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BLOOD GROUPING REAGENT

Anti-Jk^a (Monoclonal) Anti-Jk^b (Monoclonal) Gamma-clone®

By Tube and MicroplateTests

Preservative: <0.1% Sodium Azide 1°C 10°C IVD **Rx ONLY**

CAUTION: THE PACKAGING OF THIS PRODUCT (DROPPER BULBS) MAY CONTAIN DRY NATURAL RUBBER. DO NOT PIPETTE THIS PRODUCT BY MOUTH, AS THE ABSENCE OF MURINE VIRUS HAS NOT BEEN DETERMINED.
DO NOT USE IF MARKEDLY TURBID.

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IMMUCOR

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Made in USA

Intended Use:

Gamma-clone Anti-Jk^a (Monoclonal) and Anti-Jk^b (Monoclonal) Blood Grouping Reagents are intended for the detection of the Jk^a (JK1) and Jk^b (JK2) antigens, respectively, on red blood cells by tube and microplate tests.

Summary of the Test:

Anti-Jk^a was first reported by Allen, Diamond and Niedziela in 1951[1], and the first example of the antithetical anti-Jk^b was identified in 1953 by Plaut and her co-workers[2]. Both antibodies have been implicated as the cause of hemolytic disease of the newborn and hemolytic transfusion reactions. The phenotype Jk(a–b–), first reported by Pinkerton and associates in a person of Filipino/Chinese decent[3], is rare among whites, has not been described among African-Americans in the US population, but appears to be relatively common among certain Pacific Island and Asian populations[4]. Immunized individuals of this phenotype may produce an antibody, anti-Jk3, that reacts with all red blood cells that are either Jk(a+) or Jk(b+).

Gamma-clone Anti-Jk^a (Monoclonal) and Gamma-clone Anti-Jk^b (Monoclonal) Blood Grouping Reagents are used to detect the presence of the Jk^a and Jk^b antigens on donor or patient red blood cells. Typing of donor red blood cells facilitates the selection of antigen-negative units for transfusion to patients with the corresponding antibody. Red blood cell typing also serves as final verification of the identification of an alloantibody in patient or donor serum.

Principle of the Test:

The presence of the Jk^a and Jk^b antigens is determined by testing with Anti-Jk^a and Anti-Jk^b by tube and automated microplate tests. Agglutination of the test red blood cells constitutes a positive test result and indicates the presence of the relevant antigen. No agglutination constitutes a negative test result and indicates that the antigen is not present.

Reagents:

Gamma-clone Anti-Jk^a (Monoclonal) Blood Grouping Reagent is prepared from IgM antibodies from the human/murine heterohybridoma cell line MS-15 grown in fluid culture and suitably diluted in a proprietary diluent containing bovine albumin to achieve the appropriate level of potency for the test procedure as described. Sodium azide is added as a preservative (at less than 0.1% w/v). Ready for use as supplied.

Gamma-clone Anti-Jk^b (Monoclonal) Blood Grouping Reagent is prepared from IgM antibodies from the human/murine heterohybridoma cell line MS-8 grown in fluid culture and suitably diluted in a proprietary diluent containing bovine albumin to achieve the appropriate level of potency for the test procedure as described. Sodium azide is added as a preservative (at less than 0.1% w/v). Ready for use as supplied.

Any Bovine Albumin used in the manufacture of this product is sourced from donor animals of United States origin that have been inspected and certified by USDA Food Safety and Inspection Service inspectors to be disease-free. This ruminant-based product is deemed to have a low-TSE (Transmissible Spongiform Encephalopathy) risk.

Storage:

- Store at 1ºC to 10ºC when not in use.
- Do not use beyond the expiration date which is expressed as CCYY-MM-DD (year-month-date).
- Do not freeze.

Precautions:

- For in vitro diagnostic use.
- Do not dilute.
- Effort should be made to minimize contamination during use.
- Do not use if markedly turbid.

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Sodium azide is added as a preservative (at less than 0.1% w/v). Waste fluids arising from the use of Gamma-clone Anti-Jk^a (Monoclonal) and Gamma-clone Anti-Jk^b (Monoclonal) must be flushed with large quantities of water to avoid accumulation of potentially explosive compounds in laboratory plumbing.

Handle and dispose of reagent as potentially infectious.

Specimen Collection and Preparation:

No special preparation of the patient is required prior to specimen collection. Blood should be drawn by aseptic technique, with or without an anticoagulant. Samples drawn into EDTA, ACD, CPD, CP2D and CPDA-1, as well as red blood cells that have been stored in the additive solutions AS-1, AS-3 and AS-5 can be used for testing. The specimen should be tested as soon as possible after collection. If delay in testing should occur, the specimen must be stored at 1°C to 10°C. Bacterial contamination of the specimen may cause false test results. Blood drawn into EDTA should not be stored for longer than ten days. Clotted specimens may be tested up to 21 days after collection, and donor blood may be tested up to the expiration date. Storage may result in weaker-than-normal reactions.

Red blood cells that are Direct Antiglobulin Test (DAT) positive can be used for testing. Red blood cells that have been EDTA Glycine-Acid (EGA) treated can be used for testing.

Procedure:

Materials Provided:

Gamma-clone Anti-Jk^a (Monoclonal) or Anti-Jk^b (Monoclonal)

Additional Materials Required for Automated Microplate Method:

GammaZyme-B
Refer to information provided in the instrument operator manual.

Additional Materials Required for Manual Tube Method:

1. Test tubes (12x75 mm or 10x75 mm)
2. Pipettes
3. Isotonic saline or phosphate-buffered (approximately 15 mM) isotonic saline pH 6.5-7.5
4. Centrifuge*
5. An optical aid such as a hand lens or concave mirror
6. Red blood cells of known Kidd phenotypes for use as controls.

*It is the users responsibility to validate an accessory device (either listed or otherwise) for its intended use. Validation results should be maintained as part of the laboratory's records for review by regulatory agencies.

Test Method:

Automated Microplate Method:

For microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

North American Market Automated Microplate Method is for donor testing only.

Manual Tube Method:

Since this test method applies to either reagent, extreme care should be exercised in selecting and using the appropriate reagent.

1. Place one (1) drop of Gamma-clone Anti-Jk^a (Monoclonal) or Gamma-clone Anti-Jk^b (Monoclonal) into a properly labeled test tube.
2. Add one (1) drop of an approximate 2-5% suspension of the red blood cells to be tested to the test tube (from step 1 above). The red blood cells to be tested should previously have been washed at least one time and resuspended in saline.
3. Mix the test tube contents well by gently shaking the tube and incubate the tube for five (5) to fifteen (15) minutes at room temperature (15ºC to 30º C). Incubating for the upper end of the time range may enhance reactivity.
4. Centrifuge the test tube.*
5. After centrifugation, immediately resuspend the red blood cells by gently shaking the test tube and examine for macroscopic agglutination. Negative reactions may be examined with an optical aid; however, microscopic reading is not recommended. Record the results.

*Suggested centrifugation time and RCF: 15 to 30 seconds at 900-1000 xg or a time and speed, appropriate for the centrifuge used, that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy suspension of antigen-negative red blood cells.

Stability of Reaction:

Following centrifugation, the tube test should be read immediately and interpreted without delay.

Automation reads and interprets the results immediately.

Key:
Underline = Addition or significant change ▲ = Deletion of text

Quality Control:

The reactivity of blood grouping reagents should be confirmed on each day of use by testing with red blood cells known to be negative and positive for the relevant antigens. Jk(a+b+) red blood cells are the most suitable positive control red blood cells for both Gamma-clone Anti-Jk^a (Monoclonal) and Gamma-clone Anti-Jk^b (Monoclonal). Each reagent is satisfactory for use if it reacts only with antigen-positive red blood cells. Immucor Reagent Red Blood Cells are a convenient source of control cells and may be used as supplied.

Interpretation of Results:

Automated Microplate Method:

For the interpretation of results associated with automated instrumentation, refer to information provided in the instrument operator manual.

Manual Tube Method:

Agglutination of the red blood cells constitutes a positive test result and indicates the presence of the relevant antigen.

No agglutination constitutes a negative test result, and indicates the absence of the relevant antigen.

The reaction patterns possible with Anti-Jk^a and Anti-Jk^b are shown in Table 1, together with the frequencies of the resulting phenotypes in some ethnic populations.

Reagent		Phenotype	Frequency (%) [5]		
Anti-Jk^a	Anti-Jk^b		Caucasians	Blacks	Asians
+	0	Jk(a+b–)	26.3	51.1	23.2
+	+	Jk(a+b+)	50.3	40.8	49.1
0	+	Jk(a–b+)	23.4	8.1	26.8
0	0	Jk(a–b–)	Rare	Rare	0.9 (Polynesians)

Table 1: The reaction patterns of Anti-Jk^a and Anti-Jk^b and the approximate frequencies of the resulting phenotypes in some ethnic populations.

Limitations:

1. Factors that may cause false test results include the following:
   a. Bacterial or chemical contamination of blood specimens, reagent and/or supplementary materials.
   b. Improper storage of materials.
   c. Aged or stored blood specimens. Such specimens may yield weaker reactions than those obtained with fresh red blood cells.
   d. Too heavy a red blood cell suspension of the specimen.
   e. Improper incubation time or temperature.
   f. Improper centrifugation. Proper centrifuge calibration is particularly important to the proper performance of the test. Excessive centrifugation may lead to difficulty in resuspending the red blood cell button in the tube test leading to a possible false positive result. At the same time, inadequate centrifugation may yield unclear red blood cell button patterns and agglutinates that are too readily dispersed leading to a possible false negative result.
   g. Improper examination for agglutination (usually too vigorous shaking). The resuspension of reactions in the tube test procedure must be carried out by gentle shaking. Shaking too vigorously may cause agglutinates to be dispersed.
   h. Deviation from the recommended test procedure such as the omission of test reagents.
2. Positive reactions of red blood cells from persons of unusual Kidd genotypes may be weaker than those reactions obtained with randomly selected positive control red blood cells tested in parallel. For these reasons, caution should be exercised when assigning genetic significance on the basis of test results.
3. Red blood cells that have been enzyme-treated must not be used for testing as either red blood cells under investigation or as a source of control red blood cells because use of these enzyme-treated red blood cells may yield erroneous results.
4. For details regarding specific limitations associated with automated microplate testing, refer to the instrument operator manual.

Specific Performance Characteristics:

Each lot of Gamma-clone Anti-Jk^a (Monoclonal) and Anti-Jk^b (Monoclonal) is tested by insert methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity and specificity. The specificity of the murine monoclonal antibodies secreted by the cell lines used to manufacture these Blood Grouping Reagents has been determined by testing with red blood cells of varying phenotypes.
The performance of this product is dependent upon adhering to the package insert recommended methodology.

Performance on NEO Iris and Galileo NEO

CE-marked assays: Method comparison studies were performed at one (1) internal site.
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Specimens were tested with the reagent and also a comparator reagent. Samples with Initial equivocal results were retest. Test results were evaluated for agreement between reagents.

Note: Agreement between methods does not indicate which method is correct.

CE-marked assay is for donor and patient testing.

Results N=1145		Comparator Reagent			
		Positive	Negative		
Anti-Jk^a	Positive	840	0	Positive Percent Agreement	100%
				PPA (95% 1-Sided LCI)	99.7%
	Negative	0	305	Negative Percent Agreement	100%
				NPA (95% 1-Sided LCI)	99.2%

For CE-marked assay only; not applicable to North American Market.

Results N=1146		Comparator Reagent			
		Positive	Negative		
Anti-Jk^b	Positive	837	0	Positive Percent Agreement	100.00%
				PPA (95% 1-Sided LCI)	99.7%
	Negative	0	309	Negative Percent Agreement	100%
				NPA (95% 1-Sided LCI)	99.3%

For CE-marked assay only; not applicable to North American Market.

North American Market Assays: Method comparison studies were performed at one (1) external blood collection site and one (1) internal site. Immucor, Inc., as the manufacturer, was the internal site. Specimens were tested with the reagent and also a comparator reagent. Samples with initial equivocal results were retest. Test results were evaluated for agreement between reagents. Combined results from all sites are summarized in the following table:

Note: Agreement between methods does not indicate which method is correct.

North American Market assays are for donor testing only.

Initial Results N=696		Comparator Reagent			
		Positive	Negative		
Anti-Jk^a	Positive	485	0	Positive Percent Agreement	100.00%
				PPA (95% 1-Sided LCI)	99.50%
	Negative	0	238	Negative Percent Agreement	100.00%
				NPA (95% 1-Sided LCI)	99.04%

Initial Results N=695		Comparator Reagent			
		Positive	Negative		
Anti-Jk^b	Positive	418	0	Positive Percent Agreement	100.00%
				PPA (95% 1-Sided LCI)	99.45%
	Negative	0	277	Negative Percent Agreement	100.00%
				NPA (95% 1-Sided LCI)	99.17%

For additional information or for technical support, contact Immucor at 855-IMMUCOR (466-8267).

Bibliography:

1. Allen FH, Diamond LK, Niedziela B. A new blood group antigen. Nature 1951; 167:482.
2. Plaut G, Ikin EW, Mourant AE, Sanger R, Race RR. A new blood group antibody (anti-Jk^b). Nature 1953; 171:431.
3. Pinkerton FJ, Mermod LE, Liles BA, Jack JJ, Noades J. The phenotype Jk(a–b–) in the Kidd blood group system. Vox Sang 1959; 4:155-160.

4. Race RR, Sanger R. Blood groups in man. 6th ed. Oxford, Blackwell Scientific Publications;1975:336.
5. Reid ME, Lomas-Francis C. The blood group antigen facts book. 3rd ed. San Diego: Elsevier Academic Press, 2012:377.

Symbols Glossary:
The Symbols Glossary (ID No. 400) is provided electronically at
http://adextranet.immucor.com/EN/Pages/PackageInserts.aspx
Additional symbols that appear in product labeling:

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