

This is
Bio-Rad.



ISO 15189 QC Requirements : The Bio-Rad Solutions

Jean-Baptiste Raimbourg
Category development manager

Introduction

Why Are Controls Used?

- ✓ To measure the **precision** of the tests
- ✓ To measure the **trueness**
- ✓ To verify the calibration
- ✓ Because the systems fail
- ✓ Because manufacturers ask for it
- ✓ Sometimes because it's mandatory ?



Yes for all these reasons , ...

=> but first and foremost, **to validate the reliability of patient results**, because results of laboratory tests are used for diagnosis and treatment planning.

Introduction

2 conditions for my QC to validate **the reliability of patient results** :

Having the good QC Material



ISO 15189:2012

Using it and Managing the data in the correct way



5.6.2 Quality control

5.6.2.1 General

*The laboratory **shall** design quality control procedures that verify the attainment of the intended quality of results.*

BIO-RAD

Accreditation Requirements

Bio-Rad Solutions

QC as close as possible to patient samples

Participate in an interlaboratory program

Perform internal quality control

Ensure traceability of QC results

Establish performance goals

Perform method validation Determine measurement uncertainty

Provide staff training and education



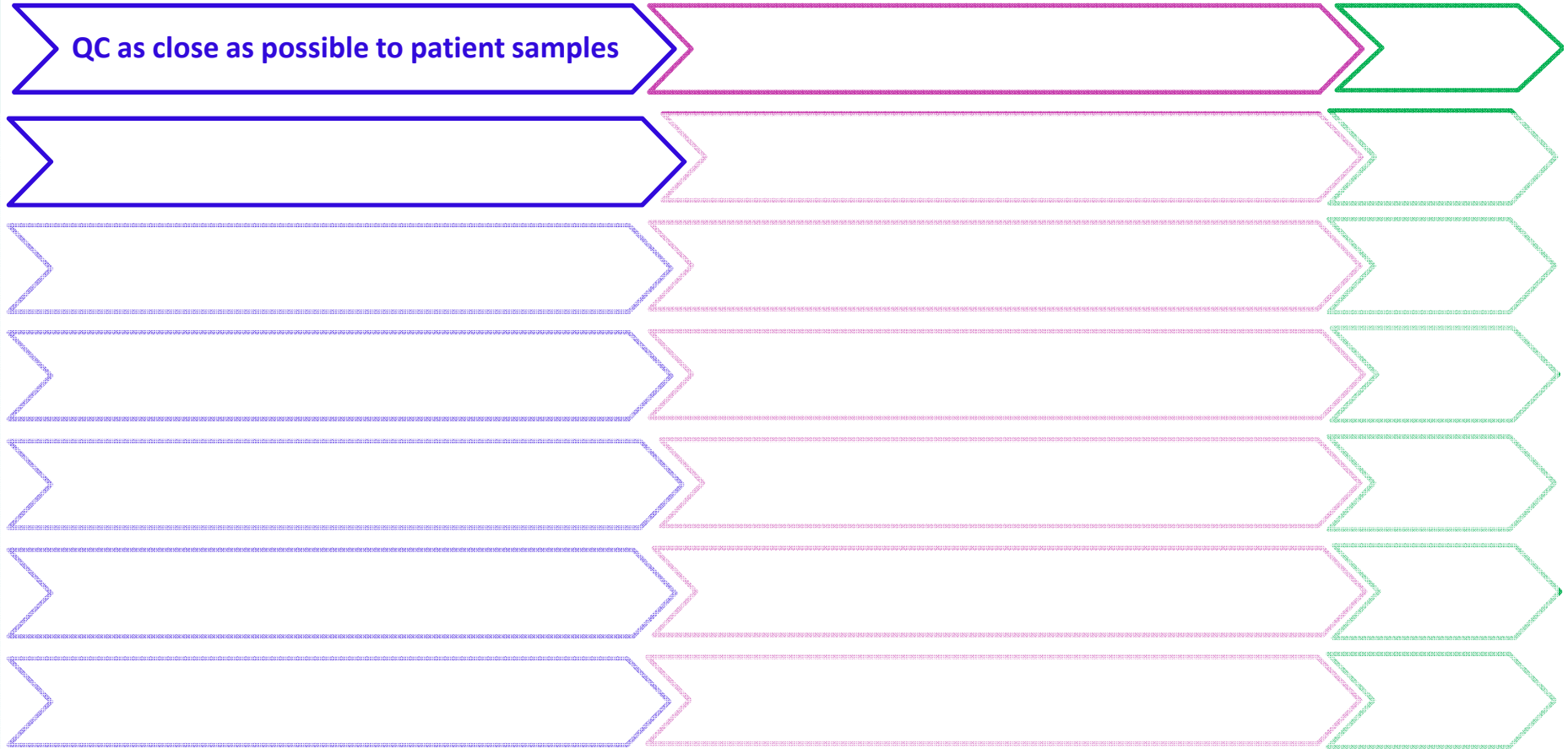
ISO 15189:2012

BIO-RAD

Accreditation Requirements

Bio-Rad Solutions

QC as close as possible to patient samples



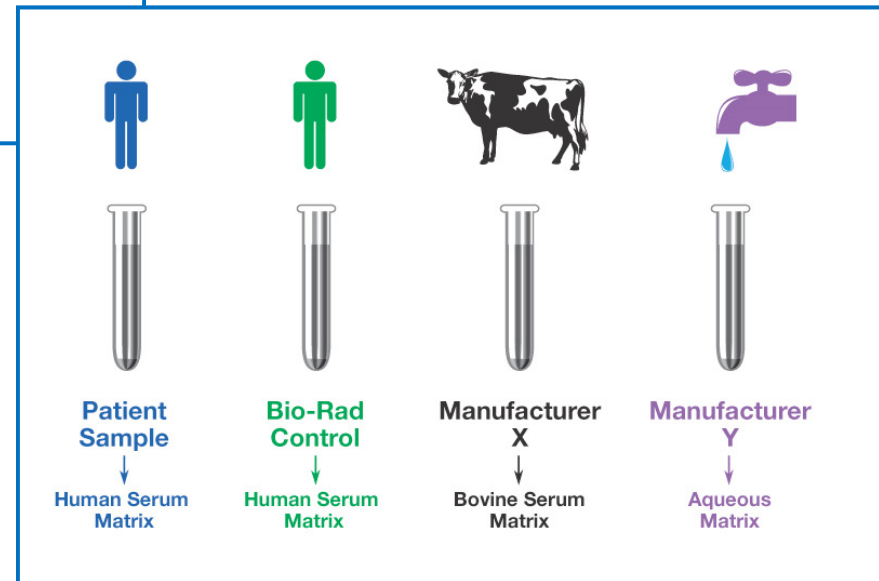
Quality Control Definitions

Independent Control (QC materials)

*“The laboratory shall use quality control materials that react to the examining system in a manner as close **as possible to patient samples.**”*
– ISO 15189:2012(E), Subclause 5.6.2.2



QC materials should be manufactured starting from human biological matrix



Quality Control Definitions

Independent Control (QC materials)

Note 1 :





The laboratory should choose concentrations of control materials, whenever possible, especially at or **near clinical decision values**, which ensures the validity of decisions made.

– ISO 15189:2012(E), Subclause 5.6.2.2



For example :

Bio-Rad has introduced a full range of Cardiac Assessment Controls that allow laboratories to select the Troponin value best suited to the 99th percentile upper reference limit of their platform

Control Level	Relative Tni Value
 1	100%
 1A	120%
 1B	60%
 1C	40%

Troponin I	Assay Values					Bio-Rad Control Levels							
	Platform	UNITS	Range Low High	99th Percentile	Group	LEVEL 1 - 23601 MEAN RANGE		LEVEL 1A - 23604 MEAN RANGE		LEVEL 1B - 23605 MEAN RANGE		LEVEL 1C - 23606 MEAN RANGE	
Siemens Dimension Series (CTNI)	ng/mL	0,04	40	0,07	1A	0.051	<0.040 - 0.067	0.054	<0.040 - 0.072	<0.040		<0.040	
Siemens Stratus CS	ng/mL	0,03	50	0,07	1A	<0.030	- 0.039	<0.030	- 0.042	<0.030		<0.030	
Siemens ADVIA Centaur / Centaur XP (TnI Ultra)	ng/mL	0,006	50	0,04	1B	0.109	0.071 - 0.147	0.136	0.088 - 0.184	0.037	0.024 - 0.050	0.043	0.028 - 0.058
Siemens ADVIA Centaur CP (TnI Ultra)	ng/mL	0,006	50	0,04	1B	0.115	0.075 - 0.155	0.135	0.088 - 0.182	0.040	0.026 - 0.054	0.045	0.029 - 0.061
Siemens Dimension EXL LOCI Module	ng/mL	0,017	40	0,056	1C	0.136	0.095 - 0.177	0.171	0.120 - 0.223	0.045	0.031 - 0.057	0.053	0.037 - 0.069
Siemens Dimension Vista Systems (CTNI) (LOCI)	ng/mL	0,015	40	0,045	1C	0.131	0.091 - 0.170	0.171	0.119 - 0.222	0.044	0.031 - 0.057	0.050	0.035 - 0.065

Quality Control Definitions

Independent Control (QC materials)

Note 2 :

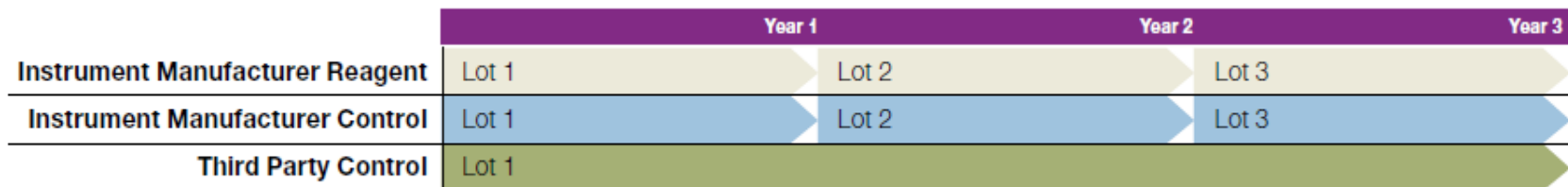
Use of **independent** third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.

– ISO 15189:2012(E), Subclause 5.6.2.2



Third party controls are manufactured independently of the test system calibrators and reagents.

Third party controls offer a longer shelf life. This allows use of the same control lot over multiple changes in reagents and calibrators.



What is Quality Control?

Selection criteria for a good QC material :

- ✓ Of human origin matrix
- ✓ independent
- ✓ Multicomponent
- ✓ Lyophilized or liquid
- ✓ Life and stability after major opening
- ✓ Rate decisive
- ✓ Values determined on a large panel of methods and parameters

Internal Quality Control

External Quality Control

Independent Control



- Bio-Rad provides QC that fulfill all these criteria

BIO-RAD

Accreditation Requirements

Bio-Rad Solutions

QC as close as possible to patient samples

All Bio-Rad QC are human matrix
Rate decisive



Participate in an
interlaboratory program



Participate in an Interlaboratory Program

*“The laboratory **shall participate in an interlaboratory comparison programme(s)** (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results.*

– ISO 15189:2012(E), 5.6.3.1 Interlaboratory comparisons

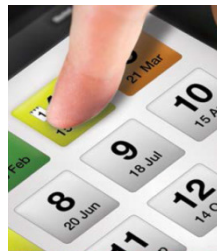


Is your laboratory a statistical island?

Bio-Rad provides 2 interlaboratory programs :



EQAS



Unity



BIO-RAD

2 fully complementary Interlaboratory Programs



EQAS Program



1 QC per month:

→ Snapshot of performance at a **specific time T**.

- Evaluation of **accuracy**, monthly.

Corrective actions are taken upon publication of the monthly report.

UNITY Program



All daily QC:

→ **Ongoing** performance monitoring.

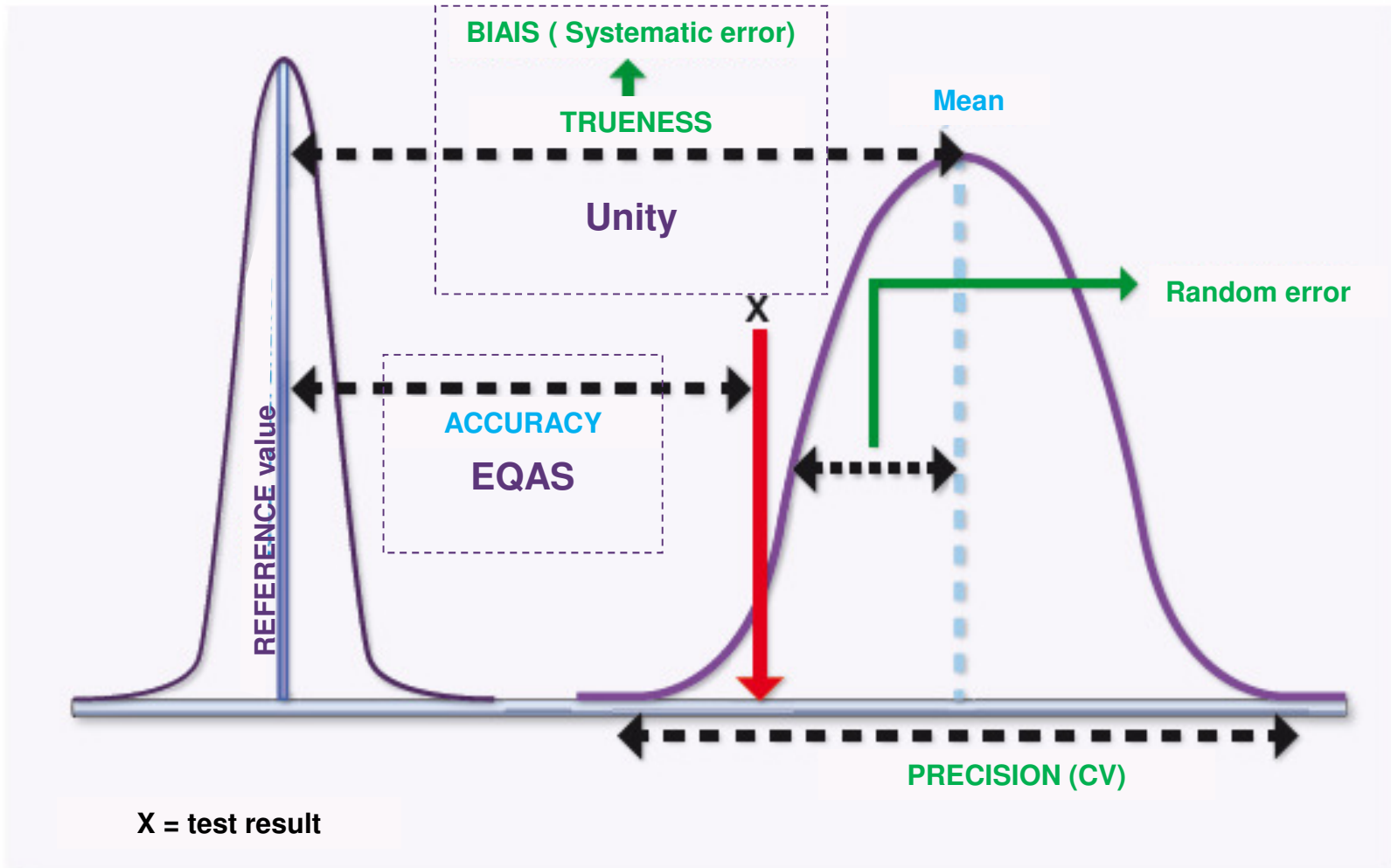
- Evaluation of **trueness** (Bias) daily

Corrective actions are taken immediately.

The EQAS and UNITY programs are fully complementary, ensuring the satisfaction of ALL standard requirements for achieving accreditation.

BIO-RAD

Participate in an Interlaboratory Program



Participate in an Interlaboratory Program



EQAS →
performance T



UNITY →
ongoing
performance



S = Submission
R = Report

EQAS and UNITY : Fully Complementary

BIO-RAD

Participate in an Interlaboratory Program

Bio-Rad EQAS Programs

Blind sample evaluation is mandatory to meet the requirements of ISO 15189.

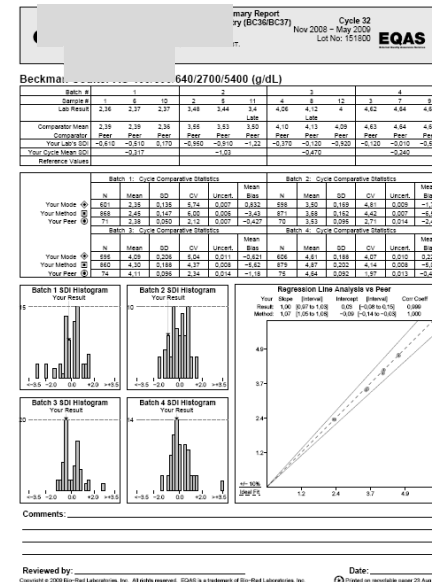
- Participants receive twelve Sample Reports and one End-of-Cycle report over each program cycle.
- Detailed reports are presented in an easy-to-read graphical format.

External
Quality
Assurance
Services



= +

1 QC per month



Participate in an Interlaboratory Program

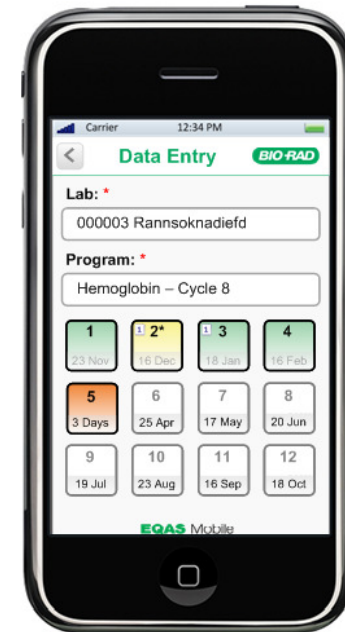
Bio-Rad EQAS Programs

Two convenient electronic reporting options to choose from (EQAS Online, EQAS Mobile)

Lab ID:

Hemoglobin Program - Cycle 9 Messages (1)

1 15 Jan	2* 18 Jan	3 15 Feb	4 21 Mar	5 18 Apr	6 16 May	7 20 Jun	8 18 Jul	9 15 Aug	10 19 Sep	11 17 Oct	12 21 Nov
-------------	--------------	-------------	-------------	-------------	-------------	-------------	-------------	-------------	--------------	--------------	--------------



Participate in an Interlaboratory Program

External Quality Assurance Services (EQAS)

Currently 12 different monthly programs available

1. Blood Gas (BC30/31)
 2. Coagulation Program (BC33/34)
 3. Cardiac Markers (BC38/39)
 4. Clinical Chemistry Program (BC5L/50)
 5. Ethanol/Ammonia (BC35)
 6. Hematology Program (BC90A,B,C,D)
 7. Hemoglobin Program (BC80)
 8. Immunoassay (Monthly) Program (BC7L/70/75)
 9. Lipids (BC46/47)
 10. Serum Proteins (BC23)
 11. Therapeutic Drug Monitoring Program (BC05/10)
 12. Urine Chemistry Program (BC40/45)
- New in Q1 2016
13. Urinalysis
 14. HIV/Hepatitis
 15. ToRCH/EBV/MuMZ
 16. Syphilis
 17. Blood Typing

<http://www.qcnet.com/EQAS/EQASProductInformation/tabid/447/language/en-US/Default.aspx>



EQAS Programs

Note :

*“The laboratory should participate in interlaboratory comparison programmes that **substantially fulfil the relevant requirements of ISO/IEC 17043.***

– ISO 15189:2012(E), Subclause 5.6.3 Interlaboratory comparisons



Bio-Rad EQAS programs are **fully accredited** according to **ISO/IEC 17043:2010** to help meet the regulatory needs of today's clinical laboratories.



EQAS Programs

EQAS Sample Reports

Report 1: Data on File Report
 Lab: 55555 DMO LAB
 555 5th STREET DEMO, DM 55555
 Cycle 7 Jul 2008 - Jun 2009
 Sample No: 11
 EQAS

Analyte	Unit	Result
ALB	g/L	29.8
ALP	U/L	103
ALT	U/L	142
AMP	U/L	358
AST	U/L	154
GGT	mmol/L	14.5
DBL	µmol/L	14.8
CR	mmol/L	1.76
CL	mmol/L	94.6
VEL	mmol/L	1.45
CHOL	mmol/L	5.8
CK	U/L	107
CREA	µmol/L	78
GGT	U/L	92.2
GLUC	mmol/L	7.7
LPH	U/L	96
LIP	U/L	48.5
MG	mmol/L	0.76
PHOS	mmol/L	0.81
K	mmol/L	3.58
TP	g/L	47.1
NA	mmol/L	153
TRIG	mmol/L	0.97
UREA	mmol/L	7.58
URIC	mmol/L	0.29

Report 2: Glucose Report
 Lab: 55555 DMO LAB
 555 5th STREET DEMO, DM 55555
 Cycle 7 Jul 2008 - Jun 2009
 Sample No: 11
 EQAS

Your Result
7.68 mmol/L

PEER DISTRIBUTION
 Histogram showing distribution of results with your result at 7.68.

Report 3: Sample Summary Report
 Lab: 55555 DMO LAB
 555 5th STREET DEMO, DM 55555
 Cycle 7 Jul 2008 - Jun 2009
 Sample No: 11
 EQAS

Analyte Checklist:
 Albumin
 Aspartate Phosphatase
 ALT (ALAT/PT)
 Amylase
 AST/AST
 Bicarbonate (CO2)
 Bilirubin, Direct
 Calcium
 Creatinine
 Creatinine, Total
 Creatinine, HDL
 Creatinine, Total
 Creatinine, Free
 Creatinine
 D-Glucose
 Glucose
 GGT
 Lipase
 Magnesium
 Phosphorus
 Potassium
 Protein, Total
 Sodium
 Triglyceride
 Urea
 Urea, Acid

Report 4: Configuration Report
 Lab: 55555 DMO LAB
 555 5th STREET DEMO, DM 55555
 Cycle 7 Jul 2008 - Jun 2009
 Sample No: 11
 Sample Date: 26 May 09
 Lab No: 210000
 EQAS

Selected Options:
 Data Input: all view
 Report Receipt: QDR

Analyte	Method	Reagent	Unit
007 ALB	800 Bioblock green	800 DeLubated Reagent	g/L
008 ALP	300 PAP, PAP (Jura)	300 DeLubated Reagent	U/L
009 ALT	100 U'vamed PAP	100 DeLubated Reagent	U/L
010 AMP	210 U'vamed	210 DeLubated Reagent	U/L
014 AST	100 U'vamed	100 DeLubated Reagent	U/L
047 CR	407 i-memo	407 DeLubated Reagent	mmol/L
054 CHOL	807 Cholesterol	807 DeLubated Reagent	mmol/L
060 CK	600 MCL-10	600 DeLubated Reagent	U/L
058 CL	020 05-48	020 DeLubated Reagent	mmol/L
046 CO2	110 Dapline	110 DeLubated Reagent	mmol/L
070 CREA	116 Dapline	116 DeLubated Reagent	µmol/L
006 DBL	600 Dapline	600 DeLubated Reagent	µmol/L
006 GGT	885 G-glu	885 DeLubated Reagent	U/L
006 GLUC	027 Hemo	027 DeLubated Reagent	mmol/L
002 HDL	002 Hemo	002 DeLubated Reagent	mmol/L
106 K	020 05-48	020 DeLubated Reagent	mmol/L
110 LPH	360 Lephase	360 DeLubated Reagent	U/L
102 LIP	004 Cobase	004 DeLubated Reagent	mmol/L
100 MG	410 Hemo	410 DeLubated Reagent	mmol/L
108 NA	020 05-48	020 DeLubated Reagent	mmol/L
140 PHOS	028 Phosph	028 DeLubated Reagent	mmol/L
144 TP	210 Hemo	210 DeLubated Reagent	g/L
160 TRIG	020 Dapline	020 DeLubated Reagent	mmol/L
160 UREA	110 Dapline	110 DeLubated Reagent	mmol/L
074 URIC	118 Dapline	118 DeLubated Reagent	mmol/L

Report 5: Monthly Clinical Chemistry Program (BC50/BC5L)
 Cycle 7: July 2008 - June 2009
 Sample No: 11 Sample Date: 26 May 09
 EQAS

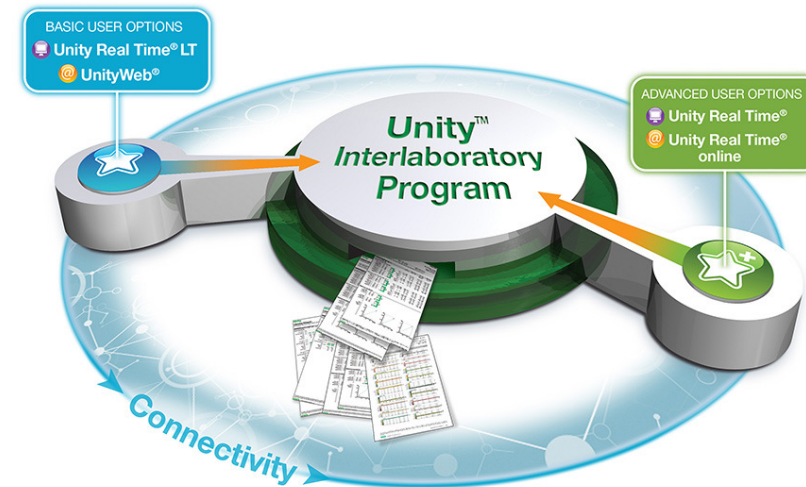
Exceptions Table:

Analyte	Instrument	Result	Unit	SCI	Comparator
X Bilirubin, Total	Roche Hitachi System (USA)	49.4	µmol/L	3.97	Pass
X Protein, Total	Roche Hitachi NT120RA	42.2	g/L	-1.79	Pass
Y Sodium	Roche Hitachi NT120RA	121.4	mmol/L	-2.01	Pass

Customer Information:
 Lab: 55555
 Attn: JOHN DEMO
 DEMO LAB
 555 5th STREET
 DEMO, DM
 55555

Unity™ Interlaboratory Program

All daily QC



- Largest interlaboratory program in the world for diagnostic laboratories
- Benefit from peer QC data generated from more than
 - **43,000 instruments**
 - **in 92 countries,**
 - **23 000 labs Worldwide**
- Help to meet accreditation and regulatory requirements.
- Help identify trends or shifts that may occur **between** proficiency surveys.

BIO-RAD

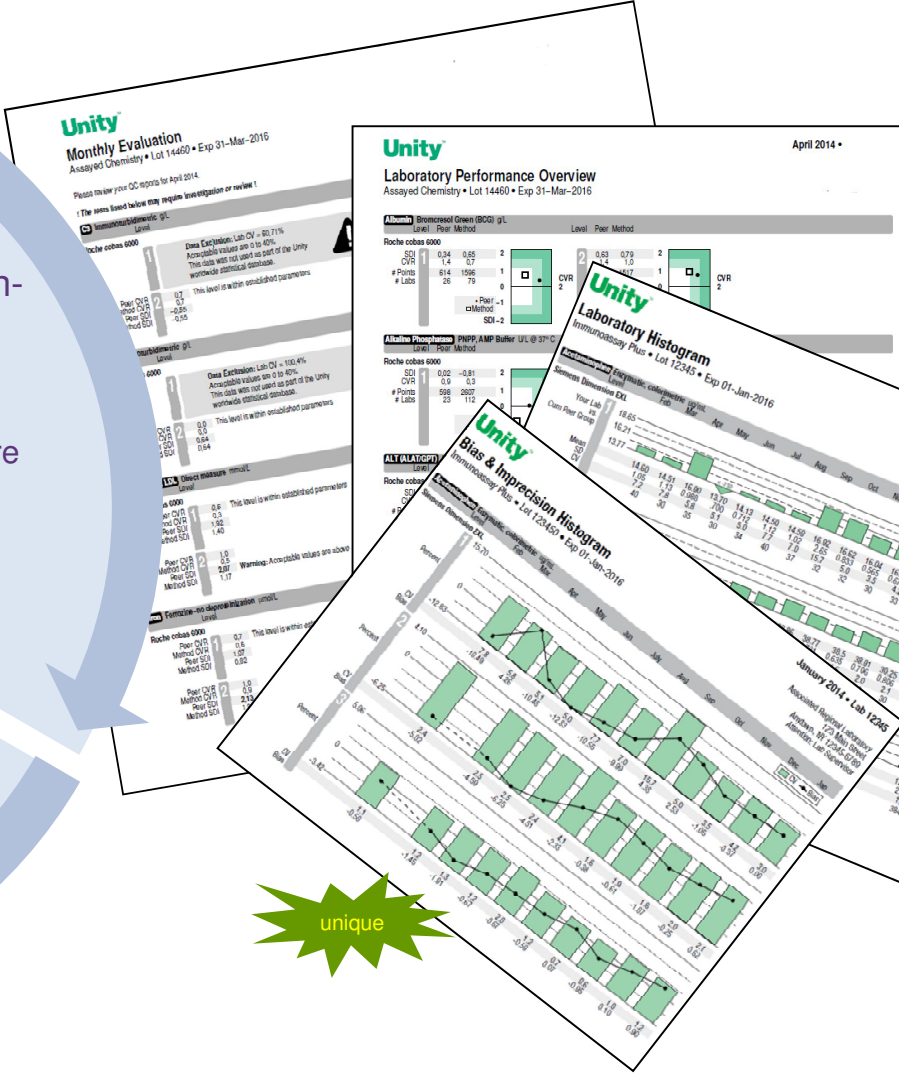
Unity™ Interlaboratory Program



Submit daily data in real time using one of the Bio-Rad Unity™ software solutions.

Receive on-demand and Monthly comparison reports to measure and improve analytical performance

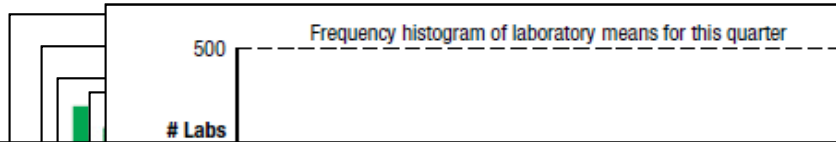
Download peers data in Unity Software to set analytical goals in addition of statistical process



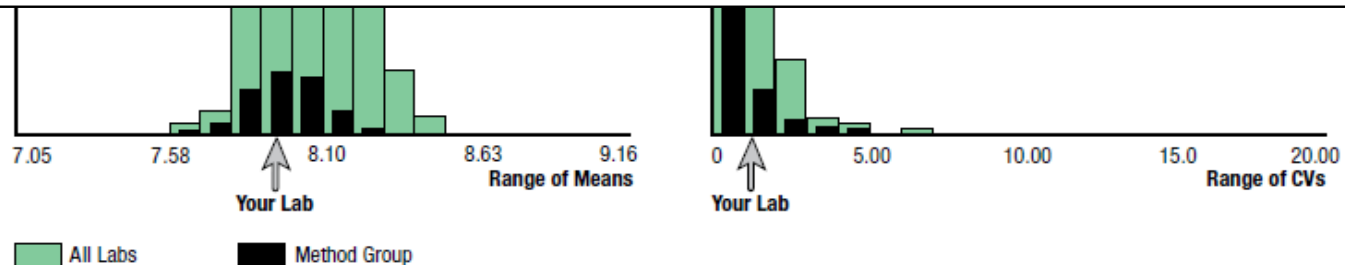
Unity™ Interlaboratory Program

Unity™ Interlaboratory Program provides a variety of **Reports** :

- ❑ Monthly Evaluation
- ❑ Laboratory Performance Overview
- ❑ Laboratory Histogram
- ❑ Bias & imprecision Histogram
- ❑ Statistical profil



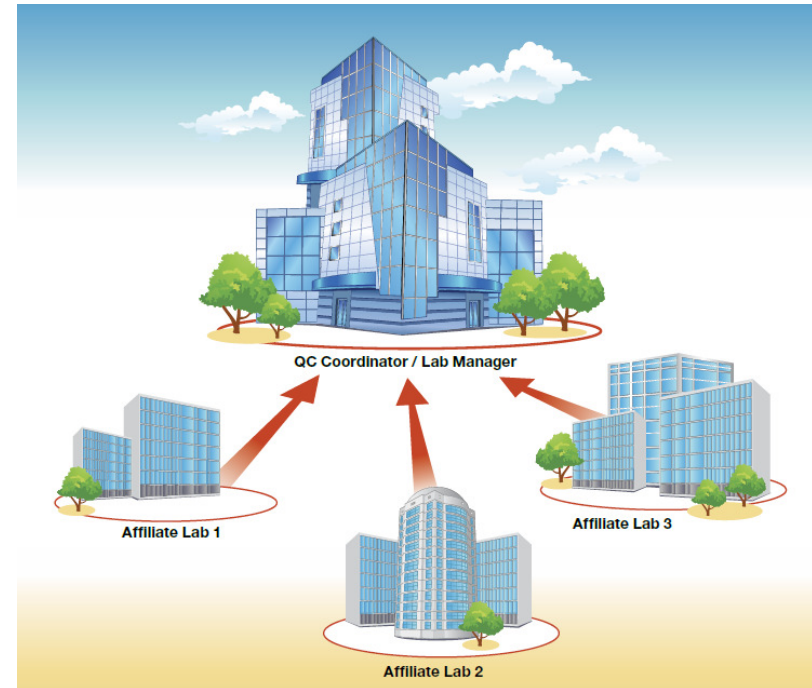
Percentile Distribution	10°		20°		30°		40°		Median 50°		60°		70°		80°		90°		95°		
	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	
Peer																					
Bias	1	0.160	0.174	0.160	0.247	0.160	0.617	0.250	0.987	0.267	1.13	0.267	1.45	1.25	1.55	1.25	2.33	1.63	3.30	1.63	3.54
SD		0.070	0.000	0.070	0.049	0.070	0.062	0.080	0.069	0.082	0.094	0.082	0.100	0.084	0.112	0.084	0.143	0.093	0.148	0.093	0.150
CV		0.866	0.000	0.866	0.617	0.866	0.756	1.00	0.850	1.02	1.16	1.02	1.21	1.06	1.37	1.06	1.80	1.16	1.81	1.16	1.94
Method																					
Bias	1	0.184	0.237	0.438	0.510	0.647	0.678	0.827	0.892	1.03	1.20	1.18	1.57	1.56	1.87	2.06	2.23	2.37	2.70	2.80	3.29
SD		0.061	0.066	0.071	0.074	0.077	0.081	0.082	0.087	0.087	0.095	0.093	0.103	0.104	0.113	0.121	0.131	0.149	0.163	0.196	0.187
CV		0.761	0.818	0.888	0.925	0.969	1.00	1.02	1.08	1.08	1.18	1.16	1.29	1.30	1.41	1.51	1.63	1.85	2.03	2.45	2.32
All Labs																					
Bias	1	0.283	0.242	0.608	0.620	0.930	0.916	1.22	1.20	1.52	1.51	1.83	1.88	2.24	2.28	2.81	2.80	3.48	3.35	4.19	3.91
SD		0.074	0.078	0.085	0.091	0.094	0.104	0.104	0.115	0.115	0.128	0.126	0.140	0.138	0.153	0.156	0.169	0.190	0.201	0.216	0.244
CV		0.924	0.969	1.06	1.12	1.17	1.29	1.29	1.42	1.42	1.58	1.5	1.74	1.72	1.89	1.93	2.10	2.36	2.46	2.67	3.05



Unity™ Interlaboratory Program

Affiliated Laboratory Comparison Report

- Provides the CVR and SDI for the peer, method, and affiliated groups.
- Allows statistical comparison of each affiliated laboratory's results.

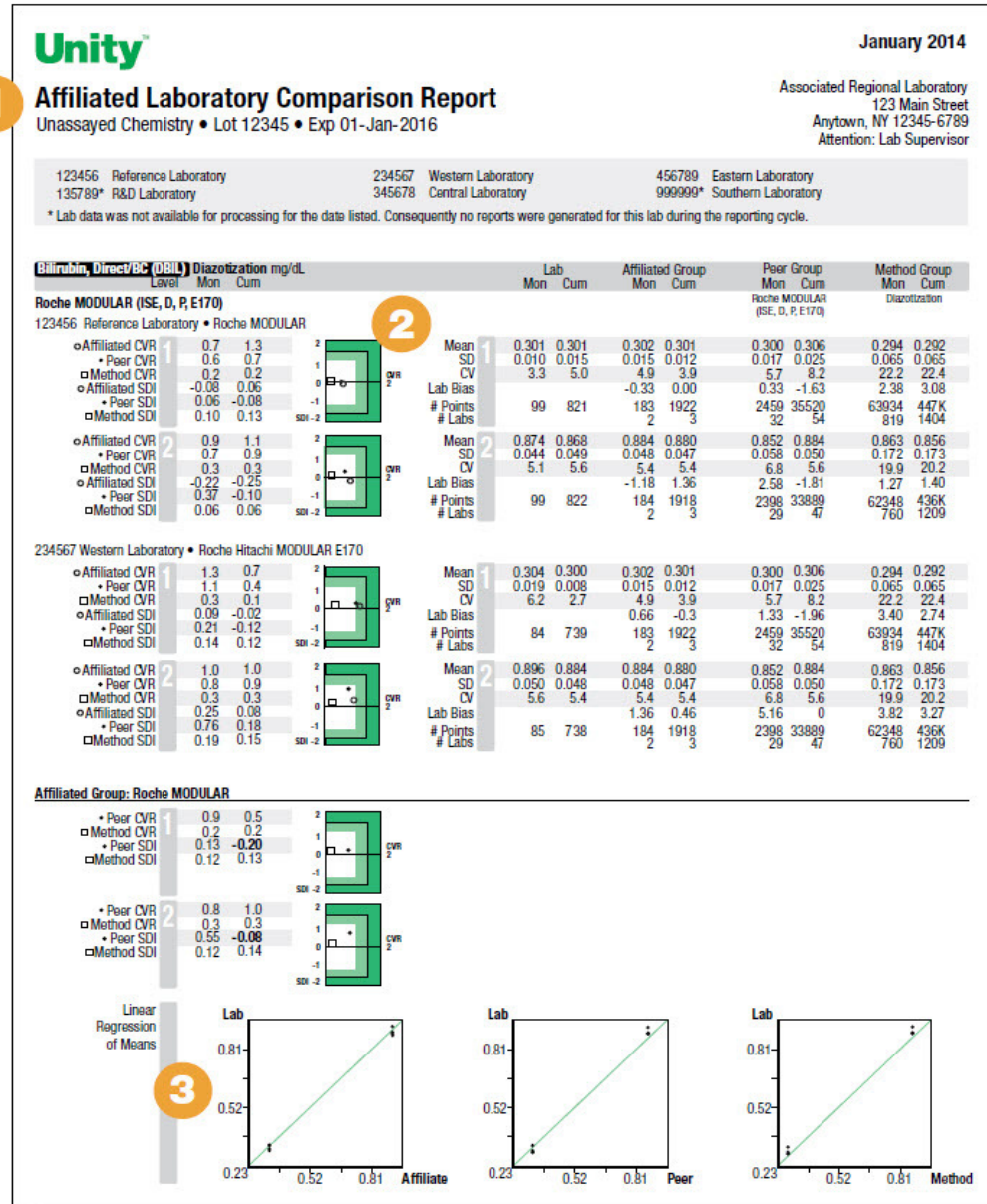


This report is an excellent tool used to meet regulatory and accreditation requirements.

Because it is easy to monitor data from **one site to another**.

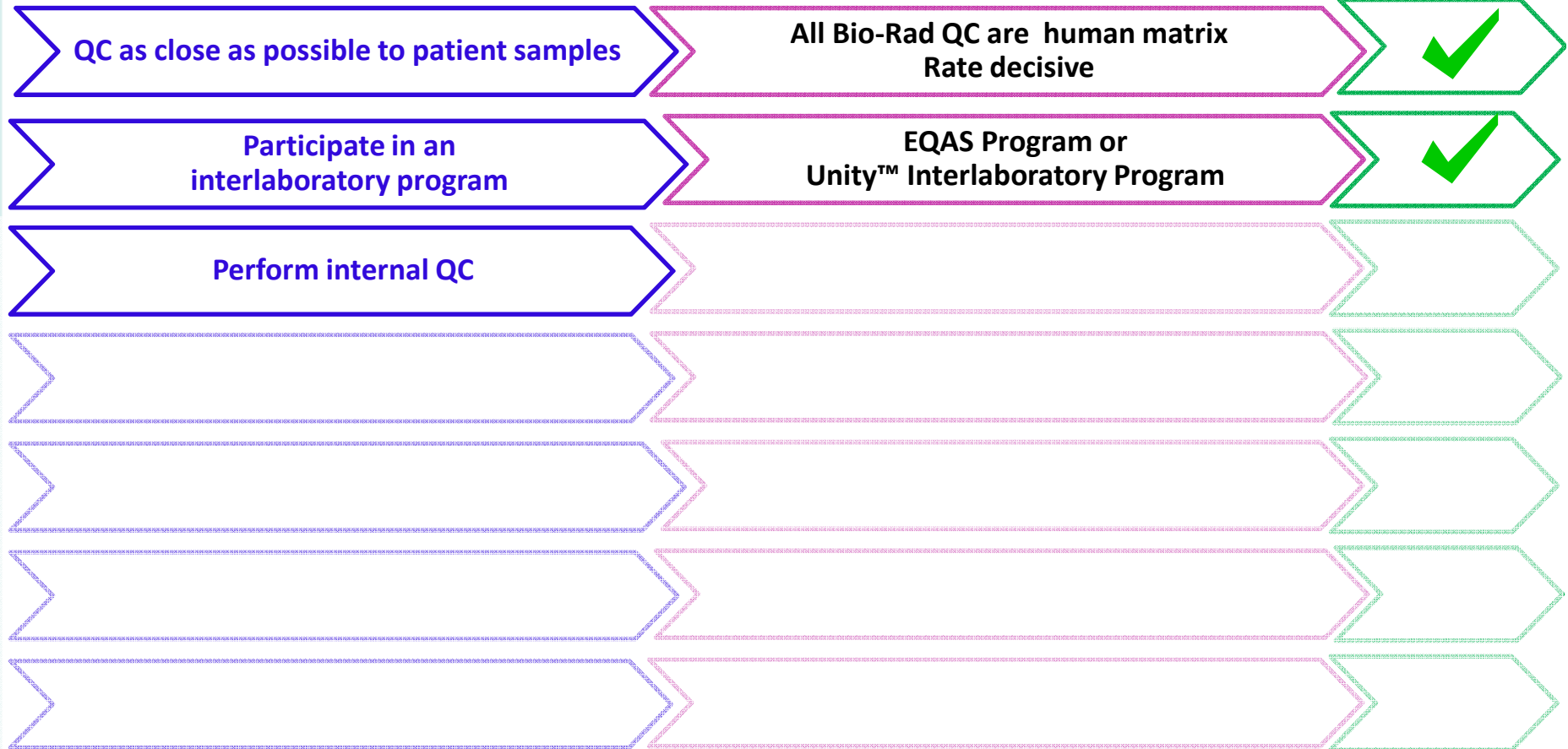
Unity™ Interlaboratory Program

1. Comprehensive performance comparisons of each lab versus Affiliated, Peer and Method for the month and cumulative.
2. Modified Youden graphs.
3. Linear regression plots of means for multiple instrument comparisons.



Accreditation Requirements

Bio-Rad Solutions



Perform Internal Quality Control

*The laboratory shall have a procedure to prevent the release of patient results **in the event of quality control failure**....*

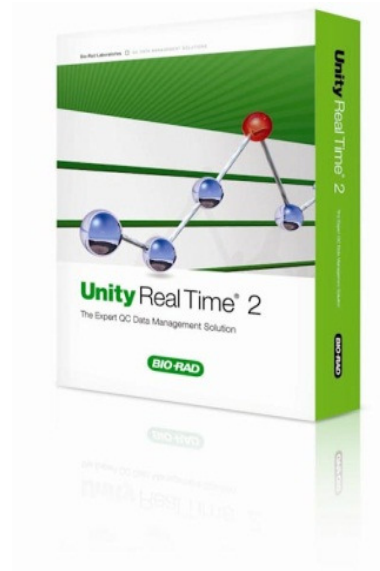
...Quality control data shall be reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system.

When such trends are noted, preventive actions shall be taken and recorded.

– ISO 15189:2012(E), 5.6.2.3 Quality control data



Unity Real Time[®] 2



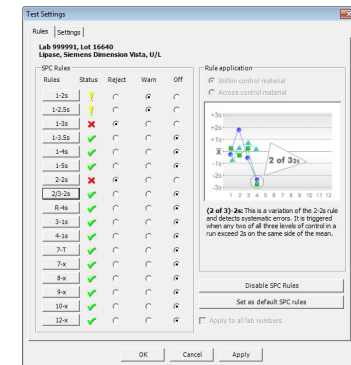
BIO-RAD

Perform Internal Quality Control

Unity Real Time 2 Bench and Supervisor: Data Review

the technologist and supervisor review data using the SPC rules :

- ❑ In a standardized manner by all staff
- ❑ Using the same software
- ❑ In real time



Révisé	N° du labo	N° du lot	Nom du contrôle	Instrument	Analyte	Date/Heure	Niveau	Valeur	Moyenne évaluée	ET évaluée z	Règles	État	Par	Action	Commentaires	Révisé par	Date
✓	99991	17650	ANA, Homogène	Abbott ARCHITECT c	ANA, Homogèneous Patt	07/07/2010	1	(Positive at)				Acc	sa				26/10/21
✓	99991	17650	ANA, Homogène	Bio-Rad PHD	ANA, Homogèneous Patt	08/07/2010	1	(Positive at)				Acc	sa				26/10/21
✓	99991	17650	ANA, Homogène	Bio-Rad PHD	ANA, Homogèneous Patt	08/07/2010	1	(Positive at)				Acc	sa				26/10/21
✓	99991	17650	ANA, Homogène	Bio-Rad PHD	ANA, Homogèneous Patt	08/07/2010	1	(Positive at)				Acc	sa				26/10/21
✓	99991	17650	ANA, Homogène	Bio-Rad PHD	ANA, Homogèneous Patt	08/07/2010	1	(Positive at)				Acc	sa				26/10/21
✓	99991	17650	ANA, Homogène	Bio-Rad PHD	ANA, Homogèneous Patt	08/07/2010	1	(Positive at)				Acc	sa				26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Sodium	14/07/2010	3	107,00	109,37	0,96	-2,4	1-2RT(5)	Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Sodium	14/07/2010	3	155,00	155,48	0,68	-0,7		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Glucose	14/07/2010	1	3,30	3,30	0,03	0,00		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Glucose	14/07/2010	3	20,30	20,11	0,20	0,95		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	GOT (ASAT)AST	14/07/2010	1	25,00	25,01	0,00	-0,0		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	GOT (ASAT)AST	14/07/2010	3	218,00	218,37	2,17	-0,1		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	GPT (ALAT)ALT	14/07/2010	1	20,00	19,84	0,97	0,16		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	GPT (ALAT)ALT	14/07/2010	3	174,00	173,67	1,77	0,19		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	LD (Lactate Dehydrog)	14/07/2010	1	108,00	107,81	1,63	0,95		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	LD (Lactate Dehydrog)	14/07/2010	3	371,00	367,27	3,34	1,32		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Magnésium	14/07/2010	1	0,41	0,41	0,02	0,00		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Magnésium	14/07/2010	3	1,68	1,66	0,03	0,07		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Phosphatase Alcaline	14/07/2010	1	28,27	28,27	1,10	0,00	TE-[0]T	Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Phosphatase Alcaline	14/07/2010	3	365,00	365,48	3,65	-0,1		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Potassium	14/07/2010	1	3,25	3,12	0,10	2,00	2-RT(1)	Acc	sa	Test: cal nouveau lot		26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Potassium	14/07/2010	3	7,24	7,06	0,05	3,00	2-RT(1,3)	Acc	sa	Test: cal nouveau lot		26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Sodium	14/07/2010	1	108,00	109,37	0,97	-1,4		Acc	sa			26/10/21
✓	99991	46360	Multiquel 1,2,3 U	Abbott ARCHITECT c	Sodium	14/07/2010	3	155,00	155,48	0,68	-0,7		Acc	sa			26/10/21

The **Review panel** receives and refreshes QC data in real time.



Perform Internal Quality Control

Unity Real Time

Fichier Sélectionner Affichage Révision Analyse Advisor Rapports Outils Aide

Labo Lot Test Panel Multi-te... LJ Multi-LJ Histo. Youden... Yundt Analy-t... Initiale Règles OA Moyen... Rejets

Labo : 999991 Demo Lot : 62290 Quantitative Urine Matrice : Urine
 Test : Urobilinogène|Dipstick|Siemens CLINITEK 200|Réactif dédié|Qualitative|Pas de température spécifiée
 Périme : 31/12/2012

Enregistrer Date de saisie

A = Action C = Commentaires

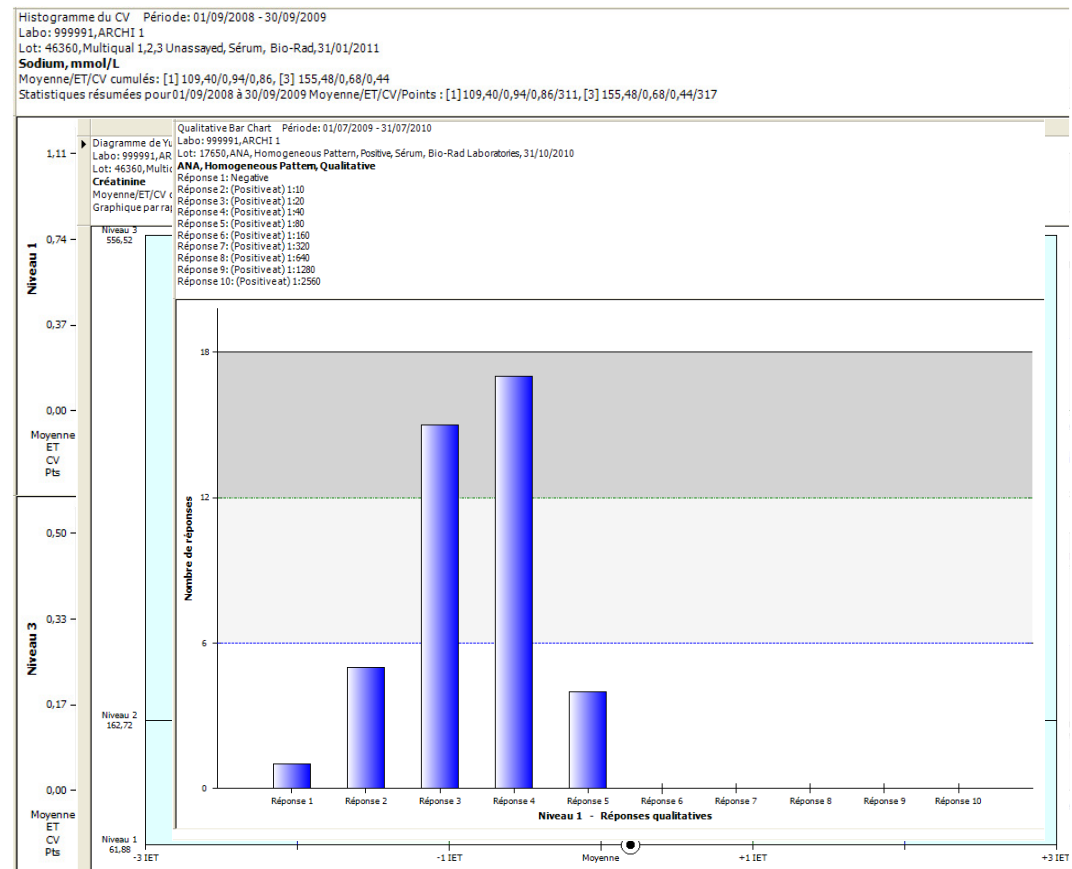
	Date et Heure	Niveau	Y/N	Ut	A	C
1	02/06/2012 20:26	Normal or 0.2 EU/dL or 3.2 umol/L	O	sa	A	C
2	03/06/2012 20:26	Normal or 0.2 EU/dL or 3.2 umol/L	O	sa	A	C
3	04/06/2012 20:26	Normal or 0.2 EU/dL or 3.2 umol/L	O	sa	A	C
4	05/06/2012 20:26	Normal or 1 EU/dL or 16 umol/L	O	sa	A	C
5	06/06/2012 20:26	Normal or 1 EU/dL or 16 umol/L	O	sa	A	C
6	07/06/2012 20:26	Normal or 1 EU/dL or 16 umol/L	O	sa	A	C
7	08/06/2012 20:26	Normal or 0.2 EU/dL or 3.2 umol/L	O	sa	A	C
8	09/06/2012 20:26	2 EU/dL or 33 umol/L	N	sa	A	C
9	09/06/2012 20:26			sa	A	C

Normal or 0.2 EU/dL or 3.2 umol/L
 Normal or 1 EU/dL or 16 umol/L
 2 EU/dL or 33 umol/L
 4 EU/dL or 66 umol/L
 8 EU/dL or 133 umol/L

Perform Internal Quality Control

Unity Real Time[®] 2 provides a variety of **charts** for internal review of QC results:

- ❑ Levey-Jennings Chart
- ❑ Multi Levey-Jennings Chart
- ❑ Bar Chart
- ❑ Yundt Chart
- ❑ Qualitative Bar Chart



BIO-RAD

Accreditation Requirements

Bio-Rad Solutions

QC as close as possible to patient samples	All Bio-Rad QC are human matrix Rate decisive	✓
Participate in an interlaboratory program	EQAS Program or Unity™ Interlaboratory Program	✓
Perform internal QC	Unity™ QC data management software	✓
Ensure traceability of QC results		



Ensure Traceability of QC Results

“Records shall be maintained for each reagent and consumable that contributes to the performance of examinations.”
– ISO 15189:2012(E), Subclause 5.3.2.7



“The laboratory must be able to justify the quality of its results at any time”

- Complete traceability in Unity Real Time 2.0
- Actions and comments can be added and displayed

Ensure Traceability of QC Results

Data Review Report

The Data Review Report shows the full traceability of QC results.

Unity Real Time BIO-RAD						
Rapport des révisions de données						
Imprimé	22/01/2010	De	01/08/2009	À	29/08/2009	Page 9
N° du labo :	999 99100	Description :	ARCHI 1			
Nom du labo :	BioRad	Service :	Demo			
Contact :	DTC	Adresse :	3 Bd Raymond Poincaré			
Ville :	Marnes	Code postal :	92430			
Région :		Nom du lot :	Immunoassay Plus			
N° du lot :	40200	Matrice :	Sûrum			
Fabricant :	Bio-Rad					
Périmé :	09/30/2010					
Date	Ut	Révision du superviseur	Date	Révision initiale	Date	
HCG,Chemiluminescence,Abbott ARCHITECT ci8200,Réactif dédié,IU/L,Pas de température spécifiée						
08/08/2009 09:27:00	SD	tk	02/10/2009 15:08:01	sa	02/10/2009 15:02:51	
Niveau 1	Valeur					6.14
Niveau 3	Valeur					152.20
10/08/2009 10:02:00	SD	tk	02/10/2009 15:08:01	sa	02/10/2009 15:02:51	
Niveau 1	Valeur					6.00
Niveau 3	Valeur					147.98
11/08/2009 09:40:00	SD	tk	02/10/2009 15:08:01	sa	02/10/2009 15:02:51	
Niveau 1	Valeur					6.14
Niveau 3	Valeur					150.12
12/08/2009 10:02:00	GB	tk	02/10/2009 15:08:01	sa	02/10/2009 15:02:51	
Niveau 1	Valeur					6.81
Niveau 3	Valeur					143.67
Commentaire(s): maintenance sav(GB)						
13/08/2009 09:33:00	SD	tk	02/10/2009 15:08:01	sa	02/10/2009 15:02:51	
Niveau 1	Valeur					5.70
Niveau 3	Valeur					141.69

Audit Trail Report

The Audit Trail keeps track of events that can change how data points are evaluated

Audit Trail Report BIO-RAD						
Date	Lab	Lot	Level	Test	Event	SPC rule change
1/26/2012 2:19:35PM	999991	16620		LD (Lactate Dehydrogenase)(Lactate to pyruvate)(Siemens Dimension Vista)(FCC 2002 (Enzymes))IU/L		
Expires:	3/31/2013 12:00:00AM					Op sa
Original/Changed to:		Off/Warn				
1/26/2012 2:19:35PM	999991	16620		LD (Lactate Dehydrogenase)(Lactate to pyruvate)(Siemens Dimension Vista)(FCC 2002 (Enzymes))IU/L		
Expires:	3/31/2013 12:00:00AM					Op sa
Original/Changed to:		Off/Reject				
1/26/2012 2:19:35PM	999991	16620		LD (Lactate Dehydrogenase)(Lactate to pyruvate)(Siemens Dimension Vista)(FCC 2002 (Enzymes))IU/L		
Expires:	3/31/2013 12:00:00AM					Op sa
Original/Changed to:		Off/Reject				
1/26/2012 2:19:35PM	999991	16620		Bilirubin, DirectBC (DBIL)(Diazotization)(Siemens Dimension Vista)(Dedicated Reagent)(mg/dL)(No Temp		
Expires:	3/31/2013 12:00:00AM					Op sa
Original/Changed to:						

Accreditation Requirements

Bio-Rad Solutions

QC as close as possible to patient samples	All Bio-Rad QC are human matrix Rate decisive	✓
Participate in an interlaboratory program	EQAS Program or Unity™ Interlaboratory Program	✓
Perform internal QC	Unity™ QC data management software	✓
Ensure traceability of QC results	Reports (Unity Real Time® 2)	✓
Establish Analytical goals		



Establish analytical Goals

“When the quality control rules are violated and indicate that examination results are likely to contain **clinically significant errors**, the results shall be rejected and relevant patient samples re- examined after the error condition has been corrected.”

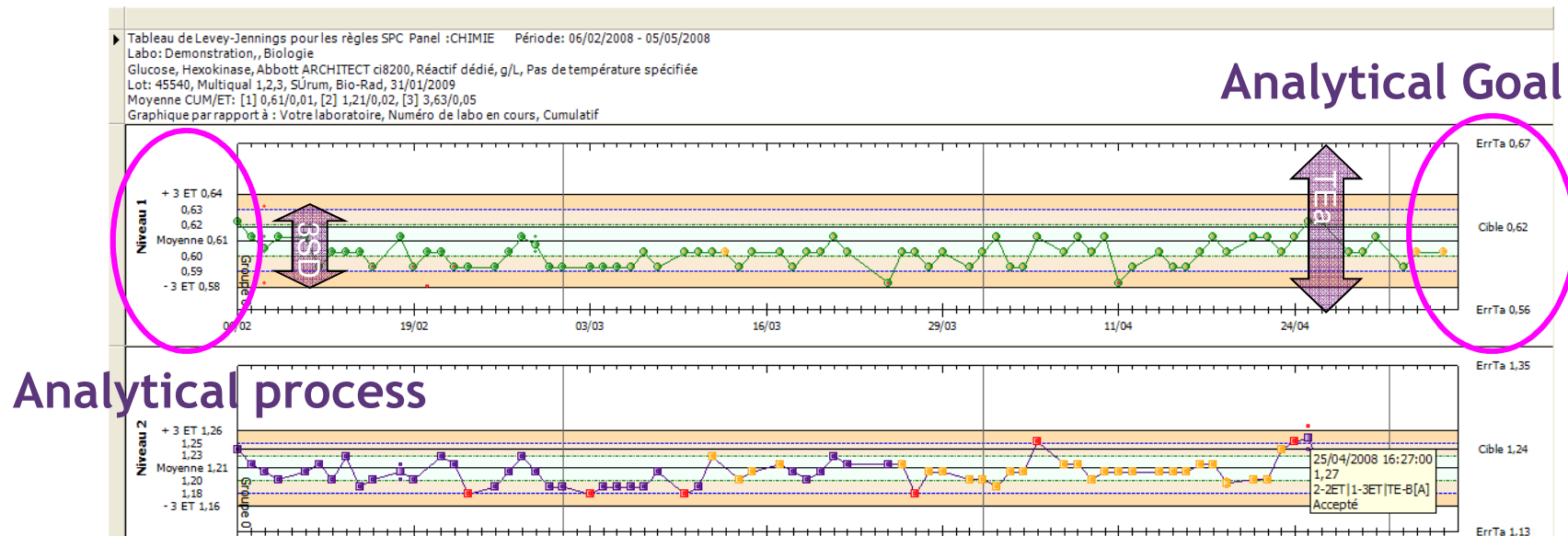
– ISO 15189:2012(E), Subclause 5.6.2.3



Simultaneous display :

3 SD

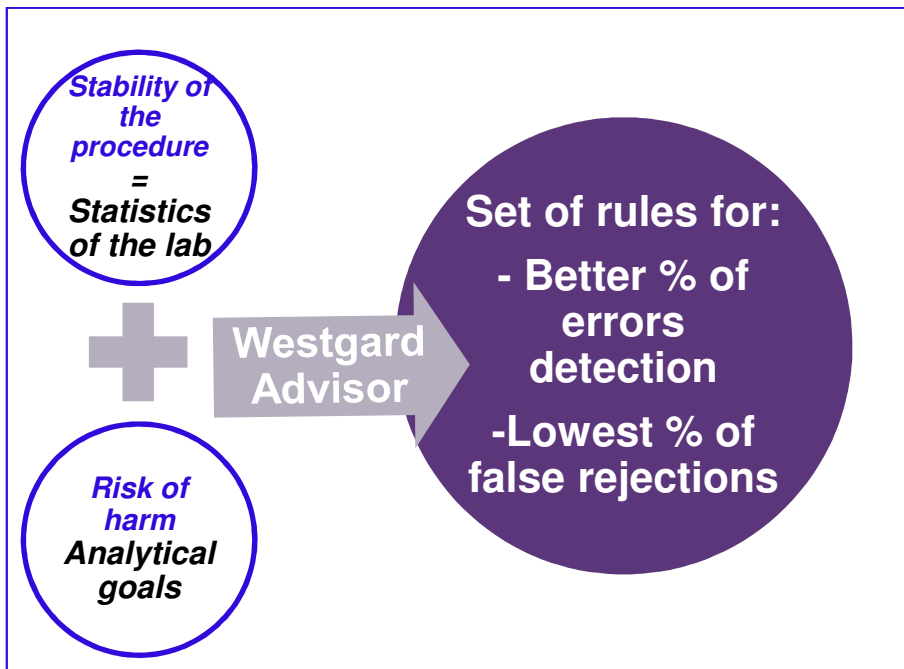
and Total allowable Error



Establish analytical Goals

Quality control materials shall be periodically examined with a frequency that is based on the **stability of the procedure** and the **risk of harm** to the patient from an erroneous result.”

– ISO 15189:2012(E), Subclause 5.6.2.2



Westgard Advisor =
Dr Westgard in the laboratory



in order to :

- ❑ Recommends and automatically applies the **best QC rules** with patented technology
- ❑ **Reduce false** rejections and desensitization to false error flags
- ❑ **Save time** and money by reducing unnecessary repeats and troubleshooting

BIO-RAD

Accreditation Requirements

Bio-Rad Solutions

QC as close as possible to patient samples	All Bio-Rad QC are human matrix Rate decisive	✓
Participate in an interlaboratory program	EQAS Program or Unity™ Interlaboratory Program	✓
Perform internal QC	Unity™ QC data management software	✓
Ensure traceability of QC results	Reports (Unity Real Time® 2)	✓
Establish performance goals	Analytical Goals (Unity Real Time® 2) Westgard Advisor	✓
Perform method validation Determine measurement uncertainty		

Measurement uncertainty

*“The laboratory shall determine measurement **uncertainty for each measurement** procedure in the examination phase used to report quantity values on patients’ samples.”*

– ISO 15189:2012(E), Subclause 5.5.1.4



NOTE 2

*“ Measurement uncertainties may be calculated using quantity values obtained by the measurement of **quality control materials** under intermediate precision conditions that include as many routine changes as reasonably possible in the standard operation of a measurement procedure...”*

– ISO 15189:2012(E), Subclause 5.5.1.4



- Extract CV's and bias from Unity Real Time for measurement **uncertainty calculations** according to regional recommendations.

Measurement uncertainty

Lab 999991 Lot 16640 Unassayed Chemistry System Serum

Data Set Configuration Configure TEa Export Print Close

Level 1 | Level 2 | All Levels

Data Set	Analyte	Method	Instrument	Reagent	Unit	Temperature	Mean	SD	CV	Pts	Labs	SDI	CVR
A	Sodium	ISE indirect	Siemens Dimensi...	Dedicated Reag...	mEq/L	No Temperature							
B1							134.46	0.88	0.66	138	1		
A	Chloride	ISE indirect	Siemens Dimensi...	Dedicated Reag...	mEq/L	No Temperature							
B1							84.58	0.64	0.76	148	1		
A	Calcium	o-cresolphthalei...	Siemens Dimensi...	Dedicated Reag...	mg/dL	No Temperature							
B1							8.41	0.12	1.41	178	1		
A	CO2 (Carbon Di...	Enzymatic	Siemens Dimensi...	Dedicated Reag...	mEq/L	No Temperature							
B1							16.70	0.75	4.49	161	1		
A	Albumin	Bromocresol Purpl...	Siemens Dimensi...	Dedicated Reag...	g/dL	No Temperature							
B1							2.80	0.01	0.52	140	1		
A	Creatinine	Alkaline picrate-...	Siemens Dimensi...	Dedicated Reag...	mg/dL	No Temperature							
B1							0.72	0.05	6.77	128	1		
A	Urease	Colorimetric	Siemens Dimensi...	Alternate Calibr...	U/L	37° C							
							154.20	5.35	3.47	143	1		

- **CVR** = CVa / CVb

- **SDI** = (Mean a – Mean b) / SDb

- **%Biais** = ((Mean a – Mean b) / Mean b) x 100

- **Sigma** = (TEa – Biais) / CVa

- **ErrT** = Biais + 1.65 Cva

- **RCV** = $\sqrt{2} \times 1.96 \times \sqrt{CV_A^2 + CV_I^2} = 2.77 \times \sqrt{CV_A^2 + CV_I^2}$

All necessary statistical are available in **few clicks** in the data grids.

Measurement uncertainty

	A	B	C	D	E	F	G	H	I	J	K	L
1	Ensemb	Analgte	Méthode	Instrument	Réactif	Unité	Température	Niveau	Moyenne	ET	CV	Pts
2	A	Sodium	ISE indirecte	Abbott ARCHITECT ci8200	Réactif dédié	mmol/L	Pas de température spécifiée	1	109,36	0,97	0,89	317
3	B1							1	108,98	1,64	1,5	23136
4	A	Potassium	ISE indirecte	Abbott ARCHITECT ci8200	Réactif dédié	mmol/L	Pas de température spécifiée	1	2,12	0,1	4,6	283
5	B1							1	2,12	0,11	5,2	22415
6	A	Magnésium	Arsenazo I	Abbott ARCHITECT ci8200	Réactif dédié	mmol/L	Pas de température spécifiée	1	0,41	0,02	4,32	248
7	B1							1	0,43	0,04	9,03	9860
8	A	LD (Lactate Déshydrogénase)	Lactate vers	Abbott ARCHITECT ci8200	Réactif dédié	U/L	37° C	1	107,91	1,62	1,51	263
9	B1							1	107,42	4,77	4,45	8060
10	A	GPT (ALAT/ALT)	UV sans P5P	Abbott ARCHITECT ci8200	Réactif dédié	U/L	37° C	1	19,84	0,97	4,9	285
11	B1							1	19,41	2,06	10,62	11819
12	A	GOT (ASAT/AST)	UV sans P5P	Abbott ARCHITECT ci8200	Réactif dédié	U/L	37° C	1	35,01	0,5	1,44	269
13	B1							1	35,1	1,3	3,69	10978
14	A	Glucose	Hexokinase	Abbott ARCHITECT ci8200	Réactif dédié	mmol/L	Pas de température spécifiée	1	3,3	0,03	0,99	299
15	B1							1	3,34	0,1	2,99	12099
16	A	GGT (Gamma Glutamyltransférase)	G-glutamyl-ca	Abbott ARCHITECT ci8200	Réactif dédié	U/L	37° C	1	27,15	0,52	1,93	237
17	B1							1	29,01	1,7	5,85	10448
18	A	Fer	Férène	Abbott ARCHITECT ci8200	Abbott MULTIGENT	µmol/L	Pas de température spécifiée	1	13,23	0,3	2,23	286
19	B1							1	12,66	0,46	3,65	1147
20	A	Créatinine	Picrate alcalin	Abbott ARCHITECT ci8200	Réactif dédié	µmol/L	Pas de température spécifiée	1	63,24	1,87	2,96	313
21	B1							1	61,26	4,01	6,55	9585
22	A	CO2 (Dioxyde de Carbone)	Enzymatique	Abbott ARCHITECT ci8200	Réactif dédié	mEq/L	Pas de température spécifiée	1	12,7	0,57	4,49	275
23	B1							1	12,87	1,32	10,26	10819
24	A	CK (Créatine Kinase)	NAC, activate	Abbott ARCHITECT ci8200	Réactif dédié	U/L	37° C	1	94,57	1,18	1,24	250
25	B1							1	94,07	3,64	3,87	9748
26	A	Cholestérol, Total	Cholestérol-c	Abbott ARCHITECT ci8200	Réactif dédié	mmol/L	Pas de température spécifiée	1	2,82	0,02	0,73	292
27	B1							1	2,84	0,06	2,03	9081
28	A	Cholestérol, HDL	Polymère-pol	Abbott ARCHITECT ci8200	Réactif dédié	mmol/L	Pas de température spécifiée	1	0,95	0,02	2,62	277
29	B1							1	0,94	0,05	5,51	7029
30	A	Chlorure	ISE indirecte	Abbott ARCHITECT ci8200	Réactif dédié	mmol/L	Pas de température spécifiée	1	76,2	0,52	0,68	282
31	B1							1	76,57	1,24	1,63	22504
32	A	Calcium	Arsenazo III	Abbott ARCHITECT ci8200	Réactif dédié	mmol/L	Pas de température spécifiée	1	1,45	0,01	0,89	296
33	B1							1	1,45	0,03	2,35	11922
34	A	Bilirubine Totale/TBIL	Jendrassik Gr	Abbott ARCHITECT ci8200	Réactif dédié	µmol/L	Pas de température spécifiée	1	6,94	0,15	2,1	256
35	B1							1	6,9	0,36	5,25	1125
36	A	Bilirubine Directe/BC (DBIL)	Diazotation	Abbott ARCHITECT ci8200	Réactif dédié	µmol/L	Pas de température spécifiée	1	5,21	0,1	1,92	234
37	B1							1	5,09	0,38	7,39	6928

Results can be exported to a **spreadsheet**



Accreditation Requirements

Bio-Rad Solutions

QC as close as possible to patient samples	All Bio-Rad QC are human matrix Rate decisive	✓
Participate in an interlaboratory program	EQAS Program or Unity™ Interlaboratory Program	✓
Perform internal QC	Unity™ QC data management software	✓
Ensure traceability of QC results	Reports (Unity Real Time® 2)	✓
Establish Analytical goals	Analytical Goals (Unity Real Time® 2) Westgard Advisor	✓
Perform method validation Determine measurement uncertainty	Data grids	✓
Provide staff training and education		

Provide Staff Training and Education

*“The laboratory shall provide training for all personnel which includes the following areas: the **quality management system**.”*

– ISO 15189:2012(E), Subclause 5.1.5



*Personnel shall take part in **continuing education**. The effectiveness of the continuing education program shall be **periodically reviewed**.*

– ISO 15189:2012(E), Subclause 5.1.8

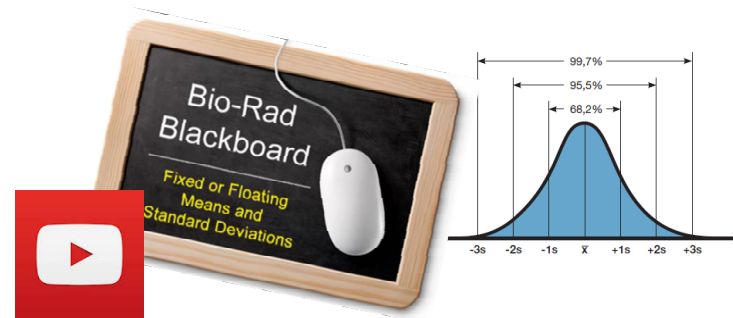


Provide Staff Training and Education

Bio-Rad offers several ways to participate in education program

□ Educational materials:

- ✓ Bio-Rad QC YouTube channel
- ✓ QC Documents
- ✓ Software Training
- ✓ QC Workbook



□ Training Program by local Bio-Rad QC specialists on site or in our Regional Training Center

Different levels of training for Unity Real Time^{®2}

- ✓ Fundamentals
- ✓ Advanced tasks
- ✓ Westgard Advisor[™]



BIO-RAD

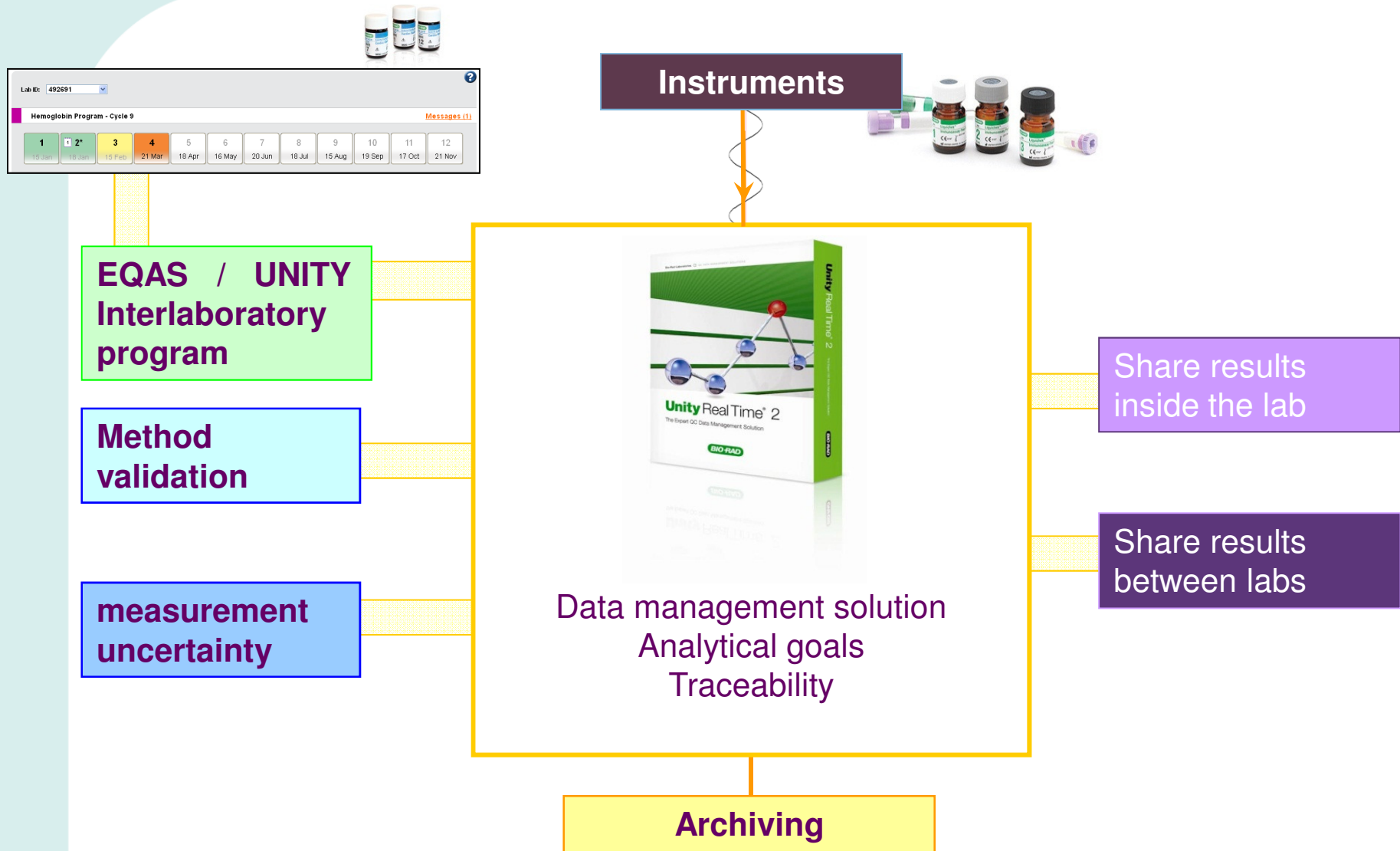
Accreditation Requirements

Bio-Rad Solutions

QC as close as possible to patient samples	All Bio-Rad QC are human matrix Rate decisive	✓
Participate in an interlaboratory program	EQAS Program or Unity™ Interlaboratory Program	✓
Perform internal QC	Unity™ QC data management software	✓
Ensure traceability of QC results	Reports (Unity Real Time® 2)	✓
Establish performance goals	Analytical Goals (Unity Real Time® 2) Westgard Advisor	✓
Perform method validation Determine measurement uncertainty	Data grids	✓
Provide staff training and education	Trainings	✓

BIO-RAD

Conclusion



Conclusion



Diagnostic Laboratories

Blood Banks

	Core Chemistry	Special chemistry Toxicology	Serology Immunology	Urinalysis Hematology Coagulation	Respiratory Care	Blood typing	Serology	Molecular
Bio-Rad daily QC	✓	✓	✓	✓	✓	✗	✓	✓ Q4 2015
Unity Solutions	✓	✓	✓	✓	✓	✓	✓	✓
EQAS	✓	✓	✓	✓	✓	✓ Q1 2016	✓ Q1 2016	

Diagnostic lab



Blood bank

Thank you

