

Laboratory News

Saint Francis Medical Center

February 2019

OSF HealthCare Laboratory Updates

Critical Value Updates across the Ministry

In collaboration across all OSF Laboratories, we have updated the critical values as outlined below; these changes went into effect on January 29, 2019. Any questions or concerns should be directed to Dr. Jiayan Sun at (309) 624-9024.

- ⇒ Carboxyhemoglobin (LAB811): >14.9%
- ⇒ Lactic Acid (LAB1243): \geq 4.0 mmol/L
- ⇒ Magnesium (LAB1269): \leq 1.0 mg/dL
- ⇒ Vancomycin Trough (LAB1702): <5.0 mcg/mL and >25.0 mcg/mL
- ⇒ Vancomycin Random (LAB1700): <5.0 mcg/mL
- ⇒ Tobramycin Random (LAB1559): >45.0 mcg/mL
- ⇒ Lead (LAB1249): No Critical Value available

Bordetella PCR testing changing Methodology at SFMC

As of February 1, 2019, the OSF System Laboratory has replaced the separate, labor intensive process of a Qiagen Robot DNA extraction followed by a Cepheid SmartCycler II Real-Time lab developed polymerase chain reaction (PCR) assay for detection of Bordetella DNA with the FDA approved B. pertussis/B. parapertussis DiaSorin Molecular Simplexa™ Bordetella direct real-time sample-to-result PCR on the LIAISON® MDX (Focus Diagnostics, CA, USA).

The new real-time PCR test includes IS481 for Bordetella pertussis (this gene is also present in B. holmesii), for greater sensitivity for the detection of Bordetella in respiratory samples than its lab developed predecessor, and also overcomes the limitations of culture and serological methods for the diagnosis of Bordetella infection.

The new system will accelerate our diagnostic process and decrease sample to result turnaround time by combining amplification and detection, and eliminating the labor intensive process of DNA extraction. However, the new test will require a change in sample collection kits (i.e., nasopharyngeal swabs). Dacron swabs placed in Remel M4, Remel M4RT, Remel M5, Remel M6, UTM, or BD UVT transport media are all acceptable. Eswabs are not acceptable (unless transported in one of above media). Appropriate sample collection kits are available from the OSF System Laboratory.

Any questions or concerns may be addressed to Dr. John Farrell, Medical Director of Clinical Microbiology & Serology Labs at (309) 624-9127.

"We must accept finite disappointment but never lose infinite hope."

- Martin Luther King Jr.

American Heart Month 2019: Let's Talk about Cholesterol

For 2019, the Division for Heart Disease and Stroke Prevention (DHDSP) will focus on the impact that high blood cholesterol can have on the heart.

Join DHDSP throughout February and beyond by starting important conversations about heart health.

Start the conversation with patients and their health care team about how heart disease can be prevented or managed by monitoring patients with high blood cholesterol.

https://www.cdc.gov/heartdisease/american_heart_month.htm

Prior Authorization for Laboratory Testing

OSF HealthCare is finalizing a process for Prior Authorization as it pertains to patient laboratory testing and we are almost ready to roll it out; please stay tuned for more details.

If you have any questions regarding Prior Authorization for patient testing, please contact your Clinical Representative.

Questions??

If you are an OSF Laboratory Outreach client and you have a billing-related question, please contact OSF's Patient Accounts and Access Center billing department at (309) 683-6750.

The PAAC billing agents will be happy to assist you with your inquiry.

If you have other questions, please contact OSF's Laboratory Customer Support department at (800) 533-6730 and they will direct you to the appropriate Laboratory Mission Partner.

TEST SPOTLIGHT: Next Generation Sequencing for Targeted Genes

Evaluating for Somatic Mutations that would allow targeted therapies for genes that are associated with Cancer

OSF HEALTHCARE SAINT FRANCIS MEDICAL CENTER SYSTEM LABORATORY & MAYO MEDICAL LABORATORIES

By: Raechel Pfahl, MLT (ASCP), BBA, MBA

Clinical Information related to Next Generation Sequencing (NGS)...

Next generation sequencing has been continuously growing as a cost-effective method for identifying mutations across specific genes known to be associated with solid tumors and/or cancer and the cancer's cellular response and/or resistance to specific targeted therapies. NGS results are then being used to guide and assess patient treatment of the cancer and/or solid tumors.

These treatments use small-molecule drugs and/or antibodies to block the metastasis and growth of specific types of cancer by interfering with the tumor's growth pathways. In recent years, multiple targeted therapies have been approved by the US FDA for treatment of specific cancers; but molecular genetic testing is needed before treatment to determine which drugs will prove most useful for the patient's specific kind of tumor. Once NGS testing has been performed, the results can identify which treatments would be the most useful for the patient and/or to determine eligibility for clinical trials of new drugs that are not amenable to (currently) approved FDA treatments. With OSF HealthCare's partnership with Mayo Medical Laboratories, the Saint Francis Medical Center's Laboratory is able to offer access to many different NGS panels to enable us to provide the best care to our patients.

It is important to note that the below Mayo testing requires Prior Authorization from patients' health insurance companies. If there are any questions regarding Prior Authorization, please contact your Clinical Representative and they will work with you to get answers.

RAS/RAF Targeted Gene Panel by NGS for Tumors

(MAYO Test Code: RASFP)

This Mayo test uses targeted NGS to evaluate for somatic mutations within the BRAF, HRAS, NRAS, and KRAS genes associated with cancer.

- ⇒ This test is helpful for the assessment of multiple genes within the EFGR pathway, as well as determining the prognosis for solid tumor patients.
- ⇒ This test is also helpful in identifying specific genes known to be responsive and/or resistant to specific cancer therapy treatments, thereby helping in assisting in drug selection for solid tumor patients.

Lung Cancer Targeted Gene Panel with Rearrangement for Tumors

(MAYO Test Code: LNGPR)

This NGS test is targeted at identifying specific cells, somatic mutations and gene alterations present within the EGFR, BRAF, KRAS, HRAS, NRAS, ALK, ERBB2, and MET pathways that are present in lung tumors.

- ⇒ This NGS testing allows for quicker diagnosis of lung cancer in patients and would provide them with (potentially) better prognoses.
- ⇒ It also allows targeted therapies to be more successful in the treatment of lung cancer by interfering with the specific mutations, gene mutations, and/or cell molecules involved in the patient's tumor growth and progression.

Targeted Exons & Codons Interrogated by RAS/RAF Gene Panel		
Gene	Exons	Codons
BRAF	11, 15	594, 596, 600
HRAS	2, 3	12, 13, 59, 61
NRAS	2, 3, 4	12, 13, 59, 61, 146
KRAS	2, 3, 4	12, 13, 59, 61, 117, 146

Rearrangements Resulting in Fusion Transcripts		
Gene	Occurrence	Exon
ALK	3-7% (NSCLC)	Exons 19/20
NTRK1	3% (lung adenocarcinoma)	Varies
RET	1% (all lung cancer)	Exon 12
ROS1	2% (NSCLC)	Varies

Somatic Mutations within the Lung Cancer Targeted Gene Panel with Rearrangement for Tumors			
Gene	Occurrence	Exons	Codons
ALK	3-7% (all lung cancer)	Exon's 22, 23, 25	1151-1170, 1172-1209, 1248-1279
BRAF	1-4% (NSCLC)	Exon 15	581-605
EGFR	10% (NSCLC)	Exon's 3, 7, 15, 18, 19, 20, 21	96-125, 277-297, 575-607, 688-727, 730-761, 762-794, 811-823
ERBB2	2-4% (NSCLC)	Exon's 19, 20, 21	737-769, 770-795, 843-883
HRAS	1% (NSCLC)	Exon's 2, 3, 4	4-28, 47-82, 114-146
KRAS	15-25% (lung adenocarcinoma)	Exon's 2, 3, 4	3-20, 52-75, 114-146
MET*	3-4% (lung adenocarcinoma)	Intron 13/Exon 14 Exon 14/Intron 14	Intron- 982-1000 1023-1028 -Intron
NRAS	1% (NSCLC)	Exon's 2, 3, 4	4-17, 43-63, 116-147

If you have further questions about Mayo testing or about any of the information in this educational spotlight, please contact your OSF Laboratory Clinical Representative today!

Raechel Pfahl.....309-624-9100

Sabrina Mullins.....309-624-9144