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LabReport

McLaren
MEDICAL LABORATORY

Vitamin D Measurement

Recently vitamin D deficiency has been reported in adults, especially in the aging population and the population living in nursing homes. Sunlight is the best source for vitamin D production. UVB from sunlight helps in synthesizing vitamin D3 in the skin from its precursor. Vitamin D2 is also commonly found in certain food forms and can be used clinically in the form of supplements. Vitamin D2 is considered biologically equally to D3. Thus, all the assays used in the clinical laboratories should mirror equally D2 and D3. Both forms of Vitamin D are then converted to 25-hydroxy vitamin D by the liver. 25-hydroxy vitamin D is converted to 1,25-dihydroxy vitamin D by the kidney. Acting principally on the duodenum, 1,25-dihydroxyvitamin D increases calcium absorption. It also acts on bone cells, both osteoblasts and osteoclasts, to mobilize calcium. Measurement of 25-hydroxyvitamin D is the recommended analyte to assay Vitamin D levels. Only in unusual instances is measurement of 1,25-dihydroxyvitamin D necessary.

Screening assays for vitamin D level should be easy to use, reliable, and cost effective. The assay used at McLaren Medical Laboratory evaluates 25-hydroxy-vitamin D level. It does not differentiate between the D2 or D3 form but yields a result that includes both. This assay is cost effective as a screening or monitoring assay. In the event results do not correlate with a patient's clinical status, or there is a concern that oral absorption of vitamin D is suboptimal, the more expensive assay Vitamin D2/D3 can be considered. This latter assay is sent to a reference laboratory and is more expensive to perform.

This Edition Contains These Topics:

Microbiology Testing

The microbiology department is regularly the busiest department at MML. Microbes do not rest and their recognition and antibiotic sensitivities require 24/7 vigilance. When MML went live on October 4, we were awed with the microbiology activity we saw. Samples arrived day and night, some registered from the subsidiaries and some not. Some samples arrived from hospitals on McKesson IT platforms and some on Cerner IT platforms. Technologists needed to quickly become familiar with both software applications, new testing equipment, pathways of workflow, and provider expectations. Needless to say our turnaround time was not to our satisfaction.

Adjustments in our planned processes were necessary. Staffing shifts to the specimen plating and gram staining area were necessary. Some shifting of personnel from chemistry and hematology took place. To expedite the plating process, specimens were moved directly from the receiving department to the microbiology laboratory for registration. In addition, benchmarks of performance expectation were established to assure our clients' needs would be met.

In our first two months of operations we have performed 25,000 cultures.

An automation line at McLaren Medical Laboratory's new centralized facility located at 4000 South Saginaw Street in Flint.

The adjustments we made have improved our operations and efficiencies with a decrease in turnaround time of 30%.

In addition, we are working with the infectious disease nurses at each of the subsidiaries to assure satisfaction with report formats and reporting requirements.

Of all departments in the clinical laboratory, molecular opportunities in microbiology present the greatest opportunities for innovation. Within a few months we hope to bring Chlamydia and Neisseria testing in house on a sophisticated Roche platform. In addition to the automation capabilities and efficiencies this will offer, delineation of high grade HPV types, including HPV16 and HPV18, will be available. Group B strep by PCR with more rapid confirmation of negative results will soon be available.

Chlamydia/ Neisseria Testing

Chlamydia trachomatis is the most prevalent sexually transmitted disease. Neisseria gonorrhea is much less prevalent. However, both organisms are frequently tested for during gynecologic exams. Pap smear, female self collection, and urine samples all can be used to test for these organisms. Molecular pathology platforms offer the most sensitive methods to detect the organism. A variety of transport media including M4 type media proprietary to GenProbe, Bectin Dickenson, and Roche diagnostics, Thin Prep, and SurePath can all be used to transport specimens from these collection efforts.

Any given testing platform must undergo FDA approval before results can be released for patient care and third party reimbursement. Not all instrument manufacturers have obtained FDA approval for all transport media available to providers. It is acceptable to test samples collected in non FDA approved transport media, but the reliability of these different media need to be validated.

The testing platform originally scheduled for use at MML was inadequate for the needs of our clients. Therefore we are in the approval phase for the appropriate equipment to test the variety of samples we anticipate arriving from providers' offices. Extensive validation to include performance measures such as accuracy, precision, sensitivity, specificity, and interfering substances will occur. Upon satisfactory completion, we will offer this test to our clients. We anticipate this process to be completed and testing available by latter January or mid February. When performed in house the anticipated turnaround time should be 3 to 4 days. Until this process is safely completed, we are sending specimens to an outside reference laboratory.

Reverse Testing for Syphilis

Syphilis used to be tested first with a non-treponemal test such as VDRL or RPR and if positive followed by a confirmatory treponemal test such as TPA, treponemal pallidum antibody. RPR and VDRL are not very specific and diseases such as Epstein Barr Virus and Rheumatoid Arthritis can yield a false positive result. Treponemal pallidum antibody is specific for syphilis. In addition, the predictive value of a laboratory test depends of the prior probability of disease prevalence. In most locals, syphilis is a less prevalent disease than it was many years ago. Therefore, testing algorithms are changing by offering the more specific test, a treponemal test, followed by a test which can gauge the disease activity, such as RPR. This is sometimes referred to the 'reverse testing algorithm'.

Two tests are available;
Syphilis diagnostic (TPA)
Syphilis reactivity (RPR)

MML has subscribed to the reverse testing algorithm. Orders for "syphilis diagnostic"will result in a TPA result. If positive, the sample will be reflexed to testing at the public health department for an RPR result. The following table describes how to interpret this algorithm.

Orders for "syphilis reactivity" will result in a VDRL determination, gauging the disease activity.

Future Articles

- Group B Strep Testing
- Special Coagulation Testing
- Electrophoresis
- Importance of history for peripheral smear reviews

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Treponemal Antibody Screen – performed at McLaren Medical Lab	Test performed at MDPH – USR	Test performed at MDPH – TP-PA	Interpretation
Negative	N/A	N/A	No serological evidence of infection with Treponema pallidum.
Positive	Negative	Negative	The Syphilis screening test did not confirm. The most likely explanation for this is a false positive Syphilis test. Recommend repeat testing in 12-14 days.
Positive	Negative	Positive	The Syphilis screening test is confirmed as a positive, the RPR test is negative indicating a past infection.
Positive	Positive	Positive	The Syphilis test is confirmed as positive, the RPR test is also positive indicating an active infection.

MEDICAL LABORATORY

Mission statement:
McLaren Health Care, through its subsidiaries, will be Michigan's best value in health care as defined by outcomes and cost.

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