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SUBJECT: New 25-Hydroxyvitamin D Assay

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On Wednesday June 24, 2009, URMCLabs at Strong will be switching to an in-house liquid chromatography-tandem mass spectrometry (LC/MS) assay for 25-hydroxyvitamin D (25-OHD) levels, replacing the current send-out immunoassay.

Comparison of the two assays: Based on a comparison study of 500 patients samples,

- Results obtained by the two assays are different.
- LC/MS results are 15-20% higher, and more so at low concentrations.
- Quantitative conversion of LC/MS results to equivalent IA results using the regression equation may not be accurate (LC/MS = IA x 0.85 + 7.3; $r^2 = 0.63$)

Accuracy of the LC/MS assay

- LC/MS method gives a more accurate measurement of 25-OHD
- It measures 25-OHD₂ and 25-OHD₃ separately, and the sum of the two is reported as Total 25-OHD.
- Infants have C-3 epimers of 25-OHD₂ or 25-OHD₃ that interfere with the LC-/MS assay. Orders for 25-OHD measurements in children less than 1 year will be sent to Mayo Medical Laboratories, which uses a special assay that is not interfered by the C-3 epimers.

Lab report and reference ranges: the lab report on 25-OHD will list three concentration results,

- 25-OHD₂, 25-OHD₃, & total 25-OHD (sum of 25-OHD₂ and 25-OHD₃).

The reference ranges for total 25-OHD will be:

- <20 ng/ml Deficient
- 21-29 ng/ml Insufficient
- 30-80 ng/ml Optimal
- >80 ng/ml Possible toxicity

The upper limit of the optimal range is not well defined, but we have chosen 80 ng/ml in order to be consistent with our reference laboratory (Mayo Medical Laboratories). Levels >80 ng/ml will be flagged as 'Possible Toxicity' because the lowest reported 25-OHD level associated with hypercalcemia is 88 ng/ml. Individuals who spend a lot of time in the sun can have 25-OHD levels >100 ng/ml, but 25-OHD levels associated with Vitamin D toxicity are almost always > 200 ng/ml.

Additional technical details about this new assay and other lab updates can be found by visiting:

www.urmc.rochester.edu/pathology_lab_medicine/clinical_labs/news_publications/provider_notifications.cfm