

SMARTLABTOOLS™ QUALITY CONTROL SYSTEM

Parallel Testing and Implementing a New Lot of QC Materials

Templates: SLT_413, SLT_417 SLT_400

Daniel W. Leighton, MS,MT(ASCP),HCLD(ABB),CLB
dan@smartlabtools.com

Ver.010817

Objective: Parallel Testing New QC Lot(s)

- SLT Templates are used to facilitate the calculations necessary to establish QC limits for a new lot of controls.
- The examples shown are for QC of the ACCESS-II immunochemistry analyzer using BioRad Controls.
- *Note: CLIA regulations require that the laboratory establish it's own mean and standard deviation through repetitive testing. 493.1218 (5d)*

CLSI C24-A3, 8.6.2. Provides the following guidance if Assayed Control Materials are used:

- The values stated on the assay sheets provided by manufacturer should be used only as guides in setting the initial control limits for testing new control materials.
- Actual values for the mean and standard deviation must be established by serial testing in the laboratory.
- The observed mean should fall within the range published by the manufacturer.
- EQA and peer-comparison provide useful measures of the means and SDs observed in other laboratories.

Step-1 Run New Set of Controls x 10 (as unknowns)

For cross-over between two different lots of control materials, lab may calculate the mean for the new material from the first 10 measurements, and use the CV from the previous lot of QC material to calculate the SD, then used to calculate QC limits.

New control materials should be run in parallel with existing controls , tested as unknowns over multiple days/runs

403/1	BIORADLOWNEWLC	Serum		
	40891	1	hFSH	9.38 mIU/mL
			hLH	4.39 mIU/mL
			Ferritin	22.0 ng/mL
			PRL	7.83 ng/mL
			TotT4	8.59 ug/dL
			FOLW	2.26 ng/mL
			TotT3	1.01 ng/mL
			PSA-Hyb	0.32 ng/mL
			TSH	0.61 uIU/mL
			VitB12	192 pg/mL
			Testo	0.97 ng/mL
			FT3	2.15 pg/mL
			FRT4	0.78 ng/dL
			E2	51 pg/mL
403/2	BIORADHIGHNEWLC	Serum		
	40893	1	hFSH	33.48 mIU/mL
			hLH	65.08 mIU/mL
			Ferritin	266.9 ng/mL
			PRL	41.34 ng/mL
			TotT4	19.13 ug/dL
			FOLW	12.06 ng/mL
			TotT3	2.72 ng/mL
			PSA-Hyb	24.96 ng/mL
			TSH	22.36 uIU/mL
			VitB12	623 pg/mL
			Testo	10.46 ng/mL
			FT3	7.90 pg/mL
			FRT4	4.48 ng/dL
			E2	747 pg/mL

1 of 10 Measurement Replicates

Step 2.

Use SLT 413 Templates to Analyze Data (Level-1 QC Shown)

Smart LabTools								
PRECISION AND ACCURACY STATISTICAL ASSESSMENT								
INTERNAL MEDICINE ASSOCIATES								
ACCESS-II PARALLEL TESTING NEW LOT OF BIORAD IA-PLUS CONTROLS								
Analyte :	FSH	LH	FERRITIN	PROLACT	TT4	FOLATE	TT3	PSA
QC Material :	BIORAD							
Lot Number :	40891							
Expiration :	6/17							
Target Values :	8.2	4.27	19.7	6.94	7.99	2.75	0.862	0.33
Ranges :	6.45-9.96	3.36-5.19	15.7-23.7	5.80-8.08	6.09-9.89	1.18-4.32	0.398-1.33	1.82-2.74
Run	L-1	L-1						
1	8.78	4.31	24.1	7.67	8.86	2.23	1.00	0.33
2	9.38	4.39	22.0	7.83	8.59	2.26	1.01	0.32
3	9.13	4.29	22.4	7.90	8.47	2.27	1.00	0.31
4	9.50	4.47	23.6	7.85	8.59	2.02	0.97	0.33
5	8.17	4.03	20.9	7.79	8.99	2.50	0.95	0.33
6	8.52	4.58	20.5	8.40	8.58	2.46	0.96	0.34
7	7.70	4.45	21.0	8.13	8.90	2.60	0.95	0.36
8	7.30	4.18	23.8	8.36	9.07	2.67	1.01	0.36
9	8.40	3.78	19.2	7.85	9.78	2.59	0.92	0.34
10	7.25	3.04	19.3	7.43	8.90	2.39	0.86	0.31
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
N :	10	10	10	10	10	10	10	10
Mean :	8.41	4.15	21.68	7.92	8.87	2.40	0.96	0.33
1 SD :	0.81	0.46	1.79	0.30	0.38	0.20	0.05	0.02
% CV :	9.65	10.96	8.27	3.78	4.26	8.48	4.90	5.31
Target Value :	8.20	4.27	19.70	6.94	7.99	2.75	0.86	0.33
% Recovery :	102.60	97.24	110.05	114.14	111.05	87.24	111.72	100.91
Clear Form	Reset	Reset						

Means from Insert Used for "Target" Values

Smart LabTools								
PRECISION AND ACCURACY STATISTICAL ASSESSMENT								
INTERNAL MEDICINE ASSOCIATES								
ACCESS-II PARALLEL TESTING NEW LOT OF BIORAD IA-PLUS CONTROLS								
Analyte :	TSH	VIT-B12	TESTO	FT3	FT4	E2		
QC Material :	BIORAD							
Lot Number :	40891							
Expiration :	6/17							
Target Values :	0.732	196	0.875	2.28	0.773	40.3		
Ranges :	0.539-0.925	143-249	0.647-1.10	1.82-2.74	0.598-0.949	<20-84.8		
Run	L-1	L-1	L-1	L-1	L-1	L-1	L-1	L-1
1	0.61	192	0.97	2.15	0.78	51		
2	0.60	195	0.93	2.19	0.80	50		
3	0.66	183	0.94	2.25	0.82	44		
4	0.70	166	0.94	1.94	0.82	48		
5	0.64	187	0.91	2.05	0.78	61		
6	0.66	190	0.92	2.22	0.92	53		
7	0.61	190	1.01	2.29	0.85	48		
8	0.60	203	1.06	2.22	0.89	57		
9	0.61	191	1.07	2.19	0.85	42		
10	0.64	182	0.89	2.27	0.83	54		
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
N :	10	10	10	10	10	10		
Mean :	0.63	187.90	0.96	2.18	0.83	50.80		
1 SD :	0.03	9.73	0.06	0.11	0.05	5.75		
% CV :	5.22	5.18	6.49	4.93	5.43	11.32		
Target Value :	0.73	196.00	0.88	2.28	0.77	40.30		
% Recovery :	86.48	95.87	110.17	95.48	107.89	126.05		
Clear Form	Reset	Reset	Reset	Reset	Reset	Reset	Reset	Reset

Note E2 %Recovery is High, but within "Insert" Limits

Step 2. (cont.)

Use SLT 413 Templates to Analyze Data (Level-3 QC Shown)

Smart LabTools								
PRECISION AND ACCURACY STATISTICAL ASSESSMENT								
INTERNAL MEDICINE ASSOCIATES								
ACCESS-II PARALLEL TESTING NEW LOT OF BIORAD IA-PLUS CONTROLS								
Analyte :	FSH	LH	FERRITIN	PROLACT	TT4	FOLATE	TT3	PSA
QC Material :	BIORAD							
Lot Number :	40893							
Expiration :	6/17							
Target Values :	31.1	55.3	269	39.0	18.6	14.9	2.48	25.1
Ranges :	24.6-37.6	44.6-65.9	174-364	33.0-44.9	15.3-22.0	7.55-22.2	1.59-3.36	19.1-31.1
Run	L-3	L-3	L-3	L-3	L-3	L-3	L-3	L-3
1	33.48	65.08	266.9	41.34	19.13	12.06	2.72	24.96
2	34.74	61.51	271.1	41.66	19.21	10.85	2.64	25.92
3	35.48	64.45	292.9	42.28	19.73	11.85	2.73	24.23
4	34.44	63.74	306.8	41.07	18.15	11.64	2.70	25.04
5	30.90	57.87	305.9	40.91	19.59	12.27	2.68	24.97
6	33.77	60.40	308.4	44.24	18.00	13.22	2.64	26.10
7	33.88	60.29	288.2	43.99	19.08	13.19	2.67	26.46
8	33.23	51.33	338.6	43.15	18.94	12.91	2.72	25.60
9	33.44	54.53	282.8	42.70	19.08	12.89	2.78	15.37
10	28.46	48.85	277.7	41.54	19.79	12.83	2.60	23.86
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
N :	10	10	10	10	10	10	10	10
Mean :	33.18	58.81	293.93	42.29	19.07	12.37	2.69	24.25
1 SD :	2.05	5.60	21.57	1.20	0.60	0.77	0.05	3.22
% CV :	6.18	9.52	7.34	2.83	3.15	6.25	1.97	13.30
Target Value :	31.10	55.30	269.00	39.00	18.60	14.90	2.48	25.10
% Recovery :	106.69	106.34	109.27	108.43	102.53	83.03	108.39	96.62
Clear Form	Reset	Reset	Reset	Reset	Reset	Reset	Reset	Reset
Comments : PARALLEL TESTING NEW LOT OF CONTROLS VS. E-INSERT								
Analyst : BRITTANY			11/22/2016			Approved by : D. LEIGHTON		

Smart LabTools								
PRECISION AND ACCURACY STATISTICAL ASSESSMENT								
INTERNAL MEDICINE ASSOCIATES								
ACCESS-II PARALLEL TESTING NEW LOT OF BIORAD IA-PLUS CONTROLS								
Analyte :	TSH	VIT B-12	TESTO	FT3	FT4	E2		
QC Material :	BIORAD							
Lot Number :	40891							
Expiration :	6/17							
Target Values :	26.1	573	9.70	7.71	4.29	798		
Ranges :	19.7-32.4	412-733	7.66-11.7	6.17-9.25	3.45-5.14	544-1051		
Run	L-3	L-3	L-3	L-3	L-3	L-3	L-3	L-3
1	22.36	623	10.46	7.90	4.48	747		
2	25.00	611	9.91	7.65	4.25	764		
3	19.36	613	10.11	7.83	4.26	813		
4	22.01	668	10.32	8.23	4.35	806		
5	21.10	599	9.73	7.53	4.14	798		
6	20.82	615	9.96	8.05	4.98	824		
7	22.30	652	10.52	7.92	4.64	858		
8	23.78	609	10.36	8.09	4.47	748		
9	20.61	634	10.23	7.75	4.43	805		
10	23.97	575	10.29	8.02	4.42	733		
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
N :	10	10	10	10	10	10		
Mean :	22.13	619.90	10.19	7.90	4.44	789.60		
1 SD :	1.74	26.40	0.26	0.21	0.24	39.99		
% CV :	7.86	4.26	2.51	2.70	5.31	5.06		
Target Value :	26.10	573.00	9.70	7.71	4.29	798.00		
% Recovery :	84.79	108.19	105.04	102.43	103.54	98.95		
Clear Form	Reset	Reset	Reset	Reset	Reset	Reset	Reset	Reset
Comments : PARALLEL TESTING NEW LOT OF CONTROLS VS. E-INSERT								
Analyst : BRITTANY			11/22/2016			Approved by : D. LEIGHTON		

Step 3. Compare Preliminary Lab Values vs. Insert .. *Mean & Range are used on the SLT_413 Form*

Means from parallel study should fall within the manufacturer's stated range.

Insert limits should be used only as guides in setting initial control limits for testing new control materials.

Convert Insert 3SD limits to 2SD for better comparison (next slide)

BIO-RAD

Liquichek™ Immunoassay Plus Control Levels 1, 2 and 3

REF	360	Trilevel	12 x 5 mL
	361	Level 1	12 x 5 mL
	362	Level 2	12 x 5 mL
	363	Level 3	12 x 5 mL
	360X	Trilevel MiniPak	3 x 5 mL

0459

IVD

EXP 2017-06-30

LOT 40890

Level 1	40891
Level 2	40892
Level 3	40893

<http://www.myeinserts.com/40890>

Revision Date 2016-11-17 → Indicates Revised Information

INSTRUMENT (1)

	Units	Level 1 - 40891		Level 2 - 40892		Level 3 - 40893	
		Mean	Range	Mean	Range	Mean	Range
BECKMAN COULTER ACCESS / 2 / 2i							
Estradiol	pg/mL	40.3	<20.0 – 84.8	339	231 – 447	798	544 – 1051
Ferritin	ng/mL	19.7	15.7 – 23.7	121	93.4 – 148	269	174 – 364
Folate (FOLW)	ng/mL	2.75	1.18 – 4.32	10.2	5.50 – 14.9	14.9	7.55 – 22.2
Follicle Stimulating Hormone (FSH) (hFSH)	mIU/mL	8.20	6.45 – 9.96	18.7	14.7 – 22.6	31.1	24.6 – 37.6
Luteinizing Hormone (LH) (hLH)	mIU/mL	4.27	3.36 – 5.19	18.7	14.3 – 23.1	55.3	44.6 – 65.9
Prolactin	ng/mL	6.94	5.80 – 8.08	16.0	13.3 – 18.6	39.0	33.0 – 44.9
PSA (Total) (Hybritech PSA)	ng/mL	0.330	0.250 – 0.410	3.71	2.82 – 4.60	25.1	19.1 – 31.1
T3 (Free) (Free T3)	pg/mL	2.28	1.82 – 2.74	5.37	4.25 – 6.45	7.71	6.17 – 9.25
T3 (Total) (Total T3)	ng/mL	0.862	0.398 – 1.33	1.72	1.05 – 2.38	2.48	1.59 – 3.36
T4 (Free) (Free T4)	ng/dL	0.773	0.598 – 0.949	2.56	2.07 – 3.06	4.29	3.45 – 5.14
T4 (Total) (Total T4)	µg/dL	7.99	6.09 – 9.89	12.2	9.61 – 14.7	18.6	15.3 – 22.0
Testosterone	ng/mL	0.875	0.647 – 1.10	4.57	3.52 – 5.62	9.70	7.66 – 11.7
Thyroid Stimulating Hormone (TSH) (hTSH, HYPERSensitive)	µIU/mL	0.732	0.539 – 0.925	5.07	4.05 – 6.09	26.1	19.7 – 32.4

FOOTNOTES

(1) All footnotes may not apply to your custom selected data chart.

(2) The assigned values were determined using the reagent and/or instrument manufacturer's protocol and may not represent $\pm 3SD$ ranges.

▲ Data is not available at this time. Please inquire.

§ The data required to establish the means and acceptable ranges for this assay were not obtained due to limited assignment participation. If your facility is interested in participating in the Value Assignment Program for this assay, please contact your local Bio-Rad office.

Step 3. (cont.) Convert Insert stated 3SD limits to 2SD limits

SLT_105 and SLT_400
Daily QC Assessment
Template setup requires
user input of 2SD limits
for each analyte.

Templates are available
that simplify conversion
calculations.

SLT_414, SLT_414.5

Until lab has run
sufficient QC data for
establishing solid 2SD
QC limits, then use of
“insert”, “peer”, or “HCV”
derived 2SD limits are
interim options.

Smart LabTools															
CONVERT QUALITY CONTROL INSERT (3SD LIMITS) TO (2SD LIMITS)															
CLEAR FORM															
< REPLACE WITH NAME OF LABORATORY >															
TEST SYSTEM:	ACCESS-2					ACCESS-2					ACCESS-2				
CONTROLS:	BIORAD IMMUNOASSAY PLUS					BIORAD IMMUNOASSAY PLUS					BIORAD IMMUNOASSAY PLUS				
LOT #S:	LEVEL-1 - 40891					LEVEL-1 - 40891					LEVEL-3 - 40893				
EXPIRATION:	EXP. 6/17					EXP. 6/17					EXP. 6/17				
ANALYTE	-3SD	+3SD	1SD	-2SD	+2SD	-3SD	+3SD	1SD	-2SD	+2SD	-3SD	+3SD	1SD	-2SD	+2SD
FERRITIN	15.7	23.7	1.33	17.03	22.37	93.4	148	9.10	102.50	138.90	174	364	31.67	205.67	332.33
FOLATE	1.18	4.32	0.52	1.70	3.80	5.5	14.9	1.57	7.07	13.33	7.55	22.2	2.44	9.99	19.76
FSH	6.45	9.96	0.59	7.04	9.38	14.7	22.6	1.32	16.02	21.28	24.6	37.6	2.17	26.77	35.43
LH	3.36	5.19	0.31	3.67	4.89	14.3	23.1	1.47	15.77	21.63	44.6	65.9	3.55	48.15	62.35

SLT_414.5 Use when SD is not given

Smart LabTools															
CALCULATE QUALITY CONTROL (2SD LIMITS) USING MEAN & 1SD															
CLEAR FORM															
REPLACE WITH NAME OF LABORATORY															
TEST SYSTEM:	PENTRA 400					PENTRA 400									
CONTROLS:	NORMAL (N) CONTROL					ABNORMAL (P) CONTROL									
LOT #S:	1602701					1503601									
EXPIRATION:	02/18					05/17									
ANALYTE	MEAN	1SD	CV	-2SD	+2SD	MEAN	1SD	CV	-2SD	+2SD	MEAN	1SD	CV	-2SD	+2SD
ALP	105.8	4.5	4.25	96.80	114.80	219	7.7	3.52	203.60	234.40					
ALT	55	2.5	4.55	50.00	60.00	174	7.4	4.25	159.20	188.80					
AST	48.7	3.2	6.57	42.30	55.10	158	7	4.43	144.00	172.00					
CK	170.9	5.7	3.34	159.50	182.30	526	17.5	3.33	491.00	561.00					

SLT_414 Use when Mean and SD are given

Step 4. Compare with Manufacturer's Peer Report

Unity™ Manufacturer Report for Beckman Coulter Immunoassay Plus • Lot 40890 • Exp 30-Jun-2017

		Estradiol, E2 Chemiluminescence pg/mL								
	Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	
Beckman Coulter Access, LXi 725, DxC 600i IA Systems										
Mean	1	51.06	52.08	2	376.6	373.3	3	825.3	818.0	
SD		12.76	12.75		38.62	33.04		59.04	60.89	
CV		25.0	24.5		10.3	8.8		7.2	7.4	
# Points		389	3332		152	1454		355	3195	
# Labs		15	21		8	11		14	18	

The lab will use the calculated mean, along with the peer CV to calculate it's interim QC limits for the new QC materials.

We note that the peer Level-1 E2 value more closely matches the E2 value from the lab study (50.8). The most current peer reports contain the more reliable comparative values.

Step 5. Using Template SLT 417 to Calculate 2SD Limits

Lab determined Means, and Peer CV's (*Historical CV's*) are used here to calculate interim 2SD Limits.

Optionally, Lab Previous Lot SD's or CV's are used with the new QC means

QC Limits are best determined by cumulative statistics from 3-6 months testing.

Smart LabTools															
CALCULATE QC LIMITS USING HISTORICAL CV% (HCV)															
INTERNAL MEDICINE ASSOCIATES LAB															
METHOD :	ACCESS-2										ACCESS-2				
CONTROLS :	BIORAD LEVEL-1										BIORAD LEVEL-3				
LOT #'s :	40891										40893				
EXPIRATION :	6/17										6/17				
ANALYTE	MEAN	HCV	SD	-2SD	+2SD	MEAN	HCV	SD	-2SD	+2SD	MEAN	HCV	SD	-2SD	+2SD
ESTRADIOL-2	50.8	24.5	12.45	25.91	75.69						790	7.4	58.46	673.08	906.92
FERRITIN	21.7	6.9	1.50	18.71	24.69						294	6.9	20.29	253.43	334.57
FOLATE	2.40	8.3	0.20	2.00	2.80						12.4	7.1	0.88	10.64	14.16
FSH	8.41	6.5	0.55	7.32	9.50						33.2	8.8	2.92	27.36	39.04
FT4	0.83	6.1	0.05	0.73	0.93						4.29	4.4	0.19	3.91	4.67
LH	4.15	7.7	0.32	3.51	4.79						58.8	5.4	3.18	52.45	65.15
PROLACTIN	7.92	5.2	0.41	7.10	8.74						42.3	4.5	1.90	38.49	46.11
PSA, HYB	0.33	6.6	0.022	0.286	0.374						24.25	4.6	1.116	22.019	26.481
TSH	0.63	5.6	0.04	0.56	0.70						22.13	6.1	1.35	19.43	24.83
TT3	0.96	9.6	0.09	0.78	1.14						2.69	5.9	0.16	2.37	3.01
TT4	8.87	7.8	0.69	7.49	10.25						19.1	6.1	1.17	16.77	21.43
VIT B12	188	8.8	16.54	154.91	221.09						620	6.9	42.78	534.44	705.56
FREE T3	2.18	7.3	0.16	1.86	2.50						7.90	5.8	0.46	6.98	8.82
TESTOST	0.96	8.7	0.08	0.79	1.13						10.2	5.9	0.60	9.00	11.40
Means from															
Initial Parallel															
study 11/2016															
CV is peer															
of 10/2016															

SLT_417 Used Here - Lab Mean & Peer CV

Step 7. Daily QC Statistical Assessment (SLT_400)

QC Form (page-1) is now ready to test data from Study to rule out typo's.

Verified QC Limits are set into Analyzer & LIS QC programs.

 INTERNAL MEDICINE ASSOCIATES LAB  DAILY Q.C. STATISTICAL ASSESSMENT 																	
TEST SYSTEM:	BECKMAN ACCESS 2					BECKMAN ACCESS 2					PEER MEAN/HCV					Bias # CTLs	
CONTROLS:	BIORAD IA-PLUS LEVEL-1					BIORAD IA-PLUS LEVEL-3					AS TARGET/QC LIMITS					2	
LOT NUMBERS:	40891					40893										Trend Flag =	
EXPIRATION:	6/30/17					6/30/17										1.5	
Analyte Description	L-1 Mean	Test Value	Bias	SDI (Z)	QC In?	L-2 Mean	Test Value	Bias	SDI (Z)	QC In?	L-3 Mean	Test Value	Bias	SDI (Z)	QC In?	Ave SDI (Z)	Trend Alert
ESTRADIOL 2	50.80	50	-0.80	-0.06	In	790.00	764	-26.00	-0.44	In						-0.25	
FERRITIN	21.70	24.1	2.40	1.60	In	294.00	271	-23.00	-1.12	In						0.24	*
FOLATE	2.40	2.23	-0.17	-0.85	In	12.40	10.9	-1.50	-1.67	In						-1.26	*
FSH	8.41	8.78	0.37	0.68	In	33.15	34.7	1.55	0.53	In						0.60	
FT4	0.83	0.80	-0.03	-0.60	In	4.29	4.25	-0.04	-0.21	In						-0.41	
LH	4.15	4.31	0.16	0.50	In	58.80	61.5	2.70	0.84	In						0.67	
PROLACTIN	7.92	7.67	-0.25	-0.61	In	42.30	41.7	-0.60	-0.32	In						-0.46	
PSA, HYB	0.33	0.33	0.00	0.00	In	24.25	25.9	1.65	1.47	In						0.73	
TSH	0.63	0.60	-0.03	-0.86	In	22.10	22.4	0.30	0.22	In						-0.32	
TT3	0.96	1.00	0.04	0.44	In	2.69	2.64	-0.05	-0.31	In						0.07	
TT4	8.87	8.86	-0.01	-0.01	In	19.10	19.2	0.10	0.09	In						0.04	
VIT B12	188.00	195	7.00	0.42	In	620.00	611	-9.00	-0.21	In						0.11	
FREE T3	2.18	2.19	0.01	0.06	In	7.90	7.65	-0.25	-0.54	In						-0.24	
TESTOST	0.96	0.93	-0.03	-0.35	In	10.20	9.91	-0.29	-0.48	In						-0.42	

Step 8. Inform Analysts Of Lot Change

- Post Clear Messages as to which QC Materials, QC Files, QC Templates are to be used once change is made.
- AVOID mix-ups such as using old material with new QC Files / Templates.. or... new QC material with old QC Files / Templates.
- BEST REMOVE OLD QC MATERIALS to avoid such incidents & resultant headaches.
- Closely monitor QC activities for first few days new QC materials are in use.
- Make on-going statistical parameter adjustments if warranted.

End..