

Outpatient Lab Manual

Update April 2024



Table of Contents

Contents

Table of Contents	1
Laboratory Services for Outpatient Testing	4
Mission of the Berkshire Medical Center Laboratories:	4
Compliance Guidelines Laboratory Personnel	5
Laboratory Services for the Physician's Office, Nursing Home or Health Center	9
Scope of Service	10
KEY LABORATORY PERSONNEL	11
Outpatient Order Documentation	12
Laboratory Manual Adapted for Outpatient Locations	14
Medical Necessity Policy	15
Advance Beneficiary Notice/Waiver (ABN) for Medicare Patients Only	16
Add On Testing to Emergency Department Specimens	18
Results Reporting	19
Acceptance/Rejection of Specimens	20
General Billing Information	22
Supplies Provided to Clients	22
Physician Attestation for Informed Consent	23
Germline Genetic Testing Form	24
Phlebotomy/ Specimen Collection Information	25
BHS LABORATORY COLLECTION STATIONS-PHONE/FAX	25
Specimen Collection (Phlebotomy) Services at Off-site Locations (Nursing Homes)	27
Order of Draw Policy	28
Micro-Collection Tubes, Tests and Minimum Amount of Blood Needed	29
Special Collections: Bone Marrow	30
Special Collections: Flow Cytometry	30

Special Collections: Molecular Aptima® Combo 2® CT/GC	30
Special Collections: Molecular C. difficile/Epi (CDIFF)	34
Special Collections: Molecular FilmArray® GI Panel (GIP)	35
Special Collections: Molecular Meningitis/Encephalitis (ME) Panel	36
Special Collections: Molecular MRSA (MRSAPCR) or PRE-Op MRSA/SAS (SAS)	37
Special Collections: Molecular MYCOBACTERIUM TUBERCULOSIS (MTBRIF)	38
Special Collections: Molecular Rapid Respiratory Panel (RESPCOV)	39
Lab Dictionary Orderable	41
Lab Testing Panels	58
Specialized Testing – Pathology	60
Surgical Pathology Specimen Collection and Handling	60
Outpatient Cytology Specimen Collection Procedures	63
ThinPrep® Pap Test	64
Sputum Specimens	67
Urine Samples	68
Breast Discharge	69
Bronchial Washing/Brushing and Bronchioalveolar Lavage	70
Body Cavity Fluids and Washings (Pleural, Peritoneal, and Pericardial Effusions)	71
Fine Needle Aspiration Biopsy	72
Specialized Testing – Chemistry	80
Drug Testing	80
Specialized Testing – Microbiology	82
Tick Testing Resources	82
Microbiology Collection and Cultures	83
Specialized Testing – Molecular	99
Molecular Testing Menu	99
ANAPLASMA & BABESIA (ANABAB)	100
C. difficile/Epi (CDIFF)	102
CHLAMYDIA/GONORRHEA (CT/NG)	103

GI Panel (GIP)	104
FACTOR II MUTATION (F2PCR)	106
FACTOR V (LEIDEN) MUTATION (F5PCR)	107
Group B Strep (GBSPCR)	108
HEPATITIS C VIRUS QUANTITATION	110
Meningitis/Encephalitis (ME) Panel	111
MRSA (MRSAPCR) or Pre-OP MRSA/SA (SAS)	113
MYCOBACTERIUM TUBERCULOSIS (MTBRIF)	114
Rapid Respiratory Panel (RESPCOV)	115

Laboratory Services for Outpatient Testing



Mission of the Berkshire Medical Center Laboratories:

- **SERVICE:** To provide cost effective, high quality, state-of-the-art laboratory information to our clients in a timely and user-friendly manner
- **TEACHING:** To provide allied health, pathology and laboratory medicine education and training.
- **CLINICALLY RELEVANT RESEARCH:** To continually improve the quality, appropriateness and relevance of laboratory medicine.

Staff and Services:

The Berkshire Medical Center, Fairview and North Adams laboratories are open 24 hours each day and are fully staffed from 7:30 a.m. to 4:00 p.m. A reduced staff is on duty during the evenings, nights, weekends and holidays. Cancer Center laboratory is open days, but is closed on evening/nights, weekends and holidays.

Results:

Test results are available in the electronic health record (EHR) for the ordering provider and in the BHS patient portal for the for the patient as soon as testing is completed. Those without HER access may receive results by fax or mail, if faxing is not available.

Courier System:

Specimens will be picked up at your office by a courier on a Monday through Friday schedule. Our couriers also deliver reports and bring supplies to you upon request. The laboratory requires contracted services for nursing home pick-ups.

Pathologist & Professional Consultation Services:



The Berkshire Health Systems Laboratories are directed by American Board of Pathology certified pathologists. All pathologists are certified in both Anatomic and Clinical Pathology. Each pathologist also has one or more subspecialty areas of certification and/or expertise. In anatomic pathology these include cytopathology, dermatopathology, and analytical Cytometry. In clinical pathology these include Hematology, Transfusion Medicine/Blood Bank, Chemistry and Microbiology. Pathologists are available 24 hours a day, seven days a week for consultation.

Compliance Guidelines Laboratory Personnel

General Job Responsibilities: All BHS employees have an obligation to follow the organization's compliance guidelines. All employees are expected to be familiar with and to comply with BHS's acceptable compliance guidelines and procedures.

Shared Employment Arrangements: Generally, shared employment arrangements are not acceptable. Employees of a client may not be paid by the BHS laboratory to provide phlebotomy service at the facility.

Collecting Diagnosis Codes: If required, a diagnosis code (an ICD-10 Code) must be received exclusively from the ordering physician or his/her designee. An ICD-10 code may be obtained from the patient, but must be followed by MD written notice. BHS cannot enter any substitute code through any manual or system default process. The ICD-10 code must be specific to that particular patient for that particular date of service. Under no circumstances should a BHS laboratory employee suggest a particular ICD-10 code to a client for a specific patient or test. A narrative diagnosis provided by the physician can be translated into an appropriate ICD-10 Code, but only by an employee who has been specifically trained by the health system. The Medical Records department of BHS has provided a list of acceptable codes to the staff for use in translating narrative diagnosis. BHS Labs provides a list of acceptable ICD-10 codes for NCD coverage for those tests requiring coding. BHS in no way is suggesting that the offices use the codes that provide coverage unless the diagnosis is appropriate for that patient and the test ordered. It is simply provided as a quick reference coverage advisor.

Recording and Documenting Diagnosis Codes: ICD-10 codes received from the ordering physician must be documented in writing, preferably of the test request form or on the office face sheet. The documentation must be retained and it must be promptly available on request. All requisitions are scanned and originals saved. If the ICD-10 code is obtained from the physician or his/her designee by telephone, the call must be documented and the documentation must include (1) the BHS lab employees name, (2) the specific ICD-10 code or narrative diagnosis as given by the ordering physician or designee, (3) the name of the person who provided the diagnosis and (4) the date on which it was received.

Billing Computer System and/or Manual Default: Third party carriers, including Medicare, Medicaid and private insurance, require certain demographic information for each patient to be included in each claim for payment. All required demographic information must originally come from the client or the patient. System or manual defaults cannot be used for the patient's address, sex, age, date of birth, relationship to the insured, or the patient's Medicare alpha suffix.

Laboratory Policy As It Pertains to the Physician's Order: It is BHS laboratory policy that (1) when a physician is ordering tests for which Medicare or Medicaid reimbursement is sought, he/she should only order those tests that he or she believes are medically necessary for each patient, (2) that the physician should only order individual tests or a less inclusive profile where not all the tests in the customized profile are medically necessary for an individual patient and (3) that the Office of Inspector General takes the position that a physician who orders medically unnecessary tests may be subject to civil penalties. All BHS Laboratory employees are expected and required to help ensure that the BHS laboratory meet this important requirement.

Adjustments and Write-Offs: As a general rule, retroactive adjustments to client statements may only be made in cases of actual misunderstandings between the client and the laboratory or as a result of an error on the part of the laboratory. Support for the adjustment should include written documentation of the misunderstanding or error.

Limited Coverage Tests and Advance Beneficiary Notices: The Health Care Financing Administration (HCFA) has directed local Medicare carriers to identify tests for which the need exists to develop a policy to determine the medical necessity of the test and subsequent payment policy. If reimbursement is denied due to lack of information supporting medical necessity, Medicare rules prohibit the laboratory from subsequently billing the patient unless an Advance Beneficiary Notice (ABN) has been signed and dated prior to the service. The ABN (1) identifies the laboratory test, (2) gives the reason it is likely to be denied, (3) assures that a patient understands that he or she may be responsible for payment if the test is considered to be medically unnecessary by Medicare and (4) allows the beneficiary or patient to make an informed decision whether or not to receive the service and be financially responsible for the service.

Authorized Persons to Order and Receive Benefits: Federal and state laws specify who may order and receive test results. As a general rule, only a physician or otherwise licensed provider (PA, NP) may order and receive a test result. Test results should never be released to the patient or anyone else who cannot provide the laboratory with appropriate medical and legal authorization. Patients may sign a disclosure statement for HIPAA compliance and receive their own results with identification. Any questionable request for a test result that does not come from the ordering provider should be communicated to the laboratory supervisor or the corporate Compliance Officer for appropriate research and resolution.

Reimbursement Requests and Record Keeping: All BHS laboratory test requests forms, records and documents should be fully and accurately completed.

Giving or Receiving Gifts or Entertainment: BHS laboratory discourages the giving and receiving of gifts or entertainment. Giving a gift or providing entertainment to a client could appear to be an inducement. Receiving a gist or accepting entertainment from a client could create a conflict of interest. Modest gifts or entertainment may be given or received, subject to good judgment and the boundaries of reason and moderation. Nevertheless, any gifts or entertainment should first be discussed with the appropriate supervisor for approval. Any doubts should be brought to the attention of the Compliance Officer.

Patient Information and Confidentiality: BHS laboratory is committed to protecting the confidentiality of patient medical information. Confidential information about any patient should never be disclosed to any unauthorized person, including other BHS laboratory employees.

Ambiguous Test Orders and Verbal Test Orders: An "ambiguous test order" is any verbal or written order received by the BHS laboratory that does not provide sufficient information to determine clearly which test should be performed by the laboratory. When the BHS laboratory receives an ambiguous test order, the appropriate laboratory personnel must immediately contact the client and clarify the ambiguous order. Clarification must be documented, preferably on the test request for, or on another piece of paper attached to the test request form. Clarification must include (1) BHS employee name, (2) specific test to be performed exactly as stated by the ordering physician or their designee, (3) the name of the person who provided the clarification and (4) the date that the clarification was received.

Professional Courtesy: The BHS laboratory does not offer professional courtesy testing to its clients. This decision is based on the federal government's position that providing free laboratory testing to healthcare providers, their families, or their employees may be construed as an unlawful inducement. Such testing must be billed directly to the client, the patient, or the patient's insurance carrier in conformance with normal billing practices under the client's general commercial/direct bill account or third-party patient bill account.

Confirmation of Standing Orders: For standing orders, the BHS laboratory must contact each client with standing orders on file to obtain written verification of the continued validity of all current standing orders. Consistent with applicable state law, this written confirmation must be performed at least yearly. The BHS laboratory discourages standing orders and request that each test request come with a written order.

Quantity Not Sufficient/Test Not Performed Review and Billing Prevention: The BHS laboratory prohibits billing for any test that is not performed, regardless of reason. If a test is not performed for any reason, such as breakage, insufficient specimen, etc., it is the responsibility of every BHS laboratory employee to ensure that this test is not billed. If any employee becomes aware of such billings, he or she must immediately bring this matter to the attention of the supervisor and or the Compliance Officer.

Patient Charts: As a general rule, it is not permissible for a BHS laboratory phlebotomist to open and to review a patient's chart. This could be a violation of the patient's right to

confidentiality and it may result in the phlebotomist performing duties that should be performed by the facility staff.

Contracts with Clients: Contracts, bids and sale proposals are covered by Berkshire Health Systems contract review policies. Any written contracts with clients must be reviewed and approved in advance by legal counsel.

Client Discounts: Negotiating client discounts is a common practice in the clinical laboratory industry. Generally, this practice is not considered to be an illegal inducement. Problems arise, however, if the amount of the discount appears to be tied to the number or value of Medicare or Medicaid testing a client may refer to the BHS laboratory. Discounts are based on competitive factors, such as pricing and discounts offered by other laboratories. Discounts are never based on Medicare or Medicaid volume.

Loan of Laboratory Equipment: In connection with providing laboratory services, it may be permissible for BHS laboratory to loan to clients certain equipment. Such a loan restricts the use of the equipment to the collection, processing or storage of specimens to be sent to BHS laboratory for testing or the communication of test results to the client. Equipment must be used safely, and it must be promptly returned to the BHS laboratory if the client discontinues service.

Technical Assistance to "In-House" (POC) Testing: Technical assistance is provided to any in-house (POC) testing; the BHS Nursing Service performs testing under the lab's CLIA number.

Computer Placements: The BHS laboratory may provide computer software and, in some cases, hardware to transmit client test orders and results directly between a client's computer system and the BHS laboratory computer system. The software and hardware must be restricted to the ordering, receiving and managing of the BHS laboratory test data. Safeguards must be built into each system to prevent its use for purposes other than BHS testing.

Medical Waste: Laws regulating the disposal of medical waste are becoming more restrictive, making compliance more expensive. As a consequence, some clients request that laboratories pick up and dispose of infectious waste generated by them in their offices. Agreeing to do so may violate infectious waste disposal laws as well as anti- inducement laws. Any request to dispose of infectious waste for a client should be brought to the attention of the appropriate Compliance Officer. No employee should ever offer to transport or dispose of a client's infectious waste or pay a waste disposal company to transport or dispose of a client's infectious waste.

Courier Service: The BHS laboratory provides courier service for the laboratory to our outside clients. Any changes in routes, specimen pickup, etc. are to be discussed with the department director.

Laboratory Services for the Physician's Office, Nursing Home or Health Center

Laboratory Services:

We can handle all types of specimens for any laboratory test. Whether your patient is a member of an HMO, IPA, PPO, Blue Cross or any health plan you need only one laboratory to do the work. We offer a range of services to busy nursing homes and physician's offices that will maximize convenience and minimize paperwork.

Service is a framework of our organization. Call us directly at (413) 496-6895 if we can help you design specific services to meet your needs.

Results When You Need Them:

Many tests are available on a "STAT" basis at Berkshire Health Systems labs and tests done inhouse will have shorter turn-around times than tests sent out to reference labs. All in house testing and many of our reference laboratories have a direct computer link to Berkshire Health System for rapid transmission of test results. Working together we can provide the shortest turnaround time for lab tests available.

Specimens will be picked up by our courier at your office on a prearranged schedule. The tests will be performed at Berkshire Health Systems labs or at our selected reference laboratories, depending upon the test ordered. Our courier can deliver written reports to your office or another method of delivering results can be discussed. Critical values (markedly abnormal results) will be telephoned to your staff by the technologist who performed the testing. Laboratory staff will phone other requested information, such as Pro-time results.

Scope of Service

Berkshire Medical Center Laboratories is a modern community laboratory system equipped with the latest in automated analytical instrumentation. Our fully certified technical staff and modern equipment allows us to respond daily to the needs of Berkshire County's medical community. From HCFA/AMA approved panels to "STAT" test analysis, the laboratory tries to offer a variety of comprehensive laboratory tests to meet your needs.

Professional Consultation

Medical and technical specialists are available to provide assistance and information for all test procedures. They will answer your questions, discuss test results, and consult on cases as needed. To request assistance, please call the lab number below. The technologist working in the area where testing was performed should also be able to answer your questions or help you to find the answers to your inquiries.

Berkshire Medical Center Main Lab (413) 447- 2575 Fairview Hospital Lab (413) 528-0790 North Adams Regional Hospital Lab (413) 664-5160 Phelps Cancer Center Lab (413) 997-5825

Quality Control

Rigorous internal and external control programs are an integral part of all laboratory testing. Internal systems require normal and abnormal controls with patient runs and calibration standards specific to procedures and instrumentation. Computerized control reports provide continuous test monitoring as specimens are resulted. The internal systems are commercially prepared quality control programs for all sections of the laboratory. External systems include proficiency testing from the College of American Pathologists (CAP) and Health Care Financial Administration (HCFA) of the U.S. government.

Fully Accredited

Berkshire Health Systems Laboratories is accredited by the Commission of Inspection and Accreditation of Laboratories under the College of American Pathologists, The American Association of Blood Banks, the Medicare Program, and the Massachusetts Department of Public Health.

ACCREDITATIONS:

College of American Pathologists (CAP)
Health Care Financial Administration (HCFA)
Food and Drug Administration (FDA)
Massachusetts Department of Public Health (MDPH)
American Association of Blood Banks (AABB)

KEY LABORATORY PERSONNEL

PATHOLOGISTS:	
Dr. Jessica Krochmal, Medical Director Clinical Pathology	413-395-7830
Dr. Alida Hayner-Buchan, Dir. Anatomic Pathology	413-447-2567
Dr. Xiasong Li, Dir. Cytology	413-447-2571
Dr. Suzanne Homan	413-447-2570
Dr. David Jones	413-447-2570
ADMINISTRATIVE DIRECTOR:	
Mark Robert MBA, MT(ASCP)	413-447-2573
SECTION MANAGERS/SUPERVISORS:	
Dr. Kari Murad, Ph.D. Senior Lab Manager	413-553-9029
Rebecca McKeever, CT (ASCP)CM Mgr. Lab Operations	413-447-2968
Danielle Parks, HT (ASCP)) Mgr. Anatomic Path/Cytology	413-553-9024
Kathy Lavinio, Manager Outreach	413-496-6895
Jim Martin, Manager Laboratory IT	413-445-9224
Lori Moore, M.Ed, MLS (ASCP), Director Med Tech School	413-447-2580
Kristen Prew, MLS (ASCP)CM Supv. Blood Bank	413-447-2581
Brenda Alibozek, MT (ASCP) Supv. Hematology/Coag	413-447-2578
Samantha Stedman, MLS (ASCP) Supv. Specimen Processing	413-447-2575
Lisa Dansereau, Supv. Outpatient Services	413-395-7659
Jeanne Siemer, MT (ASCP) Supv. Chemistry	413-496-6816
Jana McGinnis, MS, MB (ASCP)CM Supv. Molecular and Micro	413-553-9049
Brittany Perras, HTL (ASCP) Supv. Anatomic Pathology	413-447-2598
Elizabeth White, MLS (ASCP), Supv. Evening/Nights	413-447-2575
Janelle Frenyea, MS, MLS (ASCP)CM Supv. North Adams SEF	413-644-5160
Lisa Lister, MLS (ASCP) Supv. Fairview Hospital	413-854-9612



Lauren Wick, MT (ASCP) Supv. Cancer Center

413-358-9703 x5825

Outpatient Order Documentation

Purpose: To educate providers on laboratory order requirements

Applicability: All ordering providers

Specifics:

Requisition Requirements: Patient Identification and Demographics

- FULL name (no nicknames)
- Date of Birth
- Sex at Birth
- Name (& address) of Ordering Provider (if they are not in our system)
- Signature of ordering provider
- Insurance billing information
- Address and any other demographic information to identify patient
- Diagnosis code reason for ordering testing
- Date & time of collection, if specimen drawn at office and sent in to lab
- Source of specimen and laterality, when appropriate
- Clinical information, when appropriate

Hard Copy Requisitions:

Following HCFA regulations, to ensure documentation of physician orders, requisition forms are sent to the physician offices to accompany outpatients to the Laboratory. If the practice prefers sending their "face sheet" from their office, we will accept this type of order. Patient demographics, insurance information, and diagnoses to cover all tests ordered are required. Lab tests should be clearly and legibly noted. The lab is required to have physician signature on all orders.

Electronic Orders:

LifePoint Electronic Orders:

Select offices have the ability to enter orders electronically into the LifePoint lab link. LifePoint has been installed in a select number of offices to meet provider expectation of improved quality control over requisitioning and to assure that the hospital lab gets the most current, up to date demographic information for the patient including insurance information and diagnoses to match the testing requested. Electronic ordering also includes ordering provider electronic signature.

Procedure:

When a provider places a lab order from their office, they log onto the internet to LifePoint Link. The office staff and providers have unique access through Account Number, User Name and Password.

The patient information is checked for correctness and edits to any patient demographics can be made at this point.

To place an order, the user goes to the Order Test screen, enters a diagnosis code and a requested test from a menu that has been downloaded from the Lab Meditech dictionary. On the final review page, all information is available for review including whether the diagnosis covers for medical necessity, order date, time, provider ordering the testing, copy to physicians, collection requirements including fasting, tubes to be collected, and whether the results need to be faxed or called to the ordering provider. Electronic signature is appended.

An ABN (Advance Beneficiary Notice) can be generated at this juncture if the provider wishes to discuss medical necessity with the patient, or a hard copy requisition could also be printed to give to the patient to bring to the lab.

Most providers order in LifePoint and "Save" the order to the system. When the patient presents at any of the laboratory collection stations, phlebotomists can access LifePoint to retrieve the physician's orders from the computer. The phlebotomist can print out the orders at that time and have all necessary demographic and billing information to register the patient in the Meditech system and to perform the correct testing. The office member, be it the provider themselves or their medical assistant who are instructed to place the order in LifePoint, is noted at the top of the electronic order requisition as the person responsible for the actual entry of data.

Once testing is performed and resulted, the results flow back from Meditech to LifePoint and in some cases directly into the provider's information system. The Provider's desktop shows that they have resulted testing to review.

The electronic ordering through LifePoint has made requisitioning faster, easier and more compliant. Printed requisitions eliminate the ambiguity of physician handwriting and forces the providers to comply with regulatory issues within the laboratory.

Laboratory Manual Adapted for Outpatient Locations

This manual is designed to be a useful reference tool for all office personnel with regard to laboratory testing. Included are special patient preparation requirements, proper labeling of specimens and many other answers to commonly asked questions.

Ordering Providers

BHS labs will perform testing on patients who present with an order from a Medical Doctor (MD or DO), Nurse Practitioner (NP), Physician Assistant (PA) or Nurse Midwife. A provider must have an NPI number in order to bill for testing. Qualified providers are listed in the Meditech Provider dictionary. Massachusetts recognizes the above licensed professionals as providers.

Specimen Preparation

To assure delivery of a specimen that is adequate for testing, it is important that instructions for specimen preparations be followed. Specific sections of the manual present instructions that will assure specimen stability. See additional requirement notes for 24-hour urine collection, microbiology, histology, and cytology specimens noted in this manual.

Collection and Delivery of Specimens

All specimens collected in the office or patient's home must be delivered to the laboratory as soon as possible after collection. A properly completed Laboratory Requisition Form must accompany all delivered specimens. Specimens entered as electronic order must be received at the lab with a hard copy of the electronic order accompanying the specimen. At the top of the requisition, "Client/Patient Data" must be completed in full. Medicare and Medicaid regulations are very specific regarding submission of diagnoses for testing. Physician signature on the requisition is required for payment.

All specimens are to be labeled on the body of the container (not lid) with:

- (a) Patient's full name (no nicknames)
- (b) Date of birth
- (c) Date and time of specimen collection
- (d) Site and laterality, if applicable, for Path and Micro
- (e) Initials of the person who obtained the specimen
- (f) All specimens must be delivered in a sealed zip-type "bio-hazard" bag
- (g) Note: Please be sure all lids are secured when transporting liquid specimens such as urine or specimens in formalin.

Large numbers of specimens may be transported at one time in a laboratory transport tote (i.e., small Igloo cooler).

Patient Preparation

Certain lab tests may require 8-hour or 12-hour fasting; see specific test fasting requirements in the Meditech test dictionary or call the Main Lab Processing Desk (413-447-2575)

Medical Necessity Policy

Primary/Secondary Diagnosis:

Office of the Inspector General (OIG) has established guidelines concerning the standards of practice and billing for medically necessary lab services. Some of these guidelines were incorporated into the new lab form.

In the "Compliance Plan", physicians are required to provide specific diagnostic information to support the testing ordered. You can use several diagnoses to support your requested testing. When possible, the physician should translate the narrative diagnosis into the ICD-10-CM code.

As in the past, BHS coders will continue to translate the written diagnosis into ICD-10-CM codes. Medicare requires ICD-10 codes be provided by the physician's office on any orders for lab tests. Therefore, BHS is developing training programs and educational material for physicians and their office staff to equip them to comply with this requirement.

Medical Necessity:

The Social Security Act states that "no payment be made....for expenses... which are not reasonable and necessary for the diagnosis and treatment of illness or injury."

While a physician must be able to order any tests s/he believes appropriate for the treatment of his/her patients, the physician must be aware that Medicare will pay only for the tests that meet the Medicare definition of medical necessity and may deny payment for a test the physician believes is appropriate but does not meet the Medicare definition of medical necessity. The OIG takes the position that a physician who orders medically unnecessary tests for which Medicare reimbursement is claimed may be subject to civil penalties.

Medically necessary services include the following services:

- Those established as safe and effective.
- Those consistent with the symptoms or diagnosis of the illness or injury.
- Those necessary and consistent with generally accepted medical standards.
- Those furnished at the most appropriate, safe and effective level.
- Those that are not furnished primarily for the convenience of the patient, attending physician or other physician or supplier.

Advance Beneficiary Notice/Waiver (ABN) for Medicare Patients Only

A physician office should request the patient sign an ABN only when there is a reason to believe that payment for a laboratory test will be denied:

Some common examples are:

- * a limited coverage test with no diagnostic information provided.
- ❖ a limited coverage test (NCD or LMRP) under local medical review with diagnostic information or diagnosis code provided that is not listed in the policy as covered.
- * a test that is not FDA-approved

National Coverage Decisions are for the following 22 Lab Test Groupings – there are actually 75 individual tests that are under National Coverage Decision. They are listed as follows:

TEST	TEST NAME	CPT
AFP	ALPHA FETOPROTEIN	82105
BLOOD COUNTS		
	BLOOD COUNT HEMOCRIT	85014
	BLOOD COUNT HEMOGLOBIN	85018
	CBC WITH AUTOMATED WBC DIFF	85025
	CBC WITH MANUAL WBC DIFF	85027
CA 15-3/27.29	IMMUNOASSAY TUMOR ANTIGEN	86300
CA 19.9	IMMUNOASSAY TUMOR ANTIGEN	86301
CA 125	IMMUNOASSAY TUMOR ANTIGEN	86304
CEA	CARCINOEMBRYONIC ANTIGEN	82378
DIGOXIN	DIGOXIN	80162
GGT	GLUTAMYL TRANSFERASE, GAMMA	82977
GLUCOSE	GLUCOSE, QUANTITATIVE	82947
GLYCO	HEMOGLOBIN; GLYCATED (A1C)	83036
HCG	GONADOTROPIN CHORIONIC QUANT	84702
HELICOBACTER	BREATH	83013
	SERUM ANTIBODY	86677

	STOOL	87338
HEPATITIS	HEPATITIS A ANTIBODY	86709
	HEPATITIS B CORE ANTIBODY	86705
	HEPATITIS B SURFACE ANTIGEN	87340
	HEPATITIS C ANTIBODY	86803
HIV (DIAGNOSTIC)	HIV-1 & HIV-2 SINGLE ASSAY	86703
	HIV WESTERN BLOT	86689
	HIV 1 AMPLIFIED PROBE	87535
HIV (PROGNOSIS)	HIV1 QUANT	87536
IRON STUDIES	FERRITIN	82728
	IRON	83540
	IRON BINDING CAPACITY (TIBC)	83550
	TRANSFERRIN	84466
LIPIDS	LIPID PANEL	80061
	CHOLESTEROL SERUM, TOTAL	82465
	LIPOPROTEIN, DIRECT (HDL)	83718
	LIPOPROTEIN, DIRECT (LDL)	83721
	TRIGLYCERIDES	84478
PSA	PROSTATIC SPECIFIC ANTIGEN TOTAL	84153
PTT	THROMBOPLASTIN TIME, PARTIAL	85730
PT	PROTHROMBIN TIME	85610
THYROID		
	THYROXINE - FREE	84439
	THYROID STIMULATING HORMONE	84443
URINE	CULTURE BACTERIAL IDENTIFICATION	87088
	SENSITIVITY STUDIES DISK METHOD	87184
	SENSITIVITY STUDIES MICROTITER	87186

Add On Testing to Emergency Department Specimens

PURPOSE: To instruct lab staff in the process of ordering testing on previously collected specimens. Occasionally physicians order testing on a patient specimen that was previously collected in the emergency room especially on pediatric patients and those patients for whom phlebotomy is difficult.

APPLICABILITY: All ordering lab staff

GENERAL: Additional testing should <u>NOT</u> be added to Emergency Room orders. These are specimens collected under specific circumstances and diagnostic conditions. Outpatient orders cannot be appended to these original ED orders as the chart audit and specimen audit will not correlate. There would be no documentation in the ED chart to justify the additional orders.

Therefore, if a physician demands testing added to a specimen that has been retained by the laboratory, follow the procedure listed in order to satisfy the physician needs, billing and medical records compliance.

PROCEDURE:

- 1. Physician notifies the Call Center to add testing to a retained specimen.
- 2. Call Center instructs the office to place the order in Meditech electronically or fax a hard copy requisition to the lab with the following information:
 - a. Name of the Ordering Provider
 - b. Diagnosis for the additional testing
 - c. Name, date of birth and any other demographic information necessary to register the patient
- 3. Call Center will have the new requisition registered (for same date of service as ED visit) and the test(s) ordered.
- 4. Call Center will note on the Green Add-On Slip that specimen is an add on to an ED visit to alert Main Processing desk that the labels have different <u>ACCOUNT</u> NUMBERS.
- 5. Call Center will fill out the Green Add-On slip with an original ED label for the patient (so we can retrieve the specimen) and the NEW ACCOUNT labels for labeling the specimen for testing.

EXCEPTION: Any patient who was seen in the Emergency Room who was admitted either as an Inpatient or as an Observation patient (including McGee admits) retains their original account number and the information from the emergency visit is rolled into the inpatient visit. Additional testing can be ordered by the floor.

Results Reporting

Printed/Electronic:

BHS lab results are usually completed within 24 hours of the specimen arrival at the laboratory. Some test results will take longer if they require complex testing (e.g. microbiology cultures, urine drug confirmations, serum protein electrophoresis, pathology review of slides, etc...) or if are not performed in-house and must be sent to an outside Reference Laboratory. All test results are available electronically as soon as verified.

Verbal:

Occasionally it is essential that verbal reports be given in order to facilitate medical care particularly in an emergency medical situation. This is a potential source of error and medical liability.

The Laboratory requires that the person receiving the report identify him/herself (Last name, First Initial and Title [RN or LPN]), repeat the patient's name, and reiterate the report to the person giving the message.

This will be practiced routinely and without variation or exception.

BHS laboratory services personnel will provide lab data only to persons licensed under the provisions of law relating to the healing arts or their representatives. Lab data will not knowingly be released to patients via the phone system. Patients may come to BHS Medical Records in person to receive a printout of their lab work; they will be required to sign a HIPAA release form and provide a current picture ID.

As part of our services, BHS Section Heads are available for assistance with interpretation of laboratory data for physician office staff/personnel.

Repeat Testing:

Any portion of a **serum** sample, which is not utilized in the initial testing, is stored under refrigeration for THREE days. Other specimens are kept for shorter time periods according to the stability of the specimen.

Acceptance/Rejection of Specimens

Purpose: In compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the following is the laboratory policy for the acceptance/rejection of specimens.

Specifics:

- 1. The Collection/Labeling Protocol
 - a. All specimens, inpatient and outpatient, must be labeled at the time of collection by the person who collects the specimen.
 - b. The only exception will be when specimens are obtained during invasive procedures. In those cases, the individual assisting will be responsible for the labeling of the specimen.
 - c. All specimens must be properly labeled with patient first and last name and an additional identifier [BMC Patient Identification Policy PE.A.4— two identifiers such as date of birth, medical record number, or social security number (blood bank)] and come to the lab with a completed requisition form. All specimens must have the initials and time collected of the employee that collected it. Use of Mobilab meets these requirements.
 - d. Requisition forms accompanying specimens must be completed with all requested demographic and diagnostic information.
 - e. Specimens which are submitted in a specimen container with a lid (urine, tissues, etc.) must be labeled on the body of the container. Labeling the lid only is not acceptable.
 - f. Glass slides must be labeled in pencil with the last name, first initial and a second identifier.
 - g. Any special handling requirements must be met with regard to temperature, protection from light, etc.

2. Rejection Criteria:

In general, blood, urine and most throat and nasal swabs, are considered to be readily re-obtained and strict adherence to labeling procedures is required.

- a) Unlabeled specimens are not acceptable. The test will be canceled and a comment placed in the report describing why the test was canceled. The provider will be notified that the test is being canceled. The specimen will be discarded.
- b) Specimens received without a requisition (paper or electronic) are unacceptable. Contact the provider and ask for an electronic test order or paper requisition. If the test order is not received within 24 hours, the specimen will be discarded and the test cancelled.

- c) Mislabeled specimens: e.g. meaning when the specimen identification and request form do not match, or the specimen identification is not an exact match with the requisition or medical record: Please bring the issue to a member of the lab management team or technologist in the appropriate testing department for disposition.
- d) Specimen handling requirements not met. The test will be canceled and a comment placed in the report describing why the test was canceled. The provider will be notified that the test is being canceled. The specimen will be discarded.
- e) If the lab is notified or is made aware that a specimen has been mislabeled (wrong name), The test will be canceled and a comment placed in the report describing why the test was canceled. The provider will be notified that the test is being canceled. The specimen will be discarded.
- 3. Exceptions to the Rejection Protocol for Precious Specimens
 - a) Some specimens may require special attention, such as Timed specimens e.g. timed blood drug levels, specimens collected prior to treatment or procedures, sterile body fluids and tissues which cannot be recollected.
 - b) Sterile body fluids or tissues are defined as
 - any fluid obtained operatively or by percutaneous aspiration
 - o CSF
 - o Pericardial Fluid
 - o Amniotic Fluid
 - o Bone marrow
 - Pleural Fluid
 - A sterile tissue is any tissue obtained operatively.
 - c) For Precious Specimens, every effort will be made to assure proper specimen identification which may be done via telephone between the laboratory and the provider for outpatient specimens. The test results will be commented with information regarding the specimen identification issue, eg: Specimen received unlabeled. Specimen identified by Nurse Smith. For inpatient precious specimens, the provider must come to the laboratory to ID the specimen, in no event shall a specimen be sent back to the provider.

General Billing Information

Client/Patient Billing Issues

If a patient has a concern about his/her bill for laboratory testing, please have them call the BHS Lab Compliance Manager at (413) 447-2575.

If the patient does not want to speak with anyone from the BHS Laboratory, please have them contact the Supervisor at BHS Accounting Department at (413) 447-2900.

Both the Accounting and/or Laboratory departments will review the records, investigate and report back to the patient.

General Billing Information:

Berkshire Health Systems Laboratories "Compliance Program": Due to increased federal and state scrutiny of all medical centers/hospitals regarding their compliance with a number of recent laws, BHS Labs is involved with a system-wide "Compliance Program" as its commitment to conduct business in an ethical manner and to comply with applicable state and federal laws.

Supplies Provided to Clients

BHS laboratory provides the necessary collection supplies and containers to physician offices and Nursing Homes for submission of specimens to BHS lab. These supplies are limited and free to our accounts. Some collection supplies are blood collection tubes, urine containers, etc.

Contact the Lab Call Center to request supplies (413)-395-7888; your request for supplies must be documented.

The lab does not carry a large inventory of collection supplies, thus BHS labs might only send a partial order until additional supplies are received. Approximate time on refill of partial orders is the Friday after receipt of collection supplies. Please plan ahead when doing your inventory.

In cases where the provision of free services results in a benefit to the provider, a federal anti-kickback statute is implicated. If offered or accepted in return for referral of Medicare or state health care plan business, both the lab and the physician may be violating the anti-kickback statute. Each account using BHS Lab for services will have to sign a written agreement regarding the proper use of collection supplies from BHS lab. See the attached form.

Finally, your cooperation will help us serve your facility/office. All client supplies will be monitored because BHS laboratories complies with all state and federal laws to provide appropriate supplies that are commensurate with the number of specimens submitted to BHS laboratories.

Physician Attestation for Informed Consent

Please fill out form, sign, and fax to: 413-496-6811

Berkshire Medical Center Pathology Department

Informed Consent Compliance for Germline Genetic Testing (Physician Attestation)

Name of Ordering Physician
Address
Date/
Practice
I,, acknowledge that: (name of ordering physician)
 It is my responsibility to ensure that prior to ordering any genetic test, I obtained a signed, writte consent form from the patient (or their authorized representative) as required by applicable la and/or regulations; and
 All written consent forms will be maintained by the physician as part of the patient's file and w be made available to Berkshire Medical Center Laboratories upon reasonable request.
This attestation remains in effect until an updated form is submitted.
Signature of Physician: Date & Time:
Background
Commonwealth of Massachusetts Chapter 254 of the Acts of 2000

(c) No facility, as defined in section 70E, and no physician or health care provider shall: (1) test any person for genetic information without first obtaining the prior written consent; (2) disclose the results of a genetic test to any person other than the subject thereof without first obtaining the informed written consent except where the results disclosed will be used only as is confidential research information for use in epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes or learning about the genetic basis of disease or for developing pharmaceutical and other treatments of disease; or identify the person being tested to any other person without first obtaining informed written consent or upon proper judicial order. Organizations conducting pharmaco-economic studies in systematic research to determine the cost benefits of specific treatment for genetic based disease shall be exempted from the need to re-obtain informed written consent.

Section 70(c)

Germline Genetic Testing Form

Berkshire Medical Center Pathology Department

Informed Consent for Germline Genetic Testing

of r	, agree to participate in testing forusing NA-based testing method. I understand that samples of blood will be drawn from me and/or members by family by removing a small amount of blood from a vein. I understand that the blood samples will be defer the purpose of attempting to determine if I and members of my family are carriers of the disease lie, or are affected with, or at increased risk to someday be affected with this genetic disease.			
	In some cases the DNA test directly detects an abnormality, called a mutation, in the gene, and the test is >99% accurate for detection of the specific mutation. In other cases, an indirect method called linkage analysis is used. If linkage analysis is being used, naturally occurring rearrangements in the DNA (recombination) may produce an uncertainty in predicting carrier status or diagnosis. Rare variations in the DNA of individuals can also cause uncertainty in the results. In other words, the test is not 100% accurate, and the results will be reported as a probability that I have the abnormality.			
2.	In some families, the test may not be informative. If this is the case, this DNA test cannot provide results for that family, or for some members of that family.			
3.	An error in the diagnosis may occur if the true biological relationships of the family members involved in this study are not as I have stated. For example, non-paternity means that the true biological father of an individual is not the person stated to be the father. The test may detect non-paternity, and it may be necessary to report findings to the individual who requested testing.			
4.	An erroneous clinical diagnosis in a family member can lead to an incorrect diagnosis for othe related individuals in question. I understand that the DNA analysis performed for this disease is specific only with respect to it and in no way guarantees my health. The accuracy of DNA analysis is entirely dependent on the clinical diagnosis made elsewhere, and the Department of Pathology cannot be responsible for erroneous clinical diagnosis made by others.			
5.	5. These tests are relatively new and are being improved and expanded continuously. The tests are n considered research and are considered to be the best laboratory service which can be offered at th time. This testing is often complex and utilizes specialized materials so that there is always a smirisk that the test will not work properly or that an error will occur. There is a low error rate (perhaps in 1000) even in the best laboratories. My signature below acknowledges my voluntary participation this test.			
6.	In some cases it may be possible for the laboratory to re-analyze leftover DNA samples in the future using new and improved methods. However, I understand that this is not a DNA banking facility, are my DNA samples may not be available for future studies.			
7.	7. Because of the complexity of DNA-based testing and the important implications of the test results results will be reported to me only by a physician or genetic counselor whom I have designate below. The results are confidential. They will be released to others only with my written consen Participation in DNA testing is completely voluntary.			
Sig	PATIENT Physician/counselor: I have explained DNA testing to this individual, and have answered all of their questions.			
Wit	Witnessed:			

ORDERING PROVIDER SIGNATURE

Date & Time:

Phlebotomy/ Specimen Collection Information

BHS LABORATORY COLLECTION STATIONS-PHONE/FAX

BMC Medical Arts Complex-

777 North Street Pittsfield, MA Monday-Friday -6:30am-5:00pm

Saturday -7:30am-11:30am

Tel: 413-395-7884 Fax: 447-2421

East Street Collection Station

505 East Street Suite 104 Pittsfield, MA Monday-Friday- 7:30am-4:00pm

Tel: 413-443-1912 Fax: 413-443-1914

Suburban Internal Medicine-

710 Stockbridge Road Lee, MA Monday –Friday -7:30am-4:00pm

Tel: 413-243-4563 Fax 413-243-4567

North County Collection Station-

71 Hospital Ave-Main Floor North Adams, MA

Monday-Friday: 6:30am-4:00pm Saturday-7:30am-11:30am

Tel: 413-664-5432 Fax: 413-664-557

East Mountain Medical

780 Main Street

Gt. Barrington, MA

Monday-Friday- 7:30am—4:00pm

Tel: 413-644-9725 Fax: 413-644-9332

Fairview Hospital Laboratory Collection Station-

29 Lewis Street

Gt Barrington, MA

Monday-Friday 7:30am-5:00pm

Saturday 8:00am-12 noon



Tel: 413-854-9720 Fax: 413-854-9798

Adams Collection Station

2 Park St Adams, MA Mon-Friday 7:30am-4:00pm

Tel: 413-743-2197 Fax: 413-743-2316

Specimen Collection (Phlebotomy) Services at Off-site Locations (Nursing Homes)

Services are contracted with BHS Laboratories

Hours of Operation:

Seven days per week, including Holidays (for medical emergency testing/STAT)

Location:

Berkshire Medical Center Main Laboratory, 725 North St., Pittsfield, MA 01201

Phone: (413) 447- 2575- Main Lab Desk

Fax: (413) 395-7620

Services Provided:

- Berkshire Health Systems phlebotomist will pick up blood specimens on a routine or medical emergency (STAT) basis. The phlebotomist will travel to pick up at designated location.
- Please try to have routine blood orders scheduled on the scheduled pick-up days. Most Nursing Homes/Rest Homes have pre-scheduled days for blood pick-ups. Adherence to schedule will help improve service for all off- site pick-up areas.
- No blood will be drawn on an Outpatient, after consent has been obtained, until positive patient identification has been established.
- Please have the BHS Outpatient Requisition Form properly filled out and ready for the phlebotomist. This includes patient demographics in addition to ordering provider, providers signature, test requested and the <u>diagnosis code that proves medical necessity for each test ordered.</u>

Home Draws:

BHS Labs provides a limited service for home draws. This service is provided as a courtesy to our customers on an "as needed" basis and is conducted short term. The order for draw must be initiated by a physician who must give good cause for requiring the home service. A lab supervisor may also initiate the call for home service if circumstances arise.

Written physician orders should be faxed to 413-395-7620. Scheduled time for lab draws will be set up at the convenience of BHS laboratory. Specifics with regard to this service may be discussed with the Phlebotomy Services at 413-447-2908.

Order of Draw Policy

Our tube manufacturer, as well as the Clinical and Laboratory Standards Institute (CLSI), formerly NCCLS, recommends the following specific order for collection of tubes. Their recommendation specifically states the order of collection of tubes with additives. The blood cultures are always drawn first to decrease the possibility of bacterial contamination. CLSI Standards state that a discard tube is not required for routine coagulation tests (PT/PTT) unless special factor assays are being collected or when using a winged blood collection set. This diminishes contamination with tissue fluids, which may initiate the clotting sequence.

- 1) Recommended order of tube draw:
 - a. Blood culture bottles
 - b. Coagulation tube (eg, light blue closure)
 - c. Serum tube with or without clot activator, with or without gel (eg, plain red/red/gold)
 - d. Heparin with or without gel plasma separator (eg, green)
 - e. EDTA with or without gel separator (lavender/pink BB tubes/pearl)
 - f. Glycolytic inhibitor (eg, gray closure)
 - g. Other additives

Note: Plastic or glass serum tubes containing a clot activator may cause interference in coagulation testing. Glass nonadditive serum tubes or plastic serum tubes without a clot activator may be drawn before the coagulation tube.

Note: When using a winged blood collection set for venipuncture and a coagulation tube is the first tube needed, first draw a discard tube. The discard tube must be used to prime the tubing of the collection set, which will assure maintenance of the proper anticoagulant/blood ratio in the first tube filled. The discard tube should be a non-additive or a coagulation tube and need not be completely filled.

2) Never forcefully eject blood from a syringe into a vacutainer tube. Doing so may cause hemolysis of the cells.

Micro-Collection Tubes, Tests and Minimum Amount of Blood Needed

Micro-Containers	Amount of Blood
Red Top (with separator)	750 UL- 0.75 ML
Lavender Top (EDTA)	750 UL- 0.75 ML
Green Top (Lithium Heparin)	400 UL- 0.4 ML
Blue Top (Sodium Citrate)	2.7 ML-2.7 ML
Capillary Tube	100 UL- 0.1 ML

Tests	Type of Tube	Amount Needed
Ammonia	Green Top Microtainer- On Ice	0.3 ML
BUN	Green or Red Top Microtainer	0.4 ML
Calcium	Green or Red Top Microtainer	0.4 ML
Creatinine	Green or Red Top Microtainer	0.4 ML
Electrolyte Panel	Green or Red Top Microtainer	0.4 ML
Glucose	Green or Red Top Microtainer	0.4 ML
Total Protein	Red Top Microtainer	0.4 ML
Triglycerides	Green or Red Top Microtainer	0.4 ML
Phenobarbital	Green or Red Top Microtainer	0.4 ML
Dilantin	Green or Red Top Microtainer	0.4 ML
Gentamicin	Green or Red Top Microtainer	0.4 ML
Tobramycin	Green or Red Top Microtainer	0.4 ML
MG	Green or Red Top Microtainer	0.4 ML
Theophylline	Red Top Microtainer	0.4 ML
Coombs	Pink Top Microtainer	0.3 ML
CBC	Lavender Top Microtainer	1.0 ML
ESR	Small Lavender Tube	1.0 ML
Blood Culture	Bottle (Sterile)	1.0 ML

Notes:

- 1. One Red Top Microtainer full (0.7) will usually yield enough serum for all the following tests: Glucose, BUN, Calcium, Total Protein, Electrolyte Panel, and Total Bilirubin. For any additional tests we will need another Red Top Microtainer.
- 2. For any combination of 2 tests under chemistry, we will need 0.4 ML of blood. For any combination of 3 tests we will need 0.5 ML of blood (excluding the antibiotics and anti-epileptics when 5 or more tests are ordered).
- 3. One Lavender Top Microtainer (0.3) will yield enough blood for a WBC, RBC, Hemoglobin, Hematocrit, Platelet Count, and Reticulocyte Count.
- 4. High Hematocrits on Neonates may not yield enough plasma or serum for a test, therefore, more blood than specified may be needed.
- 5. Blood cultures can be done with 1.0 ML of blood. Current recommendations for blood cultures suggest 5 ml as minimum.

Special Collections: Bone Marrow

Bone marrow tests are scheduled with the Hematology Department (Ext. 2578). Please call to schedule a bone marrow 24 hours in advance.

Special Collections: Flow Cytometry

Blood Specimens

Draw (1) 5 ML Lavender top tube

- Lypan (T4: T8 ratio)
- Leukemia/Lymphoma Panels

Tissue Samples

For Leukemia/Lymphoma panels must be fresh samples stored in RPMI medium.

The flow cytometry laboratory accepts LPANS Monday through Saturday. Other specimens are accepted Monday through Friday until 2:00 p.m. There is no weekend coverage. If there are any questions or problems, please call the flow cytometry department at 413-447-2570.

Special Collections: Molecular Aptima® Combo 2® CT/GC

Testing for Chlamydia trachomatis and Neisseria gonorrhea on the Hologic Panther may be performed with an endocervical swab, vaginal swab, throat swab, rectal swab, male urethral swab, clinician-collected gynecological specimens collected in PreservCyt®/Thin-Prep Solution, and female and male urine specimens from symptomatic and asymptomatic individuals.

SPECIMEN REQUIREMENTS

SPECIMEN	VOLUME	CONTAINER
endocervical (female)	(1) swab (blue)	Aptima® Unisex Swab
		Specimen Collection Kit
vaginal	(1) swab (pink)	Aptima® Multitest Swab
		Specimen Collection Kit
throat	(1) swab (pink)	Aptima® Multitest Swab
		Specimen Collection Kit
rectal	(1) swab (pink)	Aptima® Multitest Swab
	·	Specimen Collection Kit

urethral (male)	(1) swab (blue)	Aptima® Unisex Swab
		Specimen Collection Kit
dirty urine (female and	20–30mL urine container	Aptima® Urine Specimen
male)	free of preservatives	Collection Kit (aliquoting)
ThinPrep Pap	20mL	ThinPrep Pap Collection
		Vial/Aptima® Specimen
		Transfer Kit

IMPORTANT HANDLING PRECAUTIONS:

For the liquid media contained in the multiple collection kits, avoid contact with skin and other body parts. Handle the collection tube carefully.

- DO NOT pre-wet the swab in the liquid collection media before obtaining the sample!
- Use care to avoid splashing the contents of the tube.

Instructions for ENDOCERVICAL Swab Specimen Collection

1. CLEAN:

- a. Use cleaning swab (white swab) to remove excess mucus from cervical os and surrounding mucosa.
- b. Discard cleaning swab after use.
- c. NOTE: Cleaning excess mucus from the cervical os is required to assure an adequate sample is obtained for processing.

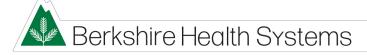
2. COLLECT:

- a. Insert collection swab (blue swab) into endocervical canal.
- b. Gently rotate the swab clockwise for 10 to 30 seconds.
- c. Withdraw swab; avoid any contact with vaginal mucosa. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Unisex Swab Specimen Collection Kit.
- d. While holding swab in hand, unscrew transport tube cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Unisex Swab Specimen Collection Kit.
- 3. ALIGN/BREAK: Immediately place swab into transport tube so black score line is at top of tube. Align the score line with top edge of tube and carefully break shaft. Discard top portion of shaft.
- 4. CAP/LABEL: Tightly re-cap the transport tube. Label the transport tube with the patient's name, date of birth, and date and time of collection. The specimen is now ready for transport.

NOTE: The specimen should only contain the blue collection swab. The specimen will be rejected if the tube contains the white swab, no swab, or 2 swabs.

Instructions for VAGINAL Swab Specimen Collection

1. COLLECT:



- a. Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. Hold swab, placing thumb and forefinger in the middle of shaft covering black score line. Do not hold shaft below score line.
- b. Carefully insert swab into the vagina about 2 inches (5 cm) past the vaginal opening/introitus and gently rotate swab for 10 to 30 seconds. Make sure swab touches vaginal walls so that moisture is absorbed by swab. Withdraw swab without touching skin.
- c. While holding swab in hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.
- 2. ALIGN/BREAK: Immediately place swab into transport tube so black score line is at top of tube. Align the score line with top edge of tube and carefully break shaft. Discard top portion of shaft.
- 3. CAP/LABEL: Tightly screw cap onto tube. Label the transport tube with the patient's name, date of birth, date and time of collection, and the specimen location (type of swab). The specimen is now ready for transport.

Instructions for THROAT specimen Collection

1. COLLECT:

- a. Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. IF the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. Hold swab, placing thumb and forefinger in the middle of shaft covering black score line. Do not hold shaft below score line.
- b. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.
- c. While holding swab in hand, unscrew the cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.
- 2. ALIGN/BREAK: Immediately place swab into transport tube so black score line is at top of tube. Align the score line with top edge of tube and carefully break shaft. Discard top portion of shaft.
- 3. CAP/LABEL: Tightly screw cap onto tube. Label the transport tube with the patient's name, date of birth, date and time of collection, and the specimen location (type of swab). The specimen is now ready for transport.

Instructions for RECTAL specimen Collection

1. COLLECT:

a. Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. Hold swab, placing thumb and forefinger in the middle of shaft covering black score line. Do not hold shaft below score line.



- b. Carefully insert swab into the rectum about 1-2 inches (3-5 cm) past the anal margin (the outside of the anus) and gently rotate swab clockwise for 5-10 seconds. Withdraw swab without touching skin.
- c. While holding swab in hand, unscrew the cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.
- 2. ALIGN/BREAK: Immediately place swab into transport tube so black score line is at top of tube. Align the score line with top edge of tube and carefully break shaft. Discard top portion of shaft.
- 3. CAP/LABEL: Tightly screw cap onto tube. Label the transport tube with the patient's name, date of birth, date and time of collection, and the specimen location (type of swab). The specimen is now ready for transport.

Instructions for MALE URETHRAL specimen Collection ***IMPORTANT HANDLING PRECAUTIONS: Patient should not urinate for at least 1 hour prior to specimen collection.

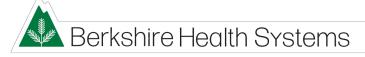
NOTE: The cleaning swab (white swab) is NOT needed for male specimen collection.

1. COLLECT:

- a. Insert specimen collection swab (blue swab) 2 cm to 4 cm into urethra. Gently rotate swab clockwise for 2 to 3 seconds in urethra. Withdraw swab. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Unisex Swab Specimen Collection Kit
- b. While holding swab in hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima Unisex Swab Specimen Collection Kit.
- 2. ALIGN/BREAK: Immediately place swab into transport tube so black score line is at top of tube. Align the score line with top edge of tube and carefully break shaft. Discard top portion of shaft.
- 3. CAP/LABEL: Tightly screw cap onto tube. Label the transport tube with the patient's name, date of birth, date and time of collection, and the specimen location (type of swab). The specimen is now ready for transport.

Instructions for URINE Specimen Collection

- Patients should not have urinated for at least one hour prior to specimen collection.
- Female patients should not cleanse the labial area prior to providing the specimen.
- Direct the patient to provide first-catch ("dirty") urine (20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives.
- IMPORTANT: Collection of larger volumes of urine results in specimen dilution that may reduce test sensitivity.



- Mid-stream clean-catch urines CANNOT be used for this test.
- Make sure the container is securely closed and label the container with the patient's name, date of birth, and date and time of collection. The specimen is now ready for transport.

Instructions for PAP Specimen Collection

- Refer to PAP collection guidance in the Cytology department for specific details on ThinPrep cervical specimens. ThinPrep® Pap Test
- Gynecologic specimens should be collected using a broom-type or endocervical brush/plastic spatula combination.

STORAGE & TRANSPORT

Swab Specimens: Swab specimens collected with the Aptima Swab Collection Kits can be shipped to the laboratory or testing site at ambient temperature. These swabs may be stored at 2–30°C for 30-60 days, depending on specimen type, once the specimens have been stabilized in the transport media.

Urine Specimens: Fresh male/female urine should be transported at 2–30°C as soon as possible. Urine MUST reach the laboratory within 24 hours of collection and be aliquoted into a specimen transport tube.

PAP Specimens: PreservCyt solution liquid pap specimens intended for CT and/or GC testing must be processed for cytology and/or transferred to an Aptima specimen transfer tube within 30 days of collection when stored at 2°C to 30°C.

CAUSES FOR REJECTION

- swab collected in any collection device other than the Aptima collection kits
- 2 swabs, 1 white swab, or NO swabs in Aptima® Multitest Swab Specimen Collection Kit or Aptima® Unisex Swab Specimen Collection Kit clean catch urine
- greater than 30mL or less than 20mL of urine in original collection container
- urine received more than 24 hours after collection

Special Collections: Molecular C. difficile/Epi (CDIFF)

SPECIMEN REQUIREMENTS: unformed (liquid or soft) stool. Stool specimens to be tested should be collected in a clean container.

Storage & Transport:

• Stool specimens may be shipped to the laboratory at room temperature (20–30°C) within 24 hours of collection. The specimen is stable for up to 5 days when stored at 2–8°C.

Causes for Rejection



- Formed/solid stool received.
- Quantity not sufficient.

INTERFERING SUBSTANCES

- Zinc oxide paste
- Vagisil ® cream

Special Collections: Molecular FilmArray® GI Panel (GIP)

SPECIMEN REQUIREMENTS human stool at least 1 gram or 5 cc a stool collection container or other clean dry container with a tight-fitting lid.

Patient Preparation:

Patient should not use antacids, barium, bismuth, antibiotics, antimalarial agents, antidiarrheal medications or oily laxatives prior to specimen collection. After administration of any of these compounds, specimen collection should be delayed for 5–10 days, or at least two weeks after barium or antibiotics.

Collection:

Specimens must be collected in such a way as to avoid contamination with urine or water.

- 1. Wash hands with soap and water.
- 2. Label the stool container with patient's full name, date of birth, and date and time of collection.
- 3. Lift the toilet seat and place plastic wrap or wax paper over the toilet seat opening. DO NOT expel the specimen directly into the stool container.
- 4. Make a depression in the wax paper or plastic wrap before securing it with adhesive tape. Make sure the sample won't fall into the toilet bowl. 5
- . Lower the toilet seat and proceed with bowel movement. DO NOT expel the specimen into the toilet. DO NOT urinate on the specimen.
- 6. Using a disposable tool, transfer the stool to the stool container.
- 7. Carefully place the lid on the container and place the container in the plastic bag and seal it. Place this bag into a larger paper or plastic bag.



- 8. Dispose of any remaining stool into the toilet and place the soiled paper or wrap in a plastic or paper bag prior to putting it in the garbage.
- 9. Wash hands thoroughly with soap and water.
- 10. Store the specimen (in paper or plastic bag) in the refrigerator until you can transport the specimen to the Berkshire Health Systems Laboratory, preferably the same day. DO NOT wait more than 24 hours.

Storage & Transport

- Stool should be processed as soon as possible but may be stored at 2–8°C for up to 24 hours prior to processing in Cary Blair medium.
- Specimens in Cary Blair medium should be tested as soon as possible, though they may be stored at room temperature (18–30°C) or under refrigeration (2–8°C) for up to 4 days.

Causes for Rejection

- Stool received more than 24 hours after collection
- Quantity not sufficient

INTERFERING SUBSTANCES Rotavirus A vaccine may be shed in stool following oral administration and Rotavirus A will be detected by the FilmArray GI Panel if vaccine is present in the test sample.

Special Collections: Molecular Meningitis/Encephalitis (ME) Panel

SPECIMEN REQUIREMENTS: CSF (unspun) 0.2 mL (200 µl) Lumbar puncture ONLY

Collection **Use infection control precautions:

- 1. Lumbar puncture procedures should be performed in an enclosed room using sterile techniques.
- 2. Everyone in the room during the lumbar puncture procedure should wear a mask due to the sensitive nature of the ME Panel assay. A minor illness can contaminate the CSF specimen and effect laboratory results. See examples below.
 - Those with active respiratory symptoms (runny nose, cough, etc) may affect assay results as Rhinovirus may cross-react with the Enterovirus target on the panel. Individuals with

active or recurrent cold sores may shed HSV-1. Healthy individuals may actively shed S. pneumoniae, H. influenzae, as well as other organisms that are detected by the ME panel.

- 3. It is recommended that the patient have sterile towels placed underneath them during the lumbar puncture procedure and that their skin be cleaned with chlorhexidine or povidone iodine.
- 4. Once the CSF is collected, cap the collection tube immediately.
- 5. Label the specimen with patient ID and initial of the individual collecting the CSF.
- 6. The Molecular department requires a minimum of 0.5 mL of unspun CSF for the ME panel test and will coordinate with the Hematology department for the proper CSF aliquot. NOTE: If not ordered initially, the laboratory will store the CSF specimen refrigerated for 7 days, if volume permits.

Transport & Storage

- Immediately transport the specimen at room temperature.
- CSF specimens should not be centrifuged before testing.
- Specimens should be processed and tested as soon as possible. If storage is required, CSF can be held: at room temperature (approximately 23°C) for up to 24 hours, at refrigerator temperature (approximately 4°C) for up to 7 days

Causes for Rejection

- Improper storage of CSF specimen
- CSF collected using indwelling medical devices (CSF shunts)

INTERFERING SUBSTANCES

• Unusually high levels of protein (>15 mg/mL) may interfere with the ME Panel assay.

Special Collections: Molecular MRSA (MRSAPCR) or PRE-Op MRSA/SAS (SAS)

SPECIMEN REQUIREMENTS nasal swab using 2 swabs Copan Venturi Transystem Collection Device

Collection To obtain adequate specimen, follow the instructions in this section closely.

1. Open the Copan Venturi Transystem Collection Device by peeling back the outer packaging.

- 2. Ask the patient to tilt his/her head back. Insert dry swabs approximately 1–2 cm into each nostril.
- 3. Rotate the swabs against the inside of the nostril for 3 seconds. Apply slight pressure with a finger on the outside of the nose to help assure good contact between the swab and the inside of the nose.
- 4. Using the same swabs, repeat for second nostril, trying not to touch anything but the inside of the nose.
- 5. Remove the plastic transport tube. Twist off the tube cap and discard it. Place the swabs into the plastic transport tube. The swabs should go all the way into the tube until they rest on top of the sponge at the bottom of the tube. Make sure the red cap is on tightly. Note: the swabs should stay attached to the red cap at all times.
- 6. Label the plastic transport tube with patient ID and send to the laboratory. Storage Store swab specimen at room temperature (15–30°C) if it will be processed within 24 hours; otherwise store swab at 2–8°C. The swab specimen is stable up to 5 days when stored at 2–8°C.

Causes for Rejection

- improper swab storage
- wrong swab used for collection (NOTE: Remel swabs should only be used for culture.)
- only one swab left attached to red cap

INTERFERING SUBSTANCES

- blood (potential interference)
- mucus (potential interference)
- nasal sprays used to relieve decongestion, nasal dryness, or irritation (potential interference)

Special Collections: Molecular MYCOBACTERIUM TUBERCULOSIS (MTBRIF)

SPECIMEN REQUIREMENTS raw sputum >2mL in any sterile leakproof container

Collection



- Collect raw sputum following standard procedures.
- Have the patient brush teeth and remove dentures and rinse mouth with water prior to collection. DO NOT ALLOW PATIENT TO USE DISINFECTANT MOUTHWASH.
- The patient should be seated or standing during collection.
- Instruct patient not to collect saliva.
- Label the container with patient name and date of birth and send to the laboratory.

Transport & Storage

- Transport and store raw sputum specimens at 2–8°C before processing.
- If necessary, raw sputum specimens can be stored at a maximum of 35°C for up to three (3) days and then at 2–8°C for an additional seven (7) days.

Causes for Rejection

- Minimum volume not received.
- Obvious food particles or other solid particulates in specimen.
- Unlabeled or mislabeled specimen.
- Delay in receiving specimen >48 hours

INTERFERING SUBSTANCES Inhibition of the Xpert MTB/RIF Assay was observed in the presence of the substances listed below resulting in a false negative result of MTB NOT DETECTED or a Rif Resistance INDETERMINATE result.

- Lidocaine at 30%
- Mucin at 5% and 2.5%
- Ethambutol at 50µg/mL, 25µg/mL, and 10µg/mL
- Guaifenesin at 5mg/mL
- Phenylephrine at 100% and 50%
- Tea tree oil at 0.5% to 0.015%

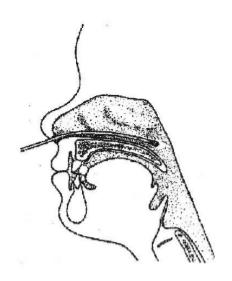
Special Collections: Molecular Rapid Respiratory Panel (RESPCOV)

 NOTE: If only Flu, RSV, or COVID is suspected, please order the Influenza, RSV, COVID19 PCR (FLURSVCOV) test. This test contains the following targets: Influenza A, Influenza B, RSV, and SARS-CoV-2 and is only available as the combo test.

SPECIMEN REQUIREMENTS nasopharyngeal swab 3 mL of transport media or saline Various acceptable media including BD Universal Viral Transport Medium available from the lab; special small pediatric nasopharyngeal swabs are also available.

Collection Use infection control precautions:

- 1. Use the nasopharyngeal swab from the collection kit.
- 2. The distance from the patient's nose to the ear gives an estimate of the distance the swab should be inserted.
- 3. Insert swab into one nostril straight back (not upwards) and back to the nasopharynx and leave in place for a few seconds.
- 4. Slowly withdraw swab with a rotating motion.
- 5. Place the tip of the swab into the tube containing 3 mL of transport media and break or cut the shaft. Be sure to leave the swab tip in the tube.
- 6. Label the specimen with patient ID and your initials.



Transport & Storage

- Note that the transport media or saline itself may be stored at room temperature.
- Specimens in transport media or saline should be processed and tested as soon as possible. If storage is required, specimens in transport media or saline can be held at room temperature (15–25°C) for up to 4 hours, at refrigerator temperature (2–8°C) for up to 3 days, or at freezer temperature (<-15°C) for up to 30 days.

INTERFERING SUBSTANCES: Recent administration of nasal influenza vaccines (e.g., FluMist) prior to NPS specimen collection could lead to accurate virus detection by the BioFire RP2.1 of the viruses contained in the vaccine but would not represent infection by those agents.

Lab Dictionary Orderable

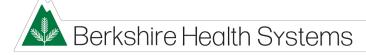
Below is the Testing Menu for BHS laboratories. Any questions please check the testing dictionary in Meditech or call the lab.

Mnemonic	Dept ID	Name	Container ID	Cpt Code
CBC	HEME	Complete Blood Count W/ Diff	LAV	
HH	HEME	Hemoglobin and Hematocrit	LAV	
IPF	HEME	Immature Platelet Fraction	LAV	
PLT	HEME	Platelet Count	LAV	85049
ESR	HEME	Erythrocyte Sedimentation Rate	LAV	85652
RET	HEME	Reticulocyte Count	LAV	
SICKL	HEME	Sickle Cell Screen	LAV	85660
FKB	HEME	FI Kleihauer Betke	LAV	85460
MAL	HEME	Malaria Smear	LAV	
ANAPLASMR	HEME	Anaplasma phagocytophila Smear	LAV	
BABSMR	HEME	Babesia Smear	LAV	
HGBA1C	HEME	Hemoglobin A1C	LAV	
SEOS	HEME.FLD	Smear for Eosinophils	SPECIMEN	
CSFCNT	HEME.FLD	Cell Count w Diff CSF	CSF	
SYNCNT	HEME.FLD	Cell Count Synovial Fluid	FLD-HEME	
UREOS	HEME.FLD	Eosinophil Smear, Urine	UR RND	89051
TBNKCS	HEME	T, B, & NK Cell Subset w/CBC	LAV	
TCS	HEME	T Cell Subset w/ CBC	LAV	
PVSEM	HEME.FLD	Post Vasectomy Semenanalysis	SEMEN	
PTINR	COAG	Prothrombin Time INR	BLUE	
PTT	COAG	Partial Thromboplastin Time	BLUE	85730
FIB	COAG	Fibrinogen	BLUE	85384
DD	COAG	D Dimer	BLUE	85379
UROSMO	CHEM.UR	Osmolality Urine	UR RND	83935
URTP	CHEM.UR	Total Protein Urine	UR RND	
URLYTES	CHEM.UR	Electrolytes Urine	UR RND	
URNA	CHEM.UR	Sodium Urine Random	UR RND	84300
URK	CHEM.UR	Potassium Urine Random	UR RND	84133
URCL	CHEM.UR	Chloride Urine Random	UR RND	82436
UR24LYTES	CHEM.UR	Electrolytes Urine 24hr	UR 24	
UR24NA	CHEM.UR	Sodium Urine 24hr	UR 24	

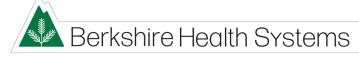
UR24K	CHEM.UR	Potassium Urine 24hr	UR 24	
UR24CL	CHEM.UR	Chloride Urine 24hr	UR 24	
URURIC	CHEM.UR	Uric Acid Urine Random	UR RND	84560
URUREAN	CHEM.UR	Urea Nitrogen,Urine Random	UR RND	84540
URCA	CHEM.UR	Calcium Urine Random	UR RND	82340
UR24PROCR	CHEM.UR	Protein/Creat Split Urine 24hr	UR 24	81050
URCREAT	CHEM.UR	Creatinine Urine Random	UR RND	82570
UR24CREAT	CHEM.UR	Creatinine Urine 24hr	UR 24	
UR48CREAT	CHEM.UR	Creatinine 48 Hour Urine	UR 24	
UR24MALB	CHEM.UR	Microalbumin & Creat Urine 24h	UR 24	
UR24TP	CHEM.UR	Total Protein Urine 24hr	UR 24	
UR24URIC	CHEM.UR	Uric Acid Urine 24hr	UR 24	
UR24UREAN	CHEM.UR	Urea Nitrogen Urine 24hr	UR 24	
UR48UREAN	CHEM.UR	Urea Nitrogen Urine 48 Hour	UR 24	
UR24GLU	CHEM.UR	Glucose Urine 24hr	UR 24	
URPREG	URIN	HCG Qualitative Urine	UR RND	
URTRI	URIN.S	Tricyclic Screen Urine	UR RND	
SYNCRYS	URIN.S	Crystals Synovial Fluid	FLD-URIN	89060
STLPH	URIN.S	pH Stool	STOOL	83986
STLFQL	URIN.S	Stool Fat, Qual (Random)	STOOL	
STLOB	URIN.S	Occult Blood Stool	STOOL	82270
IFOB	URIN.S	Immuno Fecal Occult Blood	STOOL	
FFN	URIN.S	Fetal Fibronectin	U-SWAB	82731
UA	URIN	Urinalysis	UR RND	
UARFLX	URIN	UA w/ rflx UTI Culture	UA RFLX	
URPH	URIN	pH Urine	UR RND	81003
CMP	CHEM	Comprehensive Metabolic Panel	SST	80053
LFP	CHEM	Liver Function Panel	SST	80076
BMP	CHEM	Basic Metabolic Panel	SST	80048
LYTES	CHEM	Electrolytes	SST	80051
CRUN	CHEM	BUN/Creatinine	SST	
NA	CHEM	Sodium	SST	84295
K	CHEM	Potassium	SST	84132
CL	CHEM	Chloride	SST	82435
CO2	CHEM	Carbon Dioxide	SST	82374
BUN	CHEM	Blood Urea Nitrogen (BUN)	SST	84520
CREAT	CHEM	Creatinine	SST	
INSRP	CHEM	Insulin Resistance Panel-75g	LABEL	
GTT2	CHEM	Glucose Tolerance 2 Hour-75g	LABEL	



GTT3	CHEM	Glucose Tolerance 3 Hour-75g	LABEL	
GTT3G	CHEM	Glucose Tolerance Gest 3H-100g	SST	82951
GLU	CHEM	Glucose	SST	82947
GTT2PP	CHEM	Glucose 2 Hour PP	SST	82947
GTTGDS	CHEM	Glucose Gestational Screen-50g	SST	
OSMO	CHEM	Osmolality, Serum	SST	83930
VLAC	CHEM	Venous Blood Lactate	GRAY	83605
URIC	CHEM	Uric Acid	SST	84550
CA	CHEM	Calcium	SST	82310
PHOS	CHEM	Phosphorus	SST	84100
MG	CHEM	Magnesium	SST	83735
FEPR	CHEM	Iron Profile	SST	
FE	CHEM	Iron	SST	83540
TRANS	CHEM	Transferrin	SST	84466
FER	CHEM	Ferritin	SST	82728
BILIT	CHEM	Bilirubin Total	SST	82247
BILID	CHEM	Bilirubin Direct	SST	82248
GGT	CHEM	Gamma Glutamyl Transferase	SST	82977
AST	CHEM	Aspartate Amino Transferase	SST	84450
ALT	CHEM	Alanine Aminotransferase	SST	84460
AMM	CHEM	Ammonia	GREEN-ICE	82140
LDH	CHEM	Lactate Dehydrogenase	SST	83615
CKT	CHEM	Creatine Kinase Total	SST	82550
TROPHS	CHEM.TROP	Troponin I High Sensitivity	LTGREEN	84484
CCRP	CHEM	Cardio CRP	SST	
CRP	CHEM	C Reactive Protein	SST	86141
TP	CHEM	Total Protein	SST	84155
ALB	CHEM	Albumin	SST	82040
LIPID	CHEM	Lipid Panel	SST	80061
TRIG	CHEM	Triglycerides	SST	84478
CHOL	CHEM	Cholesterol	SST	82465
LDLD	CHEM	LDL Cholesterol Direct	SST	83721
HDL	CHEM	HDL Cholesterol	SST	83718
ALKP	CHEM	Alkaline Phosphatase	SST	84075
AMY	CHEM	Amylase	SST	82150
LIPA	CHEM	Lipase	SST	83690
CEA	CHEM	Carcinoembryonic Antigen	SST	82378



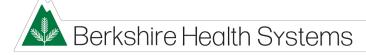
B12	CHEM	Vitamin B12	SST	82607
FOL	CHEM	Folic Acid	SST	82746
T4F	CHEM	Free Thyroxine (FT4)	SST	84439
T3F	CHEM	Free Triiodothyronine (FT3)	SST	84481
TSH	CHEM	Thyroid Stimulating Hormone	SST	84443
FSH	CHEM	Follicle Stimulating Hormone	SST	83001
LH	CHEM	Luteinizing Hormone	SST	83002
PRL	CHEM	Prolactin	SST	84146
PROG	CHEM	Progesterone	SST	84144
SPREG	CHEM	Serum Pregnancy Test, Qual	SST	84703
BHCG	CHEM	Beta HCG Quantitative	SST	84702
CORTSTIM	CHEM	Cortisol Stimulation	SST	
LTT	CHEM	Lactose Tolerance Test	SST	82951
CA125	CHEM	CA 125 Antigen	SST	86304
CA199	CHEM	Cancer Antigen 19-9	SST	86301
VITD25OH	CHEM	Vitamin D 25 Hydroxy	SST	82306
INS	CHEM	Insulin Level	SST	83525
ESTRADIOL	CHEM	Estradiol (E2) Level	SST	82670
TESTFBT	CHEM	Testosterone Free,Bio,Total	SST	
TESTT	CHEM	Testosterone Total	SST	84403
SHBG	CHEM	Sex Hormone Binding Globulin	SST	84270
MONO	CHEM	Infectious Mono Qualitative	SST	86308
HIV	CHEM	HIV (1&2) Ag and Ab, 4th Gen	SST	
BETAHYDROXY	CHEM	Beta-Hydroxybutyric Acid	SST	82010
CFIB	CHEM	Cryofibrinogens	LAV-HP	
CFIB	CHEM	Cryofibrinogens	RED-HP	
CRYO	CHEM	Cryoglobulin	RED-HP	82595
PTH	CHEM	Parathyroid Hormone (Intact)	LAV	83970
PHEN	CHEM	Phenobarbital	SST	80184
PTN	CHEM	Phenytoin (Dilantin)	SST	80185
CARB	CHEM	Carbamazepine (Tegretol)	SST	80156
DIG	CHEM	Digoxin	SST	80162



VALPT	CHEM	Valproic Acid (Depakene) Level	SST	80164
LITH	CHEM	Lithium	SST	80178
ETOH	CHEM	Ethanol	SST	82077
SALI	CHEM	Salicylate	SST	80179
ACET	CHEM	Acetaminophen	SST	80143
HEPP	HEPP	Hepatitis Panel	SST	
CA15-3	CHEM	CA 15-3 Antigen	SST	86300
BNP	CHEM	B Type Natriuretic Pept	LAV	83880
SYNGLU	CHEM.FLD	Glucose Synovial Fluid	FLD-CHEM	82945
SYNURIC	CHEM.FLD	Uric Acid Synovial Fluid	FLD-CHEM	84560
PSASC	SC	PSA Screen	SST-SC*	84153
PSADX	SC	PSA Diagnostic	SST-SC*	84153
PSAPHI	SC	PSA Dx Rflx PHI	SST-SC*	84153
PREALB	SC	Prealbumin	SST	84134
IGQT	SC	Immunoglobulins, QT (IgG/A/M)	SST	
IGG	SC	Immunoglobulin G	SST	82784
IGA	SC	Immunoglobulin A	SST	82784
IGM	SC	Immunoglobulin M	SST	82784
HAPT	SC	Haptoglobin	SST	83010
C3	SC	Complement C3	SST	86160
C4	SC	Complement C4	SST	86160
TPO	SC	Thyroid Peroxidase Antibodies	SST-SC*	86376
B2M	SC	Beta 2 Microglobulin	SST	82232
MMLA	SC	Methylmalonic Acid	SST-QST	83921
RF	SC	Rheumatoid Factor	SST	86430
RUBELIGG	SC	Rubella IgG Ab (Immune Status)	SST-LIA	86762
VARAIGG	SC	Varicella IgG Antibody Imm Sta	SST-LIA	86787
MEASIGG	SC	Rubeola (Measles) IgG Imm Stat	SST-LIA	86765
EBVS	SC	Epstein Barr Virus Evaluation	SST	
MUMPSIGG	SC	Mumps Virus IgG Ab (Immune St)	SST-LIA	86735
TREP	SC	Anti-Treponema Antibody	SST-LIA	86780
LYME	SC	Lyme Ab Screen w/ Rflx Confirm	SST-LIA	86618
LEAD	SC	Lead, Blood	GRN-LI	
LEAD	SC	Lead, Blood	MICRO_LEAD	
AFPNM	SC	AFP, Non Maternal	SST-SC*	82105
SIEP	SC.ELECT	Immunofixation, Serum	SST	
FLCHAIN	SC.ELECT	Free Kappa/Lambda Light Chain	SST	

ZZMTHFR	MB	Methylenetetrahydrofolate Redu	*CONSENT*	81291
ZZMTHFR	МВ	Methylenetetrahydrofolate Redu	LAV	81291
FLURSVCOV	MB	Influenza, RSV, COVID19 PCR	NPSWAB	87637
FLURSV	МВ	Influenza Virus (A&B)& RSV PCR	NPSWAB	87631
F2PCR	MB	Factor II (Prothrombin) PCR	*CONSENT*	81240
F2PCR	MB	Factor II (Prothrombin) PCR	LAV-UNSPUN	81240
F5PCR	MB	Factor 5 Leiden Mutation	*CONSENT*	81241
F5PCR	MB	Factor 5 Leiden Mutation	LAV-UNSPUN	81241
STLCDIFF	MB	C. Difficile PCR	STOOL	
ANAPLADNA	MB	Anaplasma phago DNA (PCR)	LAV	87468
BABDNA	MB	Babesia microti DNA (PCR)	LAV	87469
RESPPANEL	МВ	Rapid Respiratory Panel	RESPPANEL	
STLGIP	MB	GI Panel PCR	STOOL	87507
SAS	MB	MRSA PCR(SAS)-Presurgical only	SWAB	
GBSPCR	MB	Group B Strep (PCR)-Genital	SWAB	87653
ZZCF	MB	Cystic Fibrosis	LAV	
RESPCOV	MB	Rapid Resp Panel w/COVID-19	RESPPANEL	
VAGINITIS	MB	Vaginitis Panel	MULTITEST	
VAGINITISPLUS	MB	Vaginitis Plus Panel	MULTITEST	
CSFCRYPAG	MA	Cryptococcus Antigen CSF	CSF	87899
CRYPAG	MA	Cryptococcus Antigen Serum	SST	87899
URLEG	MA	Legionella Ag Detection Urine	UR RND	87449
CSFSPAG	MA	Strep Pneumo Ag Detection CSF	CSF	87449
URSPAG	MA	Strep Pneumo Ag Detection Ur	UR RND	87449
STLHPA	MA	Helicobacter Pylori Ag Stool	STOOL	87338
BORDETIGM	MSL	Bordetella pertussis IgM Ab	SST	99001
URDSCONF	TOX	Drug Screen Urine, w/confirm	UR RND	80307

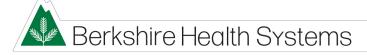
URDS	TOX	Drug Screen Urine	UR RND	80307
TBQUANT	QST	QUANTIFERON	GRN-QST R	
METHOTREX	BRL	Methotrexate	FOIL LABEL	
METHOTREX	BRL	Methotrexate	RED-FOIL	
CUVZV	QST.MIC	VZV Culture	VTM	
PROACID	QST	Prostatic Acid Phosphatase	SST	
A1ATQ	QST	Alpha-1 Antitrypsin Quant	SST-QST	
A1ATP	QST	Alpha-1 Antitrypsin Phenotype	SST-QST	
IGGS	QST	IgG Subclasses 1 to 4	SST-QST	
IGGS1	QST	IgG Subclass 1	SST-QST	82787
IGGS2	QST	IgG Subclass 2	SST-QST	82787
IGGS3	QST	IgG Subclass 3	SST-QST	82787
IGGS4	QST	IgG Subclass 4	SST-QST	82787
SYNLYMPCR	QST.FLD	Lyme Disease DNA, PCR Syn Fld	SYNOVIAL	
CSFHSVPCR	QST.FLD	HSV 1&2 DNA (PCR) CSF	CSF	
SCL70	QST	Scleroderma Antibody	SST-QST	
HYPERPNE	QST	Hypersensitivity Pneum Screen	SST-QST	
VITB1	QST	Vitamin B1(Thiamine), LC/MS/MS	FOIL LABEL	
VITB1	QST	Vitamin B1(Thiamine), LC/MS/MS	LAV-FOIL	
HEPPAABT	QST	Hepatitis A Antibody, Total	SST-QST	
HIV1RNA	QST	HIV-1 RNA, Quantitative,RT-PCR	*LAV	
RBCMG	QST	Magnesium, RBC	LAV-QST	
CSFLYMPCR	QST.FLD	Lyme Disease DNA, PCR, CSF	CSF	
HSVPCR	QST	HSV 1&2 DNA (PCR)	LAV	
VITB2	QST	Vitamin B2 (Riboflavin),Plasma	FOIL LABEL	
VITB2	QST	Vitamin B2 (Riboflavin),Plasma	LAV-FOIL	
TACRO	QST	Tacrolimus,High Sens,LC/MS/MS	LAV-QST	
SMA	QST	SMA Carrier Screen	*CONSENT*	
SMA	QST	SMA Carrier Screen	LAV-QST	
HSVINH	QST	HSV1&2 w/rflx HSV-2 Inhibition	SST-QST	
UPE	QST.FLD	Urine Protein Electrophoresis	UR RND	
MYCOABS	QST	Mycoplasma pneum IgG & IgM Ab	SST-QST	



THYROSTIM	QST	Thyroid Stimulating Immunoglob	SST-QST
STLELAST	QST.FLD	Stool Pancreatic Elastase-1	STOOL-Q
EPO	QST	Erythropoietin	SST-QST
RBCZN	QST	Zinc, RBC	RYB-LAV-Q
VWFAG	QST	von Willebrand Factor Antigen	BLUE
ARRATIO	QST	Aldosterone/Renin Ratio	LAV
ALDOST	QST	Aldosterone, LC/MS	RED
RENIN	QST	Renin Activity, Plasma	LAV
HEPPBDNA	QST	Hepatitis B Virus DNA, QT, PCR	LAV
VITA	QST	Vitamin A (Retinol)	FOIL LABEL
VITA	QST	Vitamin A (Retinol)	SST-FOIL
VITE	QST	Vitamin E (Tocopherol)	FOIL LABEL
VITE	QST	Vitamin E (Tocopherol)	SST-FOIL
GAD	QST	Glutamic Acid Decarboxylase 65	SST-QST
BKVIRUS	QST	BK Virus DNA Quantitative(PCR)	LAV-QST
HPUREA	QST	H. pylori Urea Breath Test	BAG1-T-Q
HPUREA	QST	H. pylori Urea Breath Test	BAG2-T-Q
T3R	QST	T3 Reverse	SST
VITC	QST	Vitamin C (Ascorbic Acid)	FOIL LABEL
VITC	QST	Vitamin C (Ascorbic Acid)	RED-FOIL
TRYPT	QST	Tryptase	SST-QST
ZINCPP	QST	Zinc Protoporphyrin (ZPP)	GREEN-NA
STLCAL	QST.FLD	Stool Calprotectin	STOOL
RCOF	QST	Ristocetin Cofactor	BLUE
AMIOD	QST	Amiodarone and metabolite	RED
SPNEU14	QST	S. pneumo Ab(IgG)-14 Serotypes	SST-QST
SPNEU23	QST	S. pneumo Ab(IgG)-23 Serotypes	SST-QST
OXCBP	QST	Oxcarbazepine (Trileptal)	RED
HYDP	QST	17-Hydroxyprogesterone	RED
PTHRP	QST	PTH Related Protein	GREEN-NA
EBVDNA	QST	Epstein-Barr Virus DNA (PCR)	LAV-QST



CSFEBVDNA	QST.FLD	Epstein-Barr Virus DNA PCR CSF	CSF	
APOEVAL	QST	Apolipoprotein Eval-A1,B&Ratio	SST-QST	
APOA1	QST	Apolipoprotein A-1	SST-QST	82172
APOB	QST	Apolipoprotein B	SST-QST	82172
TOXIGG	QST	Toxoplasma IgG Antibody	SST-QST	
TOXIGM	QST	Toxoplasma IgM Antibody	SST-QST	
RBCFOL	QST	Red Blood Cell Folate	LAV-QST	
LYMPCRBLD	QST	Lyme Disease DNA (PCR)	LAV-QST	
CSFLWB	QST.FLD	Lyme Disease Ab CSF IgG/IgM	CSF	
VITK	QST	Vitamin K	FOIL LABEL	
VITK	QST	Vitamin K	LAV-FOIL	
ANAPLAAB	QST	Anaplasma phagocytophila AB	SST-QST	
ZONIS	QST	Zonisamide (Zonegran) Level	RED	
AMITRI	QST	Amitriptyline	RED	
TRICYCLICQNT	QST	Tricyclic Antidepressant Eval	RED	
DNASEB	QST	Anti-DNase B (Strep)	SST-QST	
MEASIGM	QST	Rubeola (Measles) IgM Antibody	SST-QST	
HISTAB	QST	Histone Antibodies	SST-QST	
BILEACID	QST	Bile Acids Fractionated & Tot	SST-QST	
INTRINSAB	QST	Intrinsic Factor Blocking Ab	SST-QST	
GASTRIN	QST	Gastrin	SST	
PTNFREE	QST	Free Phenytoin Level	RED	
PRIM	QST	Primidone (Mysoline) Level	RED	
STLFQT	QST.FLD	Stool Total Lipids, Quant	STOOL-Q	
OMEGA	QST	Omega-3 and -6 Fatty Acids	LAV	
СКМВ	QST	Creatine Kinase MB(CK-2)	SST	
HISTOAB	QST	Histoplasma Ab	SST-QST	
HISTREL	QST	Histamine Release	RED	
IGFBP3	QST	IGF binding protein 3(IGFBP3)	SST-QST	
JCV	QST	JC Polyoma Virus DNA, RT-PCR	LAV	
ISLET	QST	Islet cell Ab ScnW/reflx titer	SST-QST	
FRUC	QST	Fructosamine	SST-QST	
TAYS	QST	Tay-Sachs Disease Mutation	LAV	
CUVIRRESP	QST.MIC	Viral Respiratory, Rapid Cultu	VTM	



STLOVAPARA	QST.MIC	Ova and Parasites	STOOL
CUFSHN	QST.MIC	Fungal Culture-Skin/Hair/Nails	STERILE-T
CUHSV	QST.MIC	HSV Culture w/ Reflex Typing	VTM
AMH	QST	Anti Mullerian Hormone, Female	SST
COCCAB	QST	Coccidioides AB, CF, Serum	SST-QST
HHV6	QST	Herpesvirus 6 Ab's (IgG,IgM)	SST-QST
CKISO	QST	Creatine Kinase isoenzymes	SST
RICKET	QST	Rickettsia Abs (IgG,IgM) w/rfx	SST-QST
CSFEVRNA	QST.FLD	Enterovirus RNA,QL, RT-PCR CSF	CSF
STRIAMUS	QST	Striated muscle Ab w/rfx titer	SST-QST
VOLTAGE	QST	Voltage-gated CA channel Ab	RED
CYCLO	QST	Cyclosporine A Trough	LAV-QST
HUAB	QST	HU Ab Scn w/Rfx to titer&WB	SST-QST
HIVGENO	QST	HIV-1 Genotype	LAV
ADENOV	QST	Adenovirus Antibody	SST-QST
DENGUE	QST	Dengue Fever Abs (IgG,IgM)	SST-QST
POLIOV	QST	Poliovirus (Types 1,3) Abs	SST-QST
SIRO	QST	Sirolimus, LC/MS/MS	LAV-QST
FTS	QST	First Trimester Screen, hCG	SST-QST
MAFP	QST	Maternal Serum AFP	SST-QST
QUAD	QST	Quad Screen	SST-QST
F10A	QST	Factor X Activity, Clotting	BLUE
ACTPRC	QST	Activated Protein C-Resistance	BLUE
F9A	QST	Factor IX Activity	BLUE
CENTAB	QST	Centromere B Antibody	SST-QST
VWFM	QST	von Willebrand Ag Multimeric	BLUE
CUCHLAM	QST.MIC	Chlamydia trachomatis Culture	VTM
CUCMV	QST.MIC	Cytomegalovirus Culture	STC
CUMYCOP	QST.MIC	Mycoplasma Pneumoniae Culture	VTM

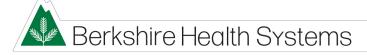
CUMYCOG	QST.MIC	Mycoplasma Genital Culture	VTM
CUBP	QST.MIC	Bordetella pertussis Culture	SPEC
SYNRFS	QST.FLD	Rheumatoid Scrn w/rflx Syn Fld	SYNOVIAL
PROTCAG	QST	Protein C Antigen	BLUE
PARIAB	QST	Parietal Cell Antibody, ELISA	SST-QST
BORDETIGG	QST	Bordetella Pertussis IgG Ab	SST-QST
YOAB	QST	Yo Ab Scn w/Rfx to titer&WB	SST-QST
ALKPISO	QST	Alkaline Phosphatase Isoenzyme	SST-QST
ALKPBS	QST	Alkaline Phosphatase Bone Spec	SST
COPEP	QST	Copeptin	SST
COBALT	QST	Cobalt	RYB-LAV-Q
CANDAB	QST	Candida albicans Ab (IgG/A/M)	SST-QST
MYELINAB	QST	Myelin Assoc Glycoprotein	SST-QST
MYCOAC	QST	Mycophenolic Acid, LC/MS/MS	RED
LKM	QST	Liver Kidney Microsomal Ab IgG	SST-QST
DHT	QST	Dihydrotestosterone	RED
INHIBINB	QST	Inhibin B	RED
RBCCU	QST	Copper, RBC	RB-EDTA-Q
CPAB	QST	Chlamydophila pneumoniae Abs	SST-QST
CSFVDRL	QST.FLD	VDRL, CSF	CSF
FLEC	QST	Flecainide	RED
CHROMIUM	QST	Chromium, Blood	RYB-LAV-Q
INHIBINA	QST	Inhibin A	SST-QST
IGD	QST	IGD	SST-QST
TBG	QST	Thyroxin Binding Globulin	SST-QST
DHEAS	QST	DHEA Sulfate, Immunoassay	SST-QST
CYSTC	QST	Cystatin C w/ eGFR	SST-QST
HISTAM	QST	Histamine, Plasma	LAV
IGFBP1	QST	IGF binding protein 1(IGFBP1)	SST-QST
TRAB	QST	TSH Receptor Binding Ab, TRAb	SST-QST
LYSO	QST	Lysozyme (Muramidase)	SST-QST
C1ESTPR	QST	C1 Esterase Inhibitor, Protein	SST-QST

CAROTENE	QST	Carotene	FOIL LABEL
CAROTENE	QST	Carotene	SST-FOIL
INSAB	QST	Insulin Autoantibody	SST
CTX	QST	Collagen Type I C-telopeptide	RED
COXAAB	QST	Coxsackie A Antibodies, Serum	SST-QST
HIPAB	QST	Heparin Induced Plt Antibody	RED
DIPAB	QST	Diptheria Antitoxoid	SST-QST
ENDOAB	QST	Endomysial Ab Scn (IgA) w/rfx	SST-QST
CSFVARI	QST.FLD	Varicella Zoster Virus PCR CSF	CSF
ANTIIGE	QST	IgE Antibody (Anti-IgE IgG)	RED
C1ESTIF	QST	C1 Esterase Inh, Functional	RED
F5A	QST	Factor V Activity, Clotting	BLUE
ZZCOXBAB	QST	Coxsackie B Antibodies, Serum	SST-QST
HOMOCYS	QST	Homocysteine	SST-QST
THYROPAN	QST	Thyroglobulin Panel- Ab and QT	SST-QST
PFADENO	QST.FLD	Adenosine Deaminase Pleural Fl	FLD
COVIDIGGSQ	QST	SARS CoV2 Ab(IgG) Semi QNT	SST-QST
CALCIT	QST	Calcitonin Level	RED
UR24UPE	QST.FLD	Protein Electro, UR24 w/IFE	UR 24
RASTCHILD	QST	RAST IgE Childhood Panel w/rfx	SST
IGE	QST	IgE	SST-QST
RASTFOODE	QST	RAST IgE Food Panel w/rfx	SST
RASTNUT	QST	RAST IgE Tree Nut Panel w/rfx	SST
RASTRESP	QST	RAST IgE Respiratory w/rfx	SST-QST
RASTMOLD	QST	RAST IgE Mold Panel	SST
RASTCEREAL	QST	RAST IgE Cereal Allergy Panel	SST
RASTVEG	QST	RAST IgE Vegetable Panel	SST
RASTGRASS1	QST	RAST IgE Grasses Allergy Panel	SST-QST
RASTSHELL	QST	RAST IgE Shellfish Panel	SST
RASTANIM	QST	RAST IgE Animal Group	SST



RASTSALAD	QST	RAST IgE Salad Allergy	SST
RASTINSECT	QST	RAST IgE Insect Panel	SST
RASTDUST	QST	RAST IgE House Dust (Greer)	SST
RASTLATEX	QST	RAST IgE Latex	SST-QST
URIFE	QST.FLD	Urine Immunofixation (IFE),RND	UR RND
JO1Q	QST	JO-1 Antibody	SST-QST
CFSCREEN	QST	Cystic Fibrosis Screen	*LAV-MB*
MTHFR	QST	Methylenetetrahydrofolate Redu	*LAV-MB*
DEXA	QST	Dexamethasone	RED
URTICARIAPANEL	QST	Chronic Urticaria Panel	RED
EVRNA	QST	Enterovirus RNA,QL,RTPCR Serum	SST-QST
DSDNA	QST	dsDNA Ab,Crithidia w rfl titer	RED
ANA	QST	Anti Nuclear Antibody	SST-QST
ANTICCP	QST	Cyclic Citrullinated IgG A	SST-QST
CELIAC	QST	Celiac Disease, Diagnostic	SST-QST
TTGAB	QST	Tissue Transglutaminase IgA Ab	SST-QST
VITB6Q	QST	Vitamin B6 (pryidoxine)	FOIL LABEL
VITB6Q	QST	Vitamin B6 (pryidoxine)	LAV-FOI-F
BARTABQ	QST	Bartonella Species Ab IgG&IgM	SST-QST
BABABQ	QST	Babesia microti Ab Panel	SST-QST
SSABQ	QST	Sjogrens Antibodies	SST-QST
VITD2D3Q	QST	Vitamin D(D2&D3) 25-Hydroxy	SST-QST
ZINCQ	QST	Zinc Level	RYB-LAV
BIOTINQ	QST	Biotin (Vitamin B7)	FOIL LABEL
BIOTINQ	QST	Biotin (Vitamin B7)	RED-FOIL
HCVGENO	QST	Hep C Viral RNA Genotype, LiPA	LAV
LEVETQ	QST	Levetiracetam (Keppra) Level	RED
STONEQ	QST	Stone Analysis	T-STONE-Q
CMVQNTQ	QST	CMV Quantitative PCR	*LAV
NMRLIPOQ	QST	NMR Lipoprotein Profile	RED
EHRLABQ	QST	Ehrlichia Antibody Panel	SST-QST
SELNQ	QST	Selenium Level	RYB-LAV
HEPPDABQ	QST	Hepatitis Delta Antibody	SST-QST

UR24STONEQ	QST.FLD	Kidney Stone Risk, 24hr Ur	UR 24
THYROGAB	QST	Thyroglobulin Antibodies	SST-QST
CMVDNAQLQ	QST.FLD	Cytomegalovirus DNA (PCR)Fluid	FLD/UR
VASCQ	QST	Vasculitis Eval w/rflx ANCA	SST-QST
ICALQ	QST	Ionized Calcium	SST-NOOPEN
ACLPQ	QST	Cardiolipin Ab IgG/IgM	SST-QST
CERUQ	QST	Ceruloplasmin	SST-QST
BETA2Q	QST	Beta 2 Glyco1-IgG/IgM/IgA	SST-QST
AMITOQ	QST	Mitochondrial Ab w/ rflx titer	SST-QST
ASMAQ	QST	Anti-Smooth Muscle Ab w/rflx	SST-QST
LAMOQ	QST	Lamotrigine (Lamictal) Level	RED
CH50Q	QST	Total Complement (CH50)	RED
HLAB27Q	QST	HLA-B27 DNA Typing	LAV-QST
CLOZQ	QST	Clozapine + Norclozapine	RED
CUQ	QST	Copper Level	RYB-LAV
HEPPCFIBQ	QST	HCV Fibrosure	SST
CHROMQ	QST	Chromogranin A,LC/MS/MS	RED
ACTHQ	QST	Adrenocorticotropic Hormone	LAV
ASPAGQ	QST	Aspergillus Antigen	SST-NOOPEN
URNTXQ	QST.FLD	NTX-Telopeptide, Urine Random	UR RND
LIPOAQ	QST	Lipoprotein (a)	SST-QST
LACPQ	QST	Lupus Anticoagulant Eval w/rfl	BLUE
ACEQ	QST	Angiotensin Converting Enzyme	SST-QST
F8AQ	QST	Factor VIII Activity	BLUE
VITD125OHQ	QST	Vitamin D1,25 Dihydroxy	SST-QST
PROTSQ	QST	Protein S Ag, Total and Free	BLUE
ACETYLBIQ	QST	Acetylcholine Recept Binding	SST-QST
SALCORTQ	QST.FLD	Cortisol, Saliva	SALIVA-Q
INSGF1Q	QST	Insulin-like Growth Factor I	SST-QST
UR24CORQ	QST.FLD	Cortisol Free, 24hr Ur w/Creat	UR 24
CPEPQ	QST	C-Peptide	SST-QST
ESTROGENQ	QST	Total Estrogens	SST-QST



ASOQ	QST	Anti-Streptolysin O Ab	SST-QST
LACOSQ	QST	Lacosamide Level	RED
HEMOCHRQ	QST	Hereditary Hemocromatosis	*CONSENT*
HEMOCHRQ	QST	Hereditary Hemocromatosis	LAV-QST
ACETYLBLQ	QST	Acetylcholine Recept Blocking	SST-QST
PMETNQ	QST	Metanephrines,Fract,Free,P	LAV
PROTCQ	QST	Protein C Activity w/rfl to Ag	BLUE
HEPPBEABQ	QST	Hepatitis Be Antibody	SST-QST
MERCURYQ	QST	Mercury	RYB-LAV-Q
DHEAUNQ	QST	Dehydroepiandrosterone	RED
CSFOLIGQ	QST.FLD	CSF Oligoclonal Bands	CSF
CSFOLIGQ	QST.FLD	CSF Oligoclonal Bands	SST-QST
CSFINDEXQ	QST.FLD	CSF IgG Index	CSF
CSFINDEXQ	QST.FLD	CSF IgG Index	SST-QST
CMVABQ	QST	Cytomegalovirus IgG/IgM Ab	SST-QST
GBMABQ	QST	Glomerular Basement Memb Ab	SST-QST
AT3PQ	QST	Antithrombin III Panel	BLUE
UR24METAQ	QST.FLD	Metanephrines Urine 24hr	UR 24
UR24CATQ	QST.FLD	Catecholamine,Frac,Ur24hr w/Cr	UR 24
PARVOB19Q	QST	Parvovirus B19 Antibody	SST-QST
TETABQ	QST	Tetanus Antibody	SST-QST
IODINEQ	QST	Iodine Level, Serum	RYB-RED
CELHLAQ	QST	HLA Typing for Celiac Disease	LAV-T-Q
THEOQ	QST	Theophylline	RED
CHIKUNQ	QST	Chikungunya Ab w/rfl Titers	SST-QST
ALDOLASEQ	QST	Aldolase	RED
AMIKPQ	QST	Amikacin, Peak	RED
AMIKRQ	QST	Amikacin, Random	RED
AMIKTQ	QST	Amikacin, Trough	RED
ACETYLMOQ	QST	Acetylcholin Recep Modulat	SST-QST
CA2729Q	QST	CA 27.29 Breast Tumor Mark	SST-QST
CATECHOLQ	QST	Frac. Catecholamine Plasma	*LAV*
COQ10Q	QST	Coenzyme Q10	FOIL LABEL

COQ10Q	QST	Coenzyme Q10	SST-FOIL
ENAQ	QST	Smith and RNP Antibodies	SST-QST
ESTRONEQ	QST	Estrone (E1)	RED
F8INHQ	QST	Factor 8 (VIII) Inhibition	BLUE
G6PDQ	QST	G6PD Screen	LAV-QST
GANGLIOABQ	QST	Ganglioside Antibody Panel	SST-QST
HAEMABQ	QST	H. Influenza Type B IgG Ab	SST-QST
HEPPBEAGQ	QST	Hepatitis Be Antigen	SST-QST
HGBEVALQ	QST	Hemoglobinopathy Eval	LAV-QST
HGHQ	QST	Human Growth Hormone	SST-QST
LEFLUQ	QST	Leflunomide Metabolite	RED
LEGABIGGQ	QST	Legionella Antibody IgG	SST-QST
LEGABIGMQ	QST	Legionella Antibody IgM	SST-QST
LMWHQ	QST	LMWH Anti-Xa	BLUE
MECONIUMQ	QST	Meconium Drug Screen 5 w rfl	STOOL
NSEQ	QST	Neuron Specif Enolase,Serum	SST-QST
PLA2RQ	QST	Phospholipase A2 RecepY AB	SST-QST
PREGNEQ	QST	Pregnenolone	RED
PROLMACQ	QST	Prolactin, Total and Monomeric	SST-QST
RABIESQ	QST	Rabies Antibody	SST-QST
RBCTPMTQ	QST	TPMT Activity Profile, RBC	LAV-QST
SEROTQ	QST	Serotonin	SST
TIAGQ	QST	Tiagabine Level	RED
TOBRPQ	QST	Tobramycin, Peak	RED
TOBRRQ	QST	Tobramycin, Random	RED
TOBRTQ	QST	Tobramycin, Trough	RED
TOPIQ	QST	Topiramate, Serum	RED
VASOPEPQ	QST	Vasointestinal Peptide	LAV
VITB3Q	QST	Vitamin B3 (Niacin)	FOIL LABEL
VITB3Q	QST	Vitamin B3 (Niacin)	LAV-FOI-F
VITB5Q	QST	Vit B5 (Pantothenic Acid)	RED
CSFACEQ	QST.FLD	Angiotensin Conv Enz, CSF	CSF
CSFLDHQ	QST.FLD	Lactate Dehydrogenase CSF	CSF
CSFMYELINQ	QST.FLD	Myelin Basic Protein CSF	CSF

STLREDQ	QST.FLD	Reducing Substaces Stool	STOOL
URHIAAQ	QST.FLD	5-HIAA Random Urine	UR RND
URMGQ	QST.FLD	Magnesium, Urine Random	UR RND
URMYOQ	QST.FLD	Myoglobin Urine Random	UR RND
URNICOTQ	QST.FLD	Nicotine Urine, Random	UR RND
URPHOSQ	QST.FLD	Phosphorus, Random Urine	UR RND
URPORPHQ	QST.FLD	Porphobililogen, Random Urine	FOIL LABEL
URPORPHQ	QST.FLD	Porphobililogen, Random Urine	UR-FOIL
URTRICHQ	QST.FLD	Trichomonas Urine	*UR RND
UR24ALDOQ	QST.FLD	Aldosterone, 24hr Ur w/Creat	UR 24
UR24CITQ	QST.FLD	Citric Acid Urine 24hr	UR 24
UR24HIAAQ	QST.FLD	5-HIAA Quant Urine 24hr	UR 24
UR24OXAQ	QST.FLD	Oxalic Acid, 24hr Urine	UR 24
MISC	OTH	Miscellaneous Lab Test	SPEC
JAK2-NEO	OTH	JAK2 V617F Mutation-Neogenomic	LAV-NEO
IGVH-NEO	OTH	CLL, IgVH Mutation-Neogenomics	LAV-NEO

Lab Testing Panels

Basic Metabolic Panel (BMP)

BUN

Creatinine

Glucose

Carbon Dioxide

Chloride

Potassium

Sodium

Calcium

Electrolytes (LYTE)

Sodium

Potassium

Carbon Dioxide

Chloride

Liver Enzymes/Hepatic Liver Function (LFP)

Albumin

Alkaline Phosphatase

Bilirubin, Total and Direct

SGOT (AST)

SGPT (ALT)

Protein, Total

Hepatitis Panel (HEPP)

Hepatitis B surface Antigen

Hepatitis B surface Antibody

Hepatitis B core Antibody

Hepatitis A Antibody

Hepatitis C Antibody

Iron Profile

Iron

Total Iron Binding Capacity

Iron Saturation

Transferrin

Ferritin

Comprehensive Metabolic (CMP)

Albumin

Alkaline Phosphatase



Bilirubin, Total

BUN

Calcium

Creatinine

Glucose

Protein, Total

SGOT (AST)

SGPT (ALT)

Potassium

Chloride

Sodium

Carbon Dioxide

Lipid Profile

Cholesterol

HDL

Triglycerides

Urine Drug Screen (URDS)

Amphetamine Screen, Urine Benzodiazepines Screen, Urine Cocaine Screen, Urine Methadone Screen, Urine Opiate Screen, Urine THS (Cannabinoid) Screen, Urine Oxycodone Screen, Urine Buprenorphine Screen, Urine Fentanyl Screen, Urine

All other tests must be ordered individually

<u>Specialized Testing – Pathology</u>

Surgical Pathology Specimen Collection and Handling

Routine Tissue Collection

Tissue specimens should be carefully removed. Tissues should not be crushed or over cauterized during surgery as this destroys cells and tissue architecture.

Tissue specimens must be placed immediately into a container of 10% neutral buffered formalin. Allowing specimens to sit before placing in formalin can cause enough tissue drying to prevent proper fixation and hinder proper processing and diagnosis. Please be sure that the tissue is immersed in the fixative and not stuck to the inside or top of the container. The volume of fixative should be about 10 times greater than the tissue specimen. Please ensure that the container is closed securely and stored at room temperature.

Special Handling

Immunofluoresence studies cannot be performed on tissue fixed in formalin. Special skin biopsies that require immunofluorescence studies should have one piece submitted in "Michel's medium". A separate piece is needed for histology and is submitted in formalin. Please make sure the tissue is immersed in fixative and not stuck to the side or lid of the container. If there is a delay in sending the specimen to the laboratory, store the specimen in Michel's medium in the refrigerator.

Chromosome studies require fresh tissue (not in formalin). This includes products of conception, fetal tissue or placental tissue. Denote request for "chromosome studies" on the requisition.

Specimen Labeling and Packaging

Specimens containers should be labeled immediately after collection in the presence of the patient at the time of collection.

Each container must have a neat and legible label affixed to the outside of the container (not the lid) that includes:

- Patient's complete first and last name.
- Date of birth.
- Specimen site, including laterality.

Place the labeled, tightly closed container(s) into a sealed zip-type "Bio-Hazard" bag. Fold the requisition and place in the outside pocket of the bag for transport to the laboratory.

Surgical Pathology Requisitions

All specimens must be accompanied by a printed electronic order via Meditech Expanse or a legible paper requisition. Information must include:

- Patient's name and address (No nick-names)
- Date of birth
- Date of service/Procedure
- Provider
- Specimen site(s) including laterality, if applicable
- Pre-Op diagnosis/Clinical information
- Insurance information

List each specimen container on the requisition. If there are multiple containers, denote the appropriate letter on each specimen label. The information on the requisition must match the information on the specimen container(s).

Specimen Tracking

A Specimen Tracking Log should be completed for each batch of specimens to ensure safe transport from physicians' offices to the laboratory. Please list patient names on the log, followed by the number of containers sent to the laboratory in parentheses. (eg. Mary Smith (2)).

Transport of Specimens

Routine transport of specimens is handled through the laboratory courier service. Routine "rounds" are scheduled. If you have special needs, please contact the Courier Service at (413) 447-2591.

Physician offices may drop-off tissue specimens at the Lab Reception Desk at the Berkshire Medical Center Laboratory, or at the Fairview Hospital Laboratory.

Routine reports will be available within 48 hours, (excluding Saturdays and Sundays). Cases requiring additional testing and evaluation may take a longer period of time.

All pathology reports are available in the Electronic Health Record (HER) in Meditech Expanse following case sign-out. Faxed reports are sent to providers that do not access the EHR.

Occasionally it is essential that verbal reports be given to facilitate medical care. Lab data will be provided only to persons licensed under the provisions of law relating to the healing arts or their representatives. Requests for verbal reports can be made to (413) 447- 2570.

Supplies



The laboratory provides:

- Pre-filled formalin containers in two sizes 20 ml and 120 ml.
- Michel's medium for immunofluorescence specimens.

Discrepancies or Missing Information

It is extremely important to have correct patient and specimen information to produce timely, accurate patient reports. Due to the irreplaceable aspect of most surgical pathology specimens, all attempts will be made to accurately correct labeling errors. If there is discrepant or missing information, it will be necessary for the laboratory staff to contact your office.

Questions or Additional Information

- Histology Lab (413) 447- 2586
- Pathology Secretaries (413) 447- 2570
- Anatomic Pathology Supervisor (413) 447-2598
- Anatomic Pathology Manager (413) 553-9024
- Medical Director of Anatomic Pathology (413) 447- 2567

Outpatient Cytology Specimen Collection Procedures

- ThinPrep® Pap Test ThinPrep® Pap Test
- Sputum Specimens Sputum Specimens
- Urine Specimens <u>Urine Samples</u>
- Breast Discharge Bronchial Washings/Brushings/BAL Breast Discharge
- Body Cavity Fluids <u>Body Cavity Fluids and Washings (Pleural, Peritoneal, and Pericardial Effusions)</u>
- Fine Needle Aspiration Fine Needle Aspiration Biopsy

If there are any questions regarding any of the procedures included herein or with any cytology specimens, please call the Cytology Department as follows:

- Director of Cytopathology (413) 447-2571
- Cytotechnologists (413) 447-2568
- Anatomic Pathology Manager (413) 553-9024
- Pathology Department (413) 447-2570

ThinPrep® Pap Test

Clinical Significance

Liquid-based pap testing is intended for use in the screening and detection of cervical cancer, pre-cancerous lesions, atypical cells and all other cytologic categories as defined by the Bethesda system for reporting results of cervical cytology.

Patient Reminders

- No intercourse for 48 hours before exam.
- No vaginal medication, personal lubricants or douching 48 hours before exam.
- Schedule appointment 2 weeks after the first day of the patient's last menstrual period.

Patient Preparation

- Specimen should not be collected during menses.
- Excessive lubricant use interferes with sample adequacy.
 - o Avoid carbomer lubricants.
 - o Only use a dime-sized amount.
 - o Personal lubricant use impedes proper sampling.

Storage Instructions

Maintain PreservCyt vials with and without cytologic samples at room temperature.

Specimen Rejection

ThinPrep vial past expiration date; no specimen collected; unlabeled or mislabeled specimen. Every effort will be made to have labeling corrected by the responsible party.

Materials Required

- ThinPrep vial with PreservCyt®
- Collection Device Either papette (broom) or spatula and brush.

Requisition –

- Order in Meditech Expanse. Print requisition.
- Or complete a requisition form with patient/specimen information.

Specimen Collection

Broom-Like Device Protocol

- 1. Obtain an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently and rotate the broom in a clockwise direction five times.
- 2. Rinse the broom as quickly as possible into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the

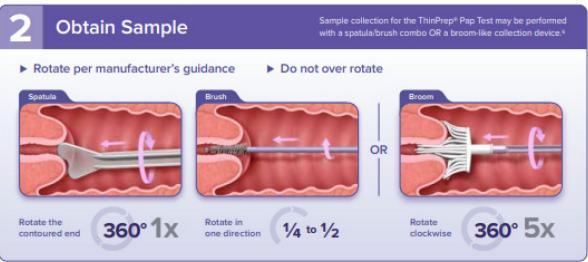
broom vigorously to further release material. Discard the collection device. **DO NOT leave the collection device in the solution vial.

- 3. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
- 4. Record the patient's name and date of birth on the vial. Complete the patient information on requisition.
- 5. Place the vial into a biohazard specimen bag, seal the bag, and place the folded requisition form into the pocket of the bag.
- 6. List specimen on Tracking Log, if applicable. Send specimen to the laboratory.

Endocervical Brush and Spatula Protocol

- 1. Using the plastic spatula, obtain an adequate sample from the ectocervix.
- 2. Rinse the spatula as quickly as possible into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.
- 3. Using the endocervical brush device, obtain an adequate sampling from the endocervix. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate ½ or ½ turn in one direction. DO NOT OVER-ROTATE.
- 4. Rinse the brush as quickly as possible in the PreservCyt® Solution by rotating the device in the solution 10 times while pushing against the PreservCyt® vial wall. Swirl the brush vigorously to further release material, then discard the brush. **DO NOT leave the collection device in the solution vial.
- 5. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
- 6. Record the patient's name and date of birth on the vial. Complete the patient information on requisition.
- 7. Place the vial into a biohazard specimen bag, seal the bag, and place the folded requisition form into the pocket of the bag.
- 8. List specimen on Tracking Log, if applicable. Send specimen to the laboratory. Refer to Specimen Collection picture below.







Sputum Specimens

Single Sputum Specimen:

Materials needed: Wide-mouthed, STERILE, leak-proof plastic container with screw top. Biohazard transport bag.

Requisition: Order in Meditech Expanse. Print requisition OR Complete Requisition form with patient/specimen information.

- 1) Patient is given the plastic cup and instructed to cough deeply and expectorate coughed up material into the cup. Care should be given by the patient to avoid saliva specimens. An early morning sputum is encouraged.
- 2) Specimen should be sealed tightly to avoid leakage. Specimen should be labeled with patient's name, date of birth and "sputum".
- 3) Specimen should be sent to the Laboratory as soon as possible. If any delay, sputum specimen should be refrigerated until it can be sent to the Lab.

Sputum Series:

Materials needed: Three (3) wide-mouthed leak-proof plastic containers with screw top Biohazard transport bag.

Requisition: Order in Meditech Expanse. Print requisition OR Complete Requisition form with patient/specimen information.

- 1. Patient is instructed to give 3 sputum samples as instructed above, one each day for THREE (3) consecutive days, in the mornings.
- 2. After each sputum is collected, the screw top should be tightly fastened to prevent leakage. Specimen should be labeled with patient's name, date of birth and "sputum/collect date".
- 3. Place container(s) into a specimen bag, seal the bag, and place the folded requisition form into the pocket on the specimen bag.
- 4. Specimen should be sent to the Laboratory as soon as possible. If any delay, sputum specimen should be refrigerated until it can be sent to the lab.
- 5. Each specimen will be processed as they arrive in the Laboratory.

Urine Samples

Materials Needed: Leak-proof plastic container, able to be tightly covered. Biohazard transport bag

Requisition: Order in Meditech Expanse, Print requisition OR Complete Requisition form with patient/specimen information.

- 1) Best urine sample is the second morning urine. (First morning urine usually contains too much degeneration.)
- 2) Patient should be instructed to drink a few glasses of water upon rising in the morning, then give a second morning urine sample.
- 3) Patient should try to give a clean urine into the container, avoiding contamination from the skin around the urethra.
- 4) Specimen should be sent to the Lab as soon as possible. If any delay, specimen should be refrigerated until it can be transported.
- 5) Label with Patient's name, date of birth, and "urine". It is important to denote the type of urine voided, catheterized, cystoscopy, etc.
- 6) Place container into a specimen bag, seal the bag, and place the folded requisition form into the pocket on the specimen bag.
- 7) Three successful second morning urines may be particularly helpful. Two or more of these in a series of urines may be combined in the Lab depending upon date and time of receipt.

Breast Discharge

Materials Needed:

Glass slide with frosted end

Fixative, either spray or jar of 95% alcohol Cardboard folder for slide transport, if applicable #2 pencil

Requisition: Order in Meditech Expanse, Print requisition OR Complete Requisition form with patient/specimen information.

- 1) Write the patient's full name, date of birth and site (example; right breast) on the frosted end of the slide with a #2 pencil. Pens or other writing instruments should not be used because they wash off in the fixation/slide staining process.
- 2) If secretion is evident, place glass slide against secretion and smear material across slide directly from the breast. Take care to ensure that the specimen is placed on the same side as the patient's name is written. Fix immediately. (Spray fix or submerge in coplin jar of 95% alcohol)
- 3) Care should be taken to obtain secretion only onto the slide and not to scrape the skin of the nipple.
- 4) If secretion is not evident, gently aid the secretion from the subareolar area to the nipple. If no secretion appears, do not massage or squeeze further. (Too vigorous manipulation is thought to loosen and possibly spread malignant cells.)
- 5) One smear may be sufficient, depending on the amount of material. If abundant material, more than one slide may be made.

Bronchial Washing/Brushing and Bronchioalveolar Lavage

INTRODUCTION: Bronchial washings and brushings are procedures that are done during flexible fiberoptic bronchoscopy (FOB) to diagnose lung disease via cytologic specimens, especially malignancy. Bronchial Washings (BW) and Bronchial Brushings (BB) techniques are often done in combination with each other and with endobronchial forceps biopsy to increase the diagnostic yield. Bronchioalveolar lavage (BAL) is a more forceful washing that accesses the terminal bronchi and alveoli and is used commonly to aid in the diagnosis of infectious organisms, especially *Pneumocystis jiroveci*. This protocol focuses on how diagnostic materials from these procedures should be collected and sent to the Department of Pathology.

MATERIALS NEEDED

- Flexible fiberoptic bronchoscope with 3-way valve, syringe, and brushing apparatus.
- Sterile saline solution or equivalent.
- Sterile container for specimen, such as Lukens tube or other leak-proof screw-capped plastic container.
- Clear glass slides with frosted end.
- For fixing direct slides, cytology spray fixative or container of 95% alcohol.
- #2 pencil
- Transport bag with pocket

Requisition: Order in Meditech Expanse. Print requisition OR Complete Requisition form with patient/specimen information.

PROCEDURES: All specimen containers received from the following procedures must be labeled with the patient's name, date of birth, type of specimen and site laterality. A requisition form or computer entry must contain specimen types and sites. If direct smears are made onto glass slides, the patient's name, date of birth and specimen site must be written on the frosted end in pencil (pens or other writing instruments should not be used because they wash off in the fixation/ slide staining process). If more than one of a particular type of specimen is obtained, such as a BW from 2 or 3 separate areas, the container and the requisition must be identified as to specific site so diagnoses can be applied to the appropriate areas. Specimen containers must be sealed in a transport bag and the requisition placed in the pocket of the bag.

Bronchial Washing (BW): The material aspirated may be suctioned directly into a container such as a Lukens tube. Also, direct slides may be made with immediate fixation with cytology spray fixative or into 95% ethyl alcohol.Be sure that the top is screwed on tightly or that any other type of container is leak proof for transport to the Laboratory. The material collected should be sent to the Lab as soon as possible; if a delay of greater than 1 hour is expected, the material should be refrigerated.

Bronchial Brushing (BB): A direct smear may be made which is immediately fixed with cytology spray fixative or the specimen slide may be placed into 95% ethyl alcohol. Preferably the brush is immediately placed into PRESERVCYT fluid. The brush may be left in the fluid if

possible or should be gently but firmly rotated in the PRESERVCYT fluid container against the inside wall to remove cellular material. Be sure that the top is screwed on tightly or that any other type of container is leak proof for transport to the Laboratory. The material collected should be sent to the Lab as soon as possible; if a delay of more than 1 hour is expected, the specimen should be refrigerated.

Bronchioalveolar Lavage (BAL): The lavage is collected in a sterile container. Be sure that the top is screwed on tightly or that any other type of container is leak proof for transport to the Laboratory as soon as possible. If a delay is expected greater than 1 hour, the specimen should be refrigerated.

Body Cavity Fluids and Washings (Pleural, Peritoneal, and Pericardial Effusions)

INTRODUCTION: Abnormal accumulation (aka. effusions) of fluid in the pericardial, peritoneal, and the two pleural body cavities happens in many benign and malignant disease processes. Fluid is removed either by needle aspiration techniques or a surgical procedure whereby a tube is inserted into the cavity. This protocol briefly describes how the collected fluid should be preserved and sent to the Department of Pathology.

MATERIALS NEEDED

- Specimen container
- Requisition: Order in Meditech Expanse. Print requisition, OR Complete Requisition form with patient/specimen information.

PROCEDURES: Specimens received from the following procedures must be placed in clean, dry, leak-proof containers. Ideally, effusions should be sampled into containers to which are added about 5 units of heparin for every cubic centimeter of aspirated fluid, or 1 ml of 1:1000 heparin solution for every 100 ml of specimen. This helps prevent bloody body fluids from clotting to a point of losing liquid properties and turning into a solid bloody proteinaceous mass.

All specimen containers received from the following procedures must be labeled with the patient's name, date of birth and type of specimen and site, and a requisition form or computer entry must contain specimen type and site. Specimen containers must be labeled on the container itself, not the cover. Containers must be leak-proof and sent to the Laboratory as soon as possible. If there will be any delay, the specimen should be refrigerated. Prefixative such as 50% ethyl alcohol should NOT be added to the specimen as this will cause precipitation of proteins in the fluid and hardens the cells which prevent them from adhering to the slides and from absorbing the stains.

Fine Needle Aspiration Biopsy

Introduction: Fine needle aspiration biopsy (FNAB) has been demonstrated reliable in assessing neoplasms, infections, and reactive lesions of salivary gland, thyroid, lymph nodes, breast, and soft tissues. Its primary advantage is **low cost, minimal morbidity, and rapid diagnosis** (less than 24 hours). Acceptable target lesions include virtually **any defined, palpable mass** of the head and neck, breast, axilla, extremities, or subcutaneous skin.

Fine needle aspiration biopsy is extremely safe for superficial lesions (intraabdominal and intrathoracic lesions carry an increased risk and should be performed under radiologic guidance by experienced operators).

The most frequent cause of a false negative diagnosis is a **geographic miss** of the lesion, an outcome with significantly increased frequency when inexperienced operators are performing the procedure. It is therefore imperative that FNAB be correlated with clinical and radiologic findings, and that discordant FNAB results be explained by repeat FNAB or another procedure.

PRE-PROCEDURE CONSIDERATIONS

1. Target Lesion

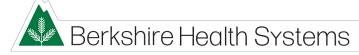
- a. Virtually any palpable, well defined subcutaneous mass is an acceptable target lesion for FNAB.
- b. Subcutaneous lesions near vital structures such as major arteries or the pleura (as in supraclavicular or chest wall FNAB) carry increased risk of significant complications and should be performed by experienced operators only.
- c. Ill-defined lesions such as post-radiotherapy induration or "thickenings" of the breast are often poor targets and frequently yield non-diagnostic results.
- d. "Blind" FNAB of lesions identified radiologically, but not palpable, should not be performed.

2. Work up Algorithm

- a. Thyroid scan should be performed prior to be FNAB due to possible interference with results by the hematoma.
- b. CT/MRI scan results are not affected by FNAB.

3. Contraindications

- a. Vague, ill-defined lesions.
- b. Lesions too near pleura or vital structures to perform FNAB safely.
- c. FNAB should not be performed on suspected carotid body tumors due to the possibility of embolic CVA
- d. Coagulopathy
 - i. For patients with major coagulopathies (i.e., hemophilia, platelet counts less than 5000, or hematologic malignancies), one may wish to consider alternative diagnostic maneuvers or therapeutic correction of the coagulopathy prior to attempting FNAB. PT/PTT and a bleeding time should be evaluated in such patients.



- ii. FNAB may be safely performed on patients on therapeutic doses (5-10 minutes) of the biopsy site after FNAB.
- iii. If the lesion is highly vascular (i.e., thyroid) or in a site (i.e. neck) that a hematoma could be life threatening, consideration should be given to alternative diagnostic maneuvers.

4. Complications

- a. As in phlebotomy, vasovagal reactions and fainting are by far the most common complications of FNAB.
- b. Hematomas may occur but can be avoided by adequate tamponade of the biopsy site.
- c. Infections have been reported but are exceedingly rare.
- d. Improper technique for lesions of the chest wall or supraclavicular region may result in pneumothorax.

CONSENT

- 1. FNAB of palpable subcutaneous masses is of similar risk to phlebotomy, and therefore written consent is not required.
- 2. It is advisable to discuss the procedure with the patient, and to document that verbal consent was obtained.
- 3. For FNAB of palpable lesions near vital structures such as major arteries or the pleura, written consent may be obtained since these procedures carry risk of more significant complications. If one is inexperienced in FNAB technique, one may wish to refer the patient to a more experienced operator, or request assistance from a BMC pathologist while performing the procedure.
- 4. Written consent is mandatory for FNAB of radiographically detected intra-abdominal or intrathoracic lesions.

ANESTHESIA

- 1. Use of anesthesia is discouraged because:
 - a. The wheal raised by the anesthetic often obscures the lesion, resulting in uncertainty as to needle placement.
 - b. Use of medication (1% Xylocaine) adds potentially life-threatening allergic reactions to an otherwise minimally morbid procedure.
 - c. The size of the needle used to administer the anesthetic approximates the size of the biopsy needle.
- 2. Anesthesia is often required in a few specific situations.
 - a. Extremely painful lesions (e.g., infectious lymphadenitis, neoplasms with perineural invasion).
 - b. Breast lesions in which the areola must be traversed by the needle.
 - c. Intraoral lesions.
 - d. Pediatric patients.
 - e. Extraordinarily anxious patients, with easily palpable target lesions.

3. A topical Xylocaine preparation, EMLA cream (Astra Pharmaceuticals) is available and works extremely well for FNAB, particularly in pediatric patients. Its primary limitation is that it must be applied at least one hour prior to the procedure.

PROCEDURE

Materials

- Exam table or chair that can be placed into Trendelenburg position
- Cameco syringe holder
- 10 ml syringes
- 23- or 25-gauge needles Alcohol swabs
- Bandaids Gloves Glass slides
- Slide folders Gauze 4 x 4's
- Spray fixative or 95% Alcohol in screw top jars CytoLyt fixative solution--sterile saline or balanced
- RPMI Flow cytometry fixative (for lymph nodes) may be obtained from BMC 1% or 2% Xylocaine and tuberculin syringes for anesthesia as needed Culture swabs or transport medium (for suspected infectious lesions)

Position

- a. The biopsy may be performed with the patient lying or sitting. If sitting, the setting should allow rapid placement of the patient into Trendelenburg should a vasovagal reaction occur.
- b. The patient should be in a position that allows the aspirator to be in a logical, comfortable position. If the operator is in an awkward position while performing the biopsy, it is unlikely diagnostic material will be obtained.
- c. The lesion should be carefully examined prior to the biopsy to ensure it can be adequately immobilized by the index and middle fingers of the non-dominant hand. Ensuring stabilization of the mass and approaching the biopsy in a comfortable, organized manner may take longer than the biopsy itself, but is well worth the effort given the increased accuracy of needle placement and quality of material obtained.
- d. For lesions near vital structures such as pleura (axilla, supraclavicular, chest wall, breast FNA) or major arteries (carotid/femoral/axillary) it is imperative to plan the FNA with the needle aligned parallel or away from the vital structure, not perpendicular to it.

Technique: The object of FNAB is to use the tip of the needle as a microscalpel to core out minute tissue fragments, with minimal contamination by peripheral blood. Suction does not contribute to the procurement of cells; rather its function is to hold the sample in the needle. Indeed, excellent samples can be obtained with no suction applied. It is highly desirable to keep the entire specimen confined to the needle alone since a sample which is drawn into the syringe usually never makes it out to the slide and is wasted.

a. Label 5-10 slides and specimen containers with patient's name, date of birth and biopsy site.

- b. Clean skin with alcohol swab (use Betadine near joints or other sterile spaces that could be accidentally entered). After excluding possible allergies, anesthetize skin if indicated.
- c. Perform biopsy
 - i. Immobilize the lesion with index and middle finger of the non-dominant hand.
 - ii. Introduce needle attached to syringe and syringe holder into the lesion. (Do not apply negative pressure). The thumb or index finger of nondominant hand can be used to stabilize the syringe as the needle is directed into the lesion.
 - iii. With needle in the lesion, apply 1-2 cc of negative pressure.
 - iv. Perform biopsy using fine, back and forth oscillations of the needle (like an electric sewing machine) for approximately 10 seconds, 10-15 cycles of the needle, or until blood appears in the hub of the needle.
 - v. Stop needle oscillations.
 - vi. Important: Always stop biopsy when blood appears in the hub of the needle Specimen in the syringe usually clots or dries, and is lost for diagnostic purposes. Excursions should be in the same horizontal and vertical planes; do not "fan" the axis of the needle as this causes increased bleeding.
 - vii. Release pressure with needle in lesion, to avoid sucking the specimen into the syringe.
- d. Remove needle from patient.
- e. Perform smears (see Part IV Smears)
- f. Perform needle rinses into sterile saline solution by drawing 1-2 ml of saline through needle into syringe and express all fluid back into saline container.
- g. Repeat rinse 2-3 times.
- h. Repeat technique for total of 3 or more biopsies.

Common Errors in Biopsy Technique

- a. Failure to adequately stabilize the mass, resulting in errant needle placement (geographic miss) and false negative biopsy.
- b. Use of too large needle (use 23 gauge or smaller to avoid excessive contamination by peripheral blood).
- c. Operator aspirates instead of biopsies (i.e., tries to "suck out" cells). Use staccato, sewing machine-like motion to core out tissue fragments. Slow, saw-like motion also results in poor cell yield.
- d. Aspirator continues to draw sample into syringe even after sample appears in hub of needle. Sample will clot and air dry inside syringe. Always stop when blood appears in the hub.
- e. Needle is removed from patient with suction on, resulting in specimen being drawn into the syringe, dried, clotted, and lost for further evaluation.
- f. Operator rinses entire specimen into CytoLyt solution. The best diagnostic sample is obtained on smeared, alcohol-fixed material. Saline or CytoLyt solution salvages

specimens caught in the syringe; however, CytoLyt preparations are less than adequate for evaluation of most lesions.

- g. Operator performs one pass.
 - Multiple passes ensure that different areas of the lesion are sampled.
 - Multiple passes ensure against geographic misses.
 - Three or more passes are essential for lesions less than 1.0 cm and greater than 3.0 cm. Large lesions may have extensive necrosis, fibrous stroma and often yield scantly cellular specimens.
- h. Operator drains cyst without sampling cyst wall. Cyst fluid, although abundant, seldom contains diagnostic cells. Always perform additional passes of the cyst bed, or any residual mass (See cysts).

SMEARS

Excellent samples can be destroyed by smears which are poorly fixed or too thick, hence good smear technique is as important as good biopsy technique. Bloody specimens must be quickly and properly handled since blood impedes fixation or clots in the needle.

Technique

- a. Remove needle and draw 10 cc of air into the syringe, replace needle.
- b. Place 3-4 mm droplet on slide, 1 cm from frosted end.
 - a. If more sample is available, prepare multiple slides, particularly if the specimen is bloody.
 - b. Use of a large droplet (greater than 5 mm of sample) is likely to result in a thick, poorly fixed, uninterpretable smear
- c. With non-dominant hand, pinch slide between thumb and forefinger, with remaining three fingers supporting back of slide.
- d. With dominant hand, lay spreader slide perpendicular to specimen slide. Observe change in surface tension.
- e. With no pressure, glide spreader slide down the length of specimen slide and instantly fix (within 3 seconds) smeared slide. (You may wish to have an assistant ready with spray fixative).
- f. Spread remaining slides with spreader slide and fix as quickly as possible.
- g. Examine smeared, fixed slides for white particles which are an indication that diagnostic material is present on the slide. Smears which appear to consist of blood only are likely to be nondiagnostic.

Common Errors in Smear Technique

• Too much specimen placed on slide. Specimen droplet should not exceed 3-4 mm in diameter and should be placed 1 cm from frosted end of the slide. For cysts and very bloody specimens, perform two or three smears and rinse the remainder into CytoLyt solution. CytoLyt solution will lyse the red blood cells and the laboratory can attempt to salvage the sample.

- Operator waits too long to fix slides. Air drying destroys cell morphology. Once a smear is prepared, it must be fixed immediately.
- Excessive pressure in smearing the specimen, resulting in crush artifact and uninterpretable cell morphology.
- Operator puts smeared slides into CytoLyt fixative solution. CytoLyt solution is not an adequate fixative for smears. Use only spray fixative or 95% ethanol in screw top jars.
- Operator fails to smear slides. Specimens that are not smeared are too thick to permit adequate interpretation.
- Operator submits slides that are not labeled with the patient's name, date of birth and source of specimen. Unlabeled slides cannot be accepted by laboratory for interpretation.
- Operator rinses entire specimen into CytoLyt solution. The best diagnostic sample is obtained on smeared, alcohol-fixed material. CytoLyt solution salvages specimens caught in the syringe; however, CytoLyt preparations are less than adequate for evaluation of most lesions.

SPECIAL CONSIDERATIONS

Lymph Nodes

All lymph nodes, whether suspected to be reactive or lymphoma, should have material obtained for flow cytometric analysis of lymphoid markers.

After obtaining specimens, perform one or two additional passes, and rinse the entire specimen into flow cytometry media (RPMI). Send specimen to flow cytometry lab. Please call 413-447-2570 if there are questions.

Suspected Infections

Cultures can be successfully obtained from FNAB material.

- If pus is obtained, prepare 1-2 smears for cytology in the standard smear fashion. Save the remainder of the specimen in the syringe.
- Remove the needle and replace with original plastic syringe cap.
- Label syringe and smear with patient name, date of birth and biopsy site. Forward to Microbiology.
- Prioritize the type of cultures needed as specimen quantity may be insufficient for all assays.

Cysts

• Whether a benign or a cavitated, necrotic malignancy, cyst fluid does not generally contain diagnostic material.

- If fluid is obtained when suction is applied to the needle, do not perform the finely oscillating biopsy technique, rather, leave the needle stationary and apply enough suction to completely drain the cyst.
- If the syringe fills prior to total decompression of the cyst, perform multiple sticks until all fluid is completely drained.
- Re-examine the patient.
 - o If a residual mass persists, perform two or more FNAB using the standard oscillating technique.
 - o If no mass persists, perform one or two "blind" FNAB of the cyst bed in an attempt to sample the wall of the cyst.
- Make one or two slides from the cyst fluid and place the remainder directly into CytoLyt solution. Label slides and specimens with patient name, date of birth and biopsy site.
 FNAB of any residual mass or "blind" sticks of the cyst should be smeared in the method described in Part V, Smears.

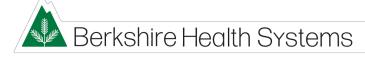
PATIENT INSTRUCTIONS

- a. If significant swelling or pain occurs after the FNAB, the patient should seek medical attention.
- b. For small amount of pain, minor analgesics such as acetaminophen are adequate as needed.
- c. There are no restrictions as to bathing, exercise, medications, etc.

SPECIMEN SUBMISSION

- a. The requisition form should include the specific site where lesion is located. Breast or "Neck" is not specific enough. Examples include:
 - i. Left breast at 6 o'clock, 3 cm from left nipple
 - ii. Right lateral neck, 1 cm from angle of jaw
 - iii. Left upper thyroid lobe
- b. All slides must be labeled with patient's name, date of birth and source of specimen.
- c. Basic patient demographic and physician's name should be included on request form.
- d. Any history of XRT, chemotherapy, recent trauma or surgery is essential, since cellular changes related to these procedures may mimic malignancy on cytology.
- e. State clinical and radiographic impressions as to benign, indeterminate, or malignant. This aids us in assessing if the cytologic findings are representative of the clinical lesion, and hence, if the mass truly has been sampled.
- f. Any history of prior malignancy. This is useful so we can compare the morphology of the prior tumor to determine if the new mass is metastatic or primary.

2. RESULTS



- a. If the specimen is received in the Cytology Lab prior to 9:30 a.m., the routine result will be available the same day.
- b. Specimens received later can be processed and interpreted the same day in emergency situations. The Cytology Lab should be notified by telephone as early as possible in the day so that arrangements can be made to rush the specimen.
- c. Rapid interpretations are routinely performed on FNAB when requested.

If you have trouble in obtaining adequate samples or have any questions, our pathologists are pleased to speak with you. We can arrange to observe your technique and give suggestions about how to improve your diagnostic yield for FNAB. In addition, our cytopathologists are available to perform rapid assessment of adequacy in instances when prior attempts at FNAB have been non-diagnostic.

If you have any further questions regarding FNAB or wish to have a cytopathologist assist you with your procedure, please call 413-447-257 0 from 8:00 a.m. to 4:00 p.m., Monday through Friday.

REFERENCES:

National Cancer Institute Consensus Conference. The Uniform Approach to Breast Fine Needle Aspiration Biopsy. Developed and approved at the national Career Institute in Bethesda, Maryland. September 9-10, 1996. Diagnostic Cytopathology 1997; 16: 295-309.

National Committee for Clinical Laboratory Standards (NCCLS). Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guidelines (NCCLS Document GP20-A). NCCLSA, 1996.

Papanicolaou Society of Cytology. Guidelines of Papanicolaou Society of Cytopathology for Fine Needle Aspiration Procedure and Reporting. Modern Pathology 1987; 10(7); 739.

<u>Specialized Testing – Chemistry</u>

Drug Testing

Chain of Custody Drug Screens

All chain of custody drug screens will be performed at Berkshire Medical Center through the Occupational Health Department.

Patients inquiring should be directed to the Occupational Health Department 447-2684.

Medical Drug Testing

When a physician requests/orders we will accept urine specimens for drug testing provided it is for medical reasons only and does not require the laboratory to:

- 1. Collect the specimen.
- 2. Maintain chain of custody for legal purposes or job substance abuse programs.

Testing usually involves a single urine specimen, <u>qualitatively</u> screened (POS/NEG) for a panel of commonly abused drugs. Confirmation of positive results is optional. Screening in this manner CANNOT:

- ✓ Determine the degree of impairment (if any) in a POSITIVE result.
- ✓ Provide information about dose or drug or the exact time of use.
- ✓ Indicate the absence of drug in a NEGATIVE result (if the drug concentration in the patient is below the cut-off value for the screening test)

The test code for ordering for the urine drug screening test is **URDS** panel. The test code for ordering a urine drug screen with confirmation is **URDSCONF**.

Screening for drugs of abuse is a qualitative procedure performed by enzyme immunoassay and reported as POSITIVE (POS) or NEGATIVE (NEG). The current panel is as follows:

Analyte	EIA cutoff level (ng/ml) –
	(under the cutoff = NEG/ over the cutoff = POS)
Amphetamine	1000
Benzodiazepine	200
Buprenorphine	5
Cocaine	300

Fentanyl	1	
Methadone	300	For drugs
Opiates	300	where
Oxycodone	100	
THC - Cannabinoids	50	

screening is not available or necessary, the test code is **URCONF** and then the specific drug confirmation testing needed needs to be indicated. Current drugs to be tested by confirmation only include:

- Tramadol
- Methylphenidate
- Gabapentin
- Pregabalin

BMC Drug Validity Testing:

All of the orders within the URDS, URDSCONF or URCONF panels come with a Creatinine screen.

Creatinine numbers can help determine the validity of a urine sample.

- Samples with a creatinine level BELOW 20 mg/dl should be considered suspect (diluted or substituted specimens). A comment will be included on the report indicating a questionable urine specimen.
- Samples with a creatinine level ABOVE 20 mg/dl can be considered within range for a normal urine sample.

BMC Disclaimer

All laboratory tests, devices, and procedures performed at the Berkshire Medical Center Laboratories comply with the Federal Food, Drug, and Cosmetic Act and the Clinical Laboratory Improvement Amendments enforced by the US Food and Drug Administration (FDA) and the Center of Medicare and Medicaid Services (CMS), respectively. The intended use of all BMC laboratory tests, devices, and procedures are defined exclusively for medical diagnostic and treatment purposes. Any request with intention to use these services for non-medical purposes may contradict these federal regulations and therefore BMC laboratories cannot provide assistance with such requests.

In addition, specimen collection and transportation for medical laboratory testing are NOT under any chain of custody. As such, the medical test results obtained in medical/healthcare settings shall not be used for pre-employment, employment and/or legal proceedings.

<u>Specialized Testing – Microbiology</u>

Tick Testing Resources

OUTPATIENT TICK TESTING

Outpatients who find a tick and request tick testing for Lyme's Disease can contact one of many commercial laboratories around the country. Using an online search engine and searching for "tick testing" is the easiest way to find commercial labs.

One website, maintained by the UMASS Center for Agriculture, Food and the Environment, has a small listing of tick testing centers. The website is...

Resources: Tick Testing Resources | Center for Agriculture, Food, and the Environment at UMass Amherst

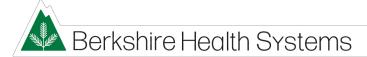
Instructions for collection of the tick, packaging, forms and cost will be dictated by the lab doing the testing. Have the patient contact the commercial testing lab directly to obtain this information.

Microbiology Collection and Cultures

TEST - CODE	SPECIMEN COLLECTION AND CULTURE NOTES
ABSCESS CULTURE	ASPIRATE FROM ABSCESS COLLECTION:
CUABS-DEEP	 Disinfect Skin for superficial sites.
CUABST- SUPERFICIAL	2. Aspirate as much purulent material as possible with a
	sterile needle and syringe.
*INDICATE DEEP OR	3. Submit entire syringe. Remove needle prior to
SUPERFICIAL	transporting.
DEEP = Internal Organ	4. Submit swab specimens only when more suitable fluid aspirates cannot be obtained.
	NOTES:
	1. Identify specimen site.
	2. Gram stain will be performed routinely.
	3. Antibiotic sensitivity will be reported on significant isolates.
	4. Preliminary report- 24 hours.
	5. Final report- minimum 48 hours.
ACID FAST BLOOD	COLLECTION:
CULTURE (TB) CUBAFB	1. Collect one 5ml lavender tube and order BLM in
	Meditech.
	NOTES:
	1. All specimens for acid fast culture must be placed in
	sealed bags for transporting.
	2. Direct acid fast smears are not performed on blood
	specimens.
	3. Specimens are batch processed daily if received by
	1pm.
	4. Specimens are sent to Mass State Lab for culture.
ACID FAST CULTURE (TB)	COLLECTION:
CUAFB	SPUTUM-
	Submit in sterile leakproof container.
	2. Patient should rinse mouth with water prior to
	specimen collection. DO NOT USE DISINFECTANT
	MOUTHWASH.
	3. First morning, deep cough specimen is recommended.
	4. Aerosol-induced sputum may be submitted.
	5. Submit specimens on 3 consecutive days for optimum
	recovery.
	URINE-
	1. Submit in sterile leak-proof container.



	T _,
	 First morning specimen is recommended. Submit specimens on 3 consecutive days for optimum recovery.
	BODY FLUIDS- Peritoneal, pleural, CSF, bone marrow, bronchial washings, etc. 1. Collect aseptically using aspiration techniques or surgical procedure. 2. Submit in syringe in sterile leak-proof container. TISSUE- 1. Collect aseptically. 2. Submit in sterile container without fixatives or preservatives.
	GASTRIC LAVAGE- 1. Submit in sterile leak-proof container. 2. Early morning specimen is recommended. 3. Wait 8 hours after ingestion of food or water. 4. Deliver promptly within 4 hours.
	 NOTES: All specimens for acid fast culture must be placed in sealed bags for transporting. Direct acid fast smears are performed routinely with all cultures except urine sources. Specimens are batch processed daily if received by 1pm. Preliminary smear results are available within 24 hrs. Negative cultures are held a minimum of 8 weeks by the Mass State Lab. Positive cultures are reported to the physician of record. Suggested limits- 3 specimens of each type per patient admission. Medical devices/hardware are not acceptable for acid fast culture
ANAEROBIC CULTURE CUANA ANAEROBIC CULTURE- CERVICAL CUANCX	ONLY SPECIMENS THAT DO NOT HAVE NORMAL ANAEROBIC FLORA. PREFERRED SPECIMENS- Pulmonary- Empyema fluid or transtracheal aspiration Abscesses- Aspirate with a syringe after surface decontamination Urine- Supra pubic aspiration



Uterine Infections- Aspirate by syringe or plastic cannula after cervical os has been decontaminated. IUD's are acceptable for culture

COLLECTION

- 1. See specific routine culture site information.
- 2. Collection of the specimen is best obtained with a syringe or needle. Remove needle before transporting.
- 3. Alternatively, submit the specimen in an anaerobic transport kit available from the BMC Storeroom or request from the courier service.
- 4. Tissue samples in sterile containers are acceptable.
- 5. Deliver the specimen to the Laboratory no later than 30 minutes after collection or call the courier service for pick- up.
- 6. Identify specimen site clearly.

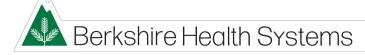
NOTES:

- 1. The following specimens are **not** acceptable for anaerobic culture: Throat, gingival swab, gastric contents, small bowel contents. Feces, coughed sputum, voided urine, vaginal swabs. Any specimen with normal anaerobic flora.
- 2. Implanted and prosthetic medical devices are unacceptable for culture, with the exception of IUD's.
- 3. Gram stains are done routinely. Cultures are held for a minimum of 7 days and are updated daily.
- 4. Anaerobic bacteria are "slow growers" in vitro.
 Cultures frequently have multiple genera and species of anaerobes present. Therefore, isolation, identification and sensitivity testing of anaerobic isolates can be quite time consuming and difficult. Final results may not be available for several days or more.
- 5. Antimicrobial susceptibility testing of anaerobic bacteria is still in developmental stages. Reported results must be considered approximate only. The procedure used at the BMC Lab yields results consistent with those reported from specialized anaerobic reference centers.
- 6. In general, the following hold true and can serve as guidelines until actual results on your culture are performed
 - a) Bacteroides Fragilis- is resistant to Penicillin, sensitive to Clindamycin and Chloramphenicol and unpredictable with Tetracyclines.

	b) Anaerobic gram positive Bacilli and Cocci
	(Clostridium, Peptococcus) are sensitive to
	Penicillin.
	c) None of the anaerobes are sensitive to the Amino
	Glycosides (Gentamicin, Tobramycin,
	Kanamycin, Amikacin).
ANTIGEN DETECTION-	COLLECTION:
BACTERIAL	CSF
LEGIONELLA (URINE)	1. Collect as for CSF culture.
LEGIONELLA AG U	2. Submit at least 1ml.
STREP PNEUMO (URINE)	URINE
STREP PNEUM UR	1. Collect as for urine culture.
	2. Submit 7 to 10 ml.
STREP PNEUMO (CSF)	
STREP PNEUM CSF	
BLOOD CULTURE	COLLECTION: Blood (10ml/bottle)
CUBLD (SET 1)	USING SYRINGE OR BUTTERFLY NEEDLE:
CUBLD2 (SET 2)	1. Prepare blood culture bottles.
	2. Check patient's identification.
	3. Wipe patient's arm with a ChloraPrep One-Step
	Applicator.
	4. Let dry. (Do not touch area to be punctured on
	patient's arm after using Cloraprep)
	5. Attach a straight sterile needle to each syringe.
	6. Fill two 10ml syringes of blood.
	7. Put blood in bottles- 10 cc in each.
	8. Label bottles with labels and initial.
	BUTTERFLY
	1. Connect butterfly to large adapter.
	2. Draw directly into bottles.
	3. Label bottles and initial.
	NOTES:
	1. Blood culture sets are available from the lab supply
	room.
	2. Optimum draws:
	Adult- 10ml blood/bottle
	Pediatric- 3-4 ml blood, using single bottle
	3. Suggested limits: 3 specimens per day, not to exceed
	6 per 48 hours.
	4. Blood cultures are held for 5 days before being
	reported as negative. Blood cultures for fungal
	pathogens are held for 28 days before being reported
	as negative.
	and meganition



	5. Reports are updated daily.
	6. Bottles should be kept at room temp.
	7. Do not incubate if there is a delay in transport
BLOOD CULTURE ACID	COLLECTION: Blood (EDTA tube)
FAST	See Acid Fast Blood Culture
CUBAFB	1. See Held I ast Blood Caltain
	NOTES:
	See notes on Acid Fast
BONE MARROW CULTURE	COLLECTION:
CUBM	Hematology Technologist will transport specimen to Microbiology Lab.
	NOTES:
	1. Gram stain performed routinely.
	2. Preliminary report in 24 hours.
	3. Culture held for 5 days before final negative report is
	issued.
	4. Report updated daily.
BRONCHIAL BRUSH	COLLECTION: Bronchial Brush
CULTURE	1. Submit brush, retracted into tubing, in sterile
CUBB	container.
	2. Gram stain not performed routinely. Direct smears
	may be submitted and special request made.
	NOTES:
	1. Antibiotic sensitivity will be reported on significant isolates.
	2. Preliminary report within 24 hours.
	3. Final report minimum 48 hours.
	4. Quantitative respiratory culture available. Consult
	Laboratory.
BRONCHIAL WASH	COLLECTION:
CULTURE CUBW	By physician during bronchoscopy.
	NOTES:
	1. Gram stain performed routinely.
	2. Preliminary report within 24 hours.
	3. Final report minimum 48 hrs.
	4. Antibiotic susceptibility reported on significant
	isolates.
	Quantitative respiratory culture available. Consult
	laboratory.
CLOTEST	COLLECTION:



CLO	By physician during endoscopic exam
	NOTES:
	1. Results available within 24 hrs.
CRYPTOCOCCAL	COLLECTION:
ANTIGEN	CSF (1ml)
SERUM	Collect as for CSF culture
CRYPTOCO AG SER	
CSF	SERUM (2ml)
CRYPTOCO AG CSF	1. Submit one 5ml red top tube.
	NOTES:
	1. Testing done by Latex agglutination.
	2. Results available within 24 hours
COP CHI THE	Positives will be tittered by request only.
CSF CULTURE	COLLECTION:
CUCSF	1. Collected by physician.
	2. Collect into sterile screw cap tubes
	3. Obtain "as much as possible". Adults- 4-5ml Pediatrics- 0.5-1.0ml
	Pediatrics- 0.5-1.0ml
	NOTES:
	1. Do not refrigerate.
	2. Transport in collection tube.
	3. Handle STAT
	4. If one tube only, send to Microbiology first if cultures
	are desired. If several tubes, usually 2 nd or 3 rd to
	Microbiology.
	5. Gram stain always performed STAT .
	6. Preliminary report within 24 hrs
	7. Final report minimum 72 hrs.
	Antibiotic sensitivity reported on all isolates.
DIALYSIS FLUID CULTURE	COLLECTION: Peritoneal Fluid
CUPERDIA	1. Inject 10ml of peritoneal fluid into each bottle of a
	two bottle blood culture set.
	2. Deliver blood culture set and peritoneal fluid
	collection bag to the Lab.
	NOTES:
	1. Gram stain will be performed on uncentrifuged and
	centrifuged specimens as necessary.
	2. Antibiotic sensitivities will be performed on all
	isolates.
	3. Preliminary report within 24 hrs.
	4. Blood culture set held 5 days.
	5. Daily report update.



EAR CULTURE CUEAR	COLLECTION: Please comment specific anatomic site.
CUEAR	 INTERNAL Cleanse external ear surface. If volume allows obtain aspirate from typanocentesis (Physician collection) Alternately, submit swab of drainage. EXTERNAL Collect specimen with a swab, scraping or by fluid aspiration. Sample active margin. Include fresh secretions from deeper areas of infected site.
	 NOTES: (Internal & External) Gram stain performed routinely. Antibiotic sensitivities will be performed on significant isolates. Preliminary report within 24 hours. Final report minimum 48 hours.
EYE CULTURE CUEYE	COLLECTION: Please comment specific anatomic site. INTERNAL 1. Surgical collection of aspirate by physician. 2. Transport immediately. EXTERNAL 1. Collection by physician. 2. Place in sterile tube. 3. Transport quickly. CONJUNCTIVAL 1. Collect with Nasopharyngeal swab. 2. Remove all makeup and ointments. 3. Avoid eyelid border and lashes. 4. Transport quickly. NOTES: Internal & External 1. Obtain maximum material. 2. Culture both eyes. 3. Label carefully. 4. Gram stain performed routinely. 5. Antibiotic sensitivities will be performed on significant isolates. 6. Preliminary report within 24 hours. 7. Final report minimum 48 hrs.



FLUID CULTURE	COLLECTION: Body Fluids- other than blood, urine,
CUBF	CSF, ex: pleural, peritoneal, synovial
CCDI	1. Decontaminate skin.
	2. Obtain specimen by sterile aspiration with a syringe.
	3. Submit swab specimens only when more suitable
	aspirates cannot be obtained.
	4. Submit entire syringe specimen (several ml's).
	storme shine syringe spoormen (continue).
	NOTES
	NOTES:
	1. Identify specimen site.
	2. Gram stain performed routinely.
	3. Antibiotic sensitivities will be performed on significant isolates.
	4. Preliminary report within 24 hrs.
	5. Final report minimum 48 hrs.
	3. Pina report minimum 48 ms.
FUNGUS CULTURE FLUID	COLLECTION: Body fluids other than blood:
CUFBF	1. Collect as for routine culture.
	NOTES:
	1. Preliminary reports weekly.
	2. Final reports minimum 28 days.
FUNGUS CULTURE OTHER	COLLECTION: Swab specimens, body orifices, tissue.
CUFOTH	
	Collect as per instructions for general bacteriology
	specimens.
	NOTES:
	1. Preliminary reports weekly
	2. Final reports minimum 28 days.
FUNGUS CULTURE	COLLECTION: Sputum/bronchial washings/lavages
RESPIRATORY CUFRESP	1. Collect as for routine cultures.
	NOTES:
	1. Preliminary reports weekly
	Final reports minimum 28 days.
GC SCREEN- NEISSERIA	COLLECTION: Vaginal, cervical, urethral, throat
GONORRHOEAE	1. Collect as for routine culture
CUGC	2. Use calcium alginate swab for urethral specimens
	3. If unable to submit swab immediately to the
	laboratory, inoculate a Jembec Transport System plate
	immediately after obtaining the specimen by rubbing

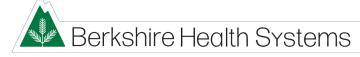
	,
	over the surface of the plate in a zigzag pattern. Place
	CO2 tablet in empty circle
	4. Inoculation plate should be room temperature
	5. Check that media is moist, extends to the edges of the
	plate, without cracks or splits.
	6. Do not use dry, cracked, or outdated plates
	NOTES:
	1. Jembec Transport Systems are available from the Lab.
	2. Before use-store Thayer Martin plates in the
	refrigerator.
	3. Bring plate to room temperature prior to inoculation
	4. Gram stains are not performed routinely
	5. Beta lactamase activity is determined routinely on all
	isolates
	6. Cultures are held for 3 days before being reported as
	negative
	7. Preliminary report within 24 hours
	Positives may be reported anytime within that period.
GENITAL CULTURE	COLLECTION:
CUGEN	VAGINAL
COGEN	1. Use speculum without lubricant.
	2. Collect secretions with a pipette or a swab high in the
	vaginal canal.
	vagmar Canar.
	CERVICAL
	1. Use speculum without lubricant.
	2. Wipe cervix clean of vaginal secretions and mucous.
	3. Gently compress cervix with blades of speculum to
	express endocervical exudate.
	4. Collect on a swab with a ringing motion.
	4. Concet on a swao with a ringing motion.
	URETHRAL- Female
	Collect one hour or more after urination.
	2. Wipe clean with sterile gauze or swab.
	3. Obtain free discharge by "milking" urethra or use
	swab to collect material from about 2 cm inside
	urethra.
	URETHRAL- Male
	1. Collect as for female.
	NOTES:
	Gram stains are performed routinely to aid in diagnosis of hasterial vaginosis.
	diagnosis of bacterial vaginosis.
	2. Culture includes setup for gonorrhoeae.
	3. Preliminary reports available 24 to 48 hrs.



	4. Final report minimum 72 hours.
GRAM STAIN ONLY GS	COLLECTION: 1. Collect as for culture. See specific culture site. 2. Submit entire specimen or one air-dried smear on a microscope slide (frosted at end). If submitting a slide-label slide on the frosted end in pencil NOTES: Results available within 24 hrs.
GROUP B STREPTOCOCCUS CULTURE PRENATAL CUGBPNP	COLLECTION: 1. Using a swab in a non-nutritive transport medium, collect a vaginal/rectal swab. 2. Transport swab specimen to the laboratory for LIM broth enrichment. The Molecular department will perform GBS screening using a GBS PCR method. If the result is positive and the patient has a history of allergic reactions to penicillin, the LIM broth will be set up for culture and sensitivities.
KOH PREPARATION KOH	COLLECTION: Any source, ex: genital, oral, skin, hair, nails 1. Collect as for general bacteriology 2. Submit entire specimen NOTES: 1. KOH prep will be made by lab staff Results available within 24 hours
MEDICAL DEVICE CULTURE CATHETER TIP CULTURE CUDEV	 COLLECTION: Central venous pressure lines, umbilical or intravenous catheters. 1. Decontaminate skin. 2. Remove catheter. 3. Sever aseptically at point that was just inside skin interface. 4. Obtain approximately a 2 inch segment. DO NOT SEND THE WHOLE DEVICE 5. Transport in sterile sealed container.
	NOTES: Gram stains are not performed. 2. Cultures are semi-quantitative. 3. Sensitivities are done routinely on cultures showing >15 colonies. 4. Preliminary report within 24 hours. 5. Final report minimum 48 hours. 6. Additionally, hardware/screws may be sent for culture



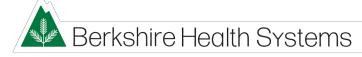
	Only aerobic culture will be performed
MRSA SCREEN FOR	COLLECTION:
OUTPATIENTS	1. Insert swab about 1 inch into nose.
CUMRSA	2. Gently rotate against nasal mucosa and remove.
	NOTES:
	Reported as present or absent Methicillin –Resistant
	Staphylococcus aureus
NOSE CULTURE	COLLECTION:
CUNOSE	1. Insert swab about 1 inch into nose.
	2. Gently rotate against nasal mucosa and remove.
	NOTES:
	1. All growth is reported.
	2. Not used for MRSA screening. See MRSA Screening
	3. Final report minimum 48 hours.
NASOPHARYNGEAL	COLLECTION:
CULTURE	1. Pass swab through nose gently into nasopharynx.
CUNP	2. Use thin wire or perinasal swab (CALIGSWAB).
	3. Stay near septum and floor of nose.
	4. Rotate and remove.
	NOTES:
	1. Specimen is handled as for nose culture.
	2. If Neisseria Meningiditis is suspected please comment
	on request form and submit a Jembec Transport
	System plate (available from lab).
	3. Final report minimum 48 hours.
	8.
PARASITE	COLLECTION:
IDENTIFICATION	1. Send specimen in any clean container.
INSECT, TICK,WORM	
PARASITE	NOTES:
	Report issued on day of receipt or next day if after 4:00pm.
PINWORM	COLLECTION:
PIN	1. Paddles available through the BMC lab.
	2. Collect specimen from patient upon arising, before
	defecation or bathing.
	3. Apply sticky side of paddle to perianal folds.
	4. Return paddle to container and deliver to lab.
	NOTES:
	Report issued on day of receipt or next day if after 4:00pm
SINUS CULTURE	COLLECTION:
CUSINUS	1. Collection by physician. Swab.
	1 - Succession of Projection, Silver,



	NOTES: 1. Gram stain performed routinely 2. Preliminary report within 24 hours 3. Final report minimum 48 hours 4. Antibiotic sensitivity reported on significant isolates 1.	
SKIN CULTURE	COLLECTION:	
CUSKIN	1. Swab skin with culturette.	
	 NOTES: Gram stain performed routinely. Antibiotic sensitivities will be performed on significant isolates. Preliminary report within 24 hrs. Final report minimal 48 hrs. 	
SPUTUM CULTURE	COLLECTION:	
CUSPU	1. Carefully instruct patient to cough deeply, not to spit.	
	2. First morning specimen is best, not 24 hr collection.	
	3. Specimen collection may require ultrasonic	
	nebulization, physiotherapy, or postural drainage.	
	4. May be refrigerated overnight.	
	NOTES: 1. Gram stain is done routinely to determine quality of specimen (extent of contamination with saliva). 2. Specimens showing oral contamination are reported as "specimen microscopically resembles saliva." 3. Antibiotic sensitivities are performed on significant	
	isolates in true sputum specimens.	
STOOL SMEAR FOR WBC'S	COLLECTION:	
WBCS	1. The best specimen is a diarrheal stool.	
	2. Collect a fresh stool specimen in any clean container with a lid.	
	3. Specimens should not be contaminated with toilet water or urine.	
	4. Specimen collection by culturette swab is acceptable.	
	Insert swab beyond anal sphincter. Swab must show feces.	
SURVEILLANCE	COLLECTION:	
CULTURES	Rectal swab in suitable transport media.	
CRE SURVEILLANCE	NOTES:	
CUCRE	1. The rectal swab should be collected without lubricant.	
FLUOROQUINOLONE	2. An axilla source is also acceptable for CRE cultures.	
RESISTANCE		
	ı	

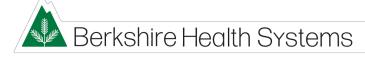


CUFQR	3. The current collection method for Fluoroquinolone	
VRE SCREEN	resistance is a liquid AIMES white capped E-swab.	
CUVRE		
THROAT CULTURE CUT	 COLLECTION: Use tongue blade Obtain specimen with swab Avoid touching tongue, teeth, cheeks or uvula Swab areas of exudation, membrane formation or inflammation Rub tonsillar crypts vigorously 	
	 NOTES: Gram stains are not performed. Specimens are examined for group A strep, group C strep, Group G strep and Arcanobacterium haemolyticum. Sensitivity on Group A strep treatment failures by request accompanying culture only. Final report minimal 24 hrs. 	
THROAT	COLLECTION:	
RAPID BETA STREP	1. As above for throat culture.	
GROUP-A ANTIGEN	NOTES:	
RAPSTR	Turnaround time: 30 minutes.	
TISSUE CULTURE CUBT	COLLECTION: Biopsy or aspirate, bone 1. Collected by physician surgically or by biopsy 2. Submit in sterile container without fixative	
	NOTES: 1. Specimens are generally homogenized before culture 2. Gram stain performed routinely. 3. Antibiotic sensitivity reported on significant isolates. 4. Preliminary report within 24 hours. Final report minimal 48 hrs.	
TRACHEAL ASPIRATE	COLLECTION:	
CUBA	1. Collected by physician.	
	NOTES: 1. Gram stain included routinely. 2. Preliminary report within 24 hours. 3. Final report minimal 48 hrs. Antibiotic sensitivity reported on significant isolates.	
TRICHOMONAS WET PREP	COLLECTION:	
WET	VAGINAL SWAB (FEMALE)	



	1. Obtain discharge material on a culture swab.	
	2. Deliver to the Lab within 15 minutes.	
	3. Do not allow to dry out.	
	URINE (MALE)	
	1. Obtain a single specimen after vigorous exercise or	
	prostatic massage.	
	NOTES:	
	Report issued on day of receipt	
TUBERCULOSIS	*See ACID FAST	
URINE CULTURES- CLEAN	COLLECTION: Mid-stream 1ml or more in sterile	
CATCH CUU	container	
	1. Instruct patient carefully in the use of the clean catch	
	urine kit.	
	2. Early morning specimen is best.	
	3. Clean genital area well.	
	4. Void 20-25ml then collect specimen, at least 1ml,	
	without stopping stream	
	NOTES:	
	1. Gram stain performed only as a "STAT" request.	
	Order as code "GRAM"	
	2. Colony count is performed	
	3. Deliver to lab within one hour	
	4. Refrigerate specimen if delay of transport to lab	
	5. Antibiotic sensitivities performed on significant	
	isolates	
	6. Cultures with 3 or more isolates indicate	
	contamination and are given limited workups	
	7. New specimens are recommended if clinically	
	indicated	
	8. Preliminary report within 24 hours	
	Final report within 24-48 hours.	
URINE CULTURES- FOLEY	INDWELLING CATHETER- Foley (1ml or more) in	
CATH	sterile container	
CUU	1. Refrigerate specimen, deliver to lab within 1 hour.	
	NOTES:	
	1. Gram stain performed only as a "STAT" request.	
	Order as code "GRAM."	
	2. Colony count is performed.	
	3. Deliver to lab within one hour.	
	4. Refrigerate specimen if delay of transport to lab.	

	5. Antibiotic sensitivities performed on significant	
	isolates.	
	6. Cultures with 3 or more isolates indicate	
	contamination and are given limited workups.	
	7. New specimens are recommended if clinically	
	indicated	
	8. Preliminary report within 24 hours.	
	Final report within 24-48 hours.	
URINE CULTURES- OTHER	COLLECTION: Cytoscopy urine (also suprapubic, ureter,	
CUUS	or kidney urine) 1ml or more in sterile container	
	Collected by physician by needle aspiration or	
	cystoscopy.	
	2. Refrigerate specimen.	
	3. Deliver to the lab within 1 hour.	
	NOTES:	
	1. Gram stain performed only as a "STAT" request.	
	Order as code "GRAM", use appropriate specimen	
	description.	
	2. Colony count not performed.	
	3. ID and sensitivity reported on all isolates.	
	4. Preliminary report within 24 hours.	
	Final report within 48 hours	
URINE CULTURE-	COLLECTION: Mid-stream 1ml or more in sterile	
PRENATAL CUUPNP	container	
	1. Instruct patient carefully in the use of the clean catch	
	urine kit.	
	2. Early morning specimen is best.	
	3. Clean genital area well.	
	4. Void 20-25ml then collect specimen, at least 1ml,	
	without stopping stream.	
URINE CULTURE-	COLLECTION:	
STRAIGHT CATHETER	STRAIGHT CATHETER URINE (1ml or more) in sterile	
CUSTR	container	
	1. Refrigerate specimen.	
	2. Deliver to lab within one hour.	
	NOTES:	
	1. Gram stain performed only as a "STAT" request.	
	Order as code "GRAM", use appropriate specimen	
	description.	
	2. Colony count is performed.	
	3. Preliminary report within 24 hours.	
	Final report within 48 hours.	
WOUND CULTURE	COLLECTION:	
CUWDC	SUPERFICIAL	



	 Decontaminate wound surface (surrounding skin). Open lesion and express pus onto swab or aspirate
	deep areas.
	3. Sample advancing margin of lesion.
	3. Sample advancing margin of lesion.
	DEEP (pus, >1ml if possible)
	1. Swab or aspirate deeply.
	2. Consider anaerobic culture.
	NOTES:
	1. Gram stain performed routinely.
	2. Antibiotic sensitivities will be performed on
	significant isolates.
	3. Preliminary report within 24 hrs.
	4. Final report minimal 48 hrs.
	NOTES:
	1. Gram stain is performed.
	2. Preliminary results within 24 hrs.
	3. Final results minimal 48 hrs.
	5. 2 mm 255310 mmmm 10 mb.
YEAST CULTURE	COLLECTION: Same as for FUNGUS CULTURE
CUYST	
	NOTES:
	1. Used for specimens when only yeast is suspected.
	Cultures are held for 5 days before being signed out as
	negative.
Updated: 4/8/24	

<u>Specialized Testing – Molecular</u>

Molecular Testing Menu

Infectious Disease Testing	Order Code	
Chlamydia and Gonorrhea**	CHLAMGONO	
Vaginitis (BV & CV/TV)	VAGINITIS, VAGINITISPLUS	
Hepatitis C Virus (HCV) Quantitation	HCVQNT	
High Risk Human Papilloma Virus with Genotyping	HPVPTH	
MRSA Screening (Inpatients Only)	MRSAPCR	
Pre-Op MRSA/SA PCR Screen SAS		
Influenza A & B/ RSV/ COVID19	FLURSVCOV	
Rapid Respiratory Panel	RESPCOV	
C. difficile**	STLCDIFF	
Gastrointestinal Panel	STLGIP	
Group B Strep (PCR) GBSPCR		
Anaplasma phagocytophilum** ANAPLADNA		
Babesia microti**	BABDNA	
Mycobacterium tuberculosis**(Inpatients Only) MTBRIF		
Meningitis/Encephalitis Panel CSFMEN		
Blood Culture Identification Panel	BCID	
**Reflex Test from Microbiology Department		

Genetic Testing* (available for outpatients only)	Order Code
Factor II Prothrombin	F2PCR
Factor V Leiden	F5PCR

*IMPORTANT: All genetic testing requires that a signed Informed Consent for Genetic Testing Form (signed by both patient and physician with date and time of physician signature) OR a Physician Attestation Form (signed one-time only by physician with date and time of signature) be on file with the Molecular Pathology Department. Copies of both forms are available online.

Clinical Oncology Testing)	Order Code
KRAS Oncogene Mutation Panel	KRAS

ANAPLASMA & BABESIA (ANABAB)

SYNONYMS: Anaplasma phagocytophilum (formerly Ehrlichia phagocytophilum), Babesia microti

INTENDED USE: Berkshire Medical Center performs a test that detects Anaplasma phagocytophilum and Babesia microti. This test is performed on the Roche cobas z 480 instrument and is a laboratory-developed real-time PCR (qPCR) assay for the in vitro, qualitative detection of Anaplasma phagocytophilum and/or Babesia microti. This assay uses extracted DNA from whole blood collected from patients with symptoms of a tick-borne disease to aid in the diagnosis of Anaplasmosis and/or Babesiosis, if used in conjunction with other clinical and epidemiological information.

The specific performance characteristics that were validated for this assay related to clinical utilization include Accuracy, Analytical Sensitivity/Limit of Detection (LoD), Analytical Specificity, Precision/Reproducibility, and Reportable Range.

Accuracy/Diagnostic Sensitivity and Specificity: Results from this real-time PCR assay on the cobas z 480 were compared to Anaplasma phagocytophilum and Babesia microti real-time PCR assays performed at Baystate Reference Laboratory and the Mayo Medical Laboratory. A total of 32 unique whole blood specimens were compared for Anaplasma phagocytophilum results and a total of 22 unique whole blood specimens were compared for Babesia microti results. The diagnostic sensitivity for the BMC Anaplasma and Babesia real-time PCR assay was determined to be 94% and 100%, respectively and the diagnostic specificity was determined to be 100%.

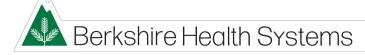
Analytical Sensitivity/Limit of Detection (LoD): The LoD of this assay for each of the target organisms in EDTA blood is as follows:

- Anaplasma phagocytophilum = approximately 1 target per microliter
- Babesia microti = approximately 1 target per microliter

Analytical Specificity: The analytical specificity of this assay is 100%. Organisms tested during validation that are potential interfering organisms were Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa, Enterococcus faecium, Haemophilus influenzae, Enterobacter cloacae, Borrelia burgdorferi, Ehrlichia chaffeensis, and Babesia divergens.

Precision/Reproducibility: Precision (inter-assay and intra-assay) is 100% for this assay.

Reportable Range: This is a qualitative assay, and results are reported as either negative or positive for Anaplasma phagocytophilum and Babesia microti.



METHODOLOGY: Real-time PCR

SPECIMEN REQUIREMENTS

SPECIMEN VOLUME CONTAINER

whole blood >2mL unshared lavender-top (EDTA) tube

Collection

- Collect whole blood by standard venipuncture in lavender-top (EDTA) tube.
- If additional testing requiring whole blood from an EDTA tube is requested, a separate tube must be drawn. A shared specimen will not be accepted.
- Label the tube with patient name, date of birth and date and time of collection before sending to the laboratory.

Transport & Storage

- EDTA whole blood can be transported and stored at room temperature for the first 24 hours. If longer storage is required, store the specimens at 2–8°C.
- Samples should be transported to the laboratory as soon as possible and should be no older than 72 hours prior to DNA extraction.

Causes for Rejection

- Whole blood collected in anticoagulant other than EDTA
- Shared EDTA tube (specimen previously used for other testing)
- Unlabeled or mislabeled specimen
- Specimen >72 hours old
- Grossly lipemic specimen

REFERENCE RANGE: NEGATIVE

MEDITECH CODE ANAPLADNA or BABDNA

CPT CODES 87798 X each organism (DOES NOT COVER LYME TITER)
AVAILABILITY Monday–Friday, 7:30 AM–4:00 PM; specimens are batched

TURNAROUND TIME 5 days

C. difficile/Epi (CDIFF)

SYNONYMS: Clostridium difficile, C. difficile, C. diff

INTENDED USE The Cepheid Xpert® C. difficile/Epi Assay is a qualitative in vitro diagnostic test for the rapid detection of toxin B gene sequences and for presumptive identification of 027/NAP1/BI strains of toxigenic Clostridium difficile from unformed (liquid or soft) stool specimens collected from patients suspected of having C. difficile infection (CDI). The test is performed on the Cepheid GeneXpert Dx System and utilizes automated real-time polymerase chain reaction (PCR) to detect toxin gene sequences associated with toxin producing C. difficile. The Xpert C. difficile/ Epi Assay is intended as an aid in the diagnosis of CDI.

TEST INCLUDES The assay detects the toxin B gene (tcdB), the binary toxin gene (CDT), and the single-base pair deletion at nucleotide 117 within the gene encoding a negative regulator of toxin production (tcdC Δ 117).

METHODOLOGY Real-Time Polymerase Chain Reaction (RT-PCR)

SPECIMEN REQUIREMENTS: unformed (liquid or soft) stool. Stool specimens to be tested should be collected in a clean container. See <u>Special Collections: Molecular C. difficile/Epi (CDIFF)</u>

REFERENCE INTERVAL: Toxigenic C. diff NEGATIVE

The Cepheid Xpert® C. difficile Real-Time PCR Assay detection of toxin B has been developed with high sensitivity and specificity as compared to cytotoxicity and immunoassays.

MEDITECH CODE STLCDIFF CPT CODES 87493

AVAILABILITY 7 days per week, 7:30 AM–4:00 PM

TURNAROUND TIME 24 hour

CHLAMYDIA/GONORRHEA (CT/NG)

SYNONYMS: Chlamydia trachomatis (CT), Neisseria gonorrhea (NG, GC)

INTENDED USE The Aptima® Combo 2® Assay is a target amplification nucleic acid probe test that utilizes target capture for the in vitro qualitative detection and differentiation of ribosomal RNA (rRNA) from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (GC) to aid in the diagnosis of chlamydial and/or gonococcal disease using the Panther® System as specified. IMPORTANT: Therapeutic failure or success cannot be determined with the Aptima Combo 2 assay since nucleic acid may persist following appropriate antimicrobial therapy. The performance of the Aptima Combo 2 assay has not been evaluated in adolescents less than 14 years of age.

METHODOLOGY Transcription Mediated Amplification (TMA)

SPECIMEN REQUIREMENTS and COLLECTION: For complete specimen requirements and collection instructions, see Aptima® Combo 2® CT/GC Specimen Collection Procedure in Outpatient Manual. Special Collections: Molecular Aptima® Combo 2® CT/GC SPECIMEN COLLECTION PROCEDURE

Storage:

Swab Specimens: Swab specimens collected with the Aptima Swab Collection Kits can be shipped to the laboratory or testing site at ambient temperature. These swabs may be stored at 2–30°C for 30-60 days, depending on specimen type, once the specimens have been stabilized in the transport media.

Urine Specimens: Fresh male/female urine should be transported at 2–30°C as soon as possible. Urine MUST reach the laboratory within 24 hours of collection and be aliquoted into a specimen transport tube.

PAP Specimens: PreservCyt solution liquid pap specimens intended for CT and/or GC testing must be processed for cytology and/or transferred to an Aptima specimen transfer tube within 30 days of collection when stored at 2°C to 30°C

Causes for Rejection:

- swab collected in any collection device other than the Aptima collection kits
- 2 swabs, 1 white swab, or NO swabs in Aptima® Multitest Swab Specimen Collection Kit or Aptima® Unisex Swab Specimen Collection Kit
- clean catch urine



- greater than 30mL or less than 20mL of urine in original collection container
- urine received more than 24 hours after collection

INTERFERING SUBSTANCES There are no specific interfering substances that interfere with the Aptima Combo 2 assay, but improper cleaning may reduce the quality of the specimen.

REFERENCE RANGE: NEGATIVE

MEDITECH CODE CHLAMGONO

CPT CODES 87491

AVAILABILITY Monday–Friday, 7:30 AM-4:00PM

TURNAROUND TIME 2-3 days

GI Panel (GIP)

SYNONYMS: FilmArray® GI Panel, Gastrointestinal Panel

INTENDED USE The BioFire FilmArray® Gastrointestinal (GI) Panel is a qualitative multiplexed nucleic acid-based in vitro diagnostic test intended for use with the FilmArray Instrument. The FilmArray GI Panel is capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and parasites directly from stool samples in Cary Blair transport media obtained from individuals with signs and/or symptoms of gastrointestinal infection. The test provides an overall sensitivity and specificity of 98.5% and 99.3%, respectively.

METHODOLOGY: Real-time PCR and RT-PCR

TEST INCLUDES: 22 Gastrointestinal Pathogens Detected in the FilmArray GI Panel

- BACTERIA: Campylobacter (C. jejuni/C. coli/C. upsaliensis) Clostridium difficile (C. difficile) toxin A/B (NOT REPORTED) * Plesiomonas shigelloides Salmonella Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae), including specific identification of Vibrio cholerae Yersinia enterocolitica
- PARASITES: Cryptosporidium Cyclospora cayetanensis Entamoeba histolytica Giardia lamblia (i.e., G. intestinalis and G. duodenalis)
- DIARRHEAGENIC E. COLI/SHIGELLA: Enteroaggregative Escherichia coli (EAEC) Enteropathogenic Escherichia coli (EPEC) Enterotoxigenic Escherichia coli (ETEC) lt/st Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2, including specific



identification of the E. coli O157 serogroup within STEC Shigella/Enteroinvasive Escherichia coli (EIEC)

• VIRUSES: Adenovirus F 40/41 Astrovirus Norovirus GI/GII Rotavirus A Sapovirus (Genogroups I, II, IV, and V)

IMPORTANT:

- The laboratory will contact providers with **any** positive result.
- Negative FilmArray GI Panel results in the setting of clinical illness compatible with
 gastroenteritis may be due to infection by pathogens that are not detected by this test or
 non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's
 disease.
- Positive results do not rule out co-infection with organisms not included in the FilmArray GI Panel. The agent detected may not be the definite cause of the disease. Further, positive results do not distinguish between a viable/replicating organism and a nonviable organism.
- The performance of the FilmArray GI Panel has not been established for monitoring treatment of infection with any of the GI Panel organisms.
- The performance of the FilmArray GI Panel has not been established for patients without signs and symptoms of gastrointestinal illness.
- The C. difficile result will not be reported on the panel. If C. difficile testing is necessary, please order the C. difficile PCR (STLCDIFF) assay.

SPECIMEN requirements (Collection/ Storage and Transport): : For complete specimen requirements and collection instructions see Special Collections: Molecular FilmArray@GI
Panel (GIP)

INTERFERING SUBSTANCES Rotavirus A vaccine may be shed in stool following oral administration and Rotavirus A will be detected by the FilmArray GI Panel if vaccine is present in the test sample.

REFERENCE RANGE Not Detected

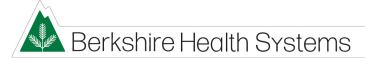
MEDITECH CODE GIP

CPT CODES 87507 Infectious agent detection by nucleic acid (DNA or RNA)

gastrointestinal pathogen, 12–25 targets

AVAILABILITY Monday–Friday, 7:30 AM–4:00 PM

TURNAROUND TIME less than 24 hours M-F



FACTOR II MUTATION (F2PCR)

SYNONYMS: Prothrombin Gene Mutation, Prothrombin G20210A, F2MUT, F2 Mutation, F2PCR

INTENDED USE Detects Factor II (G20210A) mutation as an aid in the diagnosis of individuals with suspected thrombophilia.

TEST INCLUDES The Xpert® Factor II Assay is a qualitative in vitro diagnostic genotyping test for the detection of a single base pair substitution (GfA) in the prothrombin gene (G20210A).

METHODOLOGY Real-time PCR

SPECIMEN REQUIREMENTS whole blood 5mL lavender top (EDTA) tube by routine venipuncture.

Storage: Transport specimen to the laboratory at room temperature. If there is a delay in transport, specimen should be refrigerated, but never frozen. All specimens should be sent to the laboratory immediately after collection.

Causes for Rejection

- missing signed Genetic Consent Form*
- insufficient quantity
- wrong tube
- specimen shared for other testing

INTERFERING SUBSTANCES Patients on heparin therapy and blood transfusion patients may have blood specimens that can potentially interfere with the PCR results and lead to invalid or erroneous results.

REFERENCE RANGE The laboratory provides an interpretative report.

*IMPORTANT: All genetic testing requires that a signed Genetic Consent Form (signed by both patient and physician) OR a Physician Attestation Form (signed one-time only by physician) be on file with the Molecular Pathology Department. Both forms are available online:. Physician Attestation for Informed Consent OR Germline Genetic Testing Form

MEDITECH CODEF2PCRCPT CODES81240



AVAILABILITY TURNAROUND TIME Monday-Friday, 7:30 AM-4:00 PM

1–2 days from receipt of signed genetic consent form

FACTOR V (LEIDEN) MUTATION (F5PCR)

SYNONYMS: F5 Leiden, F5 mutation, Factor 5 MUT, FVL

INTENDED USE Detects Factor V (G1691A) mutation as an aid in the diagnosis of individuals with suspected thrombophilia.

TEST INCLUDES The Xpert® Factor V Assay is a qualitative in vitro diagnostic genotyping test for the detection of a single base pair substitution (GfA) in the Factor V gene (G1691A).

METHODOLOGY Real-time PCR

SPECIMEN REQUIREMENTS: whole blood 5mL lavender-top (EDTA) tube collected by routine venipuncture.

Storage: Transport specimen to the laboratory at room temperature. If there is a delay in transport, specimen should be refrigerated, but never frozen. All specimens should be sent to the laboratory immediately after collection.

Causes for Rejection

- missing signed Genetic Consent Form*
- insufficient quantity
- wrong tube
- specimen shared for other testing

INTERFERING SUBSTANCES Patients on heparin therapy and blood transfusion patients may have blood specimens that can potentially interfere with the PCR results and lead to invalid or erroneous results.

REFERENCE RANGE The laboratory provides an interpretative report.

*IMPORTANT: All genetic testing requires that a signed Genetic Consent Form (signed by both patient and physician) OR a Physician Attestation Form (signed one-time only by physician) be on file with the Molecular Pathology Department. Both forms are available online. Physician Attestation for Informed Consent OR Germline Genetic Testing Form



MEDITECH CODEF5PCRCPT CODES81241

AVAILABILITY Monday–Friday, 7:30 AM–4:00 PM

TURNAROUND TIME 1–2 days from receipt of signed genetic consent form

Group B Strep (GBSPCR)

SYNONYMS: Group B Streptococcus, Streptococcus agalactiae

INTENDED USE The Cepheid® Xpert GBS LB Assay is a qualitative in vitro diagnostic test designed to detect Group B Streptococcus (GBS) DNA from enriched vaginal/rectal swab specimens, using fully automated real-time polymerase chain reaction (PCR) with fluorogenic detection of the amplified DNA. Xpert GBS LB Assay testing is indicated as an aid in determining GBS colonization status in antepartum women. The assay significantly increases the sensitivity and specificity to greater than 90% over traditional subculture.

IMPORTANT:

- The assay is used for antepartum testing on enriched Lim broth cultures of vaginal/rectal swabs after 18–24 hours of incubation.
- The assay does NOT provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.
- The test should NOT be used to determine therapeutic success, as nucleic acids may be present for 3–6 weeks after antimicrobial therapy.
- GBSPCR may be ordered on penicillin-allergic women. However, culture and sensitivity testing will be required for penicillin-allergic women who test positive by PCR.
- All positive results will be called to the ordering provider: For penicillin-allergic patients only, culture and sensitivity testing will automatically be performed.

TEST INCLUDES The GeneXpert® System automates and integrates sample lysis, nucleic acid purification and amplification, and detection of the target sequence in complex samples using real-time and reverse transcription Polymerase Chain Reaction (RT-PCR) and PCR assays.

METHODOLOGY Real-time PCR and RT-PCR

SPECIMEN REQUIREMENTS vaginal/rectal swab using REMEL Red Top Dual Swab Collectors (non-nutritive transport medium) available from the lab. Collection:

To obtain adequate specimen, follow the instructions in this section closely.



- 1. Using a swab in a non-nutritive transport medium, collect a vaginal/rectal swab specimen according to CDC recommendations.
- 2. Label the specimen with patient ID, date and time of collection, and your initials.
- 3. Transport swab specimen to the laboratory for Lim broth enrichment.

Storage: If the swab specimens will be processed in Lim broth for enrichment within 24 hours, store at room temperature (15–30°C). If the swab specimens will be processed in Lim broth after 24 hours, store swabs at 2–8°C for up to six days.

Causes for Rejection

- improper swab storage (freezing or exposing specimen to excessive heat)
- swabs older than 6 days
- wrong swab (swab in nutritive transport medium) used for collection
- specimen collected from patient who has used systemic or topical (vaginal) antibiotics in the week prior or from a patient with placenta previa

INTERFERING SUBSTANCES Potentially interfering substances include, but are not limited to: human amniotic fluid, meconium, serum, urine, fecal material, human blood, lubricating gel, vaginal anti-itch medications, vaginal antifungal medications, anti-diarrheal medications, laxatives, stool softeners, topical hemorrhoid ointments, body oil, body powder, deodorant sprays, enema solutions, and spermicidal foam. Substances were tested at concentrations close to saturation. None of the substances tested had a statistically significant effect on the assay performance.

REFERENCE RANGE: NOT DETECTED

ADDITIONAL INFORMATION In November 2010, the CDC published a revised guideline recommending that in addition to culture, the vaginal/rectal specimens could be tested using a nucleic acid amplification test (NAAT) after 18–24 hours of incubation at 35–37°C in an appropriate enrichment broth medium such as Lim broth to enhance the detection of GBS for antepartum specimens.

MEDITECH CODE GBSPCR CPT CODES 87653

AVAILABILITY Monday–Friday, 7:30 AM–4:00 PM

TURNAROUND TIME 24–36 hours (specimens received on Friday will not be resulted

until Monday)



HEPATITIS C VIRUS QUANTITATION

SYNONYMS: HCV QUANT, HCVQNT, HCV by Quantitative NAAT

INTENDED USE: The Aptima HCV Quant Dx assay is a nucleic acid amplification test that uses real-time Transcription-Medicated Amplification (TMA) technology to detect and quantitate HCV RNA in the following populations: individuals with antibody evidence of HCV infection and with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV.

The Aptima HCV Quant Dx assay is also indicated for use as an aid in the management of HCV infected patients undergoing HCV antiviral drug therapy.

IMPORTANT: This assay is not approved for use as a screening test for the presence of HCV RNA in blood or blood products.

ORDERING: The HCV QUANT assay will be performed automatically as a reflex from a positive HCV antibody result. This assay may also be ordered on a standalone basis to aid in management of HCV-infected patients undergoing antiviral therapy.

Please avoid ordering the HCV QUANT assay if patient has no history of HCV infection. If no history, order the HCV antibody test.

METHODOLOGY: Real-time Transcription-Mediated Amplification (TMA)

SPECIMEN REQUIREMENTS: Serum from SST tube

Causes for Rejection

- No history of HCV infection
 - NOTE: If patient is a young infant, the HCV QUANT assay can be run if the mother has HCV antibody evidence.
- Short serum specimen

REFERENCE RANGE: The normal range for this assay is NOT DETECTED. The quantitative range of this assay is 10-100,000,000 IU/mL (1.0-8.0 log/IU/mL). The lower limit of quantitation (LLOQ) is 10 IU/mL (1.0 log IU/mL).

MEDITECH CODE	HCVQNT
CPT CODES	87522
AVAILABILITY	Monday–Friday, 7:30 AM–4:00 PM



TURNAROUND TIME	1 week

Meningitis/Encephalitis (ME) Panel

SYNONYMS: CSFMEN, MENINGITIS, ENCEPHALITIS

INTENDED USE The BioFire FilmArray® Meningitis/Encephalitis (ME) Panel is a qualitative multiplexed nucleic acid test intended for use with the FilmArray Instrument for the simultaneous qualitative detection and identification of multiple bacterial, viral, and yeast nucleic acids directly from cerebrospinal fluid (CSF) specimens obtained via lumbar puncture from individuals with signs and/or symptoms of meningitis and/or encephalitis. The ME Panel has not been specifically evaluated for CSF specimens from patients without signs and/or symptoms of meningitis and/or encephalitis and has not been specifically evaluated for CSF specimens from immunocompromised individuals.

IMPORTANT:

- The ME Panel is a very sensitive and specific assay that should only be performed on patients where CNS infection is seriously being considered.
- The laboratory will contact providers with any positive result.
- A negative FilmArray ME result does not exclude the possibility of CNS infection. Negative results may occur from the presence of sequence variants or rearrangements in the region targeted by the assay, the presence of inhibitors, technical error, sample mixup or an infection caused by an organism not detected by the panel.
- Any ME Panel result should be interpreted in conjunction with clinical, laboratory, and epidemiological information.
- This PCR panel DOES NOT test for all organisms that can cause Meningitis and/or Encephalitis, including Adenovirus and Arboviruses (West Nile virus, Saint Louis Encephalitis virus, Eastern Equine Encephalitis virus). DO NOT request the ME Panel if there is a concern for a microbe causing Meningitis and/or Encephalitis that is not tested for on the BioFire PCR panel.
- This test is orderable for all medical units; however, the CSF white blood cell count (WBC) must be greater than or equal to 5/mm³. If the CSF WBC requirement is not met, testing can still be performed if Infectious Disease (ID) approval is obtained.

METHODOLOGY • Real-time PCR and RT-PCR TEST INCLUDES 14 Pathogens Detected in the FilmArray ME Panel

- BACTERIA: Escherichia coli K1, Haemophilus influenzae, Listeria monocytogenes, Neisseria meningitidis (encapsulated,) Streptococcus agalactiae, Streptococcus pneumoniae.
- VIRUSES: Cytomegalovirus (CMV), Enterovirus (EV), Herpes simplex virus 1 (HSV-1), Herpes simplex virus 2 (HSV-2), Human herpesvirus 6 (HHV-6), Human parechovirus (HPev), Varicella zoster virus (VZV),
- YEAST: Cryptococcus neoformans/gattii

SPECIMEN REQUIREMENTS CSF (unspun) 0.2 mL (200 µl) Lumbar puncture ONLY (see Special Collections: Molecular Meningitis/Encephalitis (ME) Panel Special Collections: Molecular Meningitis/Encephalitis (ME) Panel

REFERENCE RANGE Not Detected

ADDITIONAL INFORMATION Non-K1 E. coli serotypes and non-encapsulated strains of Neisseria meningitidis are NOT detected by the ME panel. In addition, the panel does NOT differentiate active from latent herpes virus infections. Clinical Sensitivity and Specificity for the FilmArray ME Panel Targets (BioFire Data)

Clinical Sensitivity and Specificity for the FilmArray ME Panel Targets (BioFire Data)

PATHOGENS	SENSITIVITY (PROSPECTIVE)	SPECIFICITY (PROSPECTIVE)
E. coli K1	100%	99.9%
H. influenzae	100%	99.9%
L. monocytogenes	n/a	100%
N. meningitidis	n/a	100%
S. agalactiae	n/a	99.9%
S. pneumoniae	100%	99.2%
CMV	100%	99.8%
EV	95.7%	99.5%
HSV-1	100%	99.9%
HSV-2	100%	99.9%
HHV-6	85.7%	99.7%
HPev	100%	99.8%
VZV	100%	99.8%
C. neoformans/gattii	100%	99.7%

MEDITECH CODE CSFMEN/ ENCEPHALITIS MENINGITIS



CPT CODES	87483
	AVAILABILITY Daily; orderable for all medical units. CSF
AVAILABILITY	WBC count must be greater than or equal to 5/mm ³ . Consult with
	ID if CSF WBC count not met.
TURNAROUND TIME	1-2 hours

MRSA (MRSAPCR) or Pre-OP MRSA/SA (SAS)

SYNONYMS: Methicillin-Resistant Staphylococcus aureus

INTENDED USE

The Cepheid® Xpert MRSA Assay performed in the GeneXpert® Dx System (Xpert MRSA) is a qualitative in vitro diagnostic test designed for rapid detection of methicillin-resistant Staphylococcus aureus (MRSA) from nasal swabs in patients at risk for nasal colonization. The Xpert MRSA Assay is intended to aid in the prevention and control of MRSA infections in healthcare settings. The Xpert MRSA Assay is NOT intended to diagnose MRSA nor to guide or monitor treatment for MRSA infections.

The Cepheid® Xpert SA Nasal Complete Assay performed in the GeneXpert® System is a qualitative in vitro diagnostic test designed for rapid detection of Staphylococcus aureus (SA) and methicillin-resistant Staphylococcus aureus (MRSA) from nasal swabs in pre-operative patients at risk for nasal colonization. The assay is intended to aid in the prevention and control of MRSA/SA infections in healthcare settings. The assay is NOT intended to diagnose, guide or monitor treatment for MRSA/SA infections, or provide results of susceptibility to methicillin.

NOTE: The test should not be used to determine therapeutic success, as nucleic acids may be present for 3–6 weeks after antimicrobial therapy.

TEST INCLUDES The GeneXpert® Dx System automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time PCR and RT-PCR assays to detect MRSA DNA.

METHODOLOGY:

Cepheid® Xpert MRSA Assay Real-time PCR and RT-PCR Cepheid® Xpert SA Nasal Complete Assay Real-time PCR

SPECIMEN REQUIREMENTS nasal swab using 2 swabs Copan Venturi Transystem Collection Device see Special Collections: Molecular MRSA (MRSAPCR) Special Collections: Molecular MRSA (MRSAPCR) or PRE-Op MRSA/SAS (SAS)



REFERENCE RANGE: NEGATIVE

MEDITECH CODE	MRSAPCR
CPT CODES	87641
AVAILABILITY	Monday–Friday, 7:30 AM–4:00 PM
TURNAROUND TIME	8 hour

MEDITECH CODE	SAS
CPT CODES	87641
AVAILABILITY	Monday–Friday, 7:30 AM–4:00 PM
TURNAROUND TIME	24 hours

MYCOBACTERIUM TUBERCULOSIS (MTBRIF)

SYNONYMS: TB, MTB RIFAMPIN R, MTB NAAT

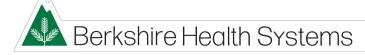
INTENDED USE The Xpert® MTB/RIF Assay, performed on the GeneXpert® Instrument Systems, is a qualitative, nested real-time polymerase chain reaction (PCR) in vitro diagnostic test for the detection of Mycobacterium tuberculosis complex DNA in raw sputum or concentrated sputum sediment prepared from induced or expectorated sputum. In specimens where Mycobacterium tuberculosis complex (MTB-complex) is detected, the Xpert MTB/RIF Assay also detects the rifampin-resistance associated mutations of the rpoB gene.

The Xpert MTB/RIF Assay is intended for use with specimens from patients for whom there is clinical suspicion of tuberculosis (TB) and who have received no antituberculosis therapy, or less than three days of therapy. This test is intended as an aid in the diagnosis of pulmonary tuberculosis when used in conjunction with clinical and other laboratory findings.

IMPORTANT

- Only patients selected by the Infection Control Department may be tested.
- Two specimens, collected at least 8 hours apart, will be tested for each patient.
- At this time, the Molecular Laboratory is only performing testing on raw sputum.
- The performance of the Xpert MTB/RIF Assay has not been evaluated with samples from pediatric patients.

METHODOLOGY Nested real-time PCR



SPECIMEN REQUIREMENTS raw sputum >2mL in any sterile leakproof container See Special Collections: Molecular MYCOBACTERIUM TUBERCULOSIS (MTBRIF) Special Collections: Molecular MYCOBACTERIUM TUBERCULOSIS (MTBRIF)

REFERENCE RANGE NOT DETECTED

ADDITIONAL INFORMATION All patients in healthcare facilities with suspected TB should be maintained in airborne infection isolation (AII) according to recommended infection control guidelines. The testing of either one or two sputum specimens by the Xpert MTB/RIF Assay may serve as an alternative to serial acid-fast stained sputum smears as an aid in the decision of whether continued infection control precautions are warranted in patients with suspected pulmonary tuberculosis. Sputum specimens that are AFB smear-negative but subsequently TB culture positive have lower MTB-complex organism loads than specimens that are AFB smearpositive. Because of the greater sensitivity of the Xpert MTB/RIF Assay for the detection of MTB-complex than that of acid-fast microscopy, MTB-complex may be detected by the Xpert MTB/RIF Assay in AFB smear-negative samples. Patients with HIV infection and pulmonary TB are known to have lower organism loads of MTB-complex in their sputum specimens relative to HIV-uninfected patients, despite more rapid disease progression if untreated. As a consequence, sputum specimens from HIV-infected patients with pulmonary TB tend to be AFB smear-negative more frequently than HIV-uninfected patients. Overall rates of detection of MTB-complex with the Xpert MTB/RIF Assay may be lower in settings with a high percentage of HIV-infected patients because these patients are more likely to produce AFB smear-negative specimens with low organism loads.

MEDITECH CODE	MTBRIF
CPT CODES	87556 + 87798
AVAILABILITY	Monday–Friday, 7:30 AM–4:00 PM
TURNAROUND TIME	4 hours

Rapid Respiratory Panel (RESPCOV)

SYNONYMS: FilmArray® RP2.1

INTENDED USE The BioFire FilmArray® RP2.1 is a qualitative multiplexed nucleic acid test intended for use with the FilmArray Instrument for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections.



IMPORTANT:

- The laboratory will contact providers with any positive result.
- A negative FilmArray RP2.1 result does not exclude the possibility of viral or bacterial infection. Negative results may occur from the presence of sequence variants in the region targeted by the assay, the presence of inhibitors, technical error, sample mix-up or an infection caused by an organism not detected by the panel.
- If only Flu, RSV, or COVID is suspected, please order the Influenza, RSV, COVID19 PCR (FLURSVCOV) test. This test contains the following targets: Influenza A, Influenza B, RSV, and SARS-CoV-2 and is only available as the combo test.

METHODOLOGY • Real-time PCR and RT-PCR

TEST INCLUDES Respiratory Pathogens Detected in the FilmArray Respiratory Panel 2.1

Respiratory Pathogens Detected in the FilmArray Respiratory Panel 2.1

ORGANISM (ABBREVIATION)	CLASSIFICATION (GENOME TYPE)
Adenovirus (AdV)	Adenovirus (DNA)
Coronavirus (CoV) 229E, HKU1, NL63, OC43	Coronavirus (RNA)
Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	Coronavirus (RNA)
Human Rhinovirus/Enterovirus	Picornavirus (RNA)
Human Metapneumovirus (hMPV)	Paramyxovirus (RNA)
Influenza A (Flu A) (subtypes H1, H1-2009, and H3)	Orthomyxovirus (RNA)
Influenza B (Flu B)	Orthomyxovirus (RNA)
Parainfluenza Virus 1 (PIV1)	Paramyxovirus (RNA)
Parainfluenza Virus 2 (PIV2)	Paramyxovirus (RNA)
Parainfluenza Virus 3 (PIV3)	Paramyxovirus (RNA)
Parainfluenza Virus 4 (PIV4)	Paramyxovirus (RNA)
Respiratory Syncytial Virus (RSV)	Paramyxovirus (RNA)
Bordetella pertussis	Bacterium (DNA)
Bordetella parapertussis	Bacterium (DNA)
Chlamydophila pneumoniae	Bacterium (DNA)
Mycoplasma pneumoniae	Bacterium (DNA)

SPECIMEN REQUIREMENTS nasopharyngeal swab 3 mL of transport media or saline Various acceptable media including BD Universal Viral Transport Medium available from the lab; special small pediatric nasopharyngeal swabs are also available. <u>Special Collections: Molecular Rapid Respiratory Panel (RESPCOV)</u>

REFERENCE RANGE Not Detected

ADDITIONAL INFORMATION Respiratory pathogens cause acute local and systemic disease of varying severity, with the most severe cases occurring in children, the elderly, and immunocompromised individuals. Respiratory symptoms can include coughing, nasal discharge, congestion, fever, wheezing, headache, and myalgia. Due to the similarity of diseases caused by many viruses and bacteria, diagnosis based on clinical symptoms alone is difficult. Identification of potential causative agents provides data to aid the physician in determining appropriate patient treatment and public health response for disease containment.

MEDITECH CODE	RESPCOV / Rapid Resp Panel w/COVID-19
AVAILABILITY	All shifts
TURNAROUND TIME	less than 24 hours