APRIL, 2017

THE University of Vermont MEDICAL CENTER

Pathology & Laboratory Medicine

Communiqué

IN THIS ISSUE

Laboratory Collection Sites Memorial Day Hours

Memorial Day May 29, 2017	
Main Campus ACC	Closed
Fanny Allen Campus	Closed
1 So. Prospect	Closed
Blair Park	Closed

LABORATORY OPERATIONS

EPA regulations regarding transport of expired sample containers

The Environmental Protection Agency (EPA) considers expired patient sample vials containing fixative or preservatives used in surgical pathology a **hazardous waste.** This also applies to larger containers of solvents that we occasionally provide to be used in processing patient samples.

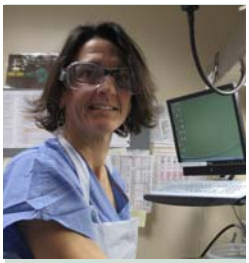
EPA regulations apply to **expired** sample containers such as PAP vials and surgical pathology biopsy containers that have small quantities of chemical fixative or preservative (methanol, ethanol, formalin etc). If the container is expired, it is considered a **"hazardous waste".**

EPA regulations do not apply if these containers have a patient sample that is being sent to UVMMC for testing. Or if the container is not expired and being shipped to you as a supply.

Federal and State law prohibits both the shipping and acceptance of expired sample containers.

What to do:

Please **do not return expired** sample containers to UVMMC.
Expired containers should enter the hazardous waste stream at your facility.
If you have any questions regarding this correspondence, please contact Lynn Bryan, Manager for Lab Business Systems at (802) 847-9540.



Maria Barton PA (ASCP)
At work in the cutting room

Spotlight on the lab
WHAT IS A PATHOLOGISTS' ASSISTANT?
By Maria Barton

APRIL 14TH IS INTERNATIONAL PATHOLOGISTS' ASSISTANT DAY

A pathologists' assistant, PA (ASCP) is a highly trained allied health professional who provides various services including gross examination and dissection of pathology specimens and the performance of post mortem examinations under the direction and supervision of a pathologist. Pathologists' assistants interact with pathologists in a manner similar to physician's assistants in surgical and medical practice, carrying out their duties under the direction of their physicians. PAs are academically and practically trained to provide accurate and timely processing of all pathological specimens. PAs are key components to helping pathologists make pathologic diagnoses.

PAs are a crucial extension of the pathologist in the healthcare setting, performing in a wide scope of clinical practices. Although the majority of pathologists' assistants work in academic and community hospitals, PAs can also be employed in other areas such as private pathology laboratories, forensic pathology laboratories and morgues, reference laboratories, government health care systems, and medical teaching facilities. Some PAs are even self-employed business owners providing their pathology expertise via long- and short-term contract.

Pathologists' assistants contribute to the overall efficiency of the laboratory or pathology practice in a cost effective manner. With increased pressure on healthcare systems to control costs, the demand for qualified pathologists' assistants is growing every year.

The primary role of UVMMC pathologists' assistants is the gross examination and dissection of anatomic pathology specimens. The PAs prepare tissue for numerous additional pathological tests including frozen section, flow cytometry, cytogenetics, Electron Microscopy, and tumor banking and are frequently tasked to photograph anatomic specimens. In addition to this, the PAs are also responsible for the majority of the gross examination instruction of the pathology residents and student fellows. Lastly, the duties of the pathologists' assistants are not always limited to anatomic and surgical pathology; they also fill administrative and supervisory roles as well. There are 6 Pathology Assistants who make a daily contribution to the needs of our patients. If you are interested in a career as a PAs, please visit pathassit.org for more information.

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CBC Stability

On February 2017, the hematology laboratory began rejecting all CBCs received after 48 hours from time of collection. Historically parts of the CBC were not being reported if run between 48 and 96 hours post collection. This practice is being discontinued due to stability recommendations from Sysmex, our cell counter manufacturer, and best practice for patient results.

Compliance Updates

Reflex genomic testing on metastatic colorectal tumors:

Evidence supports mutational testing for EGFR signaling pathway genes, since they provide clinically actionable information as negative predictors of benefit to targeted therapies for colorectal cancer. Mutations in several of the biomarkers have proven prognostic value. For these reasons, the transdisciplinary clinical team at UVMMC that manages cancers of the gastrointestinal tract have decided it is best clinical practice to reflexively submit tumor tissue from samples diagnosed as "metastatic colorectal cancer" for targeted genomic profiling in the Genomic Medicine Laboratory. The assay, GenePanel Solid Tumor, is analytically and clinically validated to detect somatic single nucleotide variants and insertion/deletion mutations in all of the genes considered "clinically-relevant" for managing this cancer type, specifically "expanded RAS testing". This policy does not apply to slide-only consultations and tissue procured in New York State.

Urine Drug Testing

Medicare created a local coverage decision several years ago that addresses Urine Drug testing. They have revised the policy several times. Here are just a few recommendations outlined in the Local Coverage Determination (LCD) Urine Drug Testing (L36037).

Presumptive testing is covered in an urgent care situation for the following:

Coma
Altered mental status in the absence of a clinically defined toxic syndrome or toxidrome
Severe or unexplained cardiovascular instability (cardiotoxicity)
Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome
Seizures with an undetermined history
To provide antagonist to specific drug

Diagnosis and treatment for substance abuse or dependence (SUD)

Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria and must be documented in the patient's chart.

Patient history, physical exam, and previous laboratory findings
Stage of treatment or recovery
Suspected abused substance
Compliance Updates Continued
Substances that may present high risk for additive or synergistic interaction with prescribed medication (e.g. benzodiazepines, alcohol).

NOTE: Frequency of testing for both screening and definitive testing for abuse or dependence (SUD) is dependent on the patient's number of consecutive days of abstinence. Refer to LCD Urine Drug Testing (L36037).

Treatment for patients on Chronic Opioid Therapy (COT)

Testing Objectives

ID absence of prescribed medication and potential for abuse, misuse, and diversion
ID undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances
ID substances that contribute to adverse events or drug-drug interactions
Provides objectivity to the treatment plan
Reinforces therapeutic compliance with the patient
Provides additional documentation demonstrating compliance with patient evaluation and monitoring
Provide diagnostic information to help assess individual patient response to medications over time for ongoing management of prescribed medications

Compliance updates continued on page 4

THE University of Vermont MEDICAL CENTER
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POSTAGE HERE

PATHOLOGY & LABORATORY MEDICINE COMMUNIQUÉ — APRIL, 2017

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WEBSITE
UVMLabs.TestCatalog.org/

Medical necessity must be based on patient-specific elements identified during the clinical assessment, and documented in the patient's medical record.

NOTE: Testing frequency for patient's receiving treatment for chronic opioid therapy is included in the policy.

Non-Covered Services:

Blanket orders- orders must be specific to the patient.
Routine standing orders for **all** patients in a physician's practice are not considered reasonable and necessary
POCT Urine Drug screening and repeat drug screening performed by the hospital laboratory on the same date of service.
Drug testing on 2 different sample types on the same date of service for the same drugs/metabolites/analytes.
Specimen validity testing which includes pH, specific gravity, oxidants and creatinine.

Here's is a link to the full policy LCD Urine Drug Testing (L36037)
http://www.fairview.org/fv/groups/intranet/documents/labprocedures/s_102628.pdf

ratory Collection Sites

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Pathology and Laboratory Medicine

Test Updates

To view the test updates follow the links below.

CK-MB Discontinuation - 5/24/2017

Beta-2 Glycoprotein 1 Antibodies, IgG and IgM and Gliadin (Deaminated) Antibodies, IgG and IgA Discontinuation - 5/24/2017

Chlamydia/N. gonorrhoeae (GC) Test Name and Result Format Change - 5/22/2017

Change in Instrumentation for Low Volume Therapeutic Drug Monitoring - 5/15/2017

Urine Drugs of Abuse Screens: Change in Assay - 5/10/2017

ANA's and Beyond: Introduction of Nova View Digital IFA Reader - 5/9/2017

Testosterone and Sex Hormone Binding Globulin New assay,
Testosterone-Free Change in Calculation and Reference Ranges - 5/3/2017

Rubella Antibodies IgG Assay Change - 4/18/2017

HIV Antibody and Hepatitis Testing Platform Change - 4/10/2017

Drugs of Abuse Confirmatory Testing Reference Range Change - 3/10/2017

THE University of Vermont MEDICAL CENTER

Department of Pathology and Laboratory Medicine

Annual Disclosure of Medicare Regulations

Please note that Medicare will only pay for tests that meet the Medicare coverage criteria and are reasonable and necessary to treat or diagnose an individual patient. Section 1862(a)(1)(A) of the Social Security Act states, "no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member."

Medicare publishes their basic coverage limitations in the Medicare Beneficiary Handbook. In addition, Medicare further defines specific coverage limitations by establishing policies, which can be applied at either a national or local level. These specific coverage policies are referred to as National Coverage Decisions (NCDs) or Local Coverage Decisions (LCDs). These policies limit and define the diagnosis (ICD-10) codes that will support medical necessity for a particular laboratory test. It is very important to submit a diagnosis (written or ICD-10 code) on the laboratory requisition which reflects the patient's signs/symptoms as to why the test was ordered because this is the means by which Medicare determines medical necessity.

Medicare also provides some preventative benefits such as screening for Cardiovascular Disease, Diabetes, Cervical Cancer, HPV screening, Colorectal Cancer, Prostate Cancer, HIV, Hepatitis C and Sexually Transmitted Infections. The details of the Medicare policies and lab related Preventative Benefits can be found in the Compliance Information section of our Lab Services Directory.
Medicare coverage policies can be issued or revised at any time. As we receive these policies we will continue to share them with our clients.

Our laboratory offers the organ or disease oriented panels listed: Basic Metabolic Panel, Comprehensive Metabolic Panel, Electrolyte Panel, Lipid Panel, Liver (Hepatic Function) Panel and Prenatal Panel. On the back of our laboratory requisition we have provided a list of tests included in each panel with the CPT code used for billing. Our Lab Joint Test Catalog also describes what is included in each panel. These panels should only be ordered when all the tests in the panel are medically necessary. Our laboratory requisition provides the option to order as a panel or individually as needed.

We are happy to provide the Medicare reimbursement schedule for any clinical laboratory procedure upon request. If this information is desired, please contact Laboratory Compliance at 847-5121. Please note that Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

Please feel free to discuss any questions that arise regarding laboratory test ordering or interpretation of results with our clinical consultants by contacting Lab Customer Service at 847-5121. A complete list of clinical consultants is available in our Laboratory Services Directory.

THE University of Vermont MEDICAL CENTER

Department of Pathology and Laboratory Medicine

Annual Disclosure of Medicare Regulations

National Coverage Decisions (NCDs):

1. Alpha-fetoprotein (AFP)
2. Blood Counts (includes Hemagram, Hemagram w/ Diff, WBC, Hemoglobin, Hematocrit, Platelet Count)
3. CA 125
4. CA 15-3/27.29
5. CA19-9
6. Carcinoembryonic Antigen (CEA)
7. Collagen Crosslinks
8. Digoxin
9. Fecal Occult Blood
10. Gamma Glutamyltransferase (GGT)
11. Glucose Testing
12. Glycated Hemoglobin/Glycated Protein (A1C)
13. HIV –Prognosis
14. HIV-Diagnosis
15. Human Chorionic Gonadatrophin (HCG)
16. Iron Studies (includes Ferritin, Iron, IBC, Transferrin)
17. Lipids (includes Lipid panel, Total cholesterol, ,Triglycerides, measured LDL, HDL, Lipoprotein quantitation and fractionation)
18. Partial Thromboplastin time (PTT)
19. Prostate Specific Antigen (PSA)
20. Prothrombin Time (PT)
21. Thyroid Testing (includes total T4, Free T4, TSH, and T3 or T4 uptake)
22. Urine Culture (includes susceptibility testing on pathogens)
23. 190.1 Histocompatibility
24. 190.3 Cytogenetics Studies
25. 190.5 Sweat Tests
26. 190.8 Lymphocyte Mitogen Response Assays

Local Coverage Decisions (LCDs):

1. B-type Natriuretic Peptide (BNP)
2. Urine Drug Testing
3. Molecular Pathology
4. RAST Type Test
5. Vitamin D Assay
6. Heavy Metal Testing

Preventive Services

1. Cardiovascular Screening
2. Colorectal Cancer Screening
3. Diabetes Screening
4. Hepatitis C Virus Screening
5. HIV Screening
6. Prostate Cancer Screening
7. Screening for Cervical Cancer with Human Papilloma virus (HPV)
8. Screening for STIs and HIBC to Prevent STIs
9. Screening Pap Tests