Benefits of a new generation of Pentra series: reliability and ergonomics

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Introduction

The Pentra DX Nexus (HORIBA Medical) is the new generation of the Pentra analytical systems able to perform CBC, 8-differential, reticulocytes, erythroblasts and the body fluids analysis (CBF).
This new generation has been conceived to improve the reliability and the efficiency of the laboratory environment, in order to guarantee friendly and comfortable working conditions.

The two aims of the evaluation were to evaluate the classic analytical performances of the system in comparison with the lab reference system XE-2100 (Sysmex) and to test the new ergonomics of the workcell.

Material and Methods

The workcell tested contained a Pentra DX Nexus, Slide Preparation System and ABX Pentra ML to manage the workflow. The blood samples were selected at the St-Joseph St-Luc Hospital in Lyon, France, from the workload of the laboratory always within 2 hours post-drawing. All tests conducting according to approved guidelines.
The performances were measured as follow: accuracy (50 normal and 100 abnormal samples); stability (4 samples for CBC-DIFF; one sample for reticulocytes and one for erythroblasts); precision (4 normal samples: one with ALY, one with IMG, one with reticulocytes and one with erythroblasts). 8 CBF were analysed by the Pentra DX Nexus and compared with the manual method. The laboratory staff in charge of the routine of the lab evaluated practicability, traceability, interaction of the operator with the environment.

Results

Stability

To address the issue related to sample conservation, stability tests were perfomed on the Pentra DX Nexus and compared to the manifacturer and the literature reccomendations . The analyzers produced completely stable results (up to 24 hours post-drawing, at room temperature or at 2 - 6°C). Afterwards, a decrease of 2.3% in WBC was observed at room temperatue. At 2 - 6°C we found an increase of 0.6% in neutrophils and a decrease of 0.4% in lymphocytes; whereas at room temperature the samples were still stable at 24h. The results were in agreement with the literature and the manufacturer specifications. A certain analyte was considered stable when its average change was smaller than the correspondent CV, allowing a 5% risk error.

Six samples were analysed in parallel at room temperature and at 2-6°C on the Pentra DX Nexus up to 48 h.

The table shows the results obtained during our test compared to the recommendations fopund on the litrature (Buttarello et al., 2004).

Test	Room temperature 18-22°C			Refrigerated 2-6°C		
	Pentra DX Nexus	Recommendation		Pentra DX Nexus	Recommendation	
CBC	Stable 24h	Butarello (2004)	Stable 24h	Stable 24h	Butarello (2004)	Stable 24h
WBC	Stable 24h	Butarello (2004)	Stable 24h	Stable 24h	Butarello (2004)	Stable 24h
MCV	Stable 24h (increase 1.1%)	Butarello (2004)	increase 2.6% at 24h	Stable 24h		
Differential count	Stable 24h			Stable 24h		
NEU	Stable 24h	Butarello (2004)	Decrease at 24h	Stable 24h	Butarello (2004)	Increase at 24h
LYM	Increase at 24h	Butarello (2004)	Increase at 24h	Stable 24h	Butarello (2004)	Decrease at 24h
Reticulocytes	Stable 24h	CLSI H44-A (1997)	Stable 6h	Stable 24h	CLSI H44-A (1997)	Stable 72h
Erythroblasts	Stable 24h	N/A		no tested	N/A	

Stability results at 18-22 °C

Stability results at 2-6°C
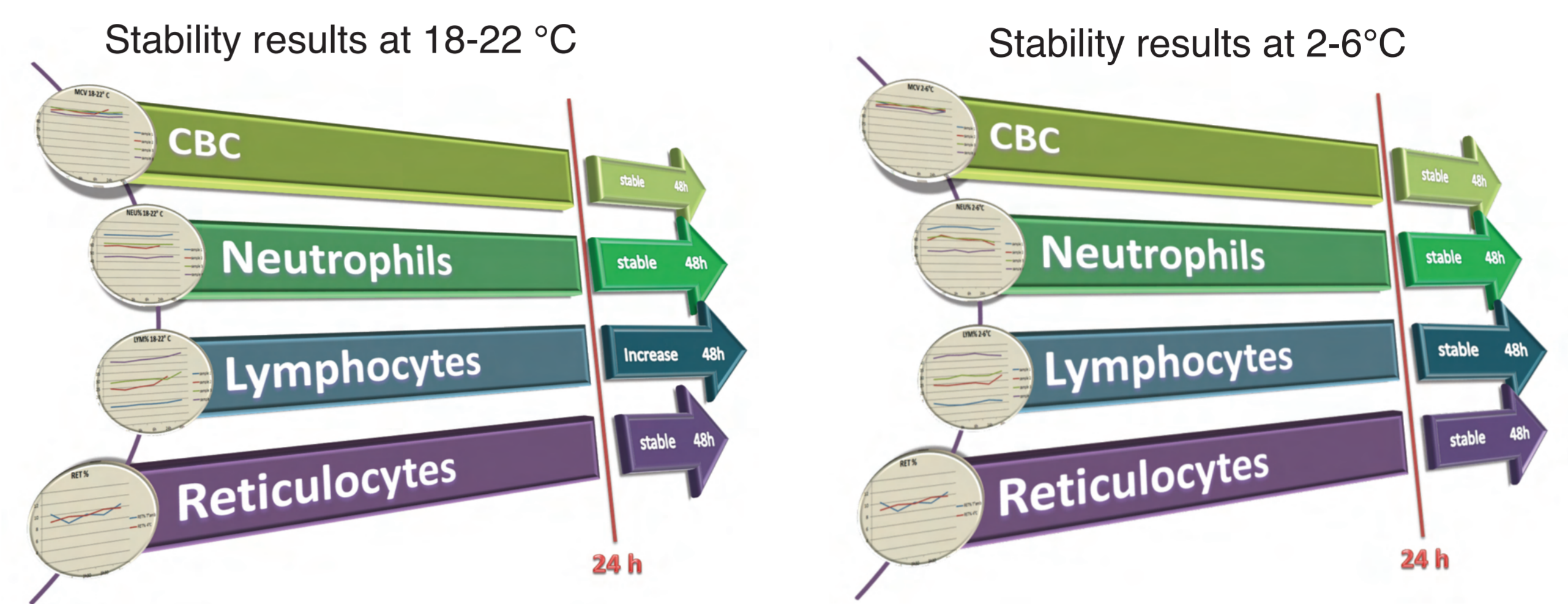
Precision

To verify the precision of the new hematology analyzer repetability tests were conducted on six samples. Each sample was repeated 10 times. The table shows for each parameter the mean CV value obtained on the six repetability tests, as well as the manifacturer specification.
The manufacturer defined the instrument specifications according to the Westgard recommendations based on the biologic variation described in the literature (Ricos C, Alvarez V, Cava F, Garcia-Lario JV, Hernandez A, Jimenez CV, Minchinela J, Perich C, Simon M. "Current databases on biologic variation: pros, cons and progress." Scand J Clin Lab Invest 1999;59:491-500. Updated in 2012.)
The results of the precision tests were in agreement with the manufacturer specifications and medical needs.

	WBC	RBC	HGB	HCT	MCV	RDW	PLT	RET%	ERB%
Mean value	7.30	4.24	14.12	42.47	92.24	12.76	259.75	1.25	10.73
Mean CV	1.46	0.82	0.57	0.79	0.55	2.24	3.27	6.43	4.65
Expected CV	<2%	<2%	<1%	<2%	<1%	<4%	<5%	<20%	

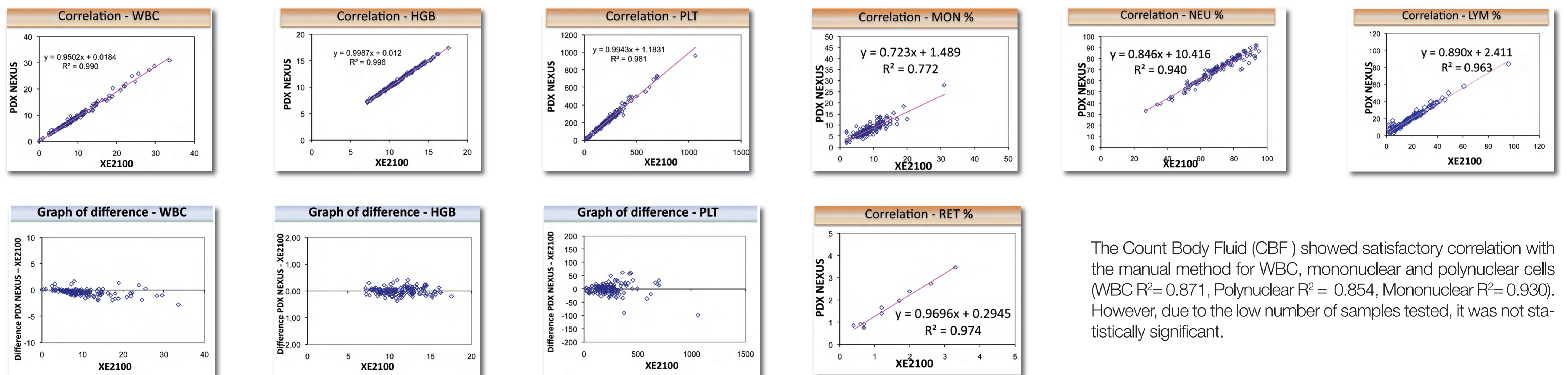|	L%	M%	N%	E%	B%	ALY%	LIC%	IMM%	IMG%
Mean value	35.35	6.59	61.73	2.30	1.27	0.88	0.85	0.88	2.23
Mean CV	3.59	7.82	1.59	9.26	18.42	18.71	22.23	27.36	15.36
Expected CV	<5%	<10%	<3%	<20%	<30%	<40%	<40%	<40%	<40%

Accuracy

The comparison between the Pentra DX Nexus and the XE-2100 was done on 50 normal and 100 abnormal samples.
The acceptable bias were defined on basis of the Westgard recommendations and the tests showed satisfying results (WBC R^2=0.9904; HGB R^2=0.9939; PLT R^2=0.9813; RET R^2=0.9747) as shown in the table.

The accuracy obtained on the WBC subpopulations (NEU and LYM) may be related to the compilation of normal and abnormal samples and that two instruments employ different principles to count these subpopulations. Moreover the MCV results may also reflect the variation in measure principles and calculations of red blood cells volume used by the two manufacturers.

Parameter	WBC	RBC	HGB	MCV	MCH	PLT	LYM%	MON%	NEU%	EOS%	RET%
Deming fit	y = 0.950x + 0.019	y = 1.016x 0.040	y = 0.983x + 0.003	y = 1.013x + 0.416	y = 0.986x + 0.982	y = 0.994x + 1.183	y = 0.890x + 2.411	y = 0.723x + 1.489	y = 0.846x + 10.42	y = 0.860x + 9.564	y = 0.970x + 0.294
R^2	R^2 = 0.9904	R^2 = 0.9930	R^2 = 0.9939	R^2 = 0.9218	R^2 = 0.9641	R^2 = 0.9813	R^2 = 0.9638	R^2 = 0.7721	R^2 = 0.9404	R^2 = 0.9527	R^2 = 0.9747

Correlation - WBC
$y = 0.9502x + 0.0184$
$R^2 = 0.990$

Correlation - HGB
$y = 0.9987x + 0.012$
$R^2 = 0.996$

Correlation - PLT
$y = 0.9943x + 1.1831$
$R^2 = 0.981$

Correlation - MON %
$y = 0.723x + 1.489$
$R^2 = 0.772$

Correlation - NEU %
$y = 0.846x + 10.416$
$R^2 = 0.940$

Correlation - LYM %
$y = 0.890x + 2.411$
$R^2 = 0.963$

Graph of difference - WBC

Graph of difference - HGB

Graph of difference - PLT

Correlation - RET %
$y = 0.9696x + 0.2945$
$R^2 = 0.974$

The Count Body Fluid (CBF) showed satisfactory correlation with the manual method for WBC, mononuclear and polynuclear cells (WBC R^2=0.871, Polynuclear R^2 = 0.854, Mononuclear R^2=0.930). However, due to the low number of samples tested, it was not statistically significant.

Reliability and ergonomics

The **color touch screen** of the Pentra DX Nexus offers a reliable and comfortable tool. A virtual keyboard allows to rapidly enter the data and the staff considered it more useful than a physical keyboard. The access to the different funtions is done through pertinent and easy-to-understand icons constitued of up-to-date pictures.

The **new laser source** dissipates less the heat and consequently the noise is greatly reduced. Moreover, thanks also to its reduced size, the staff found the system friendly and comfortable for the laboratory environnment and routine.

The **new traceability function** in the ABX Pentra ML station offers a complete information for each run. The new traceability function complies with quality norms and it is therefore indispensable for accreditation requirements.
Indeed for each run a pop-up window details the status of the reagents (type, lot, date/time) and the status of the quality control (instrument, protocol, samples ID, date and comments) at the time of the result.

The feature allows rapidly tracing back on the same screen all important information about the sample analysis conditions in agreement with the accreditation requirements.
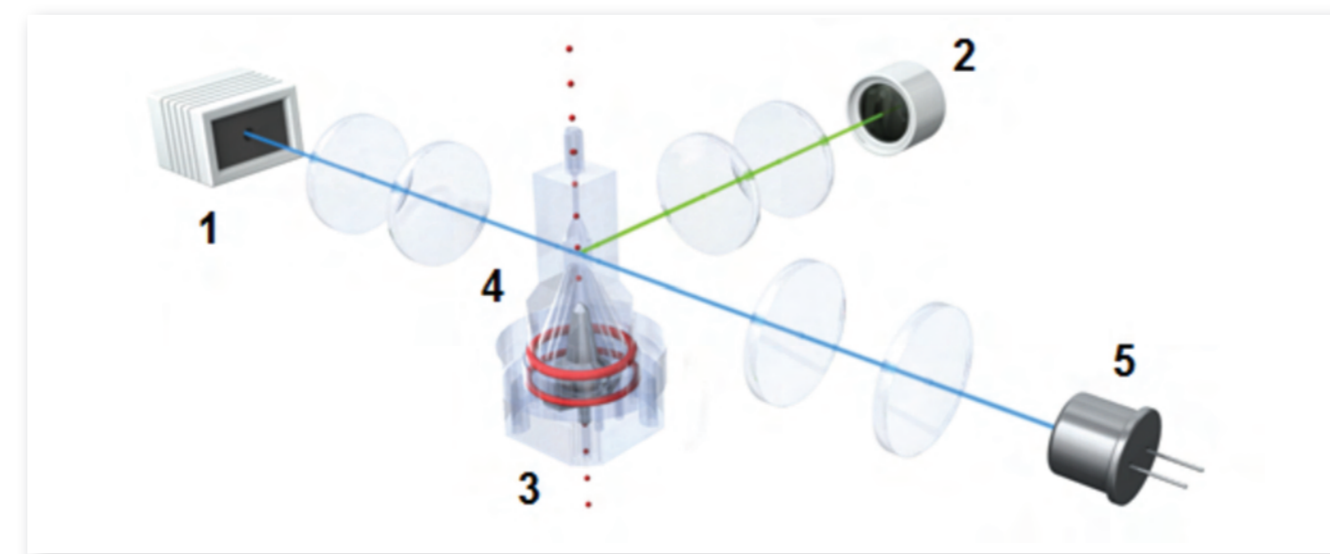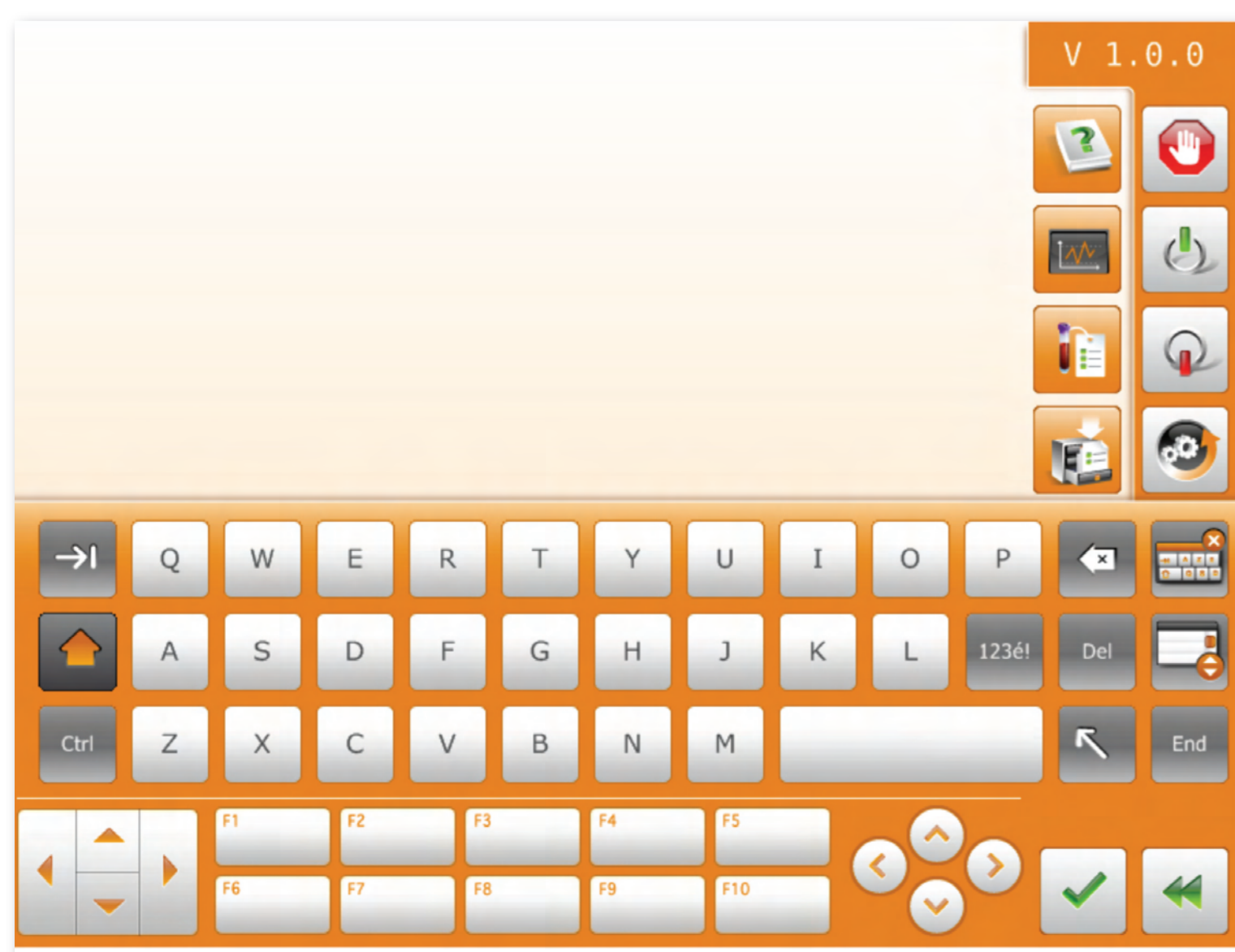
1. Laser LED
2. Photomultiplier
3. Hydrophocalisation
4. Impedancemetry
5. Optical measurement
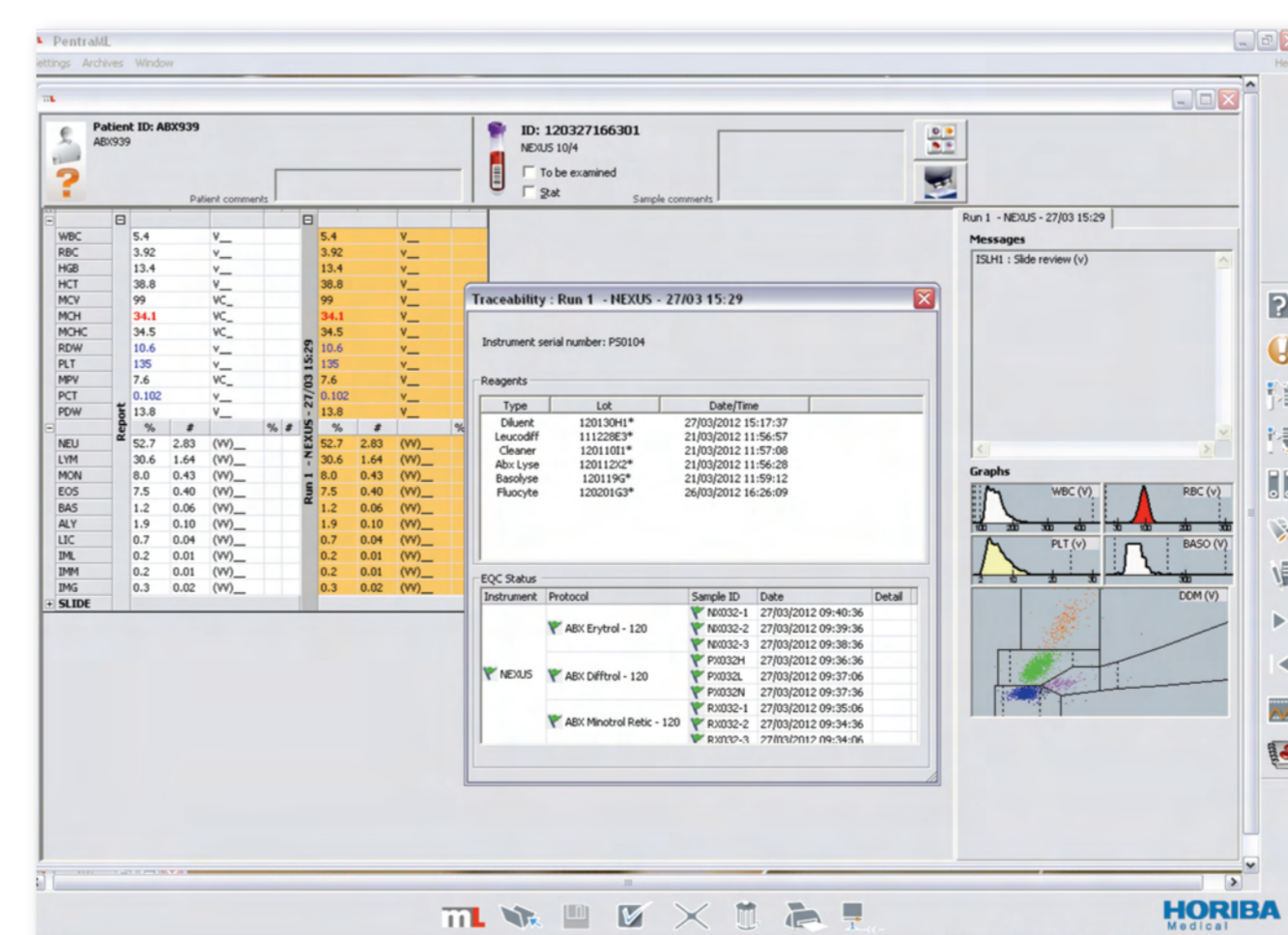
We confirmed the use of the reflex testing rules (reticulocytes, erythroblasts, slides) are automatically triggered.
Yet some improvements could be realized :
1) the design of the quality control menu of the Pentra ML ;
2) the switch toward the CBF mode could be enhanced.

Conclusions

The new haematology workcell consists in a Pentra DX Nexus, a Slide Preparation System and ABX Pentra ML to manage the workflow. This study showed satisfying analytical performances.
The repeatability and stability were very good, as well as the correlation coefficients obtained with the XE-2100.
In the same way, the system offers significant improvements over previous generation of Pentra analyzers in traceability, ergonomics and environment.
His compact form and the new laser source require less space, reducing heat production and noise. Its features make the Pentra DX Nexus suitable to fit any laboratory complying with accreditation requirements.