ONE MAN KIT OKS 2511-1

CE 0543

Instruction for ONE MAN KIT with ELDONCARD 2511 (REF 500-08).

Kit with 1 ELDONCARD™ 2511 for 1 ABO and RhD Blood Grouping (Slide technique)

Instructions for use No. 466-en (rev. 2022-03-03)

Intended use:

IVD For in-vitro diagnostic use by professionals.

Manual test for the detection of the presence or absence of antigens A, B and RhD on erythrocytes from one individual per ELDONCARD 2511. Prior to transfusion, the resulting ABO group must be confirmed by reverse testing, and donor's blood found RhD negative must be tested for weak RhD antigens by more sensitive methods (see 'Performance characteristics and limitations').

Test principle:

The test is based on forward haemagglutination. The dried antibody reagents on the card will agglutinate erythrocytes with the corresponding antigens. No agglutination in a field indicates the absence of the corresponding antigen (see 'Performance characteristics and limitations'). The blood group of the tested individual is determined from the agglutination pattern on the EldonCard (see 'Results').

Reagents:

The anti-A field contains murine IgM monoclonal anti-A from cell line Birma-1 (Titre* ≥ 1 32) and a green colour (Patent Blue Violet + Tartrazine).
The anti-B field contains murine IgM monoclonal anti-B from cell line LB-2 (Titre* ≥ 1 32) and a red dye (Chromotrope FB).
The anti-D field contains human monoclonal IgM anti-D from cell line MS-201 (Titre* ≥ 1 32) and a yellow dye (Tartrazine).
The Control field contains no antibodies but the same phosphate buffer as the other fields, and a blue dye (Patent Blue Violet).
Before drying, the reagents had a pH of 7.2. After reconstitution to 40 µl, they contain 0.074 % sodium azide.

* The titre is determined by titration on EldonCard material in order to reflect the conditions of use as closely as possible.

Storage and Stability:

EldonKits contain either one or more EldonCards in moisture proof aluminium/plastic envelopes.
EldonCards should be stored between 5 and 37 °C. Keep away from rain and store in dry conditions. Package shall not be exposed to sunlight. When kept inside this temperature range, the cards are stable for 2 years.
The expiry month (see 'Symbols') is printed on the label and on the card in the format yyyy-mm. Use before the end of the indicated month.

⚠ When an envelope is cut open, the card should be used within the same day.
The function of the cards may be destroyed by humidity and high temperatures.

Quality control:

Upon receipt of a ONE MAN KIT, check for proper function to exclude possible damage during transportation. Do not use cards from damaged envelopes. The function of the cards may be destroyed by humidity.

Before using a card, inspect that all fields contain coloured reagent spots of approximately the same size (Green, red, yellow, and blue from the left to the right).

Content of the ONE MAN KIT OKS 2511

See the label of the kit.

Before you perform the test:

- Read the instructions for use thoroughly before performing the test.
- One ELDONCARD 2511 is suitable for 1 blood type determination.
- This test is for single use.
- Store at room temperature (5 – 37°C).
- Use the test before the "Expiry" date on the package.

Additional materials required:

Either clean tap water, distilled water, isotonic saline or phosphate buffered saline (Procedures 1 and 2)
Phosphate buffered saline (Procedure 3).
Pipettes and pipette tips for 10 and 30 µl (Procedure 2).

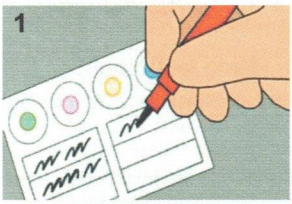
Sample material:

A) Capillary blood (Procedure 1)
B) Venous blood stabilised with either anticoagulant CPD or EDTA (Procedure 2).
C) Red blood cells washed and/or diluted with Phosphate Buffered Saline to a concentration of ≥ 5 % (Procedure 3).

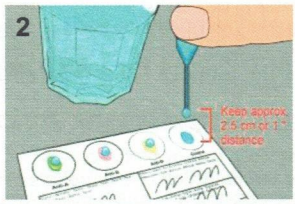
Please use all test material at room temperature to avoid interference from cold agglutinins. See "Limitations".

Procedure 1 for capillary blood

Collect all materials needed, open the envelope and take out the card.

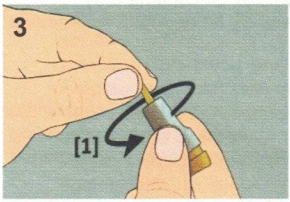


Step 1 Check that coloured reagent spots of approx. same size are present in all fields before proceeding. Fill in the data of the patient being tested. Separate the EldonSticks into four individual Eldon-Sticks before any use



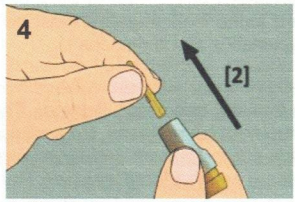
Step 2 Apply one drop of water directly onto each of the coloured reagent spots, using the plastic pipette.

Take care to avoid any mixing between circles.



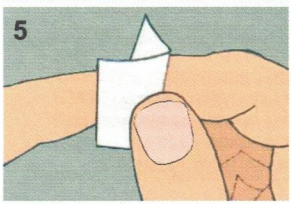
Step 3 Take the lancet and twist the yellow protective cap (tip).

Be careful not to activate the lancet; it can only be used once.

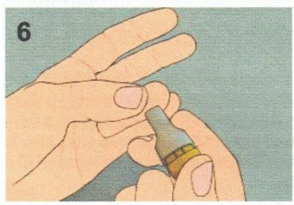


Step 4 Pull the yellow protective cap (tip) straight out of the safety lancet.

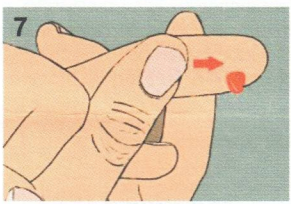
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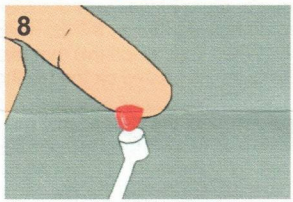
Step 5 Disinfect the finger at the puncture site with the cleansing tissue. Let the finger air-dry.



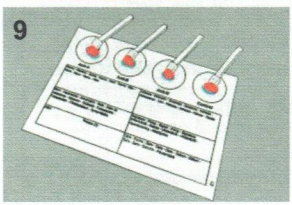
Step 6 Press the safety lancet body firmly against the puncture site and press the push-button to activate the device. After the "click" you can remove the lancet from your finger.



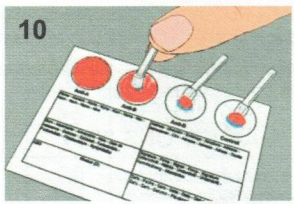
Step 7 Gently massage the finger towards the fingertip to increase blood flow. Maintain the pressure on your fingertip when blood start to flow to obtain a drop of blood.



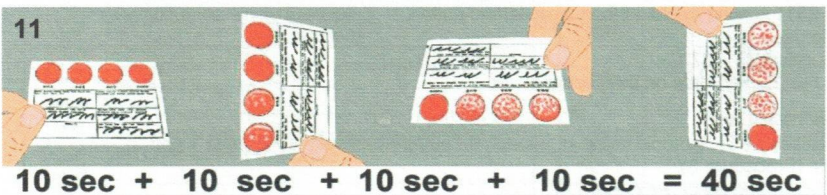
Step 8 Collect the drop onto an EldonStick which is approached from beneath. Place the stick onto the first circular field.
The blood shall touch the water applied in step 2.



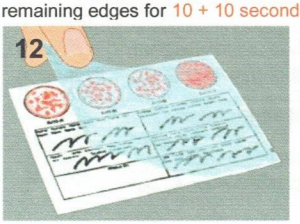
Step 9 Repeat the procedure in step 7 and 8 three times using the remaining EldonSticks. Keep each stick inside its own field. Use a new stick for each field.



Step 10 Stir each circle with its proper EldonStick for 10 seconds to dissolve the reagent. Then spread the blood to cover the entire circle. Caution: Keep the liquid inside the circle. Repeat the procedure in the other fields using their own sticks.
The blood must not clot. Begin the stirring within two minutes after the blood was applied onto the first EldonStick.



Step 11 To develop all possible agglutinates, the card must be tilted for at least 40 seconds. Tilt the EldonCard to an almost upright position and wait 10 seconds. A wave of blood will move the red cells slowly to the bottom of the fields.
Tilt to the opposite vertical position and wait another 10 seconds while the blood flow down the fields. Tilt twice more on the remaining edges for 10 + 10 seconds. The results can now be read and recorded. See "Results".

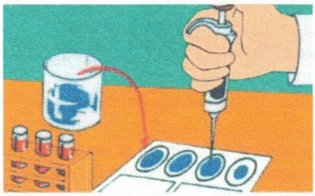


Step 12 If you wish to keep the card with the result, leave it on a horizontal surface to dry. You may use a hair-dryer to speed up the drying. Alternatively, you may discard it at this point (see "Disposal").

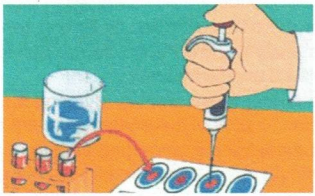
When the blood is completely dry, use a piece of ELDONFOIL 2511 to encapsulate the blood and preserve the result. With the EldonFoil you can glue the EldonCard onto your patient's case sheet.

Procedure 2 for use of Venous Blood:

Step 1: Check that coloured reagent spots, fill in patient data, and separate the EldonSticks (As step 1 in procedure 1).



Step 2: With a pipette, apply 10 µl of water onto each of the circular fields.



Step 3: With a pipette, apply 30 µl of blood onto each of the circular fields.

Steps 4 - 7: Continue with steps 10 – 12 as described in procedure 1.

Procedure 3 for washed suspensions of red blood cells:

Washing of cells or dilution of blood should be done with phosphate buffered saline.
Step 1 as above, omit steps 2-8. Apply 30 – 50 µl or just "one drop" of the washed or diluted erythrocytes onto each of the circular fields. Continue from step 10 as described Procedure 1. Tilt with caution so that the reaction mixtures do not run out of their fields.

Comments to the procedures:

In procedure 1, 20 µl of water is recommended. This will ensure a sufficient amount of liquid for the tilting step, even with only 5 µl of blood. To avoid coagulation begin the stirring within 2 minutes after application of blood onto the first EldonStick. The addition of water described in procedure 2 is not strictly necessary, but is recommended because it makes the flow of the reaction mixtures easier during the tilting steps. This is important for the development of agglutinates. The amount of water is thus not very critical but should not exceed 20 µl when the amount of blood is 30 µl.

In procedure 1, "a drop" of blood is specified. A full drop of blood (with a size of 3-4 mm) is just about 30 µl, for which the reagents are optimised. However, the cards will work with 40 as well as 5 µl of whole blood, if the total reaction volume is kept at 40 µl with water. More than 40 µl of blood may disguise agglutination. Agglutinates with small amounts of blood will be smaller but still clearly visible with the naked eye.

Make sure that the reagents are completely dissolved. It is essential for the reading of the results that the blood is spread over the entire field.

Step 11: Tilting is crucial for the development of agglutination, and therefore the total amount of liquid on each of the 4 fields are important. If the reaction mixtures do not flow as described, agglutinates may not be developed to a visible size. This can be caused by gel formation of the blood, a phenomenon that may be seen with aged blood. In such cases, the test should be repeated with more water, and tilting should be performed with caution so that the reaction mixtures do not run out of their fields. Agglutinates are most easily recognised immediately after the tilting step. Record them at this time.

Results:

Agglutination of the red cells in a field is considered a positive result and denoted '+' in the table below.
No agglutination is considered a negative result and denoted '–' in the table.
The possible reaction patterns on the card and the corresponding blood groups:

Reaction in field				Blood Group	
Anti-A	Anti-B	Anti-D	Control	ABO	RhD
—	—	+	—	O	Pos
—	—	—	—	O	Neg
+	—	+	—	A	Pos
+	—	—	—	A	Neg
—	+	+	—	B	Pos
—	+	—	—	B	Neg
+	+	+	—	AB	Pos
+	+	—	—	AB	Neg
+	+	+	+	Invalid result	

If a positive reaction is observed in the Control field, the test result is invalid. Repeat the test using blood diluted 1:1 with PBS. If the reaction in the control field persists, use washed erythrocytes (procedure 3). The result is valid, when there is no agglutination in the control field. (see 'Performance characteristics and limitations').
If a sample of donor's blood or blood from new-borns are found negative in the anti-D field it should be tested with a more sensitive method. (see 'Performance characteristics and limitations').

Examples of agglutinates:



Performance Characteristics and Limitations:

The ELDONCARD 2511 is a forward haemagglutination test for erythrocyte group antigens. It is recommended to routinely use two successive independent samples of blood for mutual confirmation of results.

The result should furthermore be confirmed by testing serum/plasma for circulating antibodies (reverse typing).

Eldon Biologicals A/S's ***Multi Centre Performance Study on 3000 Blood Samples*** (www.eldoncard.com) revealed the following characteristics and limitations:

- The anti-A field will detect most weak A antigens but not all. If suspicion arises of the presence of a weak A-antigen, further routine studies of the erythrocytes are indicated.
- The anti-D field will detect some weak and variant D antigens but not all. The variant D^{VI}, which is incapable of forward haemagglutination, will consequently remain undetected. To detect possible weak or variant D antigens, samples of donors' blood or blood from newborns found negative in the D-field should be tested with a more sensitive method.
- Umbilical cord blood shall due to Wharton's Jelly always be collected with caution. Testing on EldonCards compare favourably with other forward haemagglutination systems used for this purpose.
- In rare instances unspecific reactions may cause agglutination or an agglutination-like reaction in all fields, including the Control field. This may be due to the presence of abnormal proteins or plasma expanders in the sample. An example of abnormal proteins is cold agglutinins that cause unspecific reaction at lower temperatures. Unspecific reaction may also be due to the presence of interfering substances in water applied to the EldonCard. If a reaction in the Control field occurs, the test should be repeated at temperatures above 20 degrees, with a diluted sample or washed erythrocytes (see 'Results') and either clean tap water, distilled water, isotonic saline or phosphate buffered saline (in Procedure 2 use only phosphate buffered saline) free of interfering substances. This may reduce the chance of false positive result due to cold agglutinin autoantibodies (CAA), but this will not prevent all false positive results. If the repeated test shows positive reaction in Control field, the blood should be tested with another test method (which typically involves cold-adsorption studies to remove the CAA from the blood or plasma).

Disposal of ELDONCARD 2511:

After drying, the cards can be kept for further reference if covered by EldonFoil.

The basic material for cards is polypropylene. EldonFoil is made of polypropylene. Both are non-halogenated materials. The best way of disposal is by incineration.

Used symbols:

Symbol	Meaning
IVD	In vitro diagnostic medical device.
LOT	Lot number, Batch code. The lot number of EldonCards tells the production week. It contains 5 digits, yywwx, where yy is the two last digits from the year (08 for 2008), ww is the week number, and x is an internal number.
TR	Tracking number. State this number and the lot number in case of complaints
Σ	Contains sufficient for <n> tests.
	Do not reuse, single use only.
Anti-A	The circular field contains a desiccated formulation of the blood group antibody A.
Anti-B	The circular field contains a desiccated formulation of the blood group antibody B,
Anti-D	The circular field contains a desiccated formulation of the blood group antibody D.
Control	In the Control field the blood group antibody has been replaced with a phosphate buffer.

Symbol	Meaning
	Consult instructions for use (this paper).
	Special attention required regarding handling of opened EldonBags to ensure the safe storage of the EldonCards
	Temperature limitation. EldonCards should be stored between 5 and 37 °C (41 and 99 °F).
	Use by, or expiration time. Given as yyyy-mm-dd, e.g. 2020-08-28 means "Use before August 28, 2020".
	Date of manufacture. For EldonCards, this is the date where the cards were wrapped in envelopes or EldonBags.
	Manufacturer
	Keep away from rain and store in dry conditions.
	Package shall not be exposed to sunlight.
	Do not use cards from damaged envelopes or EldonBags.

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