

DOCTOR'S KIT DKS RhD-25

Kit with 25 ELDONCARD RhD for 75 Determinations of Rhesus Factor (Slide technique)

Instructions for Use No. 473 (rev. 2007-07-11)

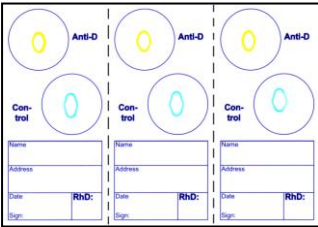
A. General Information

IVD For the determination of the Rhesus factor in pregnant women's blood

Manual test for detection/confirmation of the presence or absence of Rhesus Factor RhD on human red blood cells from three individuals per ELDONCARD RhD. To be used in hospitals and clinics using re-suspended red cells, venous or capillary blood.

Test principle:

The test is based on direct haemagglutination. The Anti-D formulations on the card will agglutinate red blood cells from Rhesus positive individuals. No agglutination in a field indicates the absence of Rhesus Factor, (see "Limitations"). The Rhesus status of the tested individuals are determined from the agglutination pattern on the EldonCard (see "How to read the results").



ELDONCARD RhD:

The ELDONCARD RhD contains three blood-grouping panels, each containing the reagents described below.

The card is shown here in 40% of its original size, 105 x 73 mm.

The dotted lines represent perforations on ELDONCARD RhD, making it easy to divide the card into three equal single cards, each for one blood RhD determination.

The lot number of the card is printed on each single card, on the other side.

Reagents:

The Anti-D field contains human monoclonal IgM anti-D from cell line MS-201 (Titre* \geq 1:32) and a yellow dye (Tartrazine).

The Control field contains no antibodies but the same phosphate buffer as the Anti-D field, and a blue dye (Patent Blue Violet).

Before drying, the reagents had a pH of 7.2. After reconstitution to 40 μ l, 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:

The EldonCards are placed in an EldonBag. An EldonBag is opened by cutting at the indicated line on the label, so that it can be re-sealed with the zipper. When opening the bag for the first time, record the date in the frame provided on the label. After removal of cards, close the zipper carefully. Cards kept in properly closed EldonBags are stable for up to 6 months after the first opening, if the desiccant sachet is still present, and if the EldonBag is not opened more than 50 times.

EldonCards that have been out of their EldonBag for more than 30 minutes should be used within the same day. When sliding cards into an EldonBag, make sure that the reagent sides of all the cards face towards the label of the bag.

Before you perform the test:

- Read the instructions for use thoroughly before performing the test.
- You must follow all directions carefully to get an accurate reading. Also you may see a video demonstration (in English) of the procedure on our homepage, www.eldoncard.com.
- One ELDONCARD RhD is suitable for three and only three RhD determinations.
- Don't open the zipper of the EldonBag below 18 °C (64 °F).
- Store at room temperature (5 – 37°C, 41 and 99 °F).
- Use the test before the "Expiry" date on the package.

Quality control:

Upon receipt of a shipment of kits, check for possible damage during transportation and ensure the quality of the kits by testing with red cells with and without the RhD antigen, (see Limitations).

Before using a card, inspect that all fields contain coloured reagent spots of approximately the same size (Yellow in the three Anti-D fields, and blue in the three Control fields - as shown on the picture above).

Contents of the kit

| | |
|----------|---|
| 1 pc. | ELDON BAG RhD-25 with 25 pcs. of ELDONCARD RhD |
| 5 pc. | Plastic pipettes 20 µl |
| 75 pcs. | Standard Lancets with short edge |
| 150 pcs. | ELDON STICKS |
| 25 pcs. | ELDON FOIL divisible into 3, (for 3 single cards) |
| 1 pc. | Package Insert |

Not included

A glass with water
A clock or timer

Additional materials required:

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

Sample material:

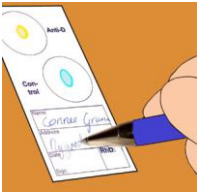
- Venous blood stabilised with either anticoagulant CPD or EDTA (Procedure 1).
- Red blood cells washed and/or diluted with Phosphate Buffered Saline to a concentration of $\geq 5\%$ (Procedure 2).
- Capillary blood (Procedure 3)

To avoid interference from cold agglutinins, please use all test material at room temperature. See "Limitations".

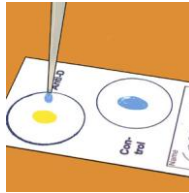
B. Instruction for Use of Venous Blood or Suspension of Red Blood Cells

Procedure 1 for stabilised, venous blood:

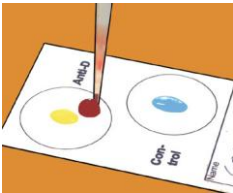
Collect all materials needed, open the bag and take out the card. Check that coloured reagent spots of approx. same size are present in all fields before proceeding. The procedure is shown with one third of a card = one blood-grouping panel. If you don't break the card, the blood applied on the first panel(s) must be tilted and read before any additional blood grouping.



1. Fill in the data of the person being tested.



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

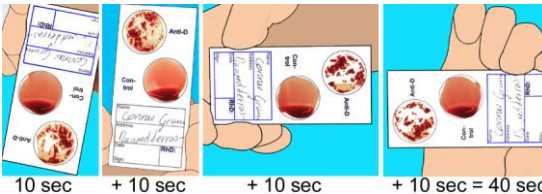


3. With a pipette, apply 30 µl of blood onto each of the circular fields.



4. Stir the blood in the Anti-D field with an EldonStick until the reagent is completely dissolved (approx. 10 sec). **Then spread the blood to cover the entire field.**

Repeat the procedure in the Control field using another EldonStick.



5: To develop a possible agglutinate, 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 flows down the fields.

Tilt twice more on the remaining edges for **10 + 10 seconds**. The results can now be read and recorded. See Results.



6. The EldonCard may be disposed of at this point (see "Disposal"), or it can be left on a horizontal surface to dry. When dry, it can be covered with one third of an ELDON FOIL and kept as a permanent record of the result.

With an EldonFoil you can glue the card into your patient's record.

Procedure 2 for dilute suspensions of red blood cells:

Washing of cells or dilution of blood should be done with phosphate buffered saline.

Step 1 as above, omit step 2. In step 3, apply 30 – 50 μl or just "one drop" of the washed or diluted erythrocytes. Continue with steps 4 and 5 above. Tilt with caution so that the reaction mixtures do not run out of their fields.

Comments to procedures 1 and 2:

The addition of water described in step 2 of procedure 1 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 step 3 of procedure 1, 30 μl of blood is specified. 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 macroscopically.

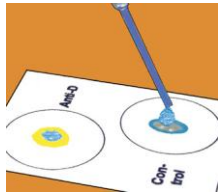
Step 5: Tilting is crucial for the development of agglutinates. If the reaction mixtures do not flow as described, agglutinates may not be developed to a visible size. It can be caused by gel formation of the blood, a phenomenon that may be seen with aged blood. In such a case, the test should be repeated with the addition of more water. In that case, tilt 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.

C: Instruction for Use of Capillary Blood (Procedure 3):

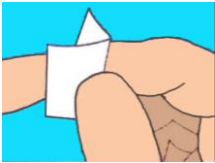
(Also shown with one third of a card)



1. Fill in the data of the patient being tested.



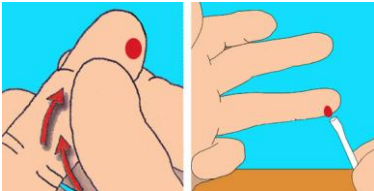
2: Apply one drop of water onto each of the coloured reagent spots, using the plastic pipette.



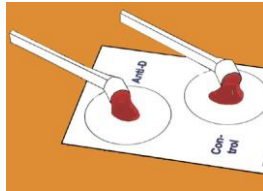
3: Disinfect the finger at the puncture site and let the finger air-dry.



4: Puncture the skin by pressing the lancet firmly against the side of the fingertip.



5: Gently massage the finger close to the puncture site to obtain a drop of blood. Collect the drop onto an EldonStick



6: Repeat the procedure in step 5 using another EldonStick.

Keep each stick inside its own field.
Use a new stick for each field.

which is approached from beneath. Place the stick onto the AntiD field. The blood shall touch the water applied in step 2.

Continue with steps 7, 8 and 9, which are the same as steps 4, 5 and 6 of procedure 1.

Comment to procedure 3:

The drop of water (approx. 20 μl) recommended in step 2 will ensure a sufficient amount of liquid for the tilting step, even with only 5 μl of blood.



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Performance Characteristics and Limitations:

The ELDONCARD RhD is a haemagglutination test for the Rhesus Factor RhD.

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

- ELDONCARD RhD will detect some weak and variant D antigens but not all. The variant D^{VI}, which is incapable of direct haemagglutination, will consequently remain undetected. To detect possible weak or variant D antigens, samples found negative in the D-field should undergo further analysis.
- Results from testing of umbilical cord blood shall always be interpreted with caution. However, testing on EldonCards compare favourably with other direct 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.

Cold agglutinins are abnormal proteins that cause unspecific reaction at low temperatures. If a reaction in the Control field occurs, the test should be repeated at a higher temperature, with a diluted sample or washed erythrocytes.

Disposal of ELDONCARD RhD:

After drying, the cards can be kept for further reference if covered by ELDON FOIL RhD.

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

How to read the results

The presence or absence of an agglutinate in the Anti-D field indicates the presence or absence of the Rhesus factor.

Agglutinates may look different from test person to test person, see the examples below.

Any test producing a weak agglutinate must be repeated.

If a positive reaction is observed in the Control field, the test result is invalid and the examination has to be repeated, either with washed blood cells or by diluting the blood with isotonic saline, until agglutination in the control field fail to appear.

Examples of agglutinates



Used Symbols

| Symbol | Meaning | Symbol | Meaning |
|--------|---|--------|---|
| | In vitro diagnostic medical device. | | Consult instructions for use (this paper). |
| | 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. | | Temperature limitation. EldonCards should be stored between 5 and 37 °C (41 and 99 °F). |
| | | | Use by, or expiration time. Given as yyyy-mm, e.g. 2008-10 means "Use before the end of October 2008". |
| | Contains sufficient for <n> tests. | | Date of manufacture. For EldonCards, this is the date where the cards were wrapped in envelopes or EldonBags. |
| | Do not reuse, single use only. | | Manufacturer |
| | The circular field contains a desiccated formulation of the blood group antibody D. | | In the Control field the blood group antibody D has been replaced with a phosphate buffer. |