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TO: HCHS/SOL Quality Control Committee
CC: Cai, Jianwen

FROM: Daniela Sotres-Alvarez, HCHS/SOL Coordinating Center
DATE: December 11, 2013

RE: HCHS/SOL Quality Control Report, December 2013

MEMORANDUM

This report includes the Reliability of 3 additional laboratory measurements (Cystatin, GGT and Ferritin) from HCHS/SOL baseline data analyzed by the Central Lab during the summer of 2013.

Tables 3.1 – 3.2(a-e) Reliability of Anthropometric and Laboratory measurements

Background: To estimate the reliability of laboratory and anthropometric measurements, some participants provided an additional sample of blood or urine, or had anthropometric measurements repeated by a second technician on the same visit. The same technician obtains replicate biospecimen samples by either (1) drawing 2nd tube of blood or sample, or (2) dividing urine into 2 separate containers. These additional QC specimens are labeled with a *phantom* participant ID that is indistinguishable from other ID numbers, so that the laboratory is blinded to the QC process.

Two statistics of great interest in Tables 3.1 and 3.2 (a-e) are the reliability coefficient and the coefficient of variation (CV). A reliability coefficient close to 1 suggests that only a small proportion of the total variance due is due measurement error (or laboratory) variation. Because power is so compromised for reliabilities below 0.60, analyses for this study should focus on variables with reliability coefficients of 0.60 or higher. Ideally, we would like all reliabilities to be above 0.80. The CV a measure of within-specimen variation expressed as a percentage of the mean, – we would like to see CV values below 10%. The statistics under the “Difference” column indicate whether there is evidence of a systematic difference between measurements obtained from the original and QC specimens. Since the specimens were obtained at the same time, we would not expect to see any systematic difference in measurements.

The reliability coefficients for all of the anthropometric measures are excellent (0.96 or higher) at all centers. All laboratory measurements have reliabilities above 0.85 (tables 3.2 a-e) except for Basophils (% and count) and Monocyte Count. However, these analytes have mean values that are close to 0 and so the reliability statistic is not very meaningful. The coefficient of variation for urine microalbumin and albumin/creatinine ratio are high in the Bronx (191.7 and 136.8 respectively). The central Lab investigated this and found that the high CVs were due to a couple of highly discrepant values. On more detailed investigation, these were most likely due to mislabeled blinded specimen and a contaminant. The CVs for urinary microalbumin and the ratio in Bronx are lower if these outliers are dropped out of the statistics.

References

Chambless LE, McMahon RP, Brown SA, Patsch W, Heiss G, Shen YL. Short-term intraindividual variability in lipoprotein measurements: the Atherosclerosis Risk in Communities (ARIC) Study. *Am J Epidemiol.* 1992 Nov 1;136(9):1069-81.

Chambless LE, McMahon R, Wu K, Folsom A, Finch A, Shen YL. Short-term intraindividual variability in hemostasis factors. The ARIC Study. Atherosclerosis Risk in Communities Intraindividual Variability Study. *Ann Epidemiol.* 1992 Sep;2(5):723-33.

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Table 3.2f Reliability of additional laboratory measurements (Cystatin, GGT and Ferritin)

		QC Pairs						Difference				
		N	Outliers removed	Mean	Lab SD (1)	Reliab (2)	CV (3)	Mean	95% CI	Prop > 0	pval (4)	
Cystatin C (mg/L) (LABA101)	Bronx	290	7	0.8	0.03	0.98	3.3	0.01	0.01	0.01	0.65	0.000
	*Bronx	297	.	0.8	0.05	0.99	5.7	0.01	-0.00	0.01	0.64	0.000
	Chicago	156	1	0.8	0.03	0.98	3.9	0.02	0.01	0.03	0.66	0.000
	*Chicago	157	.	0.8	0.03	0.98	3.9	0.02	0.01	0.03	0.66	0.000
	Miami	206	4	0.8	0.03	0.98	3.7	0.01	0.00	0.01	0.58	0.043
	*Miami	210	.	0.8	0.04	0.96	5.6	0.01	-0.00	0.02	0.58	0.045
	San Diego	148	1	0.8	0.03	0.99	3.4	0.01	0.00	0.01	0.51	0.460
	*San Diego	149	.	0.8	0.04	0.98	4.5	0.01	0.00	0.02	0.51	0.413
	Overall	801	12	0.8	0.03	0.98	3.6	0.01	0.01	0.01	0.61	0.000
	*Overall	813	.	0.8	0.04	0.99	5.2	0.01	0.01	0.01	0.61	0.000
GGT (U/L) (LABA102)	Bronx	295	1	31.1	2.32	0.99	7.5	0.39	0.02	0.76	0.65	0.002
	*Bronx	296	.	31.3	9.65	0.91	30.8	1.02	-0.27	2.31	0.66	0.002
	Chicago	155	2	33.4	2.13	1.00	6.4	1.10	0.62	1.58	0.72	0.000
	*Chicago	157	.	34.0	9.50	0.91	28.0	1.27	-0.98	3.52	0.72	0.000
	Miami	208	2	30.5	4.71	0.97	15.4	0.46	-0.45	1.36	0.61	0.031
	*Miami	210	.	31.3	15.67	0.76	50.1	2.22	-0.76	5.21	0.62	0.023
	San Diego	147	2	34.3	1.41	1.00	4.1	0.09	-0.23	0.41	0.57	0.021
	*San Diego	149	.	34.3	4.37	0.98	12.7	0.70	-0.21	1.62	0.58	0.014
	Overall	804	8	31.9	2.53	0.99	7.9	0.55	0.31	0.78	0.64	0.000
	*Overall	812	.	32.4	10.83	0.88	33.5	1.32	0.30	2.34	0.65	0.000
Ferritin (ug/L) (LABA103)	Bronx	289	3	114.1	5.91	1.00	5.2	0.96	0.00	1.92	0.68	0.000
	*Bronx	292	.	115.8	26.23	0.94	22.6	2.62	-0.97	6.22	0.68	0.000
	Chicago	151	2	112.5	7.38	1.00	6.6	2.50	0.77	4.24	0.63	0.002
	*Chicago	153	.	119.6	17.98	0.98	15.0	4.97	0.73	9.21	0.63	0.001
	Miami	205	4	114.0	4.36	1.00	3.8	0.55	-0.29	1.39	0.55	0.264

	QC Pairs						Difference					
	N	Outliers removed	Mean	Lab SD (1)	Reliab (2)	CV (3)	Mean	95% CI	Prop > 0	pval		
										(4)		
*Miami	209	.	117.5	32.32	0.90	27.5	3.58	-2.61	9.78	0.55	0.213	
San Diego	142	4	115.9	3.72	1.00	3.2	0.65	-0.21	1.52	0.61	0.005	
*San Diego	146	.	115.3	12.21	0.99	10.6	-0.64	-3.33	2.05	0.60	0.010	
Overall	790	10	115.1	6.71	1.00	5.8	1.25	0.60	1.90	0.62	0.000	
*Overall	800	.	116.9	24.60	0.96	21.0	2.73	0.44	5.02	0.62	0.000	

Outliers (diff > 3 SD) excluded unless row label is preceded by *

(1) Standard deviation = square root (within-subject variance)

(2) The reliability coefficient is an estimate of the correlation between repeated measurements

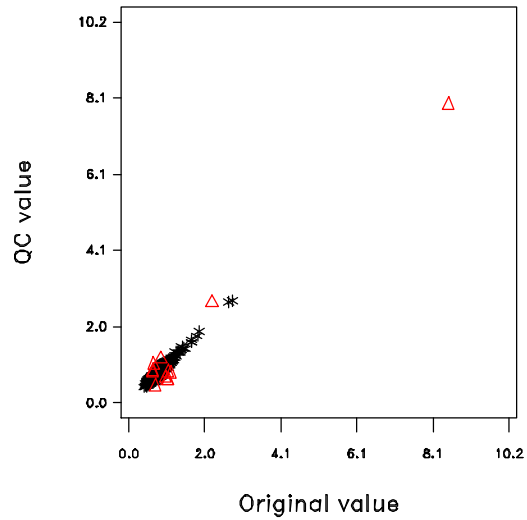
(3) The coefficient of variation (CV) is the lab SD expressed as a percent of the mean of QC pairs

(4) P-value for test that the proportion of positive differences = 50% (test for systematic bias)

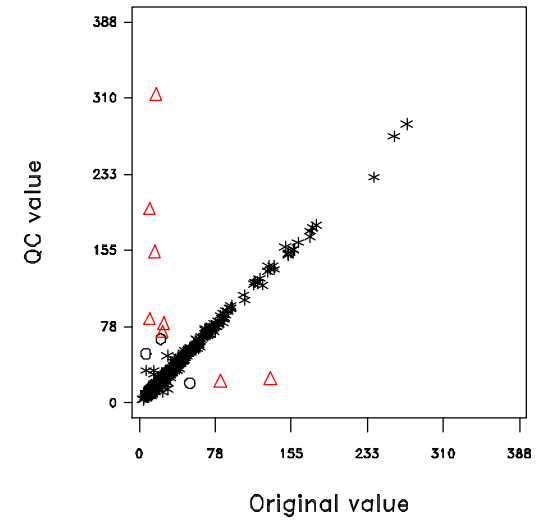
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Based on data retrieved at the CC on November 08, 2013

Table 3.2f Reliability of additional laboratory measurements (Cystatin, GGT and Ferritin)

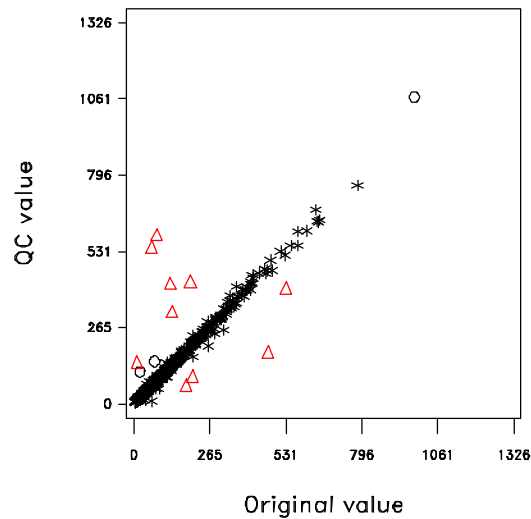
Cystatin C (mg/L) (LABA101)



GGT (U/L) (LABA102)



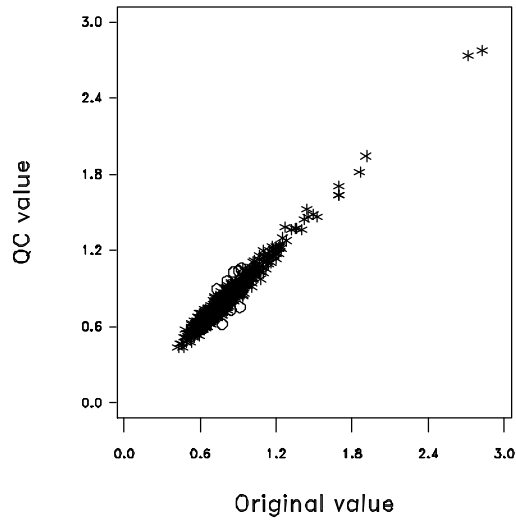
Ferritin (ug/L) (LABA103)



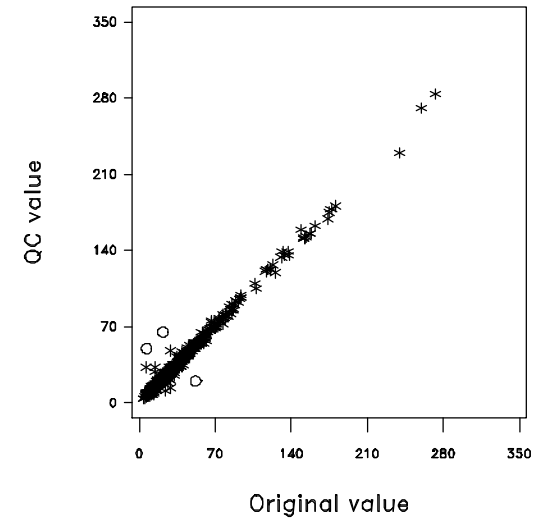
Circles indicate differences larger than 2 SD, and triangles larger than 3 SD
 Outliers excluded unless variable name is preceded by *

Table 3.2f Reliability of additional laboratory measurements (Cystatin, GGT and Ferritin), outliers (diff>3 SD) excluded

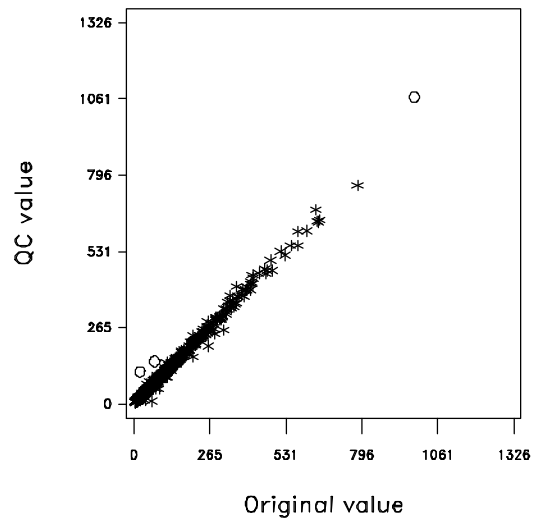
Cystatin C (mg/L) (LABA101)



GGT (U/L) (LABA102)



Ferritin (ug/L) (LABA103)



Circles indicate differences larger than 2 SD, and triangles larger than 3 SD
 Outliers excluded unless variable name is preceded by *