DIAGNOSTIC SERVICES OF MANITOBA
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Clinical Biochemistry & Genetics Discipline, MS-543 820 Sherbrook Street, Winnipeg, Manitoba, Canada R3A 1R9
Phone # 204-787-2843

LABORATORY COMMUNICATION

EFFECTIVE APRIL 10, 2012

Change in Methodology for 25 OH Vitamin D Analysis

Effective April 10, 2012, the method for 25 OH vitamin D analyses will be updated to liquid chromatography tandem mass spectrometry. In the majority of patients, this methodology has been shown to be a more accurate measurement of 25 OH vitamin D. In addition, with automated sample preparation, we are able to cost-effectively manage the increased number of vitamin D requests. With this change, we have eliminated the use of radioactivity for 25 OH vitamin D testing, and hence the storage requirements which limited capacity of the previous assay. Going forward, we will be able to provide a 25 OH vitamin D result in a time frame that is clinically relevant, with a goal of providing a result within 2 weeks of receipt of a sample in the laboratory. To attain this goal, we require your assistance by adhering to best practice approach for monitoring vitamin D levels:

Screening for vitamin D deficiency in healthy individuals is generally <u>not necessary</u>. Please see the attached risk stratification guideline to aid your decision to measure vitamin D.

In changing to liquid chromatography tandem mass spectrometry, there will be no change in the reference interval for interpretation of 25 OH vitamin D results. In order for high accuracy results, samples MUST be collected in a serum (no gel) red top tube. **Samples for 25 OH vitamin D analyses will be rejected if collected using gel-barrier tubes.**

There is presently an 18 month backlog (approximately 14,000 samples) for 25 OH vitamin D requests. In switching to our new methodology, we will continue systematically working through the back logged samples. Back logged samples collected using gel barrier tubes will not be analyzed using the new methodology, unfortunately due to the manual nature of the old method and the radioactive waste generated by that method, analyzing samples collect in gel barrier tubes is not possible. **If a gel barrier tube was used, the ordering practitioner will be notified that a recollection is required**. Otherwise, the back logged sample will be analyzed using the new methodology. Please only re-order 25 OH vitamin D testing once notified that it is required for a specific patient. Your adherence to this request will provide us with a manageable approach to the back log of requests.

As opposed to our previous methodology, the new methodology cannot resolve the 3-epimer of vitamin D which is a known non-biologically active interference for 25 OH vitamin D analyses. The 3-epimer is present in significant quantities in a significant number of children less than one year of age. For this reason, these samples will be done by an alternate

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methodology that is not affected by the 3-epimer, which is an out-of-province test. Less commonly the 3-epimer is present in sufficient quantity in other patient's samples to contribute to an overestimate to results. If you suspect an issue with the accuracy of a patient's vitamin D result, please contact the Health Science Centre Laboratory or the undersigned.

Please contact the undersigned if there are questions, or for further discussion.

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Risk Stratification for Vitamin D Monitoring

Low Risk for Vitamin D Insufficiency: Vitamin D (25-hydroxy) should generally **not** be measured in individuals at low risk for vitamin D insufficiency (such as those below age 50 years without co-morbid conditions that affect vitamin D absorption or action (1)).

Recommendation: An individual's particular needs will depend on milk intake, concurrent use of multivitamins containing vitamin D and on summer sun exposure (2). If a vitamin D supplement is used, then 800-2000 IU/day for an adult is reasonable. The safe upper limit for vitamin D_3 supplements has not been well defined, but a daily dose of up to 4,000 IU is safe and does not require laboratory monitoring to avoid toxicity in adults (6). The Canadian Pediatric Society continues to recommend a vitamin D intake of 400 IU per day, with increase to 800 IU per day for babies north of the 55th parallel (4).

Moderate Risk for Vitamin D Insufficiency: In adult individuals at moderate risk for vitamin D insufficiency (such as those over age 50 years, with documented osteoporosis or fractures, or with conditions that affect vitamin D absorption or action), an adequate supplementation dose of vitamin D [800-2000 IU/day for an adult] is appropriate. Health Canada recommends that in addition to following Canada's Food Guide, all adults over the age of 50 should take a daily vitamin D supplement (http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/context/evid-fond/vita_d-eng.php).

Recommendation: Serum vitamin D (25-hydroxy) does not need to be measured in these individuals, but if measurements are undertaken then these should follow at least 3-6 months of an adequate supplementation dose.

High risk for vitamin D insufficiency: In individuals at high risk for vitamin D insufficiency (such as those with recurrent fractures despite osteoporosis treatment or with documented osteoporosis and co-morbid conditions that affect vitamin D absorption or action), adequate supplementation with vitamin D and measurement of serum vitamin D (25-hydroxy) are appropriate.

Recommendation: Serum vitamin D (25-hydroxy) should be measured following 3-6 months of an adequate supplementation dose.

Infants that are at high risk for vitamin D insufficiency:

Profound maternal vitamin D deficiency can lead to severe vitamin D deficiency in infancy owing to lack of maternal stores to transfer to the baby. Such babies can present with hypocalcemic seizures or signs of rickets (5).
Recommendation: If mothers have had minimal pre-natal vitamins, minimal summer sun exposure and minimal milk intake during the last trimester of pregnancy; consider testing the infant and referring to a specialist for higher dose vitamin D supplementation if severely deficient.

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References:

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3. Hathcock JN, Shao A, Vieth R, Heaney R. Risk assessment for vitamin D. Am J Clin Nutr 2007 Jan;85(1):6-18
4. Canadian Paediatric Society Position Statement (FNIM 2007-01). Vitamin D supplementation: Recommendations for Canadian mothers and infants. Paediatric Child Health 2007 Sep;12(7):583-589. Available at http://www.cps.ca/english/statements/ii/fnim07-01.htm
5. Ward LM, Gaboury I, Ladhani M, Zlotkin S. Vitamin D-deficiency rickets among children in Canada. CMAJ 2007 Jul 17;177(2):169-71
6. http://www.iom.edu/Reports/2010/Dietary-Reference-Intakes-for-Calcium-and-Vitamin-D/Report-Brief.aspx

If you have any questions or concerns relating to this topic please contact the appropriate person(s) listed below:

Clinical management: Laboratory testing:

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