University of Vermont

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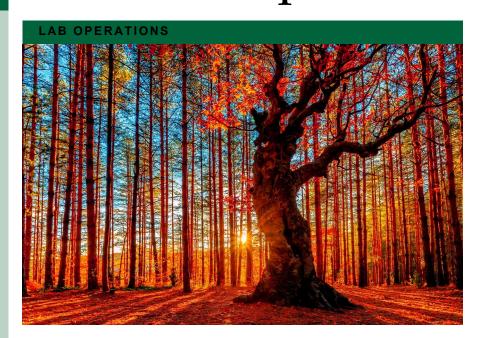
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Pathology & Laboratory Medicine

Communiqué



Holiday Hours for Blood Draw Lab Sites

All locations will be closed on Thanksgiving Day, Christmas Day and New Year's Day.

	Christmas Eve - Friday	New Year's Eve - Friday
Location	12/24/2021	12/31/2021
Main Campus		
ACC Burlington	7:00 AM – 3:00 PM	7:00 AM – 3:00 PM
Fanny Allen Campus		
MOB Colchester	6:30 AM – 3:00 PM	6:30 AM – 3:00 PM
UHC Campus		
1 South Prospect Burlington	Closed	Closed

New Test Updates

Discontinuation of Cytogenetics on Kidney Tumors



Agnes Balla MD Assistant Professor Dept of Pathology and Laboratory Medicine (802) 847-4290

Effective 10/8/21, UVMMC discontinued reflex cytogenetics testing on all kidney tumors. After looking at the data over many years, there were only extremely rare cases in which diagnoses changed based on findings of cytogenetics and clinical impact was minimal to none. Although cytogenetics has the ability to detect Xp11 translocation RCC's, which may be difficult to morphologically identify, this is a rare occurrence and that is assuming the tissue grows in the media. Furthermore, we have immunohistochemical stains that we can perform as screening for this entity and our reference laboratory (Mayo) does FISH testing off cell blocks if this entity or other rare kidney tumor types need to be excluded. The cost of continuing testing has very minimal if any patient benefit and the costs incurred to the laboratory (monetary and labor) outweigh the benefit of continuing this practice.

Please reach out to Agnes Balla, MD, Assistant Professor Department of Pathology and Laboratory Medicine, at Agnes.balla@uvmhealth.org with any questions or concerns.

H. Pylori Stool Antigen Testing



Clayton Wilburn, MD Medical Director Clinical Chemistry Phone: 847-9657

On 10/18/2021, the UVMMC Immunology lab changed the days testing is performed for samples submitted for H. pylori stool antigen testing from Tuesday and Thursday of each week to Monday and Wednesday of each week. All else surrounding the ordering and resulting of the test will remain the same.

If you have any questions or concerns please reach out to the medical director of immunology (clayton.wilburn@uvmhealth.org)

UVMMC COVID RESULTS

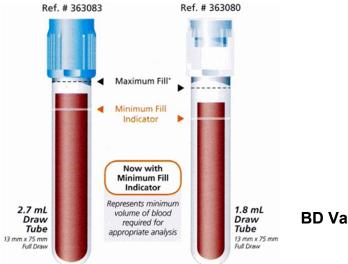
Effective 9/23/2021, the lab at UVMMC began offering Covid-19 test results in a printable format from our My Chart application. These print outs are suitable for travel and back to school or work needs.

In addition, Lab Customer Service (802 847 5121) will be able to provide Covid-19 results, via fax, to adult patients directly (we have no facility to deliver results via secure email). For reasons of patient privacy, the results can only be provided to 1) The patient themselves and 2) The ordering provider.

Temporary Replacement of 2.0mL Blue Top Tubes for 3.5mL

The blue top sodium citrate tubes we use for coagulation testing are on backorder across the US. Traditionally we have used two sizes of blue top tubes in our organization, a 2 mL tube and a 3.5 mL tube. Our supply of 2mL tubes is quite low, therefore a decision has been made to **prioritize their use for pediatric patients**. All other users are being asked to order the 3.5 mL size. (3.2% SODIUM CITRATE 3.5ML LIGHT BLU). Lab supply staff will substitute the larger sized tubes for all non-pediatric or family medicine locations ordering the 2.0mL tubes.

UVMMC Materials Management staff have been working very hard to locate alternatives and we will shortly have 2.7 mL BD tubes on order as a back up to our current 2.0 mL. Please be aware of the following change to the look of the tubes and the that the "fill to" marking on the side of the tube is different than our current tubes.



BD Vacutainer fill guide

The minimum fill marking on the BD tube is clear/etched, not a black triangle.

On the 2.7mL size the maximum is indicated at the bottom of the cap.

As with our current tubes these will automatically fill appropriately due to the vacuum as long as the tube is not opened.

Change to Courtesy Draws for Dialysis Patients

OUTPATIENT DIALYSIS LOCATIONS CONVERTING TO EPIC EMR

On Thursday April 1st 2021 all of the local and remote UVMMC outpatient dialysis locations will convert their existing EMR over to EPIC, which is the enterprise wide software system being used by both UVMMC and our network affiliates

ORDERING COURTESY LABS ON DIALYSIS PATIENTS

We recognize that a great many dialysis patients have co-morbidities and are cared for by both UVMMC clinics and community based private practices in both primary and specialty care. It has long been our practice to offer to collect other lab tests that these patients may need as a convenience to both the patients and their healthcare providers at the time of their dialysis visits. We call these "Courtesy Labs".

Going forward the process for ordering courtesy labs will change. All "courtesy lab" orders will be transcribed into EPIC with a Dialysis Phase of Care. This will allow us to centralize the orders and make sure that they are easily identifiable by the dialysis technicians and nurses collecting blood and urine samples during a patient's dialysis procedure.

- Please call the dialysis location that your patient will have lab testing collected at to notify them of the request for a
 courtesy draw at least 2 days ahead of their scheduled dialysis appointment. (A list of dialysis locations and contact
 information is included below.
- Please fax all requests for "courtesy labs" to Lab Customer Service (802 847 5905) using the attached fax cover sheet.
- Please include either your own lab requisition or one of ours and mark the order to indicate that these are "Dialysis Phase of Care Courtesy Labs"
- The order must include all of the elements required by regulation
 - ♦ First and Last Name and Middle Initial
 - O Date of Birth
 - ♦ Ordering provider First and Last Name with Middle Initial
 - ♦ Insurance information for the subscriber
 - ♦ Testing required

Thank you so much for your assistance in making this transition as smooth as possible.

Change to Courtesy Draws for Dialysis Patients

Contact information for UVMMC dialysis locations.

	CLINICS, LOCATIONS AND CONTACT INFORMATION						
Site Name	Street Address	Address 2	City	State	Zip Code	Phone	
Newport Dialysis	189 Prouty Drive		Newport	VT	05855	(802) 334-2711	
St. Albans Dialysis	8 Crest Road	Doctors Office Commons	St. Albans	VT	05478	(802) 847-5002	
Rutland Dialysis	160 Allen Street	Third Floor Dialysis	Rutland	VT	05701	(802) 747-6239	
Berlin Dialysis (CVMC)	130 Fisher Road		Barre	VT	05602	(802) 225-7033	
Chittenden Dialysis	35 Joy Drive		South Burlington	VT	05403	(802) 847-3030	
Home Dialysis	35 Joy Drive		South Burlington	VT	05403	(802) 847-2130	

Scheduled Phlebotomy Visits at the Medical Office Building

Last Summer (2020) the University of Vermont Medical Center launched appointment scheduling for blood draws at the Fanny Allen Campus lab in Colchester. This change has been very well received by the vast majority of patients. Recently, we have seen an uptick in the number of patients who are arriving at the Phlebotomy site unaware that they need an appointment. We do our best to accommodate walk-ins between scheduled appointments, though, there are times when we are busy that this may mean a longer wait for patients without an appointment.

We would be grateful if you can remind all patients who would like to get their labs drawn on the Fanny Allen Campus to call (802) 847- 8864 to schedule an appointment.

Our labs at the Main Campus and 1 South Prospect Street in Burlington will remain walk-in sites.

A flyer with details that can be hung in your office is below. Up to date information on lab locations and hours can also be found online at UVMHealth.org/MedCenterDrawSites

If you have any questions please contact Lab Customer Service by calling (802) 847-5121

Scheduled Phlebotomy Visits at the Medical Office Building

The University of Vermont Medical Center is now offering appointments for blood draws at our Colchester location. As always, walk-ins are welcome at our draw sites in Burlington and Williston.

BY APPOINTMENT

Colchester: Fanny Allen Campus

792 College Parkway, Medical Office Building, Suite 104

Monday-Friday, 6:30 am to 6 pm

Collection Stations: 4

Call (802) 847-8864 to schedule

WALK-IN SITES:

Burlington: Main Campus Burlington: 1 South Prospect Street

111 Colchester Avenue, Main Pavillion, Level 2 1st Floor Lobby

Monday—Friday, 7 am to 6 pm Monday—Friday, 7 am to 4 pm

Saturday and Sunday, 7 am to 1 pm Collection Stations: 4

Collection Stations: 6

Lab Customer Service Hours

Due to continued staffing shortages in Lab Customer Service we will be changing hours beginning today, Monday, September 13th. Lab Customer Service staff will be available during the core hours of:

Monday - Friday 6 am - 7 pm Saturday & Sunday 7 am - 3:30pm

Outside of those hours, the LCS phone line (802 847 5121) will roll over to be answered by lab testing staff, who will be able to respond to emergent request ONLY, and will ask that you call back in the morning for any other issue.

Sorry for the inconvenience while we recruit and retrain additional staff.

Ordering Lab Supplies

Providing supplies to facilitate the collection and transport of lab specimens is one of the services that we offer as a community hospital lab. The normal turnaround time for supply delivery is 48 hours. This allows our inventory control staff the time to review and package supply orders on a daily basis. Each morning orders received the previous day are reviewed, and our staff requisition the items requested and packaging them up for the routine courier delivery.

This system helps to keep costs down and provides an operational routine for our staff to work around. Recently, we have been receiving numerous "STAT" supply orders. Not only does this disrupt the normal operations in the supply room, but incurs increased courier costs for the urgent delivery.

The expectation is that your office or clinic will keep track of your own inventory levels and re-order supplies on a routine basis, with the understanding that supplies will be delivered 2 working days after the order is received. We understand that there are occasional patient care situations that demand a faster delivery for an emergent supply need and we are prepared to fulfill those, but would appreciate your help in holding these to a minimum by ordering supplies on a routine basis.

LABORATORY PATIENT SERVICE CENTER



Main Campus
Main Pavilion, Level 2
111 Colchester Avenue
Burlington, VT

Fanny Allen Campus 792 College Parkway Colchester, VT One South Prospect 1 South Prospect St First Floor Lobby Burlington, VT

Visit UVMHealth.org/MedCenterDrawSites for patient service center hours and special test considerations.

All UVM Medical Center phlebotomists are nationally certified

LABORATORY & PATHOLOGY MEDICINE COMMUNIQUÉ — FALL 2021 Compliance Updates

Secure Additional Diagnosis Information

Providers: Each test ordered requires a covering diagnosis. Without that it is likely that insurance claims will be denied and incur additional out of pocket cost to patients. To prevent that, we have a billing process that detects potential omission of a covering diagnosis and generates a call to your office before a claim is dropped to insurance. We accept both valid ICD-10 codes or narrative for transcription. Inclusion of covering diagnosis codes with the original order will prevent the additional follow-up calls.

How to Prevent Follow-up Calls from Laboratory Billing and Compliance

1. NT-BNP

Edema is not a covering diagnosis per Medicare policy.

2. Vitamin D & Vitamin B12

Fatigue, weakness, depression and nutritional screening are never covered per Medicare and MVP policies.

3. A1C

Medicare will <u>not</u> cover a "screening" test for diabetes even though USPSTF recommendations say it is covered with Z13.1, Z68.30 and Z68.45.

NOTE: Per Medicare policy Z13.1 only covers Glucose test screening, not a Hemoglobin A1C.

4. Thyroid Studies

Medicare and MVP will <u>not</u> cover thyroid testing for screening purposes.

- Please provide a sign/symptom for the order.
- If it is ordered due to possible side effects from medication the patient is taking please indicate that on the order.

5. 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" <u>and</u> the body part (ex. Insect bite thigh) then select the correct laterality.

Ex. S70.361XX - Insect bite (nonvenomous), right thigh

S70.362XX_- Insect bite (nonvenomous), left thigh

S70.369XX_ - Insect bite (nonvenomous), unspecified thigh

• If the body part is unknown- T14.8XX_- Other injury of unspecified body region

The appropriate 7th character is to be added to each code

- A initial encounter
- D subsequent encounter
- S seguela

LABORATORY & PATHOLOGY MEDICINE COMMUNIQUÉ — FALL 2021 Compliance Updates

How to Prevent Follow-up Calls from Laboratory Billing and Compliance (contd)

- 6. PSA Screening Vs Diagnostic PSA
 - **Diagnostic PSA Testing (PSA):** For patients exhibiting signs/symptoms or for monitoring purposes. *If the diagnosis submitted is not a covering diagnosis*, according to the NCD, *please submit an Advance Beneficiary Notice (ABN)*.
 - Screening PSA Testing (PSAS): A screening PSA is used for early detection of adenocarcinoma of
 the prostate and is covered once every 12 months for men over age 50. If you order a PSA more frequently
 than this you must submit an ABN. Per CMS policy, the only covering diagnosis for a screening PSA is
 Z12.5.
- 7. As of 7/1/18, Medicaid will only accept "unspecified" diagnosis codes in very few instances. Please be <u>as specific</u> <u>as possible</u> when providing the associated diagnosis codes.

For example: Specific joints affected, laterality of condition, the trimester of pregnancy.

8. Z00.00 is never a covering diagnosis for Medicare patients. Please provide signs/symptoms for why the testing is being requested. If the testing is for Preventive Services, provide the correct screening code.

REFERENCES:

Medicare Diagnostic PSA: https://d2ubrtwy6ww54e.cloudfront.net/www.uvmhealth.org/assets/migrate_files/psa-ncd.pdf? VersionId=TkpjZiiO7DfgOj9rKk7pLkKazwbfZOUt

Medicare Preventive Service Tool: https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html

UVM Lab Compliance Resources: https://www.uvmhealth.org/medcenter/departments-and-programs/pathology-and-laboratory-medicine/labservices-for-hospitals-and-clinicians/compliance-updates

If you have questions, please contact:

jessica.mesec@uvmhealth.org (802)-847-9435 or kathleen.nadeau@uvmhealth.org (802)-847-0930

Previously Distributed Test Updates

Anatomic Pathology

Temporal Artery Biopsies

We would like to alert you that the UVMMC Surgical Pathology division will be making a change to the processing of Temporal Artery Biopsies, effective 6/21/2021. These samples will no longer be made Red Hot (STAT) upon arrival. They will now be processed as routine specimens. You may still request that individual cases be treated as Red Hot (STAT) if clinically indicated.

If you have any questions or concerns please contact Valerie Cortright, Laboratory Supervisor, Anatomic Pathology (valerie.cortright@uvmhealth.org).

Lynch Syndrome Screening on Endometrial Cancer Resections

Effective June 2021, the Gynecologic Pathology Group at the UVMMC Department of Pathology will switch to performing Universal Screening for Lynch Syndrome on endometrial biopsy and curettage specimens found to have endometrial cancer, in accordance with NCCN, SGO, and ACOG guidelines. This change is primarily to avoid technical issues commonly encountered in hysterectomy specimens. If insufficient material is present in the endometrial biopsy or curettage, testing may be performed on the subsequent hysterectomy specimens.

It is important to note that as an initial screening test, immunohistochemical (IHC) staining with antibodies against four mismatch repair proteins is NOT considered a molecular test. Any follow up molecular testing (e.g. MLH1-Promoter Methylation, Microsatellite Instability by PCR, or germline testing), however, requires preauthorization or an advanced beneficiary notice (depending on patient's insurance). The most common scenario in which this is encountered is in endometrial cancers that show the following IHC results: Loss of MLH1/PMS2 and retention of MSH2 and MSH6 proteins. In these cases the following comment will always be present in the surgical pathology report:

"The majority of cancers with loss of MLH1/PMS2 protein expression are associated with somatic changes rather than an inherited mutation (Lynch syndrome). However, if additional testing to rule out Lynch syndrome is warranted in this individual, additional molecular testing (specifically MLH1 Promoter Methylation) can be ordered upon obtaining preauthorization or an advanced beneficiary notice."

If you have any questions concerning this new Universal Screening protocol, please contact the Gynecologic Pathology Team at Lab-GynPathologists@uvmhealth.org or Dr. Bronwyn Bryant at Bronwyn.Bryant@uvmhealth.org.

Initial Test	Reflex Criteria	Reflex Tests	Additional CPT Billed
Endometrial Cancer, biopsy/curettage/ Re- section	All cases of endometrial cancer	Immunohistochemical Testing (MLH1, PMS2, MSH2, MSH6)	88342 x 4 for MMR
		Performed at UVMMC	



Bronwyn Bryant MD Physician Pathology (802) 847-0031

LABORATORY & PATHOLOGY MEDICINE COMMUNIQUÉ — FALL 2021 Anatomic Pathology

Update to UVMMC PAP & HPV Testing

Effective 4/28/2021, UVMMC will modify the reflex algorithm for High Risk (HR) HPV testing to better align with the latest, age-based, ASCCP guidelines, http://www.asccp.org.

The new guidelines require that the Pap order include information defining the test as either screening or diagnostic.

- Screening: Routine exam, no recent abnormal results, not in follow up testing for dysplasia or abnormal results symptoms
- **Diagnostic**: Previous abnormal Pap findings, signs or symptoms, or has significant complaints related to the female reproductive system

HPV testing is reflexed from the Pap using different options based on the indication of screening or diagnostic:

For **Screening**, the HPV testing options are:

- HPV Regardless of Diagnosis (Co-Test) This is for patients 30 years old and older. HPV will always be performed.
- HPV if ASCUS This is for patients 25-29 years old. HPV testing will be performed if the Pap result is ASCUS.
- None (Note that Medicare patients 65 years or older are NOT eligible for HPV testing from screening Pap tests).

For **Diagnostic testing**, the HPV testing options are:

- HPV Regardless of Diagnosis (Co-Test) This is for patients 30 years old and older. HPV will always be performed.
- HPV Regardless for other diagnostic testing This is for patients that are 25-29 years old with previous abnormal Pap results that need HPV results for patient management.

*ASCUS – Atypical squamous cells of undetermined significance

A series of questions will now appear at Epic order entry. The purpose of these is to collect the pertinent information needed to ensure proper HPV reflexing and proper billing.

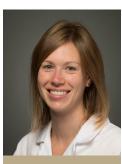
Here are sample questions:

1) Is this for Screening or Diagnostic Purposes?

Response format: Free Text, but please just indicate Screening or Diagnostic

- If Screening, would you like reflex HPV Testing? If yes, the criteria for screening are "HPV Regardless of Diagnosis (CoTest)(Ages 30+ ONLY)" and "HPV if ASCUS (Ages 25 -29 ONLY)"
 - a. Yes
 - b. No
- If Diagnostic, would you like reflex HPV Testing? If yes, the criteria for diagnostic are "HPV Regardless of Diagnosis (CoTest)(Ages 30+ ONLY) and "HPV Regardless for Other Diagnostic Testing (Ages 25 - 29 ONLY)"
 - a. Yes
 - b. No
- 4) If HPV reflex testing is desired and if "HPV Regardless of Diagnosis (CoTest)(Ages 30+ ONLY)" is the criteria that will be met, would you also like reflex HPV Genotyping per guidelines?
 - a. Yes
 - b. No
- 5) Provide Reason for reflex HPV testing if "HPV Regardless for Other Diagnostic Testing (Ages 25 29 ONLY)" is the criteria that will be met for Diagnostic reflex HPV testing

Response format: Free text



Christina Wojewoda, MD Medical Director Microbiology Lab

Anatomic Pathology

Update to UVMMC PAP & HPV Testing (contd.)

There will be a total of 16 Ask at Order Entry questions and they will cover screening/diagnostic/HPV questions, Medicare questions, and clinical history questions.

If the sample source is Vaginal and HPV testing is ordered, the sample will be sent to Mayo Medical Laboratory, as UVMMC 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 limitations of the testing approved by FDA.

If HPV genotyping is ordered, it will be performed **ONLY if all three** of the follow criteria are met - age is 30-64 years old, 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 additional information is required, the ordering provider will be contacted. If the request is deemed appropriate, the reflex testing will be performed.

Please contact Christina Wojewoda, Microbiology Medical Director; Christina. Wojewoda@uvmhealth.org with questions or concerns.



Clayton Wilburn, MD Medical Director Clinical Chemistry Phone: 847-9657

Chemistry

Hemoglobin A1C Platform Change

Effective 4/1/2021, the UVMMC Clinical Laboratory will be moving Hemoglobin A1c testing from the Tosoh G8 to the Sebia Capillarys 3 Tera platform as part of its automation improvement process. With this change will come the ability to more readily detect elevations in HbA2 levels that may indicate a patient having Beta-Thalassemia. Therefore, in addition to reflexing the Hemoglobin A1c to a Hemoglobinopathy Evaluation for suspected hemoglobin variants, we will also reflex Hemoglobin A1c studies in patients that have >3.4% HbA2 detected. The test name, ordering process, and reference range will remain the same. Correlation studies between the two assays are excellent.

Test Name	Epic Code	Atlas Code	Mayo Access ID
Hemoglobin A1c	LAB90	HA1C	FAH5419

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

LDH Assay Upgrade

Effective 4/7/2021, the UVMMC laboratory will be upgrading its LDH assay on the Ortho Clinical Diagnostics Vitros 5600 to a new generation. With this upgrade comes several changes, most notably a change in the reference ranges to LDH (LAB96), which will bring our LDH results in line with the majority of commercially available clinical chemistry analyzers. In addition, the measuring range for both LDH (LAB96) and FLDH (LAB188) will change from 100-2150 U/L to 41-1000 U/L. There will be no changes to the test names, test order codes, or where reporting occurs in the results tree. The new reference ranges for LDH (LAB96) are given below.

Test Name	Epic Code	Atlas Code	Mayo Access ID	Change(s)
LDH	LAB96	LDH	FAH257	Reference Ranges & Linearity
	<u>Age</u>	<u>Male</u>	<u>Female</u>	<u>Units</u>
	0-11 years	195-349	195-349	U/L
	12-15 years	177-358	146-297	U/L
	16-18 years	134-314	120-250	U/L
	>=19 years	120-246	120-246	U/L
Test Name	Epic Code	Atlas Code	Mayo Access ID	Change(s)
LDH, Fluid	LAB188	FLDH	FAH5930	Linearity

If you have any questions or concerns regarding this change please reach out the chemistry medical director (clayton.wilburn@uvmhealth.org).

HIV RNA and HCV RNA Platform Change

On July 26, 2021, the UVMMC Laboratory will be upgrading its instrumentation for the quantification of HIV and Hepatitis C viral loads from the Roche Ampliprep with TaqMan combined system to the Roche COBAS 6800 integrated molecular platform. The primers utilized on the new system are the same as those utilized on the predicate system. Therefore, the reporting limits and interpretations will not change with this upgrade. The test names, ordering mechanism, reflexes, and result line trending will all remain the same. The only change seen from the provider or patient side will be the performing instrument being changed to the Roche COBAS 6800.

Affected Orderables:			
Orderable Name	Epic Code	Atlas	Mayo Access ID
HIV 1 RNA Quantitation	LAB14298	HIVQU1	FAH5926
HIV 1 RNA Quantitation with Reflex to Genotype	LAB14299	HIVRX1	FAH5929
HCV RNA Detection Quantitation	LAB14296	HCVQU1	FAH5922
HCV RNA Detection Quantitation with Reflex to Genotype	LAB14297	HCVRX2	FAH5925
Employee Health Exposure (HBSAG, HCVQU, Rapid HIV 1/2 Ab)	LAB3030	EHEXP2	FAH5745

Please **do not submit samples in false bottom tubes** since samples are loaded directly onto the analyzer and false bottom tubes are not acceptable.

For questions or concerns, please contact the medical director of Clinical Chemistry Dr. Clayton Wilburn at Clayton.Wilburn@uvmhealth.org.

Urinary Assessment of Kidney Function Changes

On 3/30/2021, the UVMMC Laboratory will be making changes to two tests involved in the assessment of proteinuria and kidney function. These changes are outlined below.

 Test Name
 Epic Code
 Legacy Code
 Mayo Access ID

 Protein/Creatinine Ratio, Urine
 LAB3650
 UTPCRR
 FAH5739

• The reference range of the urine protein-to-creatinine ratio is being updated to match that of our reference laboratory, Mayo Medical Laboratories.

Current: <0.16 mg/mg creatinine for Females

< 0.11 mg/mg creatinine for Males

New: <0.18 mg/mg creatinine for both Females and Males age ≥18 years

• Furthermore, for times when the patient's urine creatinine is ≤38 mg/dL, the urine protein-to-creatinine ratio will **NOT** calculate, as we have found that for urine containing such a low level of creatinine, the urine protein over-recovers, giving a falsely elevated protein-to-creatinine ratio. This instance is usually due to a very dilute urine sample and the patient should be recollected, preferably, with a first morning void specimen.

Urinary Assessment of Kidney Function Changes (contd.)

 Test Name
 Epic Code
 Legacy Code
 Mayo Access ID

 Urine Albumin-to-Creatinine Ratio
 LAB743
 UMALBU
 FAH5821

- In line with the recommendation from the National Kidney Foundation, the test name is being updated from Microalbumin, Urine to Urine Albumin-to-Creatinine Ratio (ACR). The will be no change to the order code or reference range.
- Furthermore, for times when the patient's urine albumin is ≤0.6 mg/dL, the ACR will **NOT** calculate, as we have found that for urine containing such a low level of albumin, the resulting ACR calculated with a "<" sign can result in interpretation issues. This instance is usually due to a very dilute urine in a patient of normal muscle mass, and the patient should be recollected, preferably, with a first morning void specimen.
- Finally, as a good practice reminder, make sure that each diabetic and hypertensive patient be **monitored at least yearly** with an ACR test to detect early signs of kidney damage.

If you have any questions or concerns about these changes please reach out to the chemistry medical director (<u>clayton.wilburn@uvmhealth.org</u>).

Stability Change to CO2 Assay

On May, 24, 2021, the UVMMC clinical laboratory will reduce the acceptable sample stability time for the total Carbon Dioxide (CO2) assay on serum/plasma from 5 days to 48 hrs. Add-on lab orders for CO2 or any test including a CO2 measurement will no longer be accepted after 48 hours.

This change is part of the UVM health network standardization of laboratory testing process in preparation for EPIC golive Wave 2/3.

Test Name	Epic Code	Mayo Access ID	Atlas Code	Old Stability	New Stability
Carbon Dioxide	LAB55	FAH4976	CO2	5 days	48 hours

Orders that include CO2:

Test Name	Epic Code	Mayo Access ID	Atlas Code
Electrolytes Panel	LAB16	FAH4974	LYT
Nephrology Profile	LAB2195	N/A	NEPHR
BMP	LAB15	FAH5194	ВМР
CMP	LAB17	FAH5003	CMP
CMP, HemeOnc Use Only	LAB950	N/A	N/A

Lyme Ab Confirmation Change

On 7/19/2021, the UVMMC laboratory will be changing its methodology for Lyme antibody confirmation testing on serum. Currently, we use a traditional two-tier system comprised of a Lyme screen (Diasorin Liason Lyme Total Antibody Plus-IgG and IgM) and confirmation via immunoblot (Roboblot). We will be switching to a modified two-tier testing (MTTT) system comprised of our current Diasorin Lyme Screen and confirmation using Diasorin semi-quantitative direct IgG and IgM immunoassays. The FDA cleared MTTT for diagnosis of Lyme disease in July of 2019 (1). In our own validation studies and through literature studies, the MTTT system utilizing the Diasorin assays provides the same level of specificity as using our traditional two-tier system, but increases the sensitivity (by as much as two-fold) in early Lyme disease (2).

New Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Lyme Ab Confirmation (CLIA)	LAB16207	LAB16207	FAH5964	No Current LOINC
New Reportables	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Lyme IgG Ab	12301014878	12301014878	FAH5965	16480-6
Lyme IgM Ab	12301014879	12301014879	FAH5966	40612-4
Lyme Ab Confirmation Interpretation	12301014880	12301014880	FAH5967	9586-9
Current Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Lyme ImmunoBlot Confirmation	LAB787	LYMIB	FAH5859	34942-3

	Current	New
Test Name	Lyme ImmunoBlot Confirmation	Lyme Ab Confirmation (CLIA)
Demontable Values	Lyme IgG Immunoblot	Lyme IgG Ab
Reportable Values	Lyme IgG Band(s)	Lyme IgM Ab
	Lyme IgM Immunoblot	Lyme Ab Confirmation Interpretation
	Lyme IgM Band(s)	
	Lyme Immunoblot Interpretation	
Acceptable Container	SST (Stable 7 days)	SST (Stable 7 days)
	Markedly lipemic, icteric, or hemolyzed	Markedly lipemic, icteric, or hemolyzed samples
	Temperature/Specimen/Collect/Submit	Temperature/Specimen/Collect/Submit
Collection Requirements	Refrigerate/Serum/4 mL/0.8 mL	Refrigerate/Serum/4 mL/0.8 mL
Reference Ranges (All Ages)		
Lyme IgG Ab	Negative	Negative
Lyme IgM Ab	Negative	Negative
Instrumentation	Gold Standard Diagnostics Roboblot	DiaSorin Liaison XL
Methodology Line Immunoblot		Chemiluminescence Immunoassay
CPT Code(s)	86617 x 2	86617 x 2
NYS Approval	Yes	Yes

Lyme Ab Confirmation Change

This change will affect how Lyme confirmation testing is reported. Currently, we report the individual bands detected for the Lyme IgG and IgM immunoblot along with a positive/negative determination based on the number of bands detected for both IgG and IgM. This will be replaced by two individual results for the Lyme IgG Antibody and Lyme IgM Antibody that will be reported as either Negative, Equivocal, or Positive. There will still be a Lyme Interpretation that integrates the individual IgG and IgM results into a succinct analysis.

With this change to using the MTTT system, the Lyme Ab screen needs to be assayed using the DiaSorin method. Therefore, the Lyme confirmation test will not be orderable to clients as a stand-alone test but is a reflex-only test that will be for UVMMC lab Use Only. All confirmation testing requests must begin with the Lyme Ab screening test.

If you have any questions or concerns please contact the medical director of clinical chemistry (clayton.wilburn@uvmhealth.org).

References:

- 1. FDA. 7/29/2019. FDA clears new indications for existing Lyme disease tests that may help streamline diagnoses [Press Release]. https://www.fda.gov/news-events/press-announcements/fda-clears-new-indications-existing-lyme-disease-tests-may-help-streamline-diagnoses
- Branda JA, Strle K, Nigrovic LE, Lantos PM, Lepore TJ, Damle NS, Ferraro MJ, Steere AC. Evaluation of Modified 2-Tiered Serodiagnostic Testing Algorithms for Early Lyme Disease. Clin Infect Dis. 2017 Apr 15;64(8):1074-1080. doi: 10.1093/cid/cix043. PMID: 28329259; PMCID: PMC5399943.

QuantiFERON TB Gold Plus Platform Change

On 9/8/21, the UVMMC laboratory will transition its QuantiFERON TB Gold-Plus assay for latent TB from the Dynex DSX ELISA platform to the DiaSorin Liaison XL platform. Correlations between the current ELISA method and the new chemiluminescent (CLIA) method have been excellent. The test name will be updated, DiaSorin Liaison XL will be listed as the performing platform in the patient report, and testing will be performed Monday through Friday. There will be no other changes to this testing.

Current Test Name		New Test Name			
QuantiFERON TB Gold Plus, ELISA		QuantiFERON TB Gold Plus Qiagen			
Orderable	Epic Code	Atlas Code	Mayo Access ID	LOINC	
QuantiFERON TB Gold Plus Qiagen	LAB3051	QFTB4	FAH5825	71775-1	
Resultables	Epic Code	Atlas Code	Mayo Access ID	LOINC	
QuantiFERON Interpretation	12301002610	QFTBR	FAH5826	71773-6	
TB1 Ag Minus NIL	12301002611	QFTTB1	FAH5827	64084-7	
TB2 Ag Minus NIL	12301002612	QFTTB2	FAH5828	88517-8	
Instrumentation	Cur	rent	New		
	Dyne	x DSX	DiaSorin Liais	on XL	
Test Schedule	Current		New		
	Monday, Wednesday, Friday		Monday - Friday		

Reporting Changes for Calculated CA, Anion Gap and Calculated Total Bilirubin

On 10/24/21, the UVMMC Laboratory will be making several changes to the reporting of calculations for calculated calcium, anion gap, and calculated total bilirubin. In addition, the high critical limits for potassium and calcium included in our Dialysis Profiles will be updated. These changes come as the UVMHN prepares for the rollout of EPIC and EPIC Beaker at our partner institutions as part of Wave 2 and Wave 3, with a focus on standardization of practices/reporting in laboratory medicine.

Currently, UVMMC reports a calculated calcium with all total calcium measurements by co-measurement of serum albumin and application of the Payne formula. This formula was derived from 200 patient samples, many that had derangement of their serum protein composition, and has been shown in several studies to inappropriately classify calcium status in many patient populations. ¹⁻⁴ Therefore, UVMMC will no longer include a calculated calcium with all total calcium measurements and, should a clinician want a calculated calcium that is adjusted for serum albumin concentration, they will need to specify this on the request and order the new test, *Calculated Calcium (LAB9934).

Currently at UVMMC, if you wish to know your patient's anion gap (AGAP), it is calculated individually. Moving forward, when you order an Electrolytes Panel (LAB16) or any profile/panel that includes this set of analytes, UVMMC will calculate the AGAP [Na mmol/L – (Cl mmol/L + TCO2 mmol/L)] and report it as a calculated test result. The AGAP will be reported in the Lab Results Tree, enabling it to be trended and flagged for abnormality based on a defined reference range of 8-16 mmol/L.

One of two final calculation updates will be the inclusion of a calculated total bilirubin (Bu+Bc) with the following tests: Bilirubin, Direct & Indirect (LAB168) and Hepatic Function Panel (LAB20). Calculated total bilirubin is currently reported with Bilirubin, Neonate (LAB51) testing and this will not change. The second update will be the reporting of an Albumin/ Globulin Ratio with the following tests: CMP (LAB17) and CMP (Oncology use only – inc MG) (LAB950). This ratio can assist in the identification of patients with a possible paraproteinemia that requires further evaluation.

* Previously referred to as "Calcium, Corrected" in original communication sent on 9/13/21.

Calcium				
New Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Calcium	LAB53	LAB53	FAH5974	17861-6
Reportables	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Calcium	1230100011	CAL	FAH306	17861-6
Current Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Calcium	LAB53	CA	FAH4962	17861-6

Calculated Calcium				
New Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Calculated Calcium	LAB9934	LAB9934	FAH5975	17861-6
Reportables	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Calcium	1230100011	CAL	FAH306	17861-6
Calculated Calcium	12301001874	CALC2	FAH308	46099-8

ВМР					
New Orderable Name		Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Basic Metabolic Panel (Bl	MP)	LAB15	LAB15	FAH5970	24321-2
	0=\				
Ask at Order Entry (A	•				
Has the patient been fasti	ng for	1230001101	FASTN2	FAH5347	49541-6
8 hours or more?					
Reportables		Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Sodium		1230100005	NA	FAH253	2951-2
Potassium (K)		1230100006	K	FAH258	2823-3
Chloride (CL)		1230100007	CL	FAH4975	2075-0
CO2 (CO2)		1230100008	CO2	FAH4976	2028-9
Glucose, Serum		1230100012	SGL	FAH4902	2345-7
Calcium		1230100011	CAL	FAH306	17861-6
Blood Urea Nitrogen		1230100009	BUN	FAH4985	3094-0
Creatinine		1230100010	CREA	FAH4843	2160-0
GFR, Calculated		12301000892	CGFR	FAH5383	50210-4
Anion Gap	(new)	1230100013	AGAP	FAH5971	33037-3
Current Orderable Na	me	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Basic Metabolic Panel (B	MP)	LAB15	ВМР	FAH5194	24321-2

New Orderable Nam	ne	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Comprehensive Metabo	olic Panel	LAB17	LAB17	FAH5972	24323-8
Ask at Order Entry	(AOE)				
Has the patient been fa	sting for	1230001101	FASTN2	FAH5347	49541-6
8 hours or more?					
Reportables		Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Potassium (K)		1230100006	K	FAH258	2823-3
Sodium		1230100005	NA	FAH253	2951-2
Chloride (CL)		1230100007	CL	FAH4975	2075-0
CO2 (CO2)		1230100008	CO2	FAH4976	2028-9
Alkaline Phosphatase		12301001846	ALKP	FAH4842	6768-6
Bilirubin, Total		12301002193	TBIL	FAH5243	1975-2
AST		12301001855	AST	FAH263	1920-8
ALT		12301001850	ALT	FAH264	1742-6
Albumin		12301001839	ALB	FAH4973	1751-7
Protein, Total		12301002127	TP	FAH5010	2885-2
Creatinine		1230100010	CREA	FAH4843	2160-0
GFR, Calculated		12301000892	CGFR	FAH5383	50210-4
Blood Urea Nitrogen		1230100009	BUN	FAH4985	3094-0
Calcium		1230100011	CAL	FAH306	17861-6
Glucose, Serum		1230100012	SGL	FAH4902	2345-7
Anion Gap	(new)	1230100013	AGAP	FAH5971	33037-3
A/G Ratio	(new)	12301011565	ALBGLO	FAH5973	1759-0
Current Orderable N	Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Comprehensive Metabo	olic Panel	LAB17	CMP	FAH5009	24323-8

ONCCMP (Oncology use only	')			
New Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
CMP (Oncology use only - inc MG) LAB950	LAB950	N/A	24323-8
Ask at Order Entry (AOE) Que	estion			
Has the patient been fasting for	1230001101	FASTN2	N/A	49541-6
8 hours or more?				
Reportables	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Potassium (K)	1230100006	K	N/A	2823-3
Sodium	1230100005	NA	N/A	2951-2
Chloride (CL)	1230100007	CL	N/A	2075-0
CO2 (CO2)	1230100008	CO2	N/A	2028-9
Alkaline Phosphatase	12301001846	ALKP	N/A	6768-6
Bilirubin, Total	12301002193	TBIL	N/A	1975-2
AST	12301001855	AST	N/A	1920-8
ALT	12301001850	ALT	N/A	1742-6
Albumin	12301001839	ALB	N/A	1751-7
Protein, Total	12301002127	TP	N/A	2885-2
Creatinine	1230100010	CREA	N/A	2160-0
GFR, Calculated	12301000892	CGFR	N/A	50210-4
Blood Urea Nitrogen	1230100009	BUN	N/A	3094-0
Calcium	1230100011	CAL	N/A	17861-6
Glucose, Serum	1230100012	SGL	N/A	2345-7
Magnesium	12301002067	MG	N/A	19123-9
Anion Gap (new)	1230100013	AGAP	N/A	33037-3
A/G Ratio (new)	12301011565	ALBGLO	N/A	1759-0
Current Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
CMP (Oncology use only - inc MG	LAB950	ONCCMP	N/A	24323-8

DIALR (Dialysis use	only)				
New Orderable Name	ə	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Dialysis Routine Profile		LAB2053	LAB2053	N/A	N/A
Reportables		Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Sodium		1230100005	NA	N/A	2951-2
Potassium (DK)		12301002770	DK	N/A	2823-3
Chloride (CL)		1230100007	CL	N/A	2075-0
CO2 (CO2)		1230100008	CO2	N/A	2028-9
Dialysis Calcium		12301002883	DCAL	N/A	17861-6
Albumin		12301001839	ALB	N/A	1751-7
Phosphorus		12301002108	PHOS	N/A	2777-1
Calcium Phos Product		12301001869	CALCPH	N/A	50675-8
BUN, Predialysis		12301002765	BUNPRE	N/A	11065-0
AST		12301001855	AST	N/A	1920-8
Alk Phos		12301001846	ALKP	N/A	6768-6
Magnesium		12301002067	MG	N/A	19123-9
Anion Gap	(new)	1230100013	AGAP	N/A	33037-3
Current Orderable N	ame	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Dialysis Routine Profile		LAB2053	DIALR	N/A	N/A

DIALRH (Dialysis use only)				
New Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Dialysis Routine Profile, Home Care	LAB3093	LAB3093	N/A	N/A
Reportables	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Sodium	1230100005	NA	N/A	2951-2
Potassium (DKH)	12301002769	DKH	N/A	2823-3
Chloride (CL)	1230100007	CL	N/A	2075-0
CO2 (CO2)	1230100008	CO2	N/A	2028-9
Calcium	1230100011	CAL	N/A	17861-6
Albumin	12301001839	ALB	N/A	1751-7
Phosphorus	12301002108	PHOS	N/A	2777-1
Calcium Phos Product	12301001869	CALCPH	N/A	50675-8
BUN, Predialysis	12301002765	BUNPRE	N/A	11065-0
AST	12301001855	AST	N/A	1920-8
Alk Phos	12301001846	ALKP	N/A	6768-6
Magnesium	12301002067	MG	N/A	19123-9
Anion Gap (new)	1230100013	AGAP	N/A	33037-3
Current Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Dialysis Routine Profile, Home Care	LAB3093	DIALRH	N/A	N/A

Reporting Changes for Calculated CA, Anion Gap and Calculated Total Bilirubin

Electrolytes					
New Orderable Nam	e	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Electrolytes		LAB16	LAB16	FAH5978	24326-1
Reportables		Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Sodium		1230100005	NA	FAH253	2951-2
Potassium		1230100006	K	FAH258	2823-3
Chloride		1230100007	CL	FAH4975	2075-0
CO2		1230100008	CO2	FAH4976	2028-9
Anion Gap	(new)	1230100013	AGAP	FAH5971	33037-3
Current Orderable N	lame	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Electrolytes		LAB16	LYT	FAH4974	24326-1

TDBIL					
New Orderable Name		Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Total & Direct Bilirubin		LAB182	LAB182	FAH5976	1975-2
Reportables		Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Total Bilirubin		12301002193	TBIL	FAH5243	1975-2
Conjugated Bilirubin		12301001893	BILC	FAH4802	15152-2
Unconjugated Bilirubin		12301002219	BILU	FAH4803	1971-1
Delta Bilirubin		12301001907	BILD	FAH5248	1970-3
Calculated Total Bilirubin	(new)	12301001868	CTBIL	FAH5246	1975-2
Current Orderable Name)	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Total & Direct Bilirubin		LAB182	TDBIL	FAH5245	1975-2
LIVR					
New Orderable Name		Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Hepatic Function Panel		LAB20	LAB20	FAH5977	24325-3
Reportables		Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Albumin		12301001839	ALB	FAH4973	1751-7
Protein, Total		12301002127	TP	FAH5010	2885-2
Alkaline Phosphatase		12301001846	ALKP	FAH4842	6768-6
ALT		12301001850	ALT	FAH264	1742-6
AST		12301001855	AST	FAH263	1920-8
Unconjugated Bilirubin		12301002219	BILU	FAH4803	1971-1
Conjugated Bilirubin		12301001893	BILC	FAH4802	15152-2
Bilirubin, Total		12301002193	TBIL	FAH5243	1975-2
Delta Bilirubin		12301001907	BILD	FAH5248	1970-3
Calculated Total Bilirubin	(new)	12301001868	CTBIL	FAH5246	1975-2
Current Orderable Name	•	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Hepatic Function Panel		LAB20	LIVR	FAH4870	24325-3

References

- Payne RB, Little AJ, Williams RB, Milner JP. Interpretation of serum calcium in patient with abnormal serum proteins. Br Med J. 1973;4:643-646.
- Steen O, Clase C, Don-Wauchope A. Corrected calcium formula in routine clinical use does not accurately reflect ionized calcium in hospital patients. Canad J Gen Int Med. 2016;11(3):14-21.
- Smith JD, Wilson S, Schneider HG. Misclassification of calcium status based on albumin-adjusted calcium studies in a tertiary hospital setting. Clin Chem. 2018;64(12):1713-1722.
- Slomp J, van der Voort PH, Gerritsen RT, Berk JA, Bakker AJ. Albumin-adjusted calcium is not suitable for diagnosis of hyper- and hypocalcemia in the critically ill. Crit Care Med. 2003;31:1389-1393.

Pre-Eclampsia Protein/Creatinine Ratio, Urine

On 9/22/21, the UVMMC Laboratory will begin offering an orderable test for evaluation of the urine protein-to-creatinine ratio in pregnant patients being evaluated for pre-eclampsia. The test name is Pre-Eclampsia Protein/Creatinine Ratio, U (LAB17128).

Like the current Protein/Creatinine Ratio test (LAB3650), it will measure and report three results that will be listed with their counterparts in the EPIC results tree: Total Protein, Urine, Creatinine, Urine, and the Protein/Creatinine Ratio. The new Pre-Eclampsia Protein/Creatinine Ratio, U test has a reference range established for the Pre-Eclampsia Protein/Creatinine Ratio of <0.3 mg/mg, based on best practice guidelines and approved by Ob/GYN, and will always calculate even in the event of a < or > value for either Total Protein, Urine and Creatinine, Urine.

New Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Pre-Eclampsia Protein/Creatinine Ratio, U	LAB17128	LAB17128	FAH5968	in process
New Reportables	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Total Protein, Urine	12301002198	UTPR	FAH112	35663-4
Creatinine, Urine	12301000974	UCRR	FAH160	35674-1
Pre-Eclampsia Protein/Creatinine Ratio, U	12301016098	12301016098	FAH5969	2890-2

Specimen Collection						
Container	Specimen	Temperature	Collect Vol	Submit Vol	Min Vol	Stability
Sterile Container	Urine	Refrigerate	50 mL	5 mL	0.2 mL	3 days

CPT Codes: 84156, 82570

SARS CoV2 Test Change

On 10/27/21, the UVMMC Laboratory will be changing the Mayo antibody test reflexed from Pathology Approval for COVID-19 IgG Ab, LAB14475. The SARS CoV2 *Nucleocapsid* Total Ab, S will replace the SARS CoV2 *Spike* Antibody, Semi-Quantatative, S. This change is in-line with the approved clinical use for COVID-19 serology, testing for exposure to natural infection in individuals being evaluated for MIS-C or "Long COVID" who do not have a prior positive PCR test for COVID-19. By measuring antibodies developed to the COVID-19 Nucleocapsid, we are eliminating the interference from the current vaccines that induce antibodies to the COVID-19 spike protein in evaluating past natural infection/exposure.

Orderable Name	Epic Code	Atlas Code	Mayo ID	LOINC
Pathology Approval for COVID IgG Ab	LAB14475	LAB14475	N/A	N/A
Newly Defined Mayo Test (Lab Use Only)	Epic Code	Atlas Code	Mayo ID	LOINC
SARS-CoV-2 Nucleocapsid Total Ab, S.	LAB17155	N/A	COVTA	94762-2
Result Components	Epic Code	Atlas Code	Mayo ID	LOINC
SARS CoV 2 Nucleocapsid Total Ab, S	12301018363	N/A	COVTI	94762-2
Patient's Race	12301013084	N/A	SRACE	72826-1
Patient's Ethnicity	12301013085	N/A	SETHN	69490-1
Currently Defined Mayo Test (Lab Use Only)	Epic Code	Atlas Code	Mayo ID	LOINC
SARS-CoV-2 Spike Ab, Semi-Quant, S.	LAB15556	N/A	COVSQ	94769-7

The UVMHN laboratory still does not support testing for COVID-19 antibodies to assess vaccine response at this time. The reasons behind this are as follows: The current assays are semi-quantitative or qualitative with no set value being stated as indicative of immune status. The CDC and FDA currently do not support SARS-COV-2 ab testing post-vaccination to assess immunity (CDC COVID-19 Serology and Vaccination Guidance) and (FDA COVID-19 Serology and Vaccination Guidance) and there is no guidance on how one would modify an existing vaccination schedule or redose should a negative result be obtained.

Further guidance from the CDC for immunocompromised patients can be found here https://www.cdc.gov/vaccines/covid -19/info-by-product/clinical-considerations.html#underlying-conditions.

Should the guidance change on post-vaccination serology testing, the UVMHN will be updating our internal guidelines and testing strategy.

If you have any questions or concerns about these changes, then please reach out to the Medical Director of Clinical Chemistry (<u>clayton.wilburn@uvmhealth.org</u>).

Removal of Appended Comments for Hgb A1c, Creatinine, and Thyroid Cascade TSH

On 11/6/2021, the UVMMC Laboratory will be making three revisions to the comments generated on the following tests: Hgb A1c, Creatinine (eGFR), Thyroid Stimulating Hormone (TSH).

- 1. On Hgb A1c, the target goals for type 1 diabetics will no longer be appended to each result. This is because these targets are updated routinely, can differ depending on the clinical situation, and are best decided on in consultation with the patient's managing provider. The only appended comment that will remain is the ADA Hgb A1c ranges for normal, pre-diabetes, and diabetes.
- 2. As race is a social, not biological construct, the comment on the race correction factor to apply to the serum creatinine eGFR value for African-American patients will no longer be appended. In addition, the UVMMC laboratory will move to adopt the non-race based CKD-EPI eGFR equation recently developed by the NKF. Notification of this change will be separate and in the near future.
- 3. TSH results from the thyroid cascade will no longer have the following comment appended: "TSH cascade is not recommended for patients in which pituitary or hypothalamic disorders are suspected." This limitation is and should be well known to ordering providers and only further complicates the patient's test result report.



Clayton Wilburn, MD Medical Director Clinical Chemistry Phone: 847-9657

Affected Orderables:

Name	Epic Code	Atlas Code	Mayo Access ID
Hemoglobin A1c	LAB90	HA1C	FAH5419
POCT Hemoglobin A1c, Interfaced	POC507	N/A	N/A
Creatinine, Serum	LAB66	CREAT	FAH5382
POCT Creatinine, iSTAT	POC47	N/A	N/A
Thyroid Cascade	LAB2103	THCAS	FAH5791

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you have any questions about these changes, then please contact the Medical Director of Clinical Chemistry (clayton.wilburn@uvmhealth.org).

Blood Gas Testing Updates

On 11/6/2021, the UVMMC Laboratory will be updating the analytes and adding reference ranges (including pediatric reference ranges) for the following tests: Arterial Blood Gas, Venous Blood Gas, Cord Blood Gas-Arterial, and Cord Blood Gas-Venous. This change is part of the UVMHN standardization of laboratory reporting and reference ranges as part of the Wave II/III EPIC golive. The test builds for the Cord Blood Gas tests will be updated with new BE and BD result components. The analytes and reference ranges for each of the aforementioned tests are as follows:



Clayton Wilburn, MD Medical Director Clinical Chemistry Phone: 847-9657

Orderable Name			Epic	Code	Atlas Code LC		LOINC	
Blood Gas, Arterial		LAB:	33031		3G	24336-0		
Analyte:	рН	pCO2	pO2 tCO2		BE	BD	O2SAT	
Units:		mmHg	mmHg	mmol/L			%	
Sex	Male and	l Female						
Age								
0-1 days	7.26-7.49	27-40	55-80				95-98	
1-7 days	7.29-7.45	27-41	54-95	22-26	-2 to 3	-3 to 2		
>=7 days	7.35-7.45	35-45	80-105					
Orderable	Name		Epic	Code	Atlas	Atlas Code LOING		
Blood Gas,	Venous		LAB	3032	VE	VBG 2433		
Analyte:	рН	pCO2	pO2	tCO2	BE	BD	O2SAT	
Units:		mmHg	mmHg	mmol/L			%	
Sex	Male and Female							
Age								
All ages	7.31-7.41	41-51	30-50	22-28	-2 to 3	-3 to 2	60-85	

New Test Updates

Blood Gas Testing Updates

Orderable Name			Epic	Code	Atlas Code	LOINC
Blood Gas, Cord Arterial			LAE	33033	CBG	51974-4
Analyte:	pН	pCO2	pO2	tCO2	BE	BD
Units:		mmHg	mmHg	mmol/L		
Age						
All ages	7.18-7.38	42-71	<31	14-22	-7 to 1.8	-1.8 to 7
Sex	Male and F	emale				
	Up	dated Report	ables for	CBG		
Resultable name		Epic C	ode	Atla	as Code	LOINC
pH Cord Blood Arterial		1230100	3155	(COPH	28646-8
pCO2 Cord Blood Arterial		1230100)3158	С	PCO2	28644-3
pO2 Cord Blood Arterial		1230100	3156	С	OPO2	28648-4
tCO2 Cord Blood Arterial		1230100)3157	C	ATCO2	39466-8
Base Excess Cord Arterial	(new)	1230101	17118	12301017118		28638-5
Base Deficit Cord Arterial	(new)	1230101	17119	12301017119		30317-2
Orderable Name	Orderable Name		Epic	Code	Atlas Code	LOINC
Blood Gas, Cord Venous			LAE	33173	VCBG	51972-8
Analyte:	рН	pCO2	pO2	tCO2	BE	BD
Units:		mmHg	mmHg	mmol/L		
Age		1	•			
All ages	7.25-7.45	31-53	17-41	14-22	-7 to 0.6	-0.6 to 7
Sex	Male and	Female				
	Upd	lated Reporta	ables for V	CBG		
Resultable name		Epic (Code	Atlas Code		LOINC
pH Cord Blood Venous		123010	03159	(CVPH	28647-6
pCO2 Cord Blood Venous		123010	03162	C	OPCO2	28645-0
pO2 Cord Blood Venous		123010	03160	С	VPO2	28649-2
tCO2 Cord Blood Venous		123010	03161	С	TCO2	34520-7
Base Excess Cord Venous	(new)	123010	17615	1230	01017615	28639-3
Base Deficit Cord Venous	(new)	123010	17616	1230	01017616	28637-7

These changes will also impact the following Point of Care Tests (POCT):

Epic Code	Orderable Name
POC17	POCT Blood Gas, EG6 iSTAT
POC22	POCT Blood Gas, CG8 iSTAT
POC21	POCT EC8 iSTAT, NICU Only

If you have any questions or concerns about these changes, then please reach out to the Medical Director of Clinical Chemistry (clayton.wilburn@uvmhealth.org).

LABORATORY & PATHOLOGY MEDICINE COMMUNIQUÉ — FALL 2021 COVID and Flu

Testing for Influenza-Like Illnesses

Guidance (2020-2021) for providers using UVMMC laboratory regarding viral testing for an "Influenza-like Illness" (ILI)

Goal: To maintain diagnostic testing capacity for respiratory viral infections amidst the COVID 19 pandemic-

This document focuses on testing of **symptomatic patients only**. Asymptomatic testing guidelines of SARS-CoV-2 are covered elsewhere. **Asymptomatic patients should not be tested for influenza or RSV.**

SARS-CoV-2:

Indication: All symptomatic patients with ILI, symptoms concerning for COVID-19 (fever, cough, shortness of breath, acute loss of taste and smell, myalgias, fatigue, diarrhea, runny nose, congestion); and asymptomatic patients with high risk exposure.

Specimen Collection:

- Nasopharyngeal swab for sample of posterior nasopharynx, collected by health care worker (HCW). This specimen can also be tested for influenza, RSV (without a second collection) if indicated (see below).
- 2. Anterior nares swab, collected by HCW. <u>CANNOT be tested for influenza</u> (requires second collection).
- 3. Anterior nares swab, collected by patient, HCW observer. CANNOT be tested for influenza (requires second collection).

Influenza, RSV:

Indications: Testing for influenza and RSV in healthy outpatients <u>without</u> risk for severe disease **should not occur** <u>unless</u> there are compelling clinical reasons. All people for whom influenza testing is indicated should be tested for **both** influenza and SARS-CoV-2.

Specific testing for Influenza, RSV should occur for the following:

- 1. Symptomatic people at higher risk for serious complications from influenza:
 - A. Adults 65 and older
 - B. Children under the age of 5, especially those under the age of 2
 - C. Native Americans and Alaska Natives
 - D. People who are pregnant and up to 2 weeks postpartum
 - E. E. People with underlying medical conditions (chronic lung disease, heart disease, kidney disease, liver disease, neurologic disease, hematologic disease, DM, metabolic disorders, obesity, immunosuppression, under age of 19 receiving chronic aspirin therapy)
- 2. Symptomatic household contacts of people at higher risk of severe complications
- 3. Symptomatic ILI requiring hospitalization for any indication
- 4. Symptomatic residents of long term care facilities

Specimen Collection:

1. Nasopharyngeal swab for sample of posterior nasopharynx, collected by HCW.

Expanded Respiratory Viral Panel (metapneumovirus, parainfluenza, adenovirus, rhinovirus): *is not indicated <u>unless</u>* SARS-CoV-2, influenza, and RSV tests are negative and the patient has severe illness or a compromised immune status.

1. Nasopharyngeal swab for sample of posterior nasopharynx, collected by HCW.

Additional recommendations:

- 1. If the patient has severe disease, testing above can be performed on lower respiratory tract samples.
- 2. Empiric antiviral treatment is recommended for patients with suspected influenza who are hospitalized or at higher risk for severe disease *and should not be delayed while awaiting diagnostic testing*. See Green Book for therapeutic options and doses for adults, Purple book for children.

LABORATORY & PATHOLOGY MEDICINE COMMUNIQUÉ — FALL 2021 COVID and Flu

COVID Supplies

The Lab at UVMMC has worked diligently to provide you and your patients with COVID specimen collection supplies throughout the current pandemic. There have been many different swab and media types utilized for collecting COVID specimens since the start of testing at UVMMC. Our Lab has validated many new combinations of swab + viral media on our instruments in order to provide reliable COVID test results with the quickest possible turnaround time, utilizing variable specimen collection supplies from different vendors as availability has fluctuated from time to time.

Sometimes the variable availability means that UVMMC Lab has COVID collection supplies with very different dates of expiry on-hand. To waste as little product as possible, UVMMC inventory and supply controllers try to use supplies with the closest outdate first. So please do not be surprised if you request COVID specimen collection supplies from UVMMC and the media expiry date is only a month or two in the future. Our Microbiology group has confirmed that such media can be tested up to 2 days prior to its expiry. This 2 day limit takes into account the fact that some COVID tests can take up to 48 hours to run.

That being said, if your office currently has COVID specimen collection supplies from UVMMC that are nearing their date of expiry and you will not be able to use them, please let us know and we can provide you with replacement supplies. You can dispose of expired or nearly expired COVID specimen collection supplies. Before ordering replacement supplies, please keep in mind your typical usage rate and the possibility of receiving short-dated items. Thank you very much.

UVMMC Positive COVID Results- Beginning 8/11/2021

The Lab will no longer be calling UVMMC Clinics for positive COVID results. Positive COVID results will now route to UVMMC Nursing Clinic In Basket pools. UVMMC Clinics will follow-up with positive COVID patients.

UVMMC COVID Collection Supplies

Due to staffing shortages, effective 09/01/2021, UVMMC will be unable to meet the demand for COVID-19 collection **KITs**, that are put together here in the lab. We will continue to provide collection supplies of course, but when you order, for example, 100 Nasal collection kits, we will supply the components separately, (100 swabs, 100 media tubes, 100 biohazard bags & 100 absorbent pads).



Katherine Devitt, MD Medical Director Cytometry Lab Phone: 847-8372

Changes to UVMMC Flow Cytometry Testing

Effective 04/27/2021, the Flow Cytometry Laboratory will be transitioning testing platforms for Flow Cytometry testing. The first phase of this transition involves lymphocyte subset analysis, specifically T-Cell Subsets and T-, B-, NK-Cell Subsets. There will be changes to order codes, test names, reporting, specimen stability, and acceptable container types. A brief summary is provided below with full details in the following tables. Later this year, Phase II will transition the CD19 CD20 Panel, Stem Cell CD34 Blood, and Stem Cell CD34 Apheresis Product to the new platform. Finally, Phase III will transition 5-color Leukemia/Lymphoma Panels to 10-color screening and triage panels. More details on these phases to follow.

- Absolute CD3 (LAB2326, Legacy code TOTCD3) will be discontinued as a stand-alone, orderable test. Requests for this test have been exceedingly rare, and a total CD3 count may be ascertained by ordering T-Cell Subsets. Please note that the analytical measurement range (AMR) for this component will change to 17 5000 cells/uL. See explanation below.
- Sodium heparin (green top) will no longer be an acceptable container type.
- Absolute counts and percentage values will be reported for all cell subsets, as well as the CD4:CD8 ratio.
- Adult Reference ranges will appear slightly different. These are provided by the manufacturer
 and have been verified within our laboratory. There will be no changes to the pediatric
 reference ranges.
- Test names will be updated to reflect the most current nomenclature, replacing the term "Immunodeficiency" with "T-Cell Subsets" or "T-, B-, NK-Cell Subsets".
- Complete Blood Count with Differential (CBCDF) will no longer be required simultaneously as
 the new tests are single-platform and an absolute lymphocyte count is directly measured by
 the instrument.
- Due to the nature of single platform testing (absolute counts directly measured) vs dual-platform testing (absolute counts calculated), the AMR for each, absolute component will be more restrictive and absolute counts will no longer be reported down to <1. Results that fall above or below the AMR will be reported as such. The new AMR are listed in the table below:

Component	AMR
Absolute CD3	17 – 5000 cells/uL
Absolute CD4	11 - 3000 cells/uL
Absolute CD8	11 - 2243 cells/uL
Absolute CD19	5 – 2000 cells/uL
Absolute CD16+CD56	10 – 1069 cells/uL

Changes to UVMMC Flow Cytometry Testing

Order Codes	Old	New
Test Name	Immunodeficiency Panel	T-Cell Subsets
Epic Code	LAB2318	LAB15287
Atlas Code	IP	LAB15287
Mayo Access ID	FAH293	FAH5941
LOINC Code	N/A	65759-3
Acceptable Container		
	EDTA (Lav Top, Pedi Purple) Sodium Heparin (Green Top)	EDTA (Lav Top, Pedi Purple)
Collection Requirements		
	Ambient; Test within 48 hours	Ambient; Test within 48 hours
Adult Reference Ranges (units):		
CD3 (%)	62 - 87	56 - 84
CD4 (%)	35 - 63	31 - 64
CD8 (%)	10 - 35	9 - 39
Absolute CD3 (cells/uL)	548 - 2,118	840 - 2,669
Absolute CD4 (cells/uL)	329 - 1,427	488 - 1,734
Absolute CD8 (cells/uL)	N/A	154 - 1,097
4/8 Ratio	N/A	<u>></u> 0.9

	Resultable Codes							
	Immunodeficiency	T-Cell Subsets	Epic Code	Atlas Code	Mayo Access	LOINC Code		
Name	CD3	CD3	12301000954	CD3	FAH294	8124-0		
Name	CD4	CD4	12301000955	CD4	FAH295	8123-2		
Name	CD8	CD8	12301000956	CD8	FAH296	8101-8		
Name	N/A	Absolute CD3	12301000951	TOTCD3	FAH5580	8122-4		
Name	Absolute CD4	Absolute CD4	12301000957	TOTCD4	FAH297	24467-3		
Name	N/A	Absolute CD8	12301000960	TOTCD8	FAH5581	14135-8		
Name	N/A	4/8 Ratio	12301011933	48RATIO	FAH5938	54218-3		

Laboratory & Pathology Medicine communiqué — Fall 2021 Flow Cytometry

Changes to UVMMC Flow Cytometry Testing

Order Codes	Old	New
Test Name	Immunodef Panel B + NK	T, B, NK-Cell Subsets
Epic Code	LAB343	LAB15288
Atlas Code	IMM	LAB15288
Mayo Access ID	FAH5221	FAH5942
LOINC Code	N/A	45268-0
Acceptable Container		
	EDTA (Lav Top, Pedi Purple) Sodium Heparin (Green Top)	EDTA (Lav Top, Pedi Purple)
Collection Requirements		
	Ambient; Test within 30 hours	Ambient; Test within 24 hours
Adult Reference Ranges (units):		
CD3 (%)	62 - 87	56 - 84
CD4 (%)	35 - 63	31 - 64
CD8 (%)	10 - 35	9 - 39
CD19 (%)	5 - 22	5 - 25
CD16+CD56 (%)	5 - 23	5 - 31
Absolute CD3 (cells/uL)	548 - 2,118	840 - 2,669
Absolute CD4 (cells/uL)	329 - 1,427	488 - 1,734
Absolute CD8 (cells/uL)	66 - 750	154 - 1,097
Absolute CD19 (cells/uL)	0 - 488	73 - 562
Absolute CD16+CD56 (cells/uL)	72 - 425	108 - 680
4/8 Ratio	N/A	<u>></u> 0.9

	Resultable Codes							
	Immunodef Panel B + NK (LAB343)	T, B, NK-Cell Subsets (LAB15288)	Epic Code	Atlas Code	Mayo Access ID	LOINC Code		
Name	CD3	CD3	12301000954	CD3	FAH294	8124-0		
Name	CD4	CD4	12301000955	CD4	FAH295	8123-2		
Name	CD8	CD8	12301000956	CD8	FAH296	8101-8		
Name	CD19	CD19	12301009570	CD19	FAH5222	8117-4		
Name	CD16+CD56	CD16+CD56	12301000959	CDNK	FAH5223	42189-1		
Name	Absolute CD3	Absolute CD3	12301000951	TOTCD3	FAH5580	8122-4		
Name	Absolute CD4	Absolute CD4	12301000957	TOTCD4	FAH297	24467-3		
Name	Absolute CD8	Absolute CD8	12301000960	TOTCD8	FAH5581	14135-8		
Name	Absolute CD19	Absolute CD19	12301000961	TOT19	FAH5582	8116-6		
Name	Absolute CD16+CD56	Absolute CD16+CD56	12301000962	TOTNK	FAH5583	42188-3		
Name	N/A	4/8 Ratio	12301011933	48RATIO	FAH5938	54218-3		

Changes to UVMMC Flow Cytometry Testing Phase II (b): CD19 CD20 Panel

Effective June 29, 2021, the Flow Cytometry Laboratory will transition testing platforms for CD19 CD20 Panel as part of Phase II (b) of our move to new instruments. The ordering process will remain the same. However, there will be changes to the test name, reporting, specimen stability, acceptable container types, and more (see summary below). In addition, New York samples should be sent to Mayo Medical Laboratories (Test ID: CD20B).

Orderable Name CD19 CD20 Panel	Epic Code LAB329	Atlas Code CD1920	Mayo Access ID FAH5571	
Reportable Name	Epic Code	Atlas Code	Mayo Access ID	
CD19%	12301009256	CD19R	FAH5572	
CD20%	12301000953	CD20R	FAH5573	

	Current	Updated
Test Name	CD19 CD20 Study	CD19 CD20 Panel
Papartable Values	CD19 Research (CD19)	CD19%
Reportable Values	CD20 (CD20)	CD20%
Acceptable Container	EDTA (Lav Top, Pedi Purple)	EDTA (Lav. Tan. Dadi Dure I-)
Acceptable Container	Sodium Heparin (Green Top)	EDTA (Lav Top, Pedi Purple)
Collection Paguiromento	Ambient; Test within 30 hours (Lav Top)	Ambient, Test within 20 hours
Collection Requirements	and 48 hours (Green Top)	Ambient; Test within 30 hours
Adult Reference Ranges		
CD19 (%)	None	6 - 24%
CD20 (%)	None	6 - 24%
Instrumentation	Beckman Coulter FC500 and Navios	Becton Dickinson FACSLyrics
NYS Approval	Yes	No

GenePanel Heme Assay



Joanna Conant, MD Medical Director Hematology Lab Phone: 847-6700

Effective June 1, 2021, the Genomic Medicine Laboratory at the UVM Medical Center began performing the GenePanel Heme assay, which offers targeted, capture-based, next generation sequencing of up to 151 genes, including both DNA and RNA targets that have clinical utility across a broad spectrum of hematologic neoplasms. This test replaced the *Rapid Heme Panel LAB3703*, which was performed at Brigham and Women's Hospital, and it is orderable by Hematology/Oncology and Pathology only.

New Test Name	Epic Code	Atlas Code	Mayo Access ID
GenePanel Heme	LAB15291	N/A	N/A

Specimen Requirements						
Specimen/Container		Temperature	Collect	Submit Volume	Min	Stability
Whole Blood or Bone Marrow/EDTA		Refrigerated	4 mL	4 mL	2 mL	5 days
Whole Blood or Bone Marrow/Sodium Heparin		Refrigerated	4 mL	4 mL	2 mL	8 days
FFPE Tissue or Cell Blocks		Ambient				
Non-cell Block Cytology Slides (Pap or M	/IGG)	Ambient				
Instrumentation		Manual Extraction and Illumina Nextseq for Sequencing				
CPT Code(s)		GenePanel Heme, Myeloid: 81455				
		GenePanel He	eme, Acute	Lymphoblastic Le	ukemia: 8145	55

Standard analytical time is 10-14 days, however this testing is also available with expedited processing for new and recurrent acute myeloid leukemias requiring reporting of critical genes by day 7 for treatment decisions. The test is validated for bone marrow aspirates, whole blood, formalin-fixed paraffin embedded tissue, and non-cell block cytology slides (Pap or MGG). Other samples may be accepted with Pathologist approval.

GenePanel Heme Assay

Selection of a gene list is based on clinical indication and disease type. Two established panels are currently available for evaluation.

1. **Myeloid Panel**: 87 genes for use in a broad spectrum of myeloid-related diseases including acute myeloid leukemia, myelodysplastic syndrome, cytopenias, and myeloproliferative disorders.

ABL1	CREBBP	EZH2	IKZF1	месом	NRAS	PML	RUNX1T1	STAT5B
ASXL1	CSF1R	FGFR1	JAK1	MKL1	NUP214	PPM1D	SETBP1	TET2
BCR	CSF3R	FLT3	JAK2	MLF1	NUP98	PRDM16	SETD2	TFG
BCOR	DDX41	GATA1	JAK3	MLLT10	PDCD1LG2	PRPF8	SF3B1	TP53
CALR	DEK	GATA2	KAT6A	MLLT4	PDGFRA	PTPN11	SH2B3	U2AF1
CBFB	DNMT3A	GLIS2	KDM6A	MPL	PDGFRB	RAD21	SMC1A	WT1
CBL	EGFR	GNB1	KIT	MYH11	PDS5B	RARA	SMC3	ZRSR2
CBLB	ERG	HNRNPK	KMT2A	NF1	PHF6	RBM15	SRSF2	
CEBPA	ETNK1	IDH1	KRAS	NOTCH1	PICALM	ROS1	STAG2	
CHIC2	ETV6	IDH2	LUC7L2	NPM1	PIGA	RUNX1	STAT3	

2. **Acute Lymphoblastic Leukemia Panel**: 70 genes for use in B-lymphoblastic leukemia and T-lymphoblastic leukemia.

ABL1	CRLF2	FLT3	KDM6A	NRAS	PHF6	STIL
ABL2	CSF1R	GATA3	KLF2	NTRK3	PICALM	SUZ12
BCL11B	DNMT3A	GNB1	KMT2A	NT5C2	PTEN	TAL1
BCL2	EBF1	IDH1	KRAS	NUP214	PTK2B	TCF3
BCL6	EP300	IDH2	MLLT10	NUP98	PTPN11	TP53
BCR	EPOR	IKZF1	MLLT4	P2RY8	RUNX1	TYK2
BIRC3	ETV6	IL7R	MPL	PAX5	SETD2	WHSC1
BRAF	EZH2	JAK1	MYC	PDCD1LG2	SH2B3	WT1
CDKN2A	FBXW7	JAK2	NF1	PDGFRA	STAT3	ZCCHC7
CREBBP	FGFR1	JAK3	NOTCH1	PDGFRB	STAT5B	ZRSR2

LABORATORY & PATHOLOGY MEDICINE COMMUNIQUÉ — FALL 2021 Genomics

GenePanel Heme Assay

Full List of Genes:

ABL1	CD79A	EP300	IKZF2	MLLT10	PDCD1LG	ROS1	TFG
ABL2	CD79B	EPOR	IKZF3	MLLT4	PDGFRA	RUNX1	TNFAIP3
ALK	CDK6	ERG	IL7R	MPL	PDGFRB	RUNX1T	TP53
ASXL1	CDKN2A	ETNK1	JAK1	MYC	PDS5B	SEMA6A	TP63
ATM	CEBPA	ETV6	JAK2	MYH11	PHF6	SETBP1	TYK2
BCL11B	CHD1	EZH2	JAK3	MYD88	PICALM	SETD2	U2AF1
BCL2	CHIC2	FBXW7	KAT6A	NOTCH1	PIK3CA	SF3B1	WHSC1
BCL6	CIITA	FGFR1	KDM6A	NOTCH2	PIGA	SH2B3	WT1
BCOR	CREBBP	FLT3	KIT	NPM1	PLCG2	SMC1A	XPO1
BCR	CRLF2	FOXO1	KLF2	NRAS	PML	SMC3	ZCCHC7
BIRC3	CSF1R	GATA1	KMT2A	NF1	PPM1D	SOCS1	ZRSR2
BRAF	CSF3R	GATA2	KMT2D	NFKB2	PRDM1	SRSF2	
BTK	CXCR4	GATA3	KRAS	NOTCH1	PRDM16	STAG2	
CALR	DDX41	GLIS2	LUC7L2	NT5C2	PRPF8	STAT3	
CARD11	DEK	GNA13	MALT1	NTRK3	PTEN	STAT5B	
CBFB	DNMT3A	GNB1	MAP2K1	NUP214	PTK2B	STIL	
CBL	DUSP22	HNRNPK	месом	NUP98	PTPN11	SUZ12	
CBLB	EBF1	IDH1	MEF2B	P2RY8	RAD21	TAL1	
CCND1	EGFR	IDH2	MKL1	PAG1	RARA	TCF3	
CCND3	EIF4A1	IKZF1	MLF1	PAX5	RBM15	TET2	

Please contact Dr. Joanna Conant at <u>joanna.conant@uvmhealth.org</u> for questions.

LABORATORY & PATHOLOGY MEDICINE COMMUNIQUÉ — FALL 2021 Genomics



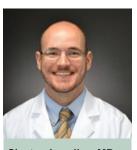
Nikoletta Sidiropoulos MD Medical Director Molecular Lab (802) 847-6600

GenePanel Solid Tumor Assay

Effective 09/15/2021, the GenePanel Solid Tumor assay as performed at UVMMC will be temporarily unavailable due to staffing redeployment for COVID-19 testing.

Genomic analysis for solid tumors will continue to be available by ordering the "Request for Genomic Analysis" and by standing reflex testing protocols. The UVMMC Genomic Medicine Laboratory will continue to triage these requests and process specimens for send out testing. Genomic sequencing will be performed at the Colorado Molecular Correlates Laboratory, a reference laboratory and the UVMMC Genomic Medicine Laboratory will facilitate return of results upon completion of testing.

If you have any questions regarding solid tumor genetic analysis, please contact Dr. Sidiropoulos.



Clayton Lavalley, MD Hematology Laboratory Phone: 847-3567

Changes in the Reporting of Nucleated Cells for Body Fluids

Effective March 1, 2021, the Hematology Laboratory will be updating the procedure for body fluid cell counts on the Sysmex XN9000 platform. This update will modify the upper limit of the reportable range for nucleated cells for Cell Count, Synovial Fluid (LAB211) and Cell Count, Body (LAB209). Currently, there is no upper limit, and manual dilutions are performed until a final result is reached. Moving forward, the upper limit of the reportable range for these tests will be >100,000 nucleated cells/cmm. This change aligns with the clinical utilization of cell counts for these specimens, as all results over the new upper limit are considered abnormal, and reporting specific results above this limit yields no additional actionable information.

There will be no other changes to these tests or to the way they are ordered or reported.

If you have any questions or concerns, please contact Dr. Clayton Lavalley (<u>clayton.lavalley@uvmhealth.org</u>) in the hematology laboratory.

Chromogenic Factor VIII

Effective March 15, 2021, the Thrombosis and Hemostasis Laboratory will offer the Chromogenic FVIII Activity Assay. This assay does <u>not</u> replace the current clot-based, 1-stage FVIII activity assay, and in most cases, the current FVIII activity assay is appropriate. Please contact the Thrombosis and Hemostasis Laboratory should you need guidance as to which activity assay is best for your patient. Please note, this new assay is available only as a routine test, and stat testing is not available.

Clinical Application:

This 2-stage, chromogenic methodology used for measuring FVIII activity is indicated for specific clinical situations:

- Aid in the initial diagnostic evaluation of hemophilia A, particularly when the clot-based FVIII activity assay is normal
- A subset of hemophilia A patients have shown discrepantly low FVIII results when measured using the chromogenic method compared to the clot-based method. Guidelines recommend performing both the chromogenic and clot-based FVIII activity assays in the initial hemophilia A diagnostic evaluation.
- Monitoring anti-hemophiliac FVIII factor replacement therapy of selected extended half-life coagulation factor replacements
- New anti-hemophiliac treatment options using an extended half-life factor replacement is best measured using the chromogenic FVIII assay, particularly when performing pharmacokinetic studies.
- Please note, the 1-stage, clot-based and 2-stage, chromogenic FVIII assay results should correlate in
 the normal population, but activity results may be discordant in the hemophilia population and when
 measuring FVIII replacement. The chromogenic FVIII assay is <u>insensitive</u> to emicizumab (Hemlibra).
- If a patient is on emicizumab will impact the aPTT-based coagulation assays, as outlined in the Table, below, and the aPTT-based assays are NOT accurate in a person taking emicizumab for up to 6 months following discontinuation of the medication.

CHROMOGENIC FACTOR VIII



Important Note

This chromogenic substrate assay (CSA) is necessary for measuring a patient's endogenous factor VIII activity or therapeutic factor VIII replacement medication, including the extended life factor replacement products.

This assay will measure these factor VIII activities and is not impacted by the new bi-specific monoclonal antibody therapy emicizumab (Hemlibra); our current one-stage assay (OSA) is a clot-based factor VIII activity assay and will overestimate a patient's endogenous or therapeutic factor VIII in the presence of emicizumab.

Finally, recent recommendations suggest using both the OSA (factor VIII) and CSA (chromogenic factor VIII) methods for the initial diagnostic investigation of Hemophilia A or where there is a clinical suspicion of Hemophilia A and yet the clotting test is normal (e.g. helpful to diagnose "Discrepant Hemophilia A").

Additional Codes

Primary ID	Epic Code	Atlas Code	Mayo Access ID	Order Code LOINC
LAB14969	LAB14969	LAB14969	FAH5939	49865-9

Result Code(s)

Reporting Name	Epic Code	Atlas Code	Mayo Access ID	LOINC
Chromogenic Factor VIII	12301012044	CHROM8R	FAH5940	49865-9

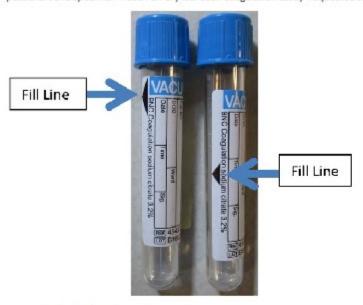
Specimen Information

Container	Specimen	Temperature	Collect Vol	Submit Vol	Min Vol	Stability
*Blue Top Tube	Plasma	Frozen	To fill line	1 mL	0.5 mL	6 months
3.5 mL Blue ⊤op	Whole Blood	Ambient	To fill line	To fill line	To fill line	2 hours
2 mL Blue Top	Whole Blood	Ambient	To fill line	To fill line	To fill line	2 hours

Chromogenic Factor VIII

Refer to Coagulation Specimen Handling before collecting. Submit 2 × 0.5 mL frozen plasma aliquots for this test.

Draw blood in light blue top tube(s). Spin down, remove plasma, spin plasma again, and place citrate platelet-poor plasma in required number of plastic vials (Glass vials cannot be accepted.) Freeze specimen at less than or equal to minus 40° C, if possible. Send specimen frozen on dry ice. Each coagulation assay requested should have its own vial.



Test Schedule / Analytical Time / Test Priority

Monday - Friday / 1 day / NOT available STAT

Method

Chromogenic Substrate Assay

Instrumentation

ACL TOP

Reference Range

≥ 18 years: 43.2 - 159.3%

CPT(s)

Description

CPT Code

Chromogenic Assay Coagulation Test

85130

Pediatrics Reference Range changes for CBC, Diff and Reticulocyte Counts



Joanna Conant, MD Medical Director Hematology Lab Phone: 847-6700

Effective 05/03/2021, the UVMMC Clinical Laboratory will be reporting updated pediatric reference ranges for a number of components of the complete blood count, including white blood cell count, hematocrit, hemoglobin, platelet count, differential cell counts, and reticulocyte count. In addition to the reference limits themselves, there will also be changes to the age ranges represented. These updated reference ranges are based on a Boston Children's Hospital study that was published in Pediatric Reference Intervals, Eighth Edition, copyright 2021, pages 209-253 by Wong, Brugnara, Straseski, Kellogg and Adeli. These were derived using the Sysmex XN testing platform on which our assays are also performed. The testing platform, test names, and ordering processes remain the same.

Updated Pediatric Reference Ranges for CBC and Reticulocyte:

		Pediatric WBC				Pediatric RBC				Pediatric HGB			
Age	M	ale	Female		Ma	Male		Female		ale	Female		
	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	
1-3 days	7.56	21.26	7.97	23.17	3.57	5.50	3.58	5.42	12.8	19.7	12.8	19.2	
4-7 days	7.54	14.91	7.93	17.11	3.89	5.64	3.80	5.76	13.3	19.3	13.0	19.4	
8-14 days	7.80	17.07	8.00	16.82	3.30	5.30	3.47	5.37	11.0	17.5	12.0	18.3	
15-30 days	6.54	15.44	6.59	15.58	3.00	4.70	3.22	4.76	9.8	15.4	10.2	15.8	
31-60 days	5.85	14.49	6.52	14.75	2.87	4.09	2.95	4.17	9.0	12.9	8.9	12.7	
61-180 days	4.40	14.77	5.51	14.63	3.21	5.48	2.98	4.68	10.1	13.2	10.0	14.1	
0.5 to <2 years	3.74	14.67	4.76	14.43	3.65	5.51	3.54	5.31	10.1	13.6	10.1	13.7	
2 to <6 years	3.97	13.45	4.19	13.63	3.34	5.41	3.65	5.34	10.2	13.7	10.3	13.7	
6 to <12 years	3.44	12.71	3.75	13.09	3.11	5.34	3.41	5.40	10.3	14.3	10.6	14.7	
12 to <18 years	3.13	12.43	3.78	12.06	3.97	5.88	3.38	5.29	11.2	16.4	10.4	14.6	

	Pedi	Pediatric HCT and MHCT				Pediatric MCV				Pediatric MCH			
Age	Ma	ale	Fen	nale	M	ale	Fen	nale	Ma	ale	Fen	nale	
	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	
1-3 days	37.6	56.6	37.4	55.7	96	111	96	112	33.2	37.9	33.3	38.7	
4-7 days	37.9	55.7	36.1	54.7	93	105	92	104	32.6	36.4	31.9	36.4	
8-14 days	32.8	50.5	35.4	53.0	92	104	94	106	31.7	36.2	32.1	36.9	
15-30 days	29.2	45.2	30.0	45.9	90	101	90	102	30.7	35.0	30.6	34.9	
31-60 days	26.3	36.9	27.3	38.6	86	97	87	97	29.3	33.3	29.4	33.4	
61-180 days	25.8	43.8	27.8	40.8	68	92	74	97	21.2	31.4	23.8	32.0	
0.5 to <2 years	28.4	41.2	25.4	40.2	68	88	71	88	19.4	29.1	20.1	29.6	
2 to <6 years	27.4	40.3	28.3	40.9	68	88	68	89	20.3	29.8	19.5	29.9	
6 to <12 years	25.6	42.6	28.4	44.4	70	90	71	93	22.8	30.7	21.6	31.1	
12 to <18 years	33.7	48.7	27.8	43.8	74	94	71	96	23.1	31.7	21.0	32.1	

Pediatrics Reference Range changes for CBC, Diff and Reticulocyte Counts

	Pediatric MCHC				P	Pediatric RDW-CV				Pediatric PLT			
Age	Ma	ale	Fen	nale	Ma	Male Female			Male		Female		
	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	
1-3 days	33.0	36.0	33.1	35.8	15.4	19.9	15.2	19.8	114	295	120	327	
4-7 days	33.8	36.0	33.8	36.0	14.7	18.9	14.6	18.4	142	400	127	391	
8-14 days	33.4	35.8	33.4	35.5	14.1	17.6	14.1	16.8	184	530	206	555	
15-30 days	33.2	35.8	33.0	35.6	13.8	17.2	13.7	16.8	200	480	202	544	
31-60 days	33.0	35.5	32.8	35.5	13.3	16.2	13.1	16.5	252	535	267	564	
61-180 days	29.8	35.8	31.6	36.0	11.8	19.7	11.6	17.3	204	576	196	591	
0.5 to <2 years	30.2	35.0	30.1	35.0	11.9	20.6	11.4	20.7	169	543	175	562	
2 to <6 years	30.3	35.6	29.6	35.4	11.8	18.5	11.7	17.6	168	492	171	504	
6 to <12 years	31.0	35.2	30.2	35.2	11.6	21.1	11.6	17.0	167	462	176	500	
12 to <18 years	30.6	35.3	29.7	35.1	11.5	16.5	11.5	19.3	152	426	159	424	

		Pediati	ric MPV			Pediat	ric RDW-	SD		Pediatric RET			
Age	Ma	ale	Fen	nale	Ma	Male Female			Male		Female		
	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Up-	
1-3 days	9.1	11.1	9.1	11.2					2.7	10.2	3.4	21.0	
4-7 days	9.5	11.9	9.5	11.9	This pa	rameter	will not re	port a ref	1.0	3.6	0.5	4.7	
8-14 days	9.8	12.1	10.1	12.2	range, but will be reported with the				0.5	5.8	8.0	9.9	
15-30 days	9.9	12.4	9.6	12.0	followin	g staten	nent, "No	reference	0.7	4.7	0.4	5.5	
31-60 days	9.2	11.3	9.3	11.4	range o	currently	y availabl	le for	1.1	6.4	1.0	4.6	
61-180 days	8.4	12.1	8.4	12.3	patient	s under	18."						
0.5 to <2 years	8.4	11.7	8.5	11.9									
2 to <6 years	8.4	12.0	8.5	12.1									
6 to <12 years	8.8	12.3	8.8	12.6									
12 to <18 years	8.9	12.8	9.0	12.6									

Pediatrics Reference Range changes for CBC, Diff and Reticulocyte Counts

Newly Added Pediatric Reference Ranges for Differential:

	Pedia		olute Ne	eutro-	Pedia		olute Lyr tes	mpho-	Pediatric Absolute Monocytes			
Age	Ma	ale	Female		Ma	Male		Female		Male		nale
	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper
1-3 days	3.03	11.01	3.02	11.02	1.75	4.35	1.77	4.52	0.53	1.63	0.56	1.46
4-7 days	1.96	4.71	1.98	6.68	2.42	5.83	1.43	5.47	0.57	1.90	0.31	1.53
8-14 days	1.87	5.63	1.71	5.92	2.25	5.58	3.01	5.65	0.68	1.69	0.58	2.18
15-30 days	1.29	4.30	1.37	4.93	2.36	5.87	2.57	5.84	0.63	1.49	0.54	1.47
31-60 days	1.24	4.64	1.31	5.61	1.91	5.59	1.76	5.67	0.53	1.41	0.50	1.43
61-180 days	1.06	7.62	1.17	5.24	2.67	5.94	1.51	5.38	0.56	1.47	0.18	1.30
0.5 to <2 years	1.12	8.76	1.20	7.29	0.68	6.37	2.49	8.17	0.31	1.52	0.35	1.44
2 to <6 years	1.29	8.46	1.35	8.92	1.31	5.75	1.35	5.80	0.33	1.33	0.30	1.30
6 to <12 years	1.27	8.69	1.24	9.22	1.08	4.64	0.94	5.01	0.29	1.22	0.28	1.17
12 to <18 years	1.35	8.54	1.51	9.19	1.03	3.71	1.09	3.94	0.28	1.15	0.26	1.07

	Pedia	ıtric Abs	olute Eo	sino-	Pediat	ric Abso	olute Bas	ophils	Pediatric Immature Grans			
Age	Ma	ale	Fen	nale	Ma	ale	Fen	nale	Ma	ale	Fen	nale
	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper	Lower	Upper
1-3 days	0.01	0.70	0.00	0.57	0.01	0.13	0.02	0.14	0.04	0.41	0.04	0.56
4-7 days	0.02	0.72	0.05	0.80	0.01	0.12	0.01	0.10	0.04	0.37	0.04	0.32
8-14 days	0.01	0.67	0.02	0.74	0.01	0.11	0.01	0.11	0.03	0.16	0.03	0.25
15-30 days	0.02	0.71	0.01	0.65	0.00	0.06	0.00	0.08	0.03	0.12	0.02	0.11
31-60 days	0.00	0.53	0.00	0.52	0.01	0.05	0.01	0.06	0.02	0.10	0.02	0.11
61-180 days	0.06	1.03	0.00	0.52	0.01	0.09	0.02	0.04	0.01	0.05	0.00	0.12
0.5 to <2 years	0.00	0.98	0.00	0.54	0.01	0.09	0.01	0.07	0.00	0.13	0.00	0.07
2 to <6 years	0.01	0.92	0.00	0.75	0.01	0.10	0.01	80.0	0.00	0.08	0.00	0.09
6 to <12 years	0.01	0.94	0.00	0.77	0.01	0.09	0.01	0.09	0.00	80.0	0.00	0.07
12 to <18 years	0.02	0.72	0.01	0.54	0.01	0.09	0.01	0.09	0.00	0.08	0.00	0.08

Change in Reporting for Kleihauer Test, Blood

Effective August 30, 2021, UVMMC Hematology Lab will be making changes related to the reporting of the Kleihauer-Betke assay. Historically, results have consisted of <u>one</u> of the following:

- No Fetal Cells Seen
- Rare Fetal Cell Seen
- Rare Fetal Cells Seen
- A numeric value representing the Fetal/Maternal Hemorrhage in mL.

Going forward, there will be three parts to the report:

- 1. Positive or Negative result
- 2. Fetal/Maternal Hemorrhage in mL
- 3. Doses of RhIG (300 mcg Intramuscular) indicated with the following statement:

"A recommended dose of Rh immune globulin (RHIG, 300 mcg, IM) is reported for all samples. RHIG (anti-D antibody) is given to Rh-negative (D-negative) mothers who are pregnant with an Rh-positive (D-positive) fetus to help prevent development of a maternal immune response (anti-D) to the D antigen on fetal red blood cells. RHIG can be given either before or after delivery. The volume of fetal-maternal hemorrhage determines the dose of RHIG to be administered. Local hospital policies and procedures should be followed to determine if the recommended dose of RHIG is indicated."

If no fetal cells are seen, the result will be reported as Negative, the volume will be reported as 0.0 mL, and the Doses of RhIG (300 mcg Intramuscular) will be reported as 1.

Example of Negative Result

Test, Kleihauer F, 30 yrs, N/A

Report Recipient:

Submitter: Hematology QA Lisa Reste Mailbox

Authorizing Provider

Conant, Joanna L, MD F: 802-847-5905 111 Colchester Avenue, Main Campus, East Pavilion, Level 2, Burlington VT 05401-1473

Kleihauer blood (Final result)

Component	Value	Ref. Range
Kleihauer Test	Negative	Negative
mL F/M HEMORRHAGE:	0.0	0.0 mL F/M HEMORRHAGE

Doses of Rhlg (300 mcg intramuscular):

A recommended dose of Rh immune globulin (RHIG, 300 mcg, IM) is reported for all samples. RHIG (anti-D antibody) is given to Rh-negative (D-negative) mothers who are pregnant with an Rh-positive (D-positive) fetus to help prevent development of a maternal immune response (anti-D) to the D antigen on fetal red blood cells. RHIG can be given either before or after delivery. The volume of fetal-maternal hemorrhage determines the dose of RHIG to be administered. Local hospital policies and procedures should be followed to determine if the recommended dose of RHIG is indicated.

Resulting Lab: UVMMC LAB

Change in Reporting for Kleihauer Test, Blood

Example of Positive Result

Test, Klehauer F, 30 yrs, N/A

Report Recipient:

<u>Submitter:</u> Hematology QA Lisa Reste Mailbox

See Values: mL F/M HEMORRHAGE: (HH), Kleihauer Test (A)

Authorizing Provider

Conant, Joanna L, MD F: 802-847-5905

111 Colchester Avenue, Main Campus, East Pavilion, Level 2, Burlington VT 05401-1473

Kleihauer blood (Final result)

Component	Value	Ref. Range
Kleihauer Test	Positive (A)	Negative
mL F/M HEMORRHAGE:	15.0 (HH)	0.0 mL F/M HEMORRHAGE

Doses of Rhlg (300 mcg intramuscular):

A recommended dose of Rh immune globulin (RHIG, 300 mcg, IM) is reported for all samples. RHIG (anti-D antibody) is given to Rh-negative (D-negative) mothers who are pregnant with an Rh-positive (D-positive) fetus to help prevent development of a maternal immune response (anti-D) to the D antigen on fetal red blood cells. RHIG can be given either

before or after delivery. The volume of fetal-maternal hemorrhage determines the dose of RHIG to be administered. Local hospital policies and procedures should be followed to determine if the recommended dose of RHIG is indicated.

Resulting Lab: UVMMC LAB

The current test, LAB762, will be inactivated and replaced by the new test, LAB15186:

New Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Kleihauer Test, Blood	LAB15186	LAB15186	FAH5943	32140-6
New Reportables	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Kleihauer Test	12301011923	LRR11923	FAH5944	32140-6
mL F/M Hemorrhage	12301011924	LRR11924	FAH5945	48555-7
Dose of Rhlg	12301011925	LRR11925	FAH5946	1313-6
Current Orderable Name	Epic Code	Atlas Code	Mayo Access ID	LOINC Code
Kleihauer Test, Blood	LAB762	KLI	FAH5917	48555-7

There will be no changes to the methodology, specimen requirements, or units of measure reported.

Parasite Exam, Blood Test: Instructions for Preparing Smears

Blood films should be made as soon as possible after collection to avoid prolonged exposure to EDTA anticoagulant. For laboratories submitting a sample (smears) for a blood parasite exam **and** the blood sample is not expected to arrive in the UVMMC lab within 2-4 hours of specimen collection, 3 thin blood smears and 2 thick blood smears should be prepared from the blood specimen. Send smears along with the original EDTA specimen and include the patient's travel history when available.

Test Name	Epic Code	Mayo Access ID	Atlas Code
Parasite Exam, Blood	LAB2545	FAH5888	BPEX

Instructions for preparation of thin and thick blood smears:

- 1. Slides must be clean and grease-free.
- 2. Prepare 3 thin blood films as follows:
 - a. Prepare 3 thin smears with either the mini prep-slide machine OR by manually dropping and spreading (with another clean slide) a thin film with a "feathered edge" that is no more than a single cell thick.
 - b. Allow the film to thoroughly air dry and then fix by briefly immersing in either absolute or 95% methyl alcohol Methanol).
 - c. Allow to air dry after fixation.
 - d. Place the slides in a transport container.
- 3. Prepare 2 thick blood smears as follows:
 - a. Place a large drop of blood (approximately the size of a dime) on a slide.
 - b. Using a corner of a second slide, spread the drop in a circular motion while applying firm pressure to literally scratch the blood onto the carrier slide. This technique allows the blood to dry quickly and adhere well to the slide. Use approximately 20 circular sweeps with the second slide. The drop of blood should be about the size of a quarter when finished.
 - c. Do not fix. Air dry thoroughly (approximately 45 minutes) before placing in transport container.

Reference: Mathison BA, Pritt BS: Update on Malaria Diagnostics and Test Utilization. J Clin Microbiol 2017 Jul; 55 (7):2009-2017

For questions, please contact the UVMMC Microbiology Lab.

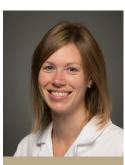
New Anatomic Sites Validated for CTGC Testing at UVMMC

Starting on 8/11/21, specimens collected using the Aptima Multitest Swab collection kit from **rectal/anal** or **oral/ throat** (**pharynx or pharyngeal**) anatomic sites can be sent to the UVMMC Laboratory for Chlamydia trachomatis/ Neisseria gonorrhea testing by nucleic acid amplification. Currently, we are forwarding these requests to Mayo. However, the Mayo test, LAB15690, will be inactivated.

Orderable to be edited	Epic Code	Atlas Code	Mayo Access ID	Mayo ID
Chlamydia/N. gonorrhoeae Detection,	LAB2664	CTGC	FAH5409	N/A
Amplified Nucleic Acid				
AOE Resultable to be edited	Epic Code	Atlas Code	Mayo Access ID	Mayo ID
Specimen	N/A	SDESCT	N/A	N/A
	Specimen Site-Code		Current/New	
drop-down list of choices:	Endocervix-ENDO		current	
	Penis-PEN		current	
	Urine-URI Urethral-URTH Vagina-VAG Cervix-CX Rectal/Anal-REC		current	
			new	
	Oral/Throat-ORA		new	
Orderable to be Inactivated	Epic Code	Atlas Code	Mayo Access ID	Mayo ID
Chlamydia/Gonorrhoeae Amplified RNA,	LAB15690	LAB15690	N/A	CGRNA
Oral/Throat or Rectal/Anal Only				

Aptima Multitest Swab Collection kits are available through UVMMC Laboratory Customer Service, (802)-847-5121. Aptima Multitest Swab Collection kit:





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

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 Lyme confirmation using Diasorin semi-quantitative direct IgG and IgM immunoassays. 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: EHRL, EPIC test code: LAB3614).

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

Tick-Borne Disease Antibodies Panel, Serum.

Tick-Borne Panel, Molecular Detection, PCR, Blood

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)

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

Update to UVMMC PAP & HPV Testing

Earlier in 2021, UVMMC modified the reflex algorithm for High Risk (HR) HPV testing to align with the latest, age-based, ASCCP guidelines, http://www.asccp.org.

The new guidelines require that the Pap order include information defining the test as either screening or diagnostic.

- Screening: Routine exam, no recent abnormal results, not in follow up testing for dysplasia or abnormal results symptoms
- **Diagnostic**: Previous abnormal Pap findings, signs or symptoms, or has significant complaints related to the female reproductive system

HPV testing is reflexed from the Pap using different options based on the indication of screening or diagnostic:

For **Screening**, the HPV testing options are:

- HPV Regardless of Diagnosis (Co-Test) This is for patients 30 years old and older. HPV will always be performed.
- HPV if ASCUS This is for patients 25-29 years old. HPV testing will be performed if the Pap result is ASCUS.
- None (Note that Medicare patients 65 years or older are NOT eligible for HPV testing from screening Pap tests).

For **Diagnostic testing**, the HPV testing options are:

- HPV Regardless of Diagnosis (Co-Test) This is for patients 30 years old and older. HPV will always be performed.
- HPV Regardless for other diagnostic testing This is for patients that are 25-29 years old with previous abnormal Pap
 results that need HPV results for patient management.

*ASCUS – Atypical squamous cells of undetermined significance





111 Colchester Avenue Burlington, VT 05401

PATHOLOGY & LABORATORY MEDICINE COMMUNIQUÉ — SUMMER 2020

PATHOLOGY & LABORATORY MEDICINE COMMUNIQUÉ

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WEBSITE

UVMHealth.org/MedCenterLabs

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 on 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