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Instruction for use

Use by professionals only
Tests per ml: max. 20

CE 0483

Revision:	29/07-2019
Product-Name:	**Product-Code:**
Anti-D MS-201	D-mono-MS201
Anti-D RUM-1	D-mono-RUM

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Bloodgroup Testreagent for specific detection of D-antigen in microplate-, tube-, slide-and plate techniques.
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,semi-automates, gel-cards or 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-D (cell line MS 201 and cell line Rum-1) are monoclonal IgM cells derived from human hybridoma cells which detect the corresponding red cell antigens in a direct agglutination reaction. Lack of agglutination indicates the absence of the corresponding antigen. Sodium azide at a final concentration of < 0,1% w/w is added as a preservative. The Bovine Albumin Solution is sourced from donor animals of United States origin that have been inspected and certified to be disease free. Most of the Dweak cells are recognised by these two cell lines but will not detect D category VI.(according to UKBTS and BCSH guidelines) Microplate- and slide-/plate techniques are not recommended for detecting Dweak cells.
Clones:	**MS-201 and RUM-1**
Note/Cautions:	Sodium azide can cause high explosive metal azide 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 the common anticoagulants (EDTA, ACID,). 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.
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:	1. Prepare a 3-5% suspension of test red cells in isotonic saline. 2. Add one drop of anti-D reagent to one appropriate test wells of a microplate. 3. Add an equal volume of the test cell suspension to the appropriate test wells. 4. Mix the contents of each well using manual means or a microplate shaker and incubate the microplate at room-temperatures for 15-20 minutes. 5. Centrifuge the microplate at 100 rcf for about 40 seconds or a time and force appropriate to produce the strongest reactions. 6. Re-suspend the red cells. Read tests macroscopically or with an automated reader. The use of an automated plate reader must be validated by the customer.
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 3-5 % suspension of red cells in 0,9% isotonic saline. 2. Add 1 drop of anti-D and one drop of red cells to the appropriately labelled tube and mix. 3. Centrifuge about 20 seconds at 900 – 1000 x g, about one minute at 1500 UpM or a time appropriate to produce the strongest reactions. 4. Gently agitate each tube to re-suspend the cell buttons and examine macroscopically for agglutination. Record results and reactivity strengths. To ensure appropriate reactivity ensure parallel testing against antigen-positive and antigen-negative cells. 5. *If desired* incubate all negative or weakly positive tests at 37°C for 5 minutes and repeat step 3. and 4. This may enhance the reaction strength in typing red cells of rare phenotypes.
Slide-tests / Plate-tests:	1. Slide-tests are performed with whole blood, plate-tests with washed Erythrocytes or whole blood. 2. Place one drop of the reagent (appr. 50 µl) on a clean glass-, plastic slide or plate. 3. Add one drop of whole blood (resp. 35-45% suspension of red cells) to the slides or 10% red-cell suspension in 0,9% saline solution resp. whole blood to the plates using a tranfer pipette or applicator stick. 4. Mix blood and reagent. On glass slides, use a separate clean applicator stick to mix each reagent/cell mixture over an area approximately 20 mm diameter. On plastic slides follow the manufacturer´s insert. 5. Read and record results. This is achieved on glass slides by slow rotation over a period up to 2 minutes and on plates after an incubation time of 5 – 10 minutes. Do not place the slides or plates on a heated illuminated surface. 6. Observe for macroscopic agglutination and record results. Care should be taken not to mistake peripheral drying or fibrin strands as agglutination.
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:	Strengths of test results are depending from the age of the blood. Falsely positive or falsely negative test results can occur from bacterial or chemical contamination of the reagent, the test materials or the saline solution, inadequate incubation time or temperature, improper centrifugation or other false of the recommended test methods.
The Rh Blood Group system:	The observations of Levine and Statson in 1939 and of Landsteiner and Weiner in 1940 provided the basis for current understanding of the clinical significance and laboratory detection of Anti-D. Approximately 15% of Caucasians lack the RhD antigen and are easily stimulated by a RhD positive pregnancy of blood transfusion to produce Anti-D. This may cause haemolytic disease of the newborn or severe haemolytic transfusion reaction.
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:	1. Landsteiner, K. & Wiener, A.S.:"An agglutinable factor in human blood recognized by immune sera for rhesus blood". N.Y., Proc. exp. Biol. 1940; 43:223 2. Levine, P. & Stefson, R.E.: "An unusual case of intragroup agglutination" J. Amer. Med. Assoc.1939; 113:126-127 3. Guidelines for the Blood Transfusion Services in the United Kingdom. 5th. Edition 2001. The Stationary Box.