

Faculty Practices of the University of Maryland School of Medicine

# UNIVERSITY OF MARYLAND PATHOLOGY ASSOCIATES

**Professional Services Manual** 

**November 2023** 

#### 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, phleobotomy services located at 16 S. Eutaw St., Suite 120 are available from 8:00 AM to 4:30 PM, phleobotomy services located at 800 Linden Ave., 10<sup>th</sup> floor, W10E102 are available from 8:30 AM to 4:45 PM, and phlebotomy services located at 5890 Waterloo road are available from 8:00 AM – 4:15pm, M-F, and Saturdays from 8:00 AM – 12:00 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 Additive (BD Hemogard<sup>TM</sup> Closure color)

<sup>a</sup>Green top

Pink top

Tan top

Clot activator only- no separator gel aRed top

<sup>a</sup>Gold top Serum separator gel (SST) and clot activator

<sup>ab</sup>Lavender top Potassium (K<sub>2</sub>) EDTA

<sup>a</sup>Light Green top Plasma separator gel (PST) Lithium heparin

Sodium Heparin

<sup>b</sup>Light Blue, yellow striped label Buffered citrate (3.2%)

Acid citrate dextrose (ACD) - A & B sol'ns Yellow top (regular closure) Royal Blue top Trace element free (K<sub>2</sub> EDTA or w/clot activator)

Gray top Sodium fluoride / Potassium oxalate

Pearl top PPT plasma separation tube Potassium (K<sub>2</sub>) EDTA with separator gel

Potassium (K 2) EDTA for Blood Bank

Potassium (K<sub>2</sub>) EDTA for Lead testing

#### **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 MOLECULAR Collection Kits (CT/GC/TV and Vaginosis/Vaginitis DNA Panel)
- VCM Media (For Chlamydia, Viral, or Mycoplasma / Ureaplasma culture)
- UVT (For SARs Cov-2, Flu A/B RSV)
- Formalin preservatives system for stool ova and parasites
- Cary-Blair transport media for stool cultures
- BD SurePath vial for pap smear and HPV
- Biopsy containers with formalin

<sup>&</sup>lt;sup>a</sup> Microtainer sizes also available

<sup>&</sup>lt;sup>b</sup> Pediatric size available

#### 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	*LDH	Free T4
*Alkaline Phosphatase	*Lipase	HbA1c%
*ALT	*Magnesium	HDL Cholesterol
*Amylase	*Phosphorus	Iron Saturation
*AST	*Potassium	Iron Total Binding Capacity
*Calcium	*Reticulocyte Count	Occult Blood
*CBC and Automated Diff	*Sodium	SARS CoV-2/Flu AB/RSV
*Chloride	*Total Bilirubin	Tacrolimus
*Cholesterol	*Total Protein	Total Protein 24 hour
*CO <sub>2</sub>	*Triglyceride	Total Protein Urine Random
*Creatinine	*Urea Nitrogen	Total Protein/Creatinine Ratio
*Direct Bilirubin	*Uric Acid	Transferrin
*Glucose	*Urinalysis	TSH, 3rd generation
*HCG Qualitative	*Urine HCG Qualitative	Urine Creatinine
*HCG Quantitative	CT/GC/TV DNA	Urine Creatinine Clearance
*Iron	Ferritin	Urine Microalbumin

#### **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
Bacterial Vaginosis/Vaginitis DNA Panel
HPV

#### The following tests are performed Tuesday and Thursday:

Intact PTH AFP

PSA, 3<sup>rd</sup> generation Vitamin B12

Folate

#### 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

WBC  $\leq 2.5 \text{ or } \geq 20.0 \text{ x } 10^3 \text{ mcL}$ 

 $\begin{array}{ll} \text{Hgb} & \leq 8.0 \text{ g/dL} \\ \text{Hct} & \leq 20\% \end{array}$ 

Platelet  $\leq 50 \times 10^3 / \text{mcL}$ 

#### Chemistry

Sodium $\leq 125 \text{ or } \geq 155 \text{ mmol/L}$ Potassium $\leq 3.0 \text{ or } \geq 6.0 \text{ mmol/L}$ \*Urea Nitrogen $\geq 100 \text{ mg/dL}$ \*Creatinine $\geq 4.0 \text{ mg/dL}$ 

Phosphorus  $\leq 1.5 \text{ mg/dL}$ 

Magnesium  $\leq 1.0 \text{ or } \geq 3.0 \text{ mg/dL}$ Glucose  $\leq 45 \text{ or } \geq 400 \text{ mg/dL}$ 

Calcium  $\leq 7.5 \text{ or } \geq 12.0 \text{ mg/dL (age } > 10 \text{ d)}$ 

 $\leq$  6.9 or  $\geq$  12.1 mg/dL (age 0- 10 d)

Amylase  $\geq 200 \text{ U/L}$ Lipase  $\geq 400 \text{ U/L}$ 

Total and/or Direct Bilirubin (infants < 14 d) ALL

Vitamin D 25-OH > 150 ng/mLTacrolimus  $\geq 20.0 \text{ ng/mL}$ HIV 1/2 Ag/Ab Reactive

#### Urinalysis

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

<sup>\*</sup>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 ( $\geq$  18 years) unless otherwise specified.

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

 $\begin{array}{ll} h = hours & M = male \\ d = days & F = female \\ w = weeks & m = months \\ y = years & \end{array}$ 

# TEST LIST

TEST REFERENCE RAN	GES SAMPLE REQUIREM	ENTS
Albumin [4 hrs]	Age       Range MF         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	1 mL in green top
Albumin, Urine / Creatinine, Urine ratio	<30 mcg/mg creatinine	10 mL random urine (urine creatinine will be
[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         Sex         Range           0-4yM&F         145-320 U/L           4-7yM&F         150-380 U/L           7-10yM&F         175-420 U/L           10-12yM         135-530 U/L           12-14yM         200-495 U/L           14-16yM         130-525 U/L           16-19yM         65-260 U/L           10-12yF         130-560 U/L           12-14yF         105-420 U/L           14-16yF         70-230 U/L           16-19yF         50-130 U/L           ≥19yM&F         38-126 U/L	1 mL in green top
Alpha-fetoprotein (AFP) [5 days]	≤ 7.5 ng/mL  Methodology: Immunochemiluminescent assay of Ortho Diagnostics VITROS analyzer. Ingestion of high dose Biotin (≥ 1000 mcg/day) may cause interference in this assay and lead to a possibly low biased result.	2 mL in gold top

		TEST LIST
TEST [Turnaround Time]	REFERENCE RANGES SA	AMPLE REQUIREMENTS
ALTV [4 hrs]	Age (0-150y) M $0-49$ U/L Age (0-150y) F $0-34$ U/L	1 mL in green top
Amylase [4 hrs]	≥18y MF 48-133 U/L  Normal reference range is for heparin plasma specimens. Values for serum are expected to be approximately 20 units/L (25%) lower.	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 large positive biases on Total Bilirubin results. At high bilirubin levels Levodopa shows a substantial negative bias & 4-Aminosalicylic acid shows a small positive bias.	Adult: 1 mL in green top Pediatric: 1 microtainer- green top protect from light
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

TEST	REFERENCE RANGES	TEST LIST SAMPLE REQUIREMENTS
[Turnaround Time]	REFERENCE RANGES	SHAM EL 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	$4.0-10.0 \times 10^3 / \text{mcL}$	be specific size. Obtain from the laboratory.) Mix
Red Cell Count	M: 4.25-5.51 x 10 <sup>6</sup> /mcL F: 4.10-5.10 x 10 <sup>6</sup> /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 <sup>3</sup> /mcL	
Mean Platelet Volume (MPV)	9.4-12.4 fL	
NRBC % NRBC Absolute	0-0% 0-0.00 x 10 <sup>3</sup> /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	

TEST	REFERENCE RANGES		SAMPLE REQUIREMENTS
[Turnaround Time]			
Creatinine	Age S	Sex Range	1 mL in green top
[4 hrs]	0-1w N	/IF0.22-0.92 mg/dl	L
	1w-1mM	IF0.22-0.63 mg/dl	L
	1m-1yN	IF0.12-0.33 mg/dL	J.
	1-12yM	IF0.22-0.63 mg/dL	
	12-18yM	IF0.42-0.92 mg/dL	
	≥ 18yN	M0.66-1.25  mg/dL	
	≥ 18yF	70.52-1.04 mg/dL	
e GFR: MF ≥18y ≥60mL/min	$/1.73 \text{ m}^2$		
Creatinine, Urine	Random - n	one	10 mL random urine
[8 hrs]			specimen
Creatinine, Urine	24 hr		Collect 24-hour urine with
24 hour	M ≥19 y:	1000-2000 mg/day	no preservative; refrigerate
[8 hrs]	F ≥19 y:	800-1800 mg/day	during collection. At end
			of collection period, draw
Creatinine Clearance	Creatinine Clearance (corrected)		one green top tube (Li
[8 hrs]	M 20-29y 90-140 mL/min/1.73m <sup>2</sup> BSA		heparin). Both specimens must arrive at the lab at
	F 20-29y		the same time with
	•	mI /min/1 72m <sup>2</sup> DCA	
	72-110 mL/min/1.73m <sup>2</sup> BSA		requisition having patient's height, weight,
	Decreases ~	6.5 mL/min/1.73m <sup>2</sup>	and the collection period.
	BSA per de		unu uno comentan persoan
Differential Leukocyte	Adult Refere	nce Ranges	3-5 mL in lavender top
[4 hrs] (Automated)	Adult Reference Ranges See pp. 28-29 for pediatric ranges		tube or 1 lavender
	microt		microtainer.
	Relative Cou	int Absolute Count (% x WBC)	
T-4-1WDC		$4.0-10.0 \times 10^3/\text{m}$	cL
Total WBC Total Neutrophils	34-71%	$1.8-7.7 \times 10^3/\text{mg}$	
Lymphocytes	19-53%	$1.0-4.8 \times 10^3/\text{m}$	
Monocytes	5-13%	$0.0-0.8 \times 10^3/\text{m}$	cL
Eosinophils	0-7%	$0-0.5 \times 10^3 / \text{mcL}$	_
Basophils	0-2%	$0-0.2 \times 10^3 / \text{mcI}$	_
Immature granulocytes	0-0.7%	$0-0.2 \times 10^3 / \text{mcL}$	_

 $\label{eq:NOTE: Automated neutrophil count = Polys + Bands.}$  Automated Immature granulocytes = Metamyelocytes + myelocytes + promyelocytes

Adult Reference Ranges	3-5 mL in lavender top
	tube or 1 lavender
Relative Count%	microtainer.
33-75%	
0-5%	
15-60%	
0-9%	
0-6%	
0-2%	
	Relative Count% 33-75% 0-5% 15-60% 0-9% 0-6%

TEST	REFERENCE RANGES SA		SAMPLE REQUIREMENTS	
[Turnaround Time]	KEFEKEN	CE KANGES	SAMPLE REQUIREMENTS	
Turnaround Time				
Ferritin [1 day]	M: 17.9-464 ng/mL F: 0-50 y 6.2 - 137 ng/mL F: ≥50 y 11.1-264 ng/mL Ingestion of high dose Biotin (≥ 1000 mcg/day) may cause interference in this assay and lead to a possibly low biased result		nL L	
Folate	Age	Sex Range	2 mL in gold top	
[5 day]	0-2y 2 – 17y	MF not define MF 5.0 – 21.0 MF 3.0 – 20.0 n	ng/mL	
Glucose (fasting) [4 hrs]	_	99 mg/dL 10 and <126mg/dL itus*: ≥ 126 mg/c	1 mL in green top	
	hyperglycemi	ce of unequivocal a or hyperglycemi should be confirm		
50 g Gestational Diabetes Screen [4 hrs]	If ≥ 140 mg/dI Obstetric GTT	L, proceed to a 100g		
	approximately GDM	140 mg/dL identific 80% of women with 130 mg/dL identifien GDM	th	
Glucose Tolerance Test 100 g Obstetric Test [4 hrs]	Two or more	ng/dL ng/dL ng/dL <b>of the venous gluc</b> o		
		s must be met or a positive diagnosis	subject should remain seated and should not smoke throughout the test.	

Glucose Tolerance Test 75 g Non-Obstetric	Normal: <140 mg/dL Prediabetes: 140 -199 mg/dL	1 mL in green top
[4 hrs]	<b>Diabetes Mellitus*:</b> ≥200 mg/dL	Fasting (no food or beverage other than
	*In the absence of unequivocal	water for at least 8
	hyperglycemia or hyperglycemic crisis, results should be confirmed by repeat testing	hours before testing).
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	REFERENC	E RANGES	SAMPLE REQUIREMEN
[Turnaround Time]			`
HCG, Quantitative Total b-hCG - continued	Gest. Age 1-10w 11-15w 16-22w 23-40 w	Range 64 – 150854 mIU 11795 - 151996 mI 9384 - 61410 mIU 1737- 98576 mIU	U/mL U/mL J/mL
	1000 mcg/day)	) may cause this assay and lea	
HDL Cholesterol [4 hrs]	Adult MF: Low: High:	<40 mg/dL ≥60 mg/dL	1 mL in green top
Hematocrit	See CBC		
Hemoglobin	See CBC		
Hemoglobin A1c%  Normal: Below 5.79  Prediabetic: 5.7 – 6.  Diabetic: 6.5% or hi		' - 6.4%	3 mL lavender top
	-	Hemoglobin A1c nosing diabetes has	not
DO NOT use HgbA1c for asscell survival, such as hemolyt DO NOT use this assay method HbSC, or >7% HbF.	sessment of patient ic diseases, pregna	s with conditions cancy, significant acu	te or chronic blood loss.
Hepatitis B Surface Antigen [3 days]	Negative		4 mL in gold top.
Hepatitis B Surface Antibody, Qualitative, Total [3 days]	Negative. Posit	ive after immunizat	ion. 3 mL in gold top.
Hepatitis B Surface Antibody, Quantitative, Total [3 days]	considered to be infection with H ≥5.00 and <12.0 Indeterminate, anti-HBs is pres with immunity. should be further considering other.	BV.  00 mIU/mL:  Unable to determinent at levels consist Patient's immune st	ne if tent tatus

≥12.00 mIU/mL: Positive, Patient is

		TEST LIST
TEST [Turnaround Time]	REFERENCE RANGES S.	AMPLE REQUIREMENTS
Hepatitis B Surface Antibody, Quantitative, Total - Continued [3 days]	considered to be immune to infection with HBV. It has not been determined what clinical significance is for values greater than ≥12 mIU/mL, other than the individual is considered to be immune to HBV infection.	
	Test is performed using the Vitros chemiluminescent method. Quantitative values from other methods/instruments should not be us interchangeably.	ed
Hepatitis B Core Antibody, Total [3 days]	Negative	3 mL in gold top.
Hepatitis C Antibody [3 days]	Negative	3 mL lavender top
	Negative indicates: Anti-HCV not detected. Patient is presumed not to be infected with HCV.  Reactive indicates: Anti-HCV detected Patient is presumed to be infected with HCV, state or associated disease not determined. Follow CDC recommendations for supplemental testing.	ed.
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 HIV 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)	M: 257-470 mcg/dL F: 274-546 mcg/dL	2 mL in green top
(calculated from Transferrin) [4 hrs]	Ç	Specimen must not be hemolyzed.
Iron Saturation (calculated) [4 hrs]	M: 20-50% F: 15-50%	

TEST LIST

TEST [Turnaround Time]	REFERENCE RANGES SA	AMPLE REQUIREMENTS
Ketones, urine	See Urinalysis, Chemical Screen	
Lactate Dehydrogenase (LDH) [4 hrs]	Age       Sex       Range         1-4yM&F	1 mL green top
LDL Cholesterol (calculated) [4 hrs]	Adult: Optimal: <100 mg/dL Near Optimal: 100-129 mg/dL Borderline High: 130-159 mg/dL High: 160-189 mg/dL Very High: ≥190 mg/dL  Estimate not valid if Triglyceride >400 mg/dL	1 mL in green top  Must be fasting sample (9-12 hrs)
<b>Lipase</b> [4 hrs]	23-300 U/L	1 mL in green top
Lipid Panel Cholesterol, Total	Adult: Desirable: <200 mg/dL Borderline High: 200-239 mg/dL High: ≥240 mg/dL	3 mL in green top tube  Results on non-fasting specimens are not interpretable. Must be
Triglycerides	Normal: <150 mg/dL Borderline High: 150-199 mg/dL High: 200-499 mg/dL Very High: ≥500 mg/dL	interpretable. Must be fasting 9-12 hours.
HDL Cholesterol	Low: <40 mg/dL High: ≥60 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: ≥190 mg/dL	
<b>Magnesium</b> [4 hrs]	1.6-2.6 mg/dL	1 mL in green top

TEST	REFERENCE RANGES SA		TEST LIST SAMPLE REQUIREMENTS
[Turnaround Time]			
Parathyroid Hormone (PTH), Intact [3 days]	MF ≥ 18y:	12 -68 pg/mL	3 mL in gold top
Phosphorus [4 hrs]	<b>Age</b> 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]	<b>Age</b> 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 pregnant female: Negative  Healthy pregnant women with hCG present (the amount will vary with gestational age and between patients): Positive		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 ng/mL Ingestion of high dose Biotin (≥ 1000 mcg/day) may cause interference in this assay and lead to a possibly low biased result		2 mL in gold top
Protein Total, Serum [4 hrs]	Age 0-6d 6d-1y 1y-4y 4-7y 7-10y 10-19y >19 y	Range MF 5.4 - 7.0 g/dL no range 5.9 - 7.0 g/dL 5.9 - 7.8 g/dL 6.2 - 8.1 g/dL 6.3 - 8.6 g/dL 6.3 - 8.2 g/dL	1 mL in green top

				TEST LIST
TEST [Turnaround Time]	REFERI	ENCE RA	ANGES SAM	IPLE REQUIREMENTS
Protein Total, Urine Random [8 hrs]	<b>Age</b> 0 – 150y	Sex MF	Range <12 mg/dL	10 mL random urine
Protein Total, Urine 24 hours [8 hrs]	<b>Age</b> 0 – 150y	Sex MF	Range 42-225 mg/dL	Collect 24-hour urine with no preservative; refrigerate during collection
Protein Total, Urine/Creatinine Ratio [8 hrs]		<b>Rang</b> < 0.2 mg		10 mL random urine (urine creatinine will be
Reducing Sugars, Urine [3 days]	are not in urinalysis specimen	cluded in for adult s and mus	ucing substances the routine or pediatric st be ordered questing clinician.	5 mL of freshly voided random urine
Reticulocyte Count [4 hrs]	Relative of $MF \ge 1y$ Absolute $MF: \ge 1$	0.5-2.2% count:	4 mL in lavender top tube or 1 lavender microtainer	
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]	evaluated adjustmen must esta based on Method in Architect equivalen	clinically nts are ma blish his o their clini s Abbott A results an at to the r	d be thoroughly before treatment ade and each user or her own ranges ical experiences. Architect. The expected to be esult determined apectrometry.	1 mL in lavender top

Thyroid Stimulating Hormone (TSH) [1 day]	1 - 6m 6m - 18y >18y Ingestion 1000 mcg interferen	Range MF  1.00 – 20.00 mcIU/mL  0.50 – 6.50 mcIU/mL  0.50 – 6.00 mcIU/mL  0.50 – 4.50 mcIU/mL  0.47 – 4.68 mcIU/mL  of high dose Biotin (≥ /day) may cause ce in this assay and lead oly low biased result	3 mL in gold top
Thyroxine, Free [1 day]	≥1y MF (	0.60 - 2.50 ng/dL	2 mL in gold top

		TEST LIST
TEST	REFERENCE RANGES	SAMPLE REQUIREMENTS
[Turnaround Time]		
Thyroxine, Free - continued	Free T4 normal reference interval children less than one year old has not been established for this test methodology.	
Transferrin [ 4 hrs]	MF 206 – 381 mg/dL	1 mL in green top
	Adult MF (fasting):	
<b>Triglycerides</b> [4 hrs]	Normal: <150 mg/dL Borderline High: 150-199 mg/	1 mL in green top
	High: 200-499 mg/ Very High: ≥500 mg/dL	dL Must be fasting sample
	<b>Comment:</b> Results on non-fasting specimens are not interpretable.	5
Urea Nitrogen (BUN) [4 hrs]	$\begin{array}{ll} M\colon & 9-20 \ mg/dL \\ F\colon & 7-17 \ mg/dL \end{array}$	1 mL in green top
Uric Acid, Serum [4 hrs]	Age       Sex       Range         0-2y.       M&F.       not defined         2-8y.       M&F.       2.0 - 5.5 mg/         ≥8y.       M.       3.5 - 7.2 mg/         ≥8y.       F.       2.6 - 6.0 mg/	/dL
Urinalysis, Chemical Screen		15 mL random urine
[4 hrs] Ketone Bilirubin Glucose Leukocyte esterase Nitrite	Negative Negative Negative Negative Negative	Store refrigerated if not transported to lab immediately; Transport to lab within 2 hours of collection
pH Protein RBC/Hemoglobin Specific Gravity	5-8 Negative-Trace Negative-Trace 1.001-1.035	

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.

0.2-1.0 E.U./dL

Urobilinogen

TEST REFERENCE RANGES SAMPLE REQUIREMENTS

[Turnaround Time]

#### **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 15 mL fresh urine

[4 hrs]

WBC  $\leq 5/\text{HPF}$  Store refrigerated if not

Transitional epithelial cells
Renal tubular epithelial cells
Casts (Hyaline)

Negative, 0-2/HPF
Negative, 0-2/HPF
Negative, 0-1/LPF

All other casts

Bacteria

Yeasts

Trichomonas

Abnormal Crystals

Negative

Negative

Negative

Negative

Note: No reference ranges for 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 (≥ 1000 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<sub>2</sub> 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 population

\*\*\*\* In conjunction with prolonged calcium supplementation may lead to hypercalciuria and decreased renal function.

\*\*\*\*\*80 ng/mL is the lowest reported level associated with toxicity. Most patients with toxicity have levels >150 ng/mL. Renal failure patients can have very high 25-OH-VitD levels without signs of toxicity, as renal conversion to the active hormone 1,25-OH-VitD is impaired or absent. Reference: Dietary Reference Intakes for Calcium and Vitamin D. Washington, DC. National Academies Press (US), 2011

White cell count, Blood See CBC

#### Molecular DNA

Negative Preferred - Endocervical or Vaginal Chlamydia trachomatis, DNA

Secondary -Urine BD MOLECULAR Collection Kit -

Transport to the lab within 5 days Preferred - Endocervical or Vaginal Negative Neisseria gonorrhoeae, DNA

Secondary -Urine

BD MOLECULAR Collection Kit -Transport to the lab within 5 days Preferred - Endocervical or Vaginal Negative Trichomonas vaginalis, DNA Secondary – Urine (Female Only) BD MOLECULAR Collection Kit -Transport to the lab within 5 days Negative

Vaginal Swab

BD MOLECULAR 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]

SARS-CoV-2 – PCR Negative UVT - NP (2-8°C)

Infuenza A,B - PCR UVT - NP (2-8°C) Negative

RSV UVT - NP (2-8°C) Negative

[48 hours]

SurePath Vial HPV with Genotyping Negative

[3 days]

## PEDIATRIC HEMATOLOGY REFERENCE RANGES

## **RED CELL PARAMETERS**

Age	Hgb	Het	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 <b>-</b> 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

#### WHITE BLOOD COUNT

Age	Total WBC
	$\times 10^3 / \text{ mcL}$
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

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

# PEDIATRIC HEMATOLOGY REFERENCE RANGES (cont'd)

# **Relative Differential (%)**

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%

#### ABSOLUTE DIFFERENTIAL

Age	Neutrophils: Poly +Bands (x 10 <sup>3</sup> /mcL)	Age	Lymphs (x 10 <sup>3</sup> /mcL)	Age	Monos (x 10 <sup>3</sup> /mcL)	Age	Eosinophils (x 10 <sup>3</sup> /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 v	3.0-9.5	>4 v	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	Basophils
	$(x 10^3/mcL)$
≥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. Each requisition must include the patient name, medical record number, test(s) ordered, date of specimen collection, source of cytological material, last menstrual period (for gynecologic specimens), location, a doctor's name and signature, and an extension or beeper number. Appropriate clinical data and prior medical history must be indicated. 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 2<sup>nd</sup> morning urine. Following the 1<sup>st</sup> 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. **Appropriate specimens should also be submitted to microbiology for culture.** 

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).
- 6. 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!

Enzyme Histochemical Stains: 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.
- 8. Make certain that your name is one the outside of the container.

# BD Molecular Urine Transport Kit

# Urine specimen collection

#### Collection procedure



1. 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.



4. Uncap the BD Molecular Urine Sample Buffer Tube and the urine sample cup. Immediately after collection, use the graduated transfer pipette to gently mix the urine specimen. Then, use the pipette to aspirate approximately 2 mL of the urine specimen from the collection cup.



2. Have the patient securely place the cap on the urine collection cup.



5. Transfer 2 mL of the urine specimen into the **BD** Molecular Urine Sample Buffer Tube. Use the graduations on the transfer pipette as a guide. DO NOT overfill or underfill the tube. NOTE: The transfer pipette is intended for use with a single specimen only.



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

NOTE: Wear clean gloves when handling BD Molecular Urine Transport Kit components and urine specimens. If gloves come into contact with the specimen, immediately change gloves.



6. Tighten the cap securely on the BD Molecular Urine Sample Buffer Tube. Invert the BD Molecular Urine Sample Buffer Tube 3 to 4 times to ensure that the specimen and reagent are well mixed.

## Storage and transport

Urine specimens can be stored for a total of 21 days at 2-30 °C in BD Molecular Urine Sample Buffer Tubes.



- 7. Label the BD Molecular Urine Sample Buffer Tube with patient identification, date, and time collected. Be careful not to obscure any barcodes on the tube.
- 8. Transport to the testing laboratory following the storage and stability requirements.

#### Approved for use with:

• BD CTGCTV2 for BD MAX™ System

# BD Molecular Swab Collection Kit

# Endocervical swab specimen collection and transfer procedure

### Clinician collection procedure

- 1. Do not collect specimen at the posterior fornix.
- 2. Lukewarm water may be used to warm and lubricate the speculum. Do not use lubricants.
- 3. Holding the swab by the cap, insert the swab into the cervical canal and rotate for 15 to 30 seconds.
- 4. Withdraw the swab carefully, avoiding contact with the vaginal mucosa.

# Swab-to-tube transfer procedure

Specimens collected using the BD Molecular Collection Swab must be transferred to the BD Molecular Swab Sample Buffer Tube immediately after collection.

#### To transfer the sample:



1. Unscrew the cap of the BD Molecular Swab Sample Buffer Tube, taking care not to contaminate the contents or the outside of the tube. Immediately after collection, insert the BD Molecular Collection Swab into the tube so that the score mark indicated by the black line is at the lip of the tube.



2. Carefully break the shaft at the score mark and allow the swab to drop into the tube.



3. Tightly re-cap the tube.



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

## Storage and transport

Endocervical swab specimens can be stored for a total of 21 days at 2–30  $^{\circ}$ C in BD Molecular Swab Sample Buffer Tubes.

#### Approved for use with:

BD CTGCTV2 for BD MAX™ System

# BD Molecular Swab Collection Kit

# Vaginal swab specimen clinician collection and transfer procedure

# Clinician collection procedure

- 1. Collect swab prior to pelvic, speculum, or bimanual exam.
- Gently slide the swab no more than 2 inches (5 cm) into the vagina. Do not use lubricants or other products containing substances such as carbomers.
- 3. Rotate the swab for 10 to 15 seconds.
- 4. Withdraw the swab without touching the skin outside the vagina.

# Swab-to-tube transfer procedure

Specimens collected using the BD Molecular Collection Swab must be transferred to the BD Molecular Swab Sample Buffer Tube immediately after collection.

#### To transfer the sample:



1. Unscrew the cap of the BD Molecular Swab Sample Buffer Tube, taking care not to contaminate the contents or the outside of the tube. Immediately after collection, insert the BD Molecular Collection Swab into the tube so that the score mark indicated by the black line is at the lip of the tube.



Carefully break the shaft at the score mark and allow the swab to drop into the tube.



3. Tightly re-cap the tube.



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

# Storage and transport

Assay	Condition	Duration
BD CTGCTV2 for BD MAX™ System	2 – 30 °C	Up to 21 days
BD MAX™ Vaginal Panel	2 – 30 °C	Up to 21 days

## Approved for use with:

- BD CTGCTV2 for BD MAX™ System
- BD MAX™ Vaginal Panel