

## INSTRUCTIONS FOR USE

**Anti-Jk<sup>a</sup> (Kidd<sup>a</sup>), -Jk<sup>b</sup> (Kidd<sup>b</sup>)**

**CE 0123**

**Anti-N, -S, -P<sub>1</sub>**

**CE**

**monoclonal (IgM)**

### Clones:

**Anti-Jk<sup>a</sup>: MS15**

**Anti-Jk<sup>b</sup>: MS8**

**Anti-N : 1422 C 7**

**Anti-S : MS94**

**Anti-P<sub>1</sub>: 650**

FOR IN VITRO DIAGNOSTIC USE

### **1. Description of products**

Anti-Jk<sup>a</sup>, Anti-Jk<sup>b</sup>, Anti-S are made from monoclonal human IgM antibodies and Anti-N, Anti-P<sub>1</sub> are made from monoclonal mouse IgM antibodies. The clone numbers are given on the labels of the test reagents.

The test reagents aid in the detection of the corresponding antigens on erythrocytes and are suitable for the test tube procedure.

NaN<sub>3</sub> (< 0.1%) is added to the test reagents as a preservative.

Anti-Jk<sup>a</sup> und Anti-Jk<sup>b</sup> contain reaction enhancer.

### **2. Principle of the test**

The testing method indicated is based on the principle of hemagglutination. A specific antigen-antibody reaction takes place once erythrocytes are added to the monoclonal test reagents if the corresponding antigen is present on the erythrocytes. This reaction is visibly recognizable by the agglutination of the erythrocytes. If no agglutination takes place, this indicates a negative result and, allowing for the limitations of the testing method, the absence of the corresponding antigen.

### **3. Storage and stability**

Store the test reagents at 2...8°C. Do not freeze! Allow the reagents to come to room temperature (18...25°C) before use and store again at 2...8°C immediately after use.

Once they have been opened the first time, the test reagents may be used up to the expiration date indicated on the label if the specified storage conditions are observed. Do not use the reagents past the expiration date indicated on the label.

### **4. Preparation of samples**

The blood samples should be collected according to the customary medical procedure. Blood samples with and without anti-coagulants (EDTA, citrate) are suitable for testing. Do not use hemolytic and/or contaminated samples! Testing should take place without delay. If this is not possible, store the sample at 2...8°C.

The strength of positive reactions depends on the age of the used blood. If erythrocytes are stored for too long before testing, the erythrocyte antigens may change, which can lead to weakened reactions (see 9. Important Notes/Limitations of the Method).

### **5. Additional materials required**

Isotonic NaCl solution  
Test tubes (75 x 12 mm)  
Single-use Pasteur pipettes  
Centrifuge

### **6. Test procedure**

#### **Tube test**

1. Wash the erythrocytes to be examined at least once and then make a suspension of 2 - 3% in isotonic NaCl solution.
2. Mix 1 drop of monoclonal test reagent and 1 drop of the erythrocyte suspension in a labeled test tube.  
Anti-S, Anti-P1, Anti-Jk<sup>a</sup>, Anti-Jk<sup>b</sup>: Incubate for 10 - 15 minutes at room temperature.  
Anti-Jk<sup>a</sup>, Anti-Jk<sup>b</sup> especially at 2...8°C.  
Anti-N: No incubation, centrifuge immediately.
2. Centrifuge 1 minute at 400 x g (1500 rpm) or at an alternative rpm with an appropriate time adjustment.
3. Resuspend the cells by gently shaking the tube and examine macroscopically for agglutination.

**Comments:** Do not examine the test microscopically.  
Erythrocytes that are positive with regard to the respective antigen (preferably heterozygote cells), and erythrocytes that are negative with regard to the respective antigen, as well as a negative control for monoclonal test reagents and an auto-control to test for autoagglutination must also be tested as controls.  
The determination of the antigens should be carried out with at least 2 different test reagents. When using two monoclonal test reagents, two different clones should be used, if possible.

### **7. Interpretation of the results**

An agglutination of the erythrocytes with the test reagent indicates the presence of the corresponding antigen.

If there is no agglutination of the erythrocytes with the test reagent, this indicates the absence of the corresponding antigen.

The test results cannot be evaluated if there is no agglutination with the known positive erythrocyte suspension, or if agglutination occurs with the known negative erythrocyte suspension or the negative control for monoclonal test reagents or the auto-control.

If discrepant results occur with two different test reagents when determining the antigen, the determination must be repeated with another test method and/or an additional test reagent.

The limitations of the method must be considered when interpreting the results (see 9. Important Notes/Limitations of the Method).

### **8. Stability of reactions**

All test results must be interpreted immediately once the test is performed.

## **9. Important Notes/Limitations of the Method**

1. The test reagents are suitable for in vitro diagnostic use only and may only be used by trained, qualified personnel.
2. In rare cases, spontaneous and non-specific agglutinations may occur with erythrocytes loaded with immunoglobulins in vivo. In such instances similar phenomena would most likely occur in blood grouping tests of other blood group systems as well. Therefore, as a control, a negative control for monoclonal test reagents and an autologous patient serum should always be tested as well. If the control tests also show a positive reaction, the result of the blood type determination cannot be interpreted.
3. Suspensions of unwashed erythrocytes in plasma or serum promote false positive reactions such as those associated with rouleaux formation or autoantibodies. The use of well-washed erythrocytes can reduce the occurrence of such false positive reactions.
4. In the serum/plasma of the patient, soluble antigens that may be present can be adsorbed on the erythrocyte surface, or they can neutralize antibodies targeted against the corresponding antigen. The use of well-washed erythrocytes can prevent the occurrence of such false positive reactions.
5. Insufficient cell concentration, reading the results of the test too late, agitating the erythrocyte sediment too strongly, and other deviations from the indicated testing procedure can lead to weaker or false negative results.
6. The test reagents should not be used for the testing of enzyme-treated erythrocytes. Particularly the S-antigen may be destroyed by enzyme treatment.
7. Hemolytic and/or contaminated samples should not be used.
8. False negative results or unexpected weak reactions may be caused by storing the erythrocytes for too long and/or under inappropriate conditions and/or by a cell concentration that is too low.
9. False negative or false positive results can result from inappropriate techniques, incorrect centrifugation or incubation, dirty tubes, incorrect pH of the isotonic NaCl solution and/or contaminated materials and samples.
10. A microbial contamination of the test reagents must be absolutely avoided because this shortens the shelf life of the products and can lead to false results.
11. False weak reactions (+/- or 1+) can occur with Anti-N monoclonal, clone 1422 C7, by MMS+ antigen constellation. In most cases the agglutination dissolve after a short time.
12. In the case of detecting the N-antigen unspecific reactions can occur due to reaction enhancer. Therefore test cells should be washed with isotonic saline as stated by the manufacturer.
13. Light cloudiness does not influence the reactivity of the product.
14. Deviation from the recommended Instructions for Use may result in less than optimal product performance. User-defined deviations such as modifications of test procedures, serum dilution for use in automat or cards, freezing of serum on microtiter plates etc. may require validation by the user.
15. Whether transfusions or transplantation have taken place should always be taken into consideration when interpreting the results. Any history of transfusions and/or transplantation, as well as the patient's medication history, should be taken into consideration when interpreting results.

## **10. Warnings and instructions for disposal**

Materials of human origin used in the manufacture of the test reagents were tested for HBsAg and antibodies to HIV and HCV. Only negative material was used for manufacture. In spite of this, all materials of biological origin used for the test should be regarded as potentially infectious since no testing method can detect all infectious pathogens. Therefore, appropriate safety precautions are recommended when handling biological materials (do not pipette using the mouth; wear protective gloves when performing the test; disinfect hands after testing).

Biological materials must be deactivated before disposal (e.g., by autoclaving). Single-use materials must be autoclaved or incinerated after use.

Spills of potentially infectious material should be removed without delay with an absorbent paper towel and the contaminated area disinfected with an appropriate disinfectant or 70% ethanol. Materials used for the removal of spills must be deactivated before disposal (e.g., by autoclaving).

The test reagents contain as preservative < 0.1% NaN<sub>3</sub>. A concentration of < 0.1% NaN<sub>3</sub> is not considered to be a harmful concentration. Nevertheless avoid contact with the skin and mucous membranes. The copper and lead used in some pipe systems can form explosive salts with azide. The amounts of azide contained in the reagents are small; nevertheless, copious amounts of water should be used for rinsing afterwards when disposing of azide-containing materials.












The disposal of all samples and test materials should be carried out according to legal directives.

**11. Package sizes** see price list

**12. Bibliography**

Applied Blood Group Serology, PD Issitt and DJ Anstee  
4<sup>th</sup> Edition, Montgomery Scientific, Durham SC, 1998

Technical manual of the American Association of Blood Banks, 15<sup>th</sup> ed., 2005

Explanation of symbols used on Labelling	
	For in vitro diagnostic use
	Storage temperature
	Batch code
	Use by
REF	Catalogue number
	Consult instructions for use
	Monoclonal IgM
	Clone
	Origin: human
	Origin: murine
	Contains Natriumazide
	Titer

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