

## Pathology & Laboratory Medicine

# Communiqué

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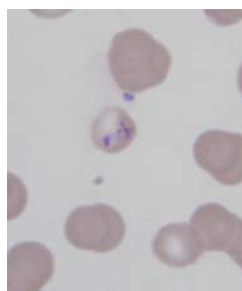
Lupus Anticoagulant Cascade

### SPOTLIGHT ON THE LAB

## Getting prepared for warmer weather: *A Primer on Summer Pests*

**Blood parasite exam is sufficient to detect *Babesia* in most situations.**

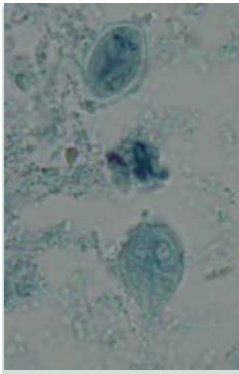
Babesiosis is an emerging zoonosis caused by an intraerythrocytic protozoan in the genus *Babesia*. *Babesia microti* is responsible for the vast majority of human cases in the United States, with hot spots of disease along the Northeast Coast and Midwest states, although the distribution of disease is spreading. *Babesia microti* shares a tick vector with *Borrelia burgdorferi* and *Anaplasma phagocytophilum*, the causative agents of Lyme disease and



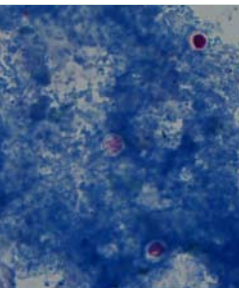
Babesia

human granulocytic anaplasmosis. Recent studies suggest that exposure to *Babesia microti* is quite common in areas endemic for Lyme disease and anaplasmosis, so it is prudent to consider testing for all three diseases concurrently. Most patients with babesiosis have a mild illness or are asymptomatic, but some develop a severe illness that may result in death. Patient symptoms may include fever, chills, extreme fatigue, and anemia. The most severe cases occur in asplenic individuals and those over 50 years of age.

The definitive laboratory diagnosis of babesiosis rests on the demonstration of *Babesia* species characteristic intraerythrocytic parasites in Giemsa-stained thick and thin blood films. This method is capable of detecting human-infective *Babesia* species. However, parasites may be difficult to identify in cases of low parasitemia, and the ring forms of *Babesia* may closely resemble those of *Plasmodium falciparum*. Babesia PCR may be useful in these rare situations when Giemsa-stained peripheral blood smears do not reveal any organisms or the organism morphology is inconclusive. Overall, a blood parasite exam is sufficient to detect *Babesia* in most situations.



Giardia Troph and Cyst



Cryptosporidium

### **Giardia & Cryptosporidium antigen detection is the preferred method for detection of stool parasites in patients who have not traveled outside of the United States.**

We recommend the [Parasitic Investigation of Stool Specimens Algorithm](#) to guide the selection of diagnostic parasitology tests based on the patient's presenting symptoms, environmental exposures, and immune status. The traditional method for identification of parasites in stool is the ova and parasite examination which involves a subjective microscopic examination by highly trained and experienced technologists. Although appropriate for identifying many exotic parasites, the method is less sensitive for detecting *Giardia* and *Cryptosporidium* which are the most common parasites in the United States. These parasites may be suspected when patients present with watery diarrhea and have a supportive history of exposure. In this setting, Giardia & Cryptosporidium antigen detection tests are more sensitive, timely and cost-effective for initial testing. Limitations to ova and parasite examination include intermittent excretion of *Giardia* cysts and shedding of *Cryptosporidium* oocysts (necessitating up to three stool exams), cumbersome processing procedures, and technician expertise. Ova and parasite examinations should be reserved for patients who reside in or have visited a developing country or area where helminth infections have been reported. Ova and parasite examinations will not detect *Cryptosporidium*, *Cylospora*, *Isospora* and *Microsporidia*. Please remember that fecal samples submitted in Total Fix or Unifix Transport Vials will be accepted for testing at UVMMLC. Fecal samples submitted in EcoFix or Formalin/PVA will be forwarded to Mayo Medical Laboratory for testing. All other transport vials will be rejected.

### **PCR is NOT the best test for West Nile Virus**

West Nile virus (WNV) is a single-stranded RNA flavivirus that primarily infects birds. The virus exhibits a bird-mosquito-bird transmission cycle. Humans become infected by WNV predominately through transmission by mosquitoes. Other modes of transmission include blood product transfusion, organ transplantation, breast-feeding, and transplacental infection. Risk for WNV in temperate climates is greatest in late summer or early fall. The majority of people who are infected with WNV are asymptomatic. It is estimated that only 20% of people who become infected with WNV develop West Nile fever with nonspecific symptoms such as fever, headache, myalgia, enlarged lymph nodes, and a skin rash on the trunk of the body. Less than 1% of WNV infections will result in neurologic disease. Symptoms suggesting neurological disease include meningitis, encephalitis, and poliomyelitis-like features (flaccid paralysis). The incubation period for West Nile fever ranges from 2 to 15 days, while the symptoms may last for days to months.

Laboratory diagnosis of WNV is best demonstrated by detection of specific IgG and IgM class antibodies in serum specimens. Most infected persons will have serologically detectable IgM antibody to WNV by the 8<sup>th</sup> day of illness. In general, IgM antibodies will be detectable for 1 to 2 months after the onset of illness, and in some cases it will remain detectable for 12 months or longer. The presence of IgG class antibodies to WNV in a serum specimen indicates infection with WNV in the past. By 3 weeks postinfection, virtually all infected persons should have developed IgG antibodies to WNV. If an acute-phase infection is suspected, serum specimens drawn within approximately 7 days postinfection should be compared with a specimen drawn approximately 14 to 21 days after infection to demonstrate rising IgG antibody levels between the two serum specimens.

The detection of WNV IgM antibodies in CSF is the recommended test to document central nervous system disease. IgM class antibody to WNV is generally detected in CSF from 3 to 5 days after the onset of symptoms. A serum specimen obtained at the time of CSF collection

should be tested in parallel. Complicating factors include low antibody levels found in CSF, passive transfer of antibody from blood, and contamination of CSF with antibodies in sera via bloody taps.

PCR methods can be used to detect WNV RNA in plasma specimens from patients in 3 to 5 days following infection when specific antibodies to the WNV are not yet present. However, the likelihood of detection is relatively low as the sensitivity of PCR detection is approximately 55% in cerebrospinal fluid and approximately 10% in blood, from patients with known WNV infection.

Overall, serology remains the preferred method for identification of WNV infection, while PCR may be indicated in certain situations.

#### **Babesia References:**

1. Homer MJ, Aguilar-Delfin I, Telford SR, et al. Babesiosis. *Clin Microbiol Rev* 2000;13(3):451-469.
2. Thompson C, Spielman A, Krause PJ. Coinfecting deer-associated zoonoses: Lyme disease, babesiosis, and ehrlichiosis. *Clin Infect Dis* 2001 Sept 1;33(5):676-685.
3. Vannier E and Krause PJ: Human Babesiosis. *N Engl J Med* 2012 Jun 21;366(25):2397-2407.
4. Gelfand JA, Vannier EG. Clinical manifestations, diagnosis, treatment, and prevention of babesiosis. In: *Uptodate, Daily J* (Ed), Uptodate, Waltham, WA. (Accessed on January 6, 2016.)

#### **Giardia & Cryptosporidium References:**

1. Rosoff JD, Sanders CA, Sonnad SS, et al. Stool diagnosis of giardiasis using a commercially available enzyme immunoassay to detect Giardia-specific antigen 65 (GSA 65). *J Clin Microbiol.* 1989 Sep;27(9):1997-2002.
2. Aziz H, Beck CE, Lux MF, et al. A comparison study of different methods used in the detection of Giardia lamblia. *Clin Lab Sci* 2001; 14:150.
3. Weber R, Bryan RT, Bishop HS, et al. Threshold of detection of Cryptosporidium oocysts in human stool specimens: evidence for low sensitivity of current diagnostic methods. *J Clin Microbiol* 1991; 29:1323.
4. Kehl KS, Cicirello H, Havens PL. Comparison of four different methods for detection of Cryptosporidium species. *J Clin Microbiol* 1995; 33:416.
5. Parisi MT, Tierno PM Jr. Evaluation of new rapid commercial enzyme immunoassay for detection of Cryptosporidium oocysts in untreated stool specimens. *J Clin Microbiol* 1995; 33:1963.

#### **West Nile Virus References:**

1. Masoner DE, Dale JC, Binnicker MJ. West Nile Virus Update. *Mayo Medical Laboratories Communique* 2008 Jul; 33(7): 1-7.
2. Dauphin G, Zientara S. West Nile virus: recent trends in diagnosis and vaccine development. *Vaccine* 2007 Jul 26;25(30):5563-76.
3. Petersen LR. Clinical manifestations and diagnosis of West Nile virus infection. In: *Uptodate, Hirsh MS* (Ed), Uptodate, Waltham, WA. (Accessed on January 4, 2016.)
4. Prince HE, Tobler LH, Lapé-Nixon M, et al. Development and persistence of West Nile virus-specific immunoglobulin M (IgM), IgA, and IgG in viremic blood donors. *J Clin Microbiol* 2005; 43:4316.
5. Nash D, Mostashari F, Fine A, et al. The outbreak of West Nile virus infection in the New York City area in 1999. *N Engl J Med* 2001; 344:1807.



**Spotlight on the Lab**  
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## Fecal Bacterial Pathogen Detection: Testing Change

Organisms that cause enteric disease are a significant cause of morbidity and mortality worldwide. Conventional culture methods take 48-96 hours to complete. Detection of nucleic acids by polymerase chain reaction (PCR) methods can be completed in hours and is more sensitive than culture. Microbiology testing for bacterial fecal pathogens (*Salmonella*, *Shigella*, *Campylobacter*, and Shiga toxin producing *E.coli*) will change from culture to PCR detection effective April 25, 2016. Testing will be performed using the BD Max instrument and results will be available within 24 hours.

Fecal culture is only available for unusual bacterial pathogens (*Aeromonas sp.*, *Plesiomonas shigelloides*, *Yersinia enterocolitica*, or *Vibrio sp.*); these are rare (and in some cases controversial) pathogens that were detected in 0.6% of stool samples tested in our Microbiology Laboratory last year. Testing for these pathogens should be considered if PCR testing is negative and there is significant travel history or unresolved diarrhea.

### Test Name: Fecal Bacterial Pathogens PCR

#### New Order Code: FECBD

**Sample requirements:** Feces in Cary Blair, do not fill above fill line. Unpreserved feces in a sterile container must arrive at the lab no later than 2 hours after collection.

**Test schedule:** Daily / Same Day / Not available STAT

**Expected Value:** No *Salmonella sp.* DNA detected, No *Shigella sp.* or Enteroinvasive *E.coli* DNA detected, No *Campylobacter sp. (jejuni or coli)* DNA detected, No Shiga toxin producing genes detected.

**CPT Code:** 87505-Gastrointestinal pathogen, multiplex, 3-5 targets

**Method:** PCR

**New York State Certification:** Yes

**Effective date:** April 25, 2016

### TEST NAME: FECES CULTURE UNUSUAL PATHOGENS

**Order Code:** FECCX

**Sample requirements:** Feces in Cary Blair, do not fill above fill line. Unpreserved feces in a sterile container must arrive at the lab no later than 2 hours after collection.

**Test Schedule:** Daily / Reported when positive, negative final at 48-hours / Not available STAT

**Expected Value:** No *Aeromonas sp.*, *Plesiomonas shigelloides*, *Yersinia enterocolitica*, or *Vibrio sp.* isolated.

**CPT Codes:** 87046-stool, aerobic, additional pathogens isolation and presumptive identification, each plate, 87046.91-addition of TCBS media for isolation of *Vibrio*

**Method:** Culture

**New York State Certification:** Yes

## Fecal Bacterial Pathogen-PCR Sample Report

THE  
**University of Vermont**  
 MEDICAL CENTER  
 111 Colchester Avenue  
 Burlington, VT 05401

**Patient Information**

Name	MRN	Sex	DOB (Age)
Aacorleone, Michael	0611205717	Male	4/22/1960 (55 y.o.)
Unit	Room	Bed	
Baird 3	B318	02	

**Provider Information**

Entered by	Ordering Prov	Authorizing Prov
	SHAFRITZ, ADAM B	SHAFRITZ, ADAM B

**FECAL BACTERIAL PATHOGENS BY PCR**

Results  
**Abnormal**

Last Update: Final result (Collected: 2/26/2016 8:10)

**Result Information**

Status	Provider Status
<b>Abnormal</b> Final result (Collected: 2/26/2016 8:10)	Ordered

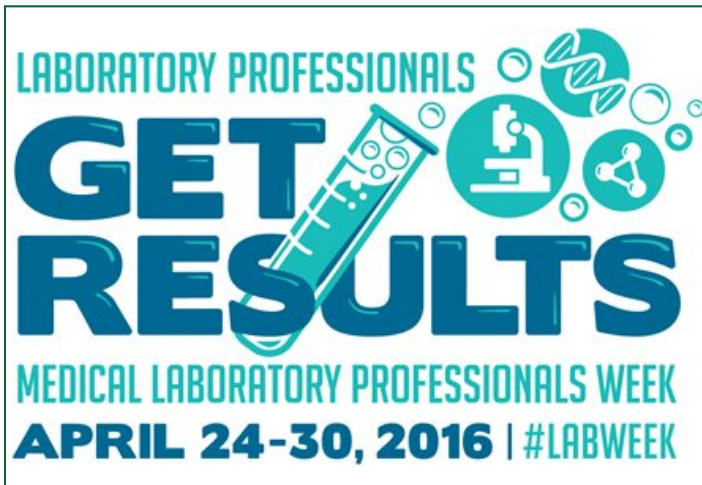
**Lab Order Information**

Lab Test	Accession #	Order #	Specimen Sourc	Specimen Descr
FECAL BACTERIAL PATHOGENS BY PCR	F2334	129020807	Feces	

2/26/2016 10:20 - Edi, Lab Results In One

**Component Results**

Component
<b>Salmonella PCR</b> No Salmonella spp. DNA detected.
<b>Shigella</b> No Shigella spp. or Enteroinvasive E.coli DNA detected.
<b>Campylobacter PCR</b> No Campylobacter spp. (jejuni or coli) DNA detected.
<b>Shiga Toxin PCR (Abnormal)</b> <b>SHIGA TOXIN PRODUCING GENE(S) DETECTED</b>



**LAB TOURS**

Come meet the Clinical Lab Scientists and see the technology behind the lab tests you send to the University of Vermont Medical Center every day. We will be hosting laboratory tours on the second Tuesday of each month. Tours are given at the Main Pavilion at 10 am (alternate times can be arranged) and will take approximately one hour. Preregistration is required. Call (802) 847-9473 or email LabAmbassador@UVMHealth.org to sign up.

**We hope to see you soon!**



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## Lupus Anticoagulant Cascade: New Testing Algorithm:

The Thrombosis and Hemostasis Laboratory is pleased to offer a Lupus Anticoagulant Cascade to aid in the diagnosis of anti-phospholipid antibody syndrome associated with thrombosis. This Cascade will be available April 21, 2016, and once this LA Cascade is implemented, the individual tests will no longer be orderable as stand-alone tests.

Anti-phospholipid syndrome (APS), the most common cause of acquired thrombophilia, is associated with significant morbidity and mortality across diverse patient populations. The most frequently detected antibodies are commonly referred to as lupus anticoagulants (LA) due to their prevalence in patients with systemic lupus erythematosus. However, the antibodies, known as anti-phospholipid antibodies (APA) associated with APS are extremely heterogeneous and are directed against a wide variety of anionic phospholipids, including cardiolipin,  $\beta$ 2 glycoprotein 1 (B2GP1), cell-membrane phosphatidylserine, and many others. While these antibodies most commonly cause *in vivo* thrombosis, these same antibodies paradoxically prolong *in vitro* clot-based laboratory assays. A panel of tests is necessary to detect APAs as no single test presently available is sufficient to detect (or exclude) this diverse group of antibodies. The LA Cascade is provided (see below) as an overview of the recommended laboratory testing and should not supplant the diagnostic interpretation provided by the Thrombosis and Hemostasis Laboratory.

### Lupus anticoagulant (LA) testing

Based upon consensus criteria from the International Society for Thrombosis and Hemostasis (ISTH), confirmation of a LA requires that the following criteria are met:

- Performing 2 or more phospholipid-dependent clotting tests demonstrating prolongation of at least one test (i.e. Silica Clot Time (SCT), dilute Russell Viper Venom Test (dRVVT))
- Evidence for inhibitory activity shown by the effect of patient plasma on normal pooled plasma. (i.e. mixing study which fails to show complete correction)
- Demonstration of phospholipid-dependence of the inhibitor on a confirmatory test as evidenced by shortening of the clotting time with the addition of additional phospholipid.

Equally important, the ISTH recommends the following are performed:

- Routine clotting tests such as the prothrombin time (PT) and partial thromboplastin time (aPTT) to evaluate for the possibility of other coagulation disorders, particularly those which interfere with LA testing methods
- Factor assays whenever there is a suspicion of a specific factor deficiency or inhibitor

**The laboratory criteria include positive testing for one of the following on 2 or more occasions, at least 12 weeks apart:**

1. Lupus anticoagulant
2. Cardiolipin antibodies (IgG or IgM) in medium or high titer, and/or
3.  $\beta$ 2-glycoprotein 1 antibodies (IgG or IgM)

Though rare, a factor-specific antibody to factor VIII can result in false positive LA testing; as part of the diagnostic interpretation, the laboratory will ask the ordering medical provider to exclude the likelihood of a factor specific inhibitor. Factor activity assays can be performed upon request.

## Interpretation of Laboratory Test Results

The Clinical Laboratory Standards Institute (CLSI) published updated 2014 guidelines for the laboratory diagnosis of APA. These guidelines state that all laboratory results and calculations in the laboratory's LA panel must undergo a step-by-step review by a qualified individual knowledgeable of the specific assays, and a written summary interpretive report must be provided to the ordering physician(s). The Thrombosis and Hemostasis Laboratory will provide a written interpretation for all LA Cascade testing.

The diagnosis of APS requires both clinical and laboratory pathologic evaluations. In addition to clinical criteria, often presenting as vascular thrombosis or pregnancy morbidity, persistently positive laboratory tests are required to render a diagnosis of APA because of transient low level increase of APA in many clinical conditions including infections and reactive processes. Testing during the acute phase (i.e. at the initial presentation of thrombosis) is not recommended.

### Cardiolipin and $\beta$ 2-glycoprotein 1 antibodies (IgG and IgM)

Please note, the solid phase testing necessary to detect cardiolipin or  $\beta$ 2-glycoprotein 1 antibodies is not included in this LA Cascade laboratory testing panel, and these assays must be ordered independently by the medical provider (Order codes CARDLI and B2PNL, respectively). These solid phase tests require serum samples and cannot be "added on" to the plasma samples used for the Lupus Cascade. Should the results from these solid phase assays be available at the time of the LA Cascade, the Thrombosis and Hemostasis Laboratory will incorporate these results into the final diagnostic interpretation.

### Routine Coagulation Screening Assays

The prothrombin time (PT) and activated partial thromboplastin time (aPTT) time are not included in this Lupus Anticoagulant Cascade. Medical providers must consider ordering these screening assays as part of their diagnostic work-up to further evaluate the possibility of other coagulation disorders.

### Direct Oral Anti-Coagulants (DOAC)

Consensus guidelines suggest testing should only occur when the patient is free from oral anticoagulation medications including warfarin and the Direct Oral Anti-Coagulants (DOAC) medications such as dabigatran, rivaroxaban, apixaban, and edoxaban.

### Existing Lupus Anticoagulant and Anti-Phospholipid Panels Are Discontinued

With this new Lupus Cascade, the previous panels will be discontinued:

1. Order Code APAB: DRVVT, aPTT 50:50 mix, and cardiolipin antibodies
2. Order Code LAW: DRVVT and aPTT 50:50 mix

The aPTT available at the UVMC Laboratories is only rated moderately sensitive to the presence of a lupus anticoagulant based on the phospholipid content in the reagent system. One must consider this fact if the aPTT is utilized as a screen for a lupus anticoagulant. The new Lupus Cascade utilizes the Dilute Russell Viper Venom Test and the Silica Clot Time, both of which have increased sensitivity for detecting a lupus anticoagulant when compared to the current aPTT assay. Additionally, the Lupus Cascade will automatically perform both these tests fulfilling the recommended ISTH and CLSI guidelines of utilizing 2 phospholipid-dependent clotting assay systems.

## Lupus Anticoagulant Cascade Test Information

Test Schedule: Tuesday and Thursday, reported next day

Test Priority: Routine; STAT testing is not available

Expected value: Lupus anticoagulant not detected

CPT Codes: DVV-85613  
 SCT-85732  
 Interpretation-85390.26  
 THT-85670 (if appropriate)  
 FIB-85384 (if appropriate)  
 ANTXAQ-85520 (qualitative anti-Xa, if appropriate)  
 HEPAS- 85525 (if appropriate)

Effective date: April 21, 2016

Order Code	Test ID	Test Name	Available Separately	Always Performed
LACASC	DVV	Dilute Russell Viper Venom Time (DRVVT), Screen	No	Yes
	LLAC	Dilute Russell Viper Venom Time (DRVVT), Confirm	No	No
	SCT	Silica Clot Time (SCT), Screen	No	Yes
	SCTC	Silica Clot Time (SCT), Confirm	No	No
	LACINT	Interpretation	No	Yes
	DVV50	DRVVT Mixing Study	No	No
	SCT50	SCT Mixing Study	No	No
	THT	Thrombin Time (TT)	Yes	No
	THTHEP	TT, hepzyme	No	No
	ANTXAQ	Anti-Xa, qualitative	No	No
	SCTHEP	SCT, hepzyme	No	No
	DVVHEP	DRVVT, hepzyme	No	No
FIB	Fibrinogen	Yes	No	

### References:

- Keeling D., et al. Guidelines on the investigation and management of antiphospholipid syndrome. *BJH*. April, 2014; 157(1): 47–58.
- Ledford-Kraemer M., et al. H60-A: Laboratory Testing for the Lupus Anticoagulant; Approved Guideline. Clinical and Laboratory Standards Institute. April, 2014; 34(6): 1-93.
- Levin JS, Branch DW, Rauch J. The antiphospholipid syndrome. *New Engl J Med*. March 7 2002; 346(10): 752-763.
- Moore GW. Recent Guidelines and Recommendations for Laboratory Detection of Lupus Anticoagulants. *Semin Thromb Hemost* 2014; 40: 163–171.
- Pengo V., et al. Subcommittee on Lupus Anticoagulant/Antiphospholipid Antibody of the Scientific and Standardisation Committee of the International Society on Thrombosis and Haemostasis. Update of the guidelines for lupus anticoagulant detection. *J Thromb Haemost* 2009; 7(10): 1737–1740.





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## Alert: Cross Reactivity of Fulvestrant in Estradiol Assay

The Laboratory has been notified by the manufacturer of the estradiol assay currently used at UVM Medical Center (Siemens Healthcare Diagnostics) that the cross reactivity of fulvestrant in this immunoassay could lead to reporting falsely elevated levels of estradiol resulting in an inappropriate clinical assessment of estrogen status. Fulvestrant is used in post-menopausal women treated for estrogen receptor positive, recurrent stage IV breast cancer. If our estradiol assay is used to assess the menopausal status of such patients, a falsely elevated level of estradiol could lead the clinician to misinterpret the patient as pre-menopausal, possibly leading to altered or discontinued use of the potentially beneficial drug fulvestrant.

If this situation has occurred, reassessing the menopausal status of the patient by other means or using an alternate estradiol measurement should be considered. ***Estradiol concentration in fulvestrant-treated women should only be measured using an assay that has negligible cross reactivity with fulvestrant such as Liquid Chromatography-Mass Spectrometry (LC-MS/MS).*** LC-MS/MS assays differentiate fulvestrant (molecular weight 606.772 g/mol) from estradiol (molecular weight 272.382 g/mol).

A statement has been added to estradiol reports: "Cross reactivity with fulvestrant could lead to falsely elevated estradiol results in patients treated with this drug."

It should be noted that finasteride, dutasteride, exemestane, and formestane have negligible cross reactivity with the estradiol assay. With the advent of new steroid based medications with similar chemical structures to estradiol, however, there is the possibility of cross-reactivity and falsely elevated results with these new agents. For diagnostic purposes, laboratory results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings. If the estradiol results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.

If you have any questions regarding this notice, please contact Dr. Greg Sharp ([Gregory.Sharp@uvmhealth.org](mailto:Gregory.Sharp@uvmhealth.org)) in the Chemistry Laboratory.

## Critical Value for CO<sub>2</sub>

On March 16, 2016 the Chemistry Laboratory added a total CO<sub>2</sub> value of less than 10 to the critical value list. Prompt communication of these results will aid in the rapid detection and monitoring of metabolic acidotic states such as diabetic ketoacidosis.

The critical value list for the laboratory is available [on our website](#). Laboratory results that meet the criteria on this list are potentially life threatening if no action is taken and reported as soon as possible to a health care provider.

If you have any questions concerning this change, please contact Dr. Greg Sharp ([Gregory.Sharp@uvmhealth.org](mailto:Gregory.Sharp@uvmhealth.org)) in the Chemistry Laboratory.

## Erythrocyte Magnesium (MG-RBC) Testing No Longer Available

In September 2012 Mayo Medical Laboratories (MML) issued a Communique stating that "...there is no demonstrable benefit to the red blood cell testing (of magnesium)". The serum magnesium test is strongly recommended for nutritional assessment. MML said there were only 2 peer-reviewed papers in the medical literature that addressed the clinical use of Mg-RBC<sup>1,2</sup> and these did not support the use of Mg-RBC for this purpose.

Additional search of the literature revealed three other articles discussing Mg-RBC<sup>3,4,5</sup>. None of these articles recommended the replacement of serum magnesium measurements with the Mg-RBC and indeed, one article specifically stated that Mg-RBC was not useful for monitoring magnesium status during nutritional supplementation<sup>4</sup>.

Since the clinical literature does not support the use of the Mg-RBC this testing will no longer be available through UVM Medical Center.

1. Sales CH, et al., Magnesium and diabetes mellitus: their relations, Clin Nutr 25; 4:554-62, 2006
2. Sales CH, et al., Influence of magnesium status and magnesium intake on the blood glucose control, in patients with type II diabetes, Clin Nutr, 2011
3. Ulger, Z, Ariogul, S, Cankurtaran, M, et al.) Intra-Erythrocyte Magnesium Levels and their Clinical Implications in Geriatric Outpatients, J. Nutr Health Aging 14:810-814, 2010
4. Basso, L E, Ubbink, J B, Delpont, R, Erythrocyte magnesium concentration as an index of magnesium status: a perspective, Clinica Chimica Acta 291: 1-8, 2000
5. Martin, B, Lyon, T, et al. Erythrocyte Magnesium in Elderly Patients: not a reliable Guide to Magnesium Status J Trace Elements Med Biol 11:44-48, 1997

## Flagging of Abnormal Values for: **Hepatitis B Surface Antigen Hepatitis C Antibody HCV RNA Quantitation HIV 1 RNA Quantitation HIV 1/2 Antibody**

With the large number of test results being reviewed by clinicians from paper reports to multiple electronic medical records, visual signals alerting physicians to important abnormal values has become a significant issue. With the multiplying complexity and number of systems displaying results users should not totally rely on the fact that their particular system will always draw their attention to a result that should be acted on. It is important to remember that depending on the clinical setting, it may not be possible for an Electronic Health Record to accurately prioritize laboratory results.

On February 17, 2016, abnormal flags for Hepatitis B surface antigen, Hepatitis C antibody, Hepatitis C viral load, Human Immunodeficiency Virus 1 viral load and HIV 1/2 Antibody were added to the result reports. These flags should alert the Health Care Provider to the presence of abnormal results and prompt appropriate clinical action may be taken. If you have any questions concerning this change please contact Dr. Greg Sharp ([gregory.sharp@uvmhealth.org](mailto:gregory.sharp@uvmhealth.org)) in the Chemistry Laboratory.

**SYRINGE  
DISPOSAL**

**The University of Vermont Medical Center does not accept sharps for disposal from patients!**

Chittenden Solid Waste District (CSWD) will accept needles that are packaged according to the instructions outlined in their pamphlet “GET THE POINT: Be safe with syringes and other sharps”. CSWD also has bright orange stickers to attach to a syringe container to warn handlers to be careful. These items are available at any CSWD location. You can also order them so that they are available for patients at your office 872-8111 or visit [www.cswd.net](http://www.cswd.net)

## Lactic Acid Normal Range and Critical Value Change

It has recently been recognized that serum lactate, a biochemical marker available for many years, can play a central role in managing patients with severe trauma or possible sepsis. To support efforts at the University of Vermont Medical Center for early diagnosis and treatment of sepsis, the Laboratory has changed the critical value for serum lactate to be 2.0 mmol/L or greater. The reference range for lactate will be < 2.0 mmol/L. Values at or above the critical value will be called to a health care provider each time they occur. This change took effect on February 3, 2016.

	<b>Normal</b>	<b>Critical Result</b>
>18 Years	up to 1.9 mmol/L	2.0 and greater

If you have any questions concerning this change, please contact Dr. Greg Sharp ([Gregory.sharp@uvmhealth.org](mailto:Gregory.sharp@uvmhealth.org)) in the Laboratory.

Reference: Bakker, Jan and Jansen, Tim. Don't take vitals, take a lactate. Intensive care Medicine (2007) 33(11): 1863-1865.

## Lead Demographic Information Required

Vermont, New Hampshire and New York require that “any laboratory performing blood lead analysis on adults or children residing in these states shall report in accordance with the rules adopted by each state.”

**The laboratory at the University of Vermont Medical center requests that this information be provided when lead testing is ordered.**

The following information is required to be reported:

- Patient’s name, date of birth, street address including town or city of residence, state and postal code. For the patient address, **the street address should be submitted instead of a PO Box whenever possible.**
- Name and address of health care provider
- Patient’s race and ethnicity
- Patient’s parent or guardian and phone number if the patient is ages 15 years or younger. If the patient has Medicaid for insurance, the child’s name should not be entered as the guarantor but instead the guardian or parents name should be submitted (the owner of the residence of the patient).
- Occupation if patient is 16 years or older and the individual’s employer at the time the blood lead test is performed when testing is a requirement of the individual’s occupation.

All of the information above is submitted to the UVM Medical Center by most clients electronically using the Lead Portal Application that is accessed through the UVMMC Gateway. If you would like information on submitting this information electronically, please contact [Laboratory.Outreach@UVMHealth.org](mailto:Laboratory.Outreach@UVMHealth.org).

## Cyclospora Detection Name Change

On March 28, 2016 the test name Cyclospora Detection (CSPORA) changed to **Modified Acid Fast Parasitology**. There will be no change in test method, only a name change to reflect that the test can be used to detect both Cyclospora and Isospora.

**TEST CATALOG**

To view a complete listing of tests available at the University of Vermont Medical Center, please visit [UVMHealth.org/MedCenterTests](http://UVMHealth.org/MedCenterTests)

**Browse by Name**

**Search**

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## HIV and Hepatitis C Testing Available for New York State

The University of Vermont Medical Center Laboratory is approved by the State of New York for the performance of Hepatitis C virus antibody testing and viral load testing. Antibody testing is performed Monday through Friday. Viral load testing is performed on Monday, Tuesday and Thursday. The Chemistry Laboratory is also approved to perform HIV antibody screening and viral load monitoring. Antibody screening is performed every day and viral load monitoring is performed on Monday and Thursday. If you have any questions concerning this testing please contact Dr. Greg Sharp [Gregory.Sharp@uvmhealth.org](mailto:Gregory.Sharp@uvmhealth.org) in the Chemistry Laboratory.

## Opiate Confirmation and Buprenorphine Testing Reference Lab Change

As of February 17, 2016 opiate confirmations and buprenorphine testing are now being sent to Burlington Laboratories rather than ~~Mayo Medical Laboratories~~. ~~This change should be technically transparent to the user since the methodologies used are similar at both laboratories.~~ Burlington Laboratories is a local company specializing in toxicological analysis, and as such we are expecting a decrease in turnaround time. If you have any questions concerning this change please contact Dr. Greg Sharp ([gregory.sharp@uvmhealth.org](mailto:gregory.sharp@uvmhealth.org)) in the Chemistry Laboratory.

## Stem Cell CD34 Peripheral Blood Sample Type

Sodium Heparin tubes are **no longer acceptable** for Stem Cell CD34 enumeration. The test will be performed on the same EDTA (Lavender) tube as the CBC. Sodium Heparin tube are still acceptable.



Fill line is not obstructed Label is placed on the length of the tube	Label obstructs Fill level
--	-------------------------------

## Coagulation Testing: Labeling Blue Top Tubes

Please take care to place identification labels on top of manufacturer's labels on specimen tubes. The technologist in the lab is required to check the fill level and the sample appearance prior to analysis. The volume of specimen in the tube is critical because there must be a ratio of 9 parts blood to 1-part anticoagulant to produce meaningful results. Sample appearance is important to be sure there is no interference from marked hemolysis or marked lipemia.

Thank you for your help. Please call the Hematology Laboratory at 847-3567 if you have any questions.

## Test Schedule Changes

Cyclic Citrullinated Peptide Antibody volumes have increased Beginning the week of January 18, 2016 the testing schedule is Monday, Wednesday, and Friday with results available the same day. (Test Code: CCP, PRISM Code: LAB2316)

As of Monday, 03/14/16 the following tests have been moved from Tuesday, Thursday to Monday, Wednesday testing Schedule:

Test Name	Test Code	PRISM Code
SS-A ANTIBODY	SSAA	LAB2377
SS-B-ANTIBODY	SSBA	LAB2378
Sm ANTIBODY	SMAA	LAB2373
RNP ANTIBODY	RNPA	LAB772

Also we will do two test runs Monday – Friday for the following tests, they should be reported out same day:

ANTINUCLEAR ANTIBODY	ANA	LAB148
ANTI NEUTROPHIL CYTOPLASMIC AB	ANCA	LAB458
SMOOTH MUSCLE ANTIBODY	SMO	LAB512
MITOCHONDRIAL ANTIBODY	MIT	LAB724
PRT ANTIBODY	PRT	LAB514

## Lab Compliance Updates

### Medicare Changes to HIV Screening- Summary 2016: Implementation Date: 3/7/16

1. **Once/year** for those **who are not** considered at **increased risk**. dx- Z11.4- Encounter for screening for HIV

2. **Once/year** for those **who are at increased risk (see criteria below)**

- dx- primary      Z11.4- Encounter for screening for HIV
- dx-secondary    Z72.89- Other problems related to lifestyle or
- Z72.51- High risk heterosexual behavior
- Z72.51- High risk homosexual behavior

*Continued on page 14 and 15*

### GET TEST RESULTS ONLINE!

MyHealth Online

Did you know that your patients can get their UVM Medical Center test results online by signing up for a MyHealth Online account?

To sign up visit: [UVMHealth.org/MedCenterMyHealth](http://UVMHealth.org/MedCenterMyHealth)

**3. Three voluntary HIV Screenings of pregnant beneficiaries:**

**When dx of pregnancy is known;**

**During the 3<sup>rd</sup> trimester;**

**At labor, if ordered by the woman’s clinician Dx- primary Z11.4 AND appropriate Obstetric code (Z34.00-Z34.03, Z34.80-Z34.83, Z34.90-Z34.93, O09.90-O09.93)**

**Increased Risk:**

- Men who have sex with men;
- Men & women having unprotected vaginal or anal intercourse;
- Past or present injection drug users;
- Men and women who exchange sex for money or drugs, or have sex partners who do;
- Individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users;
- Persons who have acquired or request testing for other sexually transmitted infectious diseases;
- Persons with a history of blood transfusions between 1978 and 1985;
- Persons who request an HIV test despite reporting no individual risk factors;
- Persons with new sexual partners; or
- Persons who, based on individualized physician interview and exam, are deemed to be at increased risk for HIV infection. The determination of "increased risk" for HIV infection is identified by the health care practitioner who assesses the patient’s history, which is part of any complete medical history.

**HPV Screening- Medicare - Implementation date: July 5, 2016**

Medicare has added HPV testing to the list of covered preventive services with the following criteria:

**Once every 5 years for asymptomatic beneficiaries aged 30-65 with a Pap test.**

To support medical necessity, **both the primary and secondary diagnosis codes must** be provided:

DX	Primary DX	Secondary DX- <b>Based on the provider’s physical exam</b>
Post- Oct. 1, 2015	<b>Z11.51-</b> encounter for screening for HPV	<b>Z01.411-</b> encounter for GYN exam with <b>abnormal finding OR</b> <b>Z01.419-</b> encounter for GYN exam <b>without abnormal finding</b>

Here is the link for the complete NCD: MM9434 – Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing—National Coverage Determination (NCD) 210.2.1

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9434.pdf>

## Lab Compliance Updates Continued

### ICD 10 coding for Chlamydia/GC Screening

It has been brought to our attention that commercial payers are requiring the following ICD-10 code for **Chlamydia/GC screening**:

**Z11.8-** Encounter for screening for chlamydia

**Z11.3-** Encounter for screening for infections with a predominantly sexual mode of transmission

**Blue Cross** will only cover this testing for females and will also cover the testing as screening if it is ordered as part of a general adult medical exam or GYN (general ) (routine) exam whether or not there are abnormal findings.

Here are the covering dx for screening per BCBSVT preventive services table. (codes for pregnant women are not included as there are numerous codes):

#### Chlamydia:

Chlamydia covered for females, limit 2 per plan year.

Covering dx: Z00.00, Z00.01, Z01.411, Z01.419, Z01.42, Z11.8, Z12.4 & Z12.72

#### Gonorrhea:

GC- Female and doesn't list a frequency limitation.

Covering dx: Z00.00, Z00.01, Z01.411, Z01.419, Z01.42, Z11.3, Z12.4, Z12.72, Z33.1

**If ordering Chlamydia/GC testing for diagnostic purposes, please include the patient's signs/symptoms.**

### LABORATORY PATIENT SERVICE CENTER



#### Main Campus

Main Pavilion, Level 2  
111 Colchester Avenue  
Burlington, VT

#### One South Prospect

1 South Prospect St  
First Floor Lobby  
Burlington, VT

#### Fanny Allen Campus

792 College Parkway  
Colchester, VT

#### Adult Primary Care Williston

353 Blair Park Road  
Williston, VT

Visit [UVMHealth.org/MedCenterDrawSites](http://UVMHealth.org/MedCenterDrawSites) for patient service center hours and special test considerations.

All UVM Medical Center phlebotomists are nationally certified

**PATHOLOGY & LABORATORY MEDICINE COMMUNIQUÉ — APRIL 2016**

**PATHOLOGY & LABORATORY  
MEDICINE COMMUNIQUÉ**

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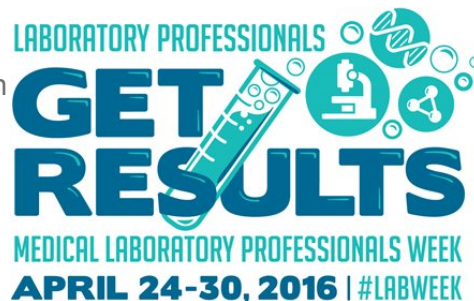
(802) 847-5905

**WEBSITE**

[UVMHealth.org/MedCenterLabs](http://UVMHealth.org/MedCenterLabs)

**NATIONAL MEDICAL LABORATORY WEEK APRIL 24—30, 2016**

Medical Laboratory Professionals Week is an annual celebration of the laboratory professionals and pathologists who play a vital role in every aspect of health care. Since we often work behind the scenes, few people know about the critical testing performed every day in the lab. Lab Week is a time to honor the more than 300,000 medical laboratory professionals around the country including 350 right here at Fletcher Allen, who perform and interpret more than 10 billion laboratory tests in the US every year. We are offering lab tours April 24-30, 2016 come help us celebrate!





# Lupus Anticoagulant Cascade

