

CX INSTRUMENTS CALIBRATION VERIFICATION - 9/2005

Synchron Control Level 1 lot #M411311	Vigil Serology Control Level 1 lot#M402071/Fin	D1 Control lot#M312111 M
Synchron Control Level 2 lot #M411312	Vigil Serology Control Level 1 lot#M409331/MHC	D1 Control lot#M405261 Fir
Synchron Control Level 3 lot #M411313	Vigil Serology Control Level 2 lot#M402072/Fin MHC	D2 Control lot#M412332
Amm/Alc Control Level 1 lot #M410151	Vigil Serology Control Level 3 lot#M402073/Fin	D3 Control lot#M412333
Amm/Alc Control Level 2 lot #M410152	Vigil Serology Control Level 3 lot#M409333/MHC	
Amm/Alc Control Level 3 lot #M5034333	HbA1c Calibrator 2 lot #M502041	T4 Low Cal lot#55639101
Biorad Multiquel Liquid Assayed Level 1 lot#45511		T4 High Cal lot #55639101
Biorad Multiquel Liquid Assayed Level 2 lot#45512		
Biorad Multiquel Liquid Assayed Level 3 lot#45513		

This required exercise; i.e., "calibration verification" isn't particularly useful for us. While we tend to generate results towards the middle of most of the assayed target ranges, the range spreads are too wide to be all that meaningful. It does document how close we typically run as a group on these measurements though. That should come as no surprise since considerable effort has been made over the years to set up identical systems or well-matched methods down often times even to the reagent lots.

sraymond 20051007

Ranges were obtained from control package inserts for the Beckman CX Instruments.
*Lithium target range is for Synchron EL-ISE System.

Beckman Synchron Controls

Site	MAE	MAW	MHC	Finley	Dyer		MAE	MAW	MHC	Finley	Dyer		MAE	MAW	MHC	Finley	Dyer		
Level	Level 1	Level 1	Level 1	Level 1	Level 1	Level 1	Level 2	Level 2	Level 2	Level 2	Level 2	Level 2	Level 3	Level 3	Level 3	Level 3	Level 3	Level 3	Level 3
Assay	Result	Result	Result	Result	Result	Range	Result	Result	Result	Result	Result	Range	Result	Result	Result	Result	Result	Result	Range
Albumin	NA	NA		2.3	2.3	NA	1.9-2.7	NA	NA	3.6	3.7	NA	3.2-4.0	NA	NA	5.1	4.9	NA	4.4-5.6
ALP	NA	NA		39	39	NA	28-48.0	NA	NA	152	142	NA	122-172	NA	NA	266	245	NA	218-298
ALT	NA	NA		14	15	13	9-19.0	NA	NA	153	158	154	132-192	NA	NA	292	289	288	257-357
Amylase	NA	NA		51	56	50	37-57.0	NA	NA	219	220	215	173-253	NA	NA	388	379	385	318-438
AST	NA	NA		21	22	21	16-26	NA	NA	174	172	172	147-197	NA	NA	318	311	313	276-356
BUN3	7	7		7	8	NA	5-9.0	34	34	34	34	NA	30-38	62	61	62	62	NA	57-59
BUN	NA	NA	NA	NA	NA		8.6-10.0	NA	NA	NA	NA	36	32-40	NA	NA	NA	NA	NA	65-80
Calcium	7.7	7.5		7.6	7.5	7.6	7.1-8.3	10.9	10.5	10.5	10.5	10.5	9.8-11.6	13.8	13.4	13.3	13.2	13.4	12.5-14.9
Chloride	83	83		82.9	82.5	82	78-88	102	102	102.7	100.8	102	98-108	119	120	119.6	117.1	119	114-126
Cholesterol	NA	NA		102	104	101	86-116	NA	NA	160	162	158	139-179	NA	NA	217	219	219	195-235
CK	NA	NA		47	54	48	44-64	NA	NA	319	336	332	303-403	NA	NA	576	599	593	538-738
CO2	11	11		10.6	11	11	9-15.0	21	21	20.4	21.6	21	17-25	30	29	28.5	29.3	27	24-34
CRE3	0.4	0.4		0.5	0.5	NA	0.3-0.7	4	4	3.9	4	NA	3.6-4.4	7.4	7.5	7.2	7.3	NA	6.8-8.0
Creatinine	NA	NA	NA	NA	0.5	0.4-0.8	NA	NA	NA	NA	3.9	3.5-4.3	NA	NA	NA	NA	NA	7.1	6.4-8.0
Iron	NA	NA	NA	49	NA	NA	36-62	NA	NA	NA	154	NA	134-174	NA	NA	NA	250	NA	214-286
GGT	NA	NA		15	14	NA	3-23.0	NA	NA	165	163	NA	133-193	NA	NA	316	309	NA	249-369
Glucose	NA	NA	NA	NA	45	37-53	NA	NA	NA	NA	231	219-249	NA	NA	NA	NA	407	NA	389-439
GLU	42	42		41	42	NA	31-55	224	219	214	214	NA	203-233	381	375	366	362	NA	334-404
HDL	NA	NA		26.3	29.7	29.2	21-33	NA	NA	42.2	45.3	44.7	36-50	NA	NA	56.2	60.3	61.9	50-68
IBCT	NA	NA	NA	192	NA	NA	137-237	NA	NA	NA	304	NA	219-369	NA	NA	NA	389	NA	301-491
Potassium	2.4	2.4		2.4	2.43	2.4	2.2-2.8	5	5	4.98	4.95	5	4.7-5.5	7.7	7.7	7.56	7.43	7.5	7.2-8.2
LD-L	NA	NA		47	48	NA	34-64	NA	NA	199	203	NA	172-252	NA	NA	341	348	NA	320-410
LDLD	NA	NA		39.7	42.7	39.6	39-51	NA	NA	70.1	74.2	72.3	67-85	NA	NA	102	108.6	109.7	91-125
Lipase	NA	NA		122	120	NA	87-149	NA	NA	76	74	NA	44-86	NA	NA	24	24	NA	13-35
Lithium*	NA	NA		0.6	NA	NA	0.3-0.7	NA	NA	1.4	NA	NA	1.3-1.9	NA	NA	2.2	NA	NA	2.2-3.2
Magnesium	NA	NA		1.1	1.1	NA	0.8-1.6	NA	NA	2.2	2.3	NA	1.7-2.9	NA	NA	3.3	3.4	NA	2.6-4.2
Salicylate	NA	NA		31.3	NA	NA	24-38	NA	NA	20.6	NA	NA	15-25	NA	NA	10.5	NA	NA	6.0-12.0
Sodium	112	113		113	111.4	114	107-121	138	137	137.6	136.5	138	131-145	162	162	160.2	159.2	160	152-174
Phosphorus	NA	NA		2	1.9	NA	1.1-2.3	NA	NA	4.4	4.3	NA	3.3-4.9	NA	NA	6.7	6.7	NA	5.5-7.7
Total Bilirubin	NA	NA		0.7	0.7	0.5	0.3-1.3	NA	NA	3.7	3.7	3.6	2.9-5.1	NA	NA	6.8	7	6.9	5.2-9.2
Total Protein	NA	NA		3.6	3.6	NA	3.3-4.1	NA	NA	5.8	5.6	NA	5.2-6.4	NA	NA	7.6	7.7	NA	7.1-8.7
Triglyceride	NA	NA		67	69	74	47-87	NA	NA	101	98	102	83-123	NA	NA	135	131	135	110-170
Uric Acid	NA	NA		2.5	2.6	NA	2.2-3.0	NA	NA	6.7	6.8	NA	6.0-7.6	NA	NA	10.7	10.6	NA	9.3-11.6

Beckman Ammonia/Alcohol Controls

Site	MHC	Finley		MHC	Finley		MHC	Finley	
Level	Level 1	Level 1	Level 1	Level 2	Level 2	Level 2	Level 3	Level 3	Level 3
Assay	Result	Result	Range	Result	Result	Range	Result	Result	Range
Ammonia		67	Fin 39-107		220	Fin 167-235		1149	1040-1193
	76		MHC 32-100	230		MHC 173-241	1076		1040-1193
Alcohol		0.05	Fin 0.04-0.06		0.1	Fin 0.09-0.12		0.48	0.421-0.509
	0.05		MHC 0.04-0.06	0.11		MHC 0.08-0.11	0.49		0.421-0.509

CX INSTRUMENTS CALIBRATION VERIFICATION - 9/2005

Beckman Vigil Serology Controls						
Site	Finley		Finley		Finley	
Level	Level 1	Level 1	Level 2	Level 2	Level 3	Level 3
Assay	Result	Range	Result	Range	Result	Range
ASO	105.4	72.9-112.1	196.5	176-236	394.1	354-444

Beckman T4 Calibrators						
Site	MHC					
Level	Low Cal	Low Cal	33%	67%	High Cal	High Cal
Assay	Result	Range	Result	Result	Result	Target
T4	0.00/0.00	0.03	5.2/5.1	11.5/11.6	18/18	19.4

Beckman D1/D2/D3 Bilirubin Controls												
Site	MHC	Finley	Dyer		MHC	Finley	Dyer		MHC	Finley	Dyer	
Level	D1	D1	D1	D1	D2	D2	D2	D2	D3	D3	D3	D3
Assay	Result	Result	Result	Range	Result	Result	Result	Range	Result	Result	Result	Range
Direct Bilirubin	0.9	0.8	0.9	0.4-1.2	3.8	3.7	3.8	3.2-4.2	5.8	5.7	5.7	5.0-6.4

Beckman Synchron Level 1 Control diluted 1:10 (Dilution prepared using Saline. Run samples as a CSF sample.)										
Site	MHC	Finley	MHC	Finley	MHC	Finley	MHC	Finley	MHC	Finley
Dilution	Saline	Saline	30%	30%	50%	50%	70%	70%	100%	100%
MTP	3	RSL	101	97	161	157	228	222	RSH	322

Biorad Multiqual Liquid Assayed Controls (Acid Phos slope set to 1.0)						
Site	MHC					
Assay	Level 1	Level 1 Range	Level 2	Level 2 Range	Level 3	Level 3 Range
Acid Phos	6.3	3.7-7.7	15.4	9.8-18.2	33	20.6-38.4

Beckman HbA1c Cal 2	Result	Result	Target
Site	Dyer		
Level	Hem Rgt	1:2 Dil	HbA1c Cal 2
Assay	Result	Result	Target
Hb	0	7.9	17.1

September 2005 LM

Hemosil Assayed Low Abnormal Control lot #N1142171	MHC D-Dimer Low Control lot #B40235
Hemosil Assayed Normal Control lot #N0153015	MHC D-Dimer High Control lot #B40235
Hemosil Assayed High Abnormal Control lot #N1040977	Finley D-Dimer Low Control lot #B40208
Hemosil Assayed Low Fibrinogen Control lot #N0353582	Finley D-Dimer High Control lot #B40208
George King Fact Control lot #D9d1	
George King A-Fact Control lot #919b1	
George King B-Fact Control lot #N7d1	

ACL 9000									
Hemosil Assayed Control Material									
Site	MHC								
Level	Low Abn	Low Abn	Normal	Normal	High Abn	High Abn	Low Fib	Low Fib	
Assay	Result	Target	Result	Target	Result	Target	Result	Target	
Protime	26.6	21.8-29.6	10.9	9.6-12.6	49.4	44.2-59.8	NA	NA	
Fibrinogen	139	102-172	254	231-351	NA	NA	88.9	67-113	
Thrombin	18.4	16.1-21.9	14.5	12.5-16.5	NA	NA	NA	NA	

We're comparing Mercy results to "ACL 9000" because that's what we're running at the site and we have instrument-specific targets on the test material. The rest of the sites are compared to "ACL Classic".

ACL Classic																	
Hemosil Assayed Control Material																	
*ACL 9000 range no range listed for ACL Classic																	
Site	Finley	Dyer	MAE	MAW		Finley	Dyer	MAE	MAW		Finley	Dyer	MAE	MAW		Finley	
Level	Low Abn	Low Abn	Low Abn	Low Abn	Low Abn	Normal	Normal	Normal	Normal	Normal	High Abn	High Abn	High Abn	High Abn	High Abn	Low Fib	Low Fib
Assay	Result	Result	Result	Result	Target	Result	Result	Result	Target	Result	Result	Result	Result	Result	Target	Result	Target
Protime	23.5	24.4	25.3	26.8	20.5-27.7	10.1	10.8	10.2	10	8.8-11.8	48.3	46.5	45.6	51.4	*44.2-59.8		NA
Fibrinogen	145	NA	NA	NA	121-161	272	NA	NA	NA	226-316	NA	NA	NA	NA	NA	105	65-137

ACL 9000							
George King Biomedical Assayed Control Material							
Target value listed in package insert was obtained using bioMerieux Automated APTT/MLA 900C.							
Site	MHC						
Level	Fact	Fact	A-Fact	A-Fact	B-Fact	B-Fact	
Assay	Result	Target	Result	Target	Result	Target	
Factor VIII	114	116	11.4	7	27.9	39	
Factor IX	101	115	11.1	7	41.3	45	

ACL 9000						
D-Dimer						
Site	MHC					
Level	Low Control	Low Control	1:1 dil	Calc target	High Control	High Control
Assay	Result	Range	Result	Range	Result	Range
D-Dimer	354	257-417	467	489.5	639	532-752

ACL 7000						
D-Dimer						
Site	Finley					
Level	Low Control	Low Control	1:1 dil	Calc target	High Control	High Control
Assay	Result	Range	Result	Range	Result	Range
D-Dimer	303	265-441	489	486	668	569-770

MISCELLANEOUS INSTRUMENTS CALIBRATION VERIFICATION - 9/2005

BNP Calibration Verification kit lot #153116	MHC BNP Cartridge lot #W36822B
MHC/Dyer i-Stat Calibration Verification Material lot #B0497456	Fin BNP Cartridge lot #W36387B
MAE i-Stat Calibration Verification Material lot #B0476983	MAE i-Stat cartridge lot #U05114
MHC i-Stat cartridge lot #L05074A	Dyer i-Stat cartridge lot #L05074A
Beckman D1 Bilirubin Control lot #M405261	Beckman D3 Bilirubin Control lot #M412333
Beckman D2 Bilirubin Control lot #M412332	Beckman D4 Bilirubin Control lot #M312114



BNP Calibration Verification																		
Site	MHC			Finley			MHC			Finley			MHC			Finley		
Level	Level A	Level A	Level A	Level B	Level B	Level B	Level C	Level C	Level C	Level D	Level D	Level D	Level E	Level E	Level E			
Assay	Result	Result	Range	Result	Result	Range	Result	Result	Range	Result	Result	Range	Result	Result	Range			
BNP	19.4	18.4	<5.0-37.7	27.6	31.7	15.5-51.9	722	635	487-1250	3600	3500	1820->5000	3400	2980	1970->5000			

i-Stat Calibration Verification Material lot #B0497456										
MAE Serial #2-37917										
Site	MAE		MAE		MAE		MAE		MAE	
Level	Level 1	Level 1	Level 2	Level 2	Level 3	Level 3	Level 4	Level 4	Level 5	Level 5
Assay	Result	Range	Result	Range	Result	Range	Result	Range	Result	Range
pO2	67	50.8-76.8	77	62.9-88.9	101	83.6-108.4	137/135	104.4-135.6	376	304.0-407.6
pCO2	88.3	81.24-98.90	58.6	55.12-67.36	25.2	20.18-30.96	17.9/18.3	13.39-23.68	15.7	10.5-20.30
pH	6.81	6.774-6.872	7.16	7.128-7.226	7.45	7.402-7.500	7.69/7.688	7.645-7.743	8.1	8.061-8.159

i-Stat Calibration Verification Material lot#B0497456																
MHC Serial #42636																
Dyer Serial #2-46876																
Site	MHC		Dyer		MHC		Dyer		MHC		Dyer		MHC		Dyer	
Level	Level 1	Level 1	Level 1	Level 2	Level 2	Level 2	Level 3	Level 3	Level 3	Level 4	Level 4	Level 4	Level 5	Level 5	Level 5	
Assay	Result	Result	Range	Result	Result	Range	Result	Result	Range	Result	Result	Range	Result	Result	Range	
pO2	62	62	50.8-76.8	76	75	62.9-88.9	94	95	83.6-108.4	124	114	104.4-135.6	370	362	304.0-407.6	
pCO2	85.9	90.6	81.24-98.9	59.7	61.8	55.12-67.36	25.1	26.9	20.18-30.96	18.6	20.2	13.39-23.68	16.6	16.9	10.5-20.3	
pH	6.822	6.817	6.774-6.872	7.169	7.169	7.128-7.226	7.446	7.444	7.402-7.500	7.687	7.676	7.645-7.743	8.105	8.11	8.061-8.159	

Advance Bilirubinometer (Since we use the CX Calibrator for this instrument, ranges listed are for the Synchron CX Systems.)												
Site	MAE		MAW		MAE		MAW		MAE		MAW	
Level	Level 1	Level 1	Level 1	Level 2	Level 2	Level 2	Level 3	Level 3	Level 3	Level 4	Level 4	Level 4
Assay	Result	Result	Range	Result	Result	Range	Result	Result	Range	Result	Result	Range
Total Bilirubin	1.6	1.6	0.6-2.6	6.1	5.9	5.0-6.4	8.6	9	7.9-9.7	15.3	16	no ranges
Direct Bilirubin	0.6	0.5	0.5-0.7	3.5	3.5	3.2-4.2	5.3	5.6	5.0-6.4	9.7	10.7	no ranges

Nanoduct Sweat Chloride						
Site	MHC					
Level	Level 1	Level 1	Level 2	Level 2	Level 3	Level 3
Assay	Result	Range	Result	Range	Result	Range
Chloride	42	38-50	72	67-79	138	124-150



 We need to combine these on the next set

Miscellaneous Instruments Calibration Verification

Site MAC-West

BNP Calibration Verification kit lot #	BNP Cartridge lot #
i Stat Linearity Material lot #	i-Stat cartridge lot #
Beckman D1 Bilirubin Control lot #	Beckman D3 Bilirubin Control lot #
Beckman D2 Bilirubin Control lot #	Beckman D4 Bilirubin Control lot #

BNP Calibration Verification Date _____

Level	Level 1	Level 1	Level 2	Level 2	Level 3	Level 3	Level 4	Level 4	Level 5	Level 5
Assay	Result	Range	Result	Range	Result	Range	Result	Range	Result	Range
BNP										

iStat Calibration Verification Material Date _____

Serial # _____

Level	Level 1	Level 1	Level 2	Level 2	Level 3	Level 3	Level 4	Level 4	Level 5	Level 5
Assay	Result	Range	Result	Range	Result	Range	Result	Range	Result	Range
pO2										
pCO2										
pH										

TOSOH Hb/A1c linearity Date 11-8-05

Dilution	A	B	C	D	E
HbA1c	4.8 / 4.8	6.9 / 6.8	8.3 / 8.2	9.7 / 9.6	11.8 / 11.8

expected / observed

Advance Bilirubinometer Date _____

Level	Level 1	Level 1	Level 2	Level 2	Level 3	Level 3	Level 4	Level 4
Assay	Result	Range	Result	Range	Result	Range	Result	Range
Total Bilirubin								
Direct Bilirubin								

OK
[Signature]
 2005/11/4

G7 Automated HPLC Analyzer

Linearity Study: HbA1c

Account Name: Medical Associates

Date: 11/08/05

Technologist: Rosemary Keleher

Expected Value	Observed Value	Mean	% Recovery			
4.8	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;">4.8</td></tr> <tr><td style="text-align: center;">4.8</td></tr> <tr><td style="text-align: center;">4.8</td></tr> </table>	4.8	4.8	4.8	4.8	100%
4.8						
4.8						
4.8						
6.9	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;">6.9</td></tr> <tr><td style="text-align: center;">6.8</td></tr> <tr><td style="text-align: center;">6.8</td></tr> </table>	6.9	6.8	6.8	6.8	99%
6.9						
6.8						
6.8						
8.3	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;">8.3</td></tr> <tr><td style="text-align: center;">8.2</td></tr> <tr><td style="text-align: center;">8.2</td></tr> </table>	8.3	8.2	8.2	8.2	99%
8.3						
8.2						
8.2						
9.7	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;">9.7</td></tr> <tr><td style="text-align: center;">9.6</td></tr> <tr><td style="text-align: center;">9.6</td></tr> </table>	9.7	9.6	9.6	9.6	99%
9.7						
9.6						
9.6						
11.8	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="text-align: center;">11.8</td></tr> <tr><td style="text-align: center;">11.8</td></tr> <tr><td style="text-align: center;">11.7</td></tr> </table>	11.8	11.8	11.7	11.8	100%
11.8						
11.8						
11.7						
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