UC Health LABORATORY

Lab Update

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LabUpdate is a periodic publication of the Clinical Laboratories of UC Health. By way of this publication, lab users are provided: 1) updated operational information relevant to the practice of laboratory medicine within UC Health facilities, and 2) didactic material generally applicable to laboratory medicine.

LAB UPDATE
University Hospital Clinical Laboratory

If you are interested in the on site availability of a particular test, please contact the Laboratory Client Services Department at 585-LABS.

MICROBIOLOGY
Urine Transport Tubes

Urine tubes (gray tops) containing boric acid as a stabilizing agent is provided for transporting urine to the lab for urine culture. These tubes are marked with a minimum fill level (approximately 3.5 mL) to provide the correct concentration of boric acid in the urine. The UC Health Microbiology recently completed a monitor of volume in these tubes and discovered that a significant proportion of the tubes are under-filled. Under-filling results in a higher than intended concentration of boric acid in the tubes, which can adversely effect our ability to culture bacteria from the urine. The manufacturer of the tubes recommends that under-filled tubes be rejected and new samples be requested. The lab performed an internal study to evaluate the stability of two common urine micro-organisms, *Escherichia coli* and *Enterococcus faecalis*, in under-filled urine transport tubes. Our data showed that tubes containing at least 2 mL of urine are stable for 8 hours. Based on our study and the manufacturer's recommendation, the lab will be requesting a new specimen in cases in which less than 2 mL of urine are added to the gray-topped urine tube. The ordering location will be contacted prior to cancellation of the urine culture, to request that a new, adequately filled tube of urine is provided for culture. In cases in which it is not possible to obtain another sample, upon request of the ordering physician, under-filled samples will be cultured. In those cases, the following comment will be appended to the culture results: *Review culture results critically. Less than two mL of urine received in a urine transport tube, which can adversely affect the recovery of micro-organisms.*

The rejection policy will go into effect Aug. 1, 2012. The culture comment on under-filled tubes will begin to appear in July. If you have questions or concerns, please contact Dr. Rhodes at 584-3923.

MOLECULAR DIAGNOSTICS
Reflex HPV Testing

PAP smear cytology on cervical swabs/brushes is a widely used cost-effective screening for cervical cancer which yields valuable information for clinical management of women with human papillomavirus infection.HPV types 16 and 18 account for the development of 70 percent of cervical cancers worldwide. HPV genotyping helps to determine the specific high-risk HPV type a woman is infected with. HPV DNA testing is not only recommended for all women with equivocal cytology results but also recommended as a primary screening test in conjunction with cytology for women ≥30 years (co-testing).Our laboratory utilizes Cobas 4800 HPV test (Roche Molecular Diagnostics, Pleasanton, CA) which is a high-risk–HPV DNA-based screening assay and is FDA-approved for use with cervical specimens collected in Cobas PCR Cell Collection Media (Roche) or ThinPrepPreservCyt® solution. The test specifically identifies HPV types 16 and 18 while concurrently detecting the 12 other high-risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) at clinically relevant infection levels.

The Cobas HPV test uses amplification of target DNA by PCR and subsequent nucleic acid hybridization for the detection of 14 high-risk HPV types in a single analysis. The test involves three important steps: specimen preparation, target amplification and detection reaction. Cervical specimens collected in PreservCyt® solution are digested and lysed in the presence of

chaotropic reagent. Released HPV nucleic acids, along with the β-globin DNA are purified through adsorption to magnetic glass particles; and are washed and separated. Target amplification is achieved by the use of primer pairs specific for 14 HPV genotypes and β-globin DNA which serves as the internal control. The amplification is highly selective and has a built-in mechanism to prevent cross-contamination by other amplicons. As the targets are amplified, sequence-specific oligonucleotide probes labeled with four different fluorescent dyes serve as media for the real-time detection of amplicons. HPV16, HPV18 and β-globin signals are each detected with their own dedicated fluorescent dyes while 12 other high-risk HPV types are detected with a single common fluorescent dye.

The Cobas HPV test has quality controls; has high throughput (processes up to 280 samples in one day); is automated, and is LIS compatible The test's clinical sensitivity and specificity were comparable with those of Hybrid Capture 2 HPV DNA test (Digene Corp. of Gaithersburg, MD). Cobas HPV test has sufficient intra-laboratory and inter-laboratory reproducibility. The data demonstrated that the test fulfills all requirements of international guidelines to consider this assay clinically validated for screening purposes.

BLOOD BANK
Specimen Collection and Labeling

Blood bank type and screen samples must be accurately labeled to ensure the quality of the test results. Mislabeled specimens may lead to mistreatment of the patient, even fatality when blood components are transfused. All blood bank samples must be labeled with the following:

- Patient's complete first and last names
- Patient's medical record number (or encounter number during computer downtimes)
- Time and date of sample collection
- Signature or initials of the person collecting the blood bank sample

Since blood bank must be able to identify the collecting person for up to 1 month after sample collection, the signature or initials of the collecting phlebotomist must be recorded directly on the label affixed to the tube of blood. Phlebotomy identity recorded on a requisition or a label not attached to the actual sample is not sufficient.

The collection of a blood bank type and screen sample should have the following process as a "time out for safety" procedure, similar to time outs performed prior to surgery.

1. Obtain the physician order requesting a type and screen sample from the patient.
2. Obtain patient labels for the sample (zebra computer labels or addressograph stickers). Handwritten labels are acceptable as long as all the required information is present.
3. Ask the patient to verbally identify themselves by patient name and date of birth, if possible.
4. Verify the patient is wearing a patient identification armband.
5. Compare the physician order, the patient labels, and the patient armband to ensure all information is identical. Patient name, medical record number, and date of birth must match.
6. Draw the patient sample and label immediately without leaving the patient's side. Blood bank type and screen samples are drawn in 7ml EDTA pink top tubes.
7. Compare the labeled sample to the patient's armband again to verify information on the tube of blood is identical to the information on the armband.
8. Sign or initial the label on the tube of blood as validation that the blood specimen was drawn from the appropriate patient with the sample label accurately reflecting the information on the patient armband.
9. Send the blood bank specimen directly to the blood bank for immediate testing.

Following this "time out for safety" process, the blood bank type and screen label will never be mislabeled, unlabeled, or unsigned. Mislabeled blood bank samples can result in harm to the patient. Blood bank samples that are unlabeled, or not signed / initialed are rejected and result in delay of treatment while the patient sample is redrawn. By establishing this process as a habit for drawing blood bank samples or all lab samples, patient safety will be enhanced and patient satisfaction increased.

DRAKE CENTER COLLECTIONS

The Drake Center has implemented a two step collection verification process whereby, the sample is signed by the person collecting the sample and initialed by the person witnessing the collection.

If Nursing personnel perform the sample collection and sign the sample label, then lab personnel must witness each step of the collection process and initial the sample.

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COAGULATION

Platelet Function Testing

UC Health Clinical Laboratory is now offering a platelet function test by Accumetrics, Verify *NOW* instrument technology available in our Coagulation department. This test specifically looks at medication effect on the platelets

The Verify *NOW* Aspirin test measures the affect of aspirin on platelets. Aspirin affects platelets by irreversibly inhibiting the COX-1 enzyme involved in the conversion of arachidonic acid to thromboxane A2. The Verify NOW Aspirin test incorporates the agonist arachidonic acid to activate the platelets. Light transmittance increases as activated platelets bind and aggregate with fibrinogen coated beads. If aspirin has produced the expected anti-platelet effect, such aggregation will not occur. The instrument measures this change in optical signal caused by aggregation and reports a result in Aspirin Reaction Units (ARU). The cut off used to interpret the test is 550 ARU**.** Results below 550 show aspirin effect, whereas results equal to or above 550 shows a decreased response or no aspirin drug effect.

The Verify *NOW* P2Y12 test is designed to measure the platelet P2Y12 receptor blockade. Substances specifically known to block the P2Y12 receptor include the thienopyridines class of drugs to include clopidogrel (Plavix), prasugrel (Effient), and ticagrelor (Brilinta). The Verify *NOW* P2Y12 test incorporates the agonist ADP and PGE1 to induce platelet aggregation without fibrin formation. Light transmittance increases as activated platelets bind and aggregate with fibrinogen coated beads. If the P2Y12 receptor drug has produced the expected anti-platelet effect, such aggregation will not occur. The instrument measures this change in optical signal and reports results in P2Y12 Reaction Units (PRU). The cut off used to interpret the test is 208 PRU. Results below 208 show P2Y12 effect, whereas results equal to or above 208 show a decreased response or no P2Y12 drug effect.

This test requires a special blood collection kit and transportation to the Coagulation laboratory.

1) The specimen collection label states to call the lab for a collection kit. The kit consists of instructions, a regular blue top tube for "Waste", and then 2 blue/white partial fill tubes.
2) It is very important to use a 21 gauge needle or butterfly to draw the specimen and to draw a "Waste" tube first. The exception would be a line draw and a waste should always be drawn per line draw policy.
3) The 2 blue/white tubes each fill half way to the arrow mark.
4) The specimens need to be hand carried directly to the Coagulation department or sent STAT at room temperature from West Chester or Drake.
5) Do not send specimens through the tube system.
6) The whole blood specimen is good for 4 hours.

Potential items which can interfere with this test include the Group IIb/IIIa class of drugs. These are typically cardiac cath laboratory drugs such as Integrillin. Non steroidal drugs such as Advil or Aleve can interfere with the Aspirin test. Taking a good comprehensive medication history is very important in properly interpreting Verify *NOW* test results. For any questions about this test call the UC Health Coagulation laboratory at 584-1816.

Lastword test codes:
PLATELET FUNCTION ASPIRIN
PLATELET FUNCTION P2Y12

SPECIMEN COLLECTION
Laboratory Specimen Labeling

Laboratory accrediting agencies mandate that specimen containers, e.g., Vacutainer® tubes, containing specimens, e.g., blood or urine, intended for laboratory testing have indicated on them:

1) The date and time at which the specimen was collected
2) The full name or initials of the person who collected the specimen
3) The site and sample type in the case of a sample intended for culture, i.e., urine, mid-stream clean catch.

All such information should be recorded *legibly in ink* on the collection label affixed to the specimen container *before* that container is submitted to the laboratory. Remember to use indelible ink only; no gel pens should be used as they smear. Avoid writing through the barcode on the label.

Any unlabeled or mislabeled patient specimen received by the laboratory will prompt a call by lab personnel to healthcare providers at the patient's location. Analysis of an unlabeled/mislabeled specimen will not occur until/unless a provider familiar with the patient from whom the specimen was collected visits the laboratory and completes a Specimen Verification Form. Failure to record on the form any of the required information will necessarily delay turn-around-time because the specimen will not be processed unless/until the required information is received.