Atlas Medical

**HUMAN BLOOD GROUPING REAGENTS**
**Anti-Jk[a] and Anti-Jk[b]**

IVD *For In-Vitro and professional use only*

Store at 2° to 8° C

## INTENDE USE

Anti-Jka and Jkb are monoclonal human IgM blood grouping reagents which will detect the Jka and Jkb antigens respectively, when tested according to the tube technique. These reagents are designed for use by operators trained in serological techniques.

## 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 | Frequency % |
|---|---|---|---|
| + | 0 | Jk (a+b-) | 28 |
| + | + | Jk (a+b+) | 49 |
| 0 | + | Jk (a-b+) | 23 |
| 0 | 0 | Jk (a-b-) | - |

## PRINCIPLE

When used by the recommended technique these reagents will cause agglutination (clumping) of red cells carrying the specific antigen (positive test). Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).
These reagents have been optimised for use as supplied by the recommended technique without further dilution or additions.
These products are supplied filtered to 0.22 µm

## STORAGE

Do not freeze. Reagent vials should be stored at 2-8°C on receipt until expiry date detailed on the product label. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

## 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 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). Do not use the reagents if a precipitate is present.
4. Protective clothing should be worn when handling the reagents: such as disposable cloves and a laboratory coat.
5. The reagents have 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.
6. 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.
7. 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.
8. 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.

## ADVICE TO USERS

1. The antglobulin techniques can only be considered valid if all negative tests react positively with IgG sensitised red cells. In the Tube Technique one volume is approximately 40µl when usin1. 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. The antiglobulin techniques can only be considered valid if all negative tests react positively with IgG sensitised red cells.
3. In the Tube Technique one volume is approximately 40µl when using the vial dropper provided.
4. 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.g 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 the suitability of the reagents for use in other techniques.

## REAGENTS AND MATERIALS REQUIRED

Anti-Jka and Jkb blood grouping reagents are composed of monoclonal human IgM antibodies in a buffer solution containing macromolecular chemical potentiators. These reagents contain 0.1% (w/v) sodium azide and bovine material. Each vial (2 mL) contains sufficient material for approximately 50 tests.

## MATERIALS REQUIRED BUT NOT PROVIDED

**Tube Technique:**

- Test tube
- Isotonic saline
- 37°C Incubator
- Timer
- Centrifuge (1000 rcf)

## RECOMMENDED TECHNIQUES

### Tube TECHNIQUE

1. Prepare a 3-5% suspension of washed test red cells in isotonic saline.
2. Place in a labeled test tube: one drop (40 µl) of Anti- Jk[a] or Anti-Jk[b] reagent and one drop (40 µl) of test red cell suspension.
3. Mix well and incubate at 37°C for 5minutes.
4. centrifuge for 20 seconds at 1000 rcf .
5. Gently resuspend red cell button and read macroscopically for agglutination.
6. Incubate all negative tests at 37°C for a further 10 minutes and repeat steps 1.5 and 1.6. This may enhance the reaction strength in typing cells of rare phenotypes.

**LIMITATIONS**

1. Red cells that have a positive DAT due to a coating of IgG cannot be typed by the Indirect Antiglobulin Technique.
2. Antibodies directed at low frequency antigens may occur as unsuspected contaminants in blood grouping antisera. In addition, certain antigens (eg. Bg, Sda') can be present in an exacted state on red blood cells. These phenomena may be the source of rare false positive reactions, which may occur with more than one lot of a given specificity.
3. It is not possible to claim the absence of all contaminating antibodies, as red cells carrying antigens of low frequency or exalted antigens are not always available for testing.
4. 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 genotypes on the basis of test results.
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**

Anti-Jka monoclonal human IgM blood grouping reagent and Anti-Jkb monoclonal human IgM blood grouping reagent have been tested by the recommended technique with donor, clinical and neonatal specimens. The sample population represented all major phenotypes. The total number of tests (n), and the calculated sensitivity and specificity for each technique are displayed below:

| TECHNIQUE | Anti-Jk[a] | | | |
|---|---|---|---|---|
| | Sensitivity | | Specificity | |
| | n | % | n | % |
| Tube | 726 | 99.6 | 205 | 100 |

| TECHNIQUE | Anti-Jk[b] | | | |
|---|---|---|---|---|
| | Sensitivity | | Specificity | |
| | n | % | n | % |
| Tube | 666 | 99.5 | 265 | 100 |

**REFERENCES**


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|---|---|---|---|
| REF | Catalogue Number | | Temperature limit |
| IVD | *In Vitro* diagnostic medical device | | Caution |
| Σ | Contains sufficient for <n> tests and Relative size | | Consult instructions for use (IFU) |
| LOT | Batch code | | Manufacturer |
| | Fragile, handle with care | | Use-by date |
| | Manufacturer fax number | | Do not use if package is damaged |
| | Manufacturer telephone number | | Date of Manufacture |
| | Keep away from sunlight | | Keep dry |