HORIBA
Medical

QCP
Quality Control Program

User Guide

7th May 2014

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I- INTRODUCTION

Clinical Laboratories are encouraged by regulatory and accreditation organizations to participate in Interlaboratory Comparison Surveys (Proficiency Testing) for the assessment of the analytical performance of their in vitro diagnostic analyzers (ISO/CEI 43-1 guide).

To help laboratories participate in this quality process, HORIBA Medical enhances the service:

ABX Quality Control Program or QCP is an Online Interlaboratory Comparison Program dedicated to all Hematology & Clinical Chemistry analyzers of HORIBA Medical.

By submitting Internal Quality Control results online to QCP, a participating laboratory can obtain real time peer group statistical reports.

IMPORTANT

- Participation in QCP requires the exclusive use of HORIBA Medical instruments, reagents and control products
- For enrollment fees and conditions of participation, please contact your Local Representative

II- QCP INSTRUMENTS, CONTROL PRODUCTS AND PEER GROUPS

II-1- HEMATOLOGY INSTRUMENTS & CONTROL PRODUCTS

The following hematology instruments and control products are offered in QCP:

- **INSTRUMENTS and CONTROLS**

Control Products					ABX Pentra 120 series	ABX Pentra 80 series	ABX Pentra 60 series	ABX Micros series
ABX Difftrol	ABX Minotrol 16	ABX Minotrol CRP	ABX Minotrol Retic	ABX Erytrol	Pentra DX Nexus	Pentra XLR	ABX Pentra 60C+	ABX Micros ABC Vet
					ABX Pentra DX120	ABX Pentra XL80	ABX Pentra 60	ABX Micros 45
					Pentra DF Nexus	ABX Pentra 80	Pentra ES 60	ABX Micros 60
					ABX Pentra DF120		Pentra MS 60	ABX Micros CRP
					ABX Pentra 120 Retic			ABX Micros CRP 200
					ABX Pentra 120			ABX Micros ES60
								ABX Micros ESV
								Microsemi CRP
								Pentra MS CRP

II-2- HEMATOLOGY PEER GROUPS

QCP uses 10 Hematology peer groups for statistical reports:

Each group is constituted of different instruments of the same Series and same Product Control.

It is an important point, because there is no comparison possible between instruments of a different Series or Control Product.

<table>
<tr><th rowspan="2">Series</th><th rowspan="2">Hematology Instruments</th><th colspan="5">Hematology product Controls</th></tr>
<tr><th>ABX Difftrol
3 Levels</th><th>ABX Minotrol 16
3 Levels</th><th>ABX Minotrol CRP
3 Levels</th><th>ABX Minotrol Retic
3 Levels</th><th>ABX Erytrol
3 Levels</th></tr>
<tr><td rowspan="7">ABX Pentra 120</td><td>ABX Pentra 120</td><td rowspan="7">Difftrol - Pentra 120 DX,DF Pentra DX,DF Nexus Group</td><td rowspan="7">Minotrol 16 -Pentra 120 DX,DF Pentra DX,DF Nexus Group</td><td rowspan="7"></td><td rowspan="4"></td><td rowspan="3"></td></tr>
<tr><td>ABX Pentra DF120</td></tr>
<tr><td>Pentra DF Nexus</td></tr>
<tr><td>ABX Pentra 120 Retic</td><td rowspan="4">Minotrol Retic Pentra 120 retic,DX Pentra DX Nexus,Pentra XLR Group</td></tr>
<tr><td>Pentra DX Nexus</td><td rowspan="2">Erytrol Pentra 120 DX, Pentra DX Nexus Group</td></tr>
<tr><td>ABX Pentra DX 120</td></tr>
<tr><td rowspan="3">ABX Pentra 80</td><td>Pentra XLR</td><td rowspan="3">Difftrol - Pentra 80, XL80, XLR Group</td><td rowspan="3">Minotrol 16 - Pentra 80, XL80, XLR Group</td><td rowspan="3"></td><td rowspan="2"></td><td rowspan="3"></td></tr>
<tr><td>ABX Pentra XL80</td></tr>
<tr><td>ABX Pentra 80</td></tr>
<tr><td rowspan="4">ABX Pentra 60</td><td>ABX Pentra 60C+</td><td rowspan="4">Difftrol - ABX Pentra 60, 60C+, Pentra ES60 Group</td><td rowspan="4">Minotrol 16 - ABX Pentra 60, 60C+, Pentra ES60 Group</td><td rowspan="3"></td><td rowspan="3"></td><td rowspan="3"></td></tr>
<tr><td>ABX Pentra 60</td></tr>
<tr><td>Pentra ES60</td></tr>
<tr><td>Pentra MS60</td><td></td><td></td><td></td></tr>
<tr><td rowspan="11">ABX Micros</td><td>ABX Micros ABC Vet</td><td rowspan="11"></td><td rowspan="11">Minotrol 16 - Micros series analyzers Group</td><td rowspan="6"></td><td rowspan="11"></td><td rowspan="11"></td></tr>
<tr><td>ABX Micros 45</td></tr>
<tr><td>ABX Micros ES60</td></tr>
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<tr><td>ABX Micros CRP 200</td><td rowspan="5">Minotrol CRP Group</td></tr>
<tr><td>ABX Micros 60</td></tr>
<tr><td>ABX Micros CRP</td></tr>
<tr><td>Microsemi CRP</td></tr>
<tr><td>Pentra MS CRP</td></tr>
</table>

II-3- HEMATOLOGY PARAMETERS

Hematology Control Product: **ABX Difftrol**
Ex. : Lot PX034

Hematology Instrument	Hematology Parameters		
	Abbreviation	**Description**	**Units**
ABX Pentra 60 **ABX Pentra 60 C+** **ABX Pentra ES 60** **Pentra MS 60** **Pentra MS CRP** **Pentra XLR** **ABX Pentra 80** **ABX Pentra XL80** **Pentra DX Nexus** **Pentra DF Nexus** **ABX Pentra DX120** **ABX Pentra DF120** **ABX Pentra 120** **ABX Pentra 120 Retic**	WBC	White Blood Cells	$10^3/mm^3$ $10^9/L$
	RBC	Red Blood Cells	$10^6/mm^3$ $10^{12}/L$ $10^6/\mu L$
	HGB	Hemoglobin	g/dL g/L mmol/L
	HCT	Hematocrit	% L/L
	MCV	Mean Corpuscular Volume	μm^3 fL
	MCH	Mean Corpuscular Hemoglobin	pg fmol
	MCHC	Mean Corpuscular Hemoglobin Concentration	g/dL g/L mmol/L
	RDW	Red Cell Distribution Width	%
	PLT	Platelets	$10^3/mm^3$ $10^9/L$
	MPV	Mean Platelet Volume	μm^3 fL
	LYM %	Lymphocytes Percentage	%
	LYM #	Lymphocytes Absolute Number	#
	MON %	Monocytes Percentage	%
	MON #	Monocytes Absolute Number	#
	NEU %	Neutrophils Percentage	%
	NEU #	Neutrophils Absolute Number	#
	EOS %	Eosinophils Percentage	%
	EOS #	Eosinophils Absolute Number	#
	BAS %	Basophils Percentage	%
	BAS #	Basophils Absolute Number	#

Hematology Control Product : **ABX Minotrol 16**
Ex. : Lot MX034

Hematology Instrument	Hematology Parameters		
	Abbreviation	**Description**	**Units**
ABX Micros ABC Vet **ABX Micros 45** **ABX Micros 60** **ABX Micros CRP** **ABX Micros CRP 200** **ABX Micros ES60** **ABX Micros ESV** **Microsemi CRP** **ABX Pentra 60 *** **ABX Pentra 60 C+ *** **ABX Pentra ES 60** **Pentra MS 60** **Pentra MS CRP** **Pentra XLR** **ABX Pentra 80 *** **ABX Pentra XL80 *** **Pentra DX Nexus** **Pentra DF Nexus** **ABX Pentra DX120 *** **ABX Pentra DF120 *** **ABX Pentra 120 *** **ABX Pentra 120 Retic *** * CBC parameters only	WBC	White Blood Cells	$10^3/mm^3$ $10^9/L$
	RBC	Red Blood Cells	$10^6/mm^3$ $10^{12}/L$ $10^6/\mu L$
	HGB	Hemoglobin	g/dL g/L mmol/L
	HCT	Hematocrit	% L/L
	MCV	Mean Corpuscular Volume	μm^3 fL
	MCH	Mean Corpuscular Hemoglobin	pg fmol
	MCHC	Mean Corpuscular Hemoglobin Concentration	g/dL g/L mmol/L
	RDW	Red Cell Distribution Width	%
	PLT	Platelets	$10^3/mm^3$ $10^9/L$
	MPV	Mean Platelet Volume	μm^3 fL

Hematology Control Product : **ABX Minotrol CRP**
Ex. : Lot MC014

Hematology Instrument	Hematology Parameters		
	Abbreviation	**Description**	**Units**
ABX Micros ABC Vet **ABX Micros 45** **ABX Micros 60** **ABX Micros CRP** **ABX Micros CRP 200** **ABX Micros ES60** **ABX Micros ESV** **Microsemi CRP** **Pentra MS CRP**	WBC	White Blood Cells	$10^3/mm^3$ $10^9/L$
	RBC	Red Blood Cells	$10^6/mm^3$ $10^{12}/L$ $10^6/\mu L$
	HGB	Hemoglobin	g/dL g/L mmol/L
	HCT	Hematocrit	% L/L
	MCV	Mean Corpuscular Volume	μm^3 fL
	MCH	Mean Corpuscular Hemoglobin	pg fmol
	MCHC	Mean Corpuscular Hemoglobin Concentration	g/dL g/L mmol/L
	RDW	Red Cell Distribution Width	%
	PLT	Platelets	$10^3/mm^3$ $10^9/L$
	MPV	Mean Platelet Volume	μm^3 fL
	LYM %	Lymphocytes Percentage	%
	LYM #	Lymphocytes Absolute Number	#
	MON %	Monocytes Percentage	%
	MON #	Monocytes Absolute Number	#
	GRA %	Granulocytes Percentage	%
	GRA #	Granulocytes Absolute Number	#
	CRP	C Reactive Protein	mg/dL mg/L

Hematology Control Product : **ABX Minotrol Retic** Ex. : Lot RX034			
Hematology Instrument	**Hematology Parameters**		
	Abbreviation	**Description**	**Units**
Pentra DX Nexus **ABX Pentra DX120** **ABX Pentra 120 Retic** **Pentra XLR**	RETIC %	Reticulocyte Percentage	%
	RETIC #	Reticulocyte Absolute Number	# 10^6/µL
	MFI	Mean Fluorescence Index	%
	RBC	Red Blood Cells	10^6/µL
	PIC	Number of channels of the maxi. peak of the mature RBC	Chan

Hematology Control Product : **ABX Erytrol** Ex. : Lot NX034			
Hematology Instrument	**Hematology Parameters**		
	Abbreviation	**Abbreviation**	**Units**
Pentra DX Nexus **ABX Pentra DX120**	WBC	White Blood Cells	10^3/mm^3 10^9/L
	CWBC	Corrected White Blood Cells	10^3/mm^3 10^9/L
	ERB %	Erythroblast Percentage	%
	ERB #	Erythroblast Absolute Number	#

ESR - (With temperature correction)			
Hematology Instrument	**Hematology Parameters**		
	Abbreviation	**Abbreviation**	**Units**
Auto compact StaRRsed Inversa 24 ML	SR (VS)	Sedimentation rate	mm/h

II-4- CLINICAL CHEMISTRY INSTRUMENT & CONTROL PRODUCTS

The following clinical chemistry instrument and control products are offered in QCP:

- **INSTRUMENT**

  ABX Pentra 400 / Pentra C400 / Pentra C200

- **CONTROL PRODUCTS**

1. ABX Pentra N Control
2. ABX Pentra P Control
3. ABX Pentra Urine Control
4. ABX Pentra Immuno I Control
5. ABX Pentra Immuno II Control
6. ABX Pentra CK Control
7. ABX Pentra Low CRP Control
8. ABX Pentra Micro ALB control L/H
9. ABX Pentra Protein Control
10. ABX Pentra CO2 Control
11. CO2 Control (USA only)

II-5- CLINICAL CHEMISTRY PEER GROUPS

QCP uses 10 Clinical Chemistry peer groups for statistical reports:

		Clinical Chemistry Instrument
Clinical Chemistry Controls	Levels	ABX Pentra 400 / pentra C400 / pentra C 200
ABX Pentra N Control	None	**N/P Control**
ABX Pentra P Control	None	
ABX Pentra Urine Control	Low / High	**Urine Control**
ABX Pentra Immuno I Control	Low / High	**Immuno I Control**
ABX Pentra Immuno II Control	Low / High	**Immuno II Control**
ABX Pentra CK Control	None	**CK Control**
ABX Pentra Low CRP Control	None	**Low CRP Control**
ABX Pentra Micro-Albumin Control	Low / High	**Micro ALB Control**
ABX Pentra Protein Control	Low / High	**Protein Control**
ABX Pentra CO2 Control	None	**CO2 Control**
CO2 Control (USA only)	Level1 / Level2	**CO2 Control**

II-6- CLINICAL CHEMISTRY PARAMETERS

ABX Pentra N Control & ABX Pentra P Control Parameters - 1/2			
QCP Code	Methodology	Signification	Units
ALB	Bromocresol green	Albumin	µmol/L g/L g/dL
ALP	IFCC	Alkaline Phosphatase	U/L µkat/L
ALT	IFCC (UV without pyridoxal phosphate)	Alanine Aminotransferase	U/L µkat/L
AMY	EPS-G7	Amylase	U/L µkat/L
AST	IFCC (UV without pyridoxal phosphate)	Aspartate Aminotransferase	U/L µkat/L
BUN	GLDH (UV technique)	Blood Urea Nitrogen	mmol/L mg/dL
CA	OCP	Calcium	mmol/L mg/dL mEq/L (mval/L) g/L
CA-AS	Arsenazo	Calcium arsenazo	mmol/L mg/dL mEq/L (mval/L)
CREA-ENZ	Enzymatic creatinine	Enzymatic creatinine	µmol/L mg/L mg/dL mmol/L
CREA_RB	Jaffe/Alkaline Picrate	Creatinine jaffe rate blank	µmol/L mg/L mg/dL mmol/L
CREA3	Jaffe/Alkaline Picrate	Creatinine Jaffe	µmol/L mg/L mg/dL mmol/L
CHOL SRM909	Chol.Esterase/Oxidase	Cholesterol	mmol/L g/L mg/dL
CHOL AK	Chol.Esterase/Oxidase	Cholesterol Abell-Kendal	mmol/L g/L mg/dL
CK	IFCC/DGKC	Creatine Kinase	U/L µkat/L
Cl-E	Direct Potentiometry	Chloride	mmol/L mg/dL mEq/L (mval/L)
DBIL	DCA	Direct Bilirubin	µmol/L mg/L mg/dL
FE	Ferene	Iron	µmol/L mg/L µg/dL
GGT	SZASZ Carboxilated substrate	Gamma Glutamyltransferase	U/L µkat/L

ABX Pentra N Control & ABX Pentra P Control Parameters - 2/2			
QCP Code	Methodology	Signification	Units
GLUK	Hexokinase	Glucose Hexokinase	mmol/L g/L mg/dL
GLUP	Trinder	Glucose PAP	mmol/L g/L mg/dL
HDL	Polyanions/Detergent	HDL Cholesterol, Direct	mmol/L g/L mg/dL
K-E	Direct Potentiometry	Potassium	mmol/L mg/dL mEq/L (mval/L)
LACT	Lactate oxidase / Peroxidase	Lactic Acid	mmol/L mg/L mg/dL
LDH DGKC	DGKC	Lactate Dehydrogenase DGKC	U/L µkat/L
LDH IFCC	IFCC	Lactate Dehydrogenase IFCC	U/L µkat/L
LDL	Detergent/ Chol.Esterase/ Oxidase	LDL Cholesterol, Direct	mmol/L g/L mg/dL
LIP	Colorimetric	Lipase	U/L µkat/L
MG	Xylidyl Blue	Magnesium	mmol/L mg/dL mEq/L (mval/L) g/L
Na-E	Direct Potentiometry	Sodium	mmol/L mg/dL mEq/L (mval/L)
PHOS	Ammonium Molybdate UV	Phosphorus	mmol/L mg/L mg/dL g/L
TBIL	DCA	Total Bilirubin	µmol/L mg/L mg/dL
TP100	Biuret	Total Protein CP	g/L g/dL
TP300	Biuret	Total Protein CP	g/L g/dL
TRIG	PAP	Triglycerides	mmol/L g/L mg/dL
UA	Uricase/Peroxidase	Uric Acid	µmol/L mg/L mg/dL
UREA	GLDH (UV technique)	Urea	mmol/L g/L mg/dL

ABX Pentra Urine Control Parameters			
QCP Code	Methodology	Signification	Units
AMY	EPS-G7	Amylase	U/L µkat/L
CA-OCP	OCP	Calcium	mmol/L mg/dL mEq/L (mval/L) g/L
CREA-ENZ	Enzymatic creatinine	Creatinine enzymatic	µmol/L mg/L mg/dL mmol/L
GLUP	Trinder	Glucose PAP	mmol/L g/L mg/dL
PHOS	Ammonium Molybdate UV	Phosphorus	mmol/L mg/L mg/dL g/L
TPU	Pyrogalol red	Urinary Proteins	g/L mg/L mg/dL
UREA	GLDH (UV technique)	Urea	mmol/L g/L mg/dL
UA	Uricase/Peroxidase	Uric Acid	µmol/L mg/L mg/dL
CA-AS	Arsenazo	Calcium arsenazo	mmol/L mg/dL mEq/L (mval/L)
CHOL AK	Chol. Esterase/oxydase	Cholesterol Abell-Kendal	mmol/L g/L mg/dL

ABX Pentra Immuno I Control			
QCP Code	Methodology	Signification	Units
CRP 2	Latex TIA	C – Reactive Protein	mg/L mg/dL
RF	Latex TIA	Rheumatoid Factor	IU/mL
ASO	Latex TIA	Anti - Streptolysin O	IU/mL

ABX Pentra Immuno II Control			
QCP Code	Methodology	Signification	Units
MYO	Latex TIA	Myoglobin	ng/mL µg/L µg/dL
FERR	Latex TIA	Ferritin	ng/mL µg/dL

ABX Pentra CK Control			
QCP Code	Methodology	Signification	Units
CK	IFCC/DGKC	Creatinine Kinase NAC	U/L µkat/L
CK-MB	Immunology method	Creatinine Kinase MB	U/L µkat/L

ABX Pentra Low CRP Control			
QCP Code	Methodology	Signification	Units
CRP 2	Latex TIA	C – Reactive Protein	mg/L

ABX Pentra Micro – Albumin Control			
QCP Code	Methodology	Signification	Units
M ALB AlbT-U	TIA	Micro-Albumin	mg/L mg/dL

ABX Pentra Protein Control			
QCP Code	Methodology	Signification	Units
ALB 2	TIA	Albumin	g/L g/dL

ABX Pentra CO2 Control			
QCP Code	Methodology	Signification	Units
CO2	UV Enzymatic	Bicarbonate	mmol/L

CO2 Control (USA only)			
QCP Code	Methodology	Signification	Units
CO2-US	UV Enzymatic	Bicarbonate	mmol/L

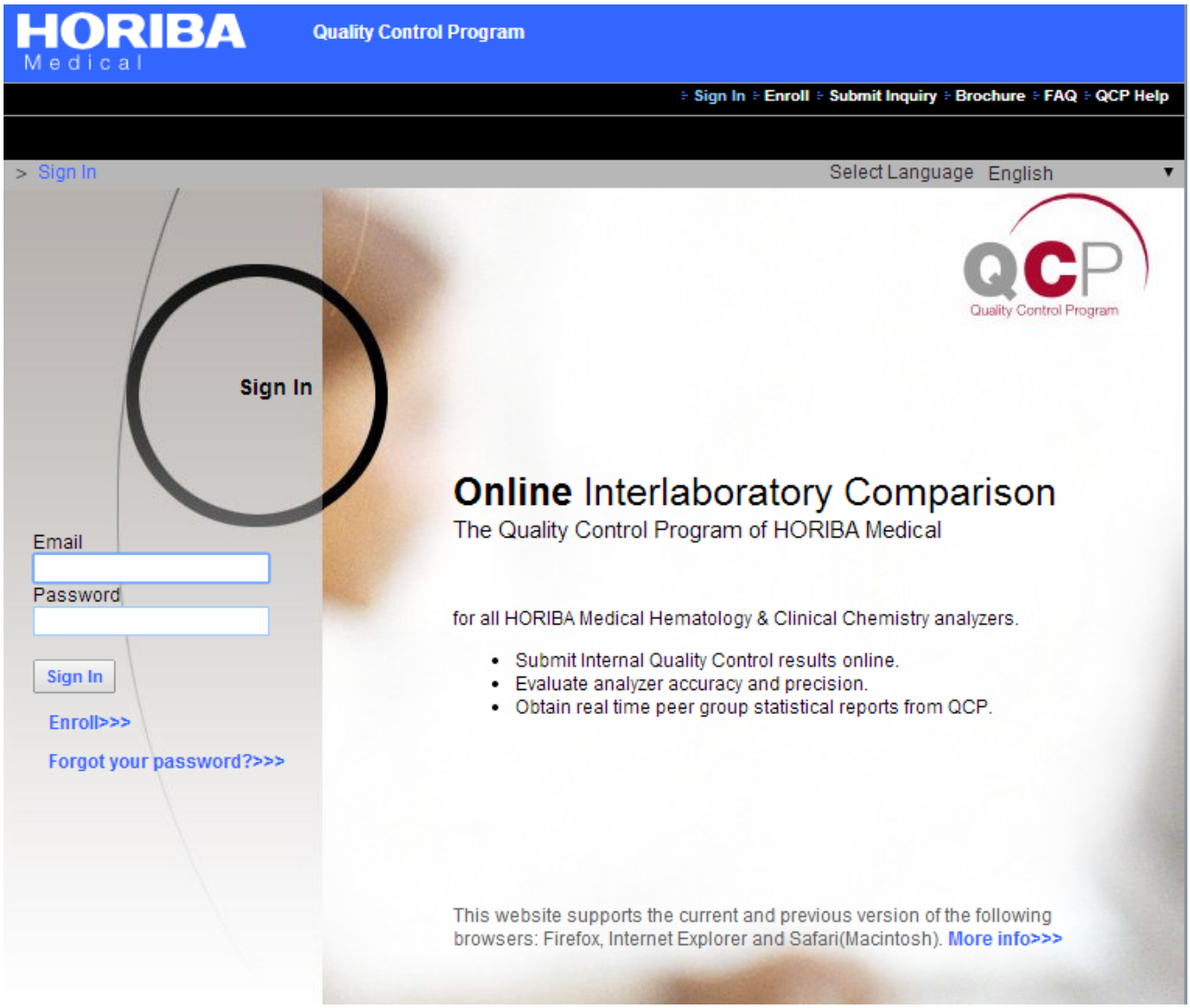
III- HOW TO USE QCP

III-1- WEBSITE ADDRESS

To use QCP go to the following internet address:

http://qcp.horiba-abx.com

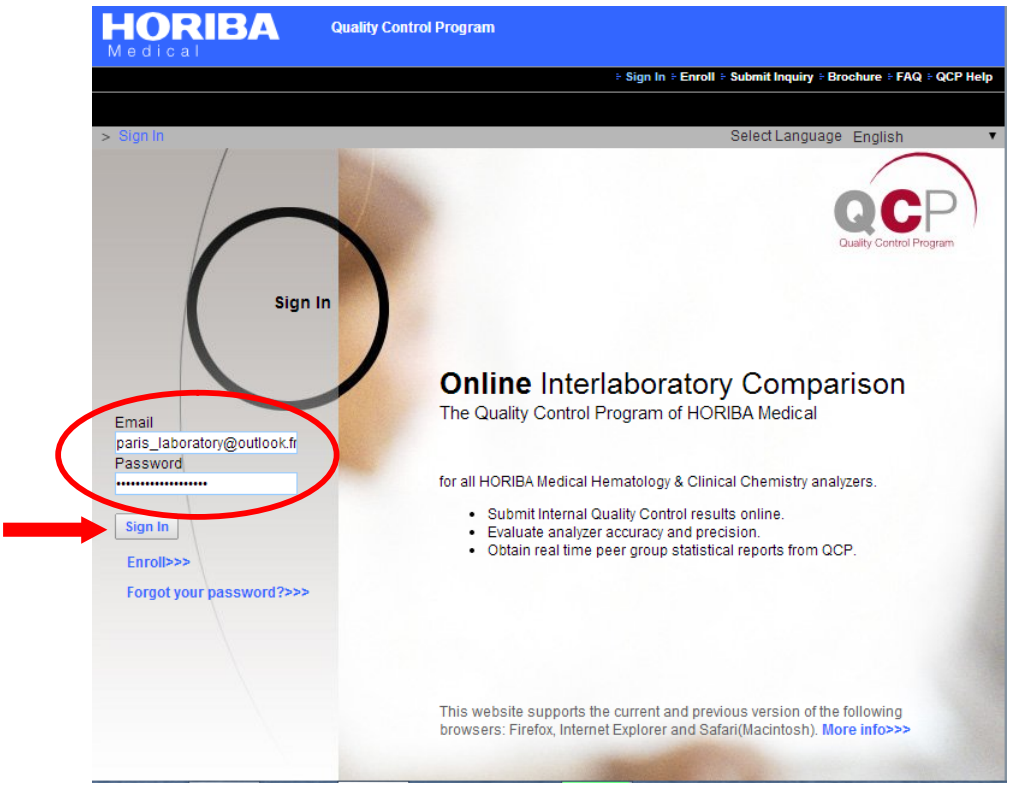
Contextual Help for each page is also available online by clicking QCP Help in the upper right of the page.



III-2- SIGN IN

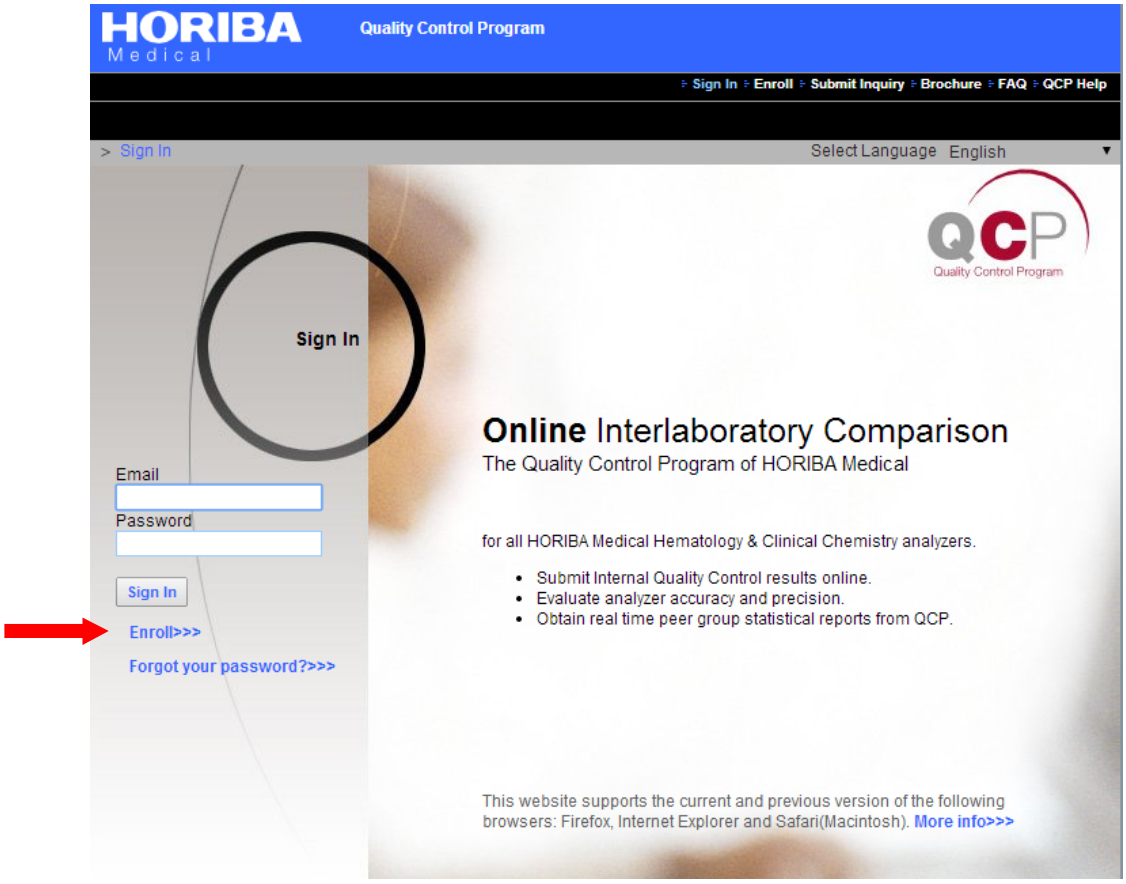
If you have already enrolled in QCP or have received an email saying you are enrolled, enter your email and password, and click SIGN IN or press ENTER.

You will be able to submit results for your registered instruments and view your statistical reports as soon as your instrument(s) have been activated by HORIBA Medical.



III-3- ENROLL

- First time QCP users will need to register an email address and password by clicking ENROLL.



IMPORTANT

According to your location, you may have been enrolled by your local HORIBA Medical Representative.
For more information, please contact your local HORIBA Medical Representative.

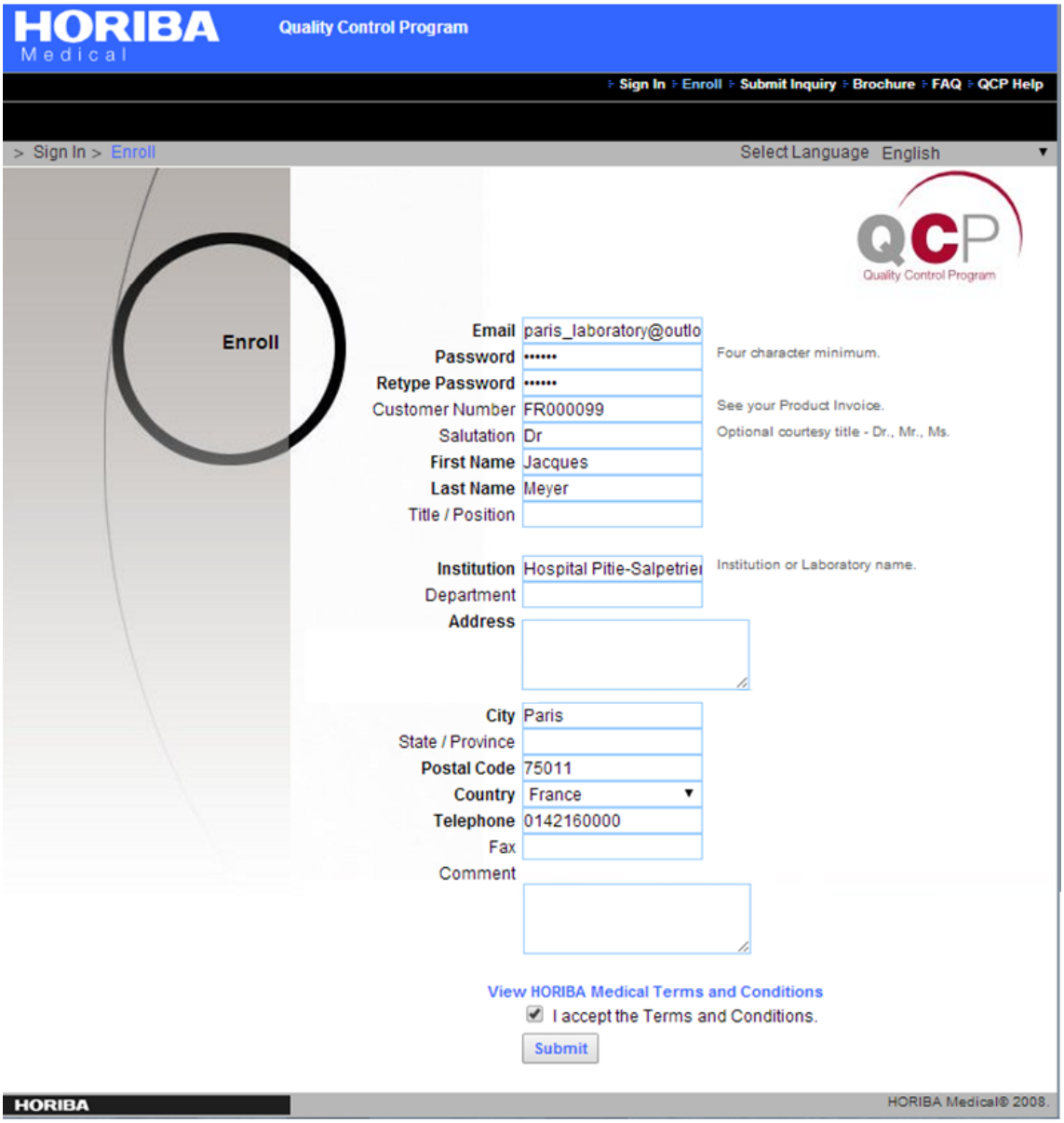
On the ENROLL page, complete the online form for your laboratory.

To move from one field to another you can use the TAB key.

The bold fields are required fields.

Click on View HORIBA Medical Terms and Conditions to read about the terms and conditions.

Before clicking SUBMIT, you will have to check: “I accept the Terms and Conditions”



IMPORTANT

According to your location, you may have been enrolled by your local HORIBA Medical Representative.
For more information, please contact your local HORIBA Medical Representative.

NOTE

- The person who registers the information in the ENROLL page, or, the person who has been enrolled by the local HORIBA Medical Representative will be identified by QCP as the MAIN USER *[see III-9 MAIN USER & USERS].* In this example, Dr Jacques Meyer is the MAIN USER.
- Registration information can be updated by the MAIN USER at any time on the USERS page.
- The MAIN USER may also setup any number of additional users and assign them instruments *[see III-9-2- Setup additional user(s) & Assign instrument(s)]*

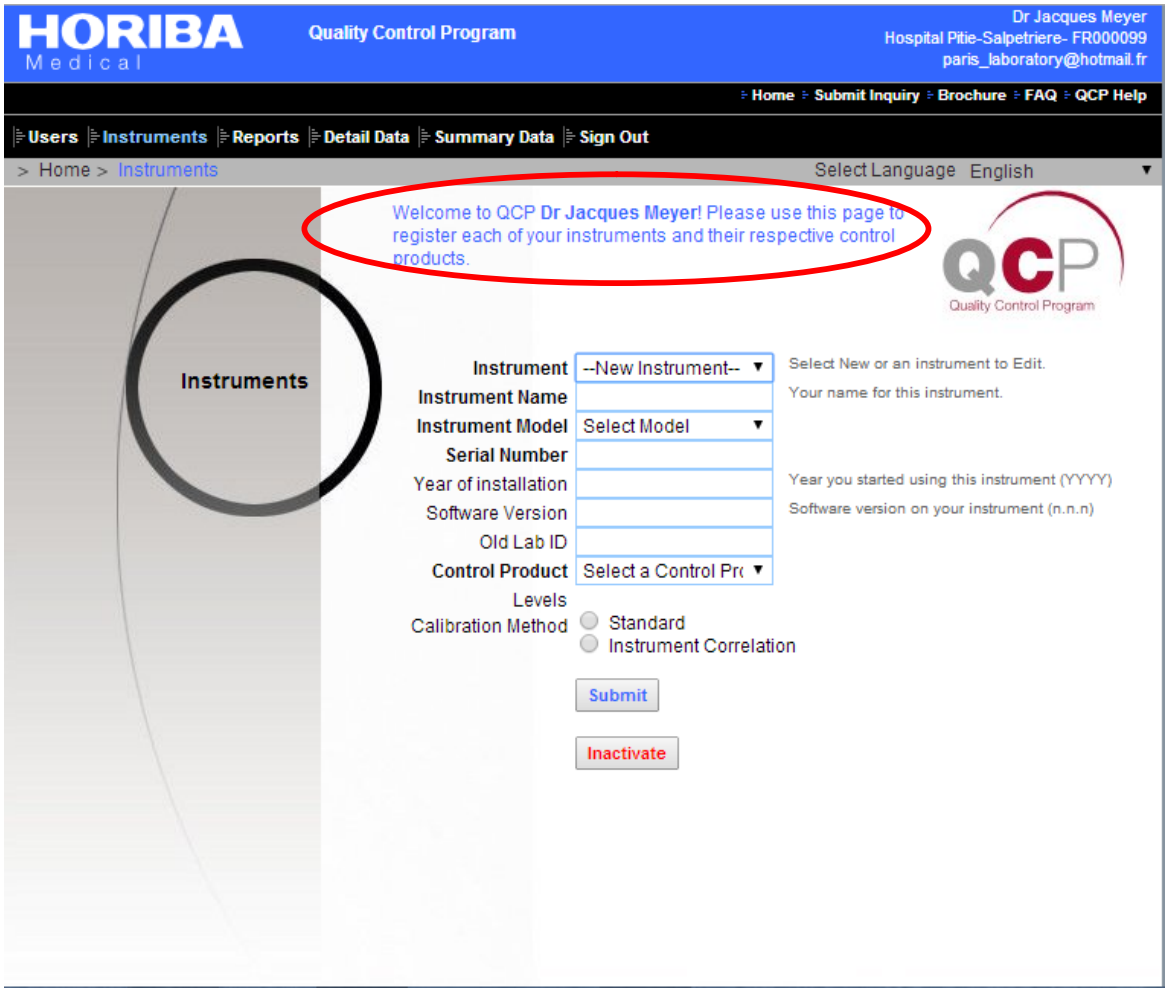
III-4- INSTRUMENTS

After you have clicked SUBMIT on the ENROLL page, a welcome message will be displayed at the top of the INSTRUMENTS page.

At the same moment, you will be sent by email your password to access QCP. You will be able to change this password in the USERS page after you have signed in QCP.

You will need to complete this page for each instrument & control product combination.

To move from one field to another you can use the TAB key



III-4-1- Registration of an instrument

One instrument can be registered with several control products.

Each instrument & control product combination will require a separate registration with a unique “Instrument Name” for each combination, such as the name “PDX120-Difftrol” for the combination ABX Pentra DX120 & ABX DIFFTROL.

You are free to choose the name you want for the field “Instrument Name”, but you will need a unique name for each combination of instrument & control product.

You will enter:

- Instrument Name
- Instrument Model
- Serial Number
- Control Product

IMPORTANT

The correct SERIAL NUMBER is mandatory for appropriate functioning of the QCP system. Please, make sure it is the exact serial number displayed at the back of the instrument.

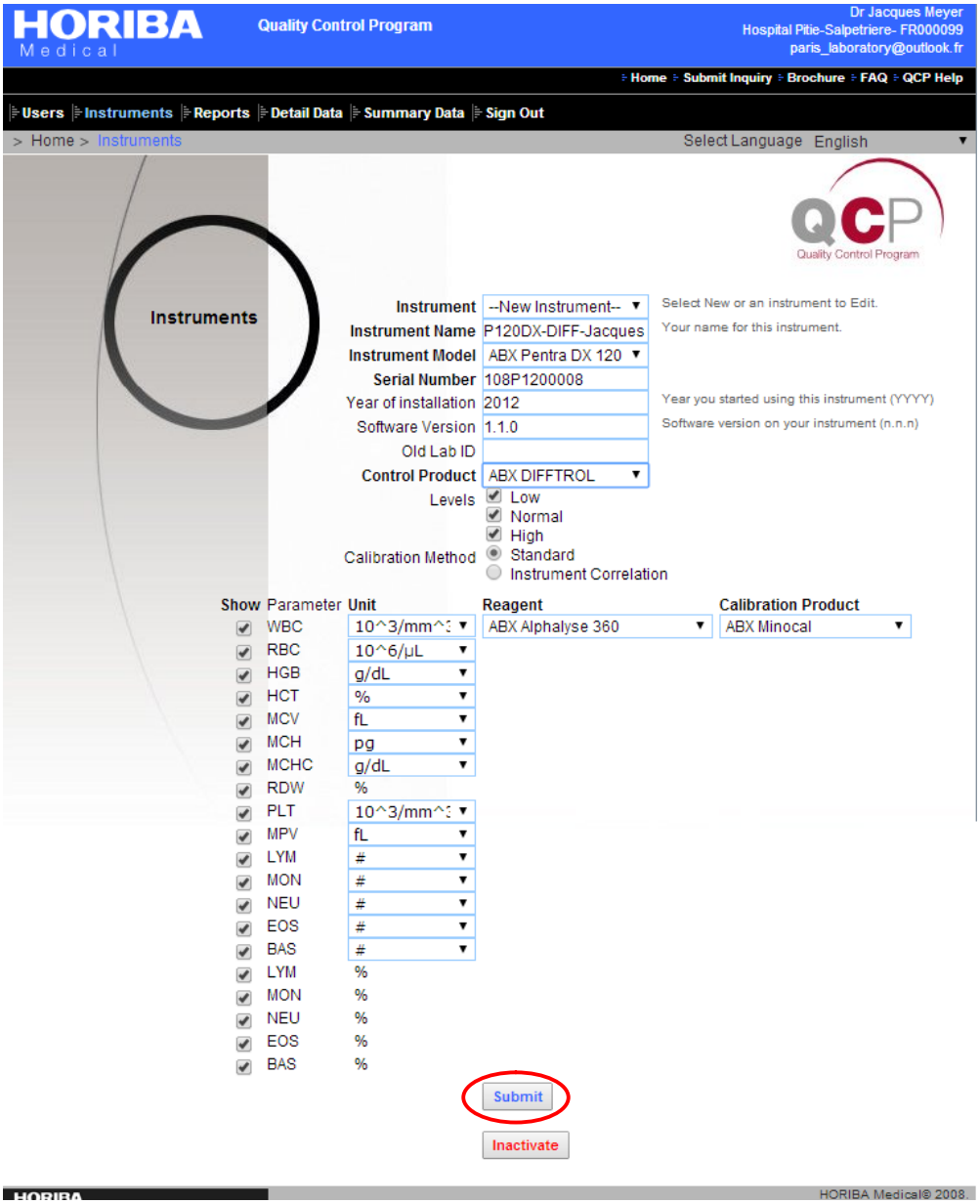
Once the Control Product is selected from the dropdown box, the corresponding Levels and Parameters will appear.

III-4-2- Levels and Parameters

After registering your instrument & control product combination, you will select the following elements:

- Levels to report
- Method of calibration (Standard or Instrument Correlation)
- A Unit for each Parameter (All the parameters are selected by default; you may hide one or several by deselecting the corresponding check button)
- Reagent
- Calibration product

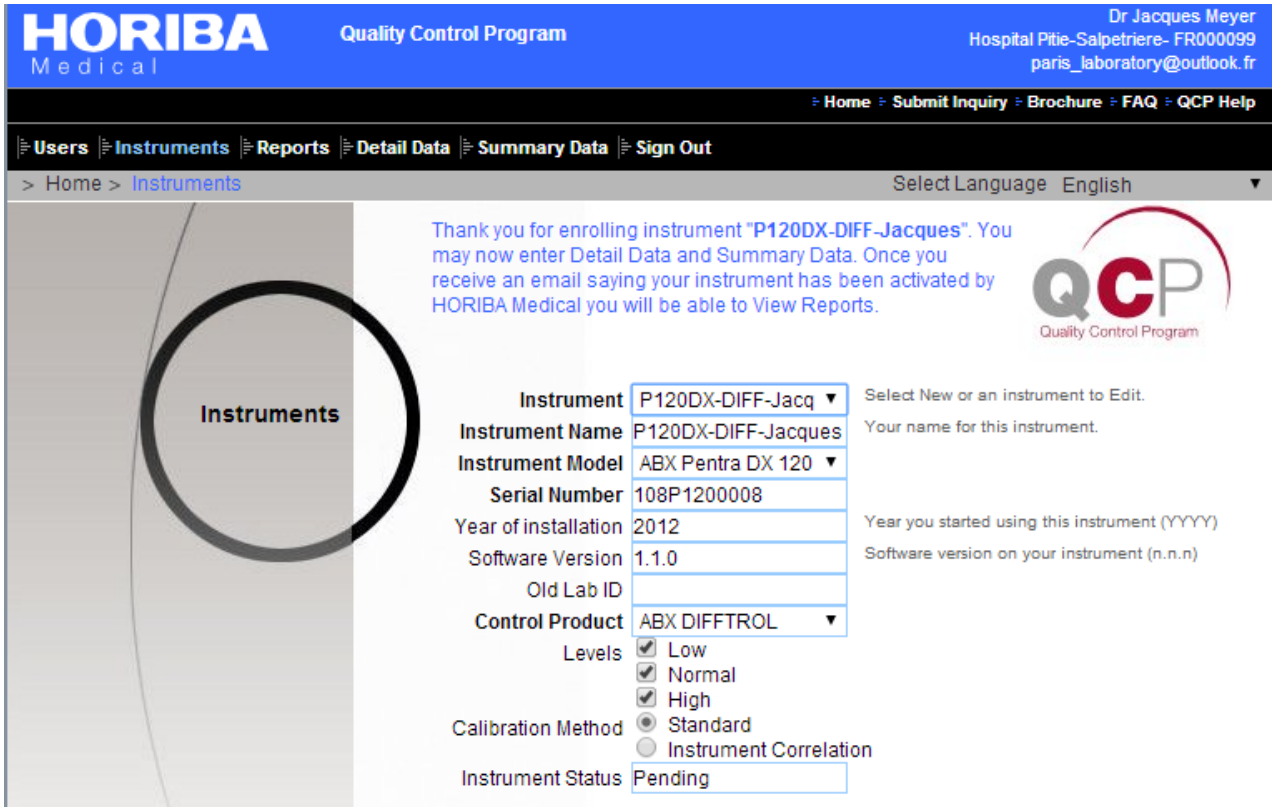
Click SUBMIT.



A message in blue will appear at the top of the page after you submit this information:

"You may now enter Detail Data and Summary Data. Once you receive an email saying your instrument has been activated by HORIBA Medical you will be able to View Reports"

At this point, you may submit QC results which will be stored in the QCP system, but without being included in the peer group. Once you receive an email saying your instrument has been activated by HORIBA Medical and the field on the INSTRUMENTS STATUS changes from "PENDING" to "ACTIVE", your data will be included in the peer group and you will have access to statistical reports.

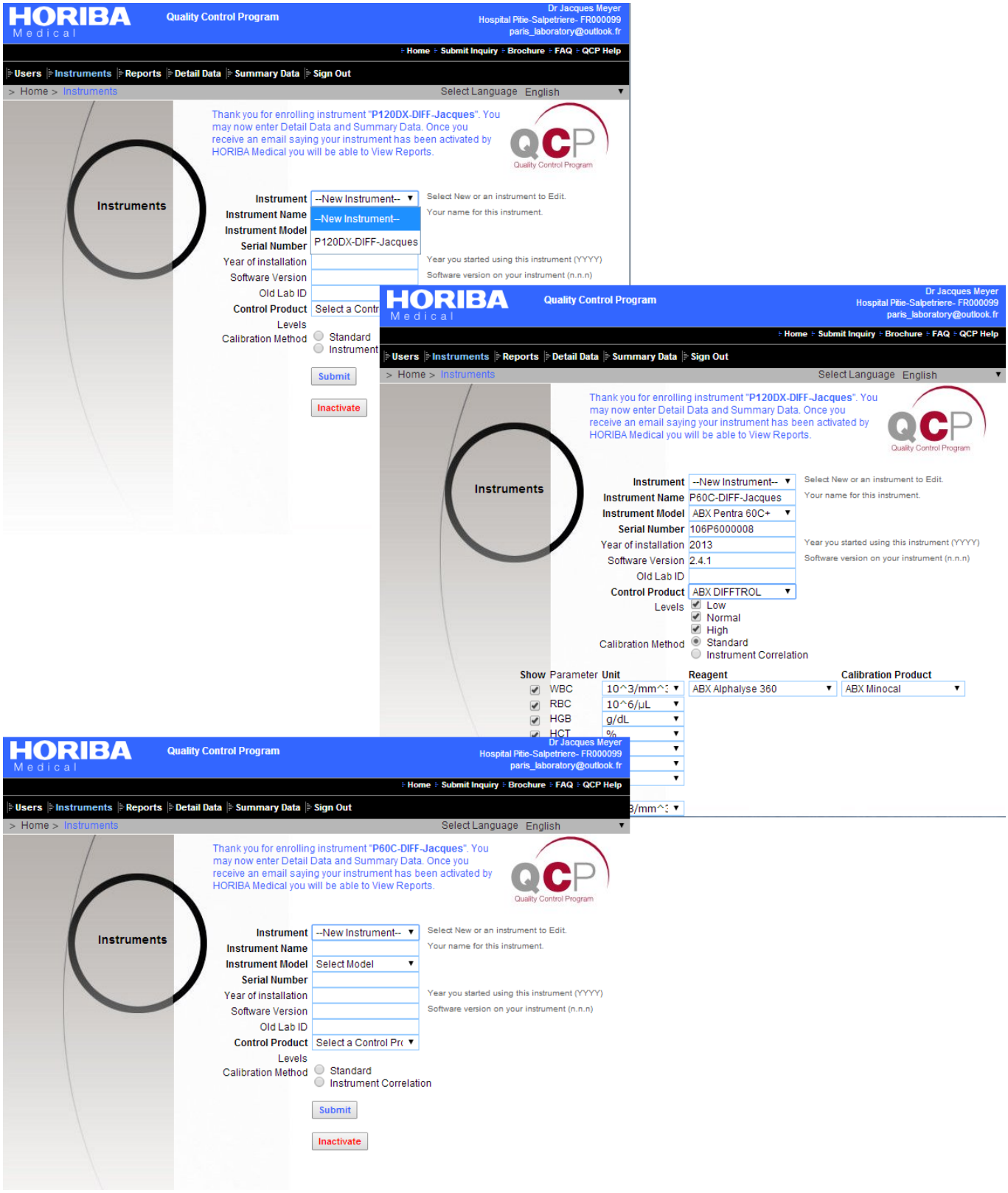


III-4-3- Registration of additional instrument(s)

To register each new instrument & control product combination, the above steps must be followed *[see III-4-1- Registration of an instrument, III-4-2- Levels and Parameters]*

You will be able to register as many combinations of instrument & control product as needed.

Already registered instruments will be displayed in the instrument dropdown box.



For each new combination instrument & control product that you add and submit, a message in blue will appear at the top of the page:

"You may now enter Detail Data and Summary Data. Once you receive an email saying your instrument has been activated by HORIBA Medical you will be able to View Reports"

At this point, you may submit QC results which will be stored in the QCP system, but without being included in the peer group. Once you receive an email saying your instrument has been activated by HORIBA Medical and the field on the INSTRUMENTS STATUS changes from "PENDING" to "ACTIVE", your data will be included in the peer group and you will have access to statistical reports.

III-4-4- Update the instrument information

A MAIN USER *[see III-9 MAIN USER & USERS]* may change all but the instrument model, the control product and the serial number for an instrument:

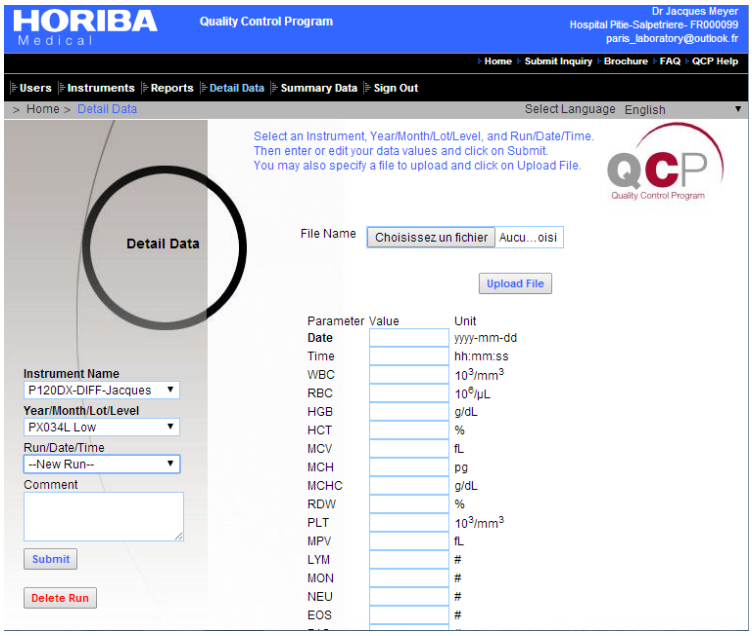
- Select the Instrument Name from the dropdown box
- Make the changes in the appropriate fields
- Click SUBMIT

III-5- SUBMIT RESULTS

There are 2 pages for submitting results:

1/ DETAIL DATA page

- ❒ Upload data from an external device.
- ❒ Manual input of daily results.



2/ SUMMARY DATA page

Manual input of summary results

NOTE
At the beginning of the month you will have the option to enter data on BOTH the SUMMARY and DETAIL pages.
Once you enter data on one of these two pages you will not be allowed to enter data for the same Month/Lot/Level on the other page.

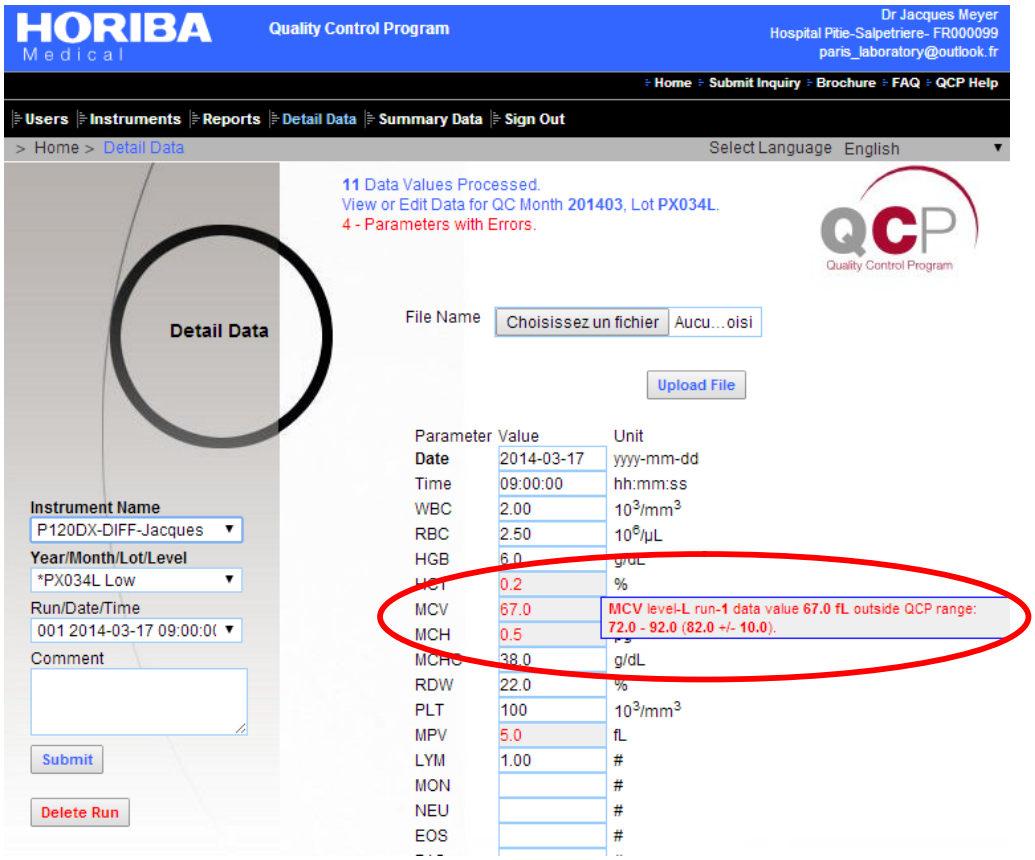
Example

1) If you enter data on the DETAIL DATA page for 2013/10 PX034 Low, then 2013/10 PX034 Low will not appear as an option on the SUMMARY DATA page for the same instrument.
2) 2013/10 PX034 Normal and 2013/10 PX034 Low High would appear as options on both the DETAIL DATA and SUMMARY DATA pages until data was entered by the customer for Normal or High.

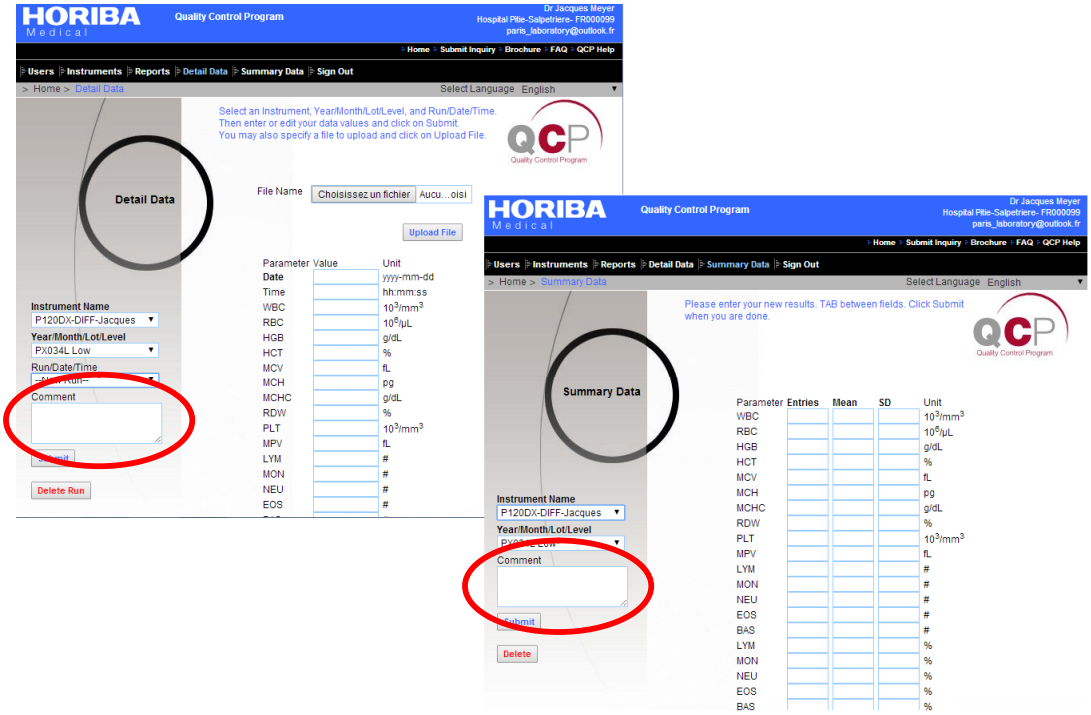
NOTES ABOUT SUBMITTING RESULTS

1/ Data entry errors or out of range values will appear in red.

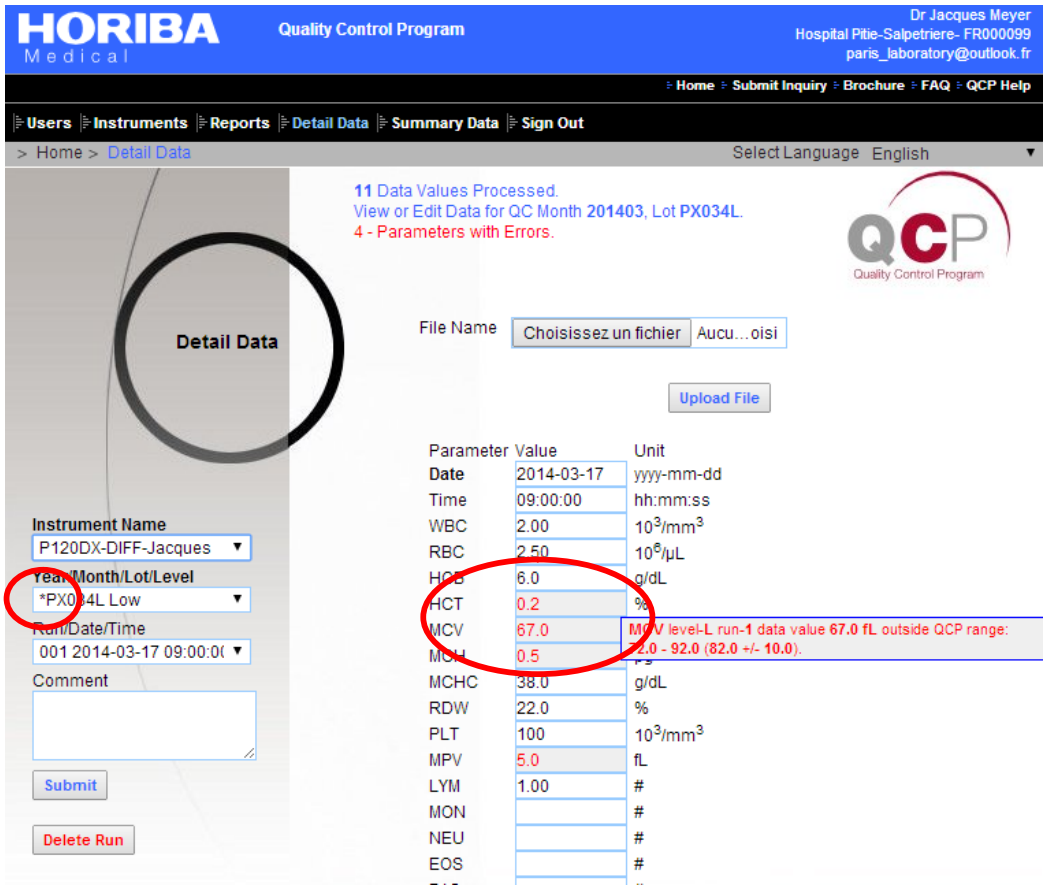
Pointing the cursor on a red value will display the target values and the ranges expected for the parameter that has a red value.



2/ Any comments you enter will reach HORIBA Medical and will be taken into account for the statistical processing of the results you submitted.



3/ "*" beside the "Lot/Level" means data has already been entered and stored as a run for this particular Year/Month/Lot/Level.



4/ You may enter data for a prior or current month.

You can choose to receive the current month's reports by email. You will need to view prior months' reports using the REPORTS page in QCP.

5/ QCP is able to process values with commas and decimal points.

III-5-1- DETAIL DATA page

III-5-1-A- Manual input of daily results

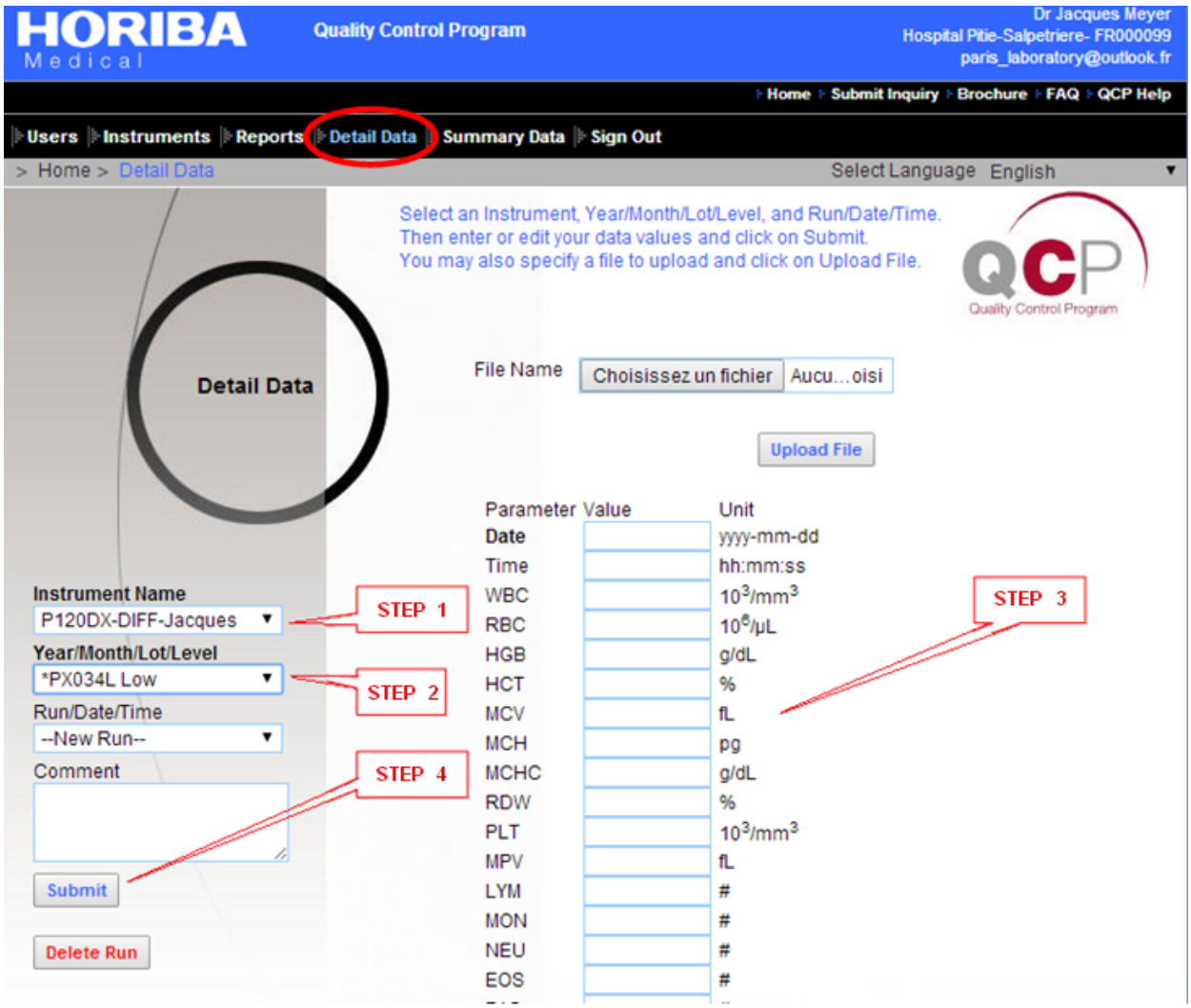
Click on DETAIL DATA and follow these steps to enter daily results for each parameter:

Step 1
Select Instrument Name

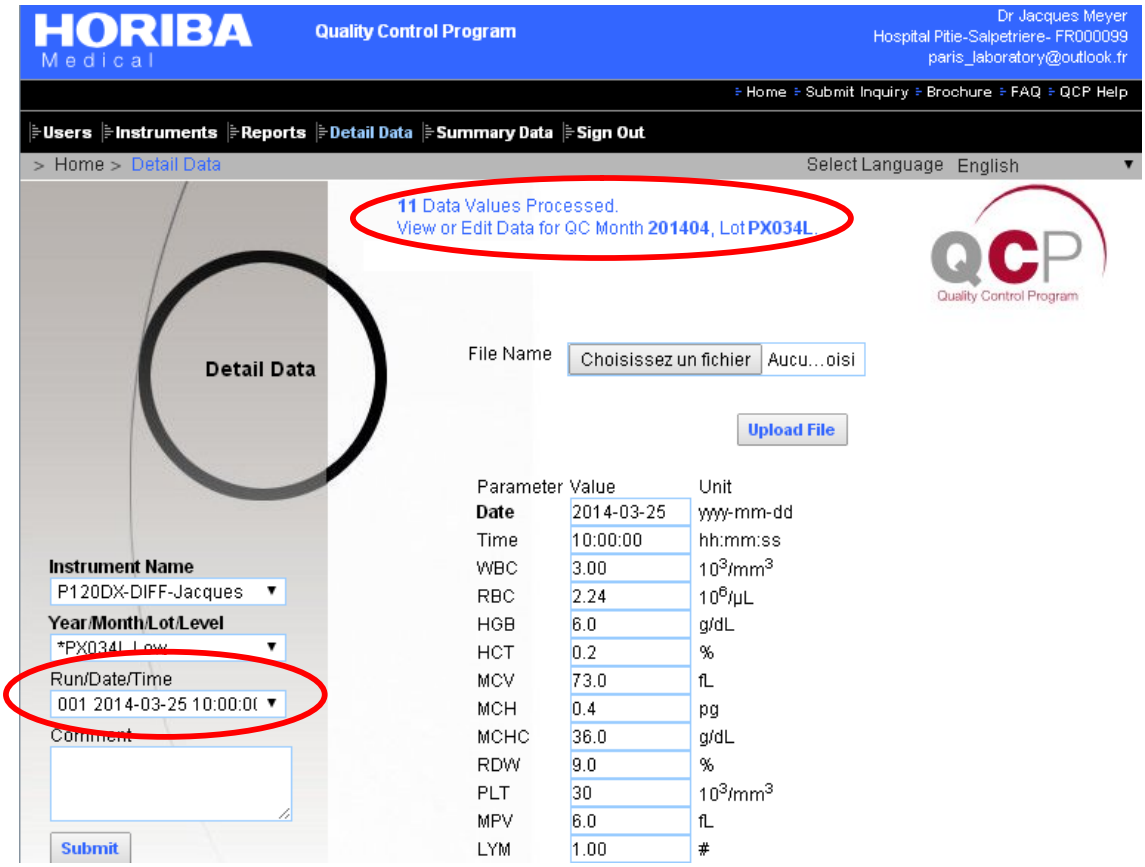
Step 2
Select the Year/Month/Lot/Level

Step 3
Enter date
Enter time (not required but this helps to identify multiple runs)
Enter your data (QC daily results for each parameter)
To move from one field to another you can use the TAB key.

Step 4
Click SUBMIT



Your submitted data will appear as a new run along with a message in blue at the top of the page.

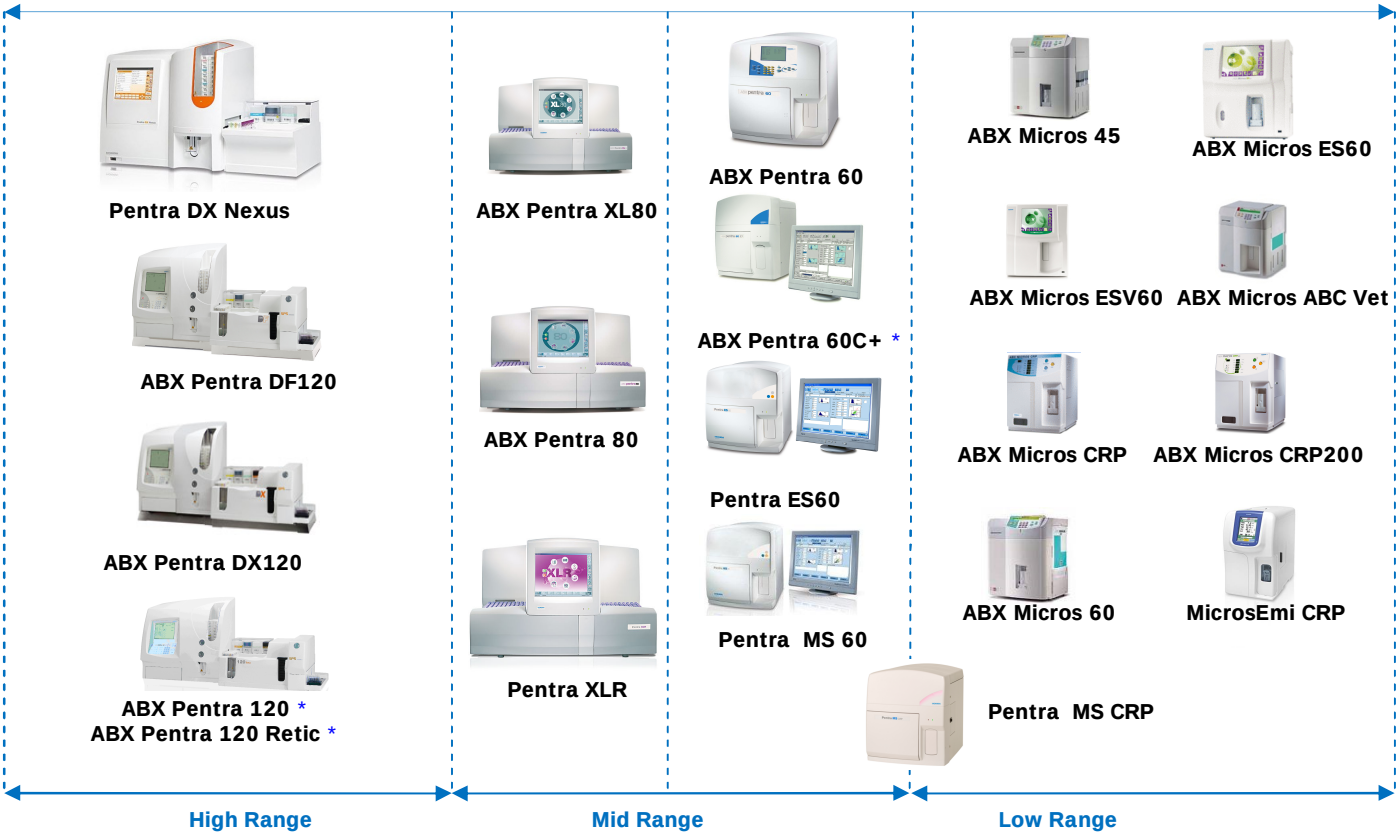


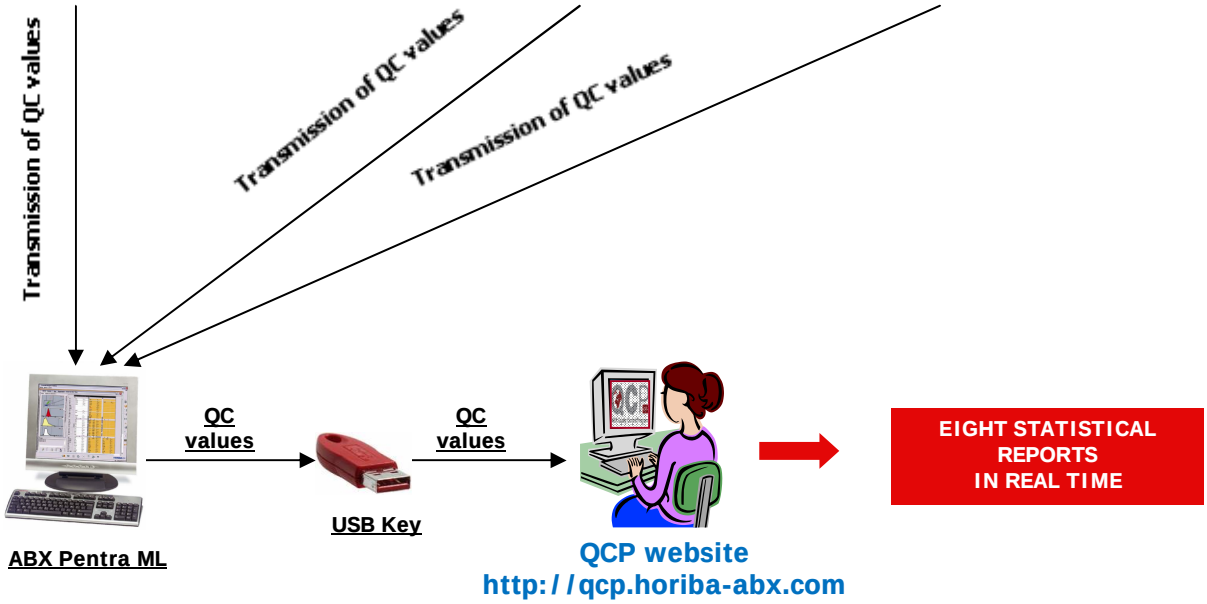
III-5-1-B- Upload data from an external device

III-5-1-B-a- External device plugged in the ABX Pentra ML

The hematology instruments may be connected to our external data management: ABX Pentra ML (Multi-Link).

This configuration allows the export of QC data of one instrument, one control lot and three levels with USB key which will allow the automatic upload of QC results into QCP (via the USB key) without any manual input.





*: If used without the ABX Pentra ML, these analyzers have the ability to export QC results to an external device for an upload into QCP: From version 2.4.1 for ABX Pentra 60C+ / From version 4.8.0 (JCMV2) for ABX Pentra 120 Retic and ABX Pentra 120 - *[see III-5-1-B-b- External device plugged directly in the instrument]*

Click on DETAIL DATA and follow these steps to upload daily results for each parameter:

Step 1
Select Instrument Name

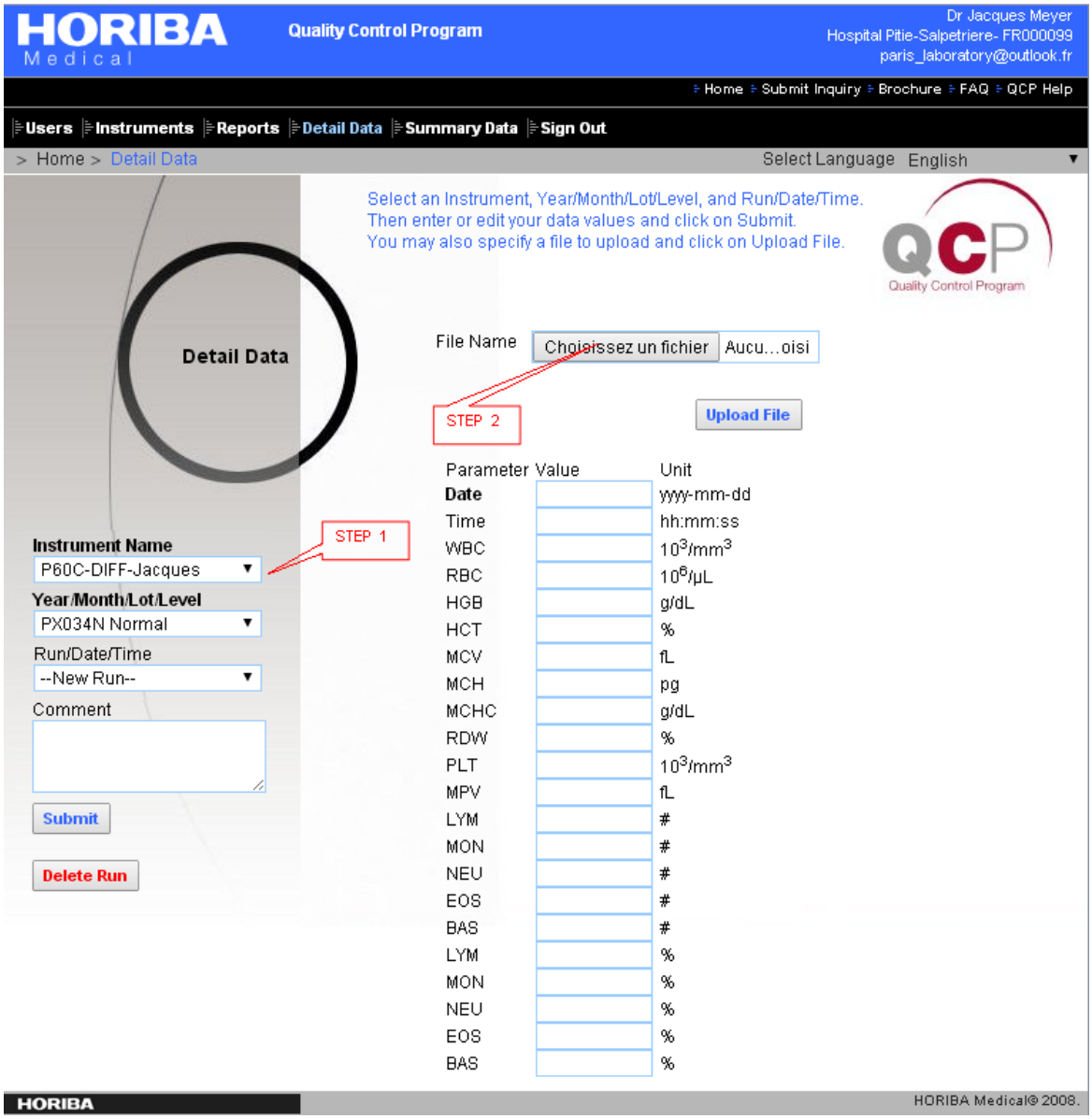
Step 2
Click the BROWSE button
Select the file that contains the results you want to submit for one control lot.

NOTE

The file shall contain data for a single QC Month. If the file contains data for more than one QC month, QCP will put the runs in the QC Month that contains the most number of runs. Thus, you should only export data that you want loaded into the current QC Month.

Example
If you start running the control when you receive it on June 28th and then continue to run it through July 31st (or even into the first few days of August) you will have more runs in July than either June or August. QCP will automatically know that ALL of this data should be loaded for the July QCP month. You should take care to NOT include this data again when you load your data for August (if you are still using the same lot).

Click UPLOAD FILE



Your submitted data will appear as a new run along with a message in blue at the top of the page.

IMPORTANT

Do not change the name of the files that have been exported from the instrument to an external device.

NOTES ABOUT UPLOADING DATA

1/ In case data is loaded at the very beginning or end of a lot's date range (period of lot validity / stability or shelf life), QCP will handle the dates following this rule:

- The [first valid QC Month] [1] will be used if the data is [prior to the first valid QC Month] [1'] for the lot being uploaded.
- The [last valid QC Month] [2] will be used if the data is [after the last valid QC Month] [2'] for the lot being uploaded.

Example
Control = ABX Difftrol
Lot = PX034
Validity = July and August

1 = [first valid QC Month] = *JULY*
1' = [prior to the first valid QC Month] = *JUNE*

2 = [last valid QC Month] = *AUGUST*
2' = [after the last valid QC Month] = *SEPTEMBER*

2/ If a parameter value is missing (blank) from a loaded run, QCP will not issue any sort of message. If all of the values in a run were missing (blank), QCP will issue a message such as: "There is 1 run with no values that was not loaded".

3/ If the runs have the same date, time and values, the duplicate run will be ignored by QCP.

4/ If the runs have the same date and time but different values, both runs will be entered in QCP and a message will alert you about the similar runs : *"There is 1 run with a date and time identical to another run with different values".* In this case you may want to remove one of the runs if they are duplicates

5/ If the external device contains 10 runs of different days (day 1, day 2, day 3, day 4, day 5, day 6, day 7, day 8, day 9, day 10), QCP uploads the 10 runs from the 10 days all at once (one upload). After the upload of the 10 runs, the run from day 1 will appear along with any messages from the upload. You will need to select another run from the Run dropdown box to see the additional runs.

Later if this external device is uploaded again with QCP data for additional days, QCP will only add the new runs because of rule number 3 above. This allows you to easily upload your data weekly or even daily if you wish.

III-5-1-B-b- External device plugged directly in the instrument

The following instruments have the ability to export QC results to an external device which will allow the automatic upload of QC results into QCP (via the external device) without any manual input.

- ABX Pentra 60C+ - version 2.4.1
- ABX Pentra 60
- Pentra ES60

- ABX Pentra 120 Retic – version 4.8.0
- ABX Pentra 120 – version 4.8.0
- Pentra DX Nexus
- Pentra DF Nexus
- ABX Pentra DX120
- ABX Pentra DF120

* Condition: JCMV2, since P120 n°1282, Oct 2003.

Click on DETAIL DATA and follow these steps to upload daily results for each parameter:

Step 1
Select Instrument Name

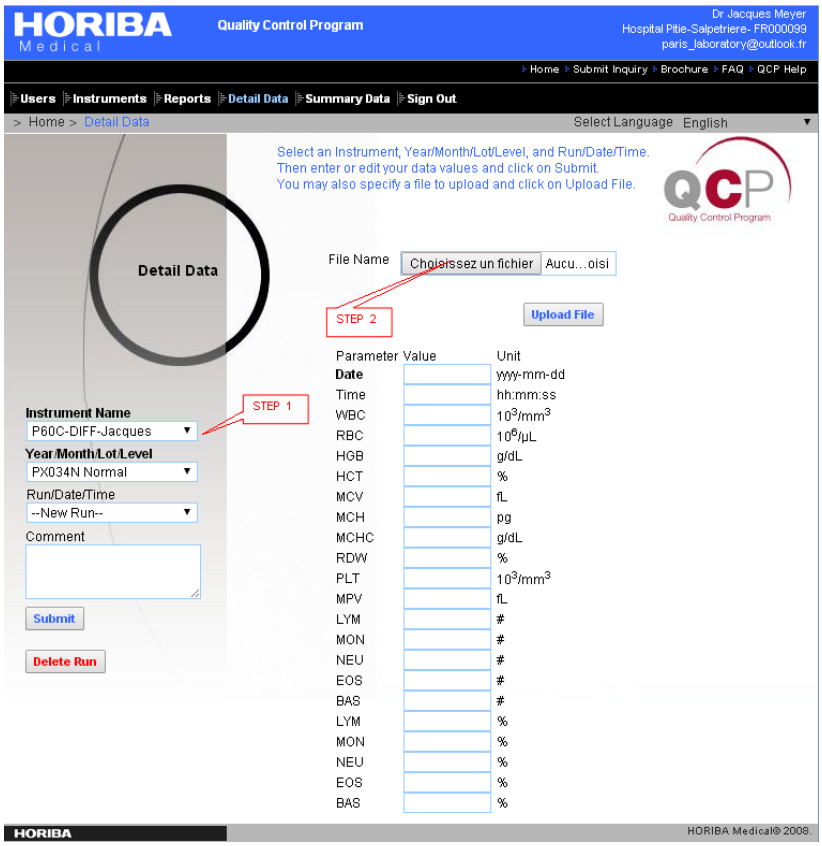
Step 2
Click the BROWSE button
Select the file that contains the results you want to submit for one control lot.

NOTE

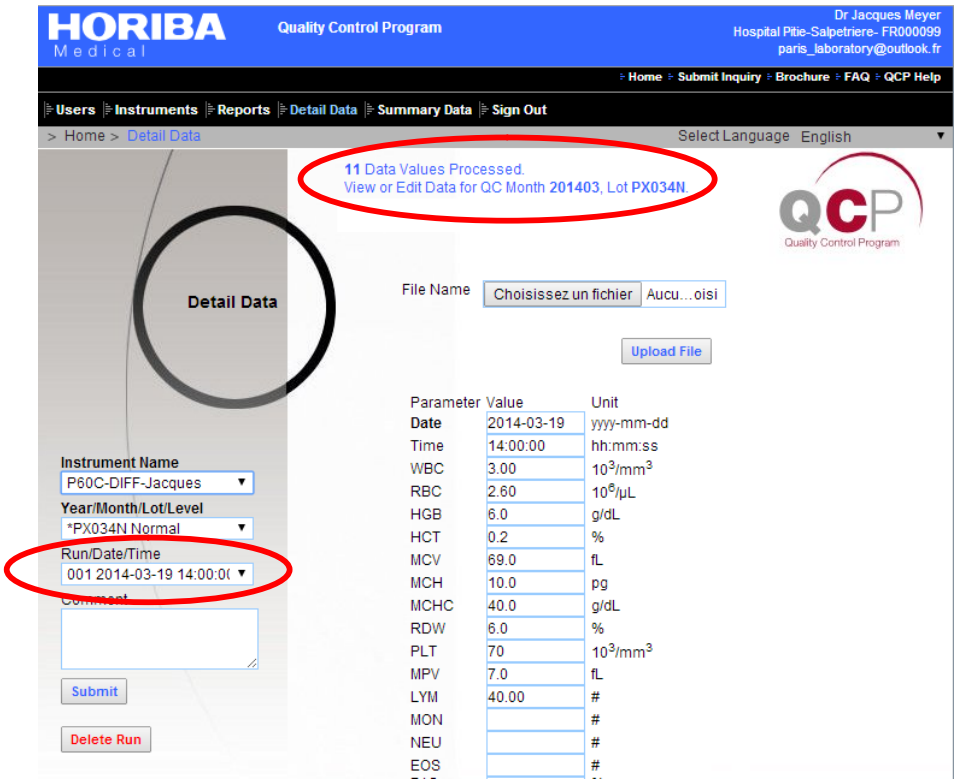
The file shall contain data for a single QC Month. If the file contains data for more than one QC month, QCP will put the runs in the QC Month that contains the most number of runs. Thus, you should only export data that you want loaded into the current QC Month.

Example
If you start running the control when you receive it on June 28th and then continue to run it through July 31st (or even into the first few days of August) you will have more runs in July than either June or August. QCP will automatically know that ALL of this data should be loaded for the July QCP month. You should take care to NOT include this data again when you load your data for August (if you are still using the same lot).

Click UPLOAD FILE



Your submitted data will appear as a new run along with a message in blue at the top of the page.



IMPORTANT

Do not change the name of the files that have been exported from the instrument to an external device.

NOTES ABOUT UPLOADING DATA

1/ In case data is loaded at the very beginning or end of a lot's date range (period of lot validity / stability or shelf life), QCP will handle the dates following this rule:

- The [first valid QC Month] [1] will be used if the data is [prior to the first valid QC Month] [1'] for the lot being uploaded.
- The [last valid QC Month] [2] will be used if the data is [after the last valid QC Month] [2'] for the lot being uploaded.

Example
Control = ABX Difftrol
Lot = PX034
Validity = July and August

1 = [first valid QC Month] = *JULY*
1' = [prior to the first valid QC Month] = *JUNE*
2 = [last valid QC Month] = *AUGUST*
2' = [after the last valid QC Month] = *SEPTEMBER*

2/ If a parameter value is missing (blank) from a loaded run, QCP will not issue any sort of message. If all of the values in a run were missing (blank), QCP will issue a message such as: "There is 1 run with no values that was not loaded".

3/ If the runs have the same date, time and values, the duplicate run will be ignored by QCP.

4/ If the runs have the same date and time but different values, both runs will be entered in QCP and a message will alert you about the similar runs : *"There is 1 run with a date and time identical to another run with different values".* In this case you may want to remove one of the runs if they are duplicates

5/ If the external device contains 10 runs of different days (day 1, day 2, day 3, day 4, day 5, day 6, day 7, day 8, day 9, day 10), QCP uploads the 10 runs from the 10 days all at once (one upload). After the upload of the 10 runs, the run from day 1 will appear along with any messages from the upload. You will need to select another run from the Run dropdown box to see the additional runs.

Later if this external device is uploaded again with QCP data for additional days, QCP will only add the new runs because of rule number 3 above. This allows you to easily upload your data weekly or even daily if you wish.

III-5-2- SUMMARY DATA page

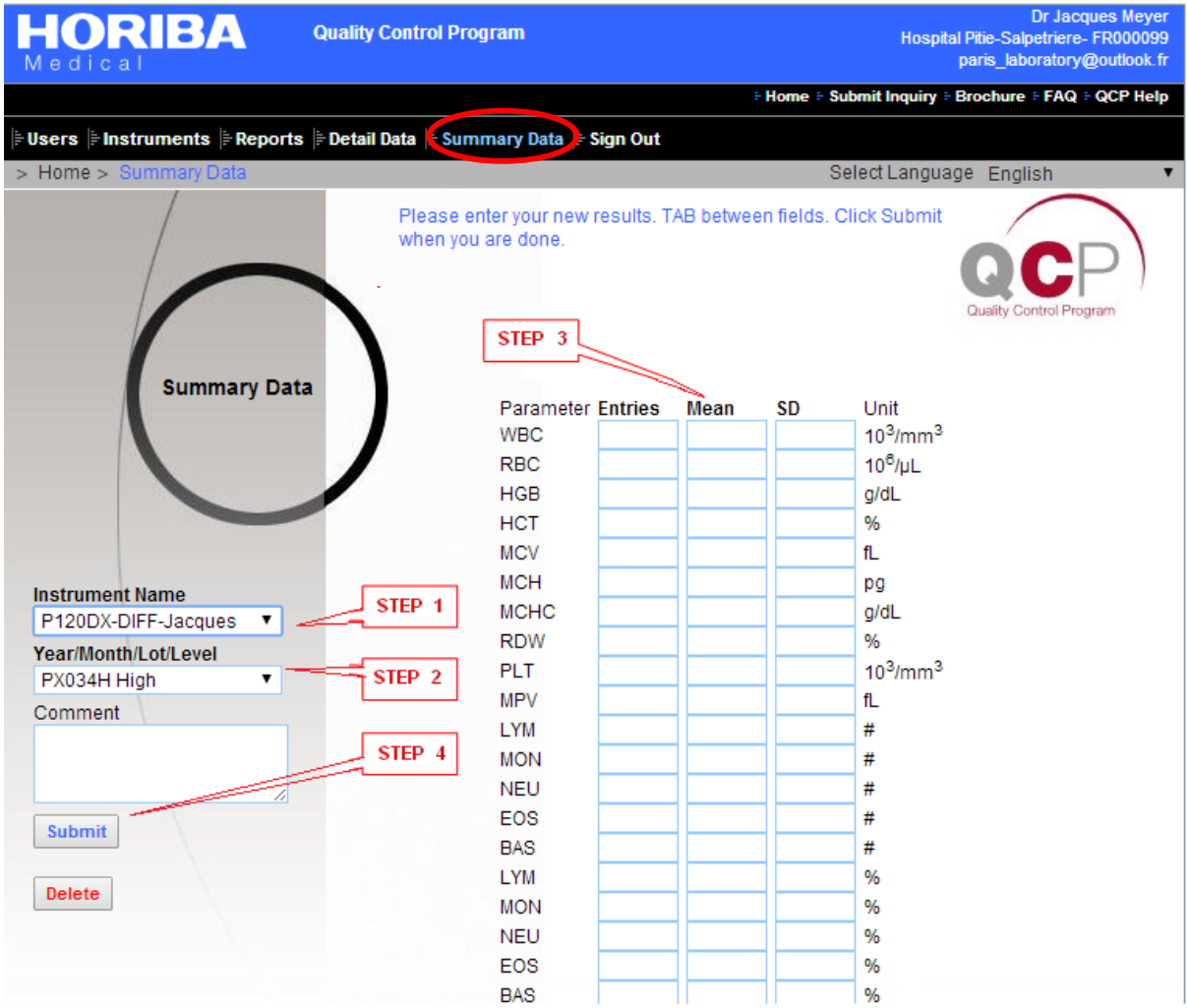
After you have printed out your final QC results from the instrument for that month, click on SUMMARY DATA and follow these steps to enter summary results for each parameter:

Step 1
Select Instrument Name

Step 2
Select the Year/Month/Lot/Level

Step 3
Enter Number of results, Mean, and SD for each parameter.
To move from one field to another you can use the TAB key.

Step 4
Click SUBMIT



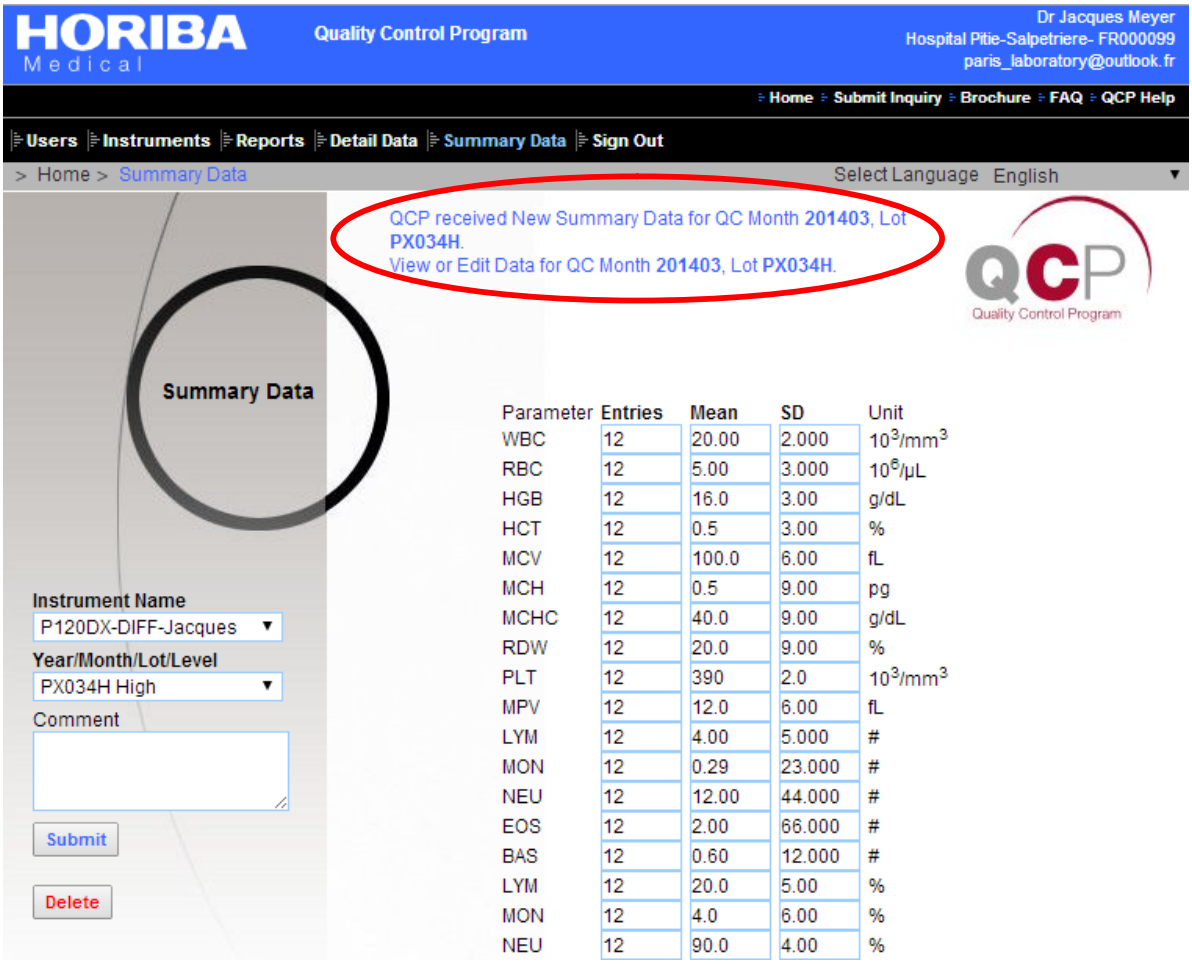
NOTE

You may enter your summary data throughout the month

Just edit any previously entered results and type over (replace) the previously entered results.

This would allow for peer group comparisons during the month

Your submitted data will appear with a message in blue at the top of the page.



III-6- EDITING/MODIFYING/DELETING SUBMITTED RESULTS

The submitted results are saved online for a 24 month period.

Follow these steps to edit/modify/delete the submitted daily/summary results:

Step 1
Click on DETAIL DATA page / SUMMARY DATA page

Step 2
Select Instrument Name

Step 3
Select the Year/Month/Lot/Level

Step 4
Select the Run/date/time (only for DETAIL DATA page)

Step 5
Click SUBMIT.
The results will be displayed.

Step 6
Select the result next to the parameter you want to modify/delete

Step 7
To delete: Press the delete key on your keyboard to remove the result
To modify: Type the value you want in the place of the selected result

Step 8
Click SUBMIT to record your change

- You will instantly see a blue message at the top of the page informing you that QCP has updated your data.
- The statistical reports will automatically include your changes.

NOTE

From the DETAIL DATA page:

- It is possible to delete an ENTIRE RUN, by selecting the "Run/date/time" and clicking DELETE RUN.

From the SUMMARY DATA page:

- It is possible to delete QC data of month / lot / level, by selecting the "Year/Month/Lot/Level" and clicking DELETE.

III-7- STATISTICAL REPORTS

Statistical Reports are available to view online anytime after data is submitted to QCP. Final Statistical Reports for a Month/Lot/Level will be available for viewing about the 15th of the month following the month the data is collected.

III-7-1- Obtain the Statistical Reports

To obtain the statistical reports click on REPORTS. Once in the REPORTS page, follow the steps below:

Step 1
Select Instrument Name

Step 2
Select Year/Month/Lot

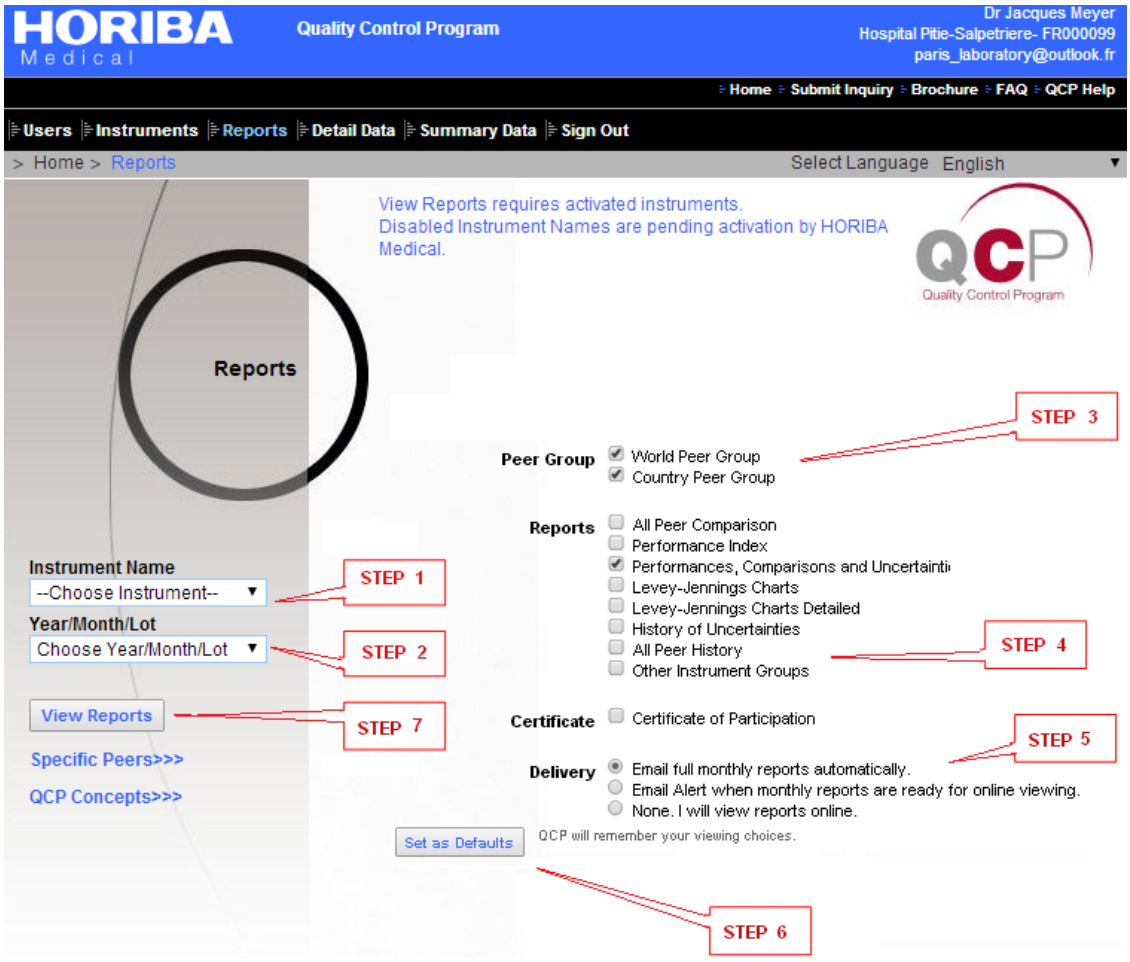
Step 3
Select World, Country, and /or Specific Peer Group(s) if created *[see III-8 SPECIFIC PEER GROUPS]*

Step 4
Select the reports you want (All Peer Comparison, Performance Index, Levey-Jennings Charts, Levey-Jennings Charts Detailed, All Peer History, Other Instrument Groups)

Step 5
Select a Delivery method for your FINAL MONTHLY REPORTS.

Step 6
Click SET AS DEFAULTS to have QCP remember your choices the next time you visit the REPORTS page.
Next visit, you will only have to do Step 1 - Step 2 - Step 7.

Step 7
Click VIEW REPORTS



NOTE

1/ For Levey-Jennings Charts and Levey-Jennings Charts Detailed any peer group selections are ignored *[see III-7-2-3- Levey-Jennings Charts, III-7-2-4- Levey-Jennings Charts Detailed]*

2/ All months with target data for the user's instrument and control product in QCP are listed in the QC Month dropdown on the REPORTS page. This allows users to view reports with their own data as well as reports with their peer data.

III-7-2- Description of the Statistical Reports

By submitting your Internal Quality Control results on the QCP website, it will be possible to obtain real time statistical reports which compare your results with those of your peer group.

QCP offers the following statistical reports:

1. All Peer Comparison
2. Performance index
3. Performances, Comparisons and uncertainties
4. Levey-Jennings Charts
5. Levey-Jennings Charts Detailed
6. History of uncertainties
7. All Peer History
8. Other Instrument Groups

III-7-2-1- All Peer Comparison

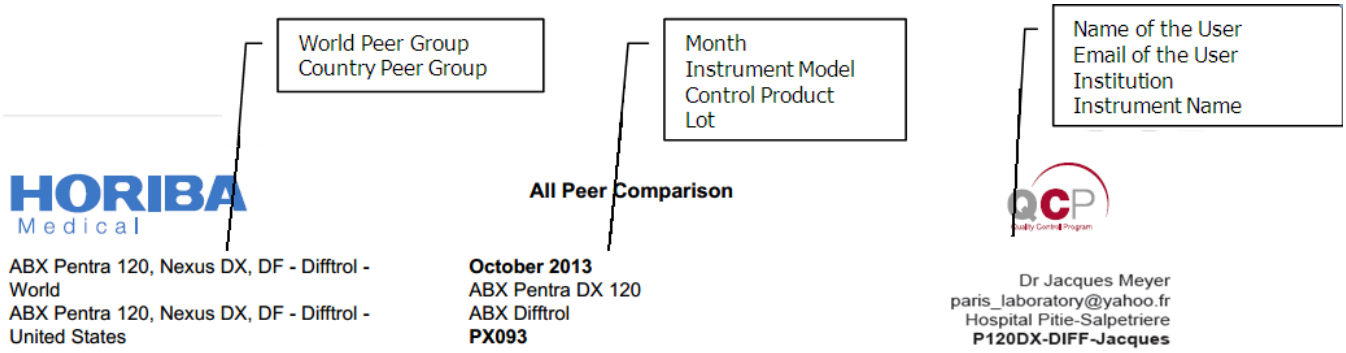
This report enables you to compare your Lab results to World, Country and Specific Peer Groups using the same control product, lot and level on similar instruments. Each parameter, in each level of the control product, is shown with the following data for your Lab and the World, Country and Specific Peer Groups.

- Number of results reporting by lab
- Instruments Reporting (number of reporting Peers)
- Mean
- SD
- 2SD
- CV
- SDI (Relative Accuracy) = (Your Mean – Group Mean) / Group SD
- PI (Relative Precision) = Your CV / Group CV

Each point could be divided in three levels:
- **Lab** : user value.
- **United states** : country level value.
- **World** : value from which the comparison should be made (lab/world).

In addition to these user data, there is another value:
- **Target** : assay value (best theoretical value).

Any errors will be noted near the bottom of the report.
Investigate rejected data, and data beyond the +/- 2 SD, to determine any cause for the unexpected results.



		WBC $10^3/mm^3$			RBC $10^6/mm^3$			HGB g/dL			HCT %		
	Level	L	N	H	L	N	H	L	N	H	L	N	H
Number of Results		**26**	**55**	**31**	**26**	**55**	**31**	**26**	**55**	**31**	**26**	**55**	**31**
Instruments	United States	5	5	5	5	5	5	5	5	5	5	5	5
	World	128	137	126	128	137	126	128	137	126	128	137	126
MEAN	**Target**	**2.30**	**7.50**	**17.70**	**2.42**	**4.63**	**5.20**	**6.8**	**13.4**	**16.1**	**19.6**	**38.4**	**46.3**
	Lab	**2.28**	**7.34**	**17.42**	**2.38**	**4.58**	**5.14**	**6.7**	**13.4**	**16.0**	**19.7**	**38.0**	**45.6**
	United States	2.35	7.49	17.91	2.39	4.60	5.14	6.8	13.4	16.1	19.7	38.1	45.5
	World	2.33	7.58	17.95	2.40	4.62	5.18	6.7	13.5	16.2	19.9	38.4	45.9
SD	**Lab**	**0.059**	**0.232**	**0.467**	**0.031**	**0.046**	**0.050**	**0.10**	**0.10**	**0.13**	**0.26**	**0.48**	**0.55**
	United States	0.099	0.242	0.492	0.035	0.052	0.057	0.11	0.15	0.21	0.32	0.47	0.53
	World	0.097	0.255	0.606	0.039	0.064	0.075	0.12	0.20	0.23	0.41	0.67	0.81
2SD	**Lab**	**0.117**	**0.464**	**0.934**	**0.062**	**0.091**	**0.099**	**0.19**	**0.21**	**0.27**	**0.52**	**0.97**	**1.09**
	United States	0.197	0.484	0.984	0.070	0.105	0.114	0.21	0.30	0.42	0.65	0.93	1.07
	World	0.194	0.510	1.211	0.078	0.129	0.150	0.24	0.40	0.45	0.82	1.34	1.62
SDI	United States	-0.73	-0.63	-1.00	-0.27	-0.38	-0.13	-0.61	-0.34	-0.55	-0.13	-0.25	0.11
	World	-0.57	-0.94	-0.89	-0.64	-0.72	-0.66	-0.41	-0.56	-0.82	-0.50	-0.62	-0.44
CV	**Lab**	**2.6**	**3.2**	**2.7**	**1.3**	**1.0**	**1.0**	**1.4**	**0.8**	**0.8**	**1.3**	**1.3**	**1.2**
	United States	4.2	3.2	2.7	1.5	1.1	1.1	1.6	1.1	1.3	1.6	1.2	1.2
	World	4.2	3.4	3.4	1.6	1.4	1.4	1.8	1.5	1.4	2.1	1.7	1.8
PI	United States	0.61	0.98	0.98	0.89	0.88	0.87	0.91	0.68	0.63	0.80	1.04	1.03
	World	0.62	0.94	0.80	0.81	0.72	0.67	0.81	0.52	0.59	0.64	0.73	0.68

III-7-2-2- All Peer History

This report enables you to compare your lab results to World, Country and Specific Peer Groups using the same control product, lot and level on similar instruments, for the last 12 months.

Each parameter, in each level of the control product is shown with the following data for your Lab, Specific, Country and World Peer Groups, for the last 12 months.

- Instruments Reporting (number of reporting Peers)
- Mean
- SD
- 2SD
- CV
- SDI (Relative Accuracy) = (Your Mean – Group Mean) / Group SD
- PI (Relative Precision) = Your CV / Group CV

HORIBA Medical

All Peer History

QCP Quality Control Program

ABX Pentra 120, Nexus DX, DF - Difftrol - World
ABX Pentra 120, Nexus DX, DF - Difftrol - United States

November 2012 - October 2013
ABX Pentra DX 120
ABX Difftrol
PX093

Dr Jacques Meyer
paris_laboratory@yahoo.fr
Hospital Pitie-Salpetriere
P120DX-DIFF-Jacques

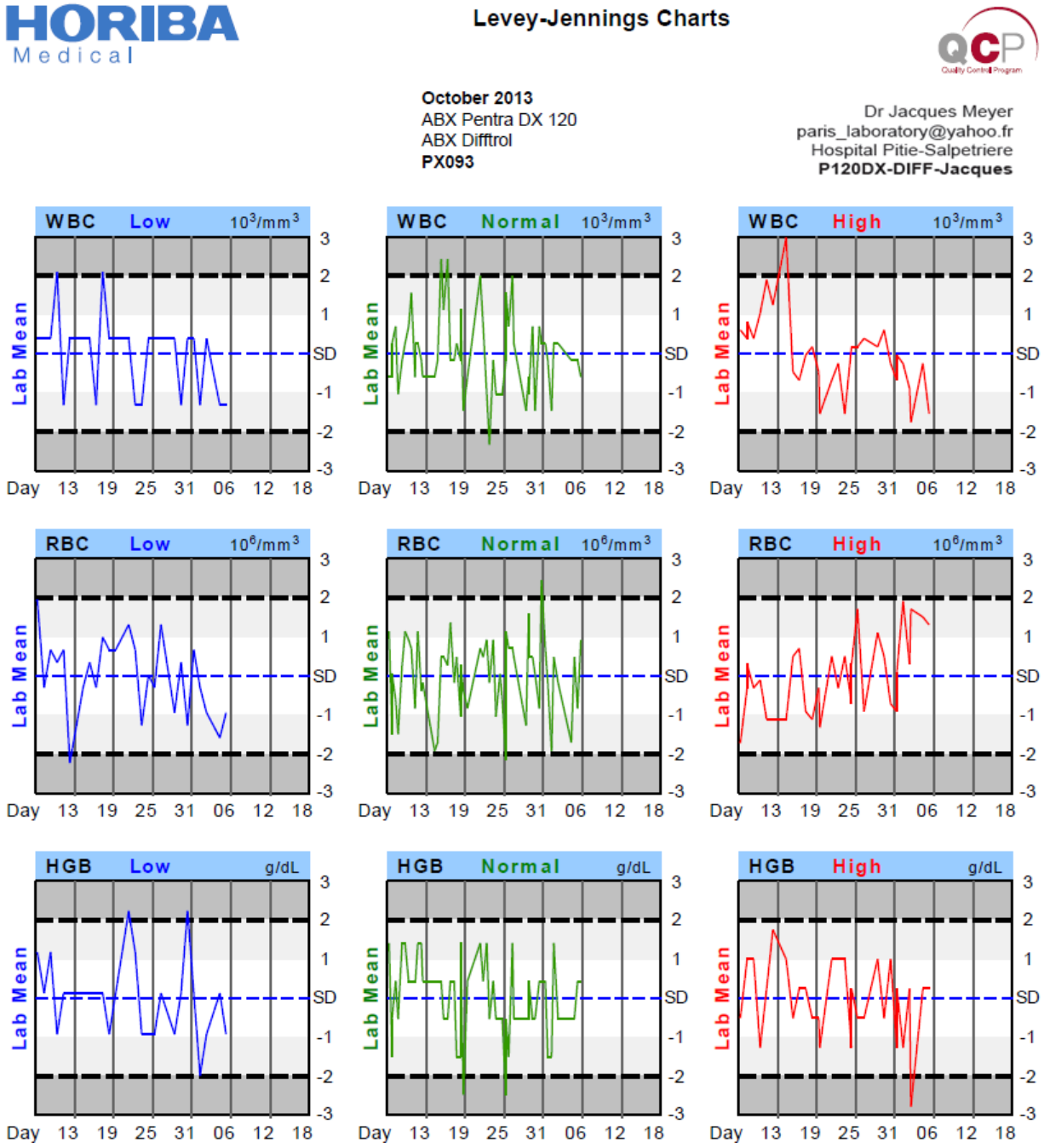
	WBC	**Low**										$10^3/mm^3$	
	Year	**2013**	**2013**	**2013**	**2013**	**2013**	**2013**	**2013**	**2013**	**2013**	**2013**	**2012**	**2012**
	Month	**Oct**	**Sep**	**Aug**	**Jul**	**Jun**	**May**	**Apr**	**Mar**	**Feb**	**Jan**	**Dec**	**Nov**
	Lot	**PX093**	**PX093**	**PX073**	**PX073**	**PX053**	**PX053**	**PX033**	**PX033**	**PX013**	**PX013**	**PX112**	**PX112**
	Number of Results	**26**	**27**	**28**	**23**	**38**	**29**	**25**	**31**	**25**	**27**	**31**	**31**
Instruments	United States	5	5	6	6	7	7	7	9	7	7	8	9
	World	128	121	125	114	122	117	116	108	106	122	115	113
MEAN	**Target**	2.30	2.30	2.50	2.50	2.50	2.50	2.40	2.40	2.50	2.50	2.50	2.50
	Lab	2.28	2.25	2.42	2.41	2.41	2.44	2.37	2.34	2.51	2.51	2.55	2.56
	United States	2.35	2.31	2.56	2.49	2.51	2.51	2.40	2.42	2.47	2.48	2.43	2.44
	World	2.33	2.32	2.47	2.46	2.50	2.50	2.42	2.42	2.49	2.49	2.50	2.47
SD	**Lab**	0.059	0.080	0.052	0.051	0.074	0.091	0.089	0.106	0.101	0.080	0.112	0.095
	United States	0.099	0.104	0.138	0.120	0.126	0.102	0.118	0.114	0.106	0.100	0.100	0.092
	World	0.097	0.102	0.102	0.110	0.102	0.097	0.104	0.105	0.105	0.107	0.106	0.107
2SD	**Lab**	0.117	0.160	0.104	0.103	0.148	0.181	0.178	0.211	0.203	0.160	0.224	0.191
	United States	0.197	0.209	0.276	0.241	0.252	0.204	0.236	0.228	0.212	0.200	0.200	0.184
	World	0.194	0.205	0.204	0.219	0.204	0.194	0.207	0.211	0.209	0.215	0.211	0.214
SDI	United States	-0.73	-0.62	-0.94	-0.72	-0.74	-0.63	-0.25	-0.66	0.41	0.27	1.15	1.31
	World	-0.57	-0.72	-0.48	-0.51	-0.82	-0.57	-0.49	-0.71	0.24	0.17	0.47	0.81
CV	**Lab**	2.6	3.6	2.1	2.1	3.1	3.7	3.8	4.5	4.0	3.2	4.4	3.7
	United States	4.2	4.5	5.4	4.8	5.0	4.1	4.9	4.7	4.3	4.0	4.1	3.8
	World	4.2	4.4	4.1	4.5	4.1	3.9	4.3	4.4	4.2	4.3	4.2	4.3
PI	United States	0.61	0.79	0.40	0.44	0.61	0.91	0.76	0.96	0.94	0.79	1.07	0.99
	World	0.62	0.81	0.52	0.48	0.75	0.95	0.88	1.03	0.96	0.74	1.04	0.86

III-7-2-3- Levey-Jennings Charts

This report shows a separate Levey-Jennings Chart for each parameter and level of the control product.

Visually check your instrument's precision by comparing how far your plotted daily results vary from your overall mean for the month.

- The x-axis or abscissa shows the days of the month.
- The y-axis or ordinate shows +/- 1SD, +/- 2SD, +/-3SD.
- The central line is your Lab Mean.



III-7-2-4- Levey-Jennings Charts Detailed

This more detailed version of a Levey-Jennings Chart allows for the values from multiple runs on a day to be shown individually.

Visually check your instrument's precision by comparing how far your plotted daily results vary from your overall mean for the month.

- The y-axis or ordinate on the right shows the Target value
- The y-axis or ordinate on the left shows your Lab Mean with +/- 1SD, +/- 2SD, +/-3SD.
- The x-axis or abscissa shows the days of the month.

Out of range values will appear in red next to the date in the table below the graph.

HORIBA Medical

Levey-Jennings Charts Detailed

QCP Quality Control Program

October 2013
ABX Pentra DX 120
ABX Difftrol
PX093

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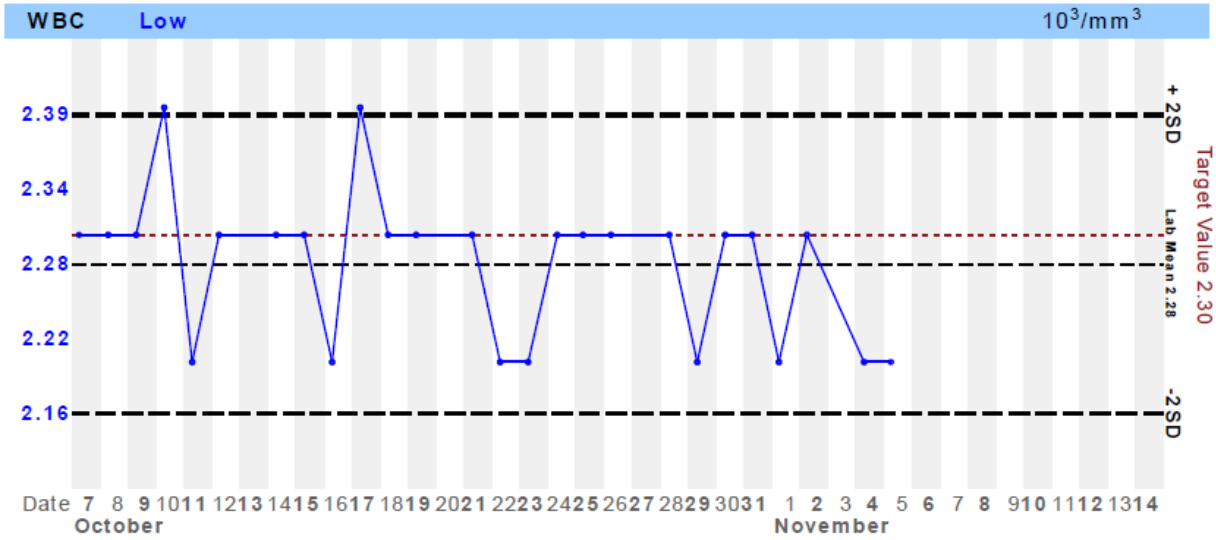
P120DX-DIFF-Jacques



Date	$\bar{x}$	Daily Results
7	2.300	**2.30**
8	2.300	**2.30**
9	2.300	**2.30**
10	2.400	**2.40**
11	2.200	**2.20**
12	2.300	**2.30**
14	2.300	**2.30**
15	2.300	**2.30**
16	2.200	**2.20**
17	2.400	**2.40**
18	2.300	**2.30**
19	2.300	**2.30**
21	2.300	**2.30**
22	2.200	**2.20**
23	2.200	**2.20**
24	2.300	**2.30**
25	2.300	**2.30**
26	2.300	**2.30**

Date	$\bar{x}$	Daily Results
28	2.300	**2.30**
29	2.200	**2.20**
30	2.300	**2.30**
31	2.300	**2.30**
1	2.200	**2.20**
2	2.300	**2.30**
4	2.200	**2.20**
5	2.200	**2.20**

NOTE

The Levey-Jennings Charts Detailed has room for 39 days of data.

The first date in the graph will be the date of the earliest run the user enters for a QC month.

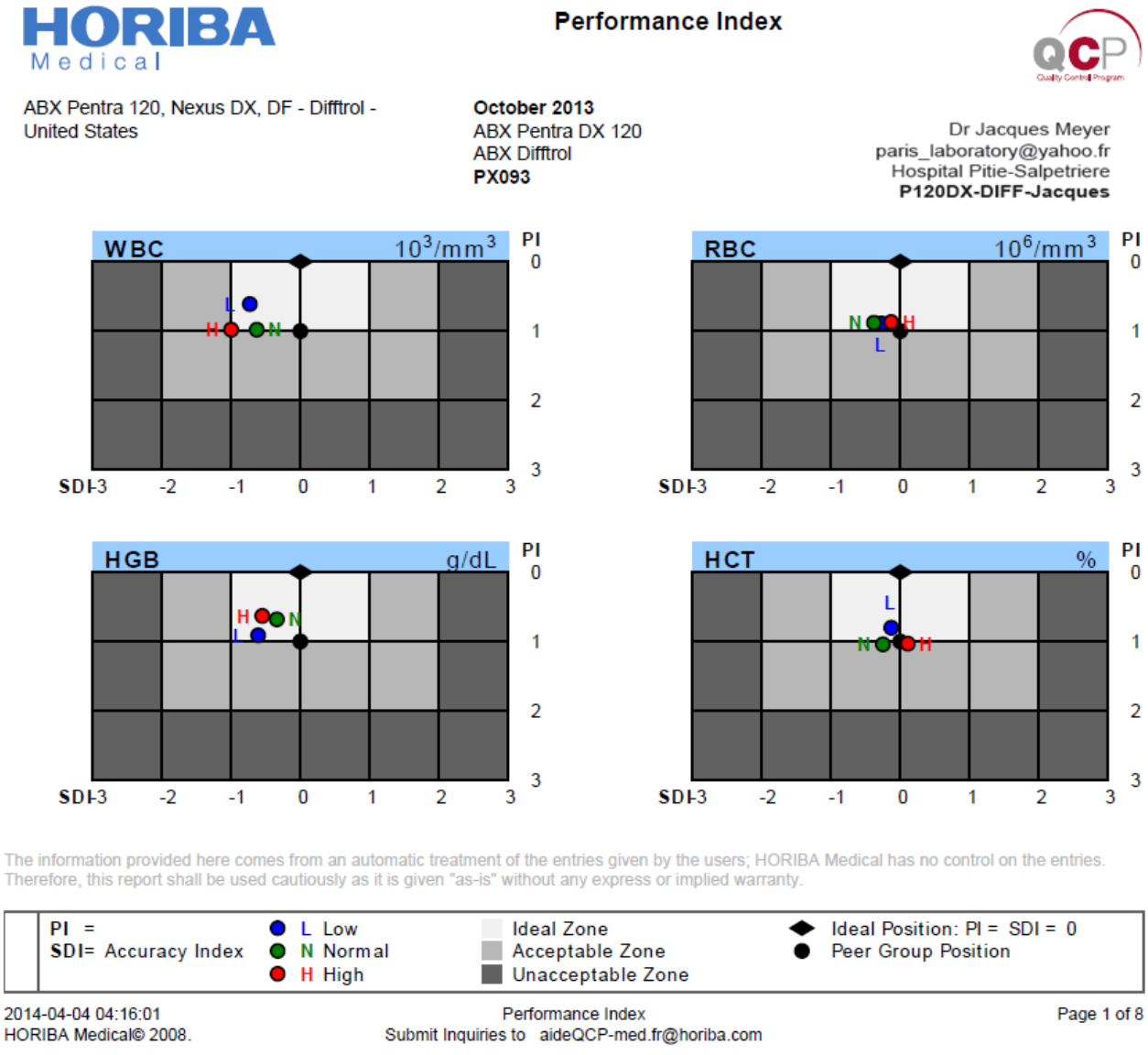
The dates could start at the end of one month, cycle through an entire month, and end with the beginning of a third month.

III-7-2-5- Performance Index

This graphical representation shows the position of each parameter in each level of the control product.

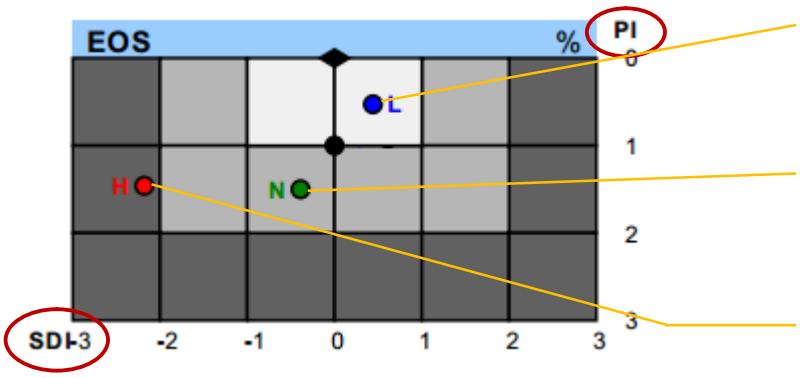
- The y-axis or ordinate shows PI
- The x-axis or abscissa shows SDI
- The Peer Group Position is shown with a black circle
- The Ideal Position (SDI = PI = 0) is shown with a black diamond
- L, N and H represent the position of the parameter in the Levels Low, Normal and High, respectively.

Check for World or Country results in the left part of the page header. Multiple sets of graphs can appear in this report depending on the peer groups selected.



The **Low**, **Normal** and **High** values are positioned in function of the **Peer Group Position**.

Example :



Low value : in the ideal zone. It's the correct area to achieve.

Normal value : within an acceptable area. The result could be better.

High value : positioned in the unacceptable zone, the value is not correct.

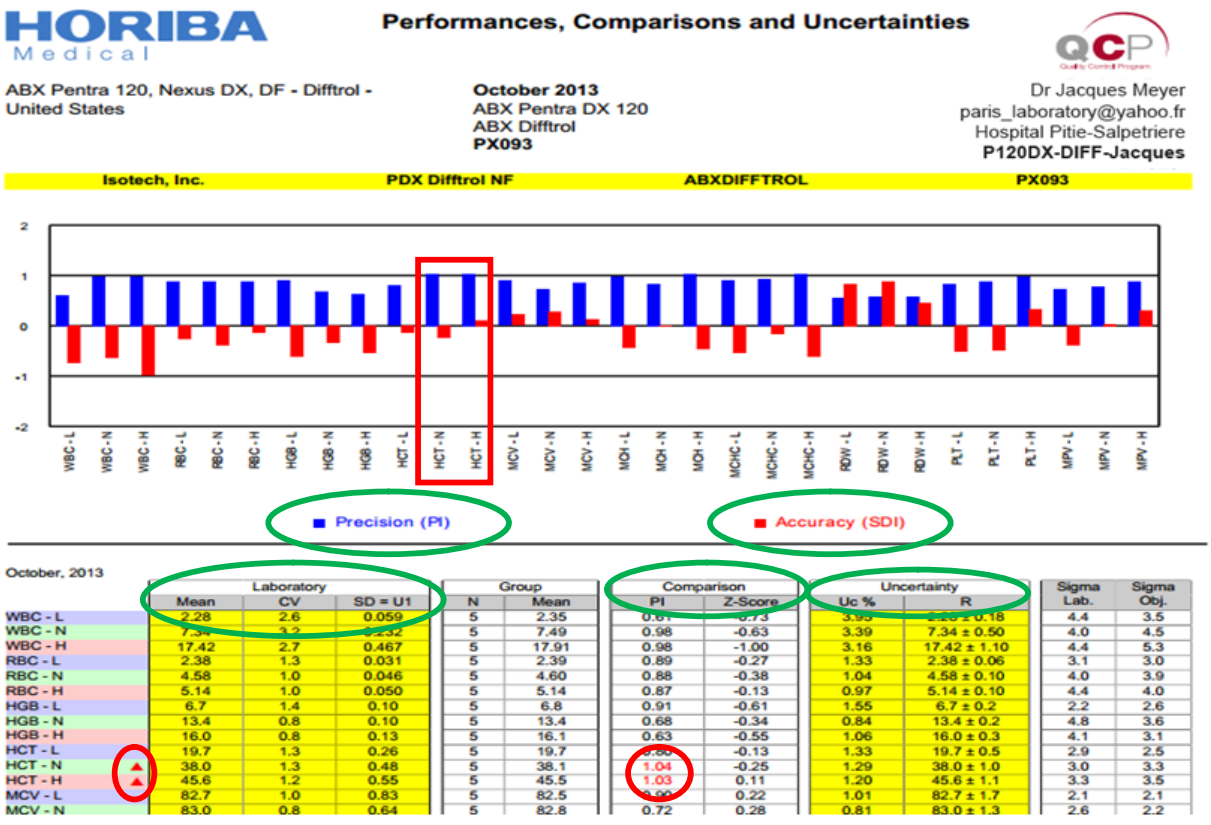
III-7-2-6- Performances, Comparisons and uncertainties

This kind of report shows different indicators which are compared to the group.

- Performance index values (precisions)
- Z-score (accuracy)

} **Compared within a graphic visualization**

-
- Variation coefficient (CV)
- Standard deviation
- Uncertainty
- Sigma indicator (gap between actual and required performances)
- Mean Lab/Group



HORIBA Medical

Performances, Comparisons and Uncertainties

QCP

ABX Pentra 120, Nexus DX, DF - Difftrol - United States

October 2013
ABX Pentra DX 120
ABX Difftrol
PX093

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Isotech, Inc. | **PDX Difftrol NF** | **ABXDIFFTROL** | **PX093**

October, 2013

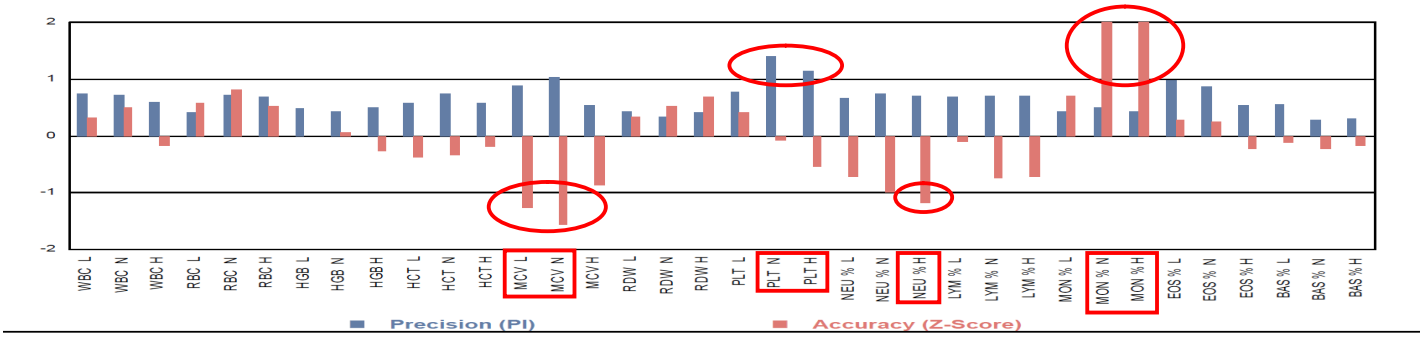
	Laboratory			Group		Comparison		Uncertainty		Sigma	Sigma
	Mean	CV	SD = U1	N	Mean	PI	Z-Score	Uc %	R	Lab.	Obj.
WBC - L	2.28	2.6	0.059	5	2.35	0.61	-0.73	3.95	2.28 ± 0.18	4.4	3.5
WBC - N	7.34	3.2	0.232	5	7.49	0.98	-0.63	3.39	7.34 ± 0.50	4.0	4.5
WBC - H	17.42	2.7	0.467	5	17.91	0.98	-1.00	3.16	17.42 ± 1.10	4.4	5.3
RBC - L	2.38	1.3	0.031	5	2.39	0.89	-0.27	1.33	2.38 ± 0.06	3.1	3.0
RBC - N	4.58	1.0	0.046	5	4.60	0.88	-0.38	1.04	4.58 ± 0.10	4.0	3.9
RBC - H	5.14	1.0	0.050	5	5.14	0.87	-0.13	0.97	5.14 ± 0.10	4.4	4.0
HGB - L	6.7	1.4	0.10	5	6.8	0.91	-0.61	1.55	6.7 ± 0.2	2.2	2.6
HGB - N	13.4	0.8	0.10	5	13.4	0.68	-0.34	0.84	13.4 ± 0.2	4.8	3.6
HGB - H	16.0	0.8	0.13	5	16.1	0.63	-0.55	1.06	16.0 ± 0.3	4.1	3.1
HCT - L	19.7	1.3	0.26	5	19.7	0.80	-0.13	1.33	19.7 ± 0.5	2.9	2.5
HCT - N ▲	38.0	1.3	0.48	5	38.1	1.04	-0.25	1.29	38.0 ± 1.0	3.0	3.3
HCT - H ▲	45.6	1.2	0.55	5	45.5	1.03	0.11	1.20	45.6 ± 1.1	3.3	3.5
MCV - L	82.7	1.0	0.83	5	82.5	0.90	0.22	1.01	82.7 ± 1.7	2.1	2.1
MCV - N	83.0	0.8	0.64	5	82.8	0.72	0.28	0.81	83.0 ± 1.3	2.6	2.2

Concerning the Normal and High HCT, we can see the symbol : ▲ That means that these values are beyond the **satisfying limit** (which is **equal to 1**).

Indeed, the **precision** value on the **HCT N/H** are, respectively, **1.04** and **1.03**.

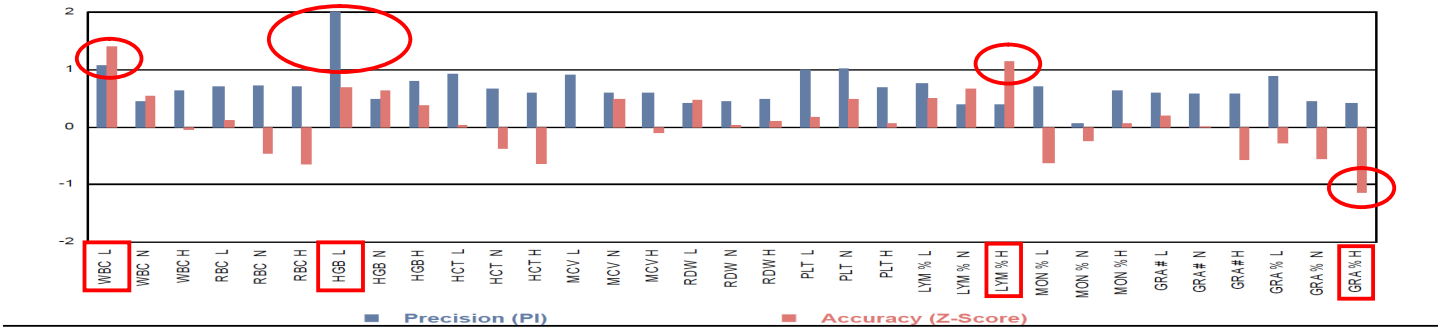
Practical examples:

QCP Alert : The QCP alert will appear when the value of Accuracy and Precision will be 2< or >2. The LQM will find these alerts in the QCP alerts reports (see manual further).



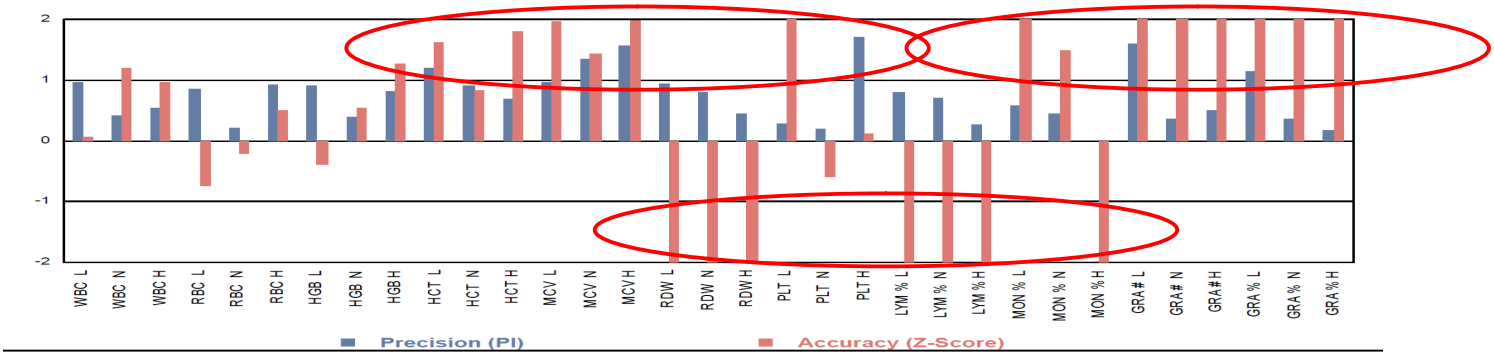
Precision:
- Tube mixing to improve values
(lower precision on PLT level N and H)

Accuracy:
- Not correct accuracy (MCV L/N), PLT N/H, NEU H, MON N/H)
- The MON N/H values are unacceptable



Precision:
- Incredible precision exclusively on Low HGB (Check individual values).

Accuracy:
- Multiples wrong values (WBC L, LYM H, GRA H)

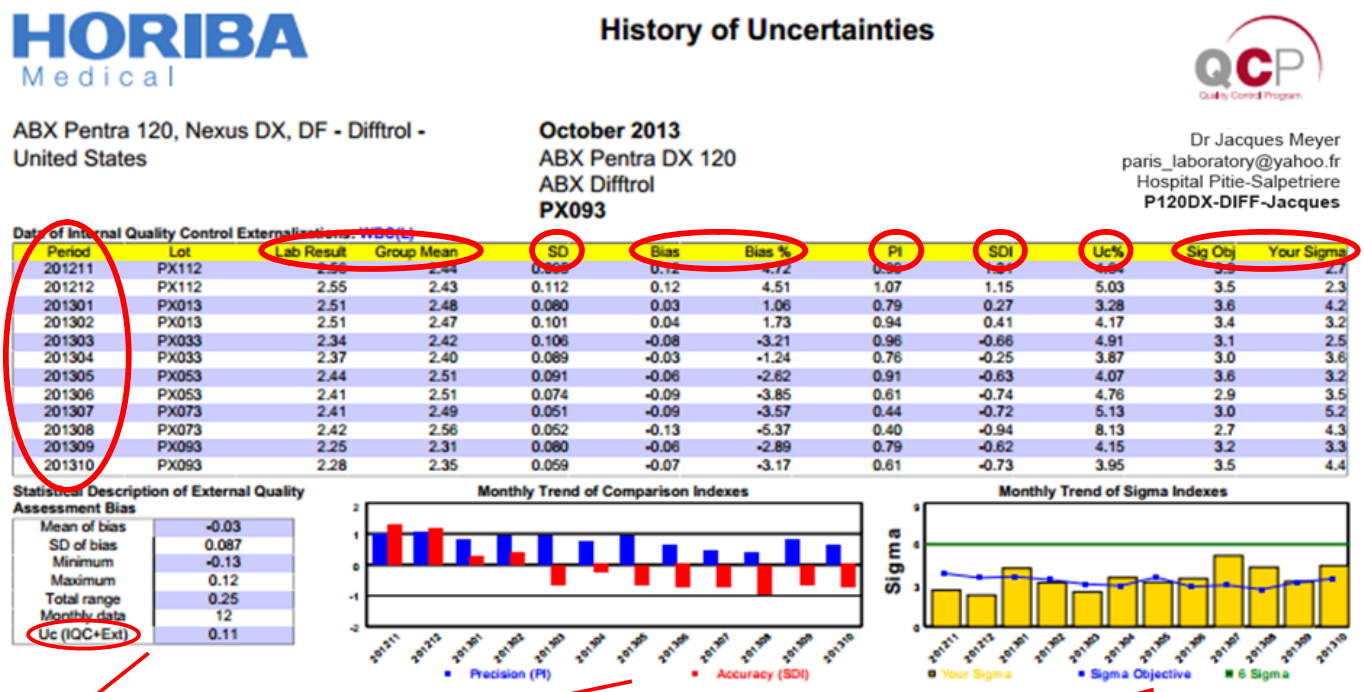


Precision:
- Wrong values (HCT L, MCV N/H, **PLT H, GRA #L,** GRA%L)

Accuracy:
- Totally bad, absolutely unacceptable values. Total lack of quality.

III-7-2- 7- History of uncertainties

Tables and graphics that present an historic of the “Performances, Comparisons and uncertainties report” :



HORIBA Medical

History of Uncertainties

QCP Quality Control Program

ABX Pentra 120, Nexus DX, DF - Difftrol - United States

October 2013
ABX Pentra DX 120
ABX Difftrol
PX093

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P120DX-DIFF-Jacques

Date of Internal Quality Control Externalization: WBC(G)

Period	Lot	Lab Result	Group Mean	SD	Bias	Bias %	PI	SDI	Uc%	Sig Obj	Your Sigma
201211	PX112	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
201212	PX112	2.55	2.43	0.112	0.12	4.51	1.07	1.15	5.03	3.5	2.3
201301	PX013	2.51	2.48	0.080	0.03	1.06	0.79	0.27	3.28	3.6	4.2
201302	PX013	2.51	2.47	0.101	0.04	1.73	0.94	0.41	4.17	3.4	3.2
201303	PX033	2.34	2.42	0.106	-0.08	-3.21	0.96	-0.66	4.91	3.1	2.5
201304	PX033	2.37	2.40	0.089	-0.03	-1.24	0.76	-0.25	3.87	3.0	3.6
201305	PX053	2.44	2.51	0.091	-0.06	-2.62	0.91	-0.63	4.07	3.6	3.2
201306	PX053	2.41	2.51	0.074	-0.09	-3.85	0.61	-0.74	4.76	2.9	3.5
201307	PX073	2.41	2.49	0.051	-0.09	-3.57	0.44	-0.72	5.13	3.0	5.2
201308	PX073	2.42	2.56	0.052	-0.13	-5.37	0.40	-0.94	8.13	2.7	4.3
201309	PX093	2.25	2.31	0.080	-0.06	-2.89	0.79	-0.62	4.15	3.2	3.3
201310	PX093	2.28	2.35	0.059	-0.07	-3.17	0.61	-0.73	3.95	3.5	4.4

Statistical Description of External Quality Assessment Bias

Mean of bias	-0.03
SD of bias	0.087
Minimum	-0.13
Maximum	0.12
Total range	0.25
Monthly data	12
Uc (IQC+Ext)	0.11

Monthly Trend of Comparison Indexes

Precision (PI) Accuracy (SDI)

Monthly Trend of Sigma Indexes

Sigma

Your Sigma Sigma Objective 6 Sigma

Summary of statistical data

Over year tendency

Precision:

Global improvement of the precision over the year.

Accuracy:

Shift of accuracy from positive to negative value, still remaining in acceptable limits.

Over year tendency

6 Sigma: Theoretical performance to achieve.
Sigma objective: Performance of the Peer Group: *slight downward trend*.

Your sigma: Ratio between actual and required performances*: improvement of performances over the year, but without achieving the theoretical performance (6 sigma).*

- **Mean** : Presentation of the history of means from the **lab** and the **group**. This way it is easy to compare the both all over the year.
- **SD** : Standard deviation
- **Bias** : Average expressed in number of standard deviation.
- **Performance index (PI)** : PI = CVI = $\mathbf{CV_{Lab} / CV_{Peer\ Group}}$
- **Standard deviation index (SDI)** : “Relative standard deviation”.

SDI = Z-score = $\mathbf{(\bar{X}_{Lab} - \bar{X}_{Peer\ Group}) / SD_{Peer\ Group}}$
The accuracy has been evaluated by calculating a "Z-score" which expresses the number of standard deviation separating the laboratory result from the average of the comparison group (ISO/FDIS 13528).

- **Uncertainty** :

- $U_1 = SD_{Repro}$: Standard deviation on the reproductibility
- U_2 = Uncertainty# / √3 : Uncertainty attributable to uncertainty. (Uncertainty# = (m – V) ; m: mean of standard deviation ; V: expected target value)
- $\mathbf{U_c = \sqrt{(U_1^2 + U_2^2)}}$: Combined uncertainty
- $U = 2U_c$: Expanded uncertainty

- **Sigma** :

Your sigma : **(TEa% – Bias%) / CV** (Difference between actual and required performance)
Sigma objective : **(TEa%) / 0.5 * CV%**

- TEa : Total error allowable.
- Bias% : Average expressed in number of standard deviation.

III-7-2- 8- Other Instrument Groups

This report shows the results of Other Instruments Groups (different than your instrument), using the same control product, the same lot and level as your instrument.

For each parameter and, level of the control product, the following data is shown:

- Instruments Reporting (number of reporting Peers)
- Mean
- CV
- SDI (Relative Accuracy) = (Your Mean – Group Mean) / Group SD

This report shows the World and Country groups of the different instruments.

HORIBA Medical

Other Instrument Groups

QCP Quality Control Program

ABX Pentra 120, Nexus DX, DF - Difftrol - World
ABX Pentra 120, Nexus DX, DF - Difftrol - United States
ABX Pentra 80 - Difftrol - World

October 2013
ABX Pentra DX 120
ABX Difftrol
PX093

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ABX Pentra 120, Nexus DX, DF - Difftrol - United States

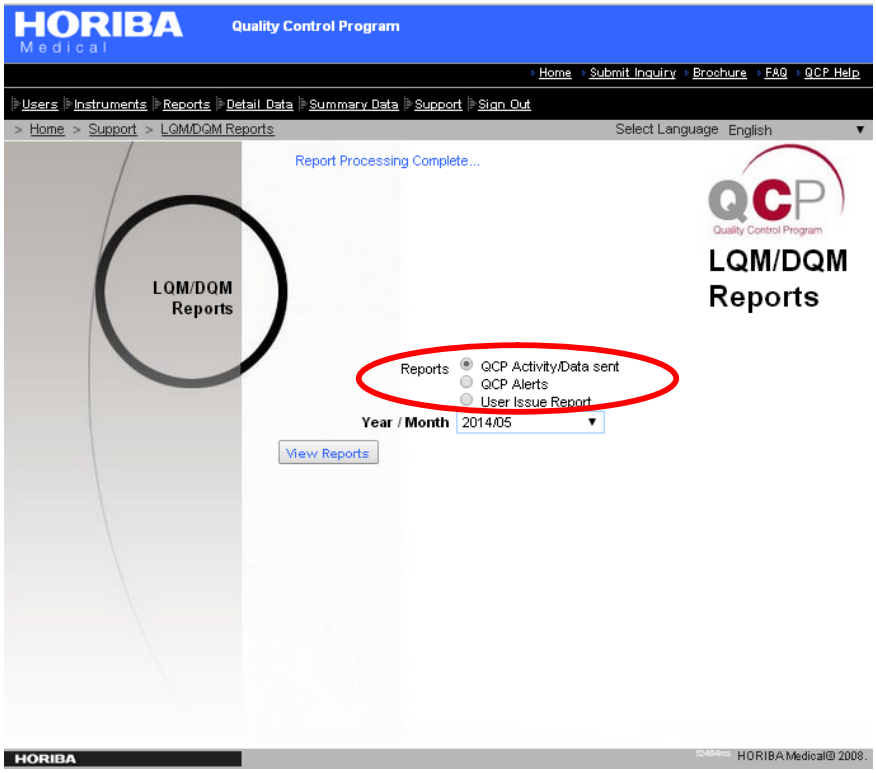
	WBC		$10^3/mm^3$	RBC		$10^6/mm^3$	HGB		g/dL	HCT		%
Level	L	N	H	L	N	H	L	N	H	L	N	H
Instruments	5	5	5	5	5	5	5	5	5	5	5	5
Mean	2.35	7.49	17.91	2.39	4.60	5.14	6.8	13.4	16.1	19.7	38.1	45.5
SDI	-0.73	-0.63	-1.00	-0.27	-0.38	-0.13	-0.61	-0.34	-0.55	-0.13	-0.25	0.11
CV	4.2	3.2	2.7	1.5	1.1	1.1	1.6	1.1	1.3	1.6	1.2	1.2
	MCV		fL	**MCH**		pg	**MCHC**		g/dL	**RDW**		%
Instruments	5	5	5	5	5	5	5	5	5	5	5	5
Mean	82.5	82.8	88.6	28.3	29.2	31.3	34.3	35.2	35.3	15.0	16.1	14.7
SDI	0.22	0.28	0.12	-0.45	-0.02	-0.47	-0.55	-0.16	-0.61	0.84	0.88	0.45
CV	1.1	1.1	1.1	1.7	1.3	1.3	1.9	1.4	1.4	3.8	3.5	3.8
	PLT		$10^3/mm^3$	**MPV**		fL	**LYM**		#	**MON**		#
Instruments	5	5	5	5	5	5	3	3	3	3	3	3
Mean	66	246	501	8.9	8.9	8.6	0.70	2.16	2.92	0.12	0.50	1.15
SDI	-0.52	-0.49	0.33	-0.39	0.03	0.31	-1.32	-0.95	-1.14	-0.78	-0.32	-0.83
CV	7.7	3.8	3.7	3.4	2.4	2.3	14.2	12.6	12.5	28.7	32.0	30.8
	NEU		#	**EOS**		#	**BAS**		#	**LYM**		%
Instruments	3	3	3	3	3	3	3	3	3	5	5	5
Mean	1.20	4.17	12.50	0.19	0.32	0.70	0.08	0.28	0.58	30.4	29.2	16.4
SDI	1.19	0.78	0.90	0.65	-0.02	-1.23	1.13	0.16	-0.20	-1.39	-0.98	-1.09
CV	6.6	6.4	4.6	22.5	20.3	23.0	12.9	12.9	27.9	12.7	11.4	11.5
	MON		%	**NEU**		%	**EOS**		%	**BAS**		%
Instruments	5	5	5	5	5	5	5	5	5	5	5	5
Mean	5.1	6.7	6.5	52.8	56.2	70.2	8.2	4.3	3.8	3.5	3.7	3.1
SDI	-0.75	-0.26	-0.62	1.29	1.00	1.10	0.82	0.09	-0.86	1.57	0.35	0.02
CV	29.6	32.0	39.4	6.5	6.3	5.8	22.2	18.1	27.8	11.7	14.2	36.6

III-7-2- 9- Certificate

It is now possible to get a certification about this interlaboratory comparison process. On this certificate is mentioned the **user**, **loboratory** and **instrument** name and the **type of control**.
Is also indicated in which **period** the lab has contributed at this comparison program.
The **signature** of the QCP Marketing Product Manager, **Philippe Milian**, come to certify this contribution.

III-8- SPECIFIC REPORTS

It is possible to have access to another kind of report, specifically to the Local Quality Manager (LQM) and Distributor Quality Manager (DQM):



III-8-1 Activity/Data sent reports

This report present the **number of data sends** by registered **instrument** and **country**.

Instrument description

Main User	Institution	Instrument Status	SN Model Control	201307	201308	201309	201310	201311	201312	201401	201402
amanh@e-bio.fr	SELAL Amanh	Active	704PC7049|ABX Pentra 60C+|ABX DIFFTROL	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A
ana21@yahoo.fr	ANA	Active	608 ver 1432|ABX Pentra 120 Retic|ABX DIFFTROL	1	1	1	1	1	2	2	1
audrey.bout@labo-caudry.fr	PORTE	Active	601PDX0230|ABX Pentra DX 120|ABX DIFFTROL	1	1	1	1	1	1	1	1

None data sent about the Pentra 60C+/ABX DIFFTROL.

The activity data sent report is visible for the local managers (CQM/LQM/DQM). This way, they are able to see if customers are **actually using** the **registered instruments**.

If it is not the case, the **local manager** can act on the registration to **prevent** the customer **to pay** a **non-used service**.

Automatic Deactivation Policy:

An instrument which is non used while 4 months, will be automatically deactivated from the database. This happens for all users already registered for more than 6 months.

III-8-2 QCP Alerts Report

This report allow to easily see every SDI and PI exceeded values by user for each parameter. Either positive (>2) or negative (<-2) excess. (see the example below):

Main User Email	Institution	Serial Number	Instrument Model	Control	Lot/Level	Level	Parameter	SDI	PI
wmcgiothlin@ksspine.com		412P4-0277	ABX Pentra 400		1107001	N	TP100	3.62	.19
shauna.cameron@nortonhealthcare.org		707P4-0795	ABX Pentra 400		1300801	N	CREA_RB	2.75	0.00
shauna.cameron@nortonhealthcare.org		707P4-0795	ABX Pentra 400		1300801	N	Na-E	2.49	.92
jshuck@cellnetix.com		803PCP7747	ABX Pentra 60C+		PX093L	L	MON %	3.36	.38
jshuck@cellnetix.com		803PCP7747	ABX Pentra 60C+		PX093L	L	MON #	2.92	.34
jshuck@cellnetix.com		803PCP7747	ABX Pentra 60C+		PX093H	H	NEU %	2.03	.66
millerk@scotlandcountyhospital.com		009PCP9693	ABX Pentra 60C+		PX093N	N	BAS %	2.57	.42
millerk@scotlandcountyhospital.com		009PCP9693	ABX Pentra 60C+		PX093N	N	BAS #	2.80	.85
millerk@scotlandcountyhospital.com		009PCP9693	ABX Pentra 60C+		PX093H	H	WBC	2.05	1.13
millerk@scotlandcountyhospital.com		009PCP9693	ABX Pentra 60C+		PX093H	H	NEU #	2.01	1.01
millerk@scotlandcountyhospital.com		009PCP9693	ABX Pentra 60C+		PX093H	H	BAS #	2.73	.66

III-8-3 User Issue Report

This report display the **activation status** for each enrolled instrument (pending activation or inactivation) and customers that have enrolled **without requesting any reports or notification email**.

qclab-med.us@horiba.com	P400 507P4	359	No email report or notification requested.
qclab-med.us@horiba.com	P60C+ 110PCP2034	No email report or notification requested.	
qclab-med.us@horiba.com	Pentra C260 908C2	125	Instrument Status is PendingInactivation.
qclab-med.us@horiba.com	P400CRP 507P4	359	Instrument Status is Pending.
shauna.cameron@nortonhealthcare.org	P400 707P4	795	No email report or notification requested.
shauna.cameron@nortonhealthcare.org	P400CO2 707P4	795	No email report or notification requested.
shauna.cameron@nortonhealthcare.org	P400 707P4	791	Instrument Status is PendingInactivation.
majella.miller@nortonhealthcare.org	P400 707P4	791	Instrument Status is PendingInactivation.
tanisha@sjonc.com	New P60C+ 205PCP11255	No email report or notification requested.	
awright2@bmhsc.org	P60C+ 604PCP6276	No email report or notification requested.	
peblesp@lhd3.org	P80 607P802358	No email report or notification requested.	
tsimkin@bighornhospital.org	PXL80 904PXL3744	No email report or notification requested.	
cwilliams@samaritanhospital.net	PXL80 604PXL2233	No email report or notification requested.	
lab@pmcmac.com	Horiba	Instrument Status is Pending.	
rbateau@bouldercityhospital.org	PXL80 705PXL2758	No email report or notification requested.	
GFiedler@dekalbclinic.com	P80 701P802667	No email report or notification requested.	
pat@peoplesclinic.net	M60IM2 906CS87400	No email report or notification requested.	
ksuddeth@dekalbclinic.com	P80 701P802667	No email report or notification requested.	
mblanchard@cddmedical.com	PXL80 911PXL3956	No email report or notification requested.	
julia6812@comcast.net	M60 002CS88569	No email report or notification requested.	

Activity status

Instrument/Reference

User e.mail

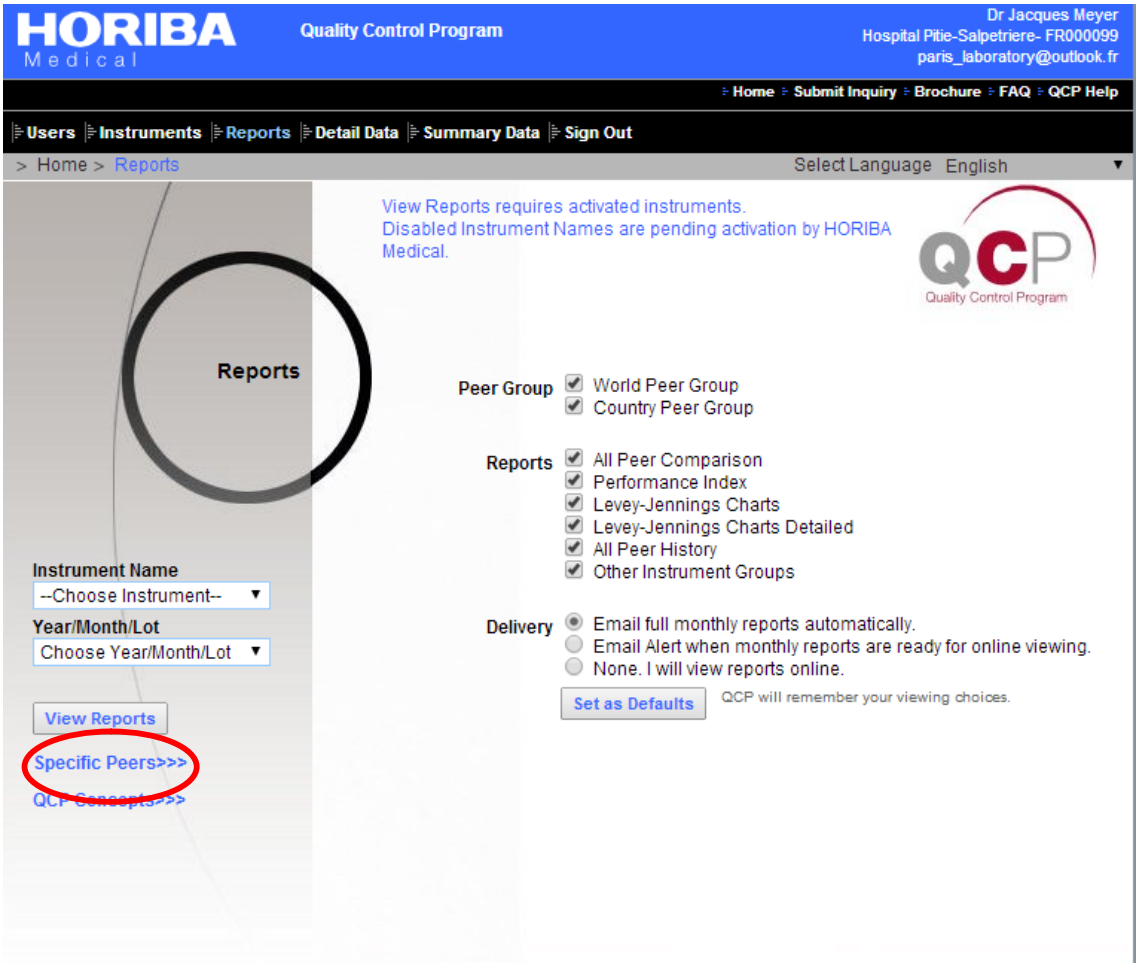
III-9- SPECIFIC PEER GROUPS

A SPECIFIC PEER GROUP is a special grouping of similar instruments determined by a MAIN USER.

Only the MAIN USER may create any number of SPECIFIC PEER GROUPS.

III-9-1- Creation of a Specific Peer Group

To create a specific peer group, click SPECIFIC PEERS in the REPORTS page.



The INVITE SPECIFIC PEERS page will be displayed :

Step 1
Select the Instrument Name

Step 2
Select New Peer Group

Step 3
Name the specific peer group.
There will be a name set by default: “Group Number / Institution Name of the user creating the Specific Peer”

Step 4
Complete the table with the information of users you would like to invite to form a Specific Peer Group.

- Email (required)
- Institution (optional)
- Address (optional)

Step 5
Click SUBMIT to send the invitation.

Step 6
The invited users will receive an email instructing them how to accept or decline your invitation on their REPORTS page.
There will be a place on the invitees REPORTS page to Accept or Decline the invitation.
The Status field will let you know if a peer has Accepted or Declined your invitation.

The list of all specific groups that are created will be in the REPORT page below the World and the Country peer groups.

It will be possible to check or uncheck these specific peer groups and to obtain the ALL PEER COMPARISON report, the ALL PEER HISTORY report and the PERFORMANCE INDEX that contains the results of the World, Country, Specific peer group(s) if selected, as well the results of your instrument, for comparison.

III-9-2- Status of a Specific Peer Group

The status of each invited peer will be displayed as follows:

- Accepted: the invited peer has accepted your invitation to form a specific peer group
- Declined: the invited peer has declined your invitation to form a specific peer group
- No instrument: the invited peer does not have the instrument for which you created the specific peer group
- Unidentified: If the email address entered does not match a user in QCP

III-9-3- Modification/Update of a Specific Peer Group

The MAIN USER can modify/update the created specific peer groups, by selecting the specific peer group in the dropdown box to edit it.

Then, the following actions may be done:

1/ Complete the information about the institution and the address, and click SUBMIT.

2/ Add or remove peers (members) to or from the Specific Peer Group at any time.

- To add a new member, add his email address and click SUBMIT, an invitation email will be sent to that user.

- To remove a member, erase his email address and click SUBMIT.
The deleted member will no longer see this specific peer group on their REPORTS page.

3/ Change the name of an already created specific peer group. The members of this group will get an automatic notification by email with the new name. The specific peer group will appear in their REPORTS page with the new name.

4/ Delete an entire Specific Peer Group with the DELETE GROUP button in the INVITE SPECIFIC PEERS page.

NOTE

1. The specific peer groups are not limited to one month

2. Specific peer groups with less than 6 peers will receive a warning message in the ALL PEER COMPARISON report saying : *"A minimum of 6 Instruments reporting provides better comparative results"*

3. An instrument may be a member of any number of Specific Peer Groups at a time.

III-10- MAIN USER & USERS

III-10-1- Create MAIN USER

The MAIN USER enrolls to create an account, or, is enrolled by the local HORIBA Medical Representative, registers each instrument & control product combination, creates additional users with restricted access to instruments, invites specific peers and inactivates instruments.

The procedure for creating a MAIN USER account is explained above *[see III-3- ENROLL, III-4- INSTRUMENTS]*

III-10-2- Setup additional user(s) & Assign instrument(s)

The MAIN USER who first registered the information in the ENROLL and INSTRUMENTS pages is able to set any number of additional users with restricted access to instruments, by following the steps below:

Step 1
Sign onto the MAIN USER account

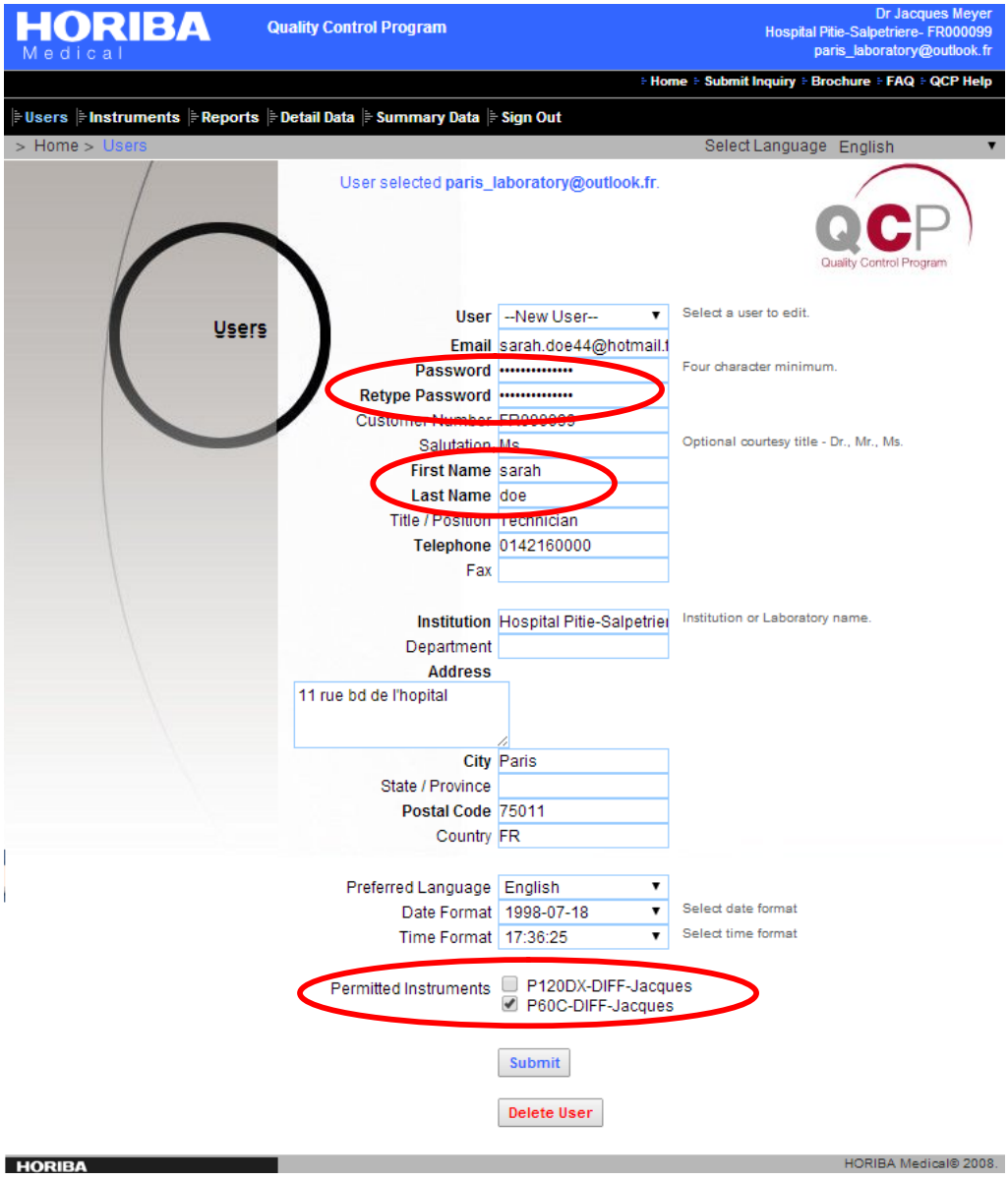
Step 2
Click on the USERS link to get to the USERS Page

Step 3
Select NEW USER from the drop-down (this will already be selected.)
QCP will default many of the fields from the MAIN USER account.

Step 4

- Enter the email address and the password for the additional user (twice)
- Enter the First and Last Names of the additional user
- Using the checkboxes, select the Instruments that this user has access to.

In this example, the MAIN USER Dr Jacques Meyer has checked the instrument “P60C-DIFF-Jacques” for the additional user Ms Sarah Doe.

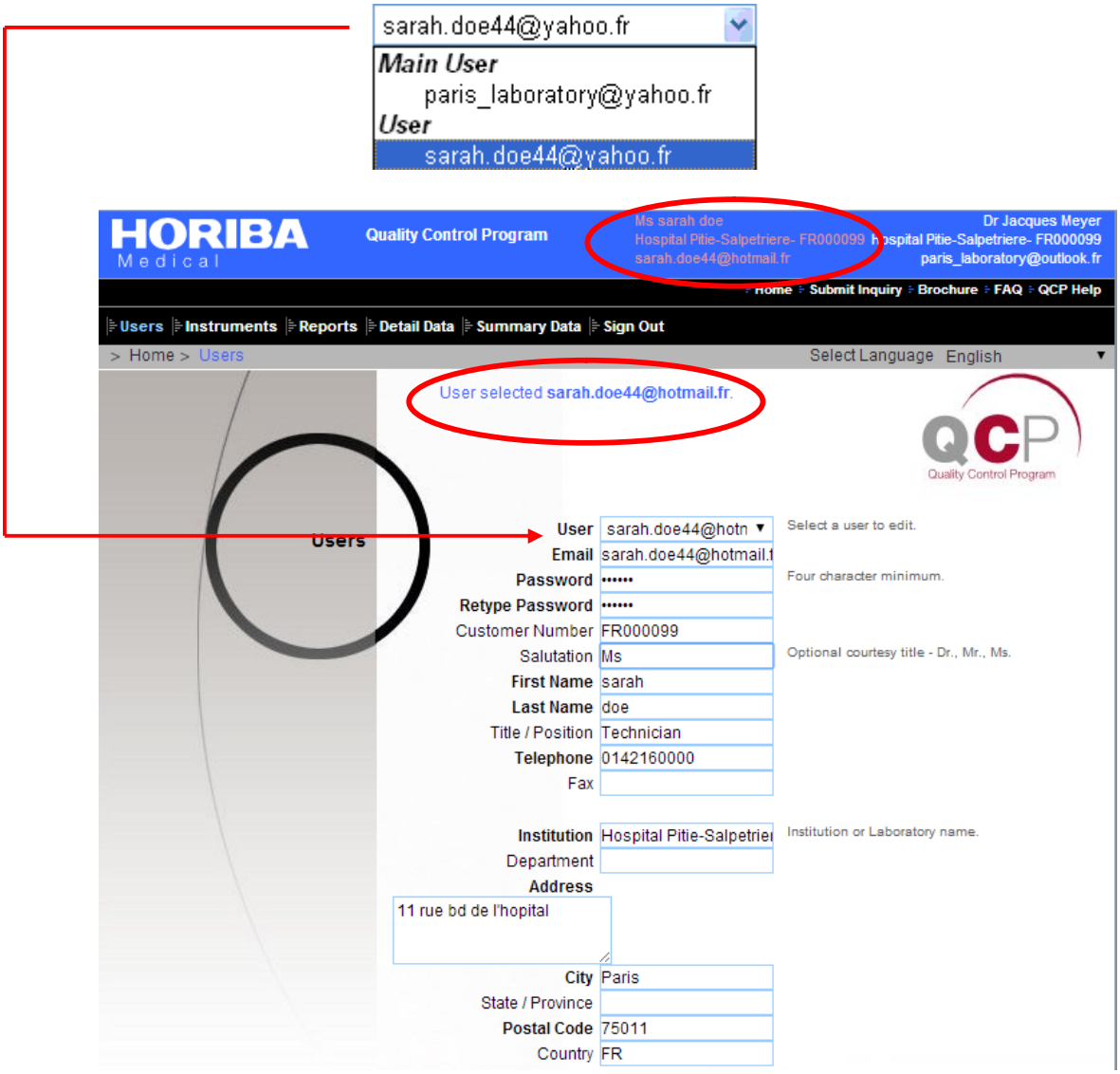


Step 5
The remaining required fields should have default information.
Check this information and make changes as needed.
Step 6
Click SUBMIT

Step 7
You will see a message in blue to confirm that the additional user has been enrolled, and to inform you that an information email is sent to this additional user.

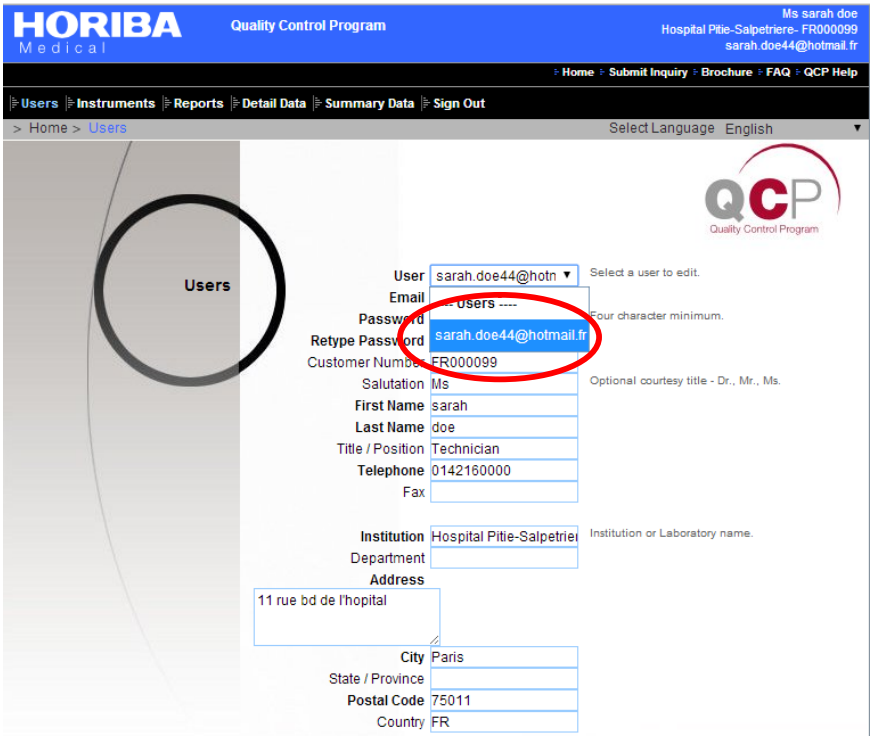
NOTE
The additional user (Ms Sarah Doe in this example) who is enrolled by the MAIN USER (Dr Jacques Meyer in this example) will receive by email a password to sign in to QCP. The additional user may change this password in the USERS page.

In the USERS page, if the MAIN USER (Dr Jacques Meyer in this example) selects in the User dropdown box the additional user (Ms Sarah Doe in this example), the information and the instrument of this additional user will be displayed.

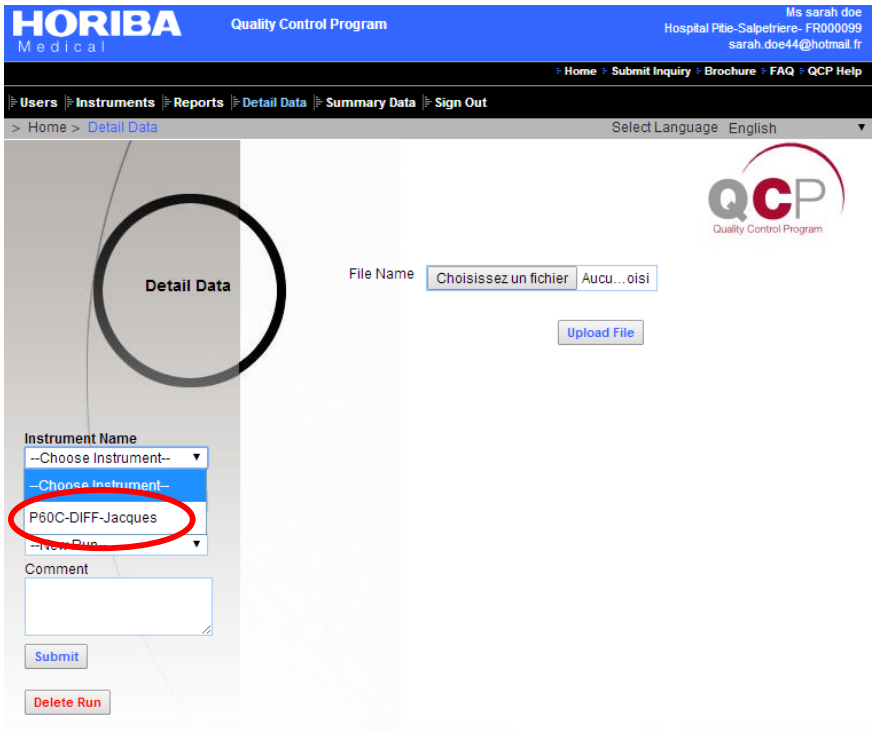


When the additional user signs in to QCP :

- Only his/her email will appear in the USER dropdown box



- Only the instrument that the MAIN USER has assigned to her/him will be available in the INSTRUMENT page

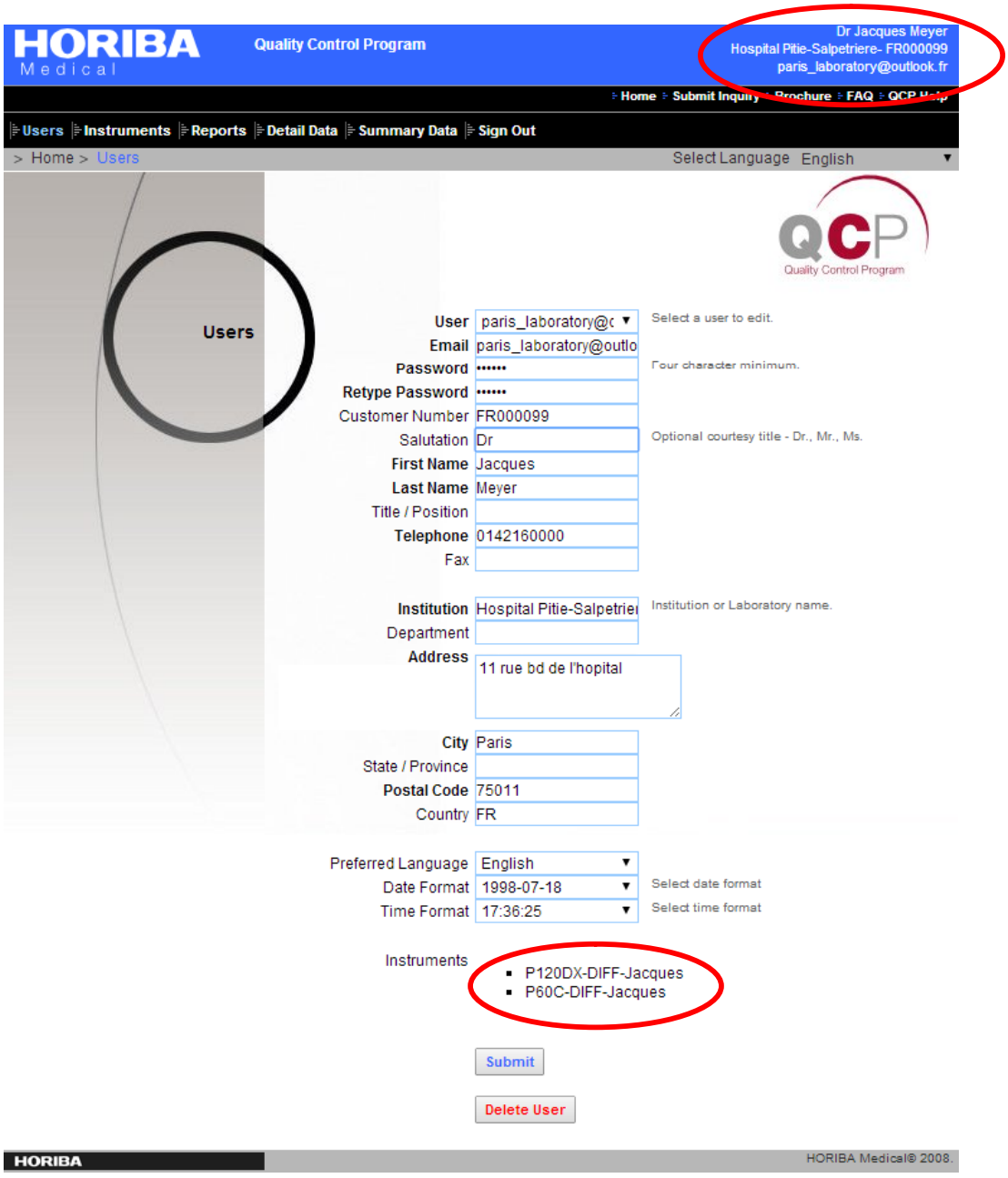


IMPORTANT

If a new instrument is added, the MAIN USER will need to edit each user that needs to access that instrument and check the instrument and click SUBMIT.

All of the laboratories instruments are always listed for a MAIN USER.

In this example, the MAIN USER is Dr Jacques Meyer: Two instruments are enrolled in QCP for his laboratory.



III-10-3- Delete users

The MAIN USER can use the following procedure to delete a user.

Step 1
Go to the USERS Page

Step 2
Select the user you want to delete from the drop-down

Step 3
Click DELETE

Step 4
Wait for QCP to return with the verification message.

IMPORTANT

All the users under a MAIN USER need to be deleted before a MAIN USER can be deleted.

III-11- INACTIVATION OF AN INSTRUMENT

The MAIN USER may inactivate an instrument by clicking INACTIVATE in the INSTRUMENTS page, after selecting the name of the instrument to inactivate.

Before you remove the instrument by inactivation, HORIBA Medical strongly recommends that you review your contract with your local representative before making this change.

IV- OTHER ONLINE FUNCTIONS

IV-1- OTHER FUNCTIONS IN THE SIGN IN PAGE

1/ Forgot your Password
A new password will arrive by email by clicking on FORGOT YOUR PASSWORD, completing the information required and clicking SUBMIT

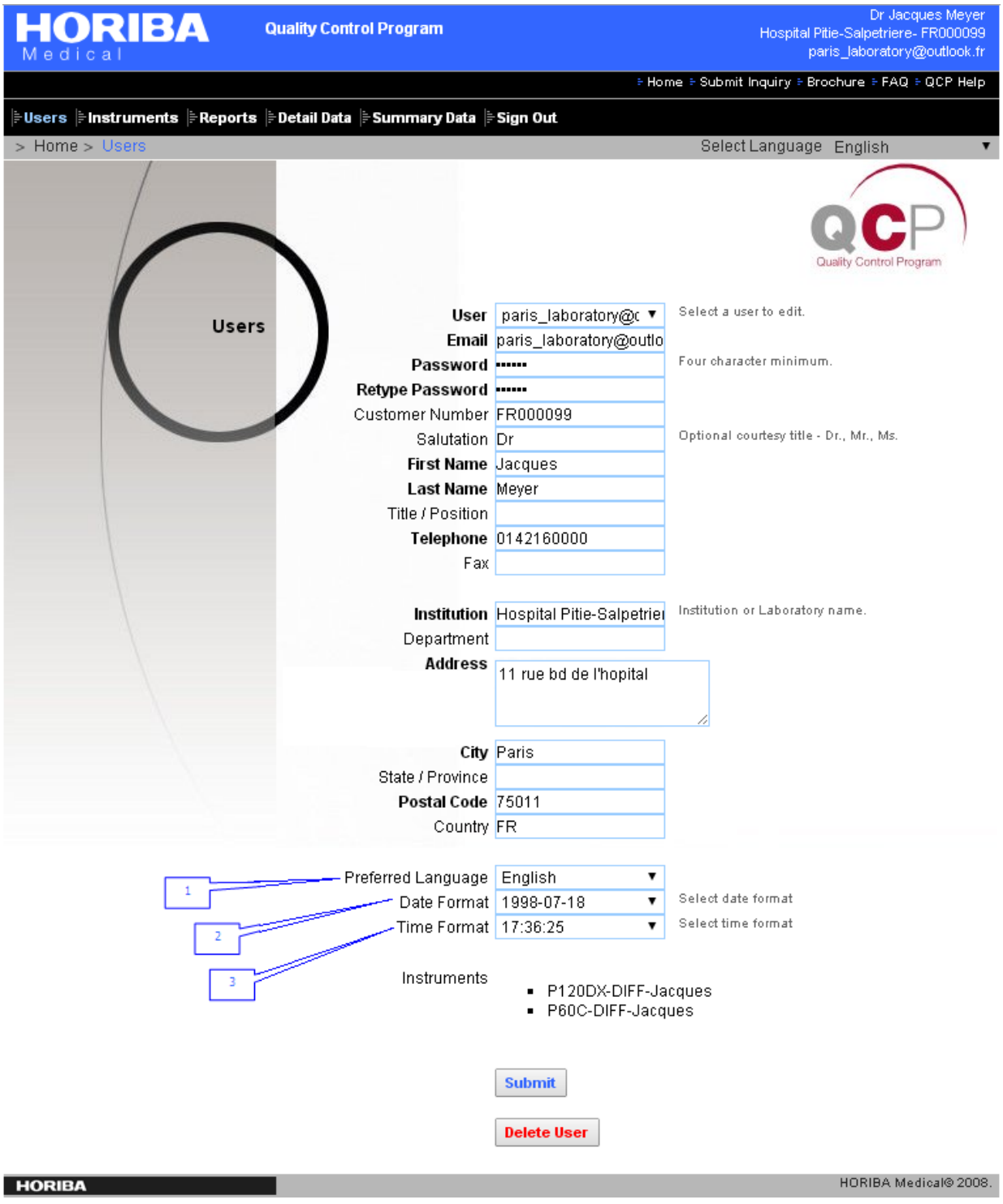
2/ More info
Learn about browser settings, browsers supported and download a PDF reader for viewing reports by clicking on MORE INFO.

IV-2- OTHER FUNCTIONS IN THE USERS PAGE

1/ Preferred Language
You can choose your preferred language, simply by choosing the language in the dropdown box.
Once you sign in, the pages of QCP will always appear with your preferred language.

2/ Date Format
You can choose the date format that will be used in the DETAIL DATA page, and that will be displayed in the statistical reports.

3/ Time Format
You can choose the time format that will be used in the DETAIL DATA page, and that will be displayed in the statistical reports.



IV-3- OTHER FUNCTION IN THE REPORTS PAGE

Clicking on QCP Concept will give you a glossary of terms to help explain the concepts used in the statistical reports.

IV-4- OTHER FUNCTIONS IN ALL PAGES

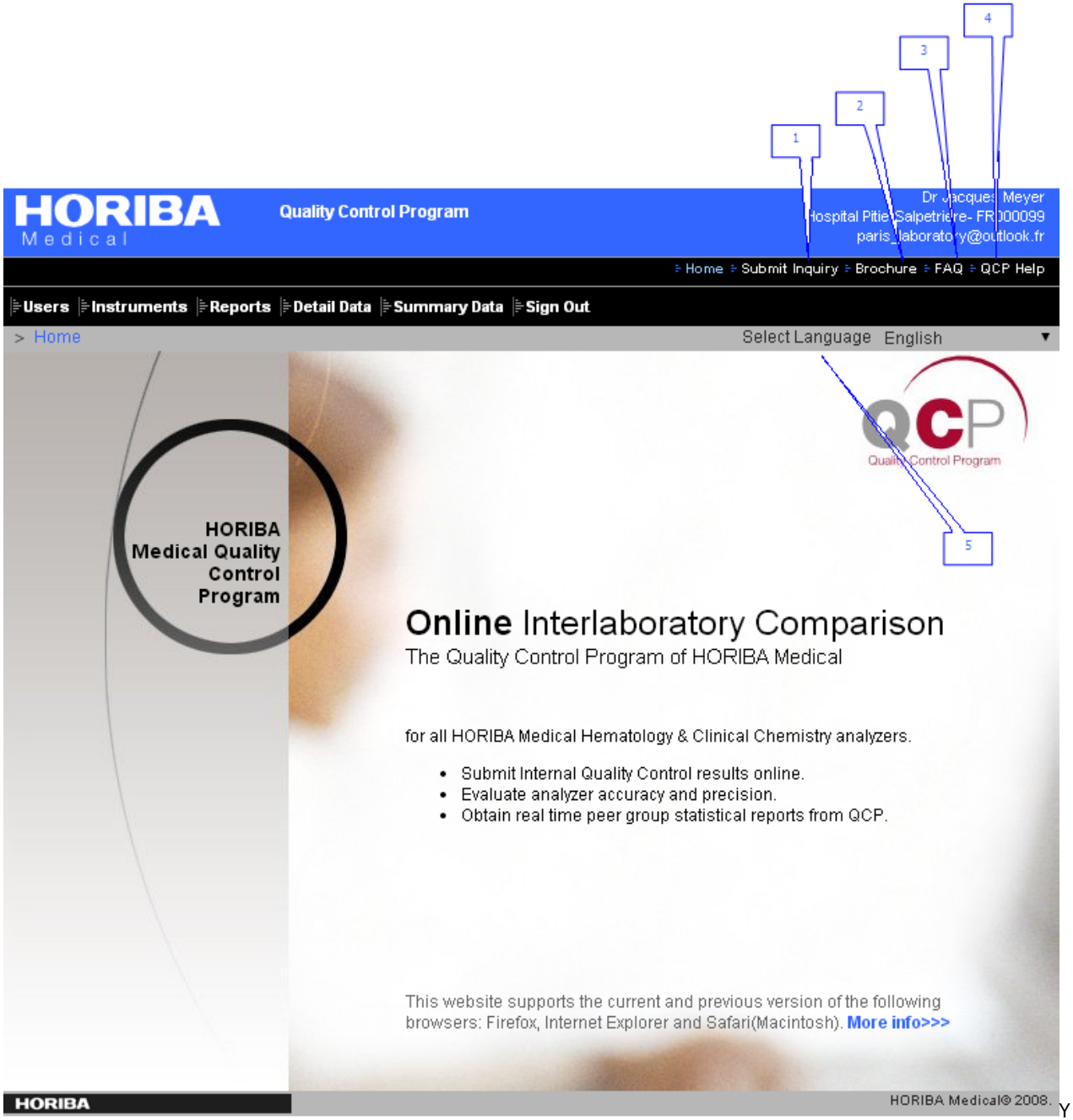
1/ Submit Inquiry
You may submit any inquiry by clicking on SUBMIT INQUIRY, completing the fields and clicking the SUBMIT INQUIRY button.

2/ Brochure
You may View and Print the QCP brochure by clicking on BROCHURE.

3/ FAQ
You can review the most Frequently Asked Questions by clicking on FAQ.

4/ QCP Help
Contextual help is available by clicking on QCP Help.

5/ Select Language



You can select your language in the dropdown box.

V- SCHEDULE

V-1- QC DATA SUBMISSION

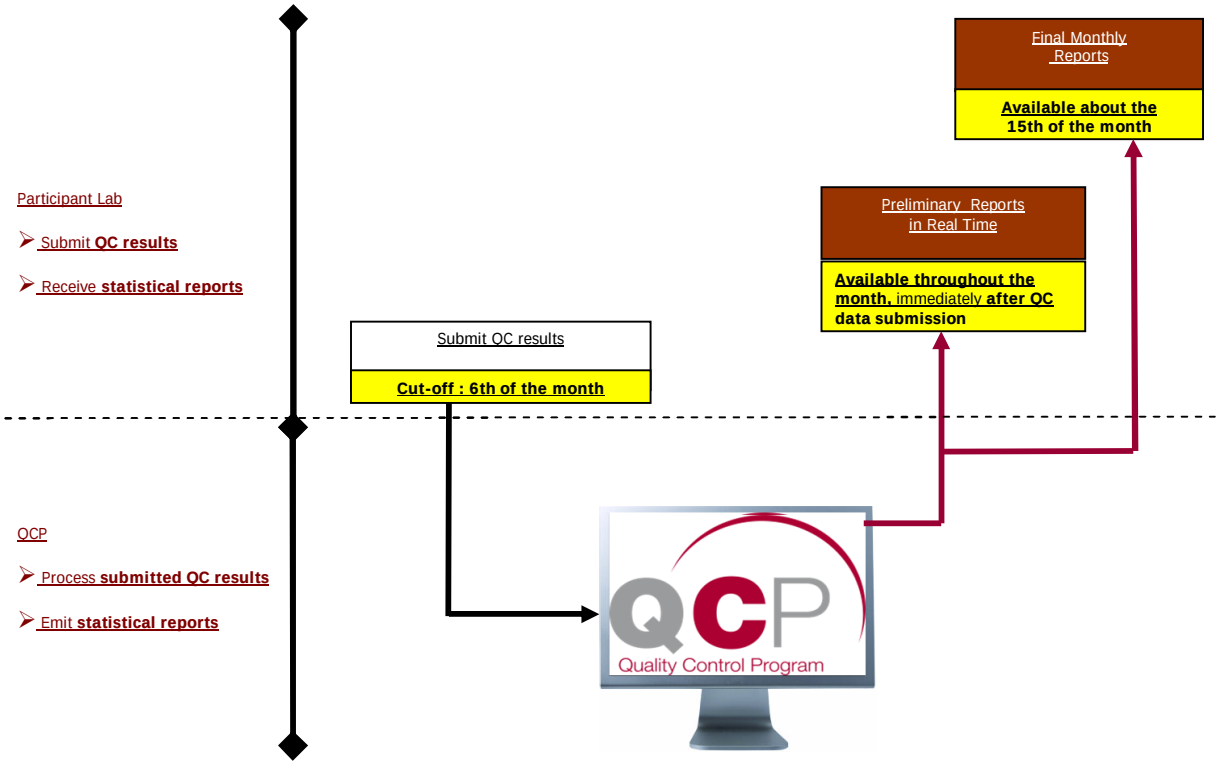
The cut-off date each month for QC data submission is the 6th of the month following the month of data collection in order to be included in the Final Monthly Report. Data for that month may still be submitted after that time. QCP will automatically recalculate the peer results to include your data and your report may be obtained online once any required review by QCP is done.

V-2- STATISTICAL REPORTS

- The Preliminary Reports are available in real time, immediately after QC data submission.
- The Final Monthly Reports are available about the 15th of the month following the month of data collection.

NOTE

- Submitted QC data and Statistical Reports are available online for a 24 month period.
- If the user has missed the 6th of the month cut-off date, it is still possible to submit the data for dates before the 6th of the month.
- The user can make corrections to the data entered for a prior month.
    - If corrections are made to a prior month, the new reports are valid when the corrections made do not have errors that need to be reviewed by Horiba Medical.
    - When the corrections made do have errors that need to be reviewed by Horiba Medical, the new reports are preliminary until the errors are reviewed for the peer group.



QCP WORKFLOW

VI - GLOSSARY

TERM	DESCRIPTION
2SD	Standard Deviation x 2. 95% of all results in a normal population fall within 2 SDs of the mean. Therefore, + or - 2 SD is considered an acceptable laboratory standard.
ABX Pentra ML	Exclusive smart "multilink" concept that allows up to 3 ABX Pentra hematology analyzers to be connected to the same validation station. For more information please go to Horiba Medical website : *http://www.horiba.com/fr/medical/*
Accuracy	Closeness to the true value or the measure of truth for a result.
Calibration Product	A material that is used to adjust the instrument that is based on or traceable to a reference preparation or material, and whose values are determined by acceptable reference methods.
Control Product	Materials that are solutions of chemically stabilized red cells, white cells and/or analogs, and platelets. The most important characteristics of control materials are their stability and physical similarity to real patient samples. They are used to monitor the performance of an instrument or procedure.
Country Peer Group	Group of all the peers in your country.
CV	Coefficient of Variation: The Standard Deviation expressed as a percentage of the mean. The smaller the CV, the more precise is the analytic method. $\%CV = \frac{SD}{Mean} \times 100$
Instruments Reporting	Number of reporting peers
Mean	The mathematical average for a group of data points. $\bar{x} = \frac{\sum_{i=1}^{N} x_i}{N}$
Number of results	Number of results entered per parameter per level
Peer	An instrument from a group of similar instrument types, using the same control product of the same lot and level.
Peer Group	Group of similar instrument types, using the same control product of the same lot and level.
PI	Precision Index: The ratio of a Lab's CV to the Group CV. PI is a measure of Relative Precision. A PI value between 0 and + 2 defines acceptable performance. $PI = \frac{Your\%CV}{Group\%CV}$
Precision	Reproducibility of replicate analyses.
Preliminary Report	Reports published before the end of a data collection month will be marked as Preliminary In QCP any report that has errors or data pending review will be marked "Preliminary." Also, any report generated before the 15th of the following month would be marked "Preliminary." Final reports will not be marked with any designation. The date and time the report was generated is always at the bottom of the report.
Rejected	Data outside the target limits for the control product used is rejected.
Run	Set of internal quality control results of different parameters collected the same date and time from an instrument
SD	Standard Deviation: A measure of the dispersion of a group of values around a mean, expressed in the units being measured. $SD = \sqrt{\frac{\sum (x_i - \bar{x})^2}{N-1}}$
SDI	Standard Deviation Index: The number of Group Standard Deviations by which a Lab's Mean differs from the Group Mean. SDI is a measure of Relative Accuracy. Accuracy indicates how close Your Mean is to the Group Mean. An SDI value between - 2 and + 2 defines acceptable performance. $SDI = \frac{Your\,Mean - Group\,Mean}{Group\,SD}$
Shift	An abrupt change in the pattern of data points on a plot, graph, or chart of data points.
Target value	A peer group specific value published on the assay sheet of the control product.
Trend	A gradual change in the pattern of data points on a plot, graph, or chart of data points.
World Peer Group	Group of all the peers in the world.

NOTES