EN

INSTRUCTIONS FOR USE

Anti-Kp^a **Anti-Lu^a** **Anti-S** **Anti-k (Cellano)** CE

Anti-Kp^b **Anti-Lu^b** **Anti-s** **Anti-Wr^a**

Anti-Fy^a (Duffy^a) **Anti-Jk^a (Kidd^a)** CE 0123

Anti-Fy^b (Duffy^b) **Anti-Jk^b (Kidd^b)**

Electronic instructions for use see www.bag-diagnostics.com

Product		REF	Product		REF
Anti-Kp^a	2 ml	6866	Anti-k	5 ml	6865
Anti-Kp^b	2 ml	6868	Anti-Wr^a	2 ml	6840
Anti-Lu^a	2 ml	6850	Anti-Fy^a	2 ml, 5 ml	6870, 6871
Anti-Lu^b	2 ml	6851	Anti-Fy^b	2 ml, 5 ml	6873, 6874
Anti-S	2 ml	6844	Anti-Jk^a	2 ml, 5 ml	6884, 6885
Anti-s	2 ml	6845	Anti-Jk^b	2 ml	6887

FOR IN VITRO DIAGNOSTIC USE

1. Description of products

Anti-Kp^a, Anti-Kp^b, Anti-Lu^a, Anti-Lu^b, Anti-S, Anti-s, Anti-k (Cellano), Anti-Wr^a, Anti-Fy^a, Anti-Fy^b, Anti-Jk^a and Anti-Jk^b are manufactured from human sera from immunized donors. The test reagents contain IgG antibodies and aid in the detection of the respectively corresponding antigens on erythrocytes in the indirect agglutination test.
NaN_3 (< 0.1%) is added to the test reagents as a preservative. Furthermore the reagents contain NaCl, sodium caprylate free bovine albumin and high molecular enhancement media.

2. Principle of the test

The testing method indicated is based on the principle of indirect hemagglutination. Once erythrocytes are added to the test reagents, a specific antigen-antibody reaction takes place if the corresponding antigen is present on the erythrocytes. Following removal of the unbound antibodies by several wash steps, an anti-human globulin serum is added to the erythrocytes. The anti-IgG antibodies in the anti-human globulin serum are bound to the specific IgG antibodies on the erythrocytes, and forming bridges between the erythrocytes. This reaction is visibly recognizable by the agglutination of the erythrocytes. If no IgG antibodies are bound to the erythrocytes, there can be no binding of the anti-IgG antibodies

and therefore no agglutination occurs. 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 samples! Testing should take place without delay whenever possible. If this is not possible, store blood samples at 2...8°C.
If erythrocytes are stored for too long before testing, the erythrocyte antigens may change, which can lead to false positive or false negative reactions (see 9. Important notes/limitations of the method).

5. Additional materials required

Isotonic NaCl solution (isotonic saline)

Bovine albumin 22%

Bromelin Solution

Anti-human globulin (AHG)

Test tubes (75 x 12 mm)

Tube rack

Single-use Pasteur pipettes

Centrifuge

Water bath (37°C ± 1°C)

Red blood cells of known phenotype

6. Test procedure

Tube test

1. Wash the erythrocytes to be examined at least once and then make an erythrocyte suspension of 2 - 3% in isotonic NaCl solution.
2. Mix 1 drops of test reagent and 1 drop of the erythrocyte suspension in a labeled test tube and incubate at 37°C for 15 - 30 minutes.
3. Wash 3 times with cold isotonic NaCl solution and then carefully decant after the last washing.
4. Add 2 drops of anti-human globulin serum and mix well.
5. Centrifuge 1 minute at 400 x g (1500 rpm) or at an alternative rpm with an appropriate time adjustment.
6. Resuspend the cells by gently shaking the tube and examine macroscopically for agglutination.

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Comments: Do not examine the test microscopically.

If there are weak reactions, repeat the test with 2 drops test reagent and an incubation time of 30 minutes.

Adding of 1 drop 22% bovine albumin in step 2 could also enhance the reaction. In case of Anti-Wr^a adding of 1 drop Bromelin would be recommended.

Controls: Erythrocytes that are positive with regard to the respective antigen (preferably heterozygote cells), and erythrocytes that are negative with regard to the respective antigen 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 two different test reagents.

7. Interpretation of the results

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 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 (e.g. BAGene KKD-TYPE, BAGene MNS-TYPE, BAGene Rare-TYPE).

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 centrifugation is complete.

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. The strength of positive reactions depends on the age of the used blood.
3. False positive results may occur because of bacterial or chemical contamination of the test reagent, the samples or the isotonic NaCl solution and/or because of incorrect centrifugation.
4. False negative results or unexpected weak reactions may be caused by an insufficient cell concentration, insufficient incubation temperature or time and/or insufficient centrifugation, but also by storing the erythrocytes for too long and/or under inappropriate conditions. Reading the results of the test too late, agitating the erythrocyte sediment too strongly, and other deviations from the indicated testing procedure can also lead to weaker or false negative results.

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5. In general, 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.
6. A microbial or chemical contamination of the test reagents must be absolutely avoided because this shortens the shelf life of the products and can lead to false results.
7. Light cloudiness does not influence the reactivity of the product.
8. No single centrifugation speed or time can be recommended for all types of available centrifuges or test applications. Centrifuges should be calibrated individually to determine the optimal time and speed required to produce a clear supernatant and a clearly delineated red cell button that can be easily resuspended.
9. For interpretation of the test results, consider if transfusion or transplantation had happened. Take the case history of the transfusion or transplantation and also the patient's medication history into consideration.
10. 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.

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 tested material was used for manufacture. Bovine albumin is sourced from bovines from BSE-free cattle stocks. 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 < 0.1% NaN_3 which 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.

Disposal of all samples, unused reagent and waste should be in accordance with country, federal, state and local regulations.

A Material Safety Data Sheet (MSDS) is available to download at www.bag-diagnostics.com .

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Explanation of symbols used on Labelling	
IVD	For in vitro diagnostic use
	Manufacturer
	Storage temperature / Temperature limitation
LOT	Batch code
	Use by
REF	Catalogue number
	Consult instructions for use
ORIG | HUM	Origin: human
POLYCL	polyclonal
CONT | NaN_3	Contains Natriumazide
TIT	Titer

Instructions for use	Version: 3/2019 / Issue: 2019-06

Instructions for use in other languages see:
http://www.bag-diagnostics.com
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