

Pathology & Laboratory Medicine
Communiqué

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**Laboratory Collection Sites Winter
2016-2017 Holiday Hours**

	Main Campus	Blair Park	Fanny MOB	1 So. Prospect
Friday 12/23/2016	7 am - 1 pm	Closed	6:30 am - 1 pm	7 am - 1 pm
Saturday 12/24/2016	Closed	Closed	Closed	Closed
Sunday 12/25/2016	Closed	Closed	Closed	Closed
Monday 12/26/2016	7 am - 1 pm	Closed	6:30 am - 1 pm	7 am - 1 pm
Friday 12/30/2016	7 am - 1 pm	Closed	6:30 am - 1 pm	7 am - 1 pm
Saturday 12/31/2016	9 am - 1 pm	Closed	9 am - 1 pm	Closed
Sunday 1/1/2017	Closed	Closed	Closed	Closed

TEST CATALOG

To view a complete listing of tests available at the University of Vermont Medical Center, please visit UVMHealth.org/MedCenterTests

Browse by Name

Search

A B C D E F
G H I J K L

 Search

Regularly scheduled hours will apply to any days not specifically addressed above, please call 847-5121 or 1-800-991-2799 for assistance.



Lynn Bryan
 Manager Laboratory
 Business Systems and
 Client Services
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Testing sent to Alternate Performing Laboratories.

All performing laboratories are not created equal, nor are all tests. While we currently perform over 97% of our testing volume here at the University of Vermont Medical Center, we are not able to offer every test in-house. We understand that clinical needs change all the time. We would like to offer the expertise of our laboratory professionals and our pathologists to help your patients get the best test performed at an accredited facility.

Our primary reference laboratory at the University of Vermont Medical Center is Mayo Medical Laboratories in Rochester, MN. Through our partnership with Mayo, we have access to some of the highest quality specialized laboratory testing and technical support 24 / 7 / 365. Turnaround times benefit from an electronic interface for orders and results that allows patient results to appear in PRISM automatically. We have preferential pricing and primary client status for all of the hospitals in Vermont, Cottage Hospital in New Hampshire and for our Health Network Partners and Canton Potsdam in upstate NY.

Of course, even Mayo doesn't offer every test, and on occasion may not offer the best test for your application. Some tests are proprietary or are offered at a particular laboratory through a contractual arrangement with a pharmaceutical company. If that's the case we would like to help you make sure the lab is appropriately accredited (as required by regulation) and that we have copies of their accreditations on file. We'd like to help you choose the best test, and to be able to negotiate pricing, if we can. We'd also like to make sure that we are informed about the testing requirements, pre-analytic processing and the lab's shipping requirements so that we can prevent patients having to wait or come back.

If you have questions about testing please send us an email at LabCustomerService@uvmhealth.org Or you may call Laboratory Customer Service at 802 847 5121, or 800 991 2799.

Kathleen Nadeau
 Laboratory
 Compliance Analyst
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COMPLIANCE UPDATES

DID YOU KNOW?

These items are available to you on our lab website under [Laboratory Compliance Info](#):

- Instructions for when and how to fill out an ABN form along with the UVMHC policy "ABN and Other Notices of Patient Financial Responsibility" policy
- Forms for Patient Financial Responsibility policy
- Quick Reference for Preventive Screening tests
- Links to all of the NCDs and LCDs
- Other helpful brochures from Medicare

<https://www.uvmhealth.org/MedCenterLabCompliance>

ABN and other Notices of Patient Financial Responsibility

Molecular Pathology tests (CPT codes 81161 - 81479) are subject to a Medicare Local Coverage Determination (LCD) Policy. ABNs are required when a test is not expected to be covered by Medicare. **Medicare does not offer prior authorization!**

For example, **Factor V Leiden and Prothrombin Coagulation factor II are never covered** by Medicare and therefore an [ABN form](#) must be **obtained prior to** the collection of the specimen.

If you are unsure whether a test is covered by Medicare, please contact Laboratory Compliance staff (847-0930) or Laboratory Customer Service (847-5121).

Most commercial payers require **prior authorization** for all molecular pathology tests as well. Notice of patient financial responsibility forms for [commercial](#), [Tricare](#) and [Medicaid](#) can be found on our [Laboratory website](#). These are to be used when prior authorization is denied by these insurers.



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TEST UPDATES

Change in Lead Reporting Ranges

In order to follow current recommendations on reporting of Lead levels, on December 14th the following changes will be made to the Chemistry Laboratory reporting values for lead testing:

A critical value of 45 ug/dL will be used for all samples.

The reference range for adult samples will be changed to 0-4 ug/dL.

The methodology used for the assay will be stated on the laboratory report - "Testing performed using Graphite Furnace Atomic Absorption Spectroscopy."

If you have any questions concerning this change, please contact Dr. Greg Sharp (gregory.sharp@uvmhealth.org) in the Chemistry Laboratory.

TEST CATALOG

To view a complete listing of tests available at the University of Vermont Medical Center, please visit UVMHealth.org/MedCenterTests

Browse by Name



Search



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Methodology Change for Mitochondrial and Smooth Muscle Antibodies and Discontinuation of Testing Parietal Cell Antibodies at UVMHC

Antibodies to smooth muscle, mitochondria, and gastric parietal cells have classically been detected by indirect immunofluorescence (IFA) on a tissue preparation containing tissues with reactivity for all 3 types of antibodies. Although the technique has been used for many years, it is highly subjective, dependent on observer skills and the technical performance of the assay. As technology has evolved, it has been recognized that IFA detects a significant number of mitochondrial antibodies in addition to the type associated with Primary Biliary Cirrhosis (PBC) which has been determined to be M2. It has also been shown that it is anti-actin antibodies that have specificity for autoimmune liver disease and are a better marker for autoimmune hepatitis than those of tissue based anti-smooth muscle assays. For these reasons the Immunology Laboratory will change from a tissue based IFA (NOVA Lite ANA Plus [Mouse Kidney & Stomach, Inova Diagnostics, San Diego, CA]) to an ELISA based assay for mitochondrial antibodies (QUANTA Lite M2 EP (MIT3) ELISA – Inova Diagnostics, San Diego, CA) and smooth muscle antibodies (QUANTA Lite Actin IgG ELISA– Inova Diagnostics, San Diego, CA). The mitochondrial ELISA assay contains the 3 immunodominant epitopes of PDC-E2, BCOADC-E2 and OGDC-E2 and has been shown to have enhanced performance over IFA or conventional PDC-E2 based ELISA tests and detects anti-mitochondrial antibodies (AMA) in over two-thirds of the sera from “AMA-negative” (by IFA) PBC patients. In addition, it has been shown that anti-actin antibodies were present in 73 of 99 (74%) patients with type 1 autoimmune hepatitis and in 0 of 83 healthy blood donors and in 3-15% of patients with other types of chronic hepatitis. From this same study it was determined that nearly all (99%) of actin positive patients were also smooth muscle antibody positive while 46% of the actin negative group had smooth muscle reactivity. Anti-actin positive patients are more prone to be unresponsive to corticosteroid therapy (16% vs. 4%) and were more prone to suffer liver failure (20% vs. 4%). Since these assays will no longer be performed using a tissue substrate that is also used for parietal cell antibodies and due to the low volume of this test, parietal cell antibody testing will be discontinued at UVMHC and sent to Mayo Medical Laboratories.

On Friday, January 27, 2017, the following test codes will be inactivated: MIT - Mitochondrial Ab, MITT - Mitochondrial Titer, SMO - Smooth Muscle Ab, SMOT - Smooth Muscle Titer, PRT - Parietal Cell Antibody, and PRTT - Parietal Cell Titer. In addition, the following new codes will be available: MIT2G - Mitochondrial IgG ab and ACTING - Actin IgG Ab ELISA. Testing for the new codes will begin Monday, January 30, 2017.

If you have any questions or concerns regarding this change, please contact Dr. Gregory Sharp (Gregory.sharp@uvmhealth.org) in the Immunology Laboratory or contact the Immunology Laboratory directly at (802) 847-7638.

REFERENCES:

1. QUANTA Lite Actin IgG ELISA Package Insert, Inova Diagnostics, San Diego, CA., February 2015,
2. QUANTA Lite M2 EP (MIT3) ELISA Package Insert, Inova Diagnostics, San Diego, CA., February 2015

Continued on page 5

SAMPLE INFORMATION

ACTIN IGG ANTIBODY, ELISA	
Test Code	ACTING Click test code to view test catalog information.
CPT	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method: 83516
Price	Please contact Laboratory Customer Service for pricing information
Division	Immunology
Method	Enzyme-Linked Immunosorbent Assay (ELISA)
Sample Requirements	Collect 4.0 mL SST and submit 1.0 mL serum, minimum volume 0.4 mL
Sample Note	Store samples at room temperature no longer than 8 hours. Refrigerate the serum for up to 48 hours at 2-8C. After 48 hours or for shipment serum must be frozen at -20C or lower.
Reference Range	<20 Units Interpretation: Negative: <20 Units Weak Positive: 20 - 30 Units Moderate to Strong Positive: >30 Units
Test Schedule / Analytical Time / Test Priority	Tuesday and Thursday / Same day / Not available STAT
Instrumentation:	Dynex DSX
NYS Certified	Yes
Effective Date	Friday January 27, 2017

MITOCHONDRIAL IGG ANTIBODY	
Test Code	MIT2G Click test code to view test catalog information.
CPT	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method: 83516
Price	Please contact Laboratory Customer Service for pricing information
Division	Immunology
Method	Enzyme-Linked Immunosorbent Assay (ELISA)
Sample Requirements	Collect 4.0 mL SST and submit 1.0 mL serum, minimum volume 0.4 mL
Sample Note	Store samples at room temperature no longer than 8 hours. Refrigerate the serum for up to 48 hours at 2-8C. After 48 hours or for shipment serum must be frozen at -20C or lower.
Reference Range	<=20 Units Interpretation: Negative: <=20 Units Equivocal: 20.1 – 24.9 Units Positive: >=25 Units
Test Schedule / Analytical Time / Test Priority	Tuesday and Thursday / Same day / Not available STAT
Instrumentation:	Dynex DSX
NYS Certified	Yes
Effective Date	Friday January 27, 2017

Confirmation Testing - Drugs of Abuse

In September of this year Mayo Medical Laboratories closed their facility in Andover MA. There is a high volume of toxicology testing in New England and unfortunately, although the other laboratories are staffing up their own programs there is a temporary shortage of labs and staff performing toxicology. This has resulted in extended turnaround times at Burlington Labs, Mayo Medical Laboratory in Rochester, MN and at Dominion Diagnostics and until they can hire and train new staff.

Turn around times for the following tests are currently 7 - 10 days.

VMETH - METHADONE CONFIRMATION TEST

VCOCN - COCAINE METABOLITE CONFIRMATION PANEL

VTHC - MARIJUANA (THC) CONFIRMATION PANEL

VAMPH - AMPHETAMINES CONFIRMATION, URINE

VOPIUR - OPIATE CONFIRMATION, URINE

VBENZ - BENZODIAZEPINES CONFIRMATION PANEL

VFENTC - FENTANYL CONFIRMATION PANEL

Discontinuation of Paper “Copy to” Reports for PRISM Users

In compliance with the initiative to reduce the use of paper and ensure documentation in the PRISM EMR the laboratory will cease the distribution of paper “copy to” reports to University of Vermont Medical Center providers effective 12/19/2016. This will apply to both Anatomic and Clinical Pathology reports. This information will be available in the patients’ medical record. We believe this is a good step forward in eliminating redundant workflows. If you have any questions, please feel free to contact Lynn Bryan (847-9540).

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 for patient service center hours and special test considerations.

All UVM Medical Center phlebotomists are nationally certified

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)

Urine Microscopic Exam Change to Reflex Criteria

Microscopic urinalysis reflex testing after dipstick results that are positive for heme, leukocyte esterase, nitrite or protein is quite common in American hospital laboratories. The value of this analysis is not clear, nor is there good evidence that physicians need or use these “unsolicited” results. Traditional urine microscopic analysis is time consuming and very labor intensive: Minimizing microscopic analysis that does not add actionable clinical information would be very desirable.

A paper in the American Journal of Clinical Pathology has looked at this issue⁽¹⁾. At their institution, they shifted to a system in which microscopic urine examination was only performed on physician request. They justified this change based on the fact that reflex on the nitrite or urine leukocyte esterase tests did not change clinical decisions and that, in general, the strip analysis was better than traditional microscopy in excluding a urinary tract infection. Similarly, routine microscopy does not add information to the hemoglobin test.

They did point out that for patients with proteinuria, the gold standard for pathologic casts is the microscopic urinalysis of fresh urine by an experienced technologist or nephrologist. It is our feeling that with fewer “routine” microscopic analyses the laboratory could concentrate on those cases where close examination was beneficial on patients with protein of 2+ or greater.

We therefore changed our reflex criteria from > trace leukocyte esterase, positive nitrite, and/or > 1+ protein to only include >1+ protein. This change took place on **November 15, 2016**. There will be no change in the reflex criteria for culture where a urine with reflex to culture is requested.

Reference:

1. Cessation of Dipstick Urinalysis Reflex Testing and Physician Ordering Behavior, American Journal of Clinical Pathology, 2012:137:486-489.

Reducing Substances - Urine and Stool Discontinued

In recent years the availability of Clinitest tablets, used for testing for reducing substances in urine and stool (PRISM Code: LAB19 and Order Code: STLPHR), and Ictotest tablets, used for testing abnormally colored urines for bilirubin, has been extremely reduced such that a reliable supply is not available. There is no alternative readily available testing system. Therefore tests for urine and stool reducing substances and the alternative test for bilirubin in urine was discontinued on November 15, 2016. Alternative tests are available from Mayo Medical Laboratories, Test 9255: Carbohydrate, Urine and Test UREDF: [Reducing Substances, Feces](#) but there will be a significant increase in turnaround time. There is no replacement for the alternative urine bilirubin testing, but this was used very rarely and not directly orderable.

[Stool pH](#) will still be available in our Chemistry Laboratory with the same ordering information (Test code: STLPH, PRISM Code: LAB3649).

If you have any questions concerning this change, please contact Dr. Greg Sharp (gregory.sharp@uvmhealth.org) in the Chemistry Laboratory.



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Anti Nuclear Antibody: New Test Code

The Antinuclear Antibody order code: ANA will be replaced with a new order code: ANAIFA. The new test code which consists of a battery of tests will result in a change in how results are reported.

Currently a positive ANA will reflex an ANA Titer (ANAT). The new battery consists of four tests: the ANAIF, which is the overall ANA interpretation and three separate tests available for up to three patterns reported at different titers if needed. Currently ANA titers are reported as dils which will now be reported as titer. Negative ANA's are currently reported as "<40 dils", but with the new test code will be reported as "Negative. No titer performed, ANA screen is negative."

This change took place on Friday 11/04/2016. There is no change in methodology, sample requirements, or sample stability and this is only a change in reporting (Refer to the Laboratory Services Directory for current information). Positive ANAIFA will still result in a reflex titer being performed at an additional charge. See a sample of current and new sample reports below.

CURRENT REPORTING		NEW REPORTING	
Test Code: ANA	PRISM Code: LAB148	Test Code: <u>ANCAIF</u>	PRISM Code: LAB148
Negative			
Anti Nuclear Ab <40	[0-40] Dils	Anti Nuclear Ab, IFA ANA Interpretation Negative [NEGAT] Performed, ANA screen is negative.	
Positive (Simple Scenario)			
Anti Nuclear Ab	Positive at 40 dils, titer to follow. [0-40] Dils	Anti Nuclear Ab, IFA ANA Interpretation A Positive [NEGAT] ANA Titer Pattern 1:80 Speckled	
ANA Titer H 80	[0-40] Dils Speckled pattern		
Positive (Complex Scenario)			
Anti Nuclear Ab	Positive at 40 Dils, titer to follow. [0-40] Dils	Anti Nuclear Ab, IFA ANA Interpretation A Positive [NEGAT] For titers greater than or equal to 1:160 (except the centromere and nucleolar patterns) it is recommended that specific, follow-up autoantibody testing (such as for dsDNA and Extractable Nuclear Antigens) be performed on all diffuse and/or speckled patterns. ANA Titer Pattern 1:80 Diffuse, Speckled and Nucleolar ANA Titer Pattern 2 1:320 Diffuse and Nucleolar ANA Titer Pattern 3 1:640 Nucleolar	
ANA Titer H 640	[0-40] Dils		
Nucleolar pattern	Diffuse pattern seen at 320 Dils Speckled pattern seen at 80 Dils		

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

ANCAIF replaces ANCA test code

The Anti-Neutrophil Cytoplasmic Antibody order code ANCA will be replaced with a new code ANCAIF. This change was necessitated by the implementation of a new interface that will streamline how this test is resulted in the laboratory and eliminate the inherent error in manual entry. The new test code which consists of a battery of tests will result in a change in how results are reported.

Currently a positive ANCA will reflex an ANCA Titer (ANCAIT). The new battery consist of three tests: the ANCAI, which is the overall ANCA interpretation and two separate tests available for up to two patterns reported at different titers if needed. Currently ANCA titers are reported as dils which will now be reported as titer. Negative ANCA's are currently reported as "<20 dils", but with the new test code will be reported as "Negative. No titer performed, ANCA screen is negative".

This change took place on Friday, 11/04/2016. There is no change in methodology, sample requirements, or sample stability and this is only a change in reporting (Refer to the Laboratory Services Directory for current information). Positive ANCAIF will still result in a reflex titer being performed at an additional charge. In addition, all Perinuclear Patterns (P-ANCA) and Cytoplasmic Patterns (C-ANCA) will reflex both a Myeloperoxidase Antibody test (Order code: MYL) and a Proteinase 3 Antibody test (Order code: PR3AB) sent to Mayo Medical Laboratories. See a sample of current and new sample reporting below.

CURRENT REPORTING	NEW REPORTING
<p>ANCA <20 [<20] Dils ANA Positive. Suggest follow-up ANA testing if clinically indicated. Cannot rule out Atypical ANCA (A-ANCA).</p>	<p>ANCA, IFA ANCA Interpretation Negative [NEGAT] (404) ANA Positive, suggest follow-up ANA testing if clinically indicated. Cannot rule out Atypical ANCA (A-ANCA). No titer performed, ANCA screen is negative.</p>
<p>ANCA Positive at 20 Dils, titer to follow [<20] Dils</p>	<p>ANCA, IFA ANCA Interpretation A Positive [NEGAT] ANCA Titer Pattern 1:640 Perinuclear Pattern</p>

CA 125 Assay: New Baselines

The Chemistry Laboratory will change the instrumentation used for the CA 125 assay from the Ortho Vitros 3600 (Ortho Clinical Diagnostics, Raritan, NJ) to the Siemens Healthcare (Malvern, PA) Advia Centaur. Both of these platforms are used widely to perform this assay as indicated by the numbers represented in the College of American Pathologists Proficiency Testing Program and both instruments also utilize chemiluminescent immunoassays. Both our comparison studies and those of the literature show that both Instruments show acceptable performance characteristics and compare well.¹ However, the literature reports that for a very few patients, substantial differences exist between methods, necessitating parallel testing.¹

In order to support this new baseline, the laboratory began performing the Advia Centaur assay on November 4, 2016 and will continue performing the old assay until the end of December 2016. During that time, any patient who has had a CA 125 previously performed on the Ortho Vitros 3600 will have an assay performed on the Vitros as well as the Centaur. New patients will only have an assay performed on the Centaur. It is important that if a patient is being monitored for CA 125 that at least one specimen be submitted during this time interval.

There is a slight change in the reference range from the manufacturer from less than 35 U/mL (Ortho) to less than 30 U/mL (Centaur). If you have any questions concerning this change please contact Dr. Greg Sharp in the Chemistry laboratory. (gregory.sharp@UVMHealth.org).

Reference

1. Performance Characteristics of Seven Automated CA 125 Assays, Moniga, S.K. et al. American Journal of Clinical Pathology 2006; 125:921-927.

Total CO2 Reference Range Change

On October 18, 2016, the Chemistry Laboratory changed the lower normal limit for CO2. This change is part of an overall review of the current reference ranges. The new range is a better reflection of current technology and the UVMHC population.

Old range: 24 – 32 mEq/L

New range: 22 – 32 mEq/L

Please contact Dr. Greg Sharp (gregory.sharp@uvmhealth.org) if you have any questions concerning this change.

Calculated Calcium Formula Change

Calcium can bind to serum proteins but it is the unbound calcium that is thought to be physiologically active. Various formulas have been used to attempt to account for the measured total calcium and the amount of protein, predominantly albumin, present in the blood. The formula that has been used at UVMHC for many years has been:

$$\text{calculated calcium} = \text{measured total calcium} + (4.4 - \text{albumin})$$

Given that the average albumin measured in UVMHC is closer to 4.0 than 4.4 this formula tends to show an increase in calculated calcium for most patients that may not necessarily reflect their physiological calcium status. Recently, when a change in lot number for albumin and calcium reagents tended to decrease the albumin and increase the measured total calcium it became apparent that this formula resulted in a significant increase in patients having calculated calcium levels outside of the normal range that did not have hypercalcemia.

Therefore, in order to better reflect the average albumin and somewhat buffer the effect of this correction, a **new formula**, will be used:

$$\text{Calculated calcium} = \text{measured total calcium} + (4.0 - \text{albumin}) * 0.8$$

As can be seen, this will result in a significant change in calculated calcium levels, but is a better “correction” than the previous formula. This change took place on October 5, 2016. A comment: “change in formula for calculated calcium on October 5” will be added to each result for 6 months. Ordering and resulting codes will not be changed.

If you have any questions concerning this change please contact Dr. Greg Sharp (gregory.sharp@uvmhealth.org) in the Chemistry Laboratory.

Tumor Marker Results Cessation of Reporting of Historical Data

Quite a few years ago, when EHR, EMR, and CPOE were unfamiliar acronyms and laboratory results were primarily reported on paper, the Laboratory began manually adding historical results to tumor marker reports to facilitate interpretation. Although this step was time consuming and allowed the possibility of manual entry error, it was felt that this was worthwhile to enable easier review of results. Fast forward to the present and paper reports are by and large no longer printed and electronic health records are ubiquitous. In this setting, it no longer seems worthwhile with the potential for error to continue to enter historical results for CEA, PSA, and CA125 on the current tumor marker reports. We therefore discontinued this practice on September 14, 2016.

(Continued from page 10)

However, recognizing that there is a need for a common record for patients seen at UVM Medical Center, but with laboratory results drawn and reported to outside hospitals, there will be the ability, on request, to have these entered into the UVM Medical Center PRISM record. If you have any questions concerning this change please contact Dr. Greg Sharp (gregory.sharp@uvmhealth.org) in the Chemistry Laboratory.



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Sample Collection for CD57 for Lyme Disease no longer Available via UVM Medical Center

While it has been reported that a decrease in numbers of CD57+ natural killer (NK) cells may be associated with chronic Lyme disease⁽¹⁾, a more recent study has failed to confirm such an association⁽²⁾. CD57 expression is not consistent across all NK-cells, and the standard approach for quantifying NK-cells involves staining for a combination of positivity for CD16 and/or CD56 together with negativity for CD3. The Centers for Disease Control and Prevention (CDC) lists quantitative CD57 lymphocyte assays as an example of an “unvalidated test” on its list of “laboratory tests that are not recommended” for the diagnosis of Lyme disease⁽³⁾.

CDC recommends a two-step testing process for establishing a serologic diagnosis of Lyme disease. If the first test (an FDA-licensed antibody screening test) is positive or equivocal, then the second test (a Western blot) is performed⁽⁴⁾.

The University of Vermont (UVM) Medical Center follows CDC’s recommended approach⁽⁵⁾. While the UVM Medical Center Laboratory has never performed CD57 testing for Lyme disease, patients sometimes present to our phlebotomy sites with requests to have a blood sample drawn for such testing.

Because of the lack of clinical evidence to support CD57 testing for Lyme disease, the UVM Medical Center will no longer collect or process blood samples for such testing.

If you have any questions concerning this change, please contact Dr. Michael Lewis (Michael.Lewis@UVMHealth.org) in the Laboratory.

REFERENCES

1. Stricker RB, Winger EE. Decreased CD57 lymphocyte subset in patients with chronic Lyme disease. *Immunol Lett* 2001;76:43-48.
2. Marques A, Brown MR, Fleisher TA. Natural killer cell counts are not different between patients with post-Lyme disease syndrome and controls. *Clin Vaccine Immunol* 2009;16:1249-1250.
3. Centers for Disease Control and Prevention (CDC). Lyme disease: Laboratory tests that are not recommended. <http://www.cdc.gov/lyme/diagnosistesting/labtest/otherlab/index.html>. Accessed 17 Feb 2016.
4. Centers for Disease Control and Prevention (CDC). Lyme disease: Two-step laboratory testing process. <http://www.cdc.gov/lyme/diagnosistesting/labtest/twostep/index.html>. Accessed 17 Feb 2016.
5. Department of Pathology and Laboratory Medicine, University of Vermont Medical Center. Test catalog – Lyme antibody. <http://uvmhlab.testcatalog.org/show/LYMAB>. Accessed 17 Feb 2016.



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POSTAGE
HERE

PATHOLOGY & LABORATORY MEDICINE COMMUNIQUÉ — JANUARY, 2017

PATHOLOGY & LABORATORY MEDICINE COMMUNIQUÉ

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(800) 991-2799

FAX LABORATORY CUSTOMER SERVICE

(802) 847-5905

WEBSITE

UVMLabs.TestCatalog.org/

PATIENT INSTRUCTION BROCHURES

We have several brochures for patients that need to collect samples at home. The following are available online by visiting UVMHealth.org/MedCenterLabServices or you can contact Lab Customer Service to receive some via mail.

- [Feces Sample Collection](#)
- [Fecal Occult Blood Collection](#)
- [Sputum Sample Collection](#)
- [Urine Sample Collection](#)

VT DEPARTMENT OF HEALTH CLINICAL LABORATORY SPECIMEN COLLECTION for ZIKA VIRUS

Specimen submission must be pre-approved by Infectious Disease Epidemiology
24/7 Phone Number: (802) 863-7240

Testing Process:

1. Identify patient who needs testing
2. Collect the required information
3. Call Infectious Disease Epidemiology at the VT Department of Health for specimen submission approval at their 24/7 phone number (802) 863-7240
4. Collect the appropriate specimens
5. Fill out the VT Department of Health Laboratory (VDHL) [Clinical Test Request Form](#) Micro 220 to submit with the specimen

1. Patient who meets criteria for testing

- Any symptomatic* person with travel to an [area with active Zika transmission](#) within previous **2 weeks** of symptom onset, **OR**
- Any symptomatic* person who had unprotected sexual exposure to a person** who had previously traveled to an [area with active Zika transmission](#), **OR**
- A pregnant woman WITH or WITHOUT symptoms* who had a history of travel to an [area with active Zika transmission](#) within the previous **12 weeks**, **OR**
- A pregnant woman WITH or WITHOUT symptoms* who had unprotected sexual exposure to a person** within the previous **12 weeks**, who had previously traveled to an [area with active Zika transmission](#)

**Symptoms consistent with Zika virus include acute febrile illness, rash, arthralgia, conjunctivitis, myalgia or headache*

***Person does NOT need to be a confirmed Zika virus case*

NOTE: Current CDC research suggests that Guillain-Barre Syndrome (GBS) is strongly associated with Zika; however, only a small proportion of people with recent Zika virus infection get GBS. If you have a patient with a GBS diagnosis and a recent travel history to an [area with active Zika transmission](#), call the VT Department of Health at (802) 863-7240 for further guidance on specimen collection for Zika lab testing.

Testing will **not** be approved for asymptomatic men, children or women considering pregnancy. The [current CDC recommendation](#) is for women to wait 8 weeks after return from travel to attempt conception.

Men should wait at least 6 months after symptoms start, or last possible exposure, before attempting to impregnate a woman. Men should use condoms or not have sex for at least 6 months after travel to area with active transmission (if asymptomatic) **or** for at least 6 months from the start of symptoms (or Zika diagnosis).

2. Required Information

- Patient's name
- Patient's demographic information
- If pregnant, estimated delivery date or date of LMP
- Symptom onset dates
- Patient's DOB
- Pertinent travel history (locations and dates)
- Clinical symptoms, if symptomatic
- Specimens collected and dates of collection

3. Call Infectious Disease Epidemiology at the VT Department of Health: (802) 863-7240

4. Collect the appropriate specimens

Person to be tested	Number of days between symptom onset and specimen collection	Type of test	What to collect
Symptomatic, non-pregnant	<14 days	rRT-PCR assay *	1-2 mL of urine AND 1 mL of serum AND 1 mL of whole blood in EDTA lavender-top tube
	≥14 days to 12 weeks	Zika IgM MAC ELISA	1 mL of serum
Pregnant and symptomatic	< 14 days	rRT-PCR assay *	1-2 mL of urine AND 1 mL of serum AND 1 mL of whole blood in EDTA lavender-top tube
	≥14 days to 12 weeks	Zika IgM MAC ELISA	1 mL of serum
	>12 weeks after return from travel or exposure	Not available	Testing currently not available
Pregnant and asymptomatic	Specimen collected <14 days after return from travel or exposure	rRT-PCR assay**	1-2 mL of urine AND 1 mL of serum AND 1 mL of whole blood in EDTA lavender-top tube
	2 – 12 weeks after return from travel or exposure	Zika IgM MAC ELISA	1 mL of serum
	>12 weeks after return from travel or exposure	Not available	Testing currently not available

* The rRT-PCR assay tests for Dengue, Chikungunya, and Zika. If negative for all three viruses, the Zika IgM MAC ELISA will be performed

** If negative, the health care provider should request collection of a follow-up serum specimen 2-12 weeks following exposure or return from travel. Follow up specimen will be tested by Zika IgM MAC ELISA.

Specimen collection and storage instructions

- Serum needs to be collected in serum separator tube and centrifuged prior to shipment. Urine needs to be in a sterile screw top tube. Collect whole blood in a filled EDTA lavender-top tube.
- Ship specimens cold (2–6°C) or frozen (-70°C) by courier to VDHL.

5. Complete the Vermont Department of Health Laboratory Micro 220 [Clinical Test Request Form](#)

Under the Virology section on page 2, beside “Other”, write in “Zika”. Testing is performed at no charge.

Send to: Vermont Department of Health Laboratory
 359 South Park Drive
 Colchester, VT 05446
 (800) 660-9997 or (802) 338-4724
 (802) 338-4706 (FAX)

Blue Cross Blue Shield of Vermont CPT changes effective 01-01-2017

NEW PRIOR APPROVAL

The following codes require prior approval by BCBSVT beginning with services provided on January 1, 2017:

81401: TPMT Genotype, Blood.

Other genetic Molecular pathology procedure, Level 2 tests may also use the same CPT code.

81403: HEA Panel

JAK2 EXON Mutation Detection (blood)

MPL Exon 10 Mutation Detection (Reflex Only)

RAS/RAF Targeted Gene Panel (Tumor), MOPATH Level 4 only

Other genetic Molecular pathology procedure, Level 4 tests may also use the same CPT code.

81413: Cardiac ion channelopathies; genomic sequence analysis panel

81414: Cardiac ion channelopathies; duplication/deletion gene analysis panel

81439: Inherited cardiomyopathy genomic sequence analysis panel

REMOVED PRIOR APPROVAL

The following revised 2017 CPT/HCPCS will no longer require prior approval, or for New England Health Plan members a referral authorization, beginning with services provided on January 1, 2017:

81267: Chimerism analysis, post transplantation specimen

81238: Chimerism analysis, post transplantation specimen with cell selection

Please call Lab Customer Service for clarification on any molecular CPT codes: 802-847-5121

PATHOLOGY & LABORATORY MEDICINE

111 Colchester Avenue | Mail Stop: 233MP1
Burlington, Vermont 05401

PHONE LABORATORY CUSTOMER SERVICE

(802) 847-5121 | (800) 991-2799

WEBSITE

www.UVMhealth.org/MedCenterLabCompliance

Urine Total Protein Method Change



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On December 22st 2016, The University of Vermont Medical Center changed the method used for quantitative urine total protein from the colorimetric slide assay designed for exclusive use with the Vitros 5600 (Ortho Clinical Diagnostics, Raritan, NJ) to a third party micro urine protein reagent from Sekisui Diagnostics. The clinical analyzer used to perform testing will remain unchanged. This change is taking place due to a bias identified by Ortho Clinical Diagnostic affecting all current inventory of their testing product.

The University of Vermont Medical Center temporarily suspended performing quantitative urine total protein testing on site to comply with manufacturer recommendations. Validation of the new methodology began shortly after the onsite suspension of testing to ensure timely results to our clients.

CLINICAL APPLICATION:

The filtration and resorption of plasma proteins in the formation of urine are important functions of the intact, healthy kidney. The presence of protein in the urine is useful in the evaluation of renal disorders. The degree of proteinuria varies with the type and severity of the disease and measuring the amount of protein excreted aids in the diagnosis and directs therapy. The presence of elevated concentrations of protein in urine (proteinuria) is a key finding in primary renal disease of glomerular, tubular, or mixed origin. Proteinuria is also seen in patients with systemic disorders that affect the kidneys such as diabetes mellitus, hypertension, vascular disease, neoplasia, drug toxicity, and certain infectious diseases. Proteinuria may also exist as either a benign or transient condition.

METHOD:

Pyrogallol red is combined with molybdenum acid. At a low pH, the dye is red, the color changes to blue under test conditions when complexed with proteins. The increase in absorbance at 600nm due to the formation of the colored complex is directly proportional to the concentration of protein in the reaction.

LIMITATIONS:

Urine samples should not be collected after intense physical exertion, fluid load or fluid deprivation.

Collect specimens prior to the administration of contrast media. Some of these media may cause significant bias.

Hemoglobin is a protein and its presence in urine results in an increase in measured protein.

Urine Total Protein, Random and 24 Hour	
Test Code	UTPR- Random, UTP24- 24 Hour Collection
PRISM Code	
CPT	84156
Price:	Please contact Laboratory Customer Service for pricing information
Division:	Chemistry 1
Method	Pyrogallol Red
Sample Requirements	Random or 24-hour samples are acceptable. Submit 5 mL aliquot from a 24-hour urine collection. Record the total volume on the lab requisition if 24-hour collected. For those accounts unable to measure volume, submit 24-hour jug.
Reference Range:	No Reference Range for Random Samples
Days Performed/Analytical Time/Test Priority	Daily 8 am-4:30 pm / Same day / Available STAT
Instrumentation:	Ortho Vitros
NYS Certified:	Yes

FOR MORE INFORMATION

Contact Laboratory Customer Service

PATHOLOGY & LABORATORY MEDICINE

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PHONE LABORATORY CUSTOMER SERVICE

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WEBSITE

www.UVMhealth.org/MedCenterLabs

