

How to read the results

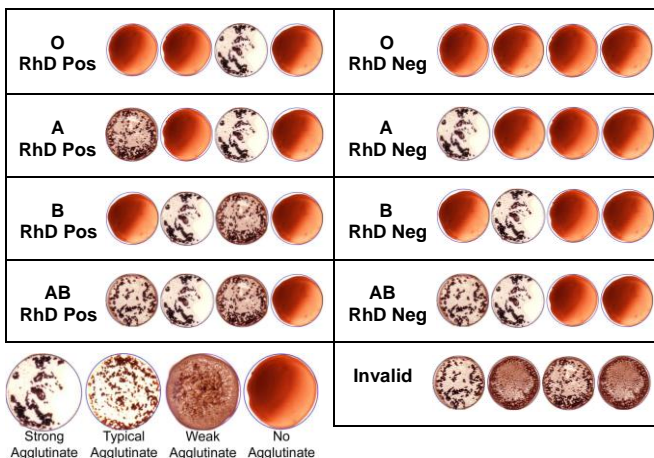
The presence or absence of agglutinates will show the blood type.

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

The possible combinations of agglutinates and the corresponding blood types are shown to the right.

Any test producing a weak agglutinate must be repeated.

If an agglutinate is seen in the control field, the result is invalid.



Examples of agglutinates:

Storage and Stability

The envelopes with EldonCards are made in a moisture proof aluminum/plastic laminate, which protects the cards against humidity. EldonCards should be stored between 5 and 37 °C (41 and 99 °F). 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 date (see "Symbols") is printed on the label in the format yyyy-mm-dd. Use the cards before expiry date.

Precautions

A small number of persons have weak RhD antigens on the blood cells, and an agglutinate may not be seen. Only specialized laboratories can detect such weak RhD antigens with certainty.

In rare cases, non-specific agglutinates may develop in the presence of certain proteins. If so, the agglutinate is also visible in the control circle, which means an invalid result. A new test has to be performed. It is possible that your blood type can only be determined in a specialized center.

Keep out of reach of children.

After your result is known put all contents back in the original box and dispose with your daily household waste products.

EldonCards are delivered in moisture proof envelopes. Once opened, use the ELDONCARD on the same day.

WARNING: Not for use for screening purposes prior to transfusion. Never use the result of this test as the basis for any medical treatment. Consult your practitioner before making any decisions.

Used symbols:

Symbol	Meaning
	In vitro diagnostic medical device.
	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 (21 for 2021), ww is the week number, and x is an internal number.
	Tracking number. State this number and the lot number in case of complaints
	Contains sufficient for <n> tests.
	Do not reuse, single use only.
	The circular field contains a desiccated formulation of the blood group antibody A.
	The circular field contains a desiccated formulation of the blood group antibody B,
	The circular field contains a desiccated formulation of the blood group antibody D.
	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.



ELDON BIOLOGICALS A/S

Sandtoften 10, DK-2820 Gentofte, Denmark
www.eldoncard.com

Intended use

The ELDON HOME KIT 2511 is a self-test kit to determine your blood type inside the AB0- and RhD blood group systems on an ELDONCARD 2511 with one test per card.

The blood grouping systems

The AB0 System classifies blood into four possible blood types, A, B, AB and 0. The RhD group of the complex rhesus system classifies blood as either positive (RhD pos) or negative (RhD neg). If blood of one type is mixed with blood of another type, it will form clumps or clusters – the so-called agglutinates – except blood of type 0 RhD neg, which does not agglutinate with any other blood type. By mixing your blood with specific monoclonal antibodies on the ELDONCARD you can determine your blood type.

Your genes determine your blood type. A blood type determination with the ELDONCARD is possible from the age of approximately 12 months and you will retain the same blood type for the rest of your life.

How does the EldonCard function?

The dried antibody reagents can be seen in circles on the ELDONCARD as spots colored green for Anti-A, red for Anti-B, yellow for Anti-D. A control circle with a blue spot serves to verify that the result is valid.

Perform the test by dissolving the dried reagent in each circle with a droplet of water and mixing it with blood. It is essential to get sufficient volume of blood and to avoid transfer of liquid between the four circles. For this purpose, you use four ELDON STICKs to transfer blood to each circle and to stir the liquid thoroughly. The tilting steps described below are also essential to complete the test.

Contents of the kit

See the label of the kit.

Materials required but not provided

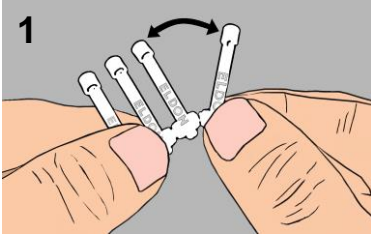
- A glass with water (drinking water).
- A clock or timer.

Important information

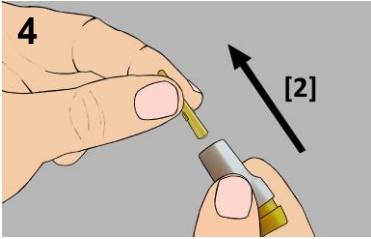
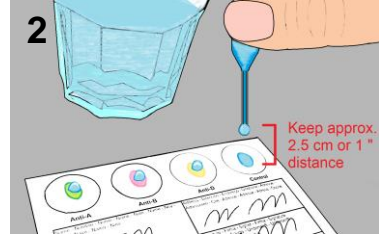
- Read the instructions for use thoroughly before performing the test.
- Follow all directions carefully to get an accurate reading. A video demonstration is available at www.eldoncard.com.
- This test is for one blood type determination per ELDONCARD 2511.
- This test is for single use.
- Store at room temperature (5 – 37 °C (41 - 99 °F)), out of reach of children.
- Do not bring other persons in contact with your blood. It can be infectious.
- Not for use by hemophiliacs.
- Use the test before the expiry date on the package.
- If any of the contents are missing, broken or opened, do not use the kit. Bring the kit back to the store where you bought it.
- Do not open the envelope until you are ready to carry out the test. Once opened, use the ELDONCARD on the same day.
- Check that colored stains of same size are present in each circular field.
- Always remember to separate the EldonSticks so that they are split-up into four individual EldonSticks.
- In order to guarantee the proper drop size (approx. 22 µL), be sure to hold the plastic pipette vertically when dispensing one drop of water directly upon the colored reagent spots without touching. Also, be sure to avoid contact with reagents or the card surface (allow the drop to fall freely) in order to guarantee the proper drop size and to avoid mixing between the reagent circles.
- An ELDON STICK must only be used in one circle, use for every circle a new ELDON STICK.
- Thoroughly wash and dry your hands before performing the finger prick in step 6.
- Do not test the safety lancet prior to use. The needle/blade inside the lancet can only be released once.
- Take care to avoid any mixing between circles.

How to perform your ELDON BLOOD TYPING KIT

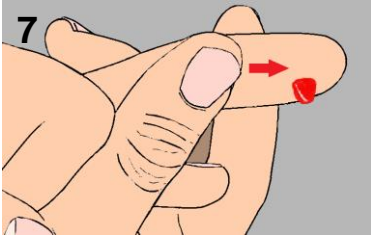
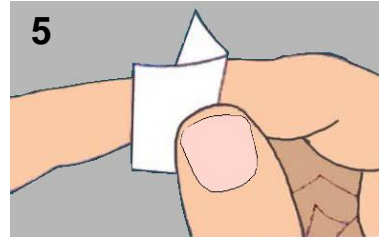
Open the envelope, collect materials, and read instructions before you begin.



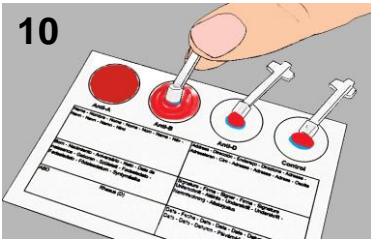
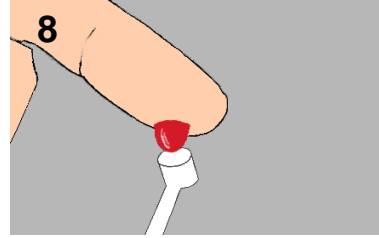
Step 1 Separate the EldonSticks into four individual EldonSticks before any use (use them separately for each circle). Next, write personal data on the ELDONCARD.



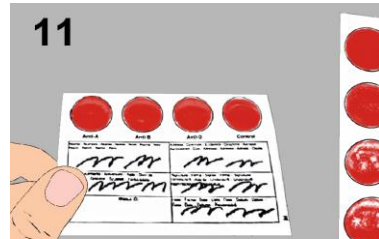
Step 4 Pull the yellow protective cap (tip) straight out of the safety lancet. **Be careful not to activate the lancet; it can only be used once.**



Step 7 Massage your finger towards your fingertip to increase blood flow. Maintain the pressure on your fingertip, when blood start to flow.



Step 10 Stir each circle with its proper EldonStick for 10 seconds. Spread the mixture of blood, water and reagent carefully within the entire reagent circle. **Take care to avoid any mixing between circles.**



10 sec + 10 sec



Step 12 Read the result being careful to **NOT TOUCH** the wet test circles until allowed to air dry. Note your blood type on the card (**before drying the card**). After the card has dried completely, peel and apply enclosed protective sheet (the EldonFoil) to cover or mount the card.

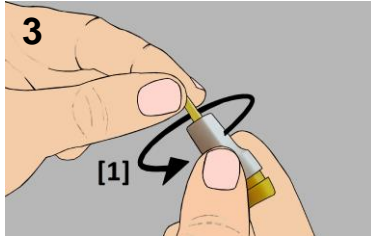
Step 2 Don't touch the colored reagents or card surface with the pipette. **Hold the plastic pipette vertically** when dispensing one drop of water directly upon the colored reagent spots of each circle (**allow drop to fall freely**).

Take care to avoid any mixing between circles.

Step 5 Clean your finger with the sterile swab. Let dry. Swing your arm to increase the blood flow to your fingers.

Step 8 Repeat pressing until a drop with a 3 to 4 mm (1/8 inch) diameter is seen.

Let a large drop of blood fall onto an EldonStick.

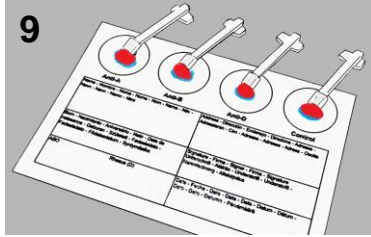


Step 3 Take the lancet and twist the yellow protective cap (tip).

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



Step 6 Press the safety lancet body firmly against the puncture site and press the push-button to activate the device.



Step 9 Place the stick with blood drop in the center of the first reagent circle and leave it laying there (blood shall touch the water applied in step 2). Take a new stick and quickly repeat step 7 and 8. Apply one drop of blood to each of the remaining circles **using a new stick for each circle**.

Step 11 Tilt the card to an almost upright position (approx. 45° angle). Hold it for 10 seconds at each angle.

Don't stop when you see the first reactions; the RhD-reaction is often slower than A and B.



10 sec + 10 sec = 40 sec

Scan to watch website with video tutorials*

Scan QR code or go to <https://www.eldoncard.com/How-to-use-video> to watch the ELDON HOME KIT video tutorial.

* Standard messaging & data rates may apply. Always read the Instruction for Use before you begin.

