

## Pathology & Laboratory Medicine

# Communiqué

### IN THIS ISSUE

Welcome Dr. Clayton Wilburn	[ pg. 1]
An update on Neutral Buffered Formalin Fixation	[pg. 2]
Serum Tube Change <i>Compliance Information</i>	[pg. 2-3]
Preventative Services	[pg. 3]
Coding Tips for Tick Bites and Lyme Disease	[pg. 3]
Genetic Testing on Medicare Patients	[pg.4]
<i>Test Updates</i>	
Urine Cytology: Introduction to the Paris System	[pg.5]
Bordetella Pertussis PCR	[pg. 6-7]
Blood Fungal & AFB Culture Specimen Volume	[pg. 8]
Fungal Smear Name Change	[pg.8]
Aptima Vaginal Swab Collection Kit Name Change	[pg. 8]
Babesia Species, Molecular Detection, PCR Blood: Change in Ability to Order	[pg.9]
HIV Viral Load Reporting Range	[pg.10]
Testosterone Reference Range Change	[pg. 11]
Hemoglobin A1c Reference Range Terminology Change	[pg.12]
HSV Type 1 & 2 Antibody IgG Change	[pg.13]
Urinalysis Method Change	[pg.13-15]

### Laboratory

#### Customer Satisfaction Survey

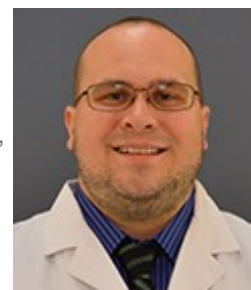
Please take the time to fill in our [brief survey](#) about the laboratory services we provide to you. Responses are confidential unless you chose to leave your name. We welcome your comments and suggestions.

### LABORATORY OPERATIONS



## Welcome Dr. Clayton Wilburn

We are pleased to introduce Dr. Clayton Wilburn our new Clinical Chemistry Director who replaced Dr. Greg Sharp who retired this summer. Dr. Wilburn graduated from Vanderbilt University Medical School, obtained his Clinical Pathology residency training at the University of Texas Medical Branch in Galveston, followed by a two year fellowship in Clinical Chemistry at Houston Methodist Hospital in Texas. In addition to Clinical Chemistry, Dr. Wilburn is also responsible for Immunology and Point-of-Care Testing sections of the laboratory.



Clayton Wilburn, MD

Mark K Fung, MD PhD FCAP

Professor, Pathology & Laboratory Medicine and Radiation Sciences

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## An Update on Neutral Buffered Formalin Fixation

The College of American Pathologists (CAP) recommendation for all breast specimens is they be placed in formalin within one hour of removal from the patient and fix for at least 6 hours. Currently, there is no standard or mandatory recommendation for specimens from other organs. However, there is a standard specimen handling recommendation by the CAP for immunohistochemistry (IHC) which recommends a minimum fixation time of 6 hours for small specimens and 24 hours for specimens larger than 4 mm. In order to improve and deliver consistent and high quality IHC staining, and in anticipation of possible upcoming CAP guidelines, Histology and Surgical Pathology at the University of Vermont Medical Center began adhering to this recommendation on May 8<sup>th</sup>, 2017. In addition, we replaced Zinc Formalin in our tissue processor with 10 % Neutral Buffered Formalin which began on July 14, 2017. This standardizes us with our network partners.

The majority of our specimens already meet the above criteria. We have been monitoring turn-around times for client hospitals and have not identified any concerns or worrisome trends in regards to both the fixation recommendation time and change to zinc formalin solution.

## Serum Tube Changes

The laboratory will change Serum Separator Tubes (SST) and Plain Red Top serum tubes. This change is necessary because we are installing new automation in the laboratory that can't accommodate the current size tubes. We will discontinue the 4 and 8 mL SST tubes and replace them with a 5 mL gel tube. Additionally, we have 6 mL plastic plain red top serum tubes available for testing that can't be collected in a gel tube. The majority of tests that currently require a red top can be collected in the new plastic tube. The current glass tubes are still required for a small number of low volume tests, including methotrexate and HLA testing and will be stocked accordingly. If you believe you need a glass tube for a particular test please contact Lab Customer Service at 847-5121.

### SERUM SEPARATOR TUBES (SST)

**Current Tubes**      **New Tube**  
 4 mL      8 mL      5 mL



### PLAIN RED TOP TUBE

**New Tube**      **Glass Tube**  
 6 mL Plastic      10 mL Glass



## COMPLIANCE INFORMATION

**Coding Corner:****The following tests are considered Preventive Services by Medicare and are subject to frequency and diagnosis coding limitations:**

Cardiovascular Screening: Lipid Profile, Cholesterol, Triglycerides

Diabetes Screening: Glucose (Does not include A1C)

Hepatitis C Screening: Hepatitis C antibody

HIV Screening

Prostate Screening: PSA

Cervical Cancer: PAP and HPV

Screening for STIs: Chlamydia/GC, Syphilis, Hepatitis B surface Antigen

Colorectal Cancer: fecal occult blood

A quick reference is available on our Lab Website to aid with coding and frequency limitations:

<https://www.uvmhealth.org/medcenter/Documents/Departments-and-Programs/Compliance%20Updated/Preventive%20Service%20NCD/ICD-10%20Quick%20ref-%20preventive%20screening.pdf>

**Coding tips for Tick bite testing for Lyme Disease:**

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

If the patient presents with signs or symptoms, you must include those codes.

In the absence of signs/symptoms, you must code to the body part that was bitten if known.

**PRISM USERS:** In the PRISM order “Associated Encounter Diagnosis” Field -Type in “insect bite” **and** the body part (ex. Insect bite thigh) then select the correct laterality.

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

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

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

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

(Continued on page 4)

## GET TEST RESULTS ONLINE!

MyHealth Online

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

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

## Genetic Testing on Medicare patients - Need for Advance Beneficiary Notice of Non-Coverage (ABNs)

When a genetic test is ordered for a Medicare beneficiary, an Advanced Beneficiary Notice of Non-Coverage (ABN) should be completed and signed by the patient. This must occur when the provider is ordering the test, as phlebotomists cannot discuss medical necessity of testing with patients.

Link to ABN form - <https://www.uvmhealth.org/medcenter/Documents/Departments-and-Programs/Compliance%20Updated/Compliance%20Forms/ABN%20of%20Noncoverage.pdf>

Many genetic tests are **not** covered by Medicare. Among these are:

Factor V Leiden (R506Q) mutation

Prothrombin G20210A mutation

5,10-Methylenetetrahydrofolate Reductase mutation

Huntington Disease (HTT) mutation analysis

Due to the complexity of the Molecular Pathology testing policy, the ABN checker in PRISM is not available.

### Background information:

Payments for laboratory testing are subject to the Local Coverage Determination process (LCD- L35000). As a result of this LCD process, Medicare does not preauthorize **any** laboratory tests as coverage for laboratory testing is predetermined based on written policies. Often, there is a misunderstanding that if prior authorization is not needed, the testing is paid for by Medicare, but unfortunately, this is not true. Without an ABN, UVMHC is not allowed to bill the patient for any testing that is subject to a Medicare policy, including the tests listed above.

Provided below is a link to the LCD policy:

Molecular Pathology LCD (L35000)- <https://www.uvmhealth.org/medcenter/Documents/Departments-and-Programs/Compliance%20Updated/MolPathLCD.pdf>

Should you have any questions about Medicare coverage for your patients, please contact our Laboratory Compliance office 847-5121.

## TEST UPDATES



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## Urine Cytology: Introduction to the Paris System

The Cytology Department will begin using the **Paris System for Reporting Urinary Cytology**. The Paris system was developed by a working group comprised of national and international experts in the urologic field, including urologists, cytopathologists and surgical pathologists. The ultimate goal is to help

standardize the reporting of urinary cytology to enhance overall patient care with improved reproducibility and communication. The **Paris System** is designed to identify high grade urothelial carcinoma with the realization that low grade lesions are typically more indolent, well-visualized by cystoscopy and often impossible to distinguish cytologically from benign reactive changes.

Two important changes will now be seen in cytology reports, effective October 1, 2017. Cases with no malignant cells will be signed out as **“Negative for High Grade Urothelial Carcinoma”**, with the knowledge that some of these cases may include low grade lesions. In addition, the atypical category will now have higher significance in that cases flagged as **“atypical”** will only include cases that have atypical cells with no significant explanation for the atypia (recent treatment, calculi, neobladder, infections). It is of vital importance for all providers to provide a thorough clinical and urologic history to help us minimize the use of the atypical category.

In conjunction with the implementation of the Paris System, the Cytology Department at UVM-MC will have volume recommendations regarding voided urine samples submitted for cytologic evaluation. Two recently published articles noted an increase in the sensitivity of detection for high grade urothelial carcinoma when volumes greater than 25cc of fresh urine were received for evaluation. Voided urine samples lacking adequate cellularity AND the recommended volume will still be evaluated for malignancy; however there will now be a statement indicating a “less than optimal” specimen with an educational comment and recommendation for possible repeat sample. When instructing patients on how to collect a voided urine sample, please encourage filling the collection cup to at least half full. In addition, please be sure to state the collection method on the requisition form (voided, instrumented, post-cystoscopic, etc.).

For providers that perform cystoscopic procedures (bladder wash, barbotage), there is a recommendation for specimen adequacy based on recently published evidence which shows barbotage specimens with less than 2600 urothelial cells, have a lower sensitivity for cytologic detection of high grade urothelial carcinoma. Therefore, adequate barbotage/wash specimens must have a total of 2600 cells for evaluation. Instrumented urine specimens that lack appropriate cellularity (less than 2600 cells but greater than 50% of recommended cellularity) will include a statement “Less than optimal specimen” with an educational comment to correlate with the clinical information. Instrumented urine specimens that have <50% of recommended cellularity will be designated “Nondiagnostic”. Any specimen with a cytologic abnormality will be flagged despite having inadequate cellularity.

### References:

1. Olson, M. et al. Adequacy in Voided Urine Cytology Specimens: The role of volume and a repeat void upon predictive values for high-grade urothelial carcinoma. *Cancer Cytopathology*. March 2016, 174-180.
2. Olson, M. et al. Adequacy of Voided Urine Specimens Prepared by ThinPrep and Evaluated using The Paris System for Reporting Urinary Cytology. *Journal of the American Society of Cytopathology*. April 2017, 155-161.
3. Barkan G. et al. Evidence-based adequacy criteria for urinary bladder barbotage cytology. *Journal of the American Society of Cytopathology*. September 2014, 57-62.
4. The Paris System For Reporting Urinary Cytology. Editors: Wojcik, Rosenthal, Kurtycz. 2016.



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## Bordetella pertussis PCR

Effective September 20, 2017, the Microbiology lab began offering *Bordetella* PCR testing. This test will replace testing that is currently being sent to Mayo Medical Laboratories. This change will decrease turn-around-time.

### CLINICAL APPLICATION

Pertussis, or whooping cough is caused by the highly contagious bacteria, *Bordetella pertussis*.

Pertussis can affect people of all ages, but is more common in school age children and can be very serious for babies less than one year old. Despite vaccination efforts, if pertussis is circulating in the community people of any age can still become infected with *Bordetella pertussis*, as the bacteria is spread from person to person.

### METHODOLOGY

PCR testing for *Bordetella pertussis* is the most sensitive and specific test for diagnosis of pertussis (whooping cough). In this qualitative assay, loop mediated isothermal amplification is used to detect *Bordetella pertussis*. A positive result indicates the presence of DNA from *Bordetella pertussis*.

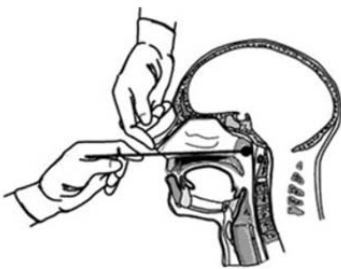
### LIMITATIONS

Cross-reactivity with *Bordetella holmesii* may occur with the Pertussis PCR assay although the prevalence of *Bordetella holmesii* is relatively low. *Bordetella holmesii* has been associated with pertussis-like symptoms. Cross-reactivity has also been demonstrated with a limited number of *Bordetella bronchiseptica* isolates. Additional testing should be performed if necessary to differentiate *B. holmesii* and *B. pertussis*. This assay does not detect *Bordetella parapertussis*.

### BORDETELLE PERTUSSIS COLLECTION

*B. pertussis* binds specifically to ciliated respiratory epithelial cells which are found in the nasopharynx, making a nasopharyngeal sample (NP), the specimen of choice for *Bordetella* PCR testing.

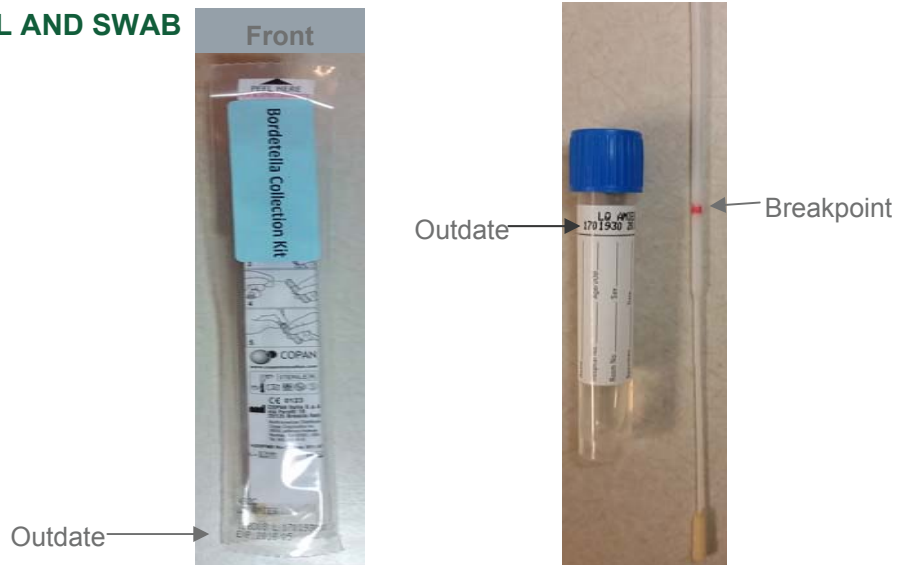
The *Bordetella* collection Kit contains Liquid Aimes broth and a floqswab



1. Insert the tip of the floqswab swab into a nostril to obtain a specimen from the posterior nasopharynx.
2. Do not force the swab; resistance will be felt when the posterior nasopharynx is reached.
3. Rotate the swab and leave it in place for 10-30 seconds or until the patient coughs.
4. Repeat the process for the second nostril.

SPECIMEN INFORMATION FOR BORDETELLA PERTUSSIS PCR	
SQ TEST CODE:	BPPCR
CPT CODE:	87798
SAMPLE REQUIREMENTS:	Bordetella Collection kit - Blue capped transport container with Amies Media and nasopharyngeal swab . After Collection insert swab into vial until the red breakpoint is below the lip of the vial and bend to break swab into vial and recap securely . Store vial refrigerated and submit sample to the laboratory within 24 hours Kit is stored at room temperature until collection. Bordetella Collection Kits can be ordered through Laboratory Customer Service 847-5121 or 1-800-991-
INSTRUMENTATION	Illumigene
NYS CERTIFIED:	Yes
DAYS PERFORMED:	Daily
ANALYTICAL TIME:	1 day
AVAILABLE STAT:	Not available STAT
EXPECTED VALUE:	Negative
EFFECTIVE DATE:	9/20/2017

**BORDETELLA COLLECTION VIAL AND SWAB**





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## Blood Fungal and AFB Culture Specimen Volume Change

Effective November 6, 2017 the minimum volumes for collection of Fungus Culture, Blood (BFC) and AFB Culture Blood (BTC) will change (see table).

Studies have shown that the ability to reliably detect septicemia/ fungemia is related to the volume of blood collected. Specimens submitted below the minimum volume will not be accepted.

There is no change in volumes for Bacterial Culture, Blood/Bone Marrow.

Container	Specimen	Temperature	Collect Volume	Submit Volume	Minimum Volume
Blood Culture Adult Isolator Tube	Whole Blood	Ambient	10 mL	10 mL	8 mL
Blood Culture Pediatric Isolator Tube	Whole Blood	Ambient	1.5 mL	1.5 mL	1.0 mL

## Fungal Smear Name Change

On September 18, 2017 the Microbiology lab will change the name of the test order *Fungal smear oral, genital (FSM)* to *Fungal smear* to have the name reflective of how it is currently being used for a variety of specimens submitted. For PRISM users the appropriate test to order is *fungus culture and smear (LAB242 or LAB2537)*, therefore *fungus smear only (FSM)* is not available to PRISM users.

## Aptima Vaginal Swab Collection Kit Name Change

The manufacturer is changing the name of the “Aptima Vaginal Swab Collection kit” (Orange Vial) to “**Aptima Multitest Swab Collection kit**”. Besides the name change there are no other changes to the packaging, kit components/transport reagent or use of the kit for the collection of vaginal specimens for Chlamydia/GC testing. The new tubes will be gradually phased in effective immediately. You may continue to use the old tubes for specimen collection.



## Babesia species, Molecular Detection, PCR, Blood: Change in ability to order

*Babesia* is a genus of intraerythrocytic protozoa within which there are many known species that can cause the human disease babesiosis. Babesiosis is characterized by fever, chills, extreme fatigue, and severe anemia. The disease is usually self-limited but, in rare instances, can be fatal. The most severe cases usually occur in asplenic individuals and those over the age of 50. Rare cases of chronic parasitemia have also been described. The majority of cases are caused by *Babesia microti* that is endemic to the northeastern coast of the United States. It is spread through the saliva of an *Ixodes scapularis* tick bite, the most common vector for *Babesia* in the northeast. *Babesia* can also be acquired through blood transfusions; therefore, it is required that donor units be screened in endemic areas. The definitive laboratory diagnosis of babesiosis involves a blood parasite examination of Giemsa-stained thick and thin blood films to identify characteristic intraerythrocytic parasites. In addition to the blood parasite examination, other methodologies are available for the diagnosis of babesiosis, including antibody serology and molecular detection by polymerase chain reaction (PCR). For the purposes of diagnosing disease, it is recommended that these tests be ordered for suspected babesiosis during the acute febrile stage of infection in patients from endemic areas, and not for asymptomatic patients.

Currently, the Microbiology Laboratory offers the blood parasite examination as an in-house test and the molecular detection by PCR as a send-out test to Mayo Medical Laboratories. Following recent review, the UVMMC laboratory has determined that, during the acute febrile stage of babesiosis, the blood parasite examination is as sensitive in detecting *Babesia* as the send-out PCR test. In fact, in the past two years, there has not been a single discordant result between the blood parasite examination and the molecular detection PCR test. The molecular test by PCR did not identify any additional positive cases. Therefore, in keeping with the principles of good test utilization, the molecular detection PCR test will no longer be orderable for the purpose of diagnosing symptomatic babesiosis. It will only be available to UVMMC's transplant service and their providers for the purpose of screening solid organ donors. All other requests will be denied.

### TEST CATALOG

To view a complete listing of tests available at the University of Vermont Medical Center, please visit <http://uvmlabs.testcatalog.org/>

#### Browse by Name

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

#### Search



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## HIV Viral Load Reporting Change

In order to meet New York State Regulatory requirements, the Chemistry laboratory will change how viral loads less than 20 copies/mL will be reported. Previously, values less than 20 copies/mL where a signal was detected were reported as “detected” and those where no signal was detected were reported as “undetected”. The new terminology will add a “<20” to the detected value. The old and new terminologies are summarized in the chart below:

Old terminology	New Terminology
Detected	< 20 Detected
Undetected	Undetected

Effective Date: **July 13, 2017.**

## Hepatitis A Name Change

It was recently brought to our attention that the test name for Hepatitis A antibodies, Hepatitis A Antibody with Reflex IgM, was causing confusion when interpreting results from patients in which the reflex Hepatitis A Antibody IgM test was performed. For example, a patient whose Hepatitis A Antibody with Reflex IgM result is given as Positive in conjunction with a Hepatitis A Antibody IgM result that is reported as Negative could easily be interpreted as contradicting test results because IgM is in the name of both tests.

The Hepatitis A Antibody with Reflex IgM test is an immunoassay that detects both IgG and IgM antibodies to Hepatitis A, but does not differentiate between the two. This is why we reflex all positive results to the IgM specific Hepatitis A Antibody IgM test.

In an effort to prevent confusion in the interpretation of Hepatitis A antibody testing, we will change the name of the **Hepatitis A Antibody with Reflex IgM** test to **Hepatitis A Total Antibody with Reflex** effective **9/13/2017**.

## Vancomycin Reporting Range Change

The reporting range of the VITROS vancomycin assay will be extended from 5-100 µg/mL to 2.5-100 µg/mL. Samples with vancomycin concentrations below 2.5 µg/mL and above 100 µg/mL will be reported as <2.5 µg/mL and >100 µg/mL, respectively. The test order name and reference ranges will remain the same.

**Effective Date: October 2, 2017**

If you have any questions concerning this change please contact Dr. Clayton Wilburn in the laboratory.

## Testosterone Reference Range Change

On May 3<sup>rd</sup>, 2017 the Chemistry Laboratory began using new testosterone and sex hormone binding globulin (SHBG) assays on the ADVIA Centaur (Siemens Healthcare Diagnostics, Tarrytown, NY) immunoassay platform. This new testosterone assay was aligned to the CDC Hormone Standardization Program Testosterone reference method. With the adoption of this new assay came changes to the testosterone reference range, a normal range that was determined by the manufacturer's evaluation of approximately 120 apparently healthy subjects in three groups, normal cycling women, post-menopausal women, and normal adult males. The manufacturer supplied testosterone reference range for men <50 and ≥50 years old differed significantly on the lower end from the prior testosterone assay with testosterone levels of 123 ng/dL and 87 ng/dL being defined as normal for men <50 and ≥50 years old, respectively.

Following the implementation of the new testosterone assay and reference range, the chemistry lab received several concerns from physicians throughout the health network. Their concern was that the new reference range was not representative of healthy subjects and would lead to hypogonadal individuals being labeled as normal. To address these concerns an investigation into the determination of the manufacturer's reference range was performed by the chemistry laboratory. This investigation included reviewing the raw data and inclusion criteria of the manufacturer's reference range study, as well as a thorough literature review. The findings of the investigation were discussed with our endocrinology and urology colleagues at UVM Medical Center.

From this discussion a consensus was reached that the current manufacturer's reference range was not representative of a healthy normal population and that the laboratory would adopt a simplified reference range based on the current literature. The study from which the new reference range is derived is a meta-analysis combining four cohorts of American and European men ages 19-89 with an N of 9,054.<sup>1</sup> The study authors normalized the testosterone levels measured in each cohort by isotope-dilution mass spectrometry to the same CDC Hormone Standardization Program Testosterone reference method utilized by the ADVIA Centaur testosterone assay. The new testosterone reference range for normal adult males, seen below, will be implemented on October 2, 2017. The testosterone reference range for normal cycling women, post-menopausal women, and pediatric patients will remain the same.

### NEW TESTOSTERONE REFERENCE RANGE EFFECTIVE DATE 10/2/2017

Male	Age - Years	Low	High	Units
	≥19	229	902	ng/dL

If you have any questions concerning this change please contact Dr. Clayton Wilburn in the laboratory.

### REFERENCES:

1. Travison, T.G., Vesper, H.W., Orwell, E. et al. Harmonized Reference Ranges for Circulating Testosterone Levels in Men of Four Cohort Studies in the United States and Europe. *J Clin Endocrinol Metab.* 2017; 102(4):1161–1173.

## Hemoglobin A1c Reference Range Terminology Change

Towards the goal of creating positive impacts to population health and simplification of message, the terminology in the reference range comment for Hemoglobin A1c (HbA1c) will be revised.

The current reference range comment for HbA1c test results is as follows:

<5.7% Normal

5.7 - 6.4% Increased risk for diabetes

=>6.5% Diagnostic for diabetes (if confirmed)

The A1c goal for nonpregnant adults in general is <7%.

The A1c goal for selected patients may be significantly lower than 7% if this can be achieved without significant hypoglycemia or other adverse effects of treatment.

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### The new reference range comment for HbA1c test results will be as follows:

<5.7% Normal

5.7 - 6.4% Prediabetes

=>6.5% Diagnostic for diabetes

Goals for glycemic control in diabetics (ADA 2017):

<7.0% Target for nonpregnant adults with diabetes

More or less stringent targets may be appropriate for individual patients

<7.5% Target for children and adolescents with type 1 diabetes

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The change to using prediabetes as the classification for patients with HbA1c results of 5.7-6.4% is towards the goal of providing patients with a more concrete understanding of their condition and the gravity of its diagnosis. The secondary goal of this change is to increase patient interest in diabetes management and nutritional programs in and outside of the UVM health network. The revision to the HbA1c stated goals in the reference range is to better specify that these are targets for glycemic control established by the American Diabetes Association for patients with a diagnosis of diabetes.

**Effective Date: October 23, 2017**

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

### REFERENCES:

1. American Diabetes Association. Classification and Diagnosis of Diabetes. Diabetes Care 2017 Jan; 40 (Supplement 1): S11-S24.
2. American Diabetes Association. Glycemic Targets. Diabetes Care 2017 Jan; 40 (Supplement 1): S48-S56.
3. American Diabetes Association. Children and Adolescents. Diabetes Care 2017 Jan; 40 (Supplement 1): S105-S113.

## HSV Type 1 & 2 Antibody IgG (HSVIGP) Change

The assay used for Herpes Simplex Virus (HSV) 1 and 2 IgG testing will be changed from the HerpeSelect (Focus Diagnostics, Inc.) manual assay to the Liaison® XL (Diasorin, Inc.) automated assay. Correlation studies between the two assays are excellent. There is no change to how the test is ordered or how results will be reported.

**Effective Date: November 6, 2017**

If you have any questions concerning this change please contact Dr. Clayton Wilburn in the laboratory.

## Urinalysis Methodology Change

On October 26, 2017 the Chemistry Laboratory will implement new methodology for performing urinalysis and urine sediment evaluation. Currently chemical urinalysis is performed on the Clinitek Advantus urine analyzer using Siemens Multistix 10 SG strips, and urine sediment analysis is performed by manual microscopic analysis. Moving forward both chemical urinalysis and urine sediment analysis will be performed on a single automated urinalysis platform, the Arkray Aution Hybrid 4050.

The Arkray Aution Hybrid 4050 system utilizes similar technology for chemical urinalysis as the Clinitek Advantus, but with Uriflet™ S 9HA test strips. The Arkray Aution Hybrid 4050 system differs from the Clinitek Advantus in the determination of specific gravity. The Arkray Aution Hybrid 4050 measures specific gravity with an on-board refractometer, a more accurate method than the indicator pad on the Clinitek Advantus. In chemical urinalysis correlation studies the Arkray Aution Hybrid 4050 has demonstrated good performance with sensitivities and specificities comparable to the current Clinitek Advantus system. The reference ranges for all analytes included in chemical urinalysis except for urobilinogen will remain the same. The reference range terminology for urobilinogen is being changed from the current 0.2-1.0 mg/dL, which is the normal range, to just state “Normal” for all samples with urobilinogen levels of 0.2-1.0 mg/dL.

For urine sediment analysis the Arkray Aution Hybrid 4050 system utilizes flow cytometry to detect and enumerate multiple cell types, bacteria, yeast, crystals, and casts that may be present in a urine specimen. Flow cytometry is the same technology used in the laboratory to perform complete blood counts. Samples flagged for crystals or casts on the Arkray Aution Hybrid 4050 will be reviewed manually at the microscope to specify crystal and cast type. Because of the significant change in methodology for urine sediment analysis the reference ranges for RBC and WBC/HPF have been updated (see table below for reference range changes). The updated RBC and WBC/HPF reference ranges are derived from a multi-center reference range study of urine sediment analyzed by flow cytometry<sup>1</sup> that has been confirmed with internal reference range studies here at UVMMC. Furthermore, the RBC/HPF reference range follows the guidelines set forth by the American Urology Association for the diagnosis of asymptomatic microhematuria.<sup>2</sup>

Finally, with the implementation of the Arkray Aution Hybrid 4050 urinalysis system ordering of urinalysis testing will be revised. The primary change is the removal of the order for chemical urinalysis with microscopic (urine sediment analysis) reflex testing if positive.

### **There will be three orders available for urinalysis:**

Urinalysis, Chemical and Sediment, Automated (Test Code: ARKCOM)

Urinalysis, Chemical, Automated (Test Code: ARKUA) If this test is ordered a sediment can be added within 24 hours of collection.

Urine Sediment Analysis, Automated (Test Code: ARKUMI)

**Effective Date: 10/26/2017**

<b>Specimen Information for Urinalysis Methodology Change</b>	
Test Code	<b>ARKCOM or ARKUA</b>
Collection Container	Sterile container preferred
Specimen	Urine, Clean catch specimen preferred. First morning voided urine preferred.
Temperature	Refrigerate
Collect Volume	10 mL
Submit Volume	10 mL
Minimum Volume	5 mL (Minimum Volume for Urine Sediment Automated [ARKUMI] is 1 mL)
Specimen Note	Sterile container needed when culture also ordered. Clean catch specimen preferred. First morning voided urine preferred.
Test Schedule	Daily
Analytical Time:	Same day
Available STAT	Yes
NYS Certified:	Yes
Section	Chemistry 1
Method	Arkay UA Chem Strip and Flow Cytometry Sediment Analysis
CPT	81001
<b>Reference Ranges Chemical (For Test Code ARKCOM and ARKUA)</b>	
Glucose	Negative
Bilirubin	Negative
Ketones	Negative
Blood	Negative
Protein	Negative
Nitrite	Negative
Leukocyte Esterase	Negative
Urobilinogen	Normal
Specific Gravity	1.001 - 1.035
pH	4.6 - 8.0
<b>Reference Range Sediment (For Test Code ARKCOM and ARKUMI)</b>	
WBC Count	0 - 3/ High Power Field
RBC Count	0 - 2/ High Power Field
Squamous Cells	None seen
Hyaline Cast	None/Few Seen
Bacteria Count	None Seen

If you have any questions or concerns please contact Dr. Clayton Wilburn in the laboratory.

Component	Current Reference Range	New Reference Range
RBC	0 - 5/HPF	0 - 2/HPF
WBC	0 - 5/ HPF	0 - 3/HPF

Table 1. Urine Sediment Analysis Reference Range Change

## REFERENCES:

1. Manoni et. al. Gender's equality in evaluation of urine particles: Results of a multicenter study of the Italian Urinalysis Group. *Clin Chim Acta*. 2014 Jan 1;427:1-5. doi: 10.1016/j.cca.2013.09.012. Epub 2013 Sep 25.
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## LABORATORY PATIENT SERVICE CENTER



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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

**Adult Primary Care Williston**  
353 Blair Park Road  
Williston, VT

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

All UVM Medical Center phlebotomists are nationally certified



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Burlington, VT 05401

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## PATHOLOGY & LABORATORY MEDICINE COMMUNIQUÉ — OCTOBER 2017

### PATHOLOGY & LABORATORY MEDICINE COMMUNIQUÉ

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## Syringe Disposal

The University of Vermont Medical Center does not accept sharps for disposal from patients. Chittenden Solid Waste District (CSWD) will accept needles that are packaged according to the instructions outlined in their pamphlet "GET THE POINT: Be safe with syringes and other sharps". CSWD also has bright orange stickers to attach to a syringe container to warn handlers to be careful. These items are available at any CSWD location. You can also order them so that they are available for patients at your office 872-8111 or visit [www.cswd.net](http://www.cswd.net)