DOS Updates

Bone Alkaline Phosphatase—Discontinued Mayo send out test effective September 6. Replaced by in house chemistry test Alkaline Phos Iso SerPl. Alkaline phos isoenzymes includes the bone, liver, macrohepatic, and intestinal alk phos isoenzymes.

CFP Analysis, 106-Mutations—Discontinued Mayo send out test, effective September 12. Replaced by in house molecular test CF 139 Mutation Analysis

CF 139 Mutation Analysis—New in house molecular test. Preferred container Lavender. Preferred volume 3 ml refrigerated whole blood, minimum volume 1 ml. Method NGS; Performed once every two weeks. TAT 14-17 working days.

Starting September 12, 2016, IU Health Molecular Pathology Laboratory will begin offering Next Generation Gene Sequencing for CFTR (Cystic Fibrosis transmembrane Conductance Regulator) Analysis. The assay will detect 139 clinically relevant CFTR variants. The variants reported by this assay were specifically chosen because they represent the full set of clinically validated variants classified as CF-causing in the CFTR2 database at Johns Hopkins University, a product of the CFTR2 initiative. The assay tests for 134 CF causing variants, one ACMG recommended panel variant (R117H, classified as a Mutation of varying Clinical Consequence, MVCC, by CFTR2); one conditionally reported modifying variant (PolyTG/PolyT); and three conditionally reported benign variants (I506V, I507V, F508C). The test is intended for carrier screening in adults of reproductive age, in confirmatory diagnostic testing of newborns and children, and as an initial test to aid in the diagnosis of individuals with suspected cystic fibrosis. For questions, please call the IU Health Molecular Pathology Laboratory at 317.491.6654.

Creutzfeldt-Jakob/Prion Disease CSF—Discontinued send out test to case Western, effective September 7. Replaced by new ARUP send out reflex test Creutzfeldt-Jakob Disease, CSF

Creutzfeldt-Jakob Disease, CSF—New ARUP send out test that reflexes to 14-3-3 Protein Tau/Theta, effective September 7. The first 2 mL of CSF that flows from the tap should be discarded. Transfer 5 mL CSF to ARUP Standard Transport Tubes. Freeze immediately. (Min: 2 mL). Method WB/ELISA/RT-PCR. TAT varies 8-18 days.

Cyanide LVL—Discontinued Mayo send out test, effective September 6. No replacement.


RBC Enzyme Evaluation—New Mayo send out test, effective September 13. Container Yellow ACD B. Preferred volume 12 ml refrigerated blood, minimum 5 ml. Method Kinetic Spectrophotometry. TAT 3-14 days.

Hemolytic Anemia Eval—Discontinued Mayo send out test, effective September 13. Replaced by Hemolytic Anemia Evaluation.

Hemolytic Anemia Evaluation—New Mayo send out test effective September 13. Two 6 ml whole blood EDTA specimens, two 6 ml whole blood ACD specimens, an EDTA control specimen, and 2 well-made peripheral blood smears (Wright stained or fixed in absolute methanol) are required for testing. Specimens must arrive at Mayo within 72 hours of draw. Refrigerate immediately after draw. Patient's age and sex are required. Minimum volume EDTA Blood: 3 mL/ACD Blood: 5 mL. Method see Mayo website. TAT 4-26 days.

North Hospital Lab News—Effective September 9, IU Health North Hospital will refer all Gentamycin and Tobramycin levels to IUHPL Central Lab.

Zika Virus Testing to SDOH—on the DOS test directory now as a Miscellaneous send out to the State Department of Health. Zika testing guidelines, flow chart, forms and instructions are available. See the guidelines on the following pages.
Updated Guidelines for Testing Patients for Zika Virus
August 31, 2016

The following information regarding Zika virus testing represents the most up to date information available from the U.S. Centers for Disease Control and Prevention (CDC) and the Indiana State Department of Health (ISDH).

**Indications for Zika virus testing:**

The ISDH will assist in coordinating Zika virus testing based on the following CDC guidelines:

1. Travelers to regions of the world with Zika virus transmission who have **any** of the FRAC (fever, rash, arthralgia, conjunctivitis) symptoms.
2. Pregnant women who have traveled to an area with Zika virus transmission, **regardless** of symptoms.
3. Pregnant women who have had unprotected sex with a man who has traveled to an area with Zika virus transmission and is symptomatic.

**Zika virus testing requires authorization by the ISDH:**

To obtain authorization for Zika virus testing, healthcare providers must ensure that the patient meets testing criteria. A detailed protocol for Zika virus testing is available at [http://www.in.gov/isdh/26971.htm](http://www.in.gov/isdh/26971.htm). Scroll to the middle of the web page and follow the step-by-step directions under the header “Zika Virus Authorization Protocol for Providers.”
Common questions and answers about Zika virus testing:

1. **Does the IU Health Pathology Laboratory offer testing for Zika virus?**

   At this time the IU Health Pathology Laboratory does not offer Zika virus testing; however, in-house testing options are currently being evaluated. An in-house testing option for Zika virus nucleic acids should be available in the near future.

2. **How do I go about getting my patient tested for Zika virus infection?**

   Refer to “**Zika virus testing requires authorization by the ISDH**” on page 1 of this document. Once authorization for testing has been granted by the ISDH, clinical specimens (e.g., blood) should be submitted to the IU Health Pathology Laboratory for submission to the ISDH.

3. **What Zika virus testing will be performed on my patient?**

   If patients meet testing criteria outlined by ISDH (see link to ISDH Zika virus website in “**Zika virus testing requires authorization by the ISDH**” on page 1 of this document), the types of tests performed will depend upon when signs and symptoms, if present, began with respect to when Zika virus testing is sought.

   a. If symptom onset was <7 days prior to the time when the patient presents for testing, **serum AND urine** should be collected for testing. Serum specimens will be tested by a real-time polymerase chain reaction (PCR) assay that detects not only Zika virus, but also dengue and chikungunya viruses. Also, serum will be referred to a reference laboratory for serological testing (i.e., testing for antibodies to Zika virus).

   b. If symptom onset was 7-14 days prior to the time when the patient presents for testing, **serum AND urine** should be collected for testing. Urine specimens will be tested by the real-time PCR assay and serum will be referred to a reference laboratory serological testing.

   c. If the patient is not symptomatic but has travel history to a region with Zika virus transmission **OR** the patient’s symptoms began >14 days prior to the time when she/he presents for testing, **serum ONLY** should be collected for testing. These specimens will be referred to a reference laboratory for serological testing.
4. How do I submit clinical specimens for Zika virus testing once ISDH has granted authorization for testing?

The ISDH will send healthcare providers a Zika virus testing authorization form and a form used to collect the patient’s demographics, symptoms, etc. **BOTH OF THESE FORMS MUST BE SUBMITTED TO THE LABORATORY ALONG WITH THE CLINICAL SPECIMENS!**

A. Test ordering in Cerner
   i. Order a **Miscellaneous Send-out test** and name it “Zika Virus Testing to ISDH.”

B. Collection Instructions by specimen type:
   i. **Serum:** collect **2 (two) full** gold-top serum separator tubes and appropriately label the tube with a patient’s Cerner label. For clients with the ability to do so, please allow the specimen to clot for 30 minutes and centrifuge the clotted blood to separate the serum from the clot. For clients without access to a centrifuge, please submit the clotted specimen; the IU Health Pathology Laboratory will separate the serum from the clot.

   ii. **Urine:** collect urine specimens in a sterile container and secure the lid on the cup following collection.

C. Specimen transport
   i. Prior to specimen transport, contact the IU Health Pathology Laboratory Department of Send-out Testing at 317.491.6857.

   ii. **For IU Health Methodist, Riley, and University Hospital locations:** please transport the specimens **AND THE AUTHORIZATION and PATIENT DEMOGRAPHICS FORMS** via the pneumatic tube system in a closed specimen bag to the IU Health Pathology Laboratory Central Processing Laboratory (tube station: 955).

   iii. **For other hospitals and clients:** please transport the specimens **AND THE AUTHORIZATION and PATIENT DEMOGRAPHICS FORMS** to the IU Health Pathology Laboratory using the standard laboratory courier system. All specimens must be stored and shipped refrigerated.

5. What will the IU Health Pathology Laboratory do with specimens once they are received in the laboratory?

Once blood and urine specimens have been received by the IU Health Send-out Testing Laboratory, aliquots of serum and urine will be sent to the ISDH Laboratories for testing.
6. **Can I send specimens directly to the ISDH Laboratories?**

To relieve the burden of appropriate specimen packing and shipping to the ISDH and CDC, and to ensure appropriate test result routing, specimens for Zika virus testing **must** be sent through the IU Health Pathology Laboratory.

7. **What is the turnaround time on Zika virus testing?**

Results of the real-time PCR assay are available within 2 – 3 business days from the time that the specimen is received by the ISDH. Results of serological testing are generally available within a few weeks from the time that the public health reference laboratory receives the serum specimen.

8. **How are the results of Zika virus testing transmitted to the clinical care team?**

At this time, the results of Zika virus testing are being scanned into PowerChart once they have been released from the ISDH and its reference laboratory. Included along with the results are test interpretation information and testing disclaimers. If several business days have passed and PCR results have not been entered into the electronic medical record, please call the IU Health Clinical Virology Laboratory at 317.491.6271 to inquire.

9. **Where can I get additional information about the Zika virus testing and interpretation of results?**


10. **If I have questions about specimen submission for Zika virus testing, who at the IU Health Pathology Laboratory can I contact?**

Please contact Dr. Ryan Relich, Medical Director of the Clinical Virology and Serology Laboratories, at 317.491.6645 or rrelich@IUHealth.org.
For more information about Zika virus and diagnostic testing

ISDH’s Zika virus web page: http://in.gov/isdh/26910.htm


## Zika Virus Testing Flow Chart

**Obtain Authorization for Zika Virus Testing Through the ISDH**

- **Visit:** [http://www.in.gov/isdh/26971.htm](http://www.in.gov/isdh/26971.htm) for details about testing eligibility criteria and authorization form
- **Fax:** Completed authorization form to ISDH Epidemiology Resource Center (317.234.2812)

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**Once You’re Authorized to Submit Specimen for Testing**

- **Complete:** Patient demographics/symptomatology form
- **Contact:** IU Health Send-out Testing Laboratory ([317] 491-6857)
- **Cerner:** Order Miscellaneous Send-out Test called Zika Virus Testing to ISDH
- **Specimen:** 2 (two) Full Gold-Top Serum Separator Tubes and urine specimen (if patient developed symptoms ≤14 days ago)
- **Transport:** Pneumatic tube (station: 955) or courier to IUHPL (send specimen refrigerated)

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**IUHPL Send-Out Testing Laboratory Will Package and Ship the Specimen to ISDH for Routing to CDC**
ISDH Zika Virus Testing Authorization Form

Please complete all fields of this form. All fields **MUST** be completed in order for testing to be authorized. Incomplete forms will result in a delay in authorization. Requests will be approved via **email not by fax**. Please ensure the “point of contact email address” provided on this form is correct.

**Provider Information**

Provider Name: ___________________________________________________________

Facility Name and Address: ______________________________

________________________________

Facility Phone Number: ___________________________________

Point of Contact Name: ____________________________________________________

Point of Contact **email address**: __________________________________________

**Patient Information**

Name (first and last): _______________________________________________________

Indiana county of residence: ___________________________

Date of birth: ___/____/____   Sex: M F

Pregnant?   Y  N   If yes, estimated date of delivery: ___/____/____

Symptoms?   Y  N   If yes, date of symptom onset: ___/____/____

If yes, please indicate:

- Fever
- Rash
- Arthralgia
- Conjunctivitis
- Other: _____________________________________________

Suspect sexual transmission?   Y  N

Has the patient traveled to an area with Zika*?   Y  N

Has the patient’s sex partner traveled to an area with Zika*?   Y  N

If yes, location of travel: _______________________________

Exact dates of travel: ___/____/____ to _____/____/_____


Upon completion of this form, **please fax to the ISDH at 317-234-2812**. An ISDH epidemiologist will follow-up with Zika virus testing authorization requests within 1 business day. For additional questions, please contact the ISDH Epidemiology Resource Center at 317-233-7125.