ABX Hematology, Infinitely Precise in Infinitely Small

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Abstract

ABX is a manufacturer dedicated to hematological test equipments, established in 1983. Today, it has the lineup of products which are centrally midium and small equipments of cell blood counting, and grew to 5th position world-wide in hematology. ABX joined the HORIBA Group in 1996, thus it has developed unique products such as Micros CRP: automatic blood cell counter plus CRP and Pentra 400 : clinical chemistry analyzer by combining each strengths in group. This paper presents the way to ABX growth, the essential technology which has supported it, and the future prospects.

1 Market Trend of Hematology and the Situation of ABX

Hematology represents 7 % of the world market in diagnostics. The original activity of ABX Diagnostics and its consequent development brought it to 5th position world-wide, behind its four main competitors; Beckman-Coulter, Abbott, Bayer and Sysmex.

Today, the technological know-how of ABX Diagnostics in reference to innovation, but especially and above all its capacity for the development and production of attractive and low cost equipment are recognised both in the market and by the competition .

Diagnosis consists of four large but separate areas of health care : Clinical Chemistry, Immunology, Bacteriology, and Hematology. In 2001 the world market in diagnosis represented an overall turnover of some 22.7 billion EUR, an increase of 46 % over a period of just ten years. Hematology, a traditional branch of diagnosis, enables the analysis of blood cells: red blood cells, white blood cells, and platelets, in order to count and differentiate them. The market for hematology is thus predominantly based upon the production and manufacture of analyzers, of which 87 % are laboratory-bound and 13 % will enjoy ambulatory activity.

The main technological developments in hematology are as Table 1.

Table 1 The Main Technological Developments in Hematology

1673	Development of the first microscope by van Leeuwenhoek (first description of blood)
1877	Aniline, first stain for studying the morphology of cells (Erlich)
1947	Development of a technique for counting red and white blood cells using impedance (W.Coulter)
1952	Presentation in Chicago (United States) of the first semi-automated counter. Coulter Model A
1963	TOA-CC series, semi-automated, 5 to 7 parameters
1965	First automated analyzer Coulter S First automated counter, in continuous flow, SMA7 (Technicon)
1970	Emergence of automated differential leukocyte analyzer using image analysis
1973 to 1979	Coulter & Technicon produced more than 25 different analyzers
1983	ABX enters the hematology market with the Minos 7, automated analyzer : 7 parameters, 60 samples per hour (twice as small & 3 times less expensive)
1996	ABX enters the HORIBA Group with a turnover of 40 million EUR
2002	ABX represents 95 % of the HORIBA Group Medical Division with a turnover of 120 million EUR

To this date (1983), ABX continues the development of the Minos range and an automated sampler (the PAM). Its opening of foreign subsidiaries, an export oriented strategy, was rewarded by an "exportation oscar". Today ABX is 5th in the hematology market and this success is based on unstoppable constant logic.

This logic follows 3 axes:

[1] Producing reliable and intuitive analyzers

[2] Using reference methods*1 (technologies) and improving them

[3] Staying aware of new technologies

Today, 25,000 analyzers per year are sold in the world. ABX Produces 7,000 analyzers per year, meaning it produces (more than 1/4) of the world analyzer production.

*1: It is authorized that the methods are accurate and precise in clinical examinations.

2 How Did the ABX Production Become Recognised as One of the Best in the World ?

2.1 Improving Quality and Productivity

Because "improving quality and productivity is production's daily preoccupation". This is an objective to which everyone in the company must contribute to all the time. Thus, for a number of years, the production department has been ceaselessly modifying unsatisfactory operations, checking every detail of the manufacturing process, endlessly improving procedures, reducing costs and eliminating services it considers unnecessary.

Every year, more than a million parts enter the production process and therefore have to meet ABX's strict quality standards.

In short, the ABX production department is perfectly organised. However, the sophisticated skills of the industrialisation department, made up of technicians, multidisciplinary engineers, not forgetting the numerous technical questions raised, are needed to ensure that everything runs smoothly. In all, a valuable link between the technical services, development, after sales and marketing.

2.2 Reference Methods

The complete success of ABX Diagnostics is also due to the fact that we use reference methods to count (CBC, Cell Blood Counting) and differentiate (DIFF, Differentiation of Leukocytes) the blood cells, but at the same time we have improved these methods.

(1) The Reference Method for CBC

In order to count cells the reference method used is "impedance"*2.

ABX counts cells with this method, but we are all aware of its limitations (in the presence of certain pathological cases). To improve the quality of results given by ABX analyzers we have introduced this method to the ABX concept of triangulation of leukocytes, in order for us to be sure of our results.

This concept compares the result given by the impedance measurement with two other methods (optical and differential lyses).

*2: It is the method that m-easures the sizes and the concentration of particles by voltage-pulse heights and numbers. A voltage pulse occurs between electrodes, which are positioned on the both sides of an aperture, when a particle comes into the aperture, in which electrolyte flows, by the impedance change in the constant current control.

(2) The Reference Method for DIFF

To determinate the leukocyte differential, the reference method used is Flow-cytometry*3 and cytochemistry combined.

ABX also uses this method but we have introduced two important technologies. Measuring the real volume of each cell inside the flow-cytometer (aperture with impedance principle) and checking the flow inside the cytometer (Double Hydro-dynamic Sequential System : DHSS™, Fig.1)

*3: It is the method that analyzes the quantity and the size of cells and others by measuring scatter and fluoresence, which occur by irradiating light into the liquid including cells in a narrow tube.

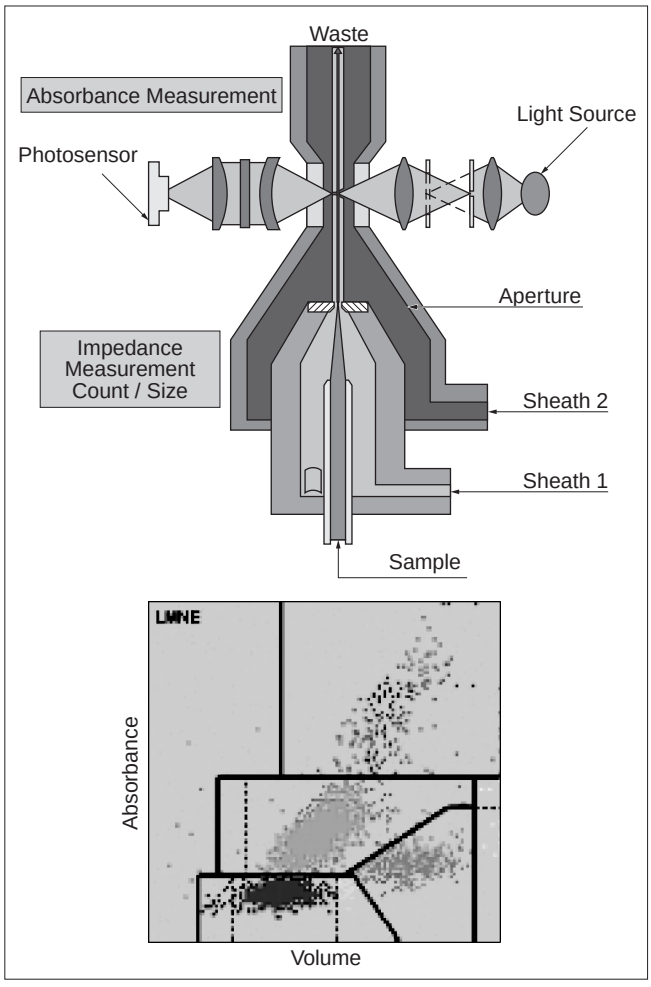

Fig.1 DHSS™: Double Hydro-dynamic Sequential System

ABX has also improved the reference method in other areas.

To obtain the reticulocyte count, a world-wide reference method known as Fluoro flow-cytometry is used. This technology requires the use of a fluorochrome (Thiazole Orange). Usually the incubation time of this reagent to stain the reticulocytes is more or less 30 minutes. ABX is the first company to have reduced this incubation time to 24 seconds.

3 Development of Products

For 5 years, ABX Diagnostics has revolutionised the hematology world with some exciting and innovating concepts:

[1] The first automate without compressor (MICROS)

[2] The first automate without shear-valve, Multi Distribution Sampling System: MDSS™, Fig.2 (Pentra 60)

[3] The first automate with fully integrated slide maker (Pentra 120)

[4] The first automate with fully integrated reticulocyte analysis on whole blood (Pentra 120 retic)

[5] The first automate with integrated validation station and touch screen (Pentra 80)

[6] The first automate with CRP measurement on whole blood integrated in corporation with HORIBA Group (MICROS CRP)

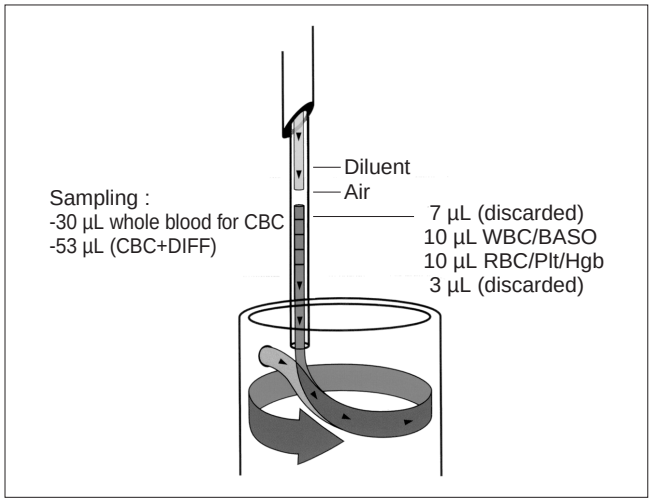

Fig.2 MDSS™: Multi Distribution Sampling System

Presently, the ABX product covers four out of six market segments. We determine the market segment by different criteria:

(A) Number of analyses per day
(B) CBC & DIFF parameters required
(C) Automation with autoloader
(D) Specific parameters (reticulocytes,…)
(E) Slide maker required
(F) Automation of analyzer fully integrated into the chain concept

If we cross the criteria we obtain six segments in the hematology market (Table 2).

The ABX range covers 75 % of market needs, this percentage is more important than our competitors, who need ABX products to cover some segments (two out of four of the biggest suppliers in hematology sell ABX products).

Table 2 Six Market Segments of Hematology

Segment	Customers	A	B	C	D	E	F	ABX Product covering
1	Point of care	< 30	CBC/3DIFF	No	No	No	No	35 %
2	Laboratory	< 45	CBC/5DIFF	No	No	No	No	100 %
3	Medium hospitals	< 80	CBC/5DIFF	Yes	No	No	No	100 %
4	Large hospital	< 200	CBC/5DIFF	Yes	Yes	No	No	100 %
5	University Hospital	< 400	CBC/5DIFF	Yes	Yes	Yes	No	100 %
6	Fully automated lab.	<1500	CBC/5DIFF	Yes	Yes	Yes	Yes	15 %

A: Number of analyses per day
B: CBC & DIFF parameters required
C: Automation with autoloader
D: Specific parameters (reticulocytes,...)
E: Slide maker required
F: Automation of analyzer fully integrated into the chain concept

4 Progressive Implementation

In 2003, the ABX range will consist of 14 analyzers including 4 new analyzers.

In the future, ABX will focus on very low and very high segments. We will increase our network know-how (internet, peer to peer station...) and introduce a technical alliance with Jobin Yvon (an HORIBA Group Company), to allow an integration of their know-how in terms of optical analysis.

Consequently, it would appear important to capitalise on theses advantages so that ABX increases its market share, proceeds with the renewal of the product range and derives support from its OEM policy. These advantages will enable ABX to progressively continue with direct implementation in the countries where the economic conditions and the installed base justify it doing so.

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