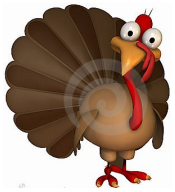
Monthly Update

OSF System Laboratory

November 2016

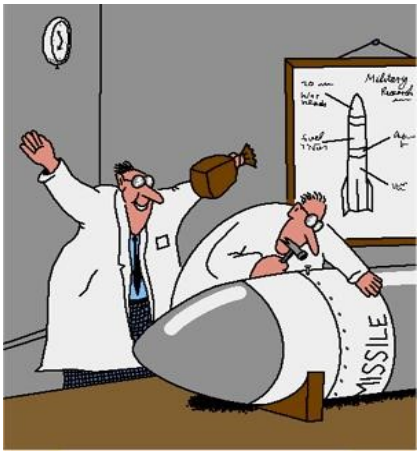


Happy Thanksgiving

2016 customer survey coming

We are in the process of finalizing the client survey for 2016. Once again this year, an email will be sent with a link to the survey. It is totally anonymous and your response is very important to us.

It will be very similar to last year's and we hope to have another excellent response rate. Please watch for the email with the link and share your opinions with us. Any input you provide helps to outline performance improvement projects and action plans directed at better service to you.



Tips to help minimize "Unsatisfactory" result on Pap smear

Unsatisfactory rates for Pap smears remain relatively low at OSF, but occasionally there are samples submitted that are unsatisfactory. Here are some tips for proper sample collection to help eliminate unsatisfactory results:

1) Do not use lubricant gels that contain carbomer or carbopol polymers (K-Y is **not** acceptable) as these agents interfere with the ThinPrep test when present in the patient's sample vial. Acceptable: Surgilube, Astroglide and Crystelle

2) If using a broom for sample collection, push the broom into the bottom of the vial **10 times**, followed by a final vigorous swirl.

3) If using a brush for sample collection, rotate the device in the solution **10 times** while pushing against the vial wall, followed by a final vigorous swirl.

4) Always discard the broom or brush. **Do not** leave any part of the collection device in the vial.

The entire Pap Collection Tips memo can be read here.

Atlas Interfaced Users

If you are an Atlas interfaced user and enter orders in your EMR, please ensure that the Atlas specimen label and the label generated from your EMR match. If specimens are received here with discrepancies to the specimen labels, unless they are deemed irretrievable, will be subject to rejection.

Test Updates and Changes

Effective 10/11, Mayo test QUAD (LAB2050) and MAFP (LAB3001) have mandatory "Ask at Order Entry" (AOE) questions in Atlas. Paper submitters will need to complete the Mayo form and include it with the specimen. Atlas users that enter via their EMR will need to access their Atlas account via the web and finish answering the mandatory questions. Epic users will be required to answer the mandatory questions when the November updates are made.

Effective 10/11, test BME, Bone Marrow, Pathology (LAB2338) now has mandatory questions to answer.

Effective 10/11, Mayo test PBORR, Lyme Disease by PCR (LAB2032) has new result codes in Atlas and a new AOE code (mandatory).

Effective 10/19, Mayo added an additional result field to the test JAK2B, JAK2 V617F Mutation Detection (LAB2204).

On 10/19, Mayo discontinued test TPMT Enzyme (Thiopurine Methyltransferase) due to performance issues. On 11/1, it was replaced with FATPM, Thiopurine Methyltransferase, RBC (LAB4657).

On 10/20, Mayo reactivated test TDP, Vitamin B1 (Thiamin), Whole Blood (LAB2046). Specimen must be frozen immediately and protected from light.

On 11/1, two new allergen panels were activated: MILKPN, Milk component panel (LAB4626) and EGGPN, Egg component panel (LAB4627).

On 11/4, Mayo discontinued MSMAR, MSMART Evaluation Marrow (LAB2280). Order a GENOR with Mayo code MSMRT Myeloma and Risk-Adapted Therapy Report. An orderable test code is being built.

Questions about your bill?

If you are an Outreach lab client and have a billing-related question, please follow the first step, which is to contact our Patient Accounts and Access Center billing department at **(309) 683-6750**. The PAAC billing agents will be happy to assist you with your inquiry.

Client Reps:

Sara Meyer (309) 624-9100

Deanna Hibbert (309) 624-9138

Marketing Support:

Gregg Simpson (309) 624-3927

Sales and Marketing Supervisor:

Gordon Koerner (309) 624-9287

Manager, Outreach Services:

Kristi Williams (309) 624-9042

Keep in mind…

"Here is a test to find whether your mission on earth is finished. If you are alive, it isn't." -*Richard Bach*

BioPlex platform will soon be live

Effective Monday, November 28th, the OSF System Laboratory will begin offering a variety of test options on the BioPlex® instrument. The BioPlex® 2200 is a fully automated Luminex-based system developed for high-throughput simultaneous analysis of autoimmune analytes in a single tube. The advantages of the BioPlex include a shorter turnaround time, detection of multiple antibodies simultaneously, and less inter-observer variability, while minimizing phlebotomy for patients.

The BioPlex® multiplex platform provides simultaneous measurements of both IgA anti-tissue transglutaminase and deamidated gliadin peptide as well as a simultaneous check for IgA deficiency (IgAD). The sensitivity and specificity for IgAD on the BioPlex platform are both 99.9%. Screening for celiac disease is based on detection of IgA anti-tissue transglutaminase (anti-tTG) antibodies. Since IgA deficiency (IgAD) is associated with celiac disease, patients with suspected celiac disease must be screened for IgAD when celiac disease is suspected to ensure appropriate use of IgA vs. IgG based diagnostic assays. The BioPlex® 2200 uses Luminex™ methodology to provide simultaneous measurement of anti-tTG and deamidated gliadin peptide (DGP) antibody levels using a fully automated random access analyzer. The flow cytometer also employs an IgA Verification Bead (AVB) to check for IgAD to ensure that IgAD patients are identified and tested appropriately with the IgG based assay.

Because this new multiplex flow-cytometry platform includes tTG IgA, DGP IgA, with a total IgA test (immunoturbidimetric assay) driving a reflex to tTG IgG and DGP IgG when the total IgA (immunoturbidimetric) is decreased, the following equivalent tests will be **removed** from electronic order options:

LAB821: Prometheus Celiac Serology
LAB820: Prometheus Celiac Genetics
LAB856: Prometheus Celiac PLUS
LAB2209: Mayo Celiac Disease Serology Cascade
LAB2210: Mayo Celiac Disease Comprehensive Cascade
LAB2213: Mayo Transglutaminase (tTG) Antibody, IgG
LAB1851 OSF Gliadin IgG/IgA, Ab, Celiac

The test code for the new Celiac Panel with reflex on the BioPlex is **LAB1850**. Anti-endomysial (EMA) IgA assays have similar sensitivity and specificity to tTG IgA assays and are not included in the BioPlex Celiac screening panel.

Two HLA-DQ combinations (HLA-DQ2 and HLA-DQ8) increase one's predisposition to celiac disease. When the results of serologic and endoscopic testing are equivocal, additional serologic testing is rarely illuminating. Although HLA typing is not required to establish a diagnosis of celiac disease, in these cases, genetic testing for HLA-DQ2 and HLA-DQ8 (LAB2208 to Mayo, CELI) should be considered.

Also changing over is Rapid Plasma Reagin (RPR) to a syphilis IgG on the BioPlex. Since this is an automated platform with direct throughput, the turnaround time for syphilis testing will be substantially improved. The new code for syphilis IgG on the BioPlex is SYPHILIS (**LAB4611**). All positive syphilis IgG tests will reflex to RPR (with titer) for confirmation of diagnosis. Patients with known history of syphilis infection may continue to be followed with serial RPR tests as in the past with the current test LAB1421 (RPR screen, titer if positive). Lab test codes **LAB1423** (RPR screen) and **LAB1422** (RPR titer only) will be inactivated.

Also moving is the enzyme-linked immunosorbent assay (ELISA) testing for the presence of antibodies against common viral and vaccine preventable infections. They will now be performed as the BioPlex multiplex flow cytometry immunoassay. The BioPlex enables the simultaneous detection and identification of multiple antibodies in a single sample. Performing multiplex flow immunoassays for Measles IgG, Mumps IgG, Rubella IgG & IgM, Herpes simplex (HSV) 1 & 2 IgG, *Toxoplasma gondii* IgG & IgM, Cytomegalovirus (CMV) IgG & IgM, Epstein-Barr virus (EBV) early antigen, nuclear antigen, IgG & IgM, Varicella zoster virus IgG, as well as TORCH and comprehensive EBV panels on the BioPlex platform will improve turnaround time for results. Patient satisfaction will also improve, since multiple tubes of blood will not be required for testing, even when multiple serologic tests are ordered. APS will change from enzyme linked immunosorbent assay (ELISA) for the detection of antiphospholipid antibodies to a comprehensive antiphospholipid antibody panel on the BioPlex® 2200 multiplex flow cytometry platform to screen for APS in patients with a clinical occurrence such as thrombosis or pregnancy loss.

LAB4656 is a new test code for ordering the APS screening panel on the BioPlex® 2200. The new panel includes: anti-β2-Glycoprotein I **(**β2GPI), Anticardiolipin, and lupus anticoagulant. The new APS screening panel was created in accord with the 2006 revised laboratory classification criteria for the diagnosis of APS that strongly recommend anti-β2-Glycoprotein I (β2GPI) antibody testing be performed on all requests for APS screening (even if only antibodies are requested). The consensus guidelines on APS testing also recommend that anti-β2GPI IgG specifically be performed when the β2GPI antibody isotype is not specified. Unfortunately, the current menu of APS test options are both confusing and time consuming for physicians and healthcare providers to navigate. We have consolidated the menu to three simple APS test options based on the consensus guidelines for APS testing.

The ANCA panel on the BioPlex® 2200 is an excellent screening test for vasculitis, with a high level of diagnostic accuracy and more rapid and consistent results than IFA based serologies.: **LAB1894** ANCA Screening Panel (anti-MPO; anti-PR3; ANCA)
LAB1890 Myeloperoxidase Ab (anti-MPO) and **LAB1892** Proteinase 3 Ab (anti-PR3)

GBM (Glomerular Basement Membrane) antibody testing will no longer be sent to Mayo, but will be performed in-house on the BioPlex. Antibodies to GBM are primarily directed towards the non-collagenous domain of type IV collagen. Antibodies directed against collagen found in glomeruli and alveoli is associated with rapidly progressive glomerulonephritis and alveolitis (Goodpasture's Syndrome). Anti-GBM may also be found in some patients with ANCA positive small vessel vasculitis, usually with anti-MPO antibodies. Since, anti-collagen antibody is detected by the BioPlex® 2200 with a high degree of sensitivity and specificity, the BioPlex system will provide excellent discrimination for these overlapping clinical entities: **LAB4613** Glomerular Basement Membrane (anti-GBM)

Lastly, ANA testing will also switch to the BioPlex and serve as the initial screening test for autoimmune disorders such as systemic lupus erythematosus (SLE). The test code for the ANA screen + reflex on the BioPlex® 2200 is **LAB695.** Positive ANA screens will reflex to the following antibodies (dsDNA, chromatin, ribosomal protein, SSA-52, SSA-60, SS-B, Sm, SmRNP, RNP-A and RNP-68, Scl-70, Anti-centromere B and Jo-1). Note: **LAB967** Smith Antibodies and Smith RNP Antibodies will be discontinued.

Any questions or concerns may be addressed to John Farrell, MD, Medical Director of Clinical Microbiology and Serology. Dr. Farrell can be reached at (309) 624-9127. All memos regarding the implementation of the BioPlex platform of testing can be read at www.osfhealthcare.org/lab/updates/