)	97.7	100
Js (a+b-)	0.0	1
Js (a+b+)	Rare	19
Js (a-b+)	100.0	80
K_0	Exceedingly rare	Exceedingly rare

Bio-Rad Anti-K Blood Group Reagent is used to test for the presence or absence of the K antigen. Bio-Rad Anti-K is used principally in the resolution of antibody problems or in family studies.

PRINCIPLES OF THE TEST

The test principle is hemagglutination. The antibodies in Anti-K (KEL1) bind to the K antigen on red blood cells and cause an antigen-antibody reaction visible as red cell agglutination.

REAGENT

[IVD]
OBSERVABLE INDICATIONS
Do not use if markedly turbid.
Do not use damaged vials.

As the reactive component Seraclone® Anti-K (KEL1) contains a human monoclonal antibody of the immunoglobulin class IgM. It is derived from cell culture supernatant and demonstrates the consistent specificity and reproducibility characteristic for monoclonal antibodies.
Antibodies are diluted in a buffered protein solution containing bovine albumin and macromolecular potentiators.

The following antibodies are produced using intermediate products produced for Bio-Rad Medical Diagnostics GmbH in a shared manufacturing agreement with Millipore (UK) Ltd., 9 Fleming Road, Kirkton Campus, EH547BN, Livingston, UK; License Number 1721.

Seraclone® Anti-K (KEL1) clone MS56 (IgM)

Preservative: 0.1% Sodium azide.

PRECAUTIONS

- For In-vitro diagnostic use.
- Store at 2 to 8°C.
- Do not use beyond the expiration date.
- Do not use if turbid.
- Handle and dispose of reagents as potentially infectious.
- Caution: Do not pipette by mouth. The absence of all viruses has not been determined.
- Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.
- Warning: Contains sodium azide (NaN_3), which may react with lead or copper plumbing to form explosive azides. If discarded in the sink, flush with large amounts of water to prevent the build-up of explosive metal azides.
- The bovine albumin used for the production of this reagent is sourced from donor animals of U.S. origin that have been inspected and certified by U.S. Veterinary Service inspectors to be disease free.
- Consult **downloads.bio-rad.com** to download the valid version of this instruction for use.

SPECIMEN COLLECTION

Fresh samples of clotted, EDTA or citrate anticoagulated whole blood collected following general blood sampling guidelines are acceptable. The specimen should be tested as soon as possible after collection. If testing is delayed, specimens should be stored at 2 to 8°C, citrated specimens (donor segments) may be stored at temperatures as low as 1°C.
Note: Blood specimens exhibiting gross hemolysis or contamination should not be used.
Clotted samples or those collected in EDTA may be tested within ten days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiration date of the donor unit.

MATERIALS

Materials provided

- Seraclone® Anti-K (KEL1)

Materials required but not provided

- Pipettes
- Isotonic saline or Phosphate Buffered Saline (PBS; pH of 7.2+/-0.1)
- Glass tubes 10 x 75mm or 12 x 75mm
- Serological centrifuge
- Interval timer
- Markers
- Agglutination viewer (optional).

TEST PROCEDURE

Tube test

1. Prepare a 3 to 5% suspension of red blood cells to be tested in saline.
2. Place one drop reagent into an appropriately labelled tube.
3. Add one drop (approx. 40 to 50µL) of red blood cell suspension into the tube and mix.
4. Incubate at room temperature (15 to 30°C) for 5 to 10 minutes.
5. Centrifuge for:
   a. 20 seconds at 800 to 1000 x g, or
   b. at time and speed appropriate for the centrifuge calibration.
6. Gently dislodge red blood cell button and observe for macroscopic agglutination. Negative reactions may be examined with an agglutination viewer, however, microscopic examination is not recommended.
7. Record results.

STABILITY OF REACTION

Following centrifugation, all tube tests should be read immediately and results interpreted without delay. Time delays may cause a dissociation of the antigen-antibody complexes resulting to false negative or more often weak positive reactions.

QUALITY CONTROL

The reactivity of all blood typing reagents should be confirmed by testing with known positive and negative red blood cells on each day of use.
To confirm the reactivity or specificity of Bio-Rad Monoclonal Anti-K Blood Grouping Reagent, it should be tested with antigen-positive (preferably from heterozygous individuals) and antigen-negative red blood cells, respectively. The reagent is satisfactory for use if it reacts only with antigen-positive red blood cells.

INTERPRETATION OF RESULTS

Agglutination of the red blood cells is a positive result and indicates the presence of the corresponding antigen. No agglutination is a negative result and indicates the absence of the corresponding antigen.

Antigen Frequency (%)[2]

	Caucasian	Blacks	Orientals	Iranian Jews	Arabs
K	9	2	Rare	12	As high as 25%

An agglutination viewer may facilitate the reading of tube tests (as recommended by the AABB Technical Manual[1]).

LIMITATIONS

- Samples with cold agglutinins or rouleaux formation may show false positive results in testing with monoclonal antibodies. Results on these samples must be interpreted with caution. False positive results or reaction suspected to be due to cold agglutinins should be resolved according to in-house procedures.
- Kell antigen expression may be dramatically weakened in some cases of Chronic Granulomatous Disease.
- Grossly icteric blood samples, blood samples with abnormally high concentrations of protein or blood samples from patients who have received plasma expanders of high molecular weight may give false positive results..
- In case of ambiguous results it is recommended to wash red blood cells at least 2 times.

- Stored red blood cells may exhibit weaker reactions.
- Some conditions that may cause false positive results are:
  - Contamination of sample or reagents
  - Autoantibodies
  - Improper storage or preparation of cells
  - Mixed field reaction due to patients pre-transfusion history
  - Cross reactions with patient's medication (e.g. antibiotics)

SPECIFIC PERFORMANCE CHARACTERISTICS

Testing is performed in accordance with FDA recommended methods.
The final release testing is performed according to the product specific SOPs. As part of the release process each lot of Bio-Rad Blood Group Reagent is tested according to the package insert method against a panel of antigen positive red blood cells (heterozygous antigen expression and if possible weakened antigen expression) to insure suitable reactivity. The products meet FDA potency requirements. The specificity testing for the presence of contaminating antibodies is performed according to the product specific SOPs.
For the product performance it is necessary to adhere to the recommended method in the instructions for use.

The performance of the Bio-Rad Anti-K was confirmed against a FDA approved reference reagent in a Multi Center Field Trial.

For Technical Support or further product information, contact Bio-Rad Laboratories, Inc. at 800-224-6723.

NOTE

Manual techniques are to be performed according to the manufacturer's instructions. Each deviation from these instructions is the sole responsibility of the user.
Used tests must be discarded as hazardous material. Manage waste according to local, state and national regulations.

GLOSSARY OF SYMBOLS

Symbol	Definition	Symbol	Definition
[LOT]	Batch Code	[IVD]	*In vitro* diagnostic medical device
!	Consult the instructions for use for important cautionary information such as warnings and precautions	I	Consult instructions for use
M	Manufacturer	e	Use by YYYY-MM-DD
s	Contains sufficient quantity for <n> tests	[REF]	Catalog number
t	Temperature limitation	[VOL]	Volume

BIBLIOGRAPHY

1. John D. Roback, MD et al. Technical Manual 17th Edition, Bethesda, MA: AABB, 2011.
2. Marion E. Reid, Christine Lomas-Francis, The Blood Group Antigen FactsBook, New York, NY: Academic Press, 2004.

Key: Underline = Addition of changes ◄ = Deletion of text