

## TRIAL AND EVALUATION OF DRY FORMAT ELDON CARD FOR ABO & Rh BLOOD GROUPING – “A NEW CARD CONCEPT ”.

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### ABSTRACT

**INTRODUCTION :** The ABO system was the first human blood group system discovered by Landsteiner in 1900 and is still the most important in transfusion practice. Although on-site blood testing is desirable and appropriate blood transfusion procedure, most conventional methods lack the required usability or portability. To overcome this inconvenience, Eldon Biological A/S Denmark has developed a dry format–Eldon cards for ABO & Rh blood grouping

**AIM AND OBJECTIVE :** The aim of this study was to evaluate the accuracy and reliability of the Eldoncard on comparison with standard conventional method

**MATERIALS AND METHODS :** Study was conducted in 808 volunteers which include Doctors, medical students, non-medical students and non-teaching staffs selected randomly from Vinayaka missions University, Salem. Blood grouping was conducted as per the instructions in the company manual. Result of this Eldon card method was compared with standard conventional method using liquid anti sera.

**RESULT :** The cards are portable, compact, and easy to use and give the reliable results within one minute. All cards showed a very good agglutination result. On comparison with the conventional method, no disparity was observed. However, there is no provision on these cards for sub groups (A1, A2, A1B & A2B) and other rare groups like Bombay blood group.

**CONCLUSION :** The present study showed that the ABO blood grouping and Rh typing tested on the Eldon cards were similar to the results obtained by standard conventional Slide and Tube method.

**KEY WORDS :** Eldon card, Blood grouping, Blood transfusion, Cross matching, Compatibility

### INTRODUCTION :

The ABO & Rh blood grouping is an indispensable laboratory technique in transfusion medicine, forensic analysis, paternity test, anthropological studies as well as an outstanding human genetic marker of historic and current interest. Conventionally, blood grouping is performed either by tube method or slide standard methods using liquid antisera.<sup>1</sup> In 1954 Danish physician ELDON invented first dry format card for

blood grouping and named as “ELDONCARD” (Figure-1).

In 1979, after preliminary analysis, a 510K registration was granted for this card in United States. Permission was granted for screening of patients in physician's office and clinics and also for educational purposes. This card was included in the military kits of US armed forces. It is also a component of emergency and military kit MKS2521 a first aid kit used in emergency

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situation and warfare. Since an extensive worldwide clinical trial was not conducted, this card is not used for screening purpose prior to blood transfusion.<sup>1,2</sup>

### **AIM AND OBJECTIVES :**

The aim of this study was to evaluate accuracy and precision of the Eldon card in comparison with liquid antisera method. We also analyzed whether blood grouping test is possible at any location using this card and also its usefulness as -“Point-of-Care Anywhere” in emergencies.<sup>2</sup>

### **MATERIALS AND METHODS :**

In this study, US- FDA approved and Denmark patent health care diagnostic laboratory<sup>3</sup> product Eldon card 2511 with lot No: 1137 was evaluated for its accuracy in blood group determination. 808 volunteers, which included students, non-teaching and teaching staffs of 9 institution of Vinayaka mission university, were randomly selected for the study. The study protocol was approved by the Ethical Committee of Vinayaka Missions Kirupanandha Variyar Medical College, Salem. Informed written consent was obtained from each subject. Result of this Eldon card method was compared with standard conventional method (Table-1) using liquid anti-sera. Results of the test were analyzed. Specificity, sensitivity, percentage of false positive, percentage of false negative, Positive Predictor Value (PPV) and Negative Predictor Value (NPV) were analyzed. (Table-2)

With a new strategy to acquire worldwide acceptance, Eldon Biological A/S Denmark has started worldwide evaluatory procedure. As a part of this process, free samples of Eldon blood grouping cards were given to us for trial and evaluation at Vinayaka Mission's Medical College & Hospital, Salem- 636 308. Using Eldoncard ABO & Rh blood grouping of volunteers were

evaluated (Table-3) and was compared against prevalent standard tube/slide method using liquid antisera<sup>4</sup>

### **RESULTS :**

Rapid user-friendly ABO & Rh blood grouping on Eldon card were checked/ confirmed with the conventional method. All cards showed a very good agglutination result with high avidity. The comparison method is an important tool in the process of analytical method validation. Two different modality using two different grouping anti-sera i.e., one is Dry chemistry and the other one is using Liquid blood grouping sera tested on slide and tube method verifying their result as showed in Table-1 showing 100% accuracy. On comparison with the conventional method, both sensitivity and specificity of the Eldon card method was found to be 100%. So were its PPV and NPV. Percentage of false positive and false negative was found to be 0%. (Table-2)

### **DISCUSSION :**

The Eldon cards we obtained from the company for ABO- and Rh D blood grouping are based upon the principle of direct agglutination. Eldon blood grouping card is fast, easy to use and the blood typing kit contains everything required to determine blood group and Rh factor using a whole blood sample obtained from a finger prick without the need for separate reagents or laboratory training. It creates a permanent blood type record for medical histories and emergencies.<sup>1,5</sup>

On our comparative analysis of this card using 808 subjects with standard slide and tube method, no ambiguity in the analyzing the resultant agglutination or divergence in the results were observed at any point of time. Clumping or adhesion as a result of antigen antibody interaction on the card was precise and so inference was made

easily. Eldon Biologicals A/S's European Multi Centre Study on 3000 samples of blood had documented that Eldon Cards are just as reliable as conventional reagents for blood group determination based upon the principle of direct agglutination<sup>6</sup>.

Apart from the accuracy in the results, several advantages were observed in this card<sup>7</sup>.

1. Eldon cards can be kept at room temperature.
2. Eldon cards can be transported, stored and used without any need of cooling and electricity.
3. Daily quality controls are not needed
4. Eldon Kits are portable, compact, easy to use and can be used in any location
5. Eldon cards provide a permanent record of the blood group. This card can be used as an "ID-CARD" also.
6. Use in the Forensic medicine: Successful DNA analysis studies have already been done using the blood stains present on the Eldon cards after being used in blood group determination.
7. Forensic experts' use of Eldon cards 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.
8. Automatic detection of interfering substances (false positives).
9. Blood grouping without washing and centrifugation procedures.
10. Midwives' use of this kit will move the rhesus determinations from the blood bank to the home of the pregnant women and can immediately administer a prophylactic treatment with Anti-D immunoglobulin.

Status about the usage of the Eldon card in Other Countries - Eldon cards have been registered for use in multiple countries like Canada, Morocco, Malaysia, Indonesia, Brazil, Russia, Turkey, Vietnam, Sri Lanka, South Africa, Nigeria and Mexico. Application for registration is pending in India, and will be filed in an additional number of countries.

Limitations: Even though, the Eldon cards are portable, compact, easy to use and give the reliable results within one minute, there is no provision in this card to identify sub groups (A1, A2, A1B & A2B) and other rare groups like Bombay blood group.

### CONCLUSION :

The present study showed that the ABO blood grouping and Rh typing tested on the Eldon cards were similar to the results obtained by standard conventional Slide and Tube method. The blood groupings tested on Eldon cards were accurate. There were no cases of discrepancies and therefore provide a permanent record of blood group, a bedside check before blood transfusion and useful to the society at large. This can be used as an excellent demo piece for medical/paramedical practical classes. This card is suggested to be preserved along with the ID card as it will be very useful in unexpected emergency conditions<sup>7</sup>.

Eldon Blood Grouping Card.

Figure: 1.

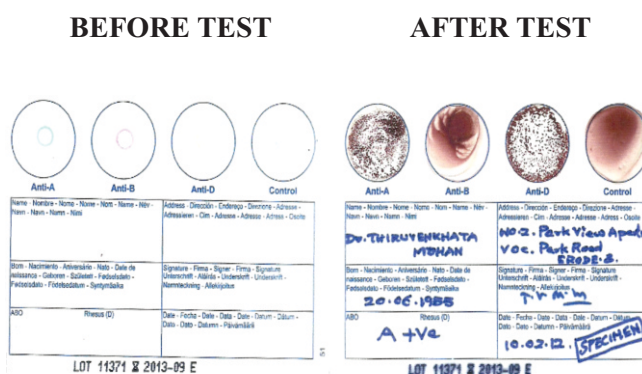


Table – 1 - Evaluation of ABO blood group and Rh typing by Eldoncard method and their comparison with conventional method

Total number of blood samples	Number of Slide Tests	Number of Tube Tests	No. of Eldoncard Tests	Results
808	808	808	808	100%

Table-2- Results of the test - Statistics:

Eldon Card method	Tube/Slide method	
	Positive	Negative
Positive	152	0
Negative	0	656

Specificity: 100 %, Sensitivity : 100 %, PPV : 100 %, NPV : 100 %, False Positive: 0%, False Negative: 0 %

Table-3 - Frequency of Blood Groups ( N=808 ) ; N= number of cases

Blood Groups ( ABO )	Number of cases ( N )	Percentage ( % )
A	152	18.8
B	257	31.8
O	322	39.9
AB	38	4.7
Rh Positive	769	95.2
Rh Negative	39	4.8

**ACKNOWLEDGEMENT :**

We express our sincere gratitude to Dr.K.Jayapal (Retired Dean) & Dr. P.S. Manoharan (Dean) , VMKV Medical College & Hospital, Salem-636 308. Tamil Nadu, for their kind permission to do this new technique of dry format blood grouping card concept in India for the first time and for the permission to publish this trial & evaluation study.

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Received on 01/02/2016, Revised on 15/02/2016, Accepted on 26/02/2016