



ELDON
BIOLOGICALS A/S

ELDONCARDS

reliable blood grouping for
Rescue and Emergency Use

EldonCards for ABO- and RhD blood grouping based upon the principle of direct agglutination

*** Prior to Transfusion,**

*** For Rhesus Determination of Pregnant Women,**

*** Before surgery**

*** Bedside Testing**



Eldon Biologicals A/S is a Danish company and the manufacturer of EldonCards and EldonKits containing EldonCards plus various accessories.

EldonCards and EldonKits are marketed and sold world-wide, and upon three markets:

1. the medical market
2. the market for educational materials
3. the alternative health market.

This report deals with the medical market.

An EldonCard is a niche product to be used under special conditions or for special purposes.

Below we have listed the qualities of EldonCards. If you can benefit from one or more, you should consider using our products.

Qualities, which in some cases make EldonCards or EldonKits the obvious choice when it comes to Rescue and Emergency:

1. EldonCards can be kept at room temperature.

EldonCards are sold with a declared shelf-life up to 24 months from the date of manufacture, if the cards have been kept at temperatures between 5 and 37 °C.

EldonCards kept in EldonBags tolerate up to six weeks storage and transportation at temperatures up to 65 °C.



2. EldonCards can be transported, stored and used without any need of cooling and electricity. Therefore EldonCards are particularly useful in developing countries, in warfare, and in rescue and emergency situations.

3. Daily quality controls are not needed

Because of the prescribed storage at room temperature, the lab personnel will never forget to place EldonCards in a refrigerator, and lack of electricity to refrigerators will not influence the quality of the cards. Therefore there is no need for daily quality controls. Each shipment shall be tested at receipt, and this is the only control recommended by Eldon Biologicals A/S.

4. EldonKits are portable, compact and easy to use.

On www.eldoncard.com please find the report: *Evaluation of lay persons' ability to use ELDONCARD IDENTITY KIT*. Each of sixty lay Dutchmen received an EldonKits, and without assistance they all succeeded in grouping their own blood.

5. **EldonKits can be used on location.**

With an EldonKit and some water (Drinking quality) you can – depending on the category of kit – determine the ABO- and RhD group of up to 50 persons, or the presence or absence of the Rhesus factor in up to 75 pregnant women.

6. **Blood group determination upon an EldonCard will take about 2½ minutes.**

7. **Washed erythrocytes, capillary blood and stabilised venous blood can be used.**

The use of whole blood, and in particular the use of capillary blood, enables the practitioner to talk with his patient, while his secretary performs the blood group determination. The physician remains responsible for the entire procedure and at the end of the consultation he can inspect the EldonCard, approve the result, and in the case of a pregnant woman inform her, whether she is rhesus positive or negative.

8. **Automatic detection of interfering substances (false positives)**

Because of the Control Field an EldonCard will disclose any false agglutination caused by such interfering substances, which in rare cases are present in the plasma or upon the surface of the cells.

Should a false agglutination develop in the Control Field, please double the volume of blood with isotonic sodium chloride. The dilution will in most cases prevent false agglutination, and now the card can be trusted.

9. **Blood grouping without washing and centrifugation procedures.**

Using EldonCards with a Control Field the analyst can use whole blood and he will save equipment, labour and time.

To remove interfering substances in blood plasma, the manufacturer of most other tests (Slide/tile tests, tube tests, micro-column tests) prescribe the use of washed red cells suspended to a certain concentration. Normally the preparation of resuspended washed cells will demand at least one centrifugation, a re-suspension of the cells in isotonic saline, an additional centrifugation and

a re-suspension to the prescribed concentration of reed cells.



10. **EldonCards provide a permanent record of the blood group.**

Using other diagnostics for blood group determination, the analyst will dispose all materials, and the result of the determination – written into a form – is the only registration of the blood group.

After drying the EldonCard is covered with a protective transparent foil and glued into the patient's record. **Can be used as ID-CARD.**

If at a later date a dispute on the blood group determination should arise, it is possible to read the agglutinations a second time and compare the reading with the blood group already written upon the EldonCard. Eldon ID cards with a photo of the owner are used in campaigns for the recruitment of new blood donors. You can also use the cards as gifts to your loyal blood donors.

11. The biological materials left upon an EldonCard can at a later time be used in a determination of the test person's DNA profile.
To protect against contamination it is important that the biological materials have been covered with an EldonFoil. For details please open www.eldoncard.com and read *Report on DNA Analyses made on the Stains of Blood present on EldonCards after the Cards being used in Blood Group Determinations.*
12. The CE₀₅₄₃ labelling upon EldonCards and EldonBags, and the CE₀₃₄₄ labelling upon EldonKits are your guarantee that the quality of the products was controlled and approved, first by the Quality Department of Eldon Biologicals A/S, and next by a notified body authorised by Danish (CE₀₅₄₃) or Dutch health authorities (CE₀₃₄₄).
13. Midwives' use of our kits will move the rhesus determinations from the blood bank to the home of the pregnant women. This means that the newborn of a rhesus negative mother can pass rhesus determination immediately after the birth, and if the baby appears to be rhesus positive the midwife can immediately administer a prophylactic treatment with Anti-D immunoglobulin.
14. Forensic experts' use of EldonCards on the scene of crime will save valuable time, and the subsequent use of the cards for DNA determinations will provide additional information on the persons being involved in the crime.

Categories of EldonCards

EldonCards are made in a special type of plastic.

Along the dotted lines ELDONCARD 2521, ELDONCARD 2531 and ELDONCARD RhD can be broken into two or three single cards. ELDON ID CARD shall carry a photo of the test person and can be folded into the size of a credit card.

Different types of EldonCards/Raw cards. Shown in 60 % of the original size, 105 x 73 mm.

	Ring-side	Text-side
ELDONCARD 2511 (Raw card 35)		ELDONCARD® 2511 For AB0 and D blood grouping Für AB0 und D Blutgruppenbestimmung Para AB0 y D agrupación de la sangre AB0 és Rh(D) vércsoportok meghatározása ELDON BIOLOGICALS A/S DK-2820 Gentofte www.eldoncard.com Anti-A: Murine IgM Birma-1 Anti-B: Murine IgM LB-2 Anti-D: Human IgM MS-201

<p>ELDONCARD 2521 (Raw card 36)</p>		<p>ELDONCARD® 2521 ELDONCARD® 2521</p> <p>For ABO and D blood grouping Für ABO und D Blutgruppbestimmung Para ABO y D agrupación de la sangre ABO és D vércsoportok meghatározása</p> <p>For ABO and D blood grouping Für ABO und D Blutgruppbestimmung Para ABO y D agrupación de la sangre ABO és D vércsoportok meghatározása</p> <p>CE 0543 Anti-A: Murine IgM Birma-1 Anti-B: Murine IgM LB-2 Anti-D: Human IgM MS-201</p> <p>ELDON BIOLOGICALS A/S ELDON BIOLOGICALS A/S DK-2820, Gentofte DK-2820, Gentofte www.eldoncard.com www.eldoncard.com</p>
<p>ELDON ID CARD (Raw card 40)</p>		<p>Min Blodgruppe My Blood Group</p> <p>Mi Grupo Sanguíneo Meine Blutgruppe</p> <p>Meine Blutgruppe My Blood Group</p> <p>ELDON BIOLOGICALS A/S DK-2820, Gentofte, Denmark www.eldoncard.com</p>
<p>ELDONCARD 2551 (Raw card 38)</p>		<p>ELDONCARD® 2551</p> <p>For confirming the ABO identity before transfusion Für ABO Identitätstest vor Transfusion Para confirmar la identidad del ABO antes de la transfusión</p> <p>CE 0543</p> <p>ELDON BIOLOGICALS A/S Anti-A: Murine IgM Birma-1 DK-2820 Gentofte, Denmark - Danmark - Dinamarca Anti-B: Murine IgM LB-2 www.eldoncard.com</p>
<p>ELDONCARD 2531</p>		<p>ELDONCARD® 2531 ELDONCARD® 2531 ELDONCARD® 2531</p> <p>En: For ABO and Rhesus D blood determination Es: Para determinación de grupo sanguíneo ABO y RhD Pt: Desde grupo sanguíneo ABO e Rhesus D Fr: Pour la détermination des groupes sanguins ABO et Rhesus D</p> <p>En: For ABO and Rhesus D blood determination Es: Para determinación de grupo sanguíneo ABO y RhD Pt: Desde grupo sanguíneo ABO e Rhesus D Fr: Pour la détermination des groupes sanguins ABO et Rhesus D</p> <p>En: For ABO and Rhesus D blood determination Es: Para determinación de grupo sanguíneo ABO y RhD Pt: Desde grupo sanguíneo ABO e Rhesus D Fr: Pour la détermination des groupes sanguins ABO et Rhesus D</p> <p>Anti-A: Murine IgM Birma-1 Anti-B: Murine IgM LB-2 Anti-D: Human IgM MS-201</p> <p>Anti-A: Murine IgM Birma-1 Anti-B: Murine IgM LB-2 Anti-D: Human IgM MS-201</p> <p>Anti-A: Murine IgM Birma-1 Anti-B: Murine IgM LB-2 Anti-D: Human IgM MS-201</p> <p>ELDON BIOLOGICALS A/S ELDON BIOLOGICALS A/S ELDON BIOLOGICALS A/S DK-2820 Gentofte DK-2820 Gentofte DK-2820 Gentofte Denmark Denmark Denmark www.eldoncard.com www.eldoncard.com www.eldoncard.com</p> <p>LOT 09231 A LOT 09231 A LOT 09231 A EXP 2011-06 EXP 2011-06 EXP 2011-06</p>
<p>ELDONCARD RhD</p>		<p>ELDONCARD® RhD ELDONCARD® RhD ELDONCARD® RhD</p> <p>For one RhD determination For one RhD determination For one RhD determination</p> <p>Anti-D: Human IgM MS-201 Anti-D: Human IgM MS-201 Anti-D: Human IgM MS-201</p> <p>ELDON BIOLOGICALS A/S ELDON BIOLOGICALS A/S ELDON BIOLOGICALS A/S DK-2820 Gentofte DK-2820 Gentofte DK-2820 Gentofte Denmark Denmark Denmark www.eldoncard.com www.eldoncard.com www.eldoncard.com</p> <p>LOT 07241 A LOT 07241 A LOT 07241 A EXP 2009-06 EXP 2009-06 EXP 2009-06</p>

Categories of Medical End-users

Blood Group determination for the purpose of a subsequent medical treatment is normally performed by analysts having received an education related to medicine and laboratory technique. In rare cases as warfare an education may be very short, or entirely missing.

Among our medical end-users we count:

1. Blood banks (who might use the EldonCards inside the blood bank and/or at the bedside of the patient to be transfused).
2. Pharmacies and practitioners.
3. Birth clinics, gynaecologists and midwives.
4. **Aid-organisations, the armed forces and police forces.**
5. Forensic Institutes.

Comments to end-users in category 3 above:

For blood grouping of pregnant women we recommend DOCTOR'S KIT DKS RhD-10 for 30 RhD determinations or DOCTOR'S KIT DKS RhD-25 for 75 RhD determinations. Using EldonCards, rhesus determination of pregnant women can be done by midwives, general practitioners, gynaecologists, and birth clinics.

Comments to end-users in category 4 above:

EMERGENCY & MILITARY KIT MKS 2521 is a first aid kit used in emergency situations and in warfare. The kit is used by the US Armed Forces in Iraq and Afghanistan, and by the National Afghan Army in Afghanistan and others.

ONE MAN KIT OKS 2511-1 is used by the US Army and the US Navy inside and outside the US.

ELDONCARD 2511 is used by various police forces. The result of the blood grouping is written into the test person's driver's license, and the police will keep the card for later determination of the test person's DNA profile – if so needed. For the same purpose the police keep EldonCards with blood group determinations of criminals' blood.

End-user's Choice of EldonCard or EldonKit

If EldonCards are used regularly inside a laboratory/blood bank, end-user will purchase one or more pieces of the following products:

Either an ELDON BOX XXXX -100 containing 100 pieces of ELDONCARD XXXX, whereby each card is placed in an EldonEnvelope.

Or an ELDON BAG XXXX - 25 containing 25 pieces of ELDONCARD XXXX plus a sachet with a desiccant.

End-user will also purchase one or more pieces of the following accessories:

A bag containing 200 pieces of EldonSticks. EldonSticks are used in various manipulations with the blood to be measured and transferred to an EldonCard. The use of EldonSticks is strongly recommended.

A bag containing 100 pieces of an ELDON FOIL XXXX, which is a transparent foil to be laminated onto an ELDONCARD XXXX, after the mixture of water, blood and antibodies has completely dried.

An EldonFoil will protect the biological materials against any physical damage.

An EldonFoil will encapsulate any infectious material present in patients' blood.

An EldonFoil can be used to glue the EldonCard into your patient's record.

The use of EldonFoil is not strictly necessary, but most end-users purchase our EldonFoil.

In the above text XXXX is the identification number of the particular EldonCards.

If EldonCards are used outside a hospital or outside a laboratory end-user will purchase one or more pieces of the following EldonKits:

DOCTOR'S KIT DKS XXXX – YY whereby XXXX is the identification number of the particular EldonCard, and YY is the number of EldonCards to be found inside the kit. YY will be either 10 or 25.

MILITARY KIT MKS 2521-25, which is a kit containing 25 pieces of the double card ELDONCARD 2521. To be used in 50 ABO- and RhD determinations on capillary blood, stabilised venous blood, or washed red cells, as the case may be.

ONE MAN KIT OKS 2511-1, which is a kit containing one ELDONCARD 2511 for one ABO- and RhD determination on capillary blood.

Clinical Qualities and Limitations related to the Use of EldonCards

Clinical Qualities and Limitations

Blood group determination upon EldonCards is based upon the principle of direct agglutination.

Eldon Biologicals A/S's European Multi Centre Study (Please see www.eldoncard.com) on 3000 samples of blood documents that EldonCards are just as reliable as conventional reagents for blood group determination based upon the principle of direct agglutination. EldonCards were not able to detect all categories of weak and partial D's, and partial D variant VI could as expected not be determined. Seven out of 39 weak D's were however detected, which means that EldonCards are somewhat more "Weak D sensitive" than the conventional diagnostics used as controls.

As a conclusion blood group determination upon EldonCards implies that:

- The grouping of patients' blood will show the best category of blood to be transfused to said patient.
- That donor's blood found rhesus positive can be transfused to any recipient with the ABO- and RhD phenotype found upon the EldonCard.
- That donor's blood found rhesus negative must pass an Indirect Antiglobulin Test (Coombs test).

Health Authorities' Registration and Approval of EldonCards and EldonKits

The QMS of Eldon Biologicals A/S is certified under ISO 13485:2012 and CMDCAS. The registration covers the design and manufacture of in-vitro-diagnostic test kits used in the detection of blood grouping including near patient in-vitro diagnostic devices.

The European Union

In the member states of the European Union and in the countries associated to the Union, in vitro diagnostics shall comply with the In Vitro Diagnostic Device Directive (IVDD), 98/79/EC issued by the European Commission and Parliament.

Notified bodies authorised by the national health authorities will audit, inspect or control, (A) the quality assurance systems set up by the manufacturers of the diagnostics, (B) the quality and sufficiency of the clinical investigations and (C) the stability studies performed by the manufacturers. If an in vitro diagnostic in every respect complies with the IVDD, the notified body will for said diagnostic issue CE Certificates, which will to the manufacturer, grant the right to label the diagnostic with CE marks. Without such CE labelling any marketing and sales of the diagnostic inside the EU is illegal.

The Danish notified body DGM granted to Eldon Biologicals A/S two CE Certificates, which allow sales of EldonCards labelled with CE₀₅₄₃ for in vitro diagnostic blood type determination (e.g. use in hospitals and clinical laboratories):

EC Type-Examination Certificate, DGM-491.1
EC Certificate, DGM-492.1

The Dutch notified body DEKRA granted to Eldon Biologicals A/S two CE Certificates, which allow sales of EldonKits labelled with CE₀₃₄₄ for professional and self-testing use (e.g. use in practitioners' clinics, in warfare and by lay persons' self testing):

EC Type-Examination Certificate, Eldon Blood typing Cards for professional and self-testing use, DEKRA No. 2109063CN.
CE Marking of Conformity, Eldon Blood typing Cards, DEKRA No. 2109063CN.

Any lot number of EldonCards labelled with CE₀₅₄₃ has been approved and released by DGM. EldonKits containing EldonCards labelled with CE₀₅₄₃ have been approved and released first by DGM and hereafter by DEKRA and are labelled with CE₀₃₄₄.

The United States of America

In the United States a 510(k) registration was granted in 1979.

The registration cleared EldonCards "for the intended use of screening in physician's offices and clinics and for educational purposes" but not for blood typing for the purpose of transfusions.

Except for military kits sold to the US Armed Forces, all EldonCards marketed and sold in the US are labelled with the text: "Not for use for screening purposes prior to transfusion".

Other Countries

With the assistance of our local distributors, EldonCards have been registered in Canada, Morocco, Malaysia, Indonesia, Brazil, Russia, Turkey, Vietnam, Sri Lanka, South Africa, Nigeria and Mexico. Application for registration is pending in India, China, Argentina and will be filed in an additional number of countries.

Additional Information

On our internet address www.eldoncard.com you will please find additional information on our products. Also you can see a video/DVD. Click on Video / Procedure, and see how to do the blood grouping upon an EldonCard.

We will be happy to forward our ELDON MANUAL and information on our prices, but before doing so we ask you to kindly inform on which market(s) you intend to promote and sell our products?

Maybe you already contacted on your company. If not please forward your company profile and other relevant information on your company.

Copenhagen June, 2012.

Hans Hedegaard
General Manager, CEO

Eldon Biologicals A/S
Sandtoften 10
DK-2820 Gentofte
Denmark

Phone: Int. +45 4593 1111
Telefax: Int. +45 4593 2423
www.eldoncard.com