

ELDON™ HOME KIT HKA 2511

Know your Blood Type

Instructions for use No. 395-en (rev. 2017-10-13)

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 coloured 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.

The test is performed 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 4 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
- 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 and 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 haemophiliacs.
- 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 coloured stains of same size are present in each circular field.
- 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 lancet prior to use. The needle can only be released once.

How to read the results

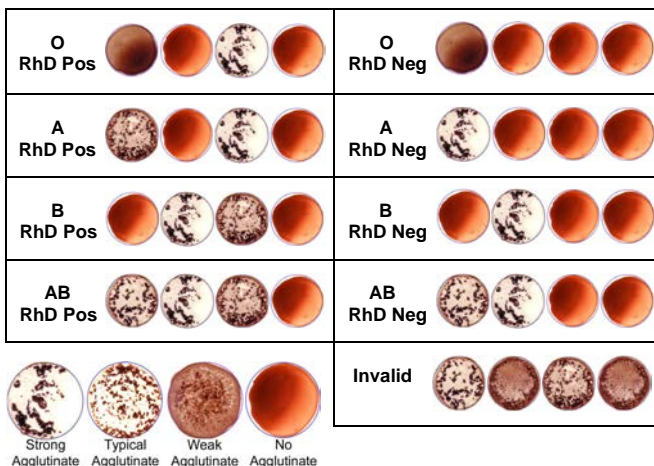
The presence or absence of agglutinates will show the blood type.

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). 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 sole basis for any medical treatment.

Consult your practitioner before making any decisions.

Used symbols:

Symbol	Meaning
	<i>In vitro</i> 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 (18 for 2018), ww is the week number, and x is an internal number.
	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.

Symbol	Meaning
	Consult instructions for use (this paper).
	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".
	Tracking number. State this number and the lot number in case of complaints.
	"Date of manufacture". The date where the EldonCards were wrapped in envelopes.
	Manufacturer.
	The circular field contains a desiccated formulation of the blood group antibody D.



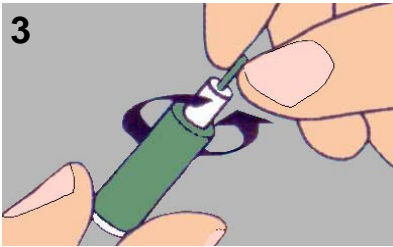
1

Step 1 Write personal data on the ELDONCARD.



2

Step 2 Apply a small drop of water in each circle. Don't touch the colored reagents.



3

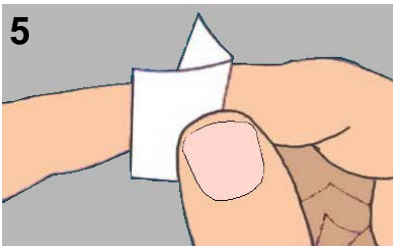
Step 3 Take the lancet and twist the colored tip.

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



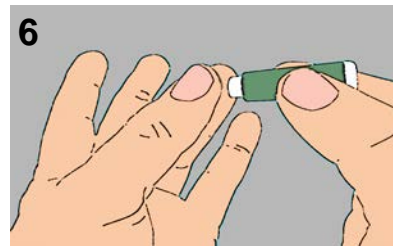
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Step 4 Pull off the tip of the safety lancet.



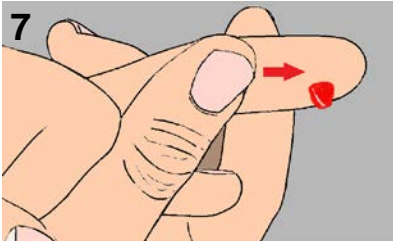
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Step 5 Clean your finger with a sterile swab. Swing your arm to increase the blood flow to your fingers.



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Step 6 Stretch and puncture the soft skin at the side of your fingertip by pushing the lancet firmly against the skin.



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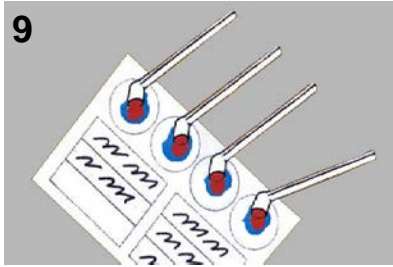
Step 7 Massage your finger towards your fingertip to increase blood flow.



8

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.

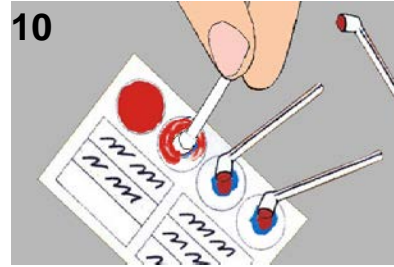
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Step 9 Place the stick with blood drop in the center of the first reagent circle.

Take a new stick and quickly repeat step 7 and 8. Transfer a drop of blood to each of the remaining circles **using a new stick for each circle.**

10



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 mixing between circles.**

11



Step 11 Tilt the card to an almost upright position. 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 + 10 sec + 10 sec = 40 sec

12



Step 12 Read the result; preferably before drying the card. Note your blood type on the card.

After drying, use an EldonFoil to cover or mount the card (**never before completely dry**).