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Instruction for use Use by professionals only Tests/ml: 25: with drop size 40µl when using separate volumetric pipettes	CE 0483
Revision:	29/07-2019
Product-Name:	**Product-Code:**
Anti-Kell **AEK4**	Kell-mono-AEK4
Anti-Kell **MS56**	Kell-mono-MS56

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Reagent for specific detection of the corresponding antigen. Bloodgroup testreagent for microplate-, tube-, slide- and plate- tests.
All described test methods are only valid for manual applications as recommended in this instruction. The user must determine their suitability for use in other techniques (automates, gel-cards, others) according to recognized techniques in individual responsibility.
Only for in-vitro diagnostic laboratory use. Store at + 2 - 8 °C when not in use.

Product description:	Anti-Kell is a reagent which monoclonal human IgM antibodies from human hybridoma cell-lines detect the respective corresponding antigen by a direct agglutinating reaction. Sodium acide (< 0,1% w/w final concentration) is added as a preservative. The absence of agglutination shows the missing of corresponding antigens.
Clone:	• **AEK4** • **MS56**
Note/Caution:	Sodium acide can cause high explosive metal acide combinations with lead and cooper. When pouring rinse with a lot of water. All materials for the manufacturing of blood group typing reagents are tested against HBsAg, HCV and HIV. Only negative tested materials are used for production. Nevertheless all blood products should be treated as potential infectious. The source human material used to produce this reagent has been tested and found to be negative for HIV and HCV antibodies and HBsAg in microbiological tests. No known regime of testing can completely guarantee that any product derived from human blood is incapable of transmitting infectious agents. Bovine albumin or respective raw materials derived from animals free of BSE. Care should be exercised in the use and the disposal of the container and its contents.
Test methods:	Samples may be drawn into common anticoagulants (EDTA, ACD,). Testing should be performed as soon as possible to minimise the chance that falsely positive or falsely negative reactions are encountered due to contamination or improper storage of a specimen. Samples that cannot be tested immediately should be stored at +2 – 8 °C. Test should be performed with blood cells dissolved in 0,9% saline solution.
Additional materials required:	Isotonic saline, transfer pipettes, glass slides, applicator slicks, slides or plates, test tubes and test tube racks, validated serological centrifuge, cell panel, timer. Microplate tests: microplates, microplate shaker (optional), validated serological centrifuge, when used with reading machine or on automates it is the users responsibility to validate any accessory device for the intended use, NaCl solution, timer, transfer pipette, if necessary Bovine Albumin.
Microplate test:	MTP from different suppliers show different characteristics which might have non-specific reaction of the red blood cells as a consequence. It is recommended to pre-treat new MTP before its first use in order to minimize the fastening of the red cells. Recommended are MTP with U-profile out of plastic. 1. Add 1 drop (30-50µl) of Bovine Albumin 22% to each well. 2. Through careful movements or on a shaker mix well so that all wells uniformly are coated. 3. Incubate 10-15 min. at RT (18-25°C). 4. Pour off Bovine Albumin and give the contents in suitable waste container 5. Rinse MTP at least 10 x with tap water. 6. Rinse MTP subsequently 2 x with distilled water. 7. MTP tip over and dap away in order to remove surplus water. 8. Dry MTP before use at the air. Alternative methods possible as far as validated by the users. 1. Prepare a 2-4 % suspension of test red cells in isotonic solution. (Recommendation 2%) 2. Add one drop of the respective reagent (30-50µl) to the appropriate test wells of a U well microplate. 3. Add an equal volume of the cell suspension to the appropriate test wells. 4. Mix the contents of each well using manual means or a microplate shaker. (30 sec.) 5. No incubation time necessary except for titrations or to the strengthening of weak Phenotypes. 6. Centrifuge the microplates at 1.500 UpM for 60 sec. or other appropriate time and UpM. 7. Re-suspend the red cells using the microplate shaker. (as in no. 4.) 8. Read tests macroscopically or with an automated plate reader. The use of an automated plate reader must be validated by the customer. The use of additional visual remedies as mirror or magnifier can ease the reading.
Tube test:	In order to improve the test results it is recommended to wash the blood cells at least one time in 0,9% saline solution. 1. Prepare a 2-3% red cell suspension of the washed red cells in isotonic saline. 2. Add 1 drop of Anti – Kell and one drop of red cells to the appropriately labelled tube. 3. Mix well, incubate at RT 10 – 15 min. and centrifuge for 1 minute at 400 g (1.500 UpM.) or at a suitable alternative force and time. 4. Gently agitate each tube to resuspend the cell buttons and examine for agglutination. 5. Record results and reactivity strengths. Do not forget positive and negative controls. 6. Incubate all negative or doubtful positive tests at 37°C for additional 5 minutes and repeat stages 3 to 5. An incubation phase of 5 minutes at 37°C may enhance the reaction strength of rare phenotypes. Prolonged incubation times of up to 60 min. has no improved effect.
Slide-test/plate-test:	1. Slide-tests are performed with whole blood, plate-tests with washed Erythrocytes or whole blood. 2. Place one drop of the reagent on a clean glass-, plastic slide or on a plate. 3. Add one drop of whole blood (respectively 35-45% suspension of red cells) to the slides or one drop of whole blood in 0,9% saline solution (respectively 10% red-cell suspension) to the plate using a transfer pipette or applicator stick. 4. Mix blood and reagent. This is achieved by slow rotation over a period up to 2 minutes (slides) and on plates after an incubation time of 5 – 10 minutes. Incubation time for whole blood testing is limited to 5 min. maximum. 5. Observe macroscopically for agglutination and record results. Care should be taken not to mistake peripheral drying as agglutination. Do not place slides on or before a heated illuminated surface.

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Advice to users:	On each test, positive and negative control red cells have to be tested in parallel, Slight turbidity might not influence the performance of the reagent. Do not freeze the test sera and use sera only until the expiry date indicated on the label / package. Manual techniques are performed according to the manufacturer advice. The use of the anti-sera in machines may require dilutions. The use of such manipulated sera asks for re-validation under the responsibility of the user. This is valid for all manipulations as for example the cold freezing of the sera for microplates. Do not use monoclonal reagents with mouse antibodies in direct Anti-Human-Globulin tests with AHG reagent.
Limitations:	The use of the anti-sera in machines may require dilutions. The use of such manipulated sera asks for re-validation under the responsibility of the user. This is valid for all manipulations as for example the cold freezing of the sera for mikroplates. Falsely positive or falsely negative test results can occur from bacterial or chemical contamination of test materials, inadequate incubation time or temperature, improper centrifugation, improper storage of materials or non consideration of the instructions of the different test methods. Strength of the results is also depending from the age of the blood-cells. Do not use monoclonal reagents with mouse antibodies in direct Anti-Human-Globulin tests with AHG-reagent. Do not freeze the sera and use sera only until the expiry date indicated on the label / package. Care should be exercised in the use and the disposal of the container and is contents. Bovine serum albumin and the corresponding raw material were derived from bovine resources exclusively free of BSE.
Product performance:	Before any batch release all corresponding production-lots are tested for its appropriate reactivity. Test performances of all reagents are depending on straight appliance of the recommended test methods. Additional information about specific tests at the time of production respectively after the batch release can be obtained upon demand.
Performance data:	The reagent fulfils the common technical specifications' requirements according to Annex II, List A der Directive 98/79/EC for in vitro diagnostics. It has the same or a better performance characteristics as comparable reagents in use. It was tested on more than 1000 samples with sensitivity and specificity of 100%.
Literature:	• Coombs, R.R.A, Mourant A, E, Race, R.R. Lancet, 1946: 264-266. • Levine P, Backer M, Ponder R. A new human hereditary blood property (Cellano) present in 99.8% of all bloods. Science 1949; 109:464. • Brecher ME, ed. Technical manual, 14 th ed. Bethesda MD: American Association of Blood Banks, 2002. • Crawford MN, Gottman FE, Gottmann CA, Microplate system for routine use in blood bank laboratories. Transfusion 1970; 10:258