Technical Bulletin

by Dr. Wesley Kim

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To better serve our clients and the community, Diagnostic Laboratory Services recently implemented its new automation clinical chemistry and immunoassay system. After extensive method validation and comparison studies, the new system went live on December 14, 2009. Although majority of testing did not show significant differences between the previous and new system, adjustments in the reference range and reporting were made for certain tests, the list of which were sent in previous bulletins to our clients. Following implementation, DLS has continued to collect data to further refine and adjust its reference ranges and validate those assays that showed significant differences from previous methods.

Effective immediately, DLS has adjusted the reference ranges for those analytes shown in Table 1.

Table 1

Analyte	Previous Reference Range	**New Reference Range**
Calcium, total	8.6 to 10.2 mg/dL	8.3 to 10.5 mg/dL
Chloride	96 to 108 mEq/L	95 to 108 mEq/L
CO2	22 to 29 mEq/L	21 to 30 mEq/L
Creatinine	0.7 to 1.5 mg/dL	0.6 to 1.4 mg/dL
Phosphorus	2.7 to 4.5 mg/dL	2.5 to 4.5 mg/dL
Free T4	0.9 to 1.7 ng/dL	0.9 to 2.1 ng/dL

In addition, for Total PSA, the previous system could only detect PSA to a level of 0.05 ng/ml. When DLS initially converted to the new system, this limit was increased to 0.08 ng/ml based on preliminary validation study data. However, after further investigation and completion of the final validation study, DLS will be reducing the quantitation limit down to 0.02 ng/ml. We hope this will allow our clients who are following patients with Total PSA values to detect low level PSA value increases or recurrences earlier during the patient's clinical course and allow for improved patient management.

Finally, DLS is aware of an increase in HDL values following implementation of the new system. The increase appears variable from patient to patient with some patients showing relatively small increases while others showing fairly substantial increases. DLS recently completed a small HDL study with Northwestern Regional Laboratory, one of the CDC lipid reference labs, the results of which showed very good correlation between our new method and the CDC reference method upon which the current NCEP-ATPIII guidelines for lipid management are based. However, to be complete and ensure quality, DLS just completed a second formal validation of the entire lipid profile (Total Cholesterol, HDL, Triglycerides, calculated LDL and direct LDL) compared with the CDC reference method. Similar to the small HDL study, the new method compares very well for Total Cholesterol, HDL, LDL (calculated and direct measurement) with bias errors within the acceptable limit as stated by the CDC. Triglycerides did show a slight negative bias, the error of which is just outside what is recommended by CDC.

DLS will continue to work with the manufacturer to bring the Triglyceride assay within acceptable limits. Table 2 shows the average bias values for the various lipid parameters as well as the recommended CDC limits of acceptability.

Table 2

Analyte	Average Absoute Bias between CDC method and DLS	Average % Bias between CDC method and DLS method	Recommended CDC limits of Acceptibility
Chloesterol, Total	-4.0	-2.0%	3% (plus or minus)
HDL	-0.2	-0.8%	5% (plus or minus)
LDL,calculated	-0.8	0.1%	
LDL,direct measurement	-3.7	-2.7%	4% (plus or munis)
Triglycerides	-8.0	-6.0%	5% (plus or minus)
CDC LDL direct vs DLS LDL calculated	2.3	1.0%	

DLS will continue over the next 6 months to analyze data and trends on the new system should any additional adjustments need to be made and we will continue to keep our clients updated and informed. If you have any questions or concerns please do not hesitate to call Dr. Wesley Kim at 589-5131 or DLS client services at 589-5101.