

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.113016

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)*

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 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	L-1	L-1	L-1	L-1	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	Reset	Reset	Reset	Reset	Reset	Reset
Comments : PARALLEL FOR NEW LOT OF CONTROLS VS. E-INSERT								
Analyst : BRITTANY	11/22/2016		Approved by : DL					

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
Comments : PARALLEL TESTING NEW LOT OF CONTROLS VS. E-INSERT								
Analyst : BRITTANY	11/22/2016		Approved by : D. LEIGHTON					

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.

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

CE 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

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. Use Template SLT 417 to Calculate 2SD Limits

Lab determined Means, and Peer CV's are used here to calculate new 2SD Limits.

Optionally, Lab
Previous CV's
are used.(HCV)

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

[illegible]

Step 6. Enter 2SD Limits into QC Assessment Template



When using the
SLT Daily QC
Assessment
Template (SLT_400),
2SD Limits are
Entered on the 2nd
page of the 2-page
Template.

[illegible]

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