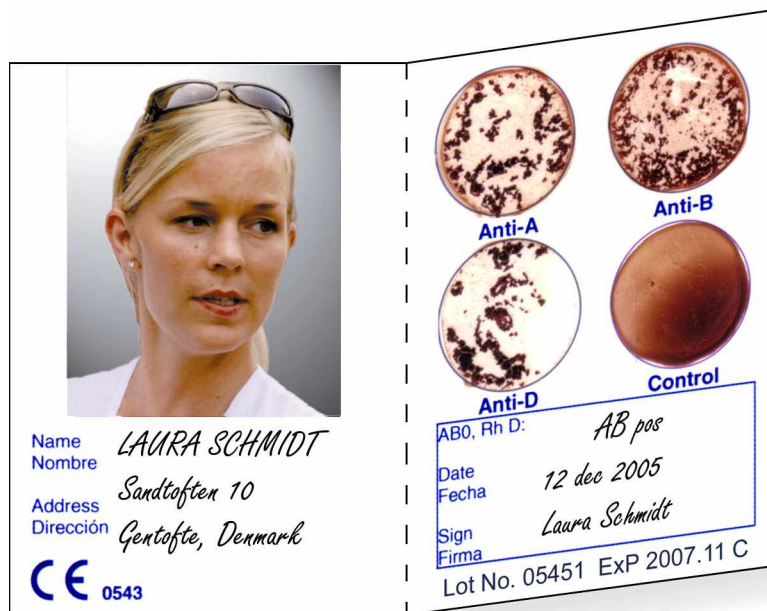


Report

Evaluation of lay-persons' ability to use ELDONCARD IDENTITY KIT



This study was performed in collaboration between
Eldon Biologicals A/S, Denmark and Imhotep Medical Products, the Netherlands

November 2005

1 Identification of the device

ELDONCARD IDENTITY KIT-1 manufactured and marketed by Eldon Biologicals A/S, Gentofte in Denmark.

The test is identical to the “ELDON HOME KIT 2521-1, also manufactured and marketed by Eldon Biologicals A/S.

For this study, the ELDON HOME KIT version was used. This version is technically identical to the ELDONCARD IDENTITY KIT. The instructions for use are also identical.

2 Objective of the study

The aim of this study is to show that blood group determinations with ELDONCARD IDENTITY KIT-1 is correctly carried out and correctly interpreted by laypersons, using the instructions for use provided, and without assistance of a medical professional or other user.

It is not the aim of this study to establish the performance characteristics of the assay as such. These have been established previously and in a professional environment. The results are part of available technical documentation and will be submitted to the notified body TNO as part of the technical file.

3 Evaluation plan and general information

As part of the clinical evaluation, participants fill out a questionnaire.

This questionnaire allows :

- The categorization of the patients according to personal and social factors.
- To obtain personal information that might be of relevance for the analysis of the results
- To assess the perception of the patients with respect to test execution
- To assess the correct interpretation by the patient

For details, see Evaluation Plan and information in the Devices for Performance Evaluation Statement and File (on file at Eldon Biologicals A/S).

4 Duration and location

The study started on November 2nd, 2005 and was terminated on November 15th, 2005.

Part I & II of the study were performed with blood donors at the Centre for Blood transfusion of Nijmegen in The Netherlands.

Part III was performed with volunteers located nearby Gennep in the Netherlands.

5 Analysis of the data from the questionnaires.

5.1 Composition of the test population

In total, 63 lay persons (51 blood donors and 12 other persons) performed blood group determinations with the ELDONCARD IDENTITY KIT-1.

The test population consisted of the following subjects

5.1.1 Sex

| | men | women | unknown |
|------------------|-----|-------|---------|
| 51 blood donors | 28 | 23 | 0 |
| 12 other persons | 5 | 7 | 0 |

5.1.2 Age

| | 18-30 | 31-40 | 41-50 | 51-60 | >60 | unkown |
|------------------|-------|-------|-------|-------|-----|--------|
| 51 blood donors | 9 | 8 | 11 | 17 | 6 | 0 |
| 12 other persons | 1 | 2 | 2 | 3 | 4 | 0 |

5.1.3 Education

| | Low secondary | High secondary | Higher education | unknown |
|------------------|---------------|----------------|------------------|---------|
| 51 blood donors | 8 | 14 | 28 | 1 |
| 12 other persons | 7 | 3 | 2 | 0 |

5.1.4 Medical background

| | medical | Not medical | unknown |
|------------------|---------|-------------|---------|
| 51 blood donors | 12 | 39 | 0 |
| 12 other persons | 0 | 12 | 0 |

5.2 Kit composition correct?

Kit lot numbers written in questionnaire : 04331

Instructions for use present in kit?
 Is the actual kit composition in agreement with what is described in the instructions?
 4 coloured circles present on the (unused) testcard?

| | Yes | No | blank |
|-------|-----|----|-------|
| 48+12 | 0 | 3 | |
| 45+12 | 5 | 1 | |
| 49+12 | 0 | 2 | |

5 persons indicated a kit with a different composition as mentioned in the package insert.

In two cases of these cases, 8 sticks (in stead of 4) were included in the kit.

The 3 other persons didn't mention the nature of the different kit composition.

5.3 Test execution

The returned questionnaires (from both groups: blood donors and other persons) are evaluated against the specifications. The following results were obtained.

| Question – possible answers | Specification | Obtained result |
|--|--------------------------|--|
| Could you easily draw blood? Yes – No | >90 % Yes | 87.3% Yes |
| Did you obtain sufficient blood for the 4 circles? Yes – No – I am not sure. | >90 % Yes | 88.9% Yes 6.3% No 4.8% I am not sure |
| What was the time between the first drop on the first circle and the mixing of the 4 circles? < 2 min – > 2 min | >90% < 2 min | 96.8% < 2 min |
| Did you use the 4 mixing sticks? 4 – 3 – 2 – 1 | >90% 4 sticks | 100% 4 sticks |
| Did you do the test as prescribed? Yes - No | >90% Yes | 96.8% Yes |
| Were the instructions for use clear? Very clear – clear – unclear – very unclear | >90% very clear or clear | 95.2% very clear or clear |
| Was the test easy to do? Very easy – easy – difficult – very difficult | >90% very easy or easy | 92.1% very easy or easy |
| Could the result clearly be read and interpreted? Very clear – clear – unclear – very unclear | >90% very easy or easy | 95.2% very easy or easy |

None of the tests were eliminated form the evaluation.

One person mentioned that the test was not carried out as described, he/she had to prick more than once to obtain enough blood. We did not concern this deviation as relevant to be excluded from the evaluation.

As shown in the table above, two specifications were not met:

Could you easily draw blood?

8 persons indicated difficulties in drawing blood. No one indicated the nature of the problems. In all cases, the agglutination patterns of the scanned pictures were clear, which indicates that, although it was difficult to obtain, enough blood was applied.

Did you obtain sufficient blood for the 4 circles?

4 persons indicated that they did not obtain enough blood. In 3 cases, after two or more pricks enough blood was applied.

3 persons indicated that they were not sure that enough blood was obtained.

One of them is a blood thinner user. The package insert clearly indicates that the test is not suitable for people using blood thinners.

Both questions are related to the blood pricking procedure.

A corrective action has been initiated to rewrite this section in the package insert. The procedure as shown in other blood pricking self tests, like the Easy Home Test Syphilis and Easy Home Test Pfeiffer (Imhotep Medical Products, the Netherlands), will be taken.

5.4 General remarks

Below a list of the relevant general remarks given by the lay persons. The major part of the remarks were related to the fingerprick procedure.

This issue has been treated in the paragraph above.

- Pricked twice (or several times) to obtain enough blood (4 remarks)
- It is difficult to open the pricker & Pricker didn't work (4 remarks)

Other remarks:

- The language used in the package insert was too professional
- It should be clearly indicated that one has to prepare all the materials 'ready to use' before starting the test
- Step 8 (turning the card in 4 directions for 10 seconds) is not clear.
- It was not easy to put the drops on the mixing sticks, they fell off
- It would be easier if the pouches could be opened without scissors
- It should be clearly mentioned on the package that the test is not suitable for persons using blood diluters
- The test is difficult to perform with trembling hands
- The package insert should be written for 'u' instead of 'je'
- Too much water gives an unclear agglutination

The relevance of the above mentioned remarks will be re-evaluated as a part of the post market surveillance.

5.5 Test results

5.5.1 Part I: Test performance by Blood donors

The test performance carried out by lay men is evaluated by comparing the obtained results, interpreted by a professional (interpretations done by lay men could be biased because they do know their blood type before the test is carried out), to the blood group determined by a reference method.

The blood type mentioned on the blood donors blood card is taken as the results of the reference method.

Of each dried test card, a copy of the agglutination pattern is scanned and stored on a CD ROM; these pictures can serve to verify the interpretation of the agglutination pattern.

51 blood donors performed the test. Results are shown in the table below.

| | | ELDONCARD IDENTITY KIT-1 | | | | | | | | |
|------------------|----|--------------------------|----|---|----|---|----|---|------|---|
| | | ABO | A | | B | | AB | | O | |
| | | Rhesus | + | - | + | - | + | - | + | - |
| Reference method | A | + | 17 | | | | | | | |
| | | - | | 4 | | | | | | |
| | B | + | | | 3* | | | | | |
| | | - | | | | 0 | | | | |
| | AB | + | | | | | 2 | | | |
| | | - | | | | | | 1 | | |
| | O | + | | | | | | | 17** | |
| | | - | | | | | | | | 7 |

* For one test (nr. 26), the result of the reference method (indicated as the Reference result by the test person), was **B negative** and the result of the ELDONCARD IDENTITY KIT-1, recorded by the professional, was **B positive**. In this case, the interpretation of the ELDONCARD IDENTITY KIT-1 (by the professional) appeared to be erroneous. This was due to a writing error. The scanned pictures of the test card show a clear B negative blood type; the interpretation done by the lay person of the same card indicates also a B negative type.

** For one test (nr. 17), the result of the reference method (indicated as the Reference result by the test person), was **O negative** and the result of the ELDONCARD IDENTITY KIT-1 was **O positive**. The scanned picture and the

interpretation done by the lay person, confirms the O positive blood type obtained with the ELDONCARD IDENTITY KIT-1.

In this case, the reference blood type was erroneously written down in the questionnaire by the lay-persons. Verification of the data hold by the blood bank revealed that the blood type determined with a reference method was **O positive**.

5.5.2 Part II: Test interpretation by blood donors

The first part of the evaluation of the test interpretation is done by the same blood donors.

A scanned picture of 3 agglutination patterns on test cards of other people, were interpreted by lay persons.

51 blood donors were asked to interpret the test cards. The results are shown in the table below.

| | | Professional interpretation | | |
|------------------------|-------------------------|-----------------------------|----|----|
| | | A- | B+ | O+ |
| Lay men interpretation | A- | 46 | | |
| | B+ | | 46 | |
| | O+ | | | 46 |
| | Blank or partial answer | 5 | 5 | 5 |

46 persons completed this part of the evaluation.

The remaining 5 persons returned the questionnaire without filling in (2) or with this part partially filled in (3).

Most probably, these persons misunderstood the purpose of this part of the evaluation, and looked for the blood types that correspond to their own blood type. Indeed, the 3 persons that partially filled in this part had a O+ blood type and they all mentioned O+ on the sheet. The 2 persons that left this part of the evaluation blank, had blood type O- and AB- , both types that were not present among the agglutination patterns.

Leaving out the blank and partial results, a 100% agreement between the interpretation done by a professional and done by the lay person is obtained for the three agglutination cards.

5.5.3 Part III: Test interpretation

The second part of the evaluation of the test interpretation is done by persons who do not know their blood type. In this evaluation the interpretation can not be biased by knowing the blood type before carrying out the test.

12 persons carried out and interpreted the test. The cards were also read by a professional. The results are shown below.

| | | Lay person interpretation | | | | | | | | |
|-----------------------------|----|---------------------------|---|---|---|---|----|---|---|---|
| | | ABO | A | | B | | AB | | O | |
| | | Rhesus | + | - | + | - | + | - | + | - |
| Professional interpretation | A | + | 4 | | | | | | | |
| | | - | | 0 | | | | | | |
| | B | + | | | 1 | | | | | |
| | | - | | | | 1 | | | | |
| | AB | + | | | | | 2 | | | |
| | | - | | | | | | 0 | | |
| O | + | | | | | | | 2 | | |
| | - | | | | | | | | 2 | |

100% agreement between the interpretation done by a professional and done by the lay person is obtained.

6 Conclusions

Besides the criterion concerning the blood collection procedure, all specifications were met.

In order to resolve the difficulties observed with the blood collection procedure, this section in the package insert will be rewritten. The description of a similar procedure shown in the Easy Home Test Syphilis and Easy Home Test Pfeiffer which are on the market as a self test using blood pricks, will be put in the package insert.

During the post market surveillance of these two tests, there was no indication of problems with the blood pricking procedure. During one year, Imhotep Medical's telephone service line did register 8 questions on these tests. Most of them were related to the clinical context of the test. None of them referred to problems with the blood pricking procedure.

From this study, we can conclude that the ELDONCARD IDENTITY KIT-1 is suitable for use by lay-persons.