

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

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) and Anti-Wr^a 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.

NaN₃ (< 0.1%) is added to the test reagents as a preservative.

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 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
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 an erythrocyte suspension of 2 - 3% in isotonic NaCl solution.
2. Mix 1 - 2 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.

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 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.

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. 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.
3. 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.
4. 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.
5. 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.
6. Light cloudiness does not influence the reactivity of the product.
7. 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 < 0.1% NaN₃ 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.

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

11. Package sizes See price list.

12. Bibliography

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
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Cellano LEVINE, P., BACKER, M., WIGOD, M. and PONDER, R.: A new human hereditary blood property (Cellano) present in 99,8% of all bloods. Science 109, 464 (1949)

Kp^a ALLEN, F.H., LEWIS, S.H.J.: Kp^a (Penny), a new antigen in the Kell blood group system. VOX Sang. 2, 81 (1957)

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

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