

Technical Memorandum

TO:	Physicians, Staff	
From:	Wesley Kim, MD, Medical Director Minnie Pang, MT(ASCP), VP Technical Operation Susan Krause, MT(ASCP), Manager, Core Lab	
Date:	December 31, 2009	
Subject:	Laboratory Automation System, Phase III	

Diagnostic Laboratory Services is pleased to inform you that validation of our new immunoassay instrumentation is now complete. The final transition is expected to go live on January 6, 2010. This will complete the change-over to the new system for the main DLS reference lab at Dole Cannery. The next major project for DLS will then be to transition the hospital lab at Queen's Medical Center to the new system. This is expected to begin around March 2010.

Attached is a list of tests, including the current reference ranges and the new reference ranges, which will be changing over in Phase III. Based on the validation study, clinicians may see slight variations in the numerical values when comparing results between the previous and new system. As such, there will be some variation in the respective reference ranges. In addition, for a few analytes, DLS will be adopting expanded age related reference ranges. It is important to remember that results for any given test do not always correlate between two different manufacturers. For those tests being used to routinely monitor patients over time, it is recommended that, where clinically indicated, patients should be re-baselined with the new assay before making clinical decisions.

We sincerely thank you for your patience and understanding during this transition period. Even though the actual physical change to the new system is complete, DLS will continue to monitor the new system very closely and make adjustments to ensure optimal performance. Because of this, it is important that any feedback, questions, or concerns that you may have in regards to laboratory performance, be immediately communicated to our client services, your marketing representative, or a DLS Laboratory Director, so that they may be addressed to ensure the quality and safety of laboratory results.

You may contact DLS Client Services at 589-5101, or Dr. Wesley J. Kim at 589-5131.

Imunoassay Test Platform

TEST	UNITS	CURRENT	NEW
		REFERENCE RANGE	REFERENCE RANGE
CA 125	u/mL	< 35	< 35
CEA	ng/mL	0.0 - 3.0	0.0 - 4.7
Cortisol	ug/dL	4A-12N: 6.0 – 28.0	4A-12N: 6.0 – 25.0
		12N-12M: 3.0 – 16.0	12N-12M: 3.0–16.0
Digoxin	ng/mL	0.9 - 2.0	0.9 - 2.0
Ferritin	ng/mL	M: 25 – 371	M: 30 – 400
		F <50Y: 11 – 137	F: 13-150
		F <u>></u> 50Y: 25 - 278	
Folate	ng/mL	> 5.2	>3.1
FSH	mIU/mL	M: 1.3 – 19.3	M: 1.5 – 12.4
		F: Follicular: 3.9 – 8.8	F: Follicular: 3.5 – 12.5
		Mid Cycle: 4.5 – 22.5	Mid Cycle: 4.7 – 21.5
		Luteal: 1.8 – 5.1	Luteal: 1.7 – 7.7
		Postmenopause: 16.7–113.6	Postmenopause: 25.8–34.8
Insulin	uU/mL	< 23.0	2.6 - 24.9
LH	U/L	M: 1.2 – 8.6	M: 1.7 – 8.6
		F: Follicular: 2.1 – 10.9	F: Follicular: 2.4 – 12.6
		Mid Cycle: 19.2 – 103	Mid Cycle: 14.0 – 95.6
		Luteal: 1.2 – 12.9	Luteal: 1.0 – 11.4
		Postmenopause: 10.9–58.6	Postmenopause: 7.7–58.5
Prolactin	ng/mL	M: 2.6 – 13.1	M: 4.1 – 15.2
		M 16Y: 2.2-16.3	F 40 222
		F: 2.7 – 26.7	F: 4.8 – 23.3
DCA Error	an er /ren I	F 16Y: 2.2-16.3 Male: > 25%	Male: > 25%
PSA, Free	ng/mL	Male:	Male:
PSA, Total	ng/mL	40-49Y: $0.0 - 2.4$	40-49Y: $0.0 - 2.4$
		40-491: 0.0 - 2.4 50-59Y: 0.0 - 3.8	40-491: 0.0 - 2.4 50-59Y: 0.0 - 3.8
		60-69Y: 0.0-5.6	60-69Y: 0.0-5.6
		>69Y: 0.0 – 6.9	>69Y: 0.0 – 6.9
RBC Folate	ng/mL	>237	>263
Rubella IgG	IU/mL	<10 = Negative	<10 = Non-Reactive
		10-15 = Equivocal	$\geq 10 = \text{Reactive}$
		>15 = Positive	
T3, Free	pg/mL	2.5 - 3.9	2.5 - 4.3
T3, Total	ng/dL	77 - 178	80 - 200
T4, Free	ng/dL	0.6 – 1.7	0.9 – 1.7
Testosterone	ng/dL	M: 190 – 1037	M: 280 - 800
	-	F: 10 - 82	F: 6 – 82
TSH	uIU/mL	0.28 - 4.02	0.27 – 4.2
		1D: 9.20-28.40	1D: 9.20-28.40
		2D: 6.60-15.60	2D: 6.60-15.60
		3D: 0.83-8.65	3D: 0.83-8.65
		1M: 0.67-5.57	1M: 0.67-5.57
Vitamin B12	pg/mL	> 175	211 - 946