

MONOCLONAL BLOOD GROUPING REAGENTS DIRECTIONS FOR USE

Anti-Jk^a and Anti-Jk^b Monoclonal: For Tube Technique.

SUMMARY

The Jk^a and Jk^b antigens were reported in 1951 and 1953 respectively. Anti-Jk^a and anti-Jk^b can both show dosage and are notorious for their evanescence: antibody titres that rise after stimulation but quickly drop, often to undetectable levels. Kidd system antibodies have been implicated in delayed and immediate Haemolytic Transfusion Reactions and Haemolytic Disease of the Newborn.

Anti-Jk ^a	Anti-Jk ^b	Phenotype	Caucasians %	Afro-Americans %
+	0	Jk(a+b-)	28	57
+	+	Jk(a+b+)	49	34
0	+	Jk(a-b+)	23	9
0	0	Jk(a-b-)	-	Very Rare

INTENDED USE

The Kidd reagents are blood grouping reagents intended to be used to qualitatively determine the presence or absence of the Jka or Jkb antigen on the red cells of blood donors or patients requiring a blood transfusion when tested in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

The reagents will cause direct agglutination (clumping) of test red cells, that carry the corresponding Kidd antigen. No agglutination generally indicates the absence of the corresponding Kidd antigen (see **Limitations**).

REAGENTS

Lorne Monoclonal Anti-Jka and Anti-Jkb grouping reagents contain human monoclonal IgM antibodies, diluted in a phosphate buffer containing sodium chloride and bovine albumin. Anti-Jk^a contains an antibody of the cell line P3HT7 and Anti-Jk^b contains an antibody of the cell line P3143. Each reagent is supplied at optimal dilution for use with all recommended techniques stated below without the 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. This reagent has undergone transportation stability studies at 37°C and -25°C as described in document BS EN ISO 23640:2015.

SAMPLE COLLECTION AND PREPARATION

Blood samples can be collected into EDTA, citrate, CPDA anticoagulants or as a clotted sample. The samples should be tested as soon as possible following collection. If a delay in testing should occur, store the samples at 2-8°C. Samples displaying gross haemolysis or microbial contamination should not be used for testing. Blood samples showing evidence of lysis may give unreliable results. It is preferable (but not essential) to wash all blood samples with PBS or Isotonic saline before being tested.

PRECAUTIONS

1. The reagents are 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 reagents past the expiration date (see **Vial Label**).
4. Do not use the reagents 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 reagents have been filtered through a 0.2 µm capsule to reduce the bio-burden. Once a vial has been opened the contents should remain viable up until the expiry date.
7. The reagents contain <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 reagents 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 REAGENT AND DEALING WITH SPILLAGES

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

CONTROLS AND ADVICE

1. It is recommended a positive control (ideally heterozygous cells) 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.

2. In the **Tube Technique** one volume is approximately 50µl when using the vial dropper provided.
3. Use of the reagents and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with requirements of the country where the reagents are in use. The user must determine suitability of the reagents for use in other techniques.

REAGENTS AND MATERIALS REQUIRED

- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- Test tube centrifuge.
- PBS solution (pH 6.8-7.2) or Isotonic saline solution (pH 6.5-7.5).
- Positive (ideally heterozygous) and negative control red cells.
- Volumetric pipettes.

RECOMMENDED TECHNIQUES

A. Tube Technique

1. Prepare a 2-3% suspension of red test cells in PBS or Isotonic saline.
2. Place in a labelled test tube: 1 volume of Lorne reagent and 1 volume of red cell suspension.
3. Mix thoroughly and incubate at room temperature for 5 minutes.
4. Centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
5. Gently resuspend red cell button and read macroscopically for agglutination.

INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of the test red cells constitutes a positive test result and within accepted limitations of test procedure, indicates the presence of the appropriate Kidd antigen on the test red cells.
2. **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 appropriate Kidd antigen on the test red cells.

STABILITY OF THE REACTIONS

1. The tube tests should be read immediately after centrifugation. Delays may result in dissociation of antigen-antibody complexes leading to false negative, or weak positive reactions.
2. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those **recommended**.

LIMITATIONS

1. Suppressed or diminished expression of certain blood group antigens may conversely give rise to false negative reactions and so caution should always be exercised when assigning phenotypes on the basis of test results.
2. Lorne's Anti-Kidd monoclonal reagents are not suitable for use with Bio-Rad or Ortho BioVue gel cards.
3. Lorne Anti-Kidd monoclonal reagents are not suitable for use with enzyme treated cells or for use in indirect antiglobulin techniques.
4. 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

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The reagents have been characterised by the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne Anti-Jk^a and Anti-Jk^b reagent is tested by the **Recommended Techniques** against a panel of antigen-positive red cells to ensure suitable reactivity.
3. The performance characteristics of the reagents are as follows:
 - Anti-Jka reagent → Sensitivity: 100%, Specificity: 100%
 - Anti-Jkb reagent → Sensitivity: 100%, Specificity: 100%
4. The Quality Control of the reagents was performed using red cells that had been washed twice with PBS or Isotonic saline prior to use.
5. The reagents comply 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 use⁶.

BIBLIOGRAPHY

1. Widman FK. Technical Manual, 9th Edition. American Association of Blood Banks, Arlington, VA, 1985; Chapter 8
2. Race RR, Sanger R. Blood Groups in Man, 6th Edition. Blackwell Scientific, Oxford 1975; Chapter 2
3. Mollison PL. Blood Transfusion in Clinical Medicine, 8th Edition. Blackwell Scientific, Oxford 1987; Chapter 7
4. Issitt PD. Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami 1985; Chapter 6
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.








AVAILABLE REAGENT SIZES

	Vial Size	Catalogue Number
Anti-Jk ^a Monoclonal	2 ml	775002
	1000 ml	775000*
Anti-Jk ^b Monoclonal	2 ml	776002
	1000 ml	776000*

*This size is For Further Manufacturing Use (FFMU) only and is therefore not CE marked.

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TABLE OF SYMBOLS

	Batch Number		<i>in-vitro</i> Diagnostic
	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		