WINTER 2025

THE University of Vermont MEDICAL CENTER

Pathology & Laboratory Medicine Communiqué

IN THIS ISSUE

Order Status and Results Explained

Typically, there are two different order statuses offered for lab results, Routine or STAT, usually defined as-

Routine – The results of the testing are being used to diagnose, treat or monitor a patient as part of their regular medical care.

STAT – The results are being used immediately to determine treatment in a critical or life-threatening situation for a patient. These tests are prioritized above all others upon being received in the laboratory. Not all testing is available STAT.

A word about lab turnaround times, typically high-volume chemistry and hematology tests result within 24 hours of being received in the lab, though it can be longer for

- Microbiology where the organisms take time to grow before drug sensitivities can be performed
- Cytology
- Surgical pathology
- Other specialized testing like flow cytometry or genetic testing
- Tests sent out to another reference laboratory

Lab Operations

DISCONTINUATION OF STAT PHONE CALLS

UVMMC Lab Customer Service will no longer call outside clients with results of tests ordered STAT. Lab Customer Service will continue to call the ordering provider's office when there are critical values to convey (See link below for UVMMC Lab Critical Values Policy).

UVMMC Lab Critical Values Policy

CELLULAR THERAPY

The Cellular Therapy Lab is undergoing renovations to become an enclosed off section of the lab for processing. This will allow us to have a dedicated space as we continue to grow and bring on additional CAR T products. Renovations should be completed in the middle of March.

COAGULATION

The UVMMC Thrombosis and Hemostasis Laboratory has updated the reportable ranges for the **von Willebrand Factor (WVF) activity and Factor XIII (13) antigen** tests to comply with the manufacturer's instructions for use:

Analyte	Reportable Ranges		Date of change
	Previous	New	
VWF Activity	<14% to >390%	**<19%** to >390%	February 24, 2025
FactorXIII (13) Antigen	<2.5% to >150%	**<3.8%** to >150%	February 10, 2025

If you have any questions, please contact any of the following:

- Kristin E. Lundy, MHA, CLS, Coagulation Technical Specialist
- Dr. Andy Goodwin, Coagulation Medical Director
- Dr. Marian Rollins-Raval, Division Chief for Hematopathology and Coagulation

Annual Note to Clinicians ordering Pap tests.

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

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

PAP AND HPV TESTING

In order to appropriately test and charge for Pap testing, our laboratory requires that **all** Pap test orders be identified as screening or diagnostic. This is to help ensure your patients do not receive bills for covered services.

- Screening: Routine exam, no current symptoms, no previous abnormal findings
- Screening-High Risk: Patients at high risk to develop cervical or vaginal cancer due to risk factors below:
  - ◊ Early onset of sexual activity (under 16 years)
  - ◊ Multiple sexual partners (5 or more in a lifetime)
  - ◊ History of sexually transmitted disease (including HIV)
  - ◊ Fewer than 3 negative Pap tests within the last 7 years
- Diagnostic: Previous abnormal Pap findings, signs or symptoms, or has significant complaints related to the female reproductive system

High Risk (HR) HPV Testing

Our high-risk HPV reflex algorithm is based on the ASCCP guidelines found at https://www.asccp.org/guidelines

Current HPV Testing Pathways:

For **screening and diagnostic testing**, HPV testing options are:

- **Regardless of Diagnosis (Co-Test)**
  - ◊ High Risk HPV testing will always be performed and include a genotyping result for HPV 16, HPV 18, and HPV Other High Risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68).
- **If ASCUS Pap Diagnosis**
  - ◊ High Risk HPV testing will be performed if the Pap test diagnosis is Atypical Squamous Cells and include genotyping results
- **None**

Please note that HPV testing options listed above may be outside of recommended ASCCP guidelines.

- HPV testing for ASCUS diagnoses is intended for patients 25-29
- Medicare patients 65 years or older are NOT eligible for HPV testing on screening Pap tests.
- HPV Regardless of Diagnosis (Co-Test) is intended for patients 30 to 65

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.

If the sample source is Vaginal and HPV testing is ordered, the sample will be sent to Mayo Clinic Laboratories, as UVMMC has not validated HPV testing on this specimen type. If the sample source is Anus, HPV testing will not be performed at UVMMC. If HPV testing is required on an anal source, the specimen will be forwarded to Mayo Clinic Laboratories for testing.

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Lab Interest

HUMAN MICROBIOME

-What is the human microbiome?

The human microbiome represents the collection of all microorganisms residing on or within the human body, including bacteria, viruses, fungi, and archaea. Bacteria in particular are a key component of the human microbiome; most sources estimate that there are actually more bacterial cells than human cells in the human body!

These tiny tenants are particularly concentrated in the skin, nose, digestive tract, and vagina. Some organisms can be pathogenic, but the vast majority are commensal (meaning they can coexist without causing problems) or mutualistic (meaning they provide a benefit to their human hosts). For example, mutualistic gut bacteria plays a key role in immune defense against pathogens, the synthesis of important vitamins (including most B vitamins, which we cannot produce for ourselves), and digestion of otherwise unusable dietary polysaccharides. As a result, alterations to the microbiome are implicated in a variety of chronic health issues, such as obesity, diabetes, cancer, and cardiovascular disease.

Although the microbiome has profound effects locally, the complex interplay of microorganisms can also have broad systemic effects, which researchers are just beginning to unravel. For example, the “brain-gut axis” is a complex network of neurotransmitters in the digestive system and central nervous system which can be modulated by the microbiome. Serotonin is a neurotransmitter that most people correctly associate with mood, and yet only about 10% of the body’s serotonin is produced in the brain! The remaining 90% is produced in the gut, with significant production by bacteria in the colon. Changes in diversity and stability of the microbiome are being investigated as possible determinants in mental health, stress response, cognitive development, and in neurocognitive disorders of the elderly.

-How do we test the microbiome, and what is the clinical utility?

Microbiome testing is typically conducted with a stool sample, and involves sequencing the genes found in the sample to determine the prevalence of different microbes. As the microbiome and its health implications have gained popularity in public awareness and the media, commercially available microbiome “test kits” have exploded in popularity, with widely variable promises of insight into the patient’s gut health. These at-home test kits are not approved by the Food and Drug Administration (FDA) and their reliability is controversial.

There is significant interest in using the gut microbiome for diagnostic purposes in medicine, but its utility is currently limited. One issue is that although stool is a convenient specimen for collection, it does not capture all microbes within the microbiome or even within the gut, particularly due to adherence of some microbes to the intestinal mucosa. Storage of stool in the rectum also alters the composition of the bacteria, which can skew proportions of different microorganisms.

The predominant method for analysis of the microbiome involves sequencing of bacterial 16S ribosomal RNA, which is an effective method for identifying and quantifying the spectrum of most microorganisms present in the sample. However, the sheer amount of information means that rare but potentially important bacteria may be missed amongst more prevalent organisms, and interpretation of the results is a significant challenge.

Another reason for the difficulty in interpretation of microbiome testing is that the composition of a bacterial microbiome can vary drastically from person to person, even in small cohorts. As a result, there is no standard defined “healthy” microbiome composition to compare against. The staggering level of microbiome diversity also is an important factor; we don’t know enough about each microorganism in the microbiome to accurately predict their role within the larger context of the human microbiome.

Lab Interest

HUMAN MICROBIOME (*CONTINUED*)

Although there are significant hurdles to overcome before microbiome testing has widespread use in diagnostic medicine, some limited uses are showing promise in clinical applications. For example, bacterial vaginosis is a condition caused by excessive growth of normal vaginal flora, also called dysbiosis. Because the vaginosis is caused by imbalance of normal vaginal organisms rather than introduction of a new pathogenic organism, traditional bacterial identification methods are of limited utility in diagnosis. However, molecular assays of the local vaginal microbiome can provide a quantitative result, reflecting the proportion of different microorganisms for more effective treatment.

Despite the challenges presented by testing and interpretation of the microbiome, significant research and clinical strategies are being explored for ways to effectively modify the microbiome to optimize health. One of the clinical applications in current use is fecal microbiota transplantation (FMT) in the treatment of severe antibiotic-refractory *Clostridium difficile* infection. FMT involves transplantation of healthy donor fecal material into an infected individual, typically through colonoscopy, enema, or oral capsule. FMT has shown remarkable effectiveness, with approximately 80-90% success in preventing *C.diff* recurrence after antibiotic therapy. FMT is only currently approved for the treatment of recurrent *C. diff* infection, but is being researched as a potential treatment strategy for a wide array of conditions, including obesity, food allergies, diabetes, and inflammatory bowel disease.

FLU SURVEILLANCE REPORT

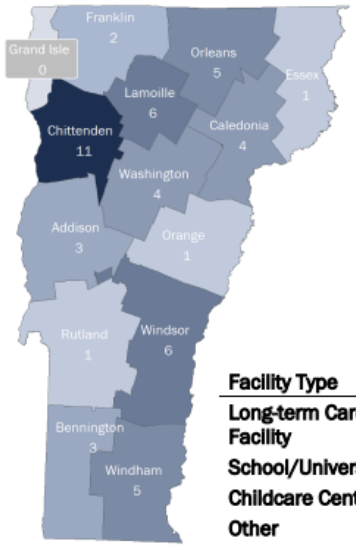
The **Health Department Lab** performs surveillance subtype testing to determine the type of flu, for example H3, H1N1, etc. This information helps determine the circulating virus strains, not the spread of flu virus. These results are reported by subtype testing date.

Type and Subtype	This week: 02/23/2025-03/01/2025	Season so far: 09/29/2024-03/01/2025
Flu A H1pdm09	33	268
Flu A H1pdm09/Flu A H3 co-infection	0	0
Flu A H3	18	137
Flu B Victoria	1	18

Reported Outbreaks

Institutional outbreaks of flu or influenza-like illness (excluding respiratory illnesses not caused by influenza viruses, e.g., COVID-19) are reportable to the Health Department.

Number of Influenza-like Illness and Influenza Lab Confirmed Outbreaks, 09/29/2024-03/01/2025



Facility Type	# Outbreaks Reported 02/23/2025-03/01/2025	Full Season 09/29/2024-03/01/2025
Long-term Care Facility	6	19
School/University	0	22
Childcare Center	0	2
Other	1	9

For more information: AHS.VDHEpiFluSurv@vermont.gov

Compliance

Disclosure of Medicare Regulations

The Office of Inspector General (OIG) guidance recommends clinical laboratories distribute a notice to ordering clinicians at least annually. This notice provides guidance used by UVMMC laboratory for submitting claims to Medicare, Medicaid and other federally funded healthcare programs.

Medical Necessity

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

National and Local Coverage Determinations

Medicare publishes their coverage limitations in the Medicare Beneficiary Handbook and further defines specific coverage limitations by establishing national or local policies. These policies are referred to as National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). They limit and define the diagnosis (ICD-10) codes that support medical necessity for laboratory tests. Diagnosis (written narrative or ICD-10 code) on the laboratory requisition reflecting the patient's signs/symptoms for the testing ordered is the means by which Medicare determines medical necessity. Diagnosis is a **required** field on our laboratory requisitions for **all** lab orders.

Medicare covers defined preventative (screening) services. Medicare NCD and LCD policies and lab related preventative services are posted on our UVMMC Pathology and Laboratory Medicine webpage in the Compliance Information link and on the final page of this document. Medicare coverage policies can be issued or revised at any time, and will be updated and shared as they are received.

Advance Beneficiary Notice

The ABN is a standardized notice that must be given to a Medicare beneficiary when certain Medicare Part B outpatient items or services may not be paid for by Medicare. Medicare does not require ABNs for "statutorily excluded" care, or services Medicare never covers. However, in these situations, a voluntary ABN may be issued. The ABN is not used for patients with a Managed Medicare plan i.e. Medicare HMO. The Commercial Advance Notice of Potential Non-Coverage must be used instead. The current, CMS-approved form R-131 must be used (UVMMC form number 032739). An ABN must be issued when Medicare is expected to deny payment for an item or service because it is not reasonable and necessary under Medicare Program standards. UVMMC has an Epic software notification for services ordered that are subject to Medicare coverage policy and associated with a non covering diagnosis code. This provides the ordering department an opportunity to either associate a diagnosis code that is covered (must be supported by documentation), or inform the patient of potential financial responsibility and obtain an ABN. The forms are also available for download on the UVMMC Pathology and Laboratory Medicine webpage.

The ABN allows beneficiaries to make an informed decision and understand the cost prior to receiving a non covered service. A correctly documented ABN is proof that a beneficiary accepts financial responsibility for services if Medicare does not pay. If an ABN is not issued or Medicare finds the ABN invalid, UVMMC may not bill the beneficiary for the services and may be financially liable.

American Medical Association (AMA) Approved Organ or Disease Oriented Panels

UVMMC offers the American Medical Association (AMA) organ or disease oriented panels listed: Basic Metabolic Panel, Comprehensive Metabolic Panel, Electrolyte Panel, Lipid Panel, Liver (Hepatic Function) Panel and Prenatal Panel. The back of our laboratory requisition contains a list of tests included in each panel with the CPT code used for billing. Our Lab Joint Test Catalog also describes what is included in each panel. These panels should only be ordered when all the tests in the panel are medically necessary. UVMMC's Laboratory requisition provides the option to order a panel or individual tests.

Reflex Testing

Reflex testing occurs when initial test results are outside of normal parameters and indicate additional related testing is appropriate and medically necessary. UVMMC laboratory offers reflex testing in accordance with the OIG Compliance Program Guidelines for Clinical Laboratories. Tests subject to reflex are on our requisitions, electronic ordering system (Epic) and Joint Test Catalog. Clinicians may decline reflex testing if it is not medically necessary. Reflex testing may result in additional charges.

Medical Laboratory Fee Schedule

The Medicare Clinical Laboratory Fee Schedule (CLFS) is available at Clinical Laboratory Fee Schedule Files | CMS Medicaid reimbursement will be ≤ the amount of Medicare reimbursement.

Physician Clinical Consultants

For questions regarding laboratory test ordering or interpretation of results with our staff pathologists, contact Lab Customer Service at 847-5121. A list of pathologists is available on our website (https://www.uvmhealth.org/medcenter/) at "FIND A DOCTOR".

Medicare Pre and Post payment probes:

Medical record documentation must support medical necessity for Medicare to cover services. The laboratory is your patient care partner and wants to provide accurate supporting documentation when submitting claims and may request additional diagnosis and medical information from your office to document the billed services are reasonable and necessary.

(Disclosure of Medicare Regulations cont.)

Compliance

Appropriate documentation includes:

- A signed office note from a visit where the provider ordered a diagnostic or other service.
- For incident to services, a care plan by the supervising physician or nonphysician practitioner.
- Lab orders for recurring tests to meet the specific needs of an individual patient
- Documentation regarding the date of the service(s) and/or any prior progress notes.

Related Content

Complying with Medical Record Documentation Requirements

Collaborative Patient Care is a Provider Partnership

Additional Development Requests

Code of Federal Regulations 42 CFR §424.5(a) (6).

National Coverage Determinations (NCD's)	
Alpha-fetoprotein (AFP)	Human Chorionic Gonadotropin (HCG)
Blood Counts (Hemagram, Hemagram w/ Diff, WBC, Hemoglobin, Hematocrit, Platelet Count)	Lipids (Lipid panel, Total cholesterol, Triglycerides, measured LDL, HDL, Lipoprotein quantitation and fractionation)
CA 125	Iron Studies (Iron, Ferritin, IBC, Transferrin
CA 15-3/27.29	Partial Thromboplastin Time (PTT)
CA 19-9	Prostate Specific Antigen (PSA)
Carcinoembryonic Antigen (CEA)	Prothrombin Time (PT)
Collagen Crosslinks	Thyroid Testing (Total & Free T4, TSH, T3 or T4 Uptake)
Digoxin	Urine Culture & Pathogen Susceptibility Testing
Fecal Occult Blood	190.1 Histocompatibility
Gamma Glutamyltransferase (GGT)	190.2 Diagnostic Pap Smears
Glucose Testing	190.3 Cytogenetics Studies
Glycated Hemoglobin/Glycated Protein (A1C)	190.5 Sweat Tests
HIV- Prognosis/Diagnosis	190.8 Lymphocyte Mitogen Response Assays

Local Coverage Determinations (LCD's)	
B-type Natriuretic Peptide (BNP)	Biomarker Testing (Prior to initial biopsy) for Prostate cancer
Urine Drug Testing	Genomic Sequence Analysis in Treatment of Hematolymphoid Diseases
Molecular Pathology Procedures	Genomic Sequence Analysis in Treatment of Solid Organ Neoplasms
Rast Type Test	Respiratory Pathogen Panel Testing
Vitamin D Assay	Multiplex Gastrointestinal Pathogen Panel for acute gastroenteritis
Heavy Metal Testing	Mass Spectrometry (MS) Testing in Monoclonal Gammopathy

Preventative Services	
Cardiovascular Disease Screening	HIV Screening
Colorectal Cancer Screening	PAP Test Screening
Diabetes Screening	Prostate Cancer Screening
Hepatitis B Virus Screening	Screening for Cervical Cancer with Human Papilloma Virus (HPV)
Hepatitis C Virus Screening	Screening for STIs and HIBC to Prevent STIs

New Test Updates

Interleukin 2 Receptor Alpha Soluble, Plasma

Effective 3/13/25, the Mayo test Interleukin 2 Receptor, Soluble (Mayo Test ID FIL2S) will be obsolete and replaced with the new test, Interleukin 2 Receptor Alpha Soluble, Plasma (Mayo Test ID SIL2R).

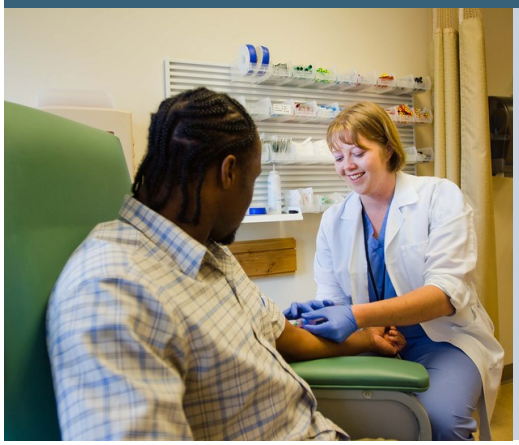
Test Build Information:

New Orderable	Epic Code	Atlas Code	Mayo Test ID	Order LOINC	CPT Code(s)
Interleukin 2 Receptor Alpha Soluble, Plasma	LAB17780	LAB17780	SIL2R	76039-7	83520
Result Component(s):	**Epic Code**	**Atlas Code**	**Mayo Test ID**	**Result LOINC**	**Notes**
IL-2 Receptor Alpha Soluble, Plasma	12301020815	M622328	622328	76039-7	
Specimen Requirements:					
Container	**Specimen**	**Temperature**	**Collect/Submit Vol**	**Min Vol**	**Stability**
Lavender Top (EDTA)	Plasma EDTA	Frozen	1 mL/0.5 mL	0.3 mL	21 days
Collection Information:					
UVMMC: Must be collected at the ACC, Main Campus.					
1. Immediately after specimen collection, place tube on wet ice.					
2. Centrifuge at 4 degrees C, 1500 x g for 10 minutes.					
3. Aliquot plasma into plastic vial.					
4. Freeze specimen within 2 hours of collection.					
If a refrigerated centrifuge is not available, it is acceptable to use a room temperature centrifuge, provided the sample is kept on ice before centrifugation and is frozen immediately afterward.					

Orderable to be Discontinued	Epic Code	Atlas Code	Mayo Test ID	Order LOINC	CPT Code(s)
Interleukin 2 Receptor, Soluble	LAB15347	LAB15347	FIL2S	76039-7	83520

For questions regarding this change, contact UVMMC Lab Outreach at laboutreach@uvmhealth.org.

LABORATORY PATIENT SERVICE CENTER



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

One South Prospect
1 South Prospect St
First Floor Lobby
Burlington, VT

Fanny Allen Campus
792 College Parkway
Colchester, VT

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

All UVM Medical Center phlebotomists are nationally certified

Previously Distributed Test Updates

Please click on the links below to view the corresponding Test Updates.

The links can be found here: http://tinyurl.com/UVMMC-Test-Updates

CMV Molecular Detection, PCR Update - Effective 2/18/2025

Change in Submit Temperature for Multiple Tests - Effective 2/26/2025

Alkaline phosphatase, Total and Isoenzymes, Serum Update - Effective 1/30/2025

Apixaban Testing - Effective 1/21/2025

Sedimentation Rate, Westergren Stability Update - Effective 12/23/2024

CSF IgG Index Profile, Serum and CSF Update - Effective 12/19/2024

Prostaglandin D2 (PGD2) - Effective 12/18/2024

Aspergillus Antigen, Bronchoalveolar Lavage (BAL) Effective 12/18/2024

Pediatric Autoimmune Encephalopathy/CNS Disorder Evaluation Testing Effective 12/16/2024

INR Critical Values Effective 12/16/2024

Creutzfeldt-Jakob Disease Evaluation, CSF Effective 12/11/2024

Arbovirus Ab Panels Effective 12/11/2024

SPEP Reporting Effective 11/25/2024

Mayo Test Updates 23BPT and NMH24 Effective 11/14/2024

ReproSource AMH Testing to be Discontinued Effective 11/18/2024

Methadone and Metabolites, Serum Testing to Resume Effective 11/18/2024

SARS CoV-2, Molecular Detection, BAL or Bronchial washings Effective 11/12/2024

Bordetella Pertussis Parapertussis, PCR Testing Effective 11/6/2024

Test Name Change from Opioids to Opiates Effective 10/30/2024

Update to Antimicrobial Susceptibility Panels Effective 11/10/2024

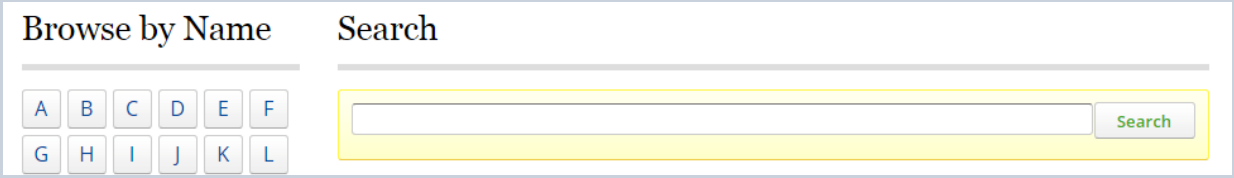
Fit Test Update Effective 10/28/2024

Genomic Testing available to Outreach Effective 10/23/2024

POC Lipid Screening Update Effective 10/10/2024

TEST CATALOG

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



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PATHOLOGY & LABORATORY MEDICINE COMMUNIQUÉ

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(800) 991-2799

FAX LABORATORY CUSTOMER SERVICE
(802) 847-5905

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