

Faculty Practices of the University of Maryland School of Medicine

UNIVERSITY OF MARYLAND PATHOLOGY ASSOCIATES

Professional Services Manual

November 2019

UNIVERSITY OF MARYLAND PATHOLOGY ASSOCIATES

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General Information

LABORATORY HOURS

The laboratory is open from 7:00 AM to 6:30 PM Monday through Friday. Phlebotomy services located at 419 W. Redwood St., suite 200 are available from 7:00 AM to 5:00 PM, and Phleobotomy services located at 16 S. Eutaw St., Suite 120 are available from 8:00 AM to 4:30 PM.

LABORATORY SPECIMEN COLLECTION AND RECEPTION

To insure the accuracy of results, we ask your cooperation in the proper labeling of specimens. All specimens must be labeled in the presence of the patient, with the patient's first and last names and a second identifier, either medical record number or date of birth, using an adhesive label. Specimens containing body fluids must be in a container with a secure, leak-proof lid and placed in a ziplock bag for transport. Lab tests must be ordered by an appropriately licensed practitioner and must be medically necessary. All specimens must be accompanied by a requisition including the patient's full name, medical record number, date of birth, sex, attending physician, ordering physician and signature, specialty location, diagnosis code, and date of onset of symptoms or disease. Please indicate date and time of collection as well as source of specimen if other than blood. When clinically relevant, specify time of last dosage. Be sure to include current physician contact information (phone number and pager number). Specimens may be delivered to Suite 060.

LABORATORY CHARGES

Current charges may be obtained upon request from the University of Maryland Pathology Associates reception desk in the laboratory (4-1444). The laboratory participates with a number of insurance plans. In order to file a claim, we ask that you submit a copy of the patient's insurance card (front and back) with the completed requisition. Medicare patients may need to complete an Advanced Beneficiary Notice. Please call the laboratory reception desk for more information and for forms.

SPECIMEN CONTAINERS

The following containers are available on request:

Evacuated blood collection tubes (BD HemogardTM Closure color) Additive

^aRed top ^aGold top ^{ab}Lavender top ^aLight Green top ^aGreen top ^bLight Blue, yellow striped label Yellow top (regular closure) Royal Blue top Gray top Pearl top PPT plasma separation tube Pink top Tan top

Clot activator only- no separator gel Serum separator gel (SST) and clot activator Potassium (K_2) EDTA Plasma separator gel (PST) Lithium heparin Sodium Heparin Buffered citrate (3.2%) Acid citrate dextrose (ACD) - A & B sol'ns Trace element free (K_2 EDTA or w/clot activator) Sodium fluoride / Potassium oxalate Potassium (K_2) EDTA with separator gel Potassium (K_2) EDTA for Blood Bank Potassium (K_2) EDTA for Lead testing

^a **Microtainer** sizes also available ^b Pediatric size available

General Information

Other Containers

- 24 hour urine containers and additives
- Urine specimen cups, sterile and non-sterile
- Culturettes: for routine cultures
- Port-A-Cul (Swabs with anaerobic transport medium)
- Transettes (Amies modified transport medium with charcoal for GC cultures)
- BACTEC VIALS (for blood cultures)
- BD UVE Collection Kits (CT/GC/TV and Vaginosis/Vaginitis DNA Panel)
- VCM Media (For Chlamydia, Viral, or Mycoplasma / Ureaplasma culture)
- ECOFIX preservatives system for stool ova and parasites
- Cary-Blair transport media for stool cultures
- BD SurePath vial for pap smear
- Biopsy containers with formalin

24-Hour Urine Collection

Please call the lab at 4-1444 to request a container for a 24-hour urine collection. Alternatively, have the patient bring their requisition to the lab and pick up the container. There are different preservatives and storage requirements for each test. Instruct the patient to collect the specimen as follows:

- 1. Start the collection at a time that will allow the specimen to be delivered to the lab at the end of the collection. The lab is open Monday through Friday from 7:00 AM to 5:00 PM.
- 2. The container may contain an acid as preservative that may burn if touched. Collect samples in a smaller container and pour them into the large container provided.
- 3. On the day of collection, empty the bladder completely and note the time. Discard this sample.
- 4. Collect all urine passed for the rest of the day and night, in the large container provided. Keep collected urine cool or refrigerated.
- 5. Obtain the last specimen exactly 24 hours after the collection began and add to the large container.
- 6. Bring the 24-hour specimen the lab as soon as possible. Make sure that the container is labeled with the date, patient's first and last name and DOB.

See listing for Creatinine Clearance for additional instructions for that test.

EMERGENCY LABORATORY PROCEDURES

STAT requests are accepted and processed as they are received in the laboratory.

- 1. To request a test be run STAT, check the "STAT" box on the requisition. Tests marked with an "*" below are performed STAT if requested. "STAT" turnaround is defined as results completed 1 hour after receipt in the specimen processing area.
- 2. If there are non-stat tests requested on the same requisition, please indicate which tests are needed STAT.

TEST PERFORMANCE SCHEDULE

This is a list of tests performed on-site in the University of Maryland Pathology Associates (UMPA) Clinical Laboratory, and the schedule of when they are performed. Other tests listed in the UMPA Professional Services Manual are referred to outside laboratories. Turn-around times vary for those tests. Call the lab at 4-1444 for information about referred tests. Test marked with an "*" may be requested STAT.

The following tests are performed throughout each workday:

*Albumin	*Iron	HDL Cholesterol
*Alkaline Phosphatase	*LDH	Iron Saturation
*ALT	*Lipase	Iron Total Binding Capacity
*Amylase	*Magnesium	Transferrin
*AST	*Phosphorus	Urine Creatinine
*Calcium	*Potassium	Urine Creatinine Clearance
*CBC and Automated Diff	*Reticulocyte Count	Urine Microalbumin
*Chloride	*Sodium	CT/GC/TV DNA
*Cholesterol	*Total Bilirubin	Tacrolimus
*CO ₂	*Total Protein	HbA1c%
*Creatinine	*Triglyceride	TSH, 3 rd generation
*Direct Bilirubin	*Urea Nitrogen	Ferritin
*Glucose	*Uric Acid	Free T4
*HCG Qualitative	*Urinalysis	Occult Blood
*HCG Quantitative	*Urine HCG Qualitative	

The following tests are performed once each day:

RPR

General Information

The following tests are performed Monday, Wednesday, and Friday:

Hepatitis B Surface Antigen -HepBsAg Hepatitis B Surface Antibody –HepBsAb (Qual and Quant.) Hepatitis B Core Antibody -HepB CoreAb Hepatitis C Virus Antibody - Anti-HCV HIV Ag/Ab Combo Vitamin D 25-OH

The following tests are performed Tuesday and Thursday:

Intact PTH	AFP
PSA, 3 rd generation	Vitamin B12

The following tests are performed Tuesday and Friday:

Bacterial Vaginosis/Vaginitis DNA Panel

RESULT REPORTING

For clients/providers that are on the EPIC- AEMR, results are available in the patient's electronic medical record immediately upon completion. For clients that are not currently on EPIC- AEMR, paper reports are delivered to the requesting practitioner's practice office daily, Monday through Friday. For Off-Campus providers, results will be mailed or faxed.

CRITICAL VALUES and TESTS

Results falling outside the following limits for these tests are considered "critical values" and will be called to the requesting practitioner or his/her designee. Critical results may be obtained by reference laboratories on specimens sent by UMPA Lab. These results will be called to the requesting practitioner or his/her designee.

Hematology

$r \ge 20.0 \text{ x } 10^3 \text{ mcL}$
g/dL
10 ³ /mcL

Chemistry

Sodium	$\leq 125 \text{ or} \geq 155 \text{ mmol/L}$	
Potassium	\leq 3.0 or \geq 6.0 mmol/L	
*Urea Nitrogen	$\geq 100 \text{ mg/dL}$	
*Creatinine	\geq 4.0 mg/dL	
Phosphorus	$\leq 1.5 \text{ mg/dL}$	
Magnesium	$\leq 1.0 \text{ or} \geq 3.0 \text{ mg/dL}$	
Glucose	\leq 45 or \geq 400 mg/dL	
Calcium	$\leq 7.5 \text{ or} \geq 12.0 \text{ mg/dL} (\text{age} > 10 \text{ d})$	
	$\leq 6.9 \text{ or} \geq 12.1 \text{ mg/dL} (age 0-10 \text{ d})$	
Amylase	≥200 U/L	
Lipase	\geq 400 U/L	
Total and/or Direct Biliru	bin (infants < 14 d) ALL	
Vitamin D 25-OH	>150 ng/mL	
Tacrolimus	$\geq 20.0 \text{ ng/mL}$	
HIV 1/2 Ag/Ab	Reactive	

Urinalysis

Urine glucose (chemical screen) \ge 3+ unless a serum glucose has been performed at the same visit.

Molecular

CT/GC DNA Positive

*For these two tests, critical values that become available during the day will be called promptly on the same day when physician's offices are expected to be open. Results that become available after hours will be called as soon as possible the following morning, including weekends and holidays. Critical values for these two tests will **NOT** be called if the patient is from Kidney Transplant, Dialysis, or Nephrology.

PHYSICIAN NOTIFICATION POLICY

- The laboratory will make every reasonable attempt to notify a patient's physician or designee about critical test results, questionably identified specimens, specimens unsuitable for the requested analysis, etc.
- Please help us to communicate with you by putting your name and telephone/pager number, and your specialty location and telephone number on the requisition.
- The laboratory result will be annotated with a comment indicating the individual who was notified or, if all attempts fail, a comment that notification was unsuccessful.

LABORATORY METHODS

Laboratory methods, performance specifications, reference ranges, and references are available upon request in the laboratory.

Note: All reference ranges given in this manual are for adults (≥ 18 years) unless otherwise specified.

For age and sex of patient, the following abbreviations are used:

h = hours	M = male
d = days	F = female
w = weeks	m = months
y = years	

Albumin	Age	Range MF	1 mL in green top
[4 hrs]	0-4 d	2.8 - 4.4 g/dL	
	4d-14y	3.8 - 5.4 g/dL	
	14-60y	3.5 - 5.2 g/dL	
	≥ 60y	3.2 - 4.6 g/dL	
Albumin, Urine / Creatinine,			10 mL random urine
Urine ratio	<30 mc	g/mg creatinine	(urine creatinine will be performed on same
[8 hrs]	Because of the variability in urinary albumin excretion, two of three specimens collected within a 3 to 6 month period should be abnormal before considering a patient to have albuminuria. Exercise within 24 hours, infection, fever, congestive heart failure, marked hyperglycemia, marked hypertension, and hematuria may elevate urinary albumin independently of kidney damage.		performed on same specimen)
Alkaline Phosphatase [4 hrs]	Age 0-4yN 4-7yN 7-10yN 10-12y 12-14y 14-16y 16-19y 12-14y 12-14y 14-16y 16-19yN	Sex Range M&F145-320 U/L 1&F150-380 U/L 1&F150-380 U/L 1&F150-380 U/L 1&F150-380 U/L M130-520 U/L M130-525 U/L M130-525 U/L M	1 mL in green top
Alpha-fetoprotein (AFP) [5 days]	\leq 7.5 ng/r Methodold Immunoch of Ortho E analyzer. I Biotin (\geq cause inte and lead t	nL ogy: nemiluminescent assay Diagnostics VITROS ingestion of high dose 1000 mcg/day) may perference in this assay to a possibly low	2 mL in gold top

TEST	REFERENCE RANGES	SAMPLE REQUIREMENTS		
[Turnaround Time]				
ALT (GPT)	M 21 – 72 U/L	1 mL in green top		
[4 hrs]	F = 9 - 52 U/L			
Amylase [4 hrs]	≥18y MF 48-133 U/L	1 mL in green top		
AST (GOT) [4 hrs]	≥18y MF 10–59 U/L	1 mL in green top		
Bilirubin, Direct [4 hrs]	≥14d MF 0.0-0.4 mg/dL	Adult: 1 mL in green top Pediatric: 1 microtainer- green top		
		protect from light		
Bilirubin, Total [4 hrs]	MF 0.3-1.2 mg/dL According to the manufacturer, Cefotiam (Pansporin) & Phenazopyridine show very larg	Adult: 1 mL in green top Pediatric: 1 microtainer- green top green top		
	positive biases on Total Bilirubi results. At high bilirubin levels Levodopa shows a substantial negative bias & 4-Aminosalicyli acid shows a small positive bias	n ic		
Calcium [4 hrs]	AgeRange MF0-10 d7.6-10.4 mg/dL10 d-2 y9.0-11.0 mg/dL2-12 y8.8-10.8 mg/dL>12 y8.6-10.2 mg/dL	1 mL in green top		
Carbon Dioxide, Total [4 hrs]	MF 21-30 mmol/L (venous)	1 mL in green top		

		TEST LIST		
TEST [Turmeround Time]	REFERENCE RANGES	SAMPLE REQUIREMENTS		
CBC [4 hrs]	Adult Reference Ranges (≥18 y) See pp. 29-31 for pediatric ranges.	3-5 mL lavender top vacutainer or lavender microtainer. (Note: lavender microtainer must		
White Cell Count	4.0-10.0 x 10 ³ /mcL	be specific size. Obtain from the laboratory.) Mix		
Red Cell Count	M: 4.25-5.51 x 10 ⁶ /mcL F: 4.10-5.10 x 10 ⁶ /mcL	lavender tops well immediately after drawing.		
Hemoglobin	M: 12.8-16.9 g/dL F: 12.0-14.7 g/dL			
Hematocrit	M: 38.2-50.6% F: 36.0-45.0%			
Mean Corpuscular Volume (MCV)	80.0-100.0 fL			
Mean Corpuscular Hemoglobin (MCH)	26.0-33.0 pg			
Mean Corpuscular Hemoglobin Concentration (MCHC)	32.0-35.0 g/dL			
Red Cell Distribution Width (RDW)	11.6-14.4%			
Platelet Count	166-362 x 10 ³ /mcL			
Mean Platelet Volume (MPV)	9.4-12.4 fL			
NRBC % NRBC Absolute	0-0% 0-0.00 x 10 ³ /mcL			
Chloride [4 hrs]	MF 98-107 mmol/L	1 mL in green top		
Cholesterol, Total [4 hrs]	Adult: Desirable: <200 mg/dL Borderline High 200-239 mg/dL High: ≥240 mg/dL	1 mL in green top		

				TEST LIST	
TEST	REFERENCE RANGES		NGES S	SAMPLE REQUIREMENTS	
[Turnaround Time]					
Creatinine [4 hrs]	AgeSexRange0-1wMF0.22-0.92 mg/dL1w-1mMF0.22-0.63 mg/dL1m-1yMF0.12-0.33 mg/dL1-12yMF0.22-0.63 mg/dL12-18yMF0.42-0.92 mg/dL $\geq 18yMF0.66-1.25$ mg/dL $\geq 18yF0.52-1.04$ mg/dL			1 mL in green top	
e GFR: MF $\geq 18y \geq 60mL/min$	/1.73 m ²				
Creatinine, Urine [8 hrs]	<u>Random</u> -	none		10 mL random urine specimen	
Creatinine, Urine 24 hour [8 hrs]	$\frac{24 \text{ hr}}{M \ge 19 \text{ y:}}$ F $\ge 19 \text{ y:}$	1000-2 800-1	2000 mg/day 1800 mg/day	Collect 24-hour urine with no preservative; refrigerate during collection. At end of collection period, draw	
Creatinine Clearance [8 hrs]	Creatinine M 20-29y 90-14 F 20-29y 72-110 Decreases BSA per d	<u>Clearanc</u> 0 mL/min 0 mL/min ~6.5 mL/ lecade	e (corrected) /1.73m ² BSA /1.73m ² BSA /min/1.73m ²	one green top tube (Li heparin). Both specimens must arrive at the lab at the same time with requisition having patient's height, weight, and the collection period.	
Differential Leukocyte [4 hrs] (Automated)	Adult Refer See pp. 28-2	Adult Reference Ranges See pp. 28-29 for pediatric ranges		3-5 mL in lavender top tube or 1 lavender	
	Relative Count Absolute Count		olute Count (% x WBC)	microtamer.	
Total WBC Total Neutrophils Lymphocytes Monocytes Eosinophils Basophils Immature granulocytes	34-71% 19-53% 5-13% 0-7% 0-2% 0-0.7%	4.0 1. 1. 0. 0. 0. 0. 0.	0-10.0 x 10 ³ /mcl .8-7.7 x 10 ³ /mcl .0-4.8 x 10 ³ /mcl .0-0.8 x 10 ³ /mcl -0.5 x 10 ³ /mcL -0.2 x 10 ³ /mcL -0.2 x 10 ³ /mcL		
NOTE: Automated neutrophil cour Automated Immature gran	nt = Polys + I ulocytes = M	3ands. letamyeloc	eytes + myelocyt	es + promyelocytes	
Differential Leukocyte	Adult Refe	erence Ra	nges	3-5 mL in lavender top	

Differential Leukocyte	Adult Reference Ranges	3-5 mL in lavende		
[4 hrs] (Manual)		tube or 1 lavender		
Cell	Relative Count%	microtainer.		
Segmented neutrophils (polys)	33-75%			
Band Neutrophils	0-5%			
Lymphocytes	15-60%			
Monocytes	0-9%			
Eosinophils	0-6%			
Basophils	0-2%			

		TEST LIST
TEST [Turnaround Time]	REFERENCE RANGES	SAMPLE REQUIREMENTS
Ferritin [1 day]	$\begin{array}{llllllllllllllllllllllllllllllllllll$	2 mL in gold top
Glucose (fasting) [4 hrs]	Normal: 70-99 mg/dL Impaired: ≥110 and <126mg/dL Diabetes Mellitus*: ≥ 126 mg/dL	1 mL in green top
	*In the absence of unequivocal hyperglycemia or hyperglycemic crisis, results should be confirmed repeat testing.	by
50 g Gestational Diabetes Screen [4 hrs]	If ≥ 140 mg/dL, proceed to a 100g Obstetric GTT	1 mL in green top
	-A cutoff of >140 mg/dL identifies approximately 80% of women with GDM -A cutoff of >130 mg/dL identifies 9 of women with GDM	90%
Glucose Tolerance Test 100 g Obstetric Test [4 hrs]	 Fasting: 95 mg/dL 1-HR: 180 mg/dL 2-HR: 155 mg/dL 3-HR: 140 mg/dL Two or more of the venous glucose concentrations must be met or exceeded for a positive diagnosis 	1 mL in green top for each hr tested. The test should be done in the morning after an overnight fast of at least 8 hrs. The subject should remain souted and should not
	exceeded for a positive diagnosis.	smoke throughout the test.
Glucose Tolerance Test 75 g Non-Obstetric [4 hrs]	Normal: <140 mg/dL Prediabetes: 140 -199 mg/dL Diabetes Mellitus*: ≥200 mg/dL	1 mL in green top Fasting (no food or beverage other than
	*In the absence of unequivocal hyperglycemia or hyperglycemic crisis, results should be confirmed repeat testing	water for at least 8 hours before testing). by
HCG, Quantitative Total b-hCG [1 day]	Reference intervals (central 97.5% range) for pregnant women of the following gestational age:	2 mL in gold top

		TEST LIST
TEST	REFERENCE RANGES S	SAMPLE REQUIREMENTS
[Turnaround Time]		
HCG, Quantitative Total b-hCG - continued	Gest. AgeRange1-10w $64 - 150854 \text{ mIU}/$ 11-15w $11795 - 151996 \text{ mIU}$ 16-22w $9384 - 61410 \text{ mIU}/$ 23-40 w $1737 - 98576 \text{ mIU/n}$ Ingestion of high dose Biotin (\geq 1000 mcg/day) may causeinterference in this assay and leada possibly low biased result	mL /mL mL mL
HDL Cholesterol [4 hrs]	Adult MF:Low: $<40 \text{ mg/dL}$ High: $\geq 60 \text{ mg/dL}$	1 mL in green top
Hematocrit	See CBC	
Hemoglobin	See CBC	
Hemoglobin A1c% <u>DO NOT</u> use HgbA1c for as cell survival, such as hemolyt <u>DO NOT</u> use this assay meth HbSC, or >7% HbF.	Normal: Below 5.7% Prediabetic: 5.7 – 6.4% Diabetic: 6.5% or higher Note: <18years Hemoglobin A1c criteria for diagnosing diabetes has n been established. sessment of patients with conditions car tic diseases, pregnancy, significant acut od monitoring glycemic control in indiv	3 mL lavender top not using shortened red blood e or chronic blood loss. viduals with HbSS, HbCC,
Hepatitis B Surface Antigen [3 days]	Negative	4 mL in gold top.
Hepatitis B Surface Antibody, Qualitative, Total [3 days]	Negative. Positive after immunization	on. 3 mL in gold top.
Hepatitis B Surface Antibody, Quantitative, Total [3 days]	<5.00 mIU/mL : Negative, Patient considered to be not immune to infection with HBV. ≥5.00 and <12.00 mIU/mL : Indeterminate, Unable to determine anti-HBs is present at levels consiste with immunity. Patient's immune stat should be further assessed by considering other clinical informatio or retesting another specimen drawn a later time. ≥12.00 mIU/mL: Positive, Patient in 17	is 3 mL in gold top e if int at at

		TEST LIST
TEST [Turnaround Time]	REFERENCE RANGES	SAMPLE REQUIREMENTS
Hepatitis B Surface Antibody, Quantitative, Total - Continued [3 days]	considered to be immune to infection with HBV. It has not been determine what clinical significance is for valu greater than ≥ 12 mIU/mL, other than the individual is considered to be immune to HBV infection.	n ed es 1
	Test is performed using the Vitros chemiluminescent method. Quantitative values from other methods/instruments should not be u interchangeably.	ised
Hepatitis B Core Antibody, Total [3 days]	Negative	3 mL in gold top.
Hepatitis C Antibody [3 days]	Negative Negative indicates: Anti-HCV not detected. Patient is presumed not to infected with HCV. Reactive indicates: Anti-HCV detec Patient is presumed to be infected w HCV, state or associated disease not determined. Follow CDC recommendations for supplemental testing.	3 mL lavender top be eted. ith
HIV 1/2 Antigen/Antibody Combo [Screen: 3 days]	HIV 1/2 Ag/Ab Screening Test: Non-reactive: HIV-1 p24 Ag and HIV-1/HIV-2 Ab not detected. Reactive: Indicates presumptive evidence of HIV-1 p24 Ag and/or H 1/HIV-2 Ab. Supplemental confirmatory assay(s) pending.	3 mL in gold top
Iron [4 hrs]	M: 49-181 mcg/dL F: 37-170 mcg/dL	2 mL in green top Specimen must not be hemolyzed.
(Total)Iron Binding Capacity (TIBC) (calculated from Transferrin) [4 hrs]	M: 257-470 mcg/dL F: 274-546 mcg/dL	2 mL in green top Specimen must not be hemolyzed.
Iron Saturation (calculated) [4 hrs]	M: 20-50% F: 15-50%	

		TEST LIST		
TEST [Turnaround Time]	REFERENCE RANGES SAM	APLE REQUIREMENTS		
Ketones, urine	See Urinalysis, Chemical Screen			
Lactate Dehydrogenase (LDH) [4 hrs]	AgeSexRange1-4yM&F500-920U/L4-7yM&F470-900U/L7-10yM&F420-750U/L10-12yM.432-700U/L12-14y14-16yM	1 mL green top		
LDL Cholesterol (calculated) [4 hrs]	Adult:Optimal:<100 mg/dL	1 mL in green top Must be fasting sample (9-12 hrs)		
Lipase	23-300 U/L	1 mL in green top		
Lipid Panel Cholesterol, Total Triglycerides	Adult:Desirable: $<200 \text{ mg/dL}$ Borderline High: $200-239 \text{ mg/dL}$ High: $\geq 240 \text{ mg/dL}$ Normal: $<150 \text{ mg/dL}$ Borderline High: $150-199 \text{ mg/dL}$ High: $200-499 \text{ mg/dL}$	3 mL in green top tube Results on non-fasting specimens are not interpretable. Must be fasting 9-12 hours.		
HDL Cholesterol	Very High: $\geq 500 \text{ mg/dL}$ Low: $<40 \text{ mg/dL}$ High: $\geq 60 \text{ mg/dL}$			
LDL Cholesterol (calculated)	Optimal: <100 mg/dL Near Optimal: 100-129 mg/dL Borderline High: 130-159 mg/dL High: 160-189 mg/dL			
[4 hrs]	Very High: $\geq 190 \text{ mg/dL}$			
Magnesium [4 hrs]	1.6-2.6 mg/dL	1 mL in green top		

		TEST LIST			
IESI [Turnaround Tima]	REFERENCE RANGES		SAWPLE KEQUIKEMENIS		
Parathyroid Hormone (PTH), Intact [3 days]	$MF \ge 18y:$	12 -68 pg/mL	3 mL in gold top		
Phosphorus [4 hrs]	Age 0-6 d 6d-4y 4-7y 7 -12y 12-14y 14-16y 16-19y ≥ 19y	Range MF 4.6 - 8.0 mg/dL 3.9 - 6.5 mg/dL 4.0 - 5.4 mg/dL 3.7 - 5.6 mg/dL 3.3 - 5.4 mg/dL 2.9 - 5.4 mg/dL 2.8 - 4.6 mg/dL 2.5 - 4.5 mg/dL	1 mL in green top		
Platelet Count	See CBC				
Potassium [4 hrs]	Age 0-4w 4w-2y 2y-8y ≥8y	Range MF 3.7-5.9 mmol/L 4.1-5.3 mmol/L 3.4-4.7 mmol/L 3.5-5.1 mmol/L	1 mL in green top Specimen must not be hemolyzed.		
Pregnancy Test, Urine [8 hrs]	Male and non Negative Healthy pregr present (the a gestational ag Positive	pregnant female: nant women with hCG mount will vary with ge and between patients	Random specimen. First morning urine is optimal. Very dilute urine, as indicated by low specific gravity,): may not contain representative urinary hCG concentrations.		
Prostate Specific Antigen (Total) [5 days]	M: 0.0 - 4.0 Ingestion of 1000 mcg/da interference a possibly lo	ng/mL high dose Biotin (≥ ay) may cause in this assay and lead w biased result	2 mL in gold top		
Protein Total, Serum [4 hrs]	Age 0-6d 6d-1y 1y-4y 4-7y	Range MF 5.4 - 7.0 g/dL no range 5.9 - 7.0 g/dL 5.9 - 7.8 g/dL	1 mL in green top		
Protein Total, Serum [4 hrs] - Continued	7-10y 10-19y >19 y	6.2 - 8.1 g/dL 6.3 - 8.6 g/dL 6.3 - 8.2 g/dL			

		TEST LIST
TEST [Turnaround Time]	REFERENCE RANGES	SAMPLE REQUIREMENTS
Rapid Plasma Reagin (RPR) Screening Test for Syphilis [1 day]	Non-reactive: Infection unlikely. request, reactive specimens are tested by FTA for confirmation.	By 1 mL in gold top
Reducing Sugars, Urine [3 days]	Negative Note: Tests for reducing substance are not included in the routine urinalysis for adult or pediatric specimens and must be ordered explicitly by the requesting clinic	5 mL of freshly voided random urine
Reticulocyte Count [4 hrs]	Relative count: $MF \ge 1y 0.5-2.2\%$ Absolute count: $MF: \ge 1 y 0.026-0.100 \times 10^{6}$	4 mL in lavender top tube or 1 lavender microtainer /μL
Sodium [4 hrs]	136-145 mmol/L	1 mL in green top Note: Sodium Heparin tubes, when filled to proper volume, will cause sodium results to be only 1-2 mmol/mL higher. Otherwise, Li Heparin (Light green) tube may be used.
Tacrolimus (Prograf) [1 day]	Each patient should be thoroughly evaluated clinically before treatm adjustments are made and each us must establish his or her own ran based on their clinical experience Method is Abbott Architect. Architect results are expected to be equivalent to the result determine by Tandem Mass spectrometry.	y 1 mL in lavender top lent ser ges es.
Thyroid Stimulating Hormone (TSH) [1 day]	AgeRange MF $0-3d$ $1.00 - 20.00 \text{ mcIU/n}$ $3d - 1m$ $0.50 - 6.50 \text{ mcIU/m}$ $1 - 6m$ $0.50 - 6.00 \text{ mcIU/m}$ $6m - 18y$ $0.50 - 4.50 \text{ mcIU/m}$ $>18y$ $0.47 - 4.68 \text{ mcIU/m}$ Ingestion of high dose Biotin (1000 mcg/day) may causeinterference in this assay and bto a possibly low biased result.	3 mL in gold top mL nL nL nL $2 \ge$ ead
Thyroxine, Free [1 day]	≥1y MF 0.60 - 2.50 ng/dL	2 mL in gold top
	<i>L</i> 1	

			TEST LIST
TEST	REFERENCE RAN	NGES SAN	MPLE REQUIREMENTS
[Turnaround Time]			
Thyroxine, Free - continued	Free T4 normal refer children less than on not been established methodology.		
Transferrin [4 hrs]	MF 206 – 381 n	ng/dL	1 mL in green top
	Adult MF (fasting)	:	
Triglycerides [4 hrs]	Normal: Borderline High:	<150 mg/dL 150-199 mg/dL	1 mL in green top
	High: Very High:	200-499 mg/dL ≥500 mg/dL	Must be fasting sample (9-12 hrs).
	Comment: Results of specimens are not in	on non-fasting terpretable.	
Urea Nitrogen (BUN) [4 hrs]	M: 9 – 20 mg/dL F: 7 – 17 mg/dL		1 mL in green top
Uric Acid, Serum [4 hrs]	Age Sex 0-2y M&F 2-8y M&F ≥8y M ≥8y F	Range . not defined .2.0 - 5.5 mg/dL .3.5 - 7.2 mg/dL .2.6 - 6.0 mg/dL	1 mL in green top
Urinalysis, Chemical Screen			15 mL random urine
Ketone	Negative		Store refrigerated if not
Bilirubin	Negative		transported to lab
Glucose	Negative		immediately; Transport
Leukocyte esterase	Negative		to lab within 2 hours of
Nitrite	Negative		collection

Urobilinogen 0.2-1.0 E.U./dL Note: Tests for reducing substances in pediatric urines are performed only if ordered explicitly by the requesting clinician. See Reducing Sugars, Urine.

Blood: The significance of a trace reaction may vary among patients. Clinical correlation is advised. False positive results may occur with urinary tract infections and certain oxidizing contaminants, e.g., hypochlorite.

5-8

Negative-Trace

Negative-Trace

1.001-1.035

pН

Protein

RBC/Hemoglobin Specific Gravity

TEST [Turnaround Time]

REFERENCE RANGES

15 mL fresh urine

Urinalysis, Chemical Screen - Continued Protein: Healthy individuals may show trace protein in their urine due to benign physiological conditions such as strenuous exercise, exposure to cold, and upright position.

Leukocyte esterase: The significance of a trace reaction may vary among patients. Clinical correlation is advised. Trace reactions may indicate the need for further testing, especially if observed repeatedly. False positive results may be produced by vaginal contamination of the specimen.

Urinalysis, Microscopic

[4 hrs]		
WBC	\leq 5/HPF	Store refrigerated if not
RBC	$\leq 2/\text{HPF}$	transported to lab immediately;
Squamous epithelial cells	Negative, 0-2/HPF, 2-5/ HPF	Transport to lab within 2 hours
Transitional epithelial cells	Negative, 0-2/HPF	of collection
Renal tubular epithelial cells	Negative, 0-2/HPF	
Casts (Hyaline)	Negative, 0-1/LPF	
All other casts	Negative	
Bacteria	Negative, Trace	
Yeasts	Negative	
Trichomonas	Negative	
Abnormal Crystals	Negative	
Note: No reference ranges for r	normal crystals, amorphous	
crystals, or mucus.		

Vitamin B12	MF: 239 – 931 pg/mL	2 mL in gold top
[5 days]	Ingestion of high dose	
	Biotin ($\geq 1000 \text{ mcg/day}$)	
	may cause interference in	
	this assay and lead to a	
	possibly high biased result	

Vitamin D 25-OH

20 - 80 ng/mL

[3 days]

1. This test is not appropriate for samples with significant amount of Vitamin D2. Please inform the laboratory if patient is on Vitamin D2 (ergocalciferol) therapy so appropriate test can be ordered.

2. Specimens with rheumatoid factor may interfere with the assay.

3. Methodology is Abbott Architect chemiluminescence microparticle immunoassay. Not for use for patients receiving vitamin D_2 supplementation.

4. This assay is susceptible to interference effects from triglycerides at >500 mg/dL.

Clinical decision values based on the 2011 Institute of Medicine report:

<10 ng/mL: severe deficiency*

10-19 ng/mL: mild to moderate deficiency**

20-50 ng/mL: optimum levels***

51-80 ng/mL: increased risk of hypercalciuria****

>80 ng/mL: toxicity possible*****

*Possible risk for osteomalacia or rickets

**Possible increased risk of osteoporosis or secondary hyperparathyroidism

		TEST LIST
TEST	REFERENCE RANGES	SAMPLE REQUIREMENTS
[Turnaround Time]		
Vitamin D 25-OH - continued ***Optimum for the healthy po	pulation	
***** In conjunction with prolor decreased renal function.	nged calcium supplementation n	hay lead to hypercalciuria and
have levels >150 ng/mL. Renal signs of toxicity, as renal conver Reference: Dietary Reference Ir	failure patients can have very hi rsion to the active hormone 1,25 ntakes for Calcium and Vitamin	igh 25-OH-VitD levels with toxicity 5-OH-VitD is impaired or absent. D. Washington, DC. National
Academies Press (US), 2011		-
White cell count, Blood	See CBC	
Molecular DNA		
Chlamydia trachomatis, DNA	Negative	Preferred - Endocervical or Vaginal Secondary –Urine BD UVE Collection Kit – Transport to the lab within 5 days
Neisseria gonorrhoeae, DNA	Negative	Preferred - Endocervical or Vaginal Secondary –Urine BD UVE Collection Kit – Transport to the lab within 5 days
Trichomonas vaginalis, DNA	Negative	Preferred - Endocervical or Vaginal Secondary –Urine (Female Only) BD UVE Collection Kit – Transport to the lab within 5 days
Bacterial Vaginosis/Vaginitis, DNA – includes the following: (L. crispatus, L. jensenii, Gardnerella vaginalis, Atopobium vaginae, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), Megasphaera- 1, C. albicans, C. tropicalis, C. parapsilosis, C.dubliniensis, Candida glabrata, Candida krusei) [3 days]	Negative	Vaginal Swab BD UVE Collection Kit – Transport to the lab within 5 days

PEDIATRIC HEMATOLOGY REFERENCE RANGES

Age	Hgb	Hct	RBC	MCV	MCH	MCHC
	(g/dL)	(%)	(M/mcL)	(fL)	(pg)	(g/dL)
3m-6 m	9.5-13.5	29-41	3.1-4.5	74-108	25-35	30-36
6 m-2 y	10.5-13.5	33-39	3.7-5.3	70-86	23-31	30-36
2-6 y	11.5-13.5	34-40	3.9-5.3	73-87	24-30	31-37
6-12 y	11.5-15.5	35-45	4.0-5.2	77-95	25-33	31-37
12-18 y-F	12.0-16.0	36-46	4.1-5.1	78-102	25-35	31-37
12-18 y-M	13.0-16.0	37-49	4.5-5.3	78-98	25-35	31-37
≥18 y-F	12.0-14.7	36-45	4.1-5.1	80.0-100.0	26.0-33.0	32.0-35.0
≥18 y-M	12.8-16.9	38.2-50.6	4.25-5.51	80.0-100.0	26.0-33.0	32.0-35.0

RED CELL PARAMETERS

WHITE BLOOD COUNT

Age	Total WBC
	x 10 ³ / mcL
2-4 months	5.5-18.0
4-6 months	6.0-17.5
6 months-2 years	6.0-17.5
2-4 years	6.0-17.0
4-6 years	5.5-15.5
6-8 years	5.0-14.5
8-14 years	4.5-13.5
14-18 years	4.5-13.0
≥ 18 years	4.0-10.0

PLATELET COUNT

 $166-362 \times 10^{3}/\text{mcL}$ (>1 week)

PEDIATRIC HEMATOLOGY REFERENCE RANGES (cont'd)

Age	Segs	Bands	Lymphs	Monos	Eos	Baso
3 m- 4 y	26-50%	0-10%	52-64%	1-6%	1-5%	0-1%
4-8 y	16-60%	0-10%	20-70%	0-7%	0-8%	0-2%
8-15 y	16-60%	0-10%	20-70%	0-7%	0-8%	0-2%
15-19 y	25-70%	0-5%	22-62%	0-9%	0-6%	0-2%
≥ 19 y	34-71%	0-5%	19-53%	5-13%	0-7%	0-2%

Relative Differential (%)

ABSOLUTE DIFFERENTIAL

Age	Neutrophils: Poly +Bands (x 10 ³ /mcL)	Age	Lymphs (x 10 ³ /mcL)	Age	Monos (x 10 ³ /mcL)	Age	Eosinophils (x 10 ³ /mcL)
2m -6 m	1.0-9.0	2m -4 m	3.0-16.0	2m -4 m	0.1-1.8	2m - 4 m	0.1-0.9
6-12 m	1.0-8.5	4-6 m	3.5-14.5	4-6 m	0.1-1.5	4-8 m	0.1-0.8
1-6 y	1.5-8.5	6-8 m	4.0-13.5	6-8 m	0.1-1.3	8-24 m	0.1-0.7
6-10 y	1.5-8.0	8-10 m	4.5-12.5	8-12 m	0.1-1.2	2-8 y	0.0-0.7
10-18 y	1.8-8.0	10-12 m	4.5-11.5	1-2 y	0.1-1.1	8-14 y	0.0-0.6
≥18 y	1.8-7.7	1-2	4.0-10.5	2-4 y	0.1-1.0	≥14 y	0.0-0.5
		2-4 y	3.0-9.5	≥4 y	0.0-0.8		
		4-6 y	2.0-8.0				
		6-8 y	1.5-7.0				
		8-10 y	1.5-6.8				
		10-12 y	1.5-6.5				
		12-14 y	1.2-6.0				
		14-16 y	1.2-5.8				
		16-18 y	1.2-5.2				
		≥18 y	1.0-4.8				
				-	Age	Basophil	S
						(x 10 ³ /mc	L)
					≥2 m	0.0-0.2	

CYTOPATHOLOGY SERVICES

Fresh specimens must be brought to the laboratory as soon as possible. If a delay in specimen transport is anticipated, containers with fixative are available; please call the laboratory for containers prior to patient visit at 4-1444 or 8-5560.

INTRUCTIONS FOR PROPERLY OBTAINING/SUBMITTING SPECIMENS FOR CYTOLOGICAL EVALUATION

- 1. Specimens should be delivered to the laboratory Monday through Friday.
- 2. In complying with CLIA (Federal) regulations, all specimens must be submitted with a completed Cytopathology requisition. <u>Each requisition must include the</u> <u>patient name, medical record number, test(s) ordered, date of specimen</u> <u>collection, source of cytological material, last menstrual period (for</u> <u>gynecologic specimens), location, a doctor's name and signature, and an</u> <u>extension or beeper number. Appropriate clinical data and prior medical</u> <u>history must be indicated.</u> ICD-10 codes should also be included.

History of a prior malignancy or a previous abnormal cytology result is extremely helpful. Sufficient clinical information aids in proper diagnosis, expedites specimen turn-around time and assures proper patient management.

- 3. Please call the laboratory at 8-5560 or 4-1444 if you are unsure how to properly obtain/submit a cytology specimen.
- 4. When submitting slides to the laboratory, please write the patient name on the slide(s) as well as affixing a label to the container in which the specimen or slides are being sent. All specimen containers must be labeled with an appropriate label or patient name and medical record number.
- 5. Specimen vials are available from the laboratory. Please call the laboratory at 8-5560 or 4-1444 in advance to request these supplies.
- 6. Syringes with needles attached will not be accepted for safety reasons.

NON-GYNECOLOGIC SPECIMENS

A. FINE NEEDLE ASPIRATIONS

Patients can be referred for an aspiration biopsy of a superficial, palpable mass. This procedure is performed by a Staff Pathologist and can be scheduled by calling the laboratory at 8-5560. Advance scheduling is preferred but unscheduled patients will be accommodated, as time and staffing permits.

NOTE: Patients with non-palpable lesions should be referred to Radiology.

Radiologically Assisted:

For Radiologically assisted fine needle aspiration procedures, a Cytotechnologist may be available to assist in making slides on-site and a Pathologist may be available for adequacy evaluation. Please call 8-5560 <u>in advance</u> to ensure proper staffing.

Non-radiologically Assisted:

For non-radiologically assisted fine needle aspiration procedures, the cytology staff may be available to assist in the making of slides on-site and adequacy evaluation from 8:00 AM - 3:30 PM. Please call 8-5560 in advance of the procedure to check availability/feasibility.

B. URINARY TRACT SPECIMENS

The best urine for cytologic examination for malignancy is the 2nd morning urine. Following the 1st morning void, wait about 30-60 minutes and collect the specimen. Water or liquid consumption during this time may be helpful. Specimens from transplant patients for polyoma virus (BK) may be obtained at any time. Remember to always obtain a clean catch specimen to evaluate for malignancy or polyoma virus.

Refrigerate urinary tract specimens if they cannot be brought directly to the laboratory. If the delay is expected to be longer than 24 hours, an equal volume of 50% ethyl alcohol may be added to the specimen for preservation. Please indicate the addition of and the approximate volume of preservative on the cytology request.

C. NIPPLE DISCHARGES AND SKIN LESIONS

Smears should be made directly on glass slides from the material obtained from the patient. Immediately drop the slides in 95% ethyl alcohol or the denatured alcohol bottles supplied by the laboratory. In the absence of 95% ethyl alcohol, smeared cellular material can be fixed with a spray fixative. **Any air drying of the smeared preparation must be avoided.**

Avoid making a thick smear. Best results are obtained with a mono-layer of cells on the slide.

D. RESPIRATORY TRACT SPECIMENS

Bronchial Brushes, Washes, Lavages, Trans Bronchial Needle Aspirations, and Sputums.

First morning, productive coughs are the best sputum samples. Deep coughing should be encouraged as upper respiratory tract and oral contamination are a problem with sputum samples.

Specimens may be submitted to cytology if the differential diagnosis includes Pneumocystis carinii (PCP), other fungal infections, Herpes Simplex virus, Cytomegalovirus. <u>Appropriate specimens should also be submitted to</u> <u>microbiology for culture.</u>

Bronchioalveolar lavage (BAL) specimens are preferred for detection of fungal organisms and viral changes.

If the specimens cannot be delivered to the laboratory right away they may be refrigerated. This will enhance preservation; however, freezing must be avoided.

E. CEREBROSPINAL FLUID

Deterioration of cells in CSF is extremely rapid. The specimen must be brought to the laboratory as quickly as possible. Refrigerating the specimen will aid in cellular preservation.

Adding a preservative such as an equal volume of 50% ethyl alcohol may precipitate proteins. However, if the specimen is obtained when the laboratory is closed (such as in the evening or on a weekend) and ethyl alcohol is added to help preserve the specimen, please indicate on the requisition that alcohol was added.

F. BODY CAVITY FLUIDS

Pleural, Abdominal, Pericardial or Joint Fluids

These fluids are best submitted fresh. Heparin may be added to the container <u>prior</u> to collection to prevent coagulation.

If the fluid cannot be submitted immediately to the Cytopathology laboratory, it may be kept in a refrigerator. Freezing must be avoided.

If fluid re-accumulates, a repeat tap often improves the yield of better preserved cells.

G. ALIMENTARY TRACT SPECIMENS

Esophageal, Gastric, Colonic Brushings

Patients should be instructed not to consume any food 8 hours prior to the endoscopy procedure.

Specimens should be smeared on glass slides and fixed immediately in 95% ethyl alcohol.

Washing specimens should be submitted fresh and as soon as possible.

GYNECOLOGIC SPECIMENS

BD (SurePath) GYN Samples:

Insert the Cervex-Brush into the endocervical canal, exert gentle pressure against the cervix and rotate the brush five times in the clockwise direction. After removing the brush from the cervix, place thumb against the brush pad to release the entire brush into the specimen vial.

Written instructions may be given to your patient prior to GYN examination so that optimum cellular material can be obtained (see patient instruction letter on page 31). Liquid based preparations may be obtained from pregnant or menstruating women.

PATIENT INSTRUCTION LETTER

Dear Patient:

Your GYN specimen will be sent to the University of Maryland Pathology Associates Cytology Laboratory for evaluation.

To help us in our screening process we have proposed the following recommendations for you to follow prior to your visit to the doctor's office:

Please do not douche or use intravaginal medication or contraceptive substance for at least 24 hours before your gynecological examination.

Please abstain from sexual intercourse the evening prior to your appointment.

An appointment should be scheduled midway through your menstrual cycle.

Always be prepared to give your physician the date of your last menstrual period (LMP) if you are still cycling or having periods. Information regarding your current medications, including birth control pills or other hormonal medications, should also be given to your physician and is an important part of our overall screening process. Current or prior use of an IUD (intrauterine contraceptive device) is also important information that should be given to your physician.

If you have had a previous abnormal Pap smear, please relay that information to your physician.

We thank you for your effort in helping us with our Pap smear screening process.

Cytology Department.

SURGICAL PATHOLOGY

The following tests are performed in Surgical Pathology:

- 1. Gross and microscopic examination of all tissue specimens removed from patients.
- 2. Gross examination only, of teeth and non-tissue foreign materials removed from patients.
- 3. Microscopic examination of microscopic slides from diagnostic procedures performed elsewhere.
- 4. Special histochemical staining.
- 5. Immunohistochemical examination for cell markers, cell and tissue components. (Please call for a list of immunohistochemical tests available).
- Ultrastructural examination (Diagnostic Electron Microscopy): Including Transmission Electron Microscopy, X-ray Analysis for identification of specific elements, Immunogold Staining for specific antigens, Scanning Electron Microscopy.

Procedures for Sending Specimen and Slides from Patients for Pathological Examination:

All specimen containers and/or slides must be clearly labeled with the patient's name, I.D. number and source of tissue. Every specimen must be accompanied by a requisition that contains all pertinent patient information, including the relevant data from the patient's history, date specimen was taken, and relevant previous procedures. The surgical procedure also has to be indicated on the requisition form. It is important that the requisition is signed and also contains the printed name and address of the physician who requests the examination. Specimens received without appropriate clinical information will not be accepted. This is an absolute requirement in order to comply with existing regulations.

<u>Rush Specimens</u>: A special option for same day processing is available for specimens that are received prior to 9:00 am of each working day. A rush procedure has to be requested by the physician through the Director of Surgical Pathology or his designee.

Reception and Accessioning: All specimens are received and accessioned at the:

University of Maryland Pathology Associates (UMPA) Laboratory 419 W. Redwood Street, Suite 60 Baltimore, Maryland 21201

<u>Fixation</u>: Routine small specimens and biopsies should be placed into the fixative solution in the jars provided by the UMPA laboratory, containing 10% buffered formalin. Special procedures may require fresh or frozen tissue. Specific questions should be addressed to the Pathologist on duty at 8-5555.

<u>Unfixed specimens</u>: A large specimen should not be fixed, but placed into a plastic biohazard bag that is securely tied, and refrigerated. Prompt delivery of the specimen is essential.

<u>Electron Microscopy</u>: Special fixatives and specimen containers are available for ultrastructural examinations upon request.

<u>Kidney Biopsies</u>: Kidney biopsies should be fixed as follows: The biopsy should be divided into three pieces. (a.) One third should be fixed in a mixture of 4% formaldehyde and 1% glutaraldehyde, available from the laboratory; (b.) One third should be fixed in 10% normal buffered formaldehyde; (c.) One third should be frozen in OCT on a chuck and shipped on dry ice or, alternatively, it may be placed in immunofluorescence transport medium available from the laboratory. The frozen specimen should be received in the laboratory the same day the specimen was frozen.

<u>Muscle Biospy</u>: Muscle biopsy can be obtained with either open or modified needle biopsy techniques usually done under local anesthesia. Selection of the appropriate muscle to biopsy is extremely important. The muscle to be studied must be affected but not so severely that is shows "end-stage" atrophy. The favored muscles of biopsy are the quadriceps femoris, biceps brachii, deltoid muscle, and soleus/gastrocnemius (in that approximate order of preference).

Enzyme histochemical staining techniques require that the tissue be snap frozen. A wide variety of techniques for snap-freezing skeletal muscle have been used with success. We prefer to use a wide-mouth thermos in which liquid nitrogen chills a metal cup or large test tube containing isopentane (2 methyl butane) to a syrupy consistency (equivalent to -150° centigrade). The specimen is submersed in this liquid for 15-20 seconds, then removed allowing excess isopentane to evaporate before placing it in any container.

The frozen skeletal muscle is allowed to equilibrate in a conventional cryostat and multiple sections are prepared for a battery of enzyme histochemical stains. Residual frozen muscle is held for possible biochemical analysis based on the histologic and ultrastructural findings.

Note: Never store muscle in a cryostat overnight. The defrosting cycle will destroy the muscle morphology!

<u>Enzyme Histochemical Stains</u>: A battery of enzyme histochemical stains is performed on each biopsy specimen, and where appropriate, additional special stains are applied. These additional stains include oil-red-O (for lipid storage), and specific enzymes such as phosphorylase, succinate dehydrogenase, cytochrome oxidase, and phosphofructokinase. Electron microscopy may be required in selected cases.

An additional small portion of the muscle is fixed in appropriate electron microscopy fixative (2.5% glutaraldehyde).

Muscle Biopsies From Referring Sites: Call the neuropathology lab at (410) 328-5500 for shipping instructions.

<u>Nerve Biopsies</u>: An important aspect of diagnosing peripheral nerve disease is the evaluation of individual nerves. Orientation of nerve tissue in the acquired biopsy is important and it is important that the orientation be maintained during the fixation process. Therefore the following procedure describes the handling of nerve biopsies that are delivered to the laboratory from a distant operating facility.

The following materials are needed prior to the acquisition of a biopsy: (1) 2.5% buffered glutaraldehyde (available from the laboratory); (2) a small piece of cardboard such as an index card; (3) a container such as a test tube; (4) Labels. Snap freezing a portion for special studies may be desirable as well.

The nerve is obtained (3-4 cm in length x 0.3-0.4 cm in diameter) and placed on the saline moistened piece of cardboard. This should be placed in the tube/container. The tube is filled with 2.5% buffered glutaraldehyde. A label identifying the patient and the tissue is placed on the outside. The tube with the specimen is placed upright into the rack for several hours fixation. Then it is delivered to the laboratory accompanied by a requisition. For information call: Histology Laboratory at 410-328-5500.

Nerve Biopsies from referring sites: Call the neuropathology lab at (410) 328-5500 for shipping instructions for both fixed and frozen tissues.

Patient Instructions Clean Catch Urine – *Female*

- 1. Wash hands thoroughly with soap and water, rinse and dry on a disposable paper towel.
- 2. Remove the sterile specimen container, 3 antiseptic towelettes, and 1 sterile gauze pad from their packaging and place them on a paper towel on the sink next to the toilet.
- 3. Lower undergarments below the knees so that they will not interfere with your urine collection.
- 4. With two fingers of one hand, hold the outer folds of your vagina apart. With the other hand, gently wash the vaginal area from **front to back** using 1 of the disposable antiseptic towelettes. Discard the towelette in the wastebasket.
- 5. Still holding the outer vaginal skin apart, repeat step 4. two more times using only 1 towelette at a time. Discard each towelette into the wastebasket after each use.
- 6. Once you have cleansed the area a total of three times, dry the area using a sterile gauze pad and discard into the wastebasket.
- 7. Continue holding your outer vaginal folds apart and **begin to urinate into the toilet first.** Lean slightly forward so that the urine flows directly into the toilet without running along the skin.
- 8. After the first few teaspoons are voided, place the sterile specimen collection container under the stream of urine and collect the rest of your urine in the container.
- 9. When you have finished, tighten the cap on the container securely and using a paper towel wipe any spilled urine from the outside of the container.
- 10. Make certain that your name is on the outside of the container.

Patient Instructions Clean Catch Urine – *Male*

- 1. Wash hands thoroughly with soap and water, rinse, and dry on a disposable paper towel.
- 2. Remove the sterile specimen container, 1 antiseptic towelette, and 1 sterile gauze pad from their packaging and place them on a paper towel on the sink next to the toilet.
- 3. Lower undergarments below your knee so that they will not interfere with your urine collection.
- 4. Holding your foreskin with one hand, if necessary, use 1 antiseptic towelette and gently wash the end of the penis. Discard the towelette into the wastebasket.
- 5. Continue holding back the foreskin and gently dry the end of your penis with the sterile gauze pad and then discard it into the wastebasket.
- 6. Still holding back the foreskin, begin to **urinate into the toilet first.** After the first few teaspoons have passed, place the sterile container under the stream of urine and collect the rest of your urine in the container.
- 7. After you have finished, tighten the cap on the container securely and using a paper towel wipe any spilled urine from the outside of the container.
 - 7. Make certain that your name is one the outside of the container.

BD MAX[™] UVE SPECIMEN Collection Kit Urine Specimen Collection

COLLECTION SITE



 Have patient collect specimen in a sterile, plastic, preservative-free specimen collection cup.

NOTE: Patient should not urinate for at least 1 hour prior to collection of specimen. Patient should collect the first 20 to 60 mL of voided urine.



 Place cap securely on urine collection cup.

NOTE: Wear clean gloves when handling urine specimen. If gloves come into contact with the specimen, immediately change gloves.

 Label collection cup with patient identification, date, and time collected.







 Uncap the BD MAX" UVE Sample Buffer Tube. Use the transfer pipette to gently mix and aspirate 1 mL of urine from the urine cup.

NOTE: Neat urine specimens must be processed within 4 hours if kept at 2-30°C, or 24 hours if kept at 2-8°C.

 Dispense approximately 1 mL into the BD MAX^M UVE Sample Buffer Tube. Discard the pipette.

NOTE: The transfer pipette is intended for use with a single specimen only.

 Tighten the cap securely on the BD MAX[™] UVE Sample Buffer Tube. Invert the tube 3 to 4 times.



 Label the BD MAX^M UVE Sample Buffer Tube with patient identification, date, and time collected. Be careful not to obscure any bar codes on the tube.

NOTE: Wear clean gloves when handling sample tubes and urine specimens.

 Use the viewing window on the BD MAX[™] Sample Buffer Tube to ensure urine specimen was added to the tube.

STORAGE AND TRANSPORT

SAMPLE BUFFER TUBE STORAGE CONDITIONS

Specimen Type	Prior to Transfer into BD MAX" UVE Sample Buffer Tube		In BD MAK [™] UVE Sample Buffer Tube Prior to Pre-Warm or Testing			
	2-30°C	2-8°C	2-30°C	2-8°C	-20°C	
Urine	4 hours	24 hours	5 days		30 days	

443376—BD MAX** UVE Specimen Collection Kit for use with the BD MAX** CT/GC/TV assay kit.

BD MAX[™] CT/GC/TV endocervical specimen collection and transfer procedure BD MAX[™] UVE Specimen Collection Kit

Clinician collection procedure

- 1. Precaution: Do not collect specimen at the posterior fornix
- 2. Lukewarm water may be used to warm and lubricate the speculum.
- If lubricant must be used, lubricant should be used sparingly (1.8 mm) and applied only to the exterior sides of the speculum blades, avoiding contact with the tip of the speculum.
- Holding the swab by the white cap, insert the swab into the cervical canal and rotate for 15 to 30 seconds.

How to use lubricant for the collection of endocervical swabs



Apply a 1.8 mm amount of lubricant on the speculum



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Appy only to exterior sides of the speculum, avoiding the tip." "Avoid use of lubricants that contain carborner (or carbopol polymers).

Avoid contact between the swab and the speculum or lubricant.

Swab to tube transfer procedure (clinician collected and patient self-collected)

To transfer the sample



 Fully insert the swab into the tube so that the tip is at the bottom.



 Carefully break the 3. Tightly re-cap shaft at the score mark. the tube.
 Be careful to avoid splashing.



 Label tube with patient information, date, and time collected. Be careful not to obscure the bar codes on the tube.

Swab Storage

and Transport Swab sample must be transferred within 2 hours after collection to the BD MAX^{III} UVE Sample Buffer Tube when kept at 2°C to 30°C.

Specimen Type:

Vaginal/Endocervical swab collection for BD MAX CT/GC/TV (requiring pre-warm)

In BD MAX UVE Sample Buffer Tube prior to testing

2–30°C	-20°C		
5 days	30 days		

BD MAX[™] Vaginal Panel specimen collection and transfer procedure BD MAX[™] UVE Specimen Collection Kit</sup>

Clinician collection procedure

- Collect swab prior to pelvic, speculum, or bimanual exam
- No lubricant is used for the sample technique.
- Gently slide the swab 2 inches (5 cm) into the vagina. If the swab does not slide easily, gently rotate the swab as you push. If it is still difficult, do not attempt to continue.
- 2. Rotate the swab for 10 to 15 seconds.
- 3. Withdraw the swab without touching the skin outside the vagina.

Precaution: if a speculum will be inserted prior to collecting the Vaginal Panel swab

- 1. Do not collect specimen at the posterior fornix.
- 2. Lukewarm water may be used to warm and lubricate the speculum.
- If lubricant must be used, lubricant should be used sparingly (1.8 mm) and applied only to the exterior sides of the speculum blades, avoiding contact with the tip of the speculum.









Appy only to exterior sides of the speculum, avoiding the tip." "Avoid use of lubricants that contain carbomer (or carbopol polymers).

- Avoid contact between the swab and the speculum or lubricant.
- 5. Insert the MAX Vaginal Panel collection swab to contact the vaginal sidewall, 2 inches (5 cm) within the vagina,

rotate gently for 10-15 seconds; withdraw the swab without touching the speculum.

Swab to tube transfer procedure (clinician collected and patient self-collected) To transfer the sample







2. Carefully break the 3. Tightly re-cap shaft at the score mark. the tube. Be careful to avoid splashing.



4. Label tube with patient information, date, and time collected. Be careful not to obscure the bar codes on the tube.

Swab Storage and Transport

Swab sample must be transferred within 2 hours after collection to the BD MAX^{III} UVE Sample Buffer Tube when kept at 2°C to 30°C.

Specimen Type:

Vaginal swab collection for
BD MAX Vaginal Panel
(not requiring pre-warm)
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Tube prior to testing			
2-30°C	2–8°C		
8 days	14 days		