LORNE LABORATORIES LTD.
GREAT BRITAIN

CE 1434

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[1]	Afro-Americans[1]
+	0	**Jk(a+b-)**	26.3%	51.1%
+	+	**Jk(a+b+)**	50.3%	40.8%
0	+	**Jk(a-b+)**	23.4%	8.1%
0	0	**Jk(a-b-)**	Rare	Rare

INTENDED PURPOSE

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 contain antibodies against the Jka or Jkb antigen on human red cells and cause direct agglutination (clumping) of human red cells that carry the Jka and/or Jkb antigen. No agglutination (no clumping) indicates the absence of the Jka and/or Jkb antigen on human red cells (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. The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. 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 - 8ºC 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 37ºC and –25ºC as described in document BS EN ISO 23640:2015.

SAMPLE COLLECTION AND PREPARATION

Blood samples can be collected into EDTA 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 bioburden but are not supplied sterile. 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. A positive control (ideally heterozygous cells) and a negative control shall be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. When typing red cells from a patient who is diagnosed with a disease that causes the red cells to become coated with antibody or other proteins (such as HDN, AIHA), it is important to test the patient's red cells using Lorne's Negative Control (catalogue # 650010). Tests must be considered invalid if red cells are agglutinated using Lorne's Negative Control.
3. Before use, let the reagent warm up to room temperature. As soon as the reagent has been used, put the reagent back in storage at 2-8ºC.
4. In the **Tube Technique** one volume is approximately 50µl when using the vial dropper provided.
5. 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 the determine suitability of the reagents for use in other techniques.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED

- 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 (**see point 3 in Limitations**).
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.
3. 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

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's Anti-Jkb monoclonal reagent was found to give false positive reactions when testing red cells that are suspended in low ionic strength diluents (such as LISS, Ortho's 0.8% Red Cell Diluent, Bio-Rad's ID-CellStab and Bio-Rad's ID-Diluent 2). When typing red cells that are suspended in a low ionic strength diluent, wash the cells at least twice with PBS to remove any traces of the diluent before re-suspending the cells in PBS/Isotonic Saline or any other normal ionic strength diluent.
4. Lorne Anti-Kidd monoclonal reagents are not suitable for use with enzyme treated cells or for use in indirect antiglobulin techniques.
5. 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. Prior to release, each lot of reagent was tested using the recommended test methods listed in this IFU. The tests complied with the test requirements as stated in the current version/issue of the "Guidelines for the Blood Transfusion Services in the United Kingdom".
2. The performance characteristics of the reagents are as follows:
   - Anti-Jka reagent → Sensitivity: 100%, Specificity: 100%
   - Anti-Jkb reagent → Sensitivity: 100%, Specificity: 100%
3. The Quality Control of the reagents was performed using red cells with phenotypes that were verified by a UK blood transfusion centre and had been washed with PBS or Isotonic saline prior to use.

DISCLAIMER

1. The end 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[6].

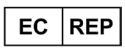
BIBLIOGRAPHY

1. Marion E.Reid & Christine Lomas-Francis, Blood Group Antigens & Antibodies, SBB Books, New York 2007; Page 181.
2. Issitt PD. Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami 1985; Chapter 6.
3. Guidelines for the Blood Transfusion Service in the United Kingdom, 6th Edition 2002. The Stationary Office.
4. AABB Technical Manual, 16th edition, AABB 2008.
5. 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	Tests per vial
Anti-Jk^a Monoclonal	2 ml	775002	40
Anti-Jk^b Monoclonal	2 ml	776002	40

TABLE OF SYMBOLS

Symbol	Definition	Symbol	Definition
	Manufacturer		Catalogue number
	Temperature limitation		Use by YYYY-MM-DD
	In vitro diagnostic medical device		Consult instructions for use.
	Authorised Representative		Lot number
	CE symbol		

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