Laboratory News

[Volume 3 Issue 5 – May 2016]

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Please email Laboratory Services with any questions or concerns or to receive this newsletter via email.

Laboratory Call Center & Specimen Pick Up: 616.774.7721

Helpful Links
- Add-on Test Request
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- Forms and Requisitions
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- Lockbox Instructions
- Supply Requisition
- Test Catalog

**Improving Test Utilization**

**Appropriate Thyroglobulin Tumor Marker and Anti-Thyroperoxidase Ordering Practices**

**Thyroid Peroxidase Antibody (anti-TPO), Blood Level** *(Test #8524)*

This is the recommended test for the evaluation of Autoimmune Thyroiditis.

**Thyroglobulin, Tumor Marker, Serum** *(Test #3069)*

It is only indicated for monitoring of thyroid cancer treatment. This result is reported with an Anti-Tg result to assess for possible interference. This test should NOT be ordered for associated anti-Tg result provided by reference laboratory.

**Thyroglobulin Antibody (anti-Tg) Test**

Historically ordered with anti-TPO for evaluation of possible autoimmune thyroiditis. The literature shows that anti-TPO, alone, has better sensitivity and specificity with only 5% of cases of Autoimmune thyroiditis with anti-TPO negative, anti-Tg positive.

Since 2/2011, requests for anti-Tg have been cancelled per Laboratory Communication: Memo Thyroglobulin Antibody 2/2011

**Spectrum Health Regional Laboratory Experience February 2015 – March 2016 (13 months):**

357 patients with both Anti-TPO and Anti-Tg results.

*Anti-Tg results were due to concomitantly ordered Thyroglobulin TM requests.

250 patients had positive Anti-TPO and/or Anti-Tg level

- 193 patients had both positive Anti-TPO and Anti-Tg level
- 56 patients had positive Anti-TPO and negative Anti-Tg level
- 1 patient had a negative Anti-TPO and positive Anti-Tg levels

Based on these results, and what is reported in the literature, we are confident of our current practices and strongly request discontinuation of Thyroglobulin TM requests for the associated Anti-Tg result.

Patient Safety

Zero Tolerance Specimen Labeling (repeat)

All specimens submitted to Spectrum Health Laboratory for testing must be appropriately labeled to assure positive identification and optimum integrity of specimens. In accordance with standards issued by the Joint Commission, at least 2 patient identifiers should be used when providing care or treatment of services. If 2 patient identifiers are not used on the specimen, the specimen will be rejected, the order will be cancelled and a request for recollection will be made. This includes Gyn Cytology (i.e. Pap) specimens.

Cytology Department News

Afirma® Gene Expression Classifier is Now Available at Spectrum Health

Spectrum Health Hospital is pleased to offer patients access to Afirma® Gene Expression Classifier (GEC), a molecular test that helps diagnose thyroid nodules from the first fine needle aspiration (FNA) biopsy.

Patient’s with thyroid nodules often undergo unnecessary surgery, with 70-80% of indeterminate nodules being benign upon surgical histopathology. By using Afirma GEC in these cases, we can reclassify about 50% of indeterminate thyroid nodules as benign, which helps resolve diagnostic uncertainty and reduce unnecessary surgery. Additionally, when cytopathology is malignant or suspicious for malignancy, Afirma Malignancy Classifiers (Afirma MTC and Afirma BRAF) provide actionable insight to help inform the choice of surgery.

Afirma GEC is well validated, including a multi-center, prospective, blinded study published in the New England Journal of Medicine. The Afirma solution represents a new standard of care for thyroid nodule patients. Afirma GEC is consistent with molecular testing recommendations from the National Comprehensive Cancer Network, UpToDate and American Thyroid Association guidelines.

Afirma GEC integrates into our thyroid diagnosis process through the following steps:

- During the first FNA, perform two extra passes in order to collect and store a separate sample in the event Afirma GEC analysis is needed.
- Spectrum Health Regional Lab will perform standard cytopathology and provide a diagnosis.
- If the cytopathology diagnosis is indeterminate (Bethesda III or IV), Afirma GEC is performed to identify benign nodules. Afirma GEC is not performed when cytopathology is benign or malignant.
- If cytopathology identifies suspicious or malignant results, Afirma offers additional genomic tests-Afirma Malignancy Classifiers – to help guide surgical decisions.

All insurance plans are accepted for Afirma testing, including Medicare. A generous financial assistance program, Afirma Access, is available for patients who need support with out-of-pocket costs. Please contact your local Afirma representative, Howie Niskar, (249-496-5626), Howie@veracyte.com for more details. To learn more, you can also visit www.Afirma.com/physicians.

Microbiology Department News

Supply Change Notification – Blood Culture Bottle
Please review this Supply Change Notification regarding New BacT/ALERT FAN® Plus Blood Culture Media Bottles.

Please refer to the Laboratory Specimen Collection Catalog or PolicyTech for information on specimen collection.

Questions regarding this supply change may be directed to Mary Coram, Manager of the Microbiology Department via email to Mary.Coram@spectrumhealth.org.

Antimicrobial Stewardship – C-diff testing (repeat)
When testing for Clostridium difficile Toxin (“C-diff”), only liquid (i.e. watery) stools should be sent for testing. Any formed or soft stools will be immediately rejected and testing will be cancelled.

In order to increase quality of care for our patients and decrease the overuse of antibiotics, when ordering Clostridium difficile Toxin, PCR, remember these important notes!

- Only test symptomatic patients; diarrhea with 3 or more liquid (i.e. watery), loose, unformed stools in 24 hours or less.
  Testing of asymptomatic patients is not clinically useful. For example, testing of asymptomatic patients will only detect colonization and not disease. Treatment of colonization is not possible or recommended.
  Testing for “Test of Cure” is also inappropriate. It only results in unnecessary treatment and creates anxiety for the patient and providers.

- Do not test patients who are having liquid/loose stools for known reasons (i.e. laxatives).

- Only one specimen is necessary for detection of toxigenic C. difficile.
  If PCR is negative, repeat testing within 7 days is not recommended.

- Test information has not been established for patients less than 2 years of age.
  Up to 50% of infants less than 2 years asymptptomatically carry C. difficile and its toxins.

Please refer to this article provided by Infectious Disease Specialist, Dr. David Dobbie: Clostridium difficile infection in adults: Clinical manifestations and diagnosis
Lamont, J Thomas, MD. “UpToDate”. December 2015
If you cannot access this article, a version can be emailed to you for educational purposes.
Please submit a request to LaboratoryServices@spectrumhealth.org.

Patient Stool Collection Instructions may be found in the Laboratory Specimen Collection Catalog (https://spectrumhealth.testcatalog.org)
Microbiology Department News (continued)

Genital Culture with Gram Stain Discontinuation (repeat)

Effective mid to late summer 2016, the Spectrum Health Regional Laboratory (SHRL, Grand Rapids) Microbiology Department will discontinue Genital Culture with Gram Stain. Alternative test methods that are available at SHRL and ordered specifically for individual pathogens are listed below.

<table>
<thead>
<tr>
<th>Test name</th>
<th>Specimen type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group B Streptococcus (GBS), PCR</td>
<td>Vaginal/Rectal eSwab Collection</td>
</tr>
<tr>
<td>Group B Streptococcus (GBS), Penicillin Allergy, PCR</td>
<td>Vaginal/Rectal eSwab Collection</td>
</tr>
<tr>
<td>Group A Streptococcus, Culture</td>
<td>Cervix/Vaginal eSwab Collection</td>
</tr>
<tr>
<td>Trichomonas, Wet Prep</td>
<td>Cervix/Vaginal eSwab Collection</td>
</tr>
<tr>
<td>Gram Stain (for bacterial vaginosis and yeast)</td>
<td>Cervix/Vaginal eSwab Collection</td>
</tr>
<tr>
<td>Fungal Culture (for yeast)</td>
<td>eSwab Collection</td>
</tr>
<tr>
<td>Wound Culture with Gram Stain (for lesions)</td>
<td>eSwab Collection</td>
</tr>
<tr>
<td>Herpes Simplex PCR for Lesions</td>
<td>Viral Transport Media (UTM)</td>
</tr>
<tr>
<td>Chlamydia Gonococcus, PCR, Genital Swab</td>
<td>Abbott multi-collect specimen collection kit</td>
</tr>
</tbody>
</table>

Please click on the links provided for more information regarding specimen collection.

Compliance with CAP (College of American Pathologists) accreditation and guidelines advises that genital culture is not recommended for women of childbearing age. Routine genital culture, with the intent of detecting what is there, rarely has an indication. Cultures ordered for specific pathogens with proper collection and selection media are recommended. The Microbiology Department will be validating criterion based Gram staining (Nugent’s criteria) for better diagnosis of bacterial vaginosis and determination of overgrowth of yeasts. The aim is better patient care by providing accurate patient results that are in tune with the clinical picture.

Any questions concerning genital cultures should be directed to either Dr. Deborah E. Blue, Technical Director, Microbiology, Deborah.Blue@spectrumhealth.org or Mary Coram, Manager, Microbiology, Mary.Coram@spectrumhealth.org.

CAP: MIC.22280
Guidelines for Performance of Genital Cultures. 3.9.1. ASM, March 2007.

General Information

April is Child Abuse Prevention Month and the Center for Child Protection at HDVCH awarded their CCP Star Award to the Laboratory’s Toxicology Department PhD: Dr. Ben Kuslikis. Dr. Kuslikis provides his knowledge and expertise on Toxicology testing for the CCP often and plays a vital role in the diagnosis of their patients. Thank you Dr. Kuslikis for working hard to protect the children of Michigan!

Congratulations to Dr. Ben Kuslikis for receiving the CCP Star Award!

Pictured left to right: Dr. Kuslikis, Tracy Cyrus, Jennifer McVay & Becky Wiersma

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