



PERFORMANCE EVALUATION STUDY OF A NOVEL LATERAL FLOW ASSAY FOR SIMULTANEOUS TYPING OF ABO, D, RHESUS SUBGROUPS AND K (“MDmulticard”)

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Background

Recently, a novel lateral flow assay (“MDmulticard”) has been developed which allows for simultaneous multi-parameter testing in a single assay, providing a stable end-point without centrifugation.¹

The aim of this study was to evaluate the **performance of MDmulticard under routine conditions** on statistically significant donor and patient populations as opposed to state-of-the-art methods (DiaMed Gel Test; Olympus PK-7200).

Methods

In **3168** blood samples, comprising **2573** samples of **blood donors** and **595 authentic clinical samples** of hospitalised patients, ABO, D, K and Rhesus subgroups were tested. Challenging samples i.e. **neonatal samples** (n = 65), **samples with weak antigen expression** (n = 65) (weak D, partial D, weak A, Ax, Ael, weak B) as well as **samples with mixed field reactions** were included. The lateral flow based assay (MDmulticard, Medion Diagnostics) was compared with established methods: a microtiter plate agglutination assay (Olympus PK-7200) in blood donors and a gel agglutination assay (ID-System, DiaMed) in clinical samples.

Briefly, in the **lateral flow method** 100 µl of diluted whole blood or erythrocyte sediment are pipetted into the application zone of the MDmulticard, followed by 300 µl of a rinsing solution (Diluent F). Results can be read after 5 minutes. Positive results are recognized as distinct red bands, negative results are recognized by the absence of the respective band (Fig. 1).

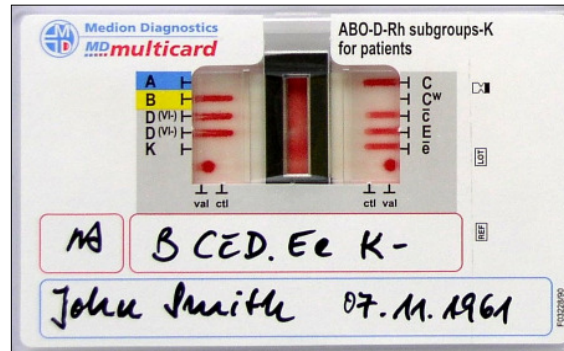


Figure 1: Lateral Flow Forward Typing Assay. Medion MDmulticard with the configuration: A-B-D^(V+)-D^(V-)-K--C-Cw-e-e. Positives are recognized as distinct red bands. Results are valid when the val signal is positive (red spot) and the ctl is negative (no signal). Result: Blood group B CcD.Ee kk

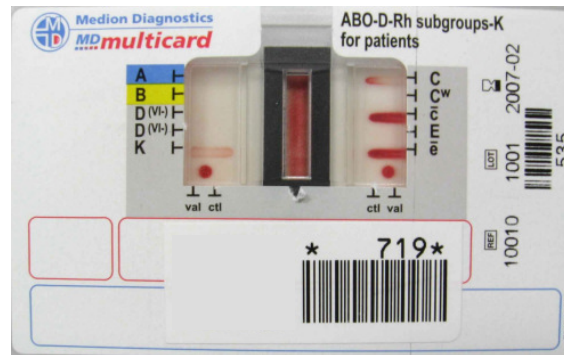


Figure 2: MDmulticard in a pretransfused patient. The patient is blood group O ccddee kk. The patient was transfused with O Ccddee and O ccddee K pos blood which is reflected by the weaker bands at K and C showing highest density in the region which is proximal to the application zone.

References

1. Löster K, Fleischhauer S, Schwind P. Lateral flow assay for simultaneous typing of ABO, Rhesus subgroups and Kell. Vox Sang 2004; 87 (Suppl. 3), 4.3.

Results

In **3164** samples ABO, D, K and Rhesus subgroup typing concurred.

5 samples showed discrepant results. In one weak A sample a positive result with Anti-A could only be observed with MDmulticard but not with the gel agglutination test. In one sample Rhesus e-antigen was typed negative in the lateral flow assay while different monoclonal antibodies gave variable results in the gel agglutination assay suggesting a partial e-antigen. In two samples non-specific results were observed initially most likely due to excessive hyperlipaemia and due to high titer IgG-autoantibodies, respectively. After washing red blood cells regular results in the lateral flow assay could be obtained in both samples. In one sample with high cold agglutinin titer due to complete auto agglutination in the application zone of the lateral flow device no band could be observed. After preincubation of the sample at 37 °C the lateral flow assay gave concurring results.

As an additional observation, it can be reported that in previously transfused patients MDmulticard exhibited superior sensitivity towards small fractions of antigen-positive red cells in comparison to the gel test (Fig. 2).

Conclusion

The lateral flow assay “MDmulticard” represents a **highly sensitive and specific method** for ABO, D, K and Rhesus subgroup antigen typing.

The **simple and rapid method** provides results within five minutes **without centrifugation**. Therefore MDmulticard is **highly suitable for emergency diagnostics**.