

The logo for HORIBA Medical, featuring the company name in white text on a blue background with a grid pattern and light effects.

HORIBA
Medical

The text 'QCP*' is displayed in white on a dark blue rectangular background that has a folded corner effect on the left side.

QCP*

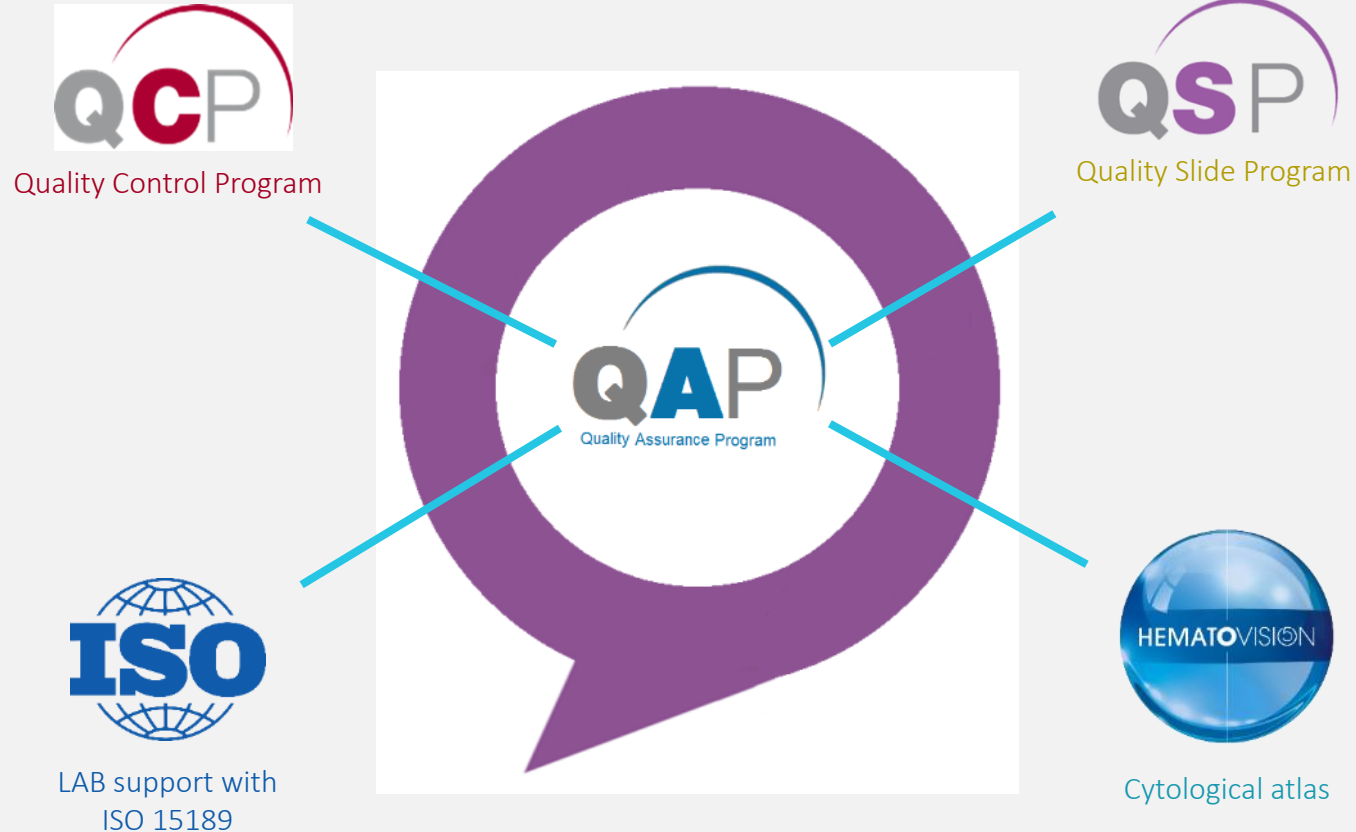
The text '*Quality Control Program' is displayed in white on a dark blue rectangular background, positioned below the 'QCP*' text.

*Quality Control Program





Heart of our quality services



The **QAP** (Quality Assurance Program) is a set of 4 different tools, to help the laboratories to improve their results and processes.

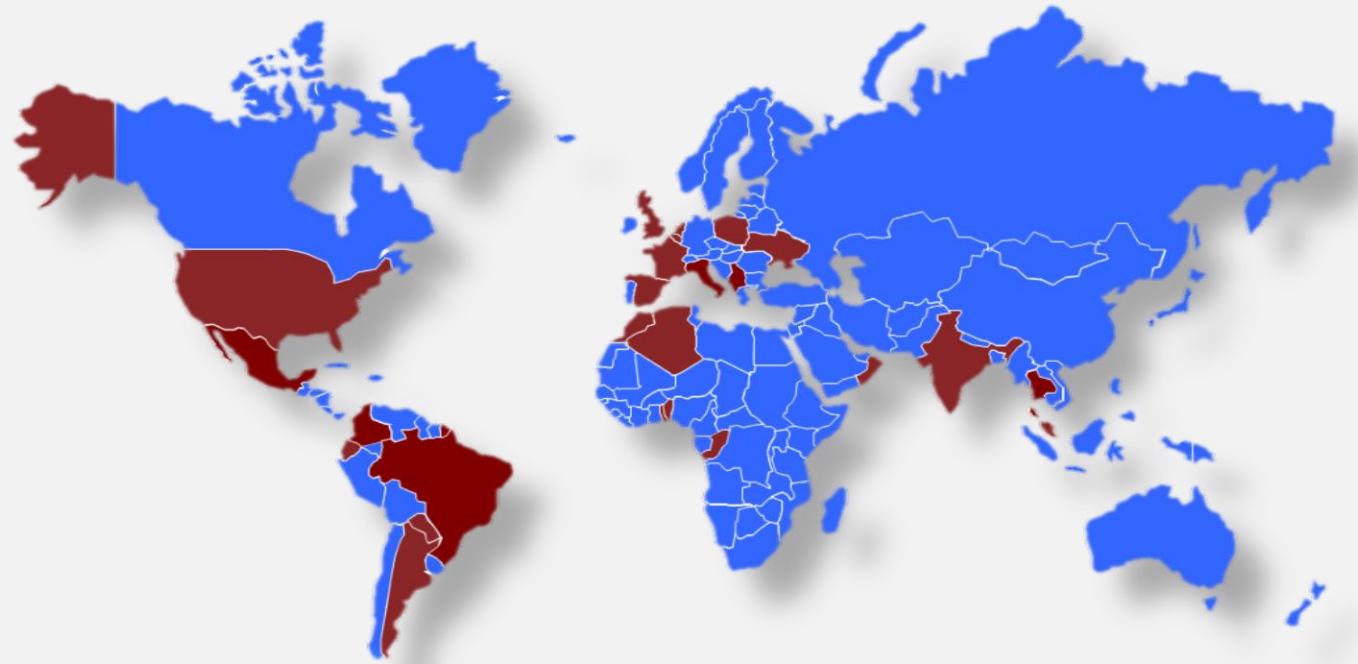




Overview



What's the QCP ?



The QCP is an **interlaboratory** data comparison program.

Collect data from about **800** labs all **over the world**.

Make available **8 statistical reports**.



Why the QCP ?

Objectives

Sending of the results on daily or monthly basis.

Comparison of **precision** and **accuracy** of the results.

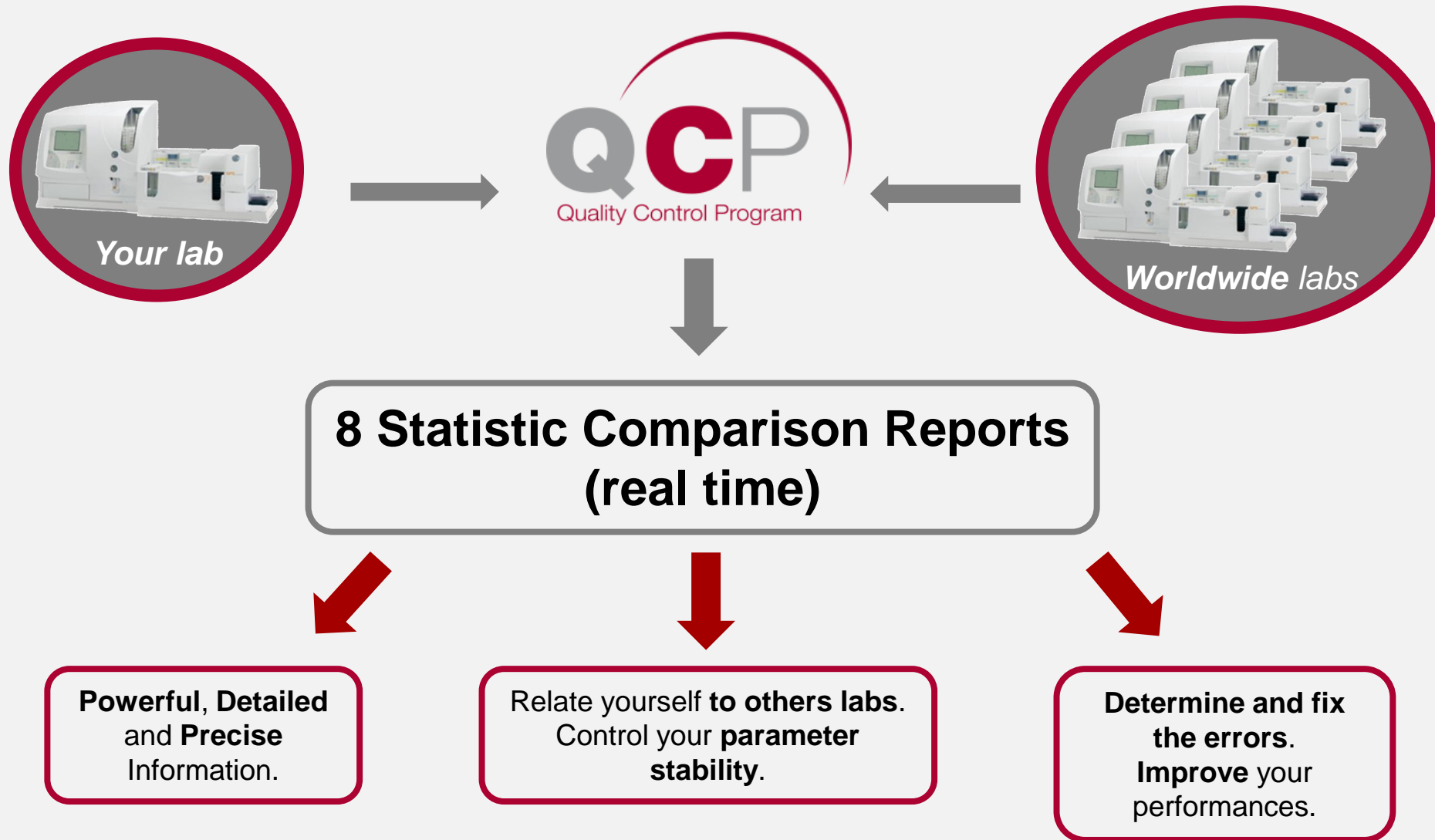
- ✓ Improve your performance and analysis reliability.
- ✓ Minimize the bias between measured values and means.
- ✓ Contributes to continuous quality improvement.

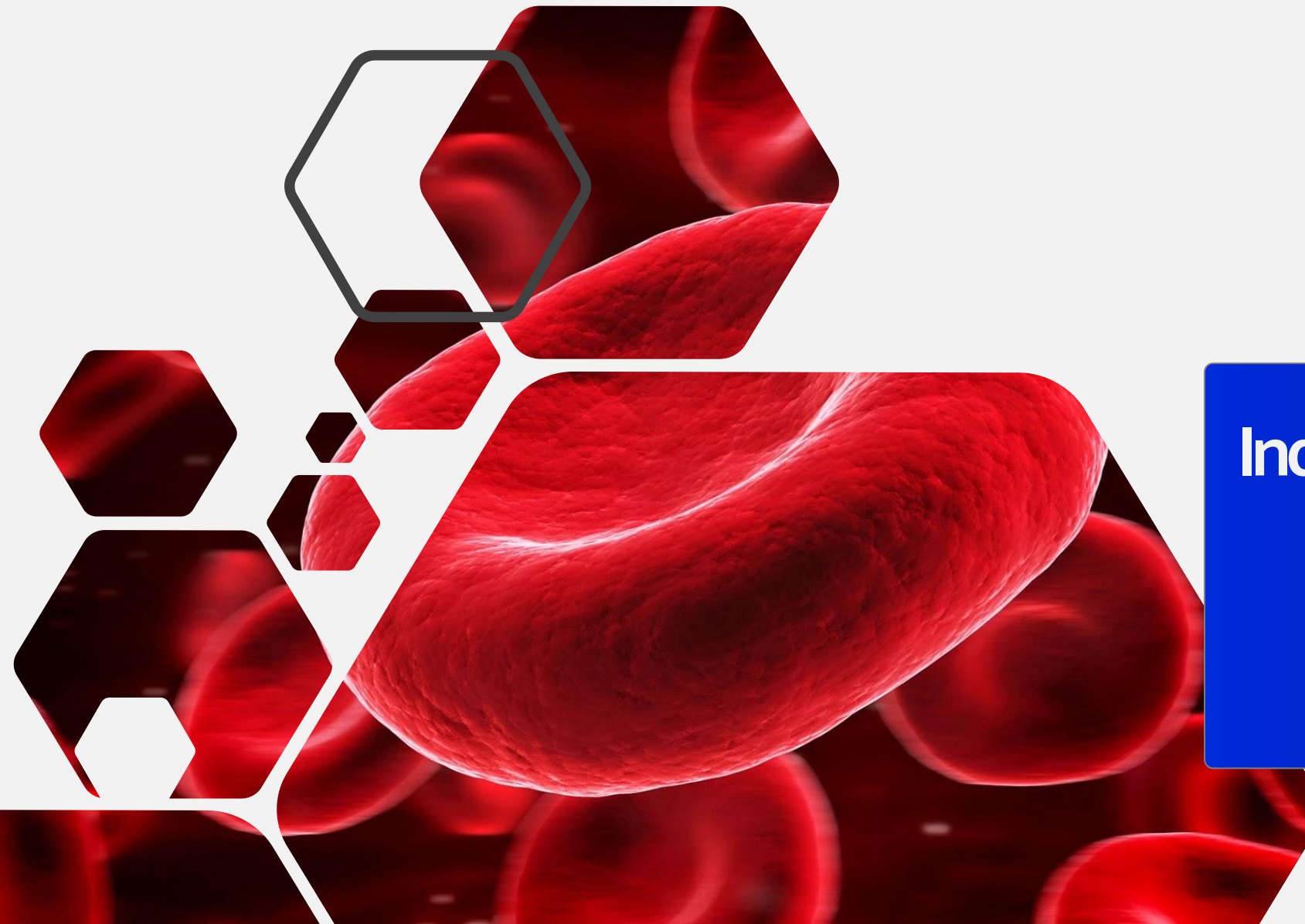


Bloods Analysis

Data transfer

Reports





Indicators Calculation

What are Precision and Accuracy ?

Precise



Precision refers to the **reproducibility** of a result.

Precise and Accurate



Closeness of a result to the **true value**.

Neither Precise nor Accurate



NONE of the results are close together, and **NONE** of them are in the bull's-eye. You cannot have accuracy without precision.





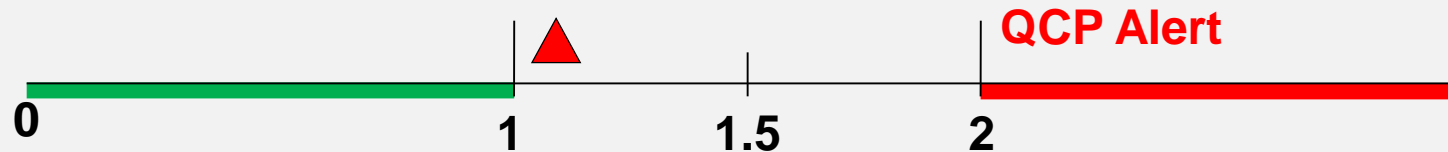
How is the Precision calculated ?

The **precision** is calculated by a ratio between the **CV of a laboratory** and the **CV of the peer group**.

$$CVI = PI = \frac{CV_{lab}}{CV_{peer\ group}}$$



CVI = 1 : equivalent performance.
CVI below 1 : better performance. 
CVI above 1 : worse performance. 



Recommended actions : Maintenance / Cleaning

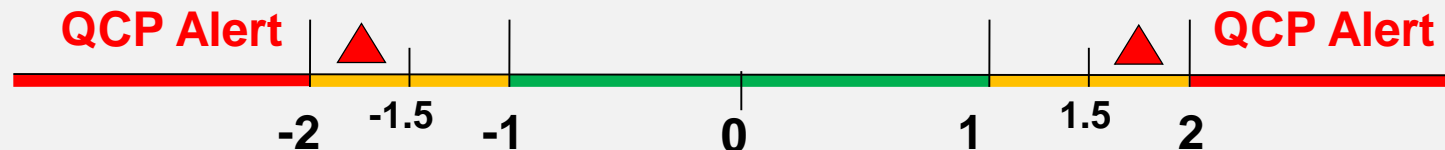
How is the Accuracy calculated ?

The **accuracy** is evaluated by calculating a "Z-score", corresponding to the **number of standard deviation** separating the **laboratory result** from the **peer group average**.

$$SDI = Z\text{-score} = \frac{\bar{X}_{lab} - \bar{X}_{peer\ group}}{SD_{peer\ group}}$$



- SDI = 0 : absence of bias.
- SDI = 0-0,5 : Excellent.
- SDI = 0,5-1 : Satisfying.
- SDI = 1-2 : Acceptable.
- SDI >2 : Action is mandatory.



Recommended actions : Adjustment of coefficients / Calibration

Mean, CV and SD Calculation

Mean : The mathematical average for a group of data points.

$$\bar{X} = \frac{\sum_{i=1}^N X_i}{N}$$

Coefficient of Variation : The Standard Deviation expressed as a percentage of the mean.

$$CV \% = \frac{SD}{Mean} \times 100$$

Standard Deviation : A measure of the dispersion of a group of values around a mean.

$$SD = \sqrt{\frac{\sum (X_i - \bar{X})^2}{N - 1}}$$

Uncertainty Calculation

"The laboratory must have procedures allowing the estimation of uncertainty of the measured values."

ISO 15189:2011 - § 5.5.1.3 Uncertainty of the analysis results

$$U_1 = SD$$

U_1 = Uncertainty linked to the Precision

$$U_2 = \frac{\text{Uncertainty \#}}{\sqrt{3}}$$

U_2 = Uncertainty linked to the Accuracy

$$U_c = \sqrt{U_1^2 + U_2^2}$$

U_c = Combined Uncertainty

$$U = 2U_c$$

U = Expanded Uncertainty

$$R = m \pm U$$

R = Result value

m = Measured value

Sigma Calculation

Sigma : Ratio between **required** and **effective** performances.

Sigma Lab

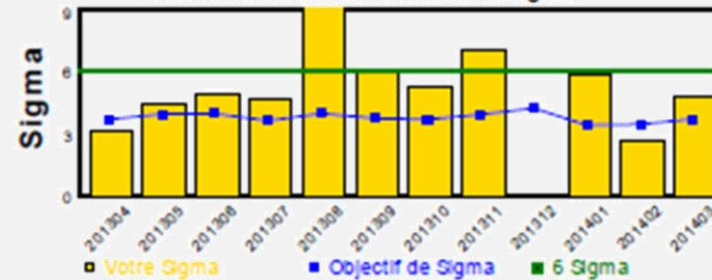
$$\text{Sigma} = \frac{(\text{TEa \%} - \text{Bias \%})}{\text{CV \%}}$$

TEa = admissible Total Error

Bias = Mean expressed in number of SD

Sigma > 6 : Performances are **optimal** (*Medical needs*).

Sigma = 3 : Performances are **minimal**.



Sigma Objective

$$\text{Sigma Obj} = \frac{(\text{Total Error \%} - \text{Bias \%})}{0,5 \times \text{CV \%}}$$

Sigma objective = Sigma of the peer group

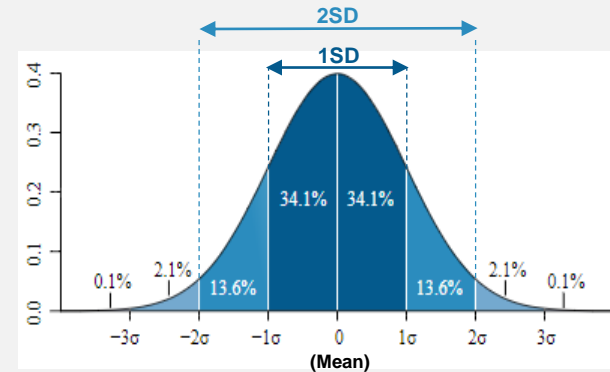
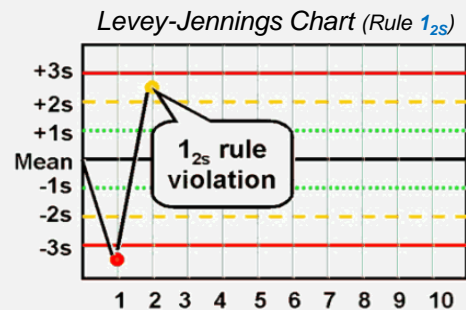
These rules are used to define if a measured value is considered as acceptable or not. The results are not correct if a **specific number of measured values** are **beyond a specific limit** (distance from the mean).

As convention, we write the rules under the following form : A_L (or A:L).

- "**A**" represents the **number of measured values** which have to be beyond the limits to **reject the results**.
- "**L**" represents the specific limit (indicated in number of Standard Deviation, SD).

Example 1 :

Rule 1_{2S} : The results are rejected if there is **ONE** measured value beyond **TWO** Standard Deviation.



Example 2 :

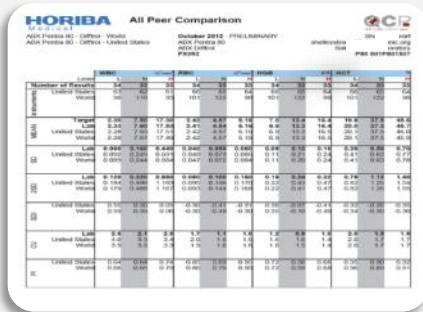
Rule $1_{3S}/2_{2S}$: The results are rejected if there is **ONE** measured value beyond **THREE** Standard Deviations **OR** **TWO** measured values beyond **TWO** Standard Deviations.

1SD : frame 68,2 % of all measured values.
2SD : frame 95 % of all measured values.
3SD : frame 99,6 % of all measured values.
4SD : frame 99,8 % of all measured values.



Real-Time Reports

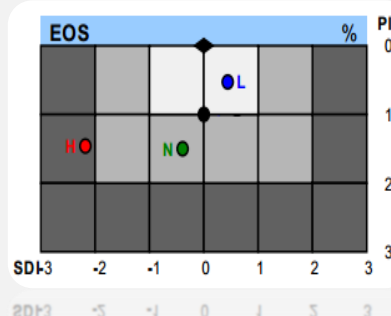
All Peer Comparison



Performances, Comparisons and Uncertainties



Performance Index



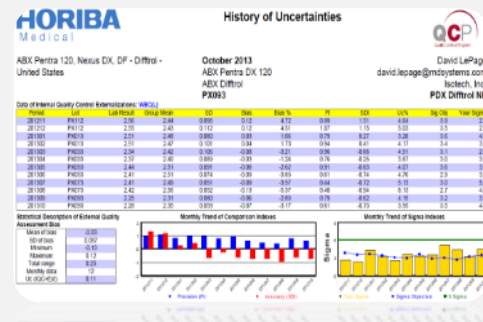
Other Instrument Group



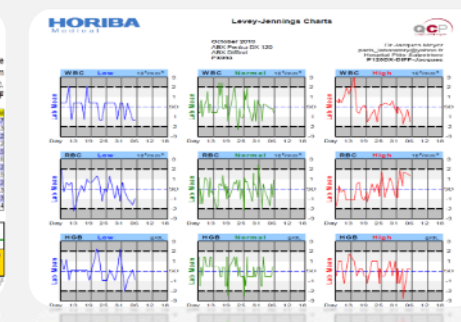
All Peer History



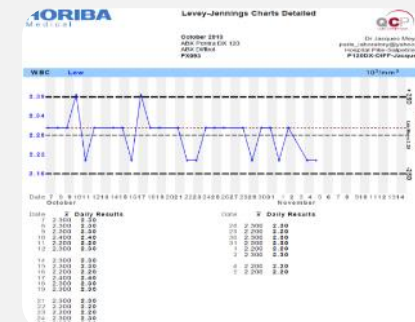
History of Uncertainties



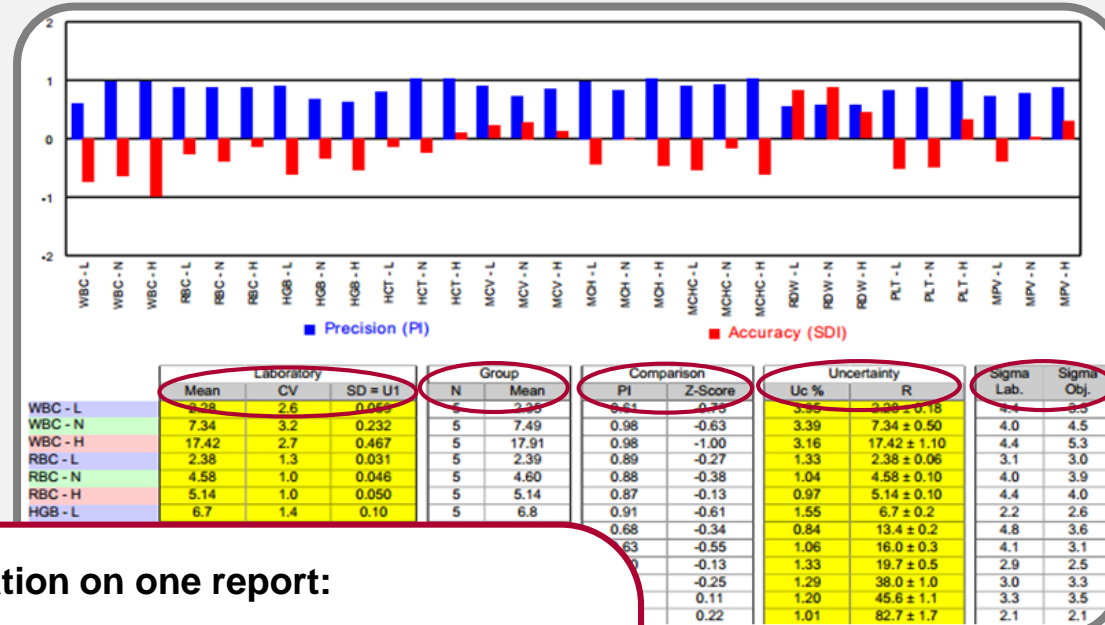
Levey-Jennings Charts



Detailed Levey-Jennings Charts



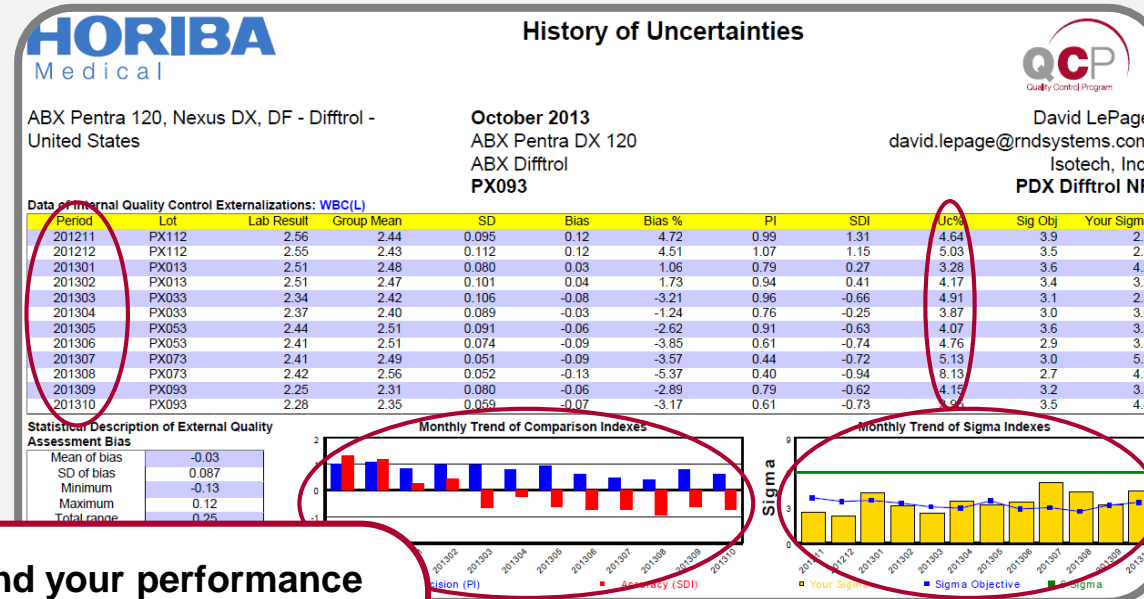
Performance, Comparisons and Uncertainties



Display the important information on one report:

- Chart : **Precision** and **Accuracy** at a glance.
- **Laboratory performances** (IQC data): Mean, CV, SD.
- **Peer Group data**: number of participants and mean (true value to achieve).
- **Comparison** : PI – Z-score
- **Uncertainty** calculation.
- **Your sigma** (Lab) / Peer Group sigma (Objective) for comparison.

History of Uncertainties



Follow the IQC evolution and your performance improvement :

- Over a 12 months period.
- Calculation of Combined uncertainty (IQC+EEQ).
- Chart : Precision/Accuracy evolution.
- Chart : Monthly evolution of sigma lab.

All Peer Comparison

Level	WBC			RBC			HGB			
	L	N	H	L	N	H	L	N	H	
Number of Results	34	33	33	34	33	33	34	33	33	
Instruments	United States	63	62	61	66	65	64	66	65	64
	World	98	118	95	101	122	98	101	122	98
MEAN	Target	2.30	7.50	17.30	2.42	4.57	5.18	7.0	13.4	16.4
	Lab	2.33	7.60	17.53	2.41	4.54	5.16	6.9	13.3	16.4
	United States	2.28	7.53	17.51	2.42	4.57	5.19	6.9	13.3	16.5
	World	2.28	7.51	17.49	2.42	4.57	5.19	6.9	13.3	16.5
SD	Lab	0.060	0.160	0.440	0.040	0.050	0.080	0.08	0.12	0.16
	United States	0.092	0.249	0.591	0.048	0.073	0.085	0.11	0.21	0.24
	World	0.089	0.244	0.584	0.047	0.072	0.084	0.11	0.20	0.24
2SD	Lab	0.120	0.320	0.880	0.080	0.100	0.160	0.16	0.24	0.32
	United States	0.184	0.498	1.183	0.095	0.146	0.170	0.19	0.30	0.38
	World	0.179	0.488	1.167	0.093	0.144	0.167	0.19	0.29	0.37
SDI	United States	0.55	0.30	0.03	-0.30	-0.41				
	World	0.59	0.39	0.06	-0.30	-0.49				
CV	Lab	2.6	2.1	2.5	1.7	1.1				
	United States	4.0	3.3	3.4	2.0	1.6				
	World	3.9	3.2	3.3	1.9	1.6				
PI	United States	0.64	0.64	0.74	0.85	0.69				
	World	0.66	0.65	0.75	0.86	0.70				

7 values...

- Number of instruments
- Mean
- Standard deviation (SD)
- 2SD
- SDI (Z-score)
- Coefficient of variation (CV)
- Precision index (PI)

... compared to peer groups :

- Assay target
- Laboratory
- Specific group
- Country
- World

All Peer History

WBC		Low								
Year		2014	2014	2014	2014	2014	2014	2014	2014	2014
Month		Aug	Jul	Jul	Jun	May	Apr	Mar	Feb	Jan
Lot		MX074	MX074	MX054	MX054	MX054	MX034	MX034	MX014	MX014
Number of Results		15	32	15	15	31	16	33	28	31
Instruments	United States	113	255	28	265	268	269	272	269	267
	World	116	257	30	268	271	274	275	274	270
MEAN	Target	2.00	2.00	1.90	1.90	1.90	2.00	2.00	2.00	2.00
	Lab	2.10	2.00	2.00	1.90	1.90	2.00	2.00	2.00	2.00
	United States	2.08	2.05	1.94	1.90	1.90	2.00	2.00	2.05	2.04
	World	2.07	2.05	1.94	1.90	1.90	2.00	2.00	2.05	2.04
SD	Lab	0.070	0.070	0.060	0.060	0.050	0.080	0.090	0.090	0.060
	United States	0.091	0.093	0.115	0.086	0.088	0.099	0.091	0.092	0.097
	World	0.092	0.093	0.115	0.086	0.088	0.098	0.091	0.092	0.097
2SD	Lab	0.140	0.140	0.120	0.120	0.100	0.160	0.180	0.180	0.120
	United States	0.182	0.187	0.231	0.172	0.177	0.197	0.181	0.184	0.194
	World	0.183	0.187	0.229	0.173	0.177	0.197	0.181	0.184	0.195
SDI	United States	0.27	-0.56	0.55	-0.03	0.00	-0.05	0.03	-0.51	-0.43
	World	0.29	-0.56	0.55	-0.03	0.00	-0.05	0.02	-0.51	-0.43
CV	Lab	3.3	3.5	3.0	3.2	2.6	4.0	4.5	4.5	3.0
	United States	4.4	4.6	6.0	4.5	4.7	4.9	4.5	4.5	4.8
	World	4.4	4.5	5.9	4.5	4.7	4.9	4.5	4.5	4.8
PI	United States	0.76	0.77	0.50	0.70	0.57	0.81	0.99	1.00	0.63
	World	0.75	0.77	0.51	0.70	0.57	0.82	0.99	1.00	0.63

Follow the **comparison evolution** over a **12 months** period and identify the positioning variations.

PI	United States	0.76	0.77	0.50	0.70	0.57	0.81	0.99	1.00	0.63
PI	World	0.75	0.77	0.51	0.70	0.57	0.82	0.99	1.00	0.63
CV	United States	4.4	4.6	6.0	4.5	4.7	4.9	4.5	4.5	4.8
CV	World	4.4	4.5	5.9	4.5	4.7	4.9	4.5	4.5	4.8

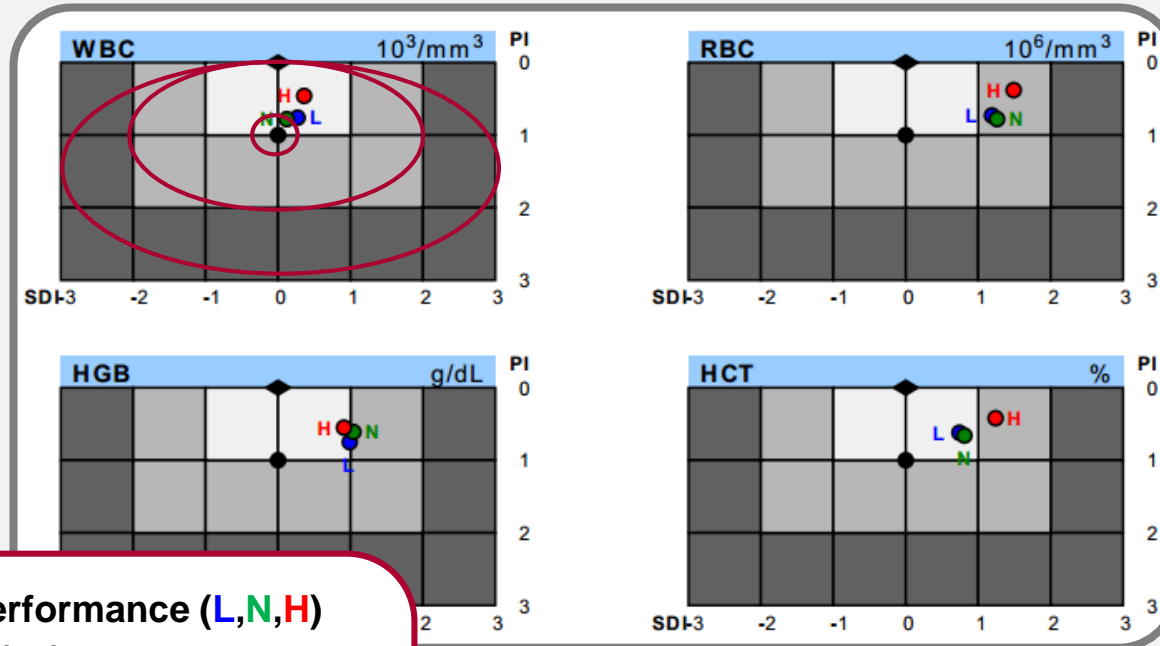


Other Instrument Group

	WBC $10^3/mm^3$			RBC $10^6/mm^3$			HGB g/dL		
Level	L	N	H	L	N	H	L	N	H
Instruments	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
SDI	-0.73	-0.63	-1.00	-0.27	-0.38	-0.13	-0.61	-0.34	-0.55
CV	4.2	3.2	2.7	1.5	1.1	1.1	1.6	1.1	1.3
	MCV fL			MCH pg			MCHC g/dL		
Instruments	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
SDI	0.22	0.28	0.12	-0.45	-0.02	-0.47	-0.55	-0.16	-0.61
CV	1.1	1.1	1.1	1.7	1.3	1.3	1.9	1.4	1.4
	PLT $10^3/mm^3$			MPV fL			LYM #		
Instruments	5	5	5	5	5	5	3	3	3
Mean	66	246	501	8.9	8.9	8.6	0.70	2.16	2.92
SDI	-0.52	-0.49	0.33	-0.39	0.03	0.31	-1.32	-0.95	-1.14
CV	7.7	3.8	3.7	3.4	2.4	2.3	14.2	12.6	12.5
	NEU #			EOS #			BAS #		
Instruments	3	3	3	3	3	3	3	3	3
Mean	1.20	4.17	12.50	0.19	0.32	0.19	0.19	0.19	0.19
SDI	1.19	0.78	0.90	0.65	-0.02	0.65	0.65	0.65	0.65
CV	6.6	6.4	4.6	22.5	20.3	20.3	20.3	20.3	20.3
	MON %			NEU %					
Instruments	5	5	5	5	5	5			
Mean	5.1	6.7	6.5	52.8	56.2	56.2			
SDI	-0.75	-0.26	-0.62	1.29	1.00	1.00			
CV	29.6	32.0	39.4	6.5	6.3	6.3			

- Performances of **other peer group**.
- For others instruments which have the **same control product, same lot and same level** than yours.

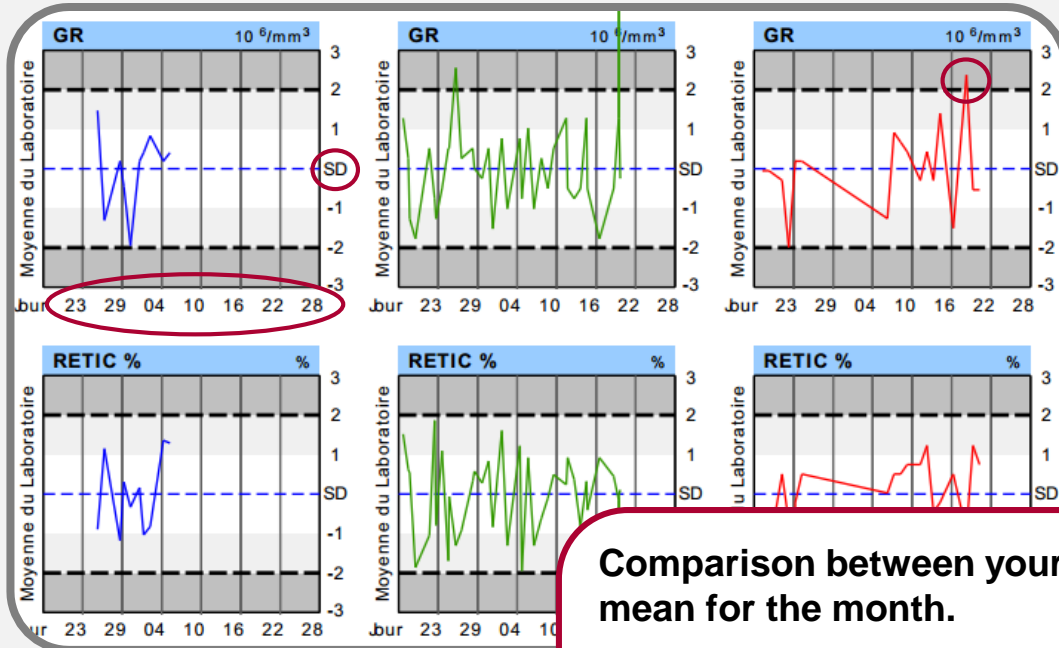
Performance



Positioning of your value performance (L,N,H) relatively to the peer group (●):

- Ideal value zone (white).
- Acceptable value zone (grey).
- Unacceptable value zone (black).

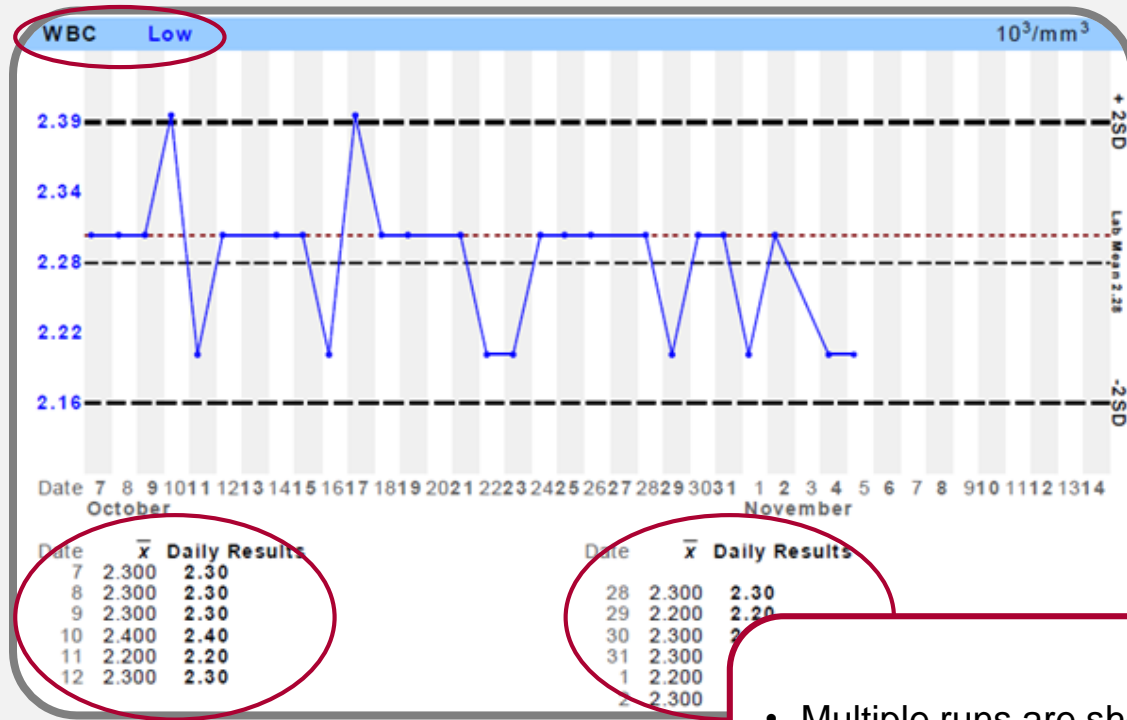
Levey-Jennings



Comparison between your daily results and your overall mean for the month.

- Visual representation of the **parameter variability**.
- Allow you to analyze the variability **over time**.
- Control if some **aberrant values** were included.

Detailed Levey-Jennings



- Multiple runs are shown **individually**.
- Detail **values** in addition of the graph.





Get a dedicated **certificate** of QCP participation at any time.

Useful in **audit** cases.

Compliance with **ISO 15189**

"The laboratory must have procedures allowing the estimation of uncertainty of the measured values."
ISO 15189:2011 - § 5.5.1.3 Uncertainty of the analysis results

QCP Compatible Instruments:

Hematology	YH1500/2500	YH550	Pentra 120	Pentra 80	Pentra 60	Micros
	YH500	Micros CRP				
Clinical Chemistry	Pentra C400	Pentra C200				
			Hemostasis			ESR
		Yumizen G ranges			Auto Compact Inversa 24 ML	



Practical Sheet

- ① **Connection**
- ② To add a new instrument
- ③ Entry and submit results
- ④ Data exportation

Primary Functions

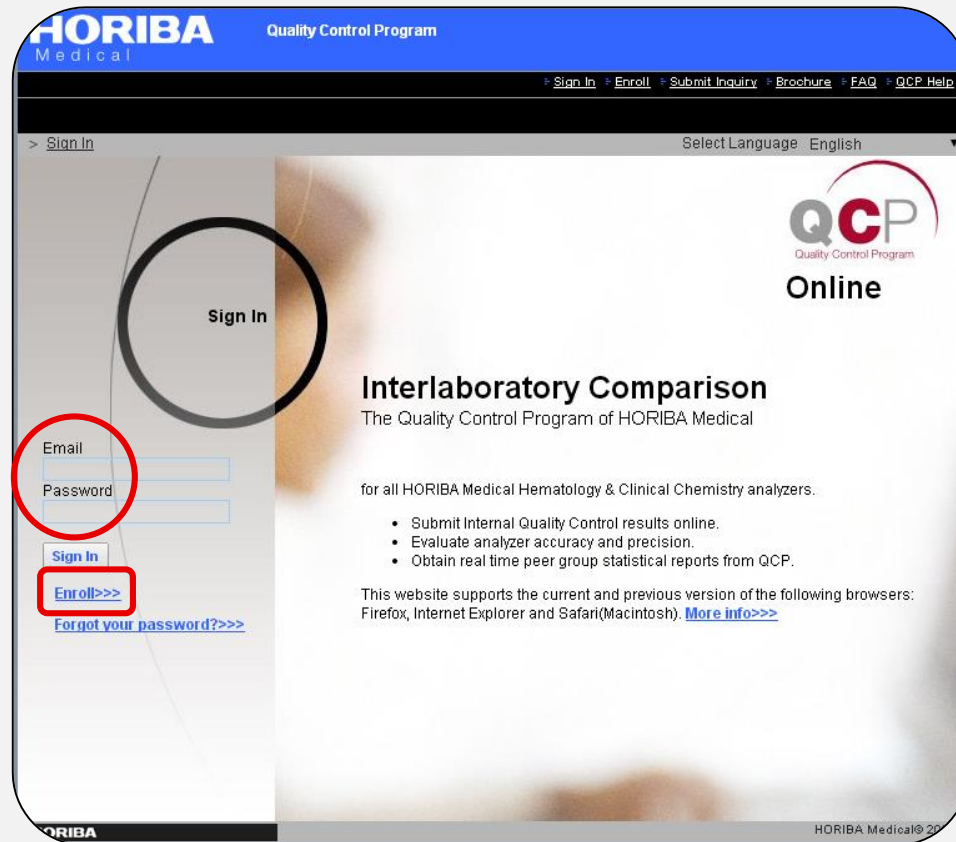
Secondary Functions

- ⑤ Delete / modify data
- ⑥ To add secondary users



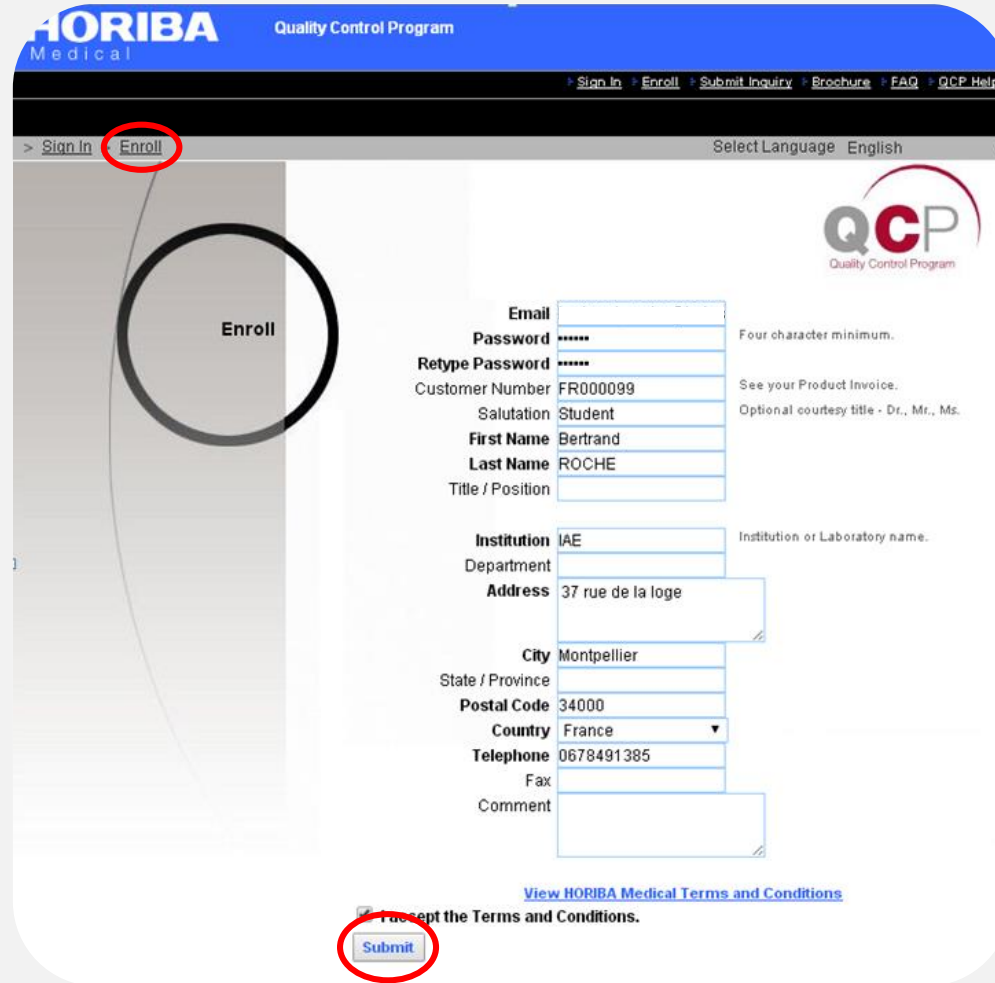
Primary Functions

<http://qcp.horiba-abx.com>



The first step is the **connection** to get access to the QCP service.

If you don't already have the information access, click on **"Enroll"**.



Enroll

QCP
Quality Control Program

Sign In Enroll Submit Inquiry Brochure FAQ QCP Help

Sign In Enroll Select Language English

Email

Password ***** Four character minimum.

Retype Password *****

Customer Number FR000099 See your Product Invoice.

Salutation Student Optional courtesy title - Dr., Mr., Ms.

First Name Bertrand

Last Name ROCHE

Title / Position

Institution IAE Institution or Laboratory name.

Department

Address 37 rue de la loge

City Montpellier

State / Province

Postal Code 34000

Country France

Telephone 0678491385

Fax

Comment

[View HORIBA Medical Terms and Conditions.](#)

I accept the Terms and Conditions.

Submit

Here you will fill the form with **personal information.**

Then you will be **enrolled** and **registered** as Main user.

Bold writing corresponds to the **mandatory information.**

TO ADD A NEW INSTRUMENTS

MANDATORY informations

Instrument --New Instrument--
Instrument Name P1200X-DIFF_Bertrand
Instrument Mode ABX Pentra DX 12C
Serial Number 108P1200008
Year of installation 2012
Software Version 1.1.0
Control Product ABX DIFFTROL
Levels
 Low
 Normal
 High
Calibration Method
 Standard
 Instrument Correlation
Instrument Status

Show	Parameter	Unit	Reagent	Calibration Product
<input checked="" type="checkbox"/>	WBC	x10 ³ /mm	ABX Alphalyse 360	ABX Minocal
<input checked="" type="checkbox"/>	RBC	x10 ⁶ /mm		
<input checked="" type="checkbox"/>	HGB	g/dL		
<input checked="" type="checkbox"/>	HCT	%		
<input checked="" type="checkbox"/>	MCV	um ³		
<input checked="" type="checkbox"/>	MCH	pg		
<input checked="" type="checkbox"/>	MCHC	g/L		
<input checked="" type="checkbox"/>	RDW	%		
<input checked="" type="checkbox"/>	PLT	x10 ³ /mm		
<input checked="" type="checkbox"/>	MPV	um ³		
<input checked="" type="checkbox"/>	LYM #	x10 ³ /uL		
<input checked="" type="checkbox"/>	MON #	x10 ³ /uL		
<input checked="" type="checkbox"/>	NEU #	x10 ³ /uL		
<input checked="" type="checkbox"/>	EOS #	x10 ³ /uL		
<input checked="" type="checkbox"/>	BAS #	x10 ³ /uL		
<input checked="" type="checkbox"/>	LYM %	%		
<input checked="" type="checkbox"/>	MON %	%		
<input checked="" type="checkbox"/>	NEU %	%		
<input checked="" type="checkbox"/>	EOS %	%		
<input checked="" type="checkbox"/>	BAS %	%		

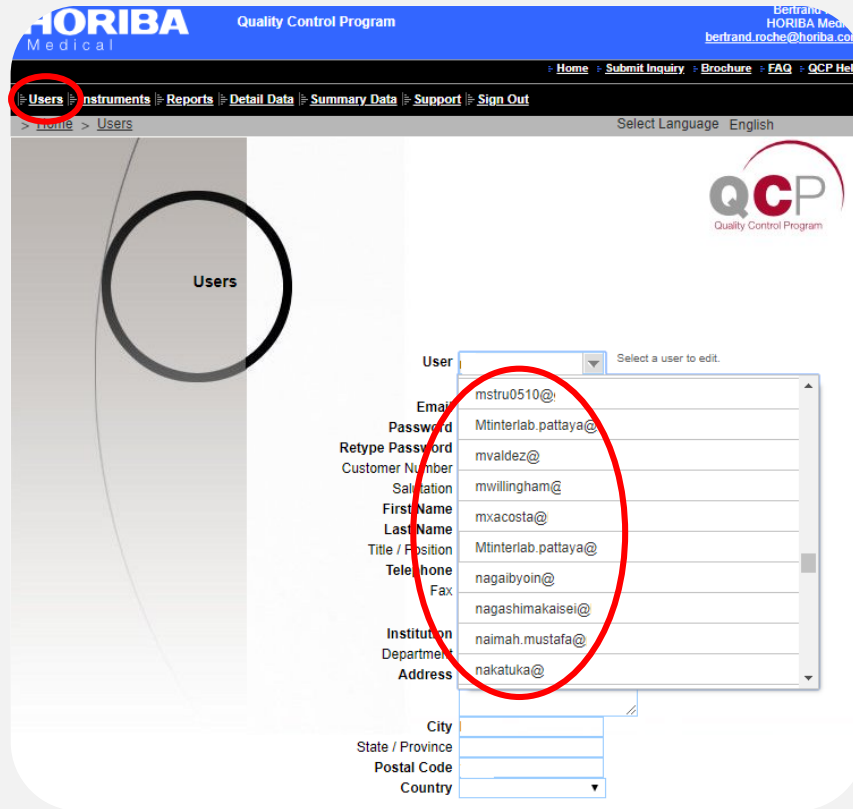
Submit
Inactivate

The second step is to **add an instrument** with all its characteristics. Be careful not to forget the **mandatory information**.

After to have submit this registration, you will be able to **upload data**.

Once you receive an email saying :
*"your **instrument** has been **activated**"*
 You will be able to **View Reports**.

TO ACTIVATE AN INSTRUMENT 1/2



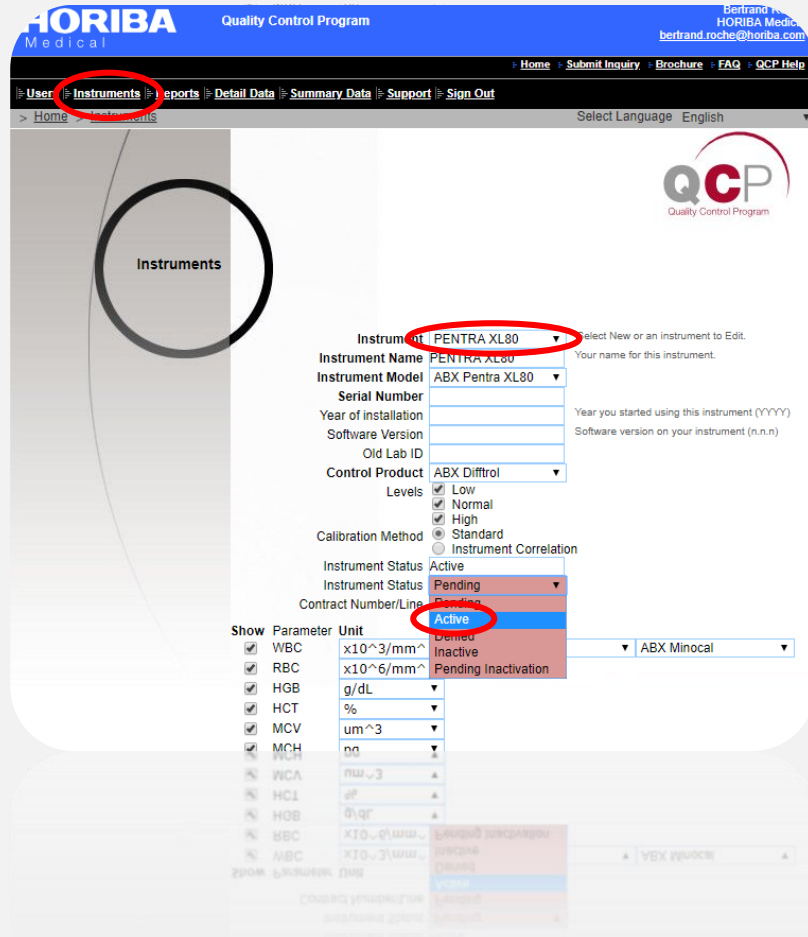
The screenshot shows the HORIBA Quality Control Program web interface. The 'Users' menu item in the top navigation bar is circled in red. A large black circle highlights the 'Users' label in the left sidebar. A dropdown menu is open, showing a list of users. The user 'nagashimakaisei@' is circled in red. The dropdown menu includes the following fields:

User	Select a user to edit.
mstru0510@	
Mtinterlab.pattaya@	
mvaldez@	
mwillingham@	
mxacosta@	
Mtinterlab.pattaya@	
nagaibyoin@	
nagashimakaisei@	
naimah.mustafa@	
nakatuka@	

Other fields visible in the form include: Email, Password, Retype Password, Customer Number, Salutation, First Name, Last Name, Title / Position, Telephone, Fax, Institution, Department, Address, City, State / Province, Postal Code, and Country.

On the "Users" menu, select the user which need to get their instruments activated.

TO ACTIVATE AN INSTRUMENT 2/2



The screenshot shows the HORIBA Quality Control Program web interface. The 'Instruments' menu is circled in red. The 'Instrument' dropdown is also circled in red and set to 'PENTRA XL80'. The 'Instrument Status' dropdown is set to 'Active', which is also circled in red. The 'Contract Number/Line' dropdown is set to 'ABX Minocal'.

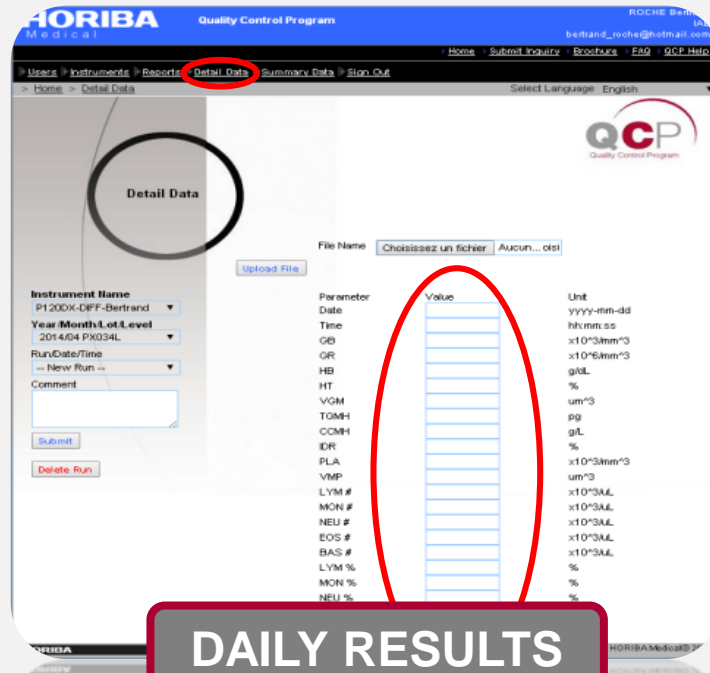
Instrument PENTRA XL80
Instrument Name PENTRA XL80
Instrument Model ABX Pentra XL80
Serial Number
Year of installation
Software Version
Old Lab ID
Control Product ABX Diffrol
Levels Low Normal High
Calibration Method Standard Instrument Correlation
Instrument Status Active
Instrument Status Pending
Contract Number/Line ABX Minocal

Show	Parameter	Unit	Instrument Status
<input checked="" type="checkbox"/>	WBC	$\times 10^3/\text{mm}^3$	Active
<input checked="" type="checkbox"/>	RBC	$\times 10^6/\text{mm}^3$	Inactive
<input checked="" type="checkbox"/>	HGB	g/dL	Pending Inactivation
<input checked="" type="checkbox"/>	HCT	%	
<input checked="" type="checkbox"/>	MCV	μm^3	
<input checked="" type="checkbox"/>	MCH	pg	
<input type="checkbox"/>	WCA	μm^3	
<input type="checkbox"/>	HCL	pg	
<input type="checkbox"/>	HGB	g/dL	
<input type="checkbox"/>	RBC	$\times 10^6/\text{mm}^3$	
<input type="checkbox"/>	WBC	$\times 10^3/\text{mm}^3$	

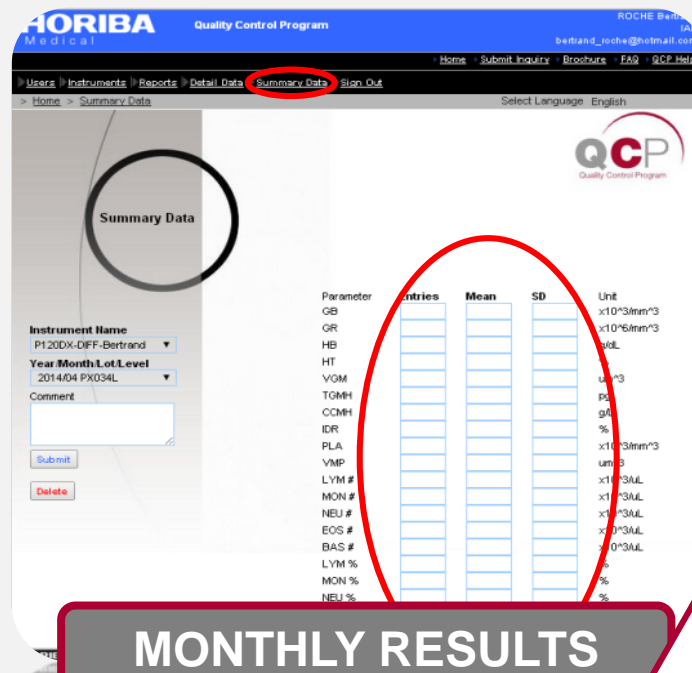
Then, to activate an instrument, go on the "Instrument" menu, and select the instrument.

Then, to activate it, select "Active" in the "Instrument status" drop down list.

Click on submit to validate the activation.



DAILY RESULTS



MONTHLY RESULTS

- **Manual**
 - **Automatic Upload**
- for the followings instruments :

- ABX Pentra 60C+ (version 2.4.1)
- ABX Pentra 120 Retic (version 4.8.0)
- ABX Pentra 120 (version 4.8.0)
- Pentra 80/XLR
- Pentra DX Nexus
- Pentra ML

Manual

The next step is to **share** your results with the QCP.

There is **two ways** to do it, daily and monthly.

Only the daily one could be **automatic**.

ENTRY AND SUBMIT RESULTS (2)



You have to choose between enter values
in **detail** or **summary** data.
You will be only able to enter values
in **one of them**.



Instrument Name
P120DX-DIFF-Bertrand ▼

Year/Month/Lot/Level
*2014/04 PX034L ▼

Run/Date/Time
001 2014-04-02 11:00:00 ▼

Comment

“*” means that **data** has already been **entered** and
stored as a **run**.

(for this particular Year/Month/Lot/Level)



The **USB key** plugged onto the **ML**, allows you to collect every files **automatically** send by the instruments, and then to share them on the **QCP website**.



Secondary Functions

This step allow you to correct the data : you just have to go in the **"Detail Data"** section, and directly **modify** or **delete** the number you entered, and click on "submit".

File Name: Choisissez un fichier Aucun...hoisi

Upload File

Parameter	Value	Unit
Date	05/03/2014	dd/mm/yyyy
Time	18:01:58	hh:mm:ss
WBC	2.70	x10 ⁹ /L
RBC	2.28	x10 ¹² /L
HGB	6.5	g/dL
HCT	18.6	%
MCV	82.0	fL
MCH	78.5	pg
MCHC	34.9	g/dL
RDW	14.6	%
PLT	78	x10 ⁹ /L
MPV	9.0	fL
LYM	0.83	#
MON	0.08	#
NEU	1.52	#
EOS	0.18	#
BAS	0.08	#

Submit

Delete Run

Delete All Runs



File Name: Choisissez un fichier Aucun...hoisi

Upload File

Parameter	Value	Unit
Date	05/03/2014	dd/mm/yyyy
Time	18:01:58	hh:mm:ss
WBC	2.70	x10 ⁹ /L
RBC	2.28	x10 ¹² /L
HGB	6.5	g/dL
HCT	18.6	%
MCV	82.0	fL
MCH	78.5	pg
MCHC	34.9	g/dL
RDW	14.6	%
PLT	78	x10 ⁹ /L
MPV	9.0	fL
LYM	0.83	#
MON	0.08	#
NEU	1.52	#
EOS	0.18	#
BAS	0.08	#

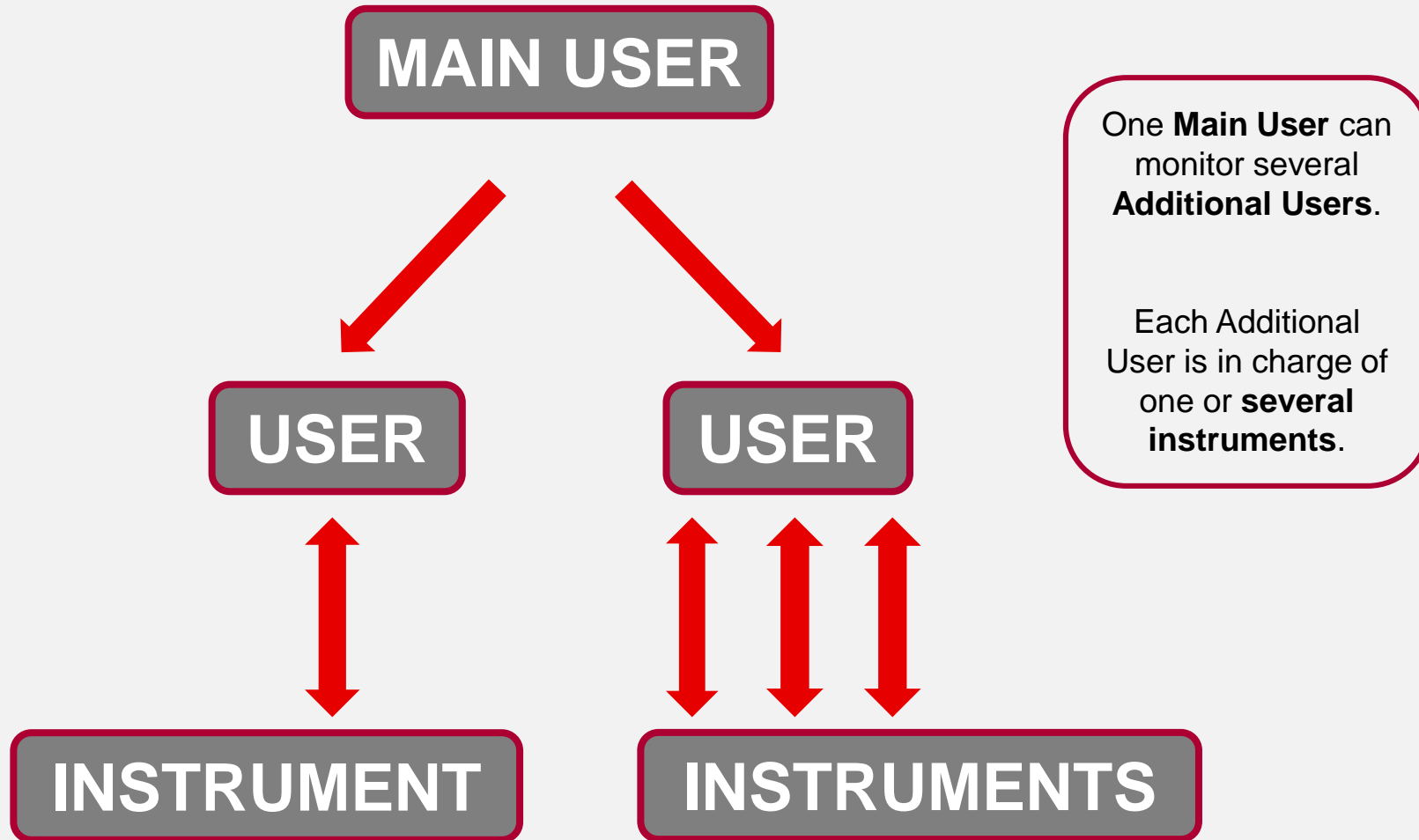
Submit

Delete Run

Delete All Runs

The procedure is the same for the **"summary data"** section.

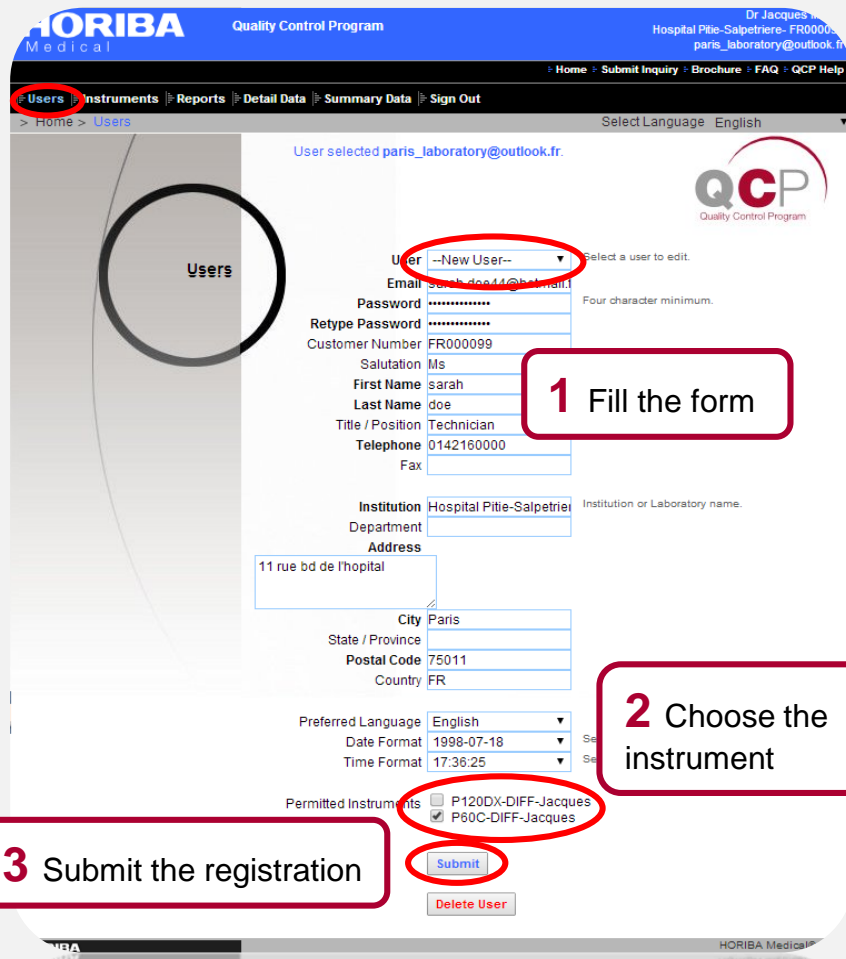
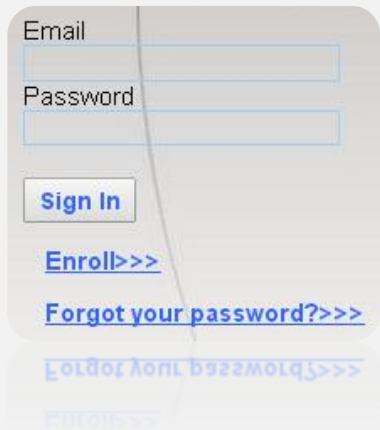
CREATE ADDITIONAL USERS



CREATE ADDITIONAL USERS (2)

To define users able to manage instruments, you can add people in the "Users" section. Then you choose what instruments they can manage.

Connect yourself as "MAIN USER" :



1 Fill the form

2 Choose the instrument

3 Submit the registration

Thank you for enrolling "sarah.doe44@hotmail.fr".
NewUser Email sent to sarah.doe44@hotmail.fr.



For other and more detailed information, see the **user manual.**





Thanks for your attention

HORIBA Medical Training Division

✉ Training.med@horiba.com

🔗 https://www.horiba.com/en_en/service/training/product-training/medical-product-training/