LifeLabs Medical Laboratory Services

BCBiomedical LABORATORIES
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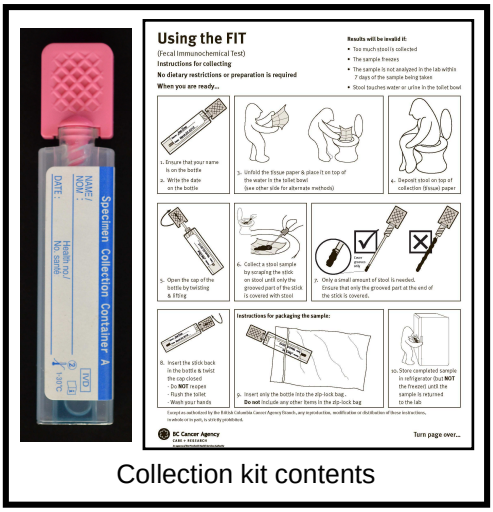
Physicians' Lab Update / Newsletter
May 2014

Update on Fecal Immunochemical Test (FIT) Sample Stability and Reporting

Sample stability studies have shown that FIT samples are stable up to 14 days after collection if they are refrigerated, and will consistently produce valid results during that time frame. In future, FIT samples will be processed up to 30 days after collection, but NEGATIVE results from samples collected 15 to 30 days before will be appended with the following comment: ***"Negative. As sample was returned more than 14 days after collection, result may be invalid and should be repeated."***. It is the clinician's responsibility to reorder the FIT if this comment is appended to the report. **Positive results from FIT samples tested up to 30 days after collection are still valid.** Specimens received after 30 days will not be tested and must be repeated; again the report will indicate that the sample is invalid and it is the clinician's responsibility to reorder the FIT.



Collection kit contents

Patient instructions for FIT will still indicate that samples must be returned to the lab within 7 days after collection to ensure that sufficient time is allowed for transportation and processing.

Dr. Cheryl Tomalty, Clinical Biochemist

Thyroglobulin Assay with Improved Sensitivity

LifeLabs recently implemented an improved thyroglobulin assay. Thyroglobulin is the biomarker of choice for detecting recurrence of differentiated thyroid cancer. The new thyroglobulin generation II (TGII) assay has been redesigned to improve the precision and sensitivity of the test particularly in the low end of the measuring range. This is intended to help detect smaller changes in TG earlier and more reliably. Due to the increased sensitivity of the new assay, patients with previously undetectable levels of thyroglobulin may now have detectable levels. The levels for those with previously detectable levels are expected to decrease by approximately 10%, but a variety of responses may be seen. Therefore, to aid in interpretation of results, we will report results from both the new and old methods for comparison. The reference cutoff has been reviewed and will remain at <60 µg/L. For customers of the former BC Bio, samples will be held for 7 days and be available for sending to the previous testing facility for comparison by calling the on-call Biochemist. Potential interferences by anti-thyroglobulin antibodies (ATG) are not expected to change, and no changes have been made to the ATG assay.

Dr. Kristin Hauff, Clinical Biochemist

Changes to Serum CTX Testing

LifeLabs is now offering a new and improved CTX test.


Roche Cobas analyzer

What is CTX?

Serum C-terminal crosslinking telopeptide of type I collagen beta form (CTX) or beta-crosslaps is a serum-based marker of bone resorption. CTX is used to assess the response to antiresorptive therapy 3−6 months after initiation of treatment in patients with osteoporosis[1]. A CTX decrease of >35% indicates a significant response to treatment; however, the expected response kinetics to treatment varies depending on the drug and dosing[2]. Due to a significant post-prandial decrease in CTX, patients will continue to be required to fast for at least 8 hours prior to serum collection. Variability between samples may be further minimized by collecting samples at approximately the same time of day and avoiding changes in certain medications[2]. When interpreting CTX results it should be noted that certain disease states, bed rest and immobilization can affect CTX levels[3]. Following a fracture CTX may remain elevated for up to 12 months. Markedly elevated baseline levels of CTX (>1.5 times the upper limit of reference interval) should be investigated for causes of high bone turnover other than osteoporosis[1].

New CTX method:

LifeLabs is replacing the current CTX ELISA with an automated immunoassay on the Roche Cobas platform. The new method offers improved analytical performance and turnaround time. Results below 0.300 ng/ml (0.300 µg/L) may be increased by approximately 10% with the new assay, while results above 0.500 ng/ml (0.500 µg/L) may be decreased by 20% or more. The reference intervals have been updated accordingly.

Ordering the new CTX test:

Due to improved day to day performance of the new method, it is no longer required to store the CTX baseline sample to be analyzed in parallel with the follow-up test. Please order “CTX” and give the patient another requisition for their follow-up sample 3 to 6 months later. Results will be available within two weeks of ordering. Blood for CTX is only collected at patient service centers in the Lower Mainland and on Vancouver Island at this time, but will be expanding to all LifeLabs facilities by fall 2014.

CTX is not currently covered by provincial health plans, but may be covered by extended health insurance plans. Contact us to find out more about this test at 1-877-507-5595.

References:

1. Naylor K, Eastell R. Bone turnover markers: use in osteoporosis. Nature Reviews Rheumatology. 2012;8:379–89.
2. Vasikaran S, Eastell R, Bruyère O, Foldes AJ, Garnero P, et al. Markers of bone turnover for the prediction of fracture risk and monitoring of osteoporosis treatment: a need for international reference standards. Osteoporosis International. 2011;22:391–420.
3. Szulc P. The role of bone turnover markers in monitoring treatment in postmenopausal osteoporosis. Clinical Biochemistry. 2012;45:907–19.

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