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Instruction for use

Use by professionals only.
Tests per ml: max. 25 with drop size 40 µl when using separate volumetric pipettes.

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Revision:	29/07-2019
Product-Name:	**Product-Code:**
Anti-A1 Lectine	A1 Lekt

Reagent for determination of A1 subgroup. Bloodgroup testreagent for tube, slide/plate- and microplate 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-A_1, lectin reagent is a purified stabil phythemagglutinatin from Dolichus biflorus for specific detection of A_1 antigen on red cells in an agglutination reaction. HBsAg, HCV and HIV contamination is impossible. Sodium acide (< 0,1% w/w final concentration) added as a preservative.
Note/Caution:	Sodium azide can cause high explosive metal azide combinations with lead and cooper. When pouring rinse with a lot of water.
Test methods:	Samples may be drawn into EDTA, ACD, others or may be drawn without anticoaggulants. Testing should be performed as soon as possible to minimise the chance that falsely positive or falsely negative reactions will be encountered due to contamination or improper storage of a specimen. Samples that cannot be tested immediately should be stored at +2 – 8 °C..
Tube test:	1. Prepare a 2 – 3 % suspension of red cells in isotonic saline. 2. Add 1 drop of anti-A_1 Lectin and one drop of red cells to the appropriately labelled tube and mix. 3. Centrifuge for 1 minute at 1.500 rpm (400 xg) 4. Gently agitate each tube to re-suspend the cell buttons and examine for agglutination. 5. Record results and reactivity strengths.
Slide-test/plate-test:	1. Slide-tests are performed with whole blood in EDTA or Citrate (35-45% Cell suspension), plate-tests with washed erythrocytes or whole blood. 2. Place one drop of the reagent on a clean glass-, plastic slide or plate. 3. Add one drop of whole blood in EDTA or Citrate (35-45% Cell suspension) during slide-test 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.
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 2-3 % 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 1 Minute at 400g (1.500 UPM) or other appropriate time and UpM. 7. Resuspend the red cells using the microplate shaker. (As in 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.
Limitations:	Tube tests should be examined directly after the centrifugation, slide tests within 2 minutes and plate tests after 5 max.15 minutes in order to avoid falsely positive reaction due to dry up occurrences. 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. 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 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.
Advice to users:	It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions. It is not required to use a reagent control in parallel with all tests using this reagent. Only in typing the red cells of patients known to have auto antibodies or protein abnormalities is the use of a reagent control recommended. This should be tested in parallel with the reagent. The reagent has been characterised by the procedure recommended in this package insert, its suitability for use in other techniques must be determined by the user. In the event of changes in the analytical performance of the device or damage to the packaging please contact the Quality Assurance department at CE-IMMUNDIAGNOSTIKA GmbH.
Performance data:	The reagent shows equal or better performance criteria as comparable reagents on the market. It fulfills the requirements of the specifications of CE-Immundiagnostika GmbH.