

The great 21st century plagues

Medion Diagnostics introduces multiplexing to **blood grouping**

After a successful Management buy-out, Medion Diagnostics is about to introduce a new device for multiparameter blood grouping which overcomes centrifugation.

► **Although founded** only in 2001, the Duedingen based company Medion Diagnostics AG continues a tradition that began 50 years ago with Merz & Dade: its 39 employees are specialized in the development, manufacturing and distribution of diagnostic tests particularly for immunohaematological applications. Formerly the affiliate of a German Biotech Holding, Medion Diagnostics GmbH gained independence in late 2005 by means of a Management Buy-Out. In a logical next step, the Company changed its corporate structure from GmbH to Medion Diagnostics AG, which is now legally Swiss based with a 100% German affiliate.



*Dr. Peter Schwind
Managing Director,
Medion
Diagnostics AG.*

The organization is FDA licensed (since 1991) and ISO 9001:2000 and 13485:2003 certified. A worldwide network of donors, a dedicated blood purchaser situated in the US and a proprietary blood bank integrated

within the Swiss production plant is prerequisite for its worldwide operation as a Reagent Red Blood Cell supplier. The range of more than 100 products is used in about 30 countries, the major markets being Germany, Switzerland, USA, Japan, Korea, Italy, Spain and Austria. The 4 main product groups distributed by Medion are: Antisera, Reagent Red Cells, Enhancers and Instruments. Typical end customers include hospitals, private laboratories and blood banks.

A specialized know-how

Immunohaematology accounts for about 20% of the Haematology diagnostic segment. The highly regulated market comprises all kind of laboratory tests (typing of erythrocyte antigens and screening/identification of anti-erythrocyte antibodies) on blood donors and patients which ensure compatible transfusion. A

further important area is the testing of pregnant women and neonates in order to prevent and correctly diagnose the Haemolytic Disease of the Newborn (HDN).

Compared to other diagnostic fields, the Immunohaematology has distinct features requiring a specialized know-how which is coped by relatively few companies worldwide. Some of these features are:

→Composition of donor antigen profiles for and production of Reagent Red Blood cells;

→Logistics of these erythrocyte containing reagents with standing orders and scheduled delivery dates every 4 weeks; and,

→Test designs. Together with the relatively small size of this market segment, these may be the reasons why none of the biggest players in the Diagnostics business are represented in the IH market.

Since 2002, Medion has started a new R&D initiative, resulting so far in an Intellectual Property portfolio of 12 patent applications. The small R&D group has in-depth expertise in cell- and particle based diagnostic assays, with a special focus on all diagnostic applications with agglutination as end-point.

Facilitating patient testing

In 2005, the company was awarded the Canton of Fribourg's special prize of innovation for one of these new proprietary technologies: the "MDmulticard" is a novel credit card sized device (*see illustration opposite*) for multiparameter determination of blood groups based on lateral flow principles. With this technique, it is possible to determine 10 blood groups in 5 minutes requiring only 2 manipulations. This allows for the first time to detect more than one blood group parameter in the same assay.

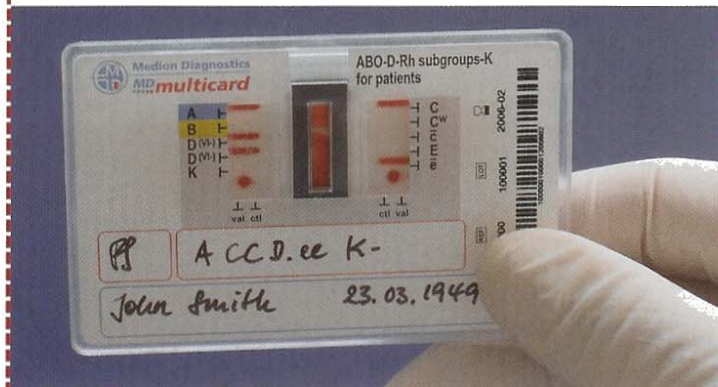
Abstract

Medion Diagnostics introduit le groupage sanguin multiple

Medion Diagnostics AG (Guin) est, avec ses 39 employés, spécialisée dans le développement, la production et la distribution de réactifs pour le diagnostic dans le domaine de l'immunohématologie (tests de laboratoire pour les donneurs de sang et les patients afin d'assurer une transfusion sanguine compatible). La compagnie vient de gagner son indépendance en sortant d'une holding allemande grâce à un «Management buy-out». Medion

l'entreprise ont été récompensés par le Prix Spécial d'Innovation du canton de Fribourg pour une de ses technologies patentée: la «MDmulticard» fait partie d'une nouvelle génération de tests de la taille d'une carte de crédit permettant la détermination multiple des groupes sanguins.

Grâce à cette technique, ne nécessitant que deux manipulations, 10 paramètres sanguins peuvent être déterminés en 5 minutes seulement. La technique ne néces-

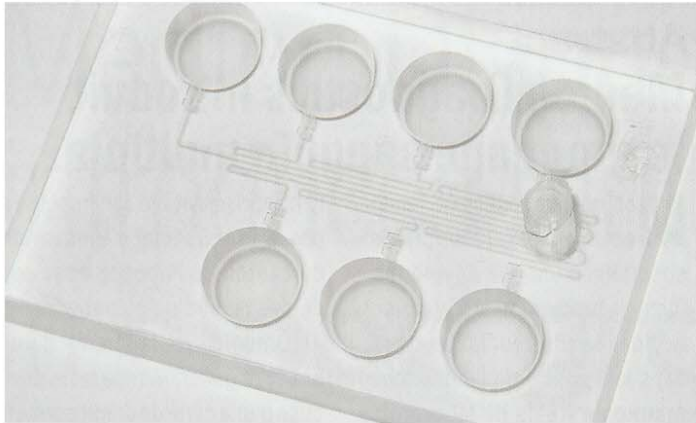


Diagnostics est certifié par les autorités européennes et la FDA américaine.

Une gamme de plus de 100 produits (Antisera, hématies tests, renforçateurs et instruments) est utilisée dans environ 30 pays. Les marchés les plus importants sont en Allemagne, en Suisse, aux Etats-Unis et au Japon. Les clients principaux sont les hôpitaux, les laboratoires privés et les banques de sang.

Depuis 2002, Medion a commencé un nouveau programme de R&D, et a, jusqu'à aujourd'hui, déposé 12 brevets. En 2005, les efforts de

site aucune étape de centrifugation (pas d'électricité!) et les résultats stables peuvent être lus par la présence de bandes colorées. La première carte de cette ligne de produits pour la détermination de ABO, D, sous-groupes Rhésus et Kell qui est actuellement en phase d'enregistrement et sera commercialisée à mi-2006. En plus, cette technologie pourrait se développer en une plateforme permettant de déterminer simultanément les groupes sanguins et de dépister les maladies infectieuses. Tout cela en une seule application de sang complet du patient! ■



Pressure driven microfluidic chip for agglutination assays, consisting of 7 cavities with backflow protection due to passive capillary burst valves.

Moreover, in contrast to the state-of-the-art methods, no centrifugation step is needed without compromising sensitivity. The results can be read as macroscopically visual bands and remain stable for days. The first card of this product line, designed to determine ABO, D, Rhesus subgroups and

Kell, is actually in the CE marking procedure and will be commercialised by the middle of 2006. The above-described features make the device especially useful for patient testing in small hospitals, emergency testing, decentralised blood donations, ambulance cars, army and catastrophe services (wherever diagnostics is needed, without electricity supply), and doctor's offices (gynaecologists). This technology may further provide a platform which enables the combination of diagnostic assays so far performed using completely distinct techniques or even in different laboratories, such as the simultaneous determination of blood group parameters together with infectious disease markers with whole blood in one single assay. ■

Reference:

L'AGEFI magazine - April 2006 - page 86 to 88

The Swiss Financial Daily

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