

Pathology & Laboratory Medicine Communiqué

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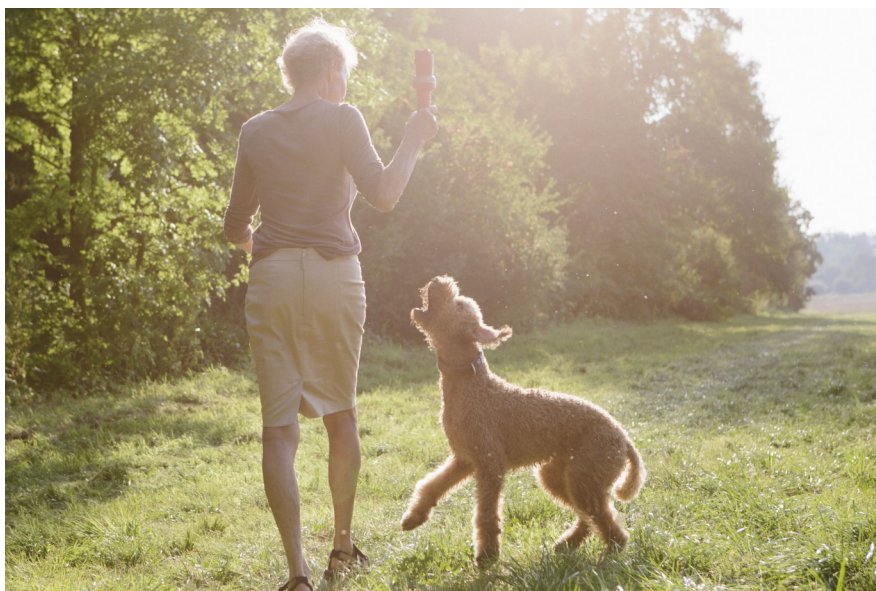
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LAB OPERATIONS



Holiday Hours for Blood Draw Lab Sites

In observance of Labor Day, our Blood Draw Lab Sites will be closed on Monday, September 7, 2020

Specimen Collection

Special Test Considerations

Some lab tests have special test considerations associated with them. These can include timed collections, the need for scheduling in advance, or must be collected at a specific Blood Draw Lab Site. When a patient arrives at a site that cannot draw the ordered test due to a special consideration, they must be turned away. Please refer to this list when advising patients as to the how and when to have their specimen collected.

<https://www.uvmhealth.org/medcenter/Documents/Departments-and-Programs/Blood%20Testing%20Lab/Special%20Test%20Considerations.pdf>

Discontinue use of Jug E for 24 hour Urine Collections

Chemistry determined that the 24 hour Urine Collection Jug E (includes 20 mL 6N HCL) is no longer required for any testing performed at UVMHC or forwarded to Mayo Medical Laboratories. For this reason, Jug E has been discontinued.

Covid-19 Testing: A Quick Guide

COVID-19 PCR Based Tests (Polymerase Chain Reaction):

The most widely available and sensitive COVID-19 testing is based on detecting viral genetic material (RNA), often from a nasal or nasopharyngeal swab. The testing requires specialized equipment, but the results are very sensitive and has a low rate for false positives and false negatives. Therefore, these assays are currently used at UVMHC and at our reference laboratories.

See this link from the Association of Public Health Laboratories for more information about Laboratory Testing:

<https://www.aphl.org/programs/preparedness/Crisis-Management/COVID-19-Response/Pages/Lab-resources.aspx>

COVID-19 Antigen Tests:

There have been a lot of questions recently about the availability of COVID-19 antigen tests. These are tests that detect viral proteins from nasal or nasopharyngeal swabs. They are relatively fast and inexpensive, but they have a high rate of both false positives and false negatives. Therefore, these assays will not be pursued currently at UVMHC.

See this link from the Association of Public Health Laboratories for more information about Laboratory Testing:

<https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf>

COVID-19 Serology Tests:

Serologic testing, which requires a blood collection specimen, has limited utility in clinical medicine. Serology testing, particularly in a region like Northern New England where the COVID-19 prevalence is low, is prone to false positive results. The UVMHC laboratory will refer this testing to our reference laboratory for patients that meet clinical criteria for testing.

See this link from the UVMHC Laboratory Test Update

<https://www.uvmhealth.org/medcenter/Documents/Departments-and-Programs/Pathology%20Test%20Updates/COVID%2019%20Serology.pdf>

GET TEST RESULTS ONLINE!

MyChart

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

To sign up visit: MyChart.UVMHealth.org

Compliance Updates

MVP and Cigna Denials

We have noticed a **significant increase** in the number of **claim denials for Vitamin D testing and Thyroid testing**. In order to reduce the number of interruptions to your offices from our staff, please review the information below.

Per MVP policy:

Vitamin D will only be reimbursed when there is a known diagnosis or condition associated with Vitamin D deficiency. **Screening for Vitamin D is NOT considered reimbursable.**

Thyroid testing- MVP has adopted the Medicare National Coverage Determination (NCD 190.22) to determine medical necessity for this testing. Thyroid testing will not be covered unless it meets the criteria outlined in the policy. Here is the link to the policy: <https://www.uvmhealth.org/medcenter/Documents/Departments-and-Programs/Compliance%20Updated/Thyroid%20NCD.pdf>

Per Cigna policy:

Vitamin D is considered medically necessary for (non-pregnant individual age 18-64 years) for any of the following:

- Condition or medical diagnosis associated with Vitamin D Deficiency
- Previously documented Vitamin D deficiency
- Known or suspected excessive Vitamin D blood levels (i.e. toxicity)

Vitamin D will NOT be reimbursed when ordered for screening purposes only.

For a list of medically necessary diagnosis codes, refer to pages 11-13 of 19 of the Cigna Vitamin D policy found on Cigna's website, www.cigna.com.

Thyroid studies are covered when used to report preventive care screenings and interventions when billed with a designated wellness diagnosis code. For a list of wellness diagnosis codes, refer to Code Group 1 Interventions on pages 24 & 25 of 27 in the Cigna Preventive Care Services policy located on Cigna's website, www.cigna.com.

For further assistance, please email LabBilling@uvmhealth.org.

Coding tips for Tick bite testing for Lyme Disease:

ICD 10 code W57.XXXA or W57.XXXD can never be used alone.

- If the patient presents with signs or symptoms, you must include those codes.
- In the absence of signs/symptoms, you must code to the body part that was bitten if known.

Epic Users: In the Epic order "Assoc Encounter Diagnosis" Field, type in "insect bite" **and** the body part (i.e. Insect bite thigh) then select the correct laterality. **Please indicate encounter: "A" for initial or "D" for subsequent, follow-up.** For example:

S70.361 – Insect bite (nonvenomous), *right* thigh (S70.361A or S70.361D)

S70.362 – Insect bite (nonvenomous), *left* thigh (S70.362A or S70.362D)

S70.369 – Insect bite (nonvenomous), *unspecified* thigh (T14.8XXA or T14.8XXD)

- If the body part is unknown, use T14.8- Other injury of unspecified body region.

Annual PAP Notice



Scott Anderson MD
Medical Director
Cytopathology Lab
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Accredited laboratories are required to remind providers at least annually of the screening nature of the Pap Test. The Department of Cytopathology of The University of Vermont Medical Center has elected to send an advisory in the form of this single communication, rather than an educational note appended to every negative Pap report emanating from the laboratory. As such, we would like to remind you that:

The Pap Test is a screening test with an inherent but low false negative rate. Regardless of the result, patients should consult you immediately if they have any suspicious signs or symptoms.

Screening Guidelines and HPV Testing

HR HPV Testing

We have modified our high risk HPV reflex algorithm to better align with the ASCCP guidelines (<http://www/asccp.org>).

For Pap tests ordered with HR HPV Testing per guidelines the reflex criteria are based on patient age and Pap result:

- Patient Age <21: No HPV Testing
- Patient Age 21-29: Pap ASCUS □ HR HPV Testing
- Patient Age > 30: Pap NIL or ASCUS □ HR HPV Testing

If HPV genotyping is ordered, it will be performed if:

- Patient Age is 30 – 64, Pap is NIL and HR HPV Testing is Positive.

There are other indications for HPV testing that are not covered by these reflex criteria. To add on an HPV order, please fax the request to 802-847-3632. These requests will be reviewed using the ASCCP guidelines for appropriateness.

If the sample source is Vaginal and HPV testing is ordered, the sample will be sent to Mayo Medical Laboratory, as UVMC has not validated HPV testing on this specimen type.

If the sample source is Anus, HPV testing will not be performed in accordance with the FDA.

Required Identifiers and History

- Two patient identifiers are required on all Pap Test sample vials (patient name, and date of birth or medical record number).
- All pertinent clinical information needs to be included on the Pap Test requisition (LMP, menstrual status, hormone use, contraceptive use and any abnormal gynecologic and/or treatment history, particularly if this occurred at another medical center).

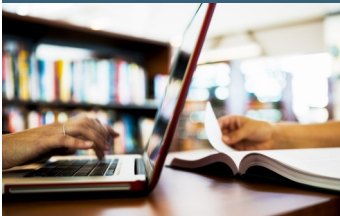
Collection Devices

- Whether the Pap Test sample is collected with a Broom Device or a Cytobrush/Plastic Spatula combination, the collection device is always discarded after rinsing in the PreservCyt Solution Vial.

COVID Tests: CPT Codes and Diagnosis Codes:

COVID Test	CPT Code (effective 4/15/2020)
COVID-19 Mayo	U0003
COVID-19 Broad Inst.	U0003
COVID-19 UVMMC Molecular LDT	U0002
COVID-19 UVMMC Panther	U0003
COVID-19 UVMMC GeneXpert	U0003

Situation	Description	Primary ICD-10	Secondary ICD-10 Examples
Positive COVID	Confirmed diagnosis of the 2019 novel coronavirus disease (COVID-19) as documented by the provider, a positive COVID-19 test result or a presumptive positive COVID-19 test result. Confirmation does not require documentation of the type of test performed. Additionally report any contributory conditions as secondary Dx.	U07.1 , Dx of coronavirus as documented by provider and/or + COVID-19 test	J12.89 Other viral pneumonia, J20.8 Acute bronchitis due to other specific organism J40 Bronchitis not specified as acute or chronic J22 Unspecified acute lower respiratory infection J98.8 Other specified respiratory disorders J80 Acute respiratory distress syndrome
Suspected COVID	If the provider documents "suspected," "possible," "probable" or "inconclusive" COVID-19. Assign a code(s) based on signs and symptoms and/or Z20.828 (Contact with and (suspected) exposure to other viral communicable diseases)	Signs and symptoms and/or Z20.828 for asympt. pts with exposure	
Screening for COVID	For asymptomatic individuals who are screened for COVID-19 and have no known exposure to the virus, and the test results are either unknown or negative, use the code encounter for screening for other viral diseases.	Z11.59	
Fetal exposure	When a newborn is born to a mother who is COVID positive but the baby's status is unknown, report code P00.2 , Newborn affected by maternal infectious and parasitic diseases. If during the hospital stay, the baby is tested and COVID infection is ruled out, report Z05.1 , Observation and evaluation of newborn for suspected infectious condition ruled out. If the baby is positive for COVID, report P00.2 and U07.1 to indicate the infection in the newborn.	P00.2 or Z05.1 or P00.2 & U07.1	
Exposure to COVID	If there is a concern about a possible exposure to COVID-19, but this is ruled out after evaluation, assign code Z03.818 , (encounter for observation for suspected exposure to other biological agents ruled out). Do not report Z03.818 if patient has other signs/symptoms. When there is an exposure to someone who is confirmed or suspected (not ruled out) to have COVID-19 and the exposed individual either tests negative or the test results are unknown, assign code Z20.828 .	Z03.818 or Z20.828 .	

LAB AMBASSADOR

Do you have a technical or operations question for the lab?
Contact LabAmbassador@UVMHealth.org for assistance!



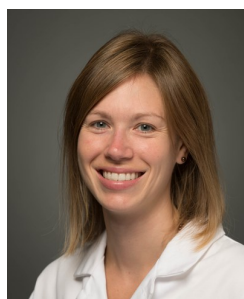
Katherine Devitt, MD
Medical Director
Flow Cytometry Lab
(802) 847-8372

Discontinuation of Flow Cytometry on BAL Samples

Effective 7/24/20, the UVMHC laboratory will no longer accept BAL (Bronchoalveolar lavage) specimens for flow cytometry due to COVID-19 safety concerns. The following tests will be affected:

<u>Test Name</u>	<u>Epic Code</u>	<u>MayoAccess ID</u>	<u>Change</u>
BAL T-Cell Subsets (CD4/CD8 Ratio BAL)	LAB3100	N/A	Inactivated
Leukemia/Lymphoma Panel by Flow Cytometry	LAB9911	FAH013	BAL samples removed as an acceptable specimen type

Please contact Dr. Katherine Devitt at Katherine.devitt@uvmhealth.org with questions or concerns about this change



Christina Wojewoda, MD
Medical Director
Microbiology Lab
(802) 847-5140

UVMHC MRSA PCR and GBS PCR Test Changes

The manufacturer of our PCR assays for MRSA and Group B Streptococcus has shifted resources to focus on COVID19 testing and we are now experiencing some shortages in product availability for both MRSA PCR and Group B PCR testing. There may be occasions when a MRSA PCR (LAB1368) test order or a Group B PCR (LAB2540) test order will need to be changed to a culture. When necessary, the UVMHC Microbiology Lab will cancel and credit the PCR order and order a bacterial culture. There will be an increase in turn-around time of up to 48-72 hours when this occurs.

For interfaced clients who order either of these PCR tests, if the order is changed to a culture, the culture result will be faxed to your location.

Please contact the UVMHC Microbiology Laboratory at (802) 847-2339 for questions.

Testing Schedule Change for HPV Genotype 16 and 18/45, ThinPrep Assay

Effective immediately, UVMHC will be changing the testing schedule for its HPV Genotype 16 and 18/45, ThinPrep Assay (LAB3272):

Current Schedule

Daily, Monday – Friday

Updated Schedule

Weekly, Thursday

This schedule change is due to a testing ancillary supply issue that is affecting many labs throughout the country during this pandemic.

Please contact the UVMHC Microbiology Laboratory at (802) 847-2339 for questions.



Andrew Goodwin, MD
Division Chief
Clinical Pathology
Phone: 847-2377

Thrombosis Panel Update

The UVMHC Thrombosis and Hemostasis Laboratory offers a Thrombosis Panel. This panel of testing is recommended when evaluating a patient with a history of thrombosis or hypercoagulability.

Appropriate timing is critical to obtain useful diagnostic information. Results are best interpreted in a medially stable patient, not having an acute thrombosis and not currently receiving anticoagulation medication therapy, including heparins, direct oral anticoagulants (aka. DOAC; e.g. direct thrombin inhibitors and direct Xa inhibitors), oral vitamin K inhibitor (e.g. warfarin), fibrinolytic agents (e.g. streptokinase, tissue plasminogen activator) or platelet GPIIb/IIIa inhibitors.

For additional information about the impact of anticoagulant medications on thrombophilia testing, please contact the laboratory or refer to the reference¹ below.

Thrombosis Panel includes:

Performed at UVMHC

- Prothrombin time
- Partial Thromboplastin time with PTT 50/50 mix, if indicated
- Factor VIII Activity (clot-based)
- D-Dimer
- Anti-Thrombin 3, Functional (chromogenic)
- Protein C, Functional (clot-based)*
- Protein S, Functional (clot-based)*
- Lupus Anticoagulant Cascade*
 - ◊ Silica clot time
 - ◊ Dilute Russell viper venom time

Performed at Mayo Clinic Laboratory

- Activated Protein C Resistance V, Plasma
- Phospholipid (Cardiolipin) Antibodies, IgG and IgM, Serum
- Beta-2 Glycoprotein 1 Antibodies, IgG and IgM, Serum

*Positive results are subject to reflex testing

Additional information regarding the Thrombosis Panel is available using the UVMHC Laboratory Services Directory.²

Proper specimen collection is critical to ensure accurate results.³

References:

1. Goodwin A and Adcock D. Thrombophilia Testing and Venous Thrombosis. N Engl J Med. 2017 Dec 7;377 (23):2297-8.
2. Profile Thrombosis available at <https://uvmlabs.testcatalog.org/show/TP1>
3. Coagulation Specimen Handling and Processing available at: <https://d2xk4h2me8pjt2.cloudfront.net/webjc/attachments/172/5fe9702-coag-handle-processing.pdf>

**Clayton Wilburn , MD**

Medical Director
Clinical Chemistry
(802) 847-9657

Stability Updates for Chemistry Testing

Effective June 1, 2020, the UVMMC Chemistry Laboratory updated the defined sample stability time for a multitude of tests. This was done as part of further optimization of the EPIC Beaker platform. The goal is to ensure that when you see a sample in EPIC to which you want to place an add-on order, that sample will be available for testing. In general, the stability time of serum and plasma tests has been set at 7 days and EDTA whole blood at 3 days, unless the nature of the test and/or analyte causes it to be shorter. Urine stabilities have been set at 5 days, unless the nature of the test and/or analyte causes it to be shorter (i.e. urinalysis and culture is stable for 24 hours). Below is a chart detailing the stability times that have been updated.

Test Name	Epic Code(s)	Old Stability	New Stability	Legacy Code(s)
Acetaminophen	LAB43	14 Days	7 Days	ACE
Calcium	LAB53	22 Days	7 Days	CA
Calcium, Urine (Random, 24 hr)	LAB371, LAB814	35 Days	5 Days	UCAR, UCA24
Chloride	LAB59	28 Days	7 Days	CL
Chloride, Urine	LAB374	7 Days	5 Days	UCLR
Creatinine	LAB66	30 Days	7 Days	CREAT
Cyclosporine	LAB874	7 days	3 Days	CYCLO
Ethanol, Blood	LAB46	14 Days	7 Days	ETOH
Gentamicin (Random, Peak, Trough)	LAB27, LAB28, LAB26	7 Days	3 Days	GENTA, GENTP, GENTT
Haptoglobin	LAB89	8 Days	7 Days	HAPTS
Hemoglobin A1C	LAB90	7 days	3 Days	HA1C
Hepatitis B Antigen	LAB471	14 days	7 days	HBSAG
Immunoglobulin G	LAB71	8 days	7 days	IGGS
Immunoglobulin M	LAB72	14 days	7 days	IGMS
K (Potassium)	LAB114	42 Days	7 Days	K
Lactic Acid	LAB729	14 Days	7 Days	LACTIC
Lead	LAB98	14 days	7 days	LEAD
Lipase	LAB99	21 Days	7 Days	LIPA
Magnesium, Urine (Random, 24 hr)	LAB405, LAB406	7 Days	5 Days	UMAGR, UMAG24
Measles	LAB657	9 days	7 days	MEASL
Methotrexate	LAB2561	14 Days	7 Days	MTXT
Phenobarbital	LAB30	8 days	7 days	PHNOB2
Potassium, Urine (Random, 24 hr)	LAB434, LAB436	7 Days	5 Days	UKR, UK24
Prealbumin	LAB115	6 months	7 days	PALBS
Rheumatoid Factor	LAB206	3 Days	5 Days	RFS
Sirolimus	LAB875	7 days	3 Days	SIRO
Sodium, Urine (Random, 24 hr)	LAB444, LAB446	7 Days	5 Days	UNAR, UNA24
SPEP	LAB119	5 days	7 days	SERPEP
SPEP w/ Immunotyping	LAB174	5 days	7 days	SPEPIT
Tacrolimus	LAB876	7 days	3 Days	FK506
Tobramycin (Random, Peak, Trough)	LAB37, LAB36, LAB38	7 Days	3 Days	TOBRA, TOBRP, TOBRT
Total Protein, CSF	LAB195	3 Days	7 Days	CTP
Valproic Acid	LAB25	14 Days	3 Days	VALP



Clayton Wilburn , MD
Medical Director
Clinical Chemistry
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Cardiolipin Ab Change

On July 22, 2020, the UVMHC immunology laboratory will no longer be offering in-house testing for Anticardiolipin IgG and IgM Antibodies, currently offered as Cardiolipin Antibody Panel, IgG and IgM (Epic code LAB464). This testing will be sent to Mayo Medical Laboratories as Test ID CLPMG Phospholipid (Cardiolipin) Antibodies, IgG and IgM, Serum. This change is due to the decreasing volume of anticardiolipin testing received by UVMHC.

If you have any questions or concerns please reach out to the Clinical Chemistry medical director (Clayton.wilburn@uvmhealth.org)

Ordering and use of COVID-19 Serology Testing

Name in EPIC: SARS Coronavirus 2 IgG Ab, Serum (COVID-19 Ab)

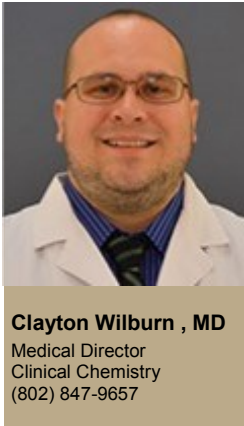
Live Date: Tuesday May 26, 2020

Limitations: Requires Pathology Approval

Recognizing that there are a small number of specific clinical applications for this test (see below) and to alleviate any confusion between serology and the diagnostic PCR test, UVMHC will send IgG serology testing out to our reference lab partner Mayo Clinical Labs but only after pathology approval for the testing. Contact Lab Customer Service at 802- 847-5121 to be connected with a pathologist. Placing the Epic order “Pathology Approval for Covid IGG AB UVMHC only” triggers a pathologist to contact the ordering provider to discuss the patient’s specific clinical situation.

Guiding Principles on Use of COVID-19 Serology:

1. Antibody testing is useful for:
 - a. Understanding how many people COVID-19 has infected (i.e., epidemiology studies, not a clinical application)
 - b. Identifying children presenting with Pediatric Multi-System Inflammatory Syndrome associated with COVID- 19 MIS-C.
 - c. Assessing COVID-19 convalescent plasma donors.
2. Antibody testing should not be used to acutely diagnose COVID-19 infection.
3. Antibody testing results should not be used to determine a person’s COVID-19 immunity status, “return-to-work” decisions, use of masks or other personal protective equipment (PPE), or safety of vulnerable persons to go into public more.
4. A positive antibody test only tells you that an individual has been infected with COVID-19 in the past.
5. Antibody testing results should be interpreted in terms of positive predicted value (PPV), being mindful of the prevalence of COVID-19 in your particular community and the false positive (FP) rate of any given test.



Clayton Wilburn, MD
Medical Director
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Ordering and use of COVID-19 Serology Testing (Contd.)

Supporting Information and Rationale:

There has been much discussion in the media and lay press on the use of serology (antibody) testing in combating the COVID-19 pandemic. Some of this information has been misleading and promises unrealistic expectations on how the testing can be used to “re-open” the economy and identify a person’s COVID-19 immunity status. This letter is to provide you with realistic expectations on the use and limitations of COVID-19 serology testing in our community.

Depending on the type of serologic test, the assay may detect IgM antibodies, IgG antibodies, or both. In general, IgM antibodies are less specific, leading to higher rates of cross-reactivity and false positives. Therefore, IgG should be the primary antibody measured for COVID-19 serology. The sensitivity of the serology assays is dependent on the length of time that has elapsed since symptom development. In patients who have only had symptoms for less than 5 days, sensitivity can range between 0-25%. Sensitivity improves the longer it has been since symptom onset, with 92-100% sensitivity observed in patients tested after 14 days.

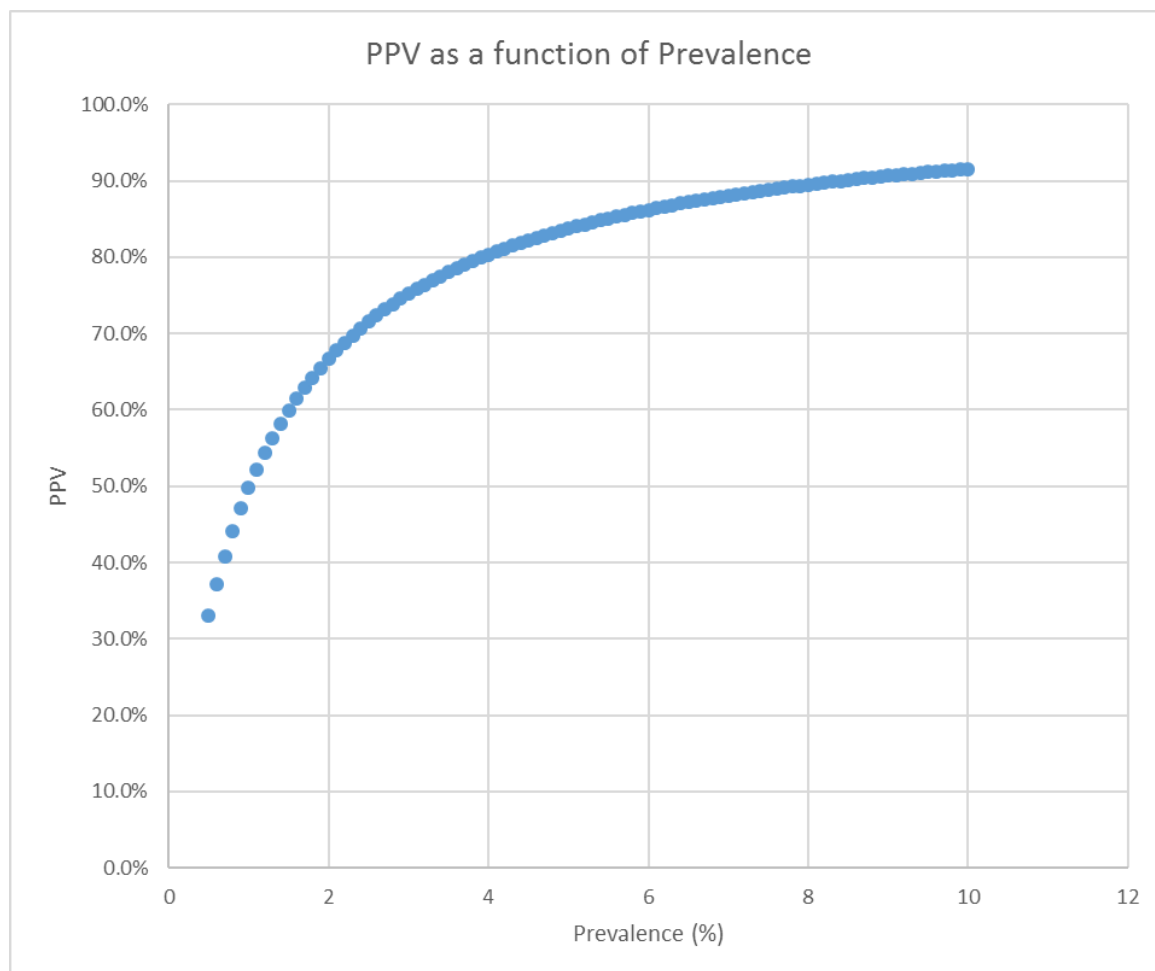
There is a general expectation that a positive antibody test to COVID-19 would suggest some immunity to future infection by the virus. Unfortunately, it is too early in our knowledge of COVID-19 to know if antibodies are protective, how long they last, or how they may impact an individual’s ability to infect others. Early data suggests that the development and the effectiveness of these antibodies may depend on an individual’s age, overall health, and the severity of his/her COVID-19 related illness. In general, those of older age and greater severity of COVID-19 illness are more likely to have developed antibodies in response to COVID-19 infection.

Another factor that complicates using COVID-19 serology, and any laboratory test for that matter, is the risk of a false negative or false positive result. The positive predictive value (PPV), or likelihood that the positive test result is correct (a “true positive”), is driven by the disease prevalence in combination with the test specificity, or rate of false positive results ($FP = 1 - \text{specificity}$). For COVID-19, the assumed prevalence in Northern NY and most of VT is around 1%. The FP rate with even the “best” COVID-19 serology test is 1%. To calculate PPV you divide the prevalence by prevalence plus the FP rate. So a patient who lives in Northern NY or most areas of VT, has a 50/50 chance (coin flip) their positive result is actually a true positive. If the prevalence of COVID-19 is less than 1%, such as in the Northeast Kingdom of VT, or in the case of a “worse” serology test with a higher FP rate, the PPV can decrease to 17% (rolling a 1 on 6-sided dice) or less. Below is a graph of PPV as a function of prevalence for a test with 98% sensitivity and 99% specificity.

**Clayton Wilburn , MD**

Medical Director
Clinical Chemistry
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Ordering and use of COVID-19 Serology Testing (Contd.)



Lead, Blood—Reporting Change

On May 13, 2020 the UVMHC laboratory began reporting blood lead testing results to the tenths instead of whole numbers. This reflects the accuracy and precision of our atomic absorption method. The ordering codes and process remain the same.

<u>Test Name</u>	<u>Epic Order Code</u>
------------------	------------------------

Lead, Blood	LAB98
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If you have any questions concerning this change, please contact Dr. Clayton Wilburn (clayton.wilburn@uvmhealth.org) in the UVMHC laboratory.



Clayton Wilburn , MD
Medical Director
Chemistry
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Tick-Borne Illness Update

With tick season upon us, testing for tick-borne illnesses is increasing. Clinical suspicion of tick-borne disease should be based on patient characteristics including illness during tick season with symptoms such as fever, chills, headache, muscle aches, joint pain, neck pain, skin rash, Bell's palsy, heart rhythm disturbances, hypotension, jaundice, sepsis, and possible tick exposure. If these criteria are met there is risk for Lyme disease, anaplasmosis, and babesiosis. Endemic areas for Lyme disease, anaplasmosis, and babesiosis include the Northeastern and Upper Midwestern United States, into Canada.

If the patient presents with a classic erythema migrans “bullseye” rash, no testing is necessary. Treatment for Lyme can be initiated while monitoring for symptoms of additional tick-borne illness. If there is no rash and clinical suspicion is high testing may be appropriate and should include a Lyme serology test, which reflexes to western blot if serology testing is positive or equivocal. Lyme serology can be insensitive in the first few weeks of infection, so repeat testing might be warranted. If there is concern for Babesia, a blood parasite exam should be ordered to look for the presence of Babesia in the red blood cells. If there is concern for Anaplasma, the best test is a PCR.

THE APPROPRIATE TESTING FOR EACH DISEASE IS:

Lyme disease (*Borrelia burgdorferi*): Lyme Antibody (Lab test code: LYMAB, EPIC test code: LAB3035)

Babesiosis: Parasite Exam, Blood (Lab test code: BPEX, EPIC test code: LAB2545).

Anaplasma: Ehrlichia/Anaplasma, Molecular Detection, PCR, Blood (Lab test code: EHRPCR, EPIC test code: LAB3614).

SEND OUT ORDERS TO MAYO ARE DISCOURAGED FOR THE FOLLOWING TESTS:

Lyme Disease, Molecular Detection, PCR

Lyme Disease, Molecular Detection, PCR, Blood

Babesia microti IgG Antibodies, Serum

Babesia species, Molecular Detection, PCR, Blood (except for kidney donors)

Tick-Borne Panel, Molecular Detection, PCR, Blood

Tick-Borne Disease Antibodies Panel, Serum.

Please let us know if you have any questions, 847-5121.



Clayton Wilburn, MD
Medical Director
Chemistry
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Lyme Ab Assay Upgrade

On 5-20-2020, the UVMMC clinical laboratory began upgrading to the next generation of Lyme Antibody assay on our DiaSorin Liaison XL immunoassay platform. The test name, reporting, reference range, and ordering process will remain the same. Correlation studies between the new and current generation assays are excellent.

<u>Test Name</u>	<u>Epic Order Code</u>
------------------	------------------------

Lyme Ab	LAB3035
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Also, a reminder on the Lyme testing algorithm, per CDC guidelines, which UVMMC follows, suspected Lyme should be evaluated with the Lyme Antibody screen first. Confirmation testing via immunoblot will only be performed on positive Lyme Antibody screens.

Reporting Change for HIV RNA Quantitation and HCV RNA Quantitation

On March 11, 2020, the Chemistry laboratory will revise the result reporting structure of the HIV 1 RNA Quantitation (LAB2678, HIVQU) and HCV RNA Quantitation (LAB2472, HCVQU) tests. This is to correct an issue with how results for both of these tests were structured to release with the upgrade to EPIC Beaker. In current state the result is listed as a single component with a quantitative value for the number of copies or IU per mL that were detected. For results where RNA from the virus was below the detectable limit, Beaker filed a result of 0 copies/IU per mL.

However this is not technically correct as these assays have a lower limit of detection of 20 copies/mL and 15 IU/mL for HIV and HCV RNA, respectively.

To correct this issue, we have redesigned both tests to have two components each, a qualitative component that states that either the viral RNA is detected or undetected and a quantitative component that will give the measured viral copies/IU per mL for samples that have a detected qualitative result. For tests with a qualitative result of undetected, the quantitative result will be suppressed.

Rheumatoid Factor Platform and Reference Range Change

On February 11, 2020 due to reagent supply access the Chemistry Laboratory switched Rheumatoid Factor testing from our Binding Site Optilite platform to Ortho Vitros 5600 automated line. The test name and ordering process will remain the same. The Vitros assay has a new, but similar reference range to the one currently in use. **The current reference range for RF is <12.5 IU/mL and the new range is <12.0 IU/mL.** This updated reference range has been verified by the lab in internal studies.



Andrew Goodwin, MD
Division Chief
Clinical Pathology
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Transgender Reference Interval Policy Update

The department of Pathology and Laboratory Medicine strives to provide high-quality, reliable results to aid in accurate diagnosis and proper patient management. When reviewing laboratory results, a reference interval (RI) is provided to provide context for laboratory results. Our laboratory follows both regulatory standards in accordance with CLIA and best practice guidelines provided by CLSI. Each analyte RI is locally validated at the UVMMC laboratory, and when required, we validate analyte reference ranges partitioned based on certain patient populations/characteristics including gender, age, ethnicity, pregnancy, for example. The laboratory clearly understands that relevant RI's can impact patient safety, and that all analytes should have a relevant RI's provided with each analyte results.

Our laboratory is committed to fostering an inclusive, supportive, and diverse community, and we recognize the need to provide the same high-quality and reliable results to all our patients. As the laboratory designs and implements the Beaker/Epic LIS, we are working to develop the best approach in when reporting RI's for our transgender patients. Validating RI in the transgender population presents a challenge, and according to published literature:

“Reference intervals from a cohort of healthy transgender individuals have not been established [5]. Laboratory regulatory guidelines stress that reference intervals should be appropriate for the population being tested, particularly if there are known physiological differences relevant to the population. At present, no reference intervals are available to guide the interpretation of laboratory results for transgender people. This is, unfortunately, not surprising since transgender patients have historically been disenfranchised from the health-care system [1]. ”

Current literature suggest current best practice for laboratory RI include the following:

Recommended laboratory best practices for transgender care.

- Create a document that details your institution's protocol for identifying transgender patients. This document should specifically highlight the several systems that indicate sex assignments, examples of which include intake forms and IT interfaces (LIS and HIS)
- Do not cancel laboratory tests based on assumed sex specificity (e.g., hCG, PSA)
- Ensure proper flagging of tumor and pregnancy related markers are implemented without sex specificity
- Provide diversity training to the phlebotomy team and ensure gender incongruence is a component
- Recognize that reference intervals for transgender patients have not been established and therefore hormone status and clinical judgment must be used to assess abnormal laboratory values

Epic informed our laboratory the following information will be collected during patient registration:

Sex at Birth

Legal Sex

Preferred Gender

When all 3 of these values are concordant, sex-specific RI will be applied. If any of the 3 values is discordant, the “undetermined” RI will apply.

Transgender RI Policy Update

Our laboratory identified 3 potential reporting solutions for those analytes which are partitioned based on gender (sex):

1. Provide both female and male RI for those analytes with separate male and female RI's
2. Create a new Epic alert symbol for those analyte results in a potential transgender patient
3. Do not report a RI and instead provide a result comment indicating a RI is not established in the transgender patient population

Given the current restrictions with Beaker LIS, options #1 and #2 are not possible. Option #3 is a patient safety concern as all the results alert notifications (i.e. Flags) are disabled when a RI is not defined in the LIS; there is significant risk that the result comment indicating a RI is not established may be overlooked.

We further discussed solutions, and proposed that the “undetermined” RI will be established in the following manner:

1. All analytes partitioned by patient sex are reviewed by pathology
2. Pathologists will extrapolate the overlap of the male and female RI
3. This overlap will serve as the “undetermined” RI
4. Any values outside the “undetermined” RI will flag and attach the following comment:

“Reference intervals for transgender patients have not been established and therefore hormone status and clinical judgment must be used to assess laboratory values”

In conclusion, the UVMMC Laboratory will follow our current state, which means ALL reference ranges will be based on patients' LEGAL gender, regardless if there is any mismatch between, sex at birth, legal gender, and preferred gender.

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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

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