

Specimen Collection Information

Pathology Consultation:

- All specimens must be accompanied by a Surgical Pathology requisition, which includes the specimen source and/or description.
- The laboratory cannot accept inadequately identified specimens.
- All containers must be labeled with 2 unique patient identifiers. Acceptable unique identifiers are medical record number (MRN) or birthdate.
- Specimen label should include: Patient name, date of birth, MRN, specimen location/source, date and time specimen was collected.
- If multiple portions of tissue from the same source are submitted, each much receive a numerical designation to reflect its distinct identity within the specimen. For example, 1 of 3.

Test Name:	Pathology Consultation
Test Type:	AP
Test Mnemonic:	Path Tissue Request
Order Number:	38550
Department:	Pathology
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	Varies
Also Known As:	Anatomic Pathology, Cutaneous Immunofluorescence, Dermatopathology, Gross and Microscopic Examination, Immunofluorescent Studies, Hematopathology, Histopathology Examination, Kidney Biopsy, Muscle Biopsy, Nerve Biopsy, Neuropathology, Pathology Tissue Request, Renal Pathology, Surgical Pathology, Uropathology

Immunofluorescent Studies, Tissue	
Collection:	Pathology/Histology departments at SBMF Central Lab must be notified at least 24 hours before biopsy procedure is scheduled.
	Specimen is collected by physician during biopsy procedure.
	Submit specimen in Michel's Solution. If Michel's Solution is not available, submit fresh, in saline moistened gauze in a properly labeled container (include the anatomic site).
	<u>Do Not</u> put tissue in Formalin.
Processing:	Sample must be kept refrigerated at all times.
	Transport by STAT courier.
	It is preferable to transport fresh tissue to SBMF Monday-Friday, 08:00-17:00 only.
Stability:	Refrigerated specimen is stable for 24 hrs.
	Inform Histology department if longer storage is expected (prior to the date of collection).
Rejection Criteria:	Tissue has air dried.
	Tissue received in formalin or other fixative.
Methodology:	Direct Immunofluorescence.
Use:	Rule out: Pemphigus, Bullous Pemphigoid, Dermatitis Herpetiformis and Lupus Erythematosus in skin lesions.
	Rule out: Lupus Erythematosus & Goodpasture's Syndrome in lung tissue.



Kidney Biopsy	
Collection:	Pathology/Histology departments at SBMF Central Lab must be notified at least 24 hours before biopsy is scheduled to provide for services of histologist at time of procedure.
	Sections of kidney (renal) tissue collected by physician during biopsy procedure.
	Minimum: 3 portions of fresh kidney (renal) tissue.
Processing:	 Kidney (renal) tissue must be processed at time of biopsy using the following guidelines: Fix specimen in 10% buffered formalin for light microscopy. Fix specimen in glutaraldehyde for electron microscopy. Submit specimen in Michele's solution for immunofluorescent studies.
Stability:	Room temp until transportation.
Causes for Rejection:	Tissue allowed to dry.
Methodology:	Immunofluorescence; paraffin processing; electron microscopy.
Use:	Evaluate acute or chronic renal disease.

Muscle Biopsy / Nerve Biopsy	
Collection:	 DO NOT collect on Fridays, weekends, or holidays. Notify Client Support (574-236-7263) before the biopsy procedure is scheduled. Once the specimen is collected, call for a STAT courier. Ensure that STAT courier will be available for immediate transport of specimen to SBMF Central Lab. Specimen should arrive at SBMF within 2 hours of collection. Specimen is collected by physician during biopsy. Tissue section collected as fresh, unfixed tissue placed on saline-moistened gauze (may remain in muscle biopsy clamp). Sample on gauze should be placed in sterile container for transport on ice. Minimum: 1-2 portions of fresh muscle tissue at least 1 cm in length; One 3 cm long section of nerve with distal end marked. Label container with patient name and anatomic site of biopsy.
Processing:	Sample must be kept refrigerated at all times. To ensure proper processing, specimen must be received on day of collection.
Stability:	Refrigerated (2-8°C) until STAT courier arrives.
Storage/Transport:	Refrigerated by STAT courier.
Methodology:	Enzyme Histochemistry and Electron Microscopy.
Use:	Evaluate muscle diseases.



Other Tissue	
Collection:	Tissue section collected by physician.
Process:	Immediately fix tissue specimens in 10% neutral buffered formalin.
	Use an amount of formalin approximating 10-20 times size of tissue.
	Document exact specimen source on requisition.
	Clearly note pertinent patient information such as "Uric Acid Crystal exam" or "Gout" on requisition to ensure that a slide will be reserved for special staining procedures.
Note:	If additional studies (such as culture) are anticipated, use an unfixed portion of specimen to send to your reference lab.
Stability:	In formalin: 48 hours room temperature (20-30°C).
Storage/Transport:	Room temperature.
Methodology:	Paraffin processing.
Use:	Histologic diagnosis.



Cytopathology Examination, Non-gynecologic:

- All specimens must be accompanied by a Non-gynecologic Cytopathology requisition.
- The laboratory cannot accept inadequately identified specimens.
- All containers must be labeled with 2 unique patient identifiers. Acceptable unique identifiers are medical record number (MRN) or birthdate.
- Specimen label should include: patient name, date of birth, MRN, specimen location/source, date and time specimen was collected, and whether cytology fixative has been added.

Test Name:	Cytopathology Examination, Non-gynecologic
Test Type:	AP
Test Mnemonic:	Path NG Cyto Request
Order Number:	38560
Department:	Pathology
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	Varies
Also Known As:	Cytologic Studies, Body Fluid; Cytologic Studies, Brushings; Cytologic Studies, Cerebrospinal Fluid; Cytologic Studies, Cyst Fluid; Cytologic Studies, Discharge; Nipple Discharge; Cytologic Studies, Fine Needle Aspirate; Cytologic Studies, Pneumocystis carinii Preparation; Cytologic Studies, Scrapings and Smears; Cytologic Studies, Sputum; Cytologic Studies, Urine, Random; Urine Cytology; Cytologic Studies, Washings; Pathology Non-Gyn Request

Cytologic Studies, Body Fluid	
Preferred Specimen:	Body fluid in plastic containers, at least one containing cytology fixative (CytoLyt®).
Requested Volume:	25.0 mL fixed fluid AND 25.0 mL unfixed fluid. *Additional fluid up to 250 mL can be submitted unfixed.
Minimum Volume:	5.0 mL fixed fluid.
Patient Preparation:	Before aspirating specimen, have patient assume various body positions (prone, side-to-side, sitting) to promote cell suspension.
Collection:	Agitate first container during fluid collection. Split off approximately 25.0 mL fluid into 2nd container. Add equal amount of cytology fixative (CytoLyt®). Label this container: "Cytology Fixative added". Document source of fluid on label and requisition.
Storage/Transport:	If not transported on day collected, refrigerate unfixed portion of specimen.
Rejection Criteria:	Improper fixation.



Cytologic Studies	s, Brushings
Preferred Specimen:	Prepared smear and/or collection brush in plastic container with Cytology Fixative (CytoLyt®).
Requested Volume:	Collection brush placed in container of Cytology Fixative (CytoLyt®).
Minimum Volume:	1-2 smears fixed with Cytology Spray Fixative or placed in 95% ETOH plastic slide container plus collection brush placed in container of Cytology Fixative (CytoLyt®).
Collection:	Preferred Collection - Brush only: Place collection brush in a container of cytology fixative (CytoLyt®). Label container: "Cytology Fixative added". Alternative Collection - Glass Slides: Label frosted-end of slides with patient name. Spray or drop a small amount of Cytology Spray Fixative on slides to help spread specimen and prevent drying. Roll collection brush across the slides. Immediately fix slides as follows: Spray slides with Cytology Spray Fixative or immediately put into 95% ETOH plastic slide container, see below. Allow slides to dry. Place fixed, dried slides face-up in a slide mailer or - Place slides in a container of reagent alcohol (95% ETOH). Label container: "Reagent Alcohol added". Place collection brush in a container of cytology fixative (CytoLyt®). Label container: "Cytology Fixative added". Document specimen source on container, slides, slide mailer, and Cytology requisition.
Storage/Transport:	Room temperature.
Rejection Criteria:	Improper fixation - slides or brush not fixed.

Cytologic Studies	, Cerebrospinal Fluid
Preferred Specimen:	Cerebrospinal Fluid (CSF) in sterile plastic tube.
Requested Volume:	3.0-5.0 mL
Minimum Volume:	1.0 mL
Collection:	Collected by physician.
	Tube numbers should correspond to collection order.
	Collect CSF in tube specified for Cytologic studies.
	Do <u>not</u> add "Cytology Fixative".
	Document specimen as "CSF" on label and requisition.
Processing:	Immediately place CSF specimen tube in container of ice slush (ice and water mixture) for rapid,
	continuous chilling, without freezing.
	If specimen not transported immediately, refrigerate.
	Do <u>not</u> freeze.
Storage/Transport:	Preferred to transport immediately in container of ice slush (ice and water mixture) for rapid,
	continuous chilling, without freezing.
	If overnight storage is required, immediately refrigerate specimen; then transport in container of ice
	slush (ice and water mixture).
Rejection Criteria:	Improper fixation.

Specimen Collection Information



Cytologic Studies, Cyst Fluid	
Preferred Specimen:	Cyst fluid in plastic container with cytology fixative (CytoLyt®).
Requested Volume:	Entire specimen.
Collection:	Add equal amount of cytology fixative (CytoLyt®) to fluid. Label container: "Cytology Fixative added". Document specimen source on labels and Cytology requisition.
Storage/Transport:	Room temperature.
Rejection Criteria:	Improper fixation.

Cytologic Studies, Discharge	
Preferred Specimen:	Nipple discharge or wound secretion on glass slide.
Requested Volume:	Two (2) spray-fixed smears or into 95% ETOH plastic slide containers.
Minimum Volume:	One (1) spray-fixed smear.
Collection:	Label frosted end of slides with patient's name. Nipple Discharge: Soak nipple with warm, sterile saline-saturated cotton or gauze for 10-15 minutes, then strip subareolar area and nipple with thumb and forefinger. When secretion occurs, allow "pea"-sized drop to accumulate on apex of nipple. Place slide end upon nipple and bring across quickly. Immediately spray slide with Cytology Spray Fixative. Make as many smears as amount of specimen allows (later smears usually contain more abnormal cells). For smears from both breasts, identify as "left" or "right" on slides and requisitions. Wound: Collect secretion on slide. Immediately spray with Cytology Spray Fixative. Document specimen source on slide and Cytology requisition. Place fixed, dried slides face up in a slide mailer.
Storage/Transport:	Room temperature.
Rejection Criteria:	Unfixed or broken slide.



Cytologic Studie	Cytologic Studies, Fine Needle Aspirate	
Preferred Specimen:	Aspiration biopsy with or without radiological guidance for most body sites, to include: breast, thyroid, liver, lung, pancreas, salivary gland, lymph node, and neck in 2 plastic containers: One container with reagent alcohol (95% ETOH). Other container with cytology fixative (CytoLyt®).	
Requested Volume:	For aspirate specimen (except thyroid): • 2 smears fixed in reagent alcohol (95% ETOH). -plus- • Cytology fixative (CytoLyt®) rinse of collection needle and syringe. For thyroid aspirate: • 2 smears fixed in reagent alcohol (95% ETOH: 1 each from first and second pass. • 2 air dried smears: 1 each from first and second pass. -plus- • Cytology fixative rinse of collection needle and syringe from each pass.	
Collection:	Contact laboratory for instructions on obtaining needle aspiration material. For fixed smear specimen: Place slide(s) in a container of reagent alcohol (95% ETOH). Label container: "Reagent Alcohol added". For aspirate rinse specimen: Rinse needle and syringe with (CytoLyt®). Place rinse solution from needle and syringe in a plastic container. Label container: "Cytology Fixative added". Document source of "fine needle aspirate" on container and Cytology requisition.	
Storage/Transport:	Room temperature.	
Rejection Criteria:	Improper fixation.	

Cytologic Studies, Pneumocystis carinii Preparation	
Preferred Specimen:	Sputum, bronchial washings, and bronchial brushings in sterile container with cytology fixative (CytoLyt®).
Requested Volume:	Variable amount of sputum or tracheal aspirate.
Minimum Volume:	Variable amount of sputum or tracheal aspirate.
Collection:	Instruct patient to expectorate first morning deep-cough sputum into sterile container or place tracheal aspirate in sterile container.
	Add an equal volume of cytology fixative (CytoLyt®).
	Label container: "Cytology Fixative added".
	Document specimen source on container and Cytology requisition.
Storage/Transport:	Room temperature.
Rejection Criteria:	Improper fixation.



Cytologic Studies, Scrapings and Smears	
Preferred Specimen:	Lesion or ulceration scraped and rinsed in plastic container with cytology fixative (CytoLyt®).
Requested Volume:	Scraping device rinsed in 30.0 mL of cytology fixative (CytoLyt®).
Collection:	Firmly scrape lesion area with saline moistened tongue depressor or cotton swab. For dry surfaces, such as lesions of skin or vulva, moisten the lesion area with saline before scraping. Thoroughly rinse scraping device in cytology fixative (CytoLyt®). Document specimen source on container and Cytology requisition.
Storage/Transport	Room temperature.
Rejection Criteria:	Improper fixation. Scraped material not fixed immediately in cytology fixative.

Cytologic Studies, Sputum	
Preferred Specimen:	Sputum in plastic container with cytology fixative (CytoLyt®).
Minimum Volume:	3.0 mL
Patient Preparation:	Collect before patient has eaten.
	Patient should thoroughly cleanse mouth before collection.
	Instruct patient to avoid contact with preservative in the container.
	Instruct patient to store container securely away from children.
Collection:	When possible, delay adding cytology fixative until after patient has expectorated into specimen container.
	Instruct patient to expectorate first morning deep-cough sputum into container of fixative.
	If container does not already contain fixative, immediately add amount equal to the volume of the expectorated specimen.
	Label container: "Cytology Fixative added".
	Document specimen as "sputum" on label and Cytology requisition.
Storage/Transport:	Room temperature.
Rejection Criteria:	Saliva or nasal aspirates are <u>not</u> acceptable.



Cytologic Studies, Urine, Random	
Preferred Specimen:	Urine in plastic container with cytology fixative (CytoLyt®).
Requested Volume:	Entire specimen.
Minimum Volume:	50.0 mL
	Equal parts of urine and cytology fixative.
Patient Preparation	Give patient several glasses of water ½ to 1 hour prior to collection.
Collection:	Urine, intraoperative washings of urinary bladder, urethra, ureters, or renal pelvis are acceptable. Ideally, specimen should be as fresh as possible. Urine retained in bladder for prolonged periods shows extensive cellular degeneration.
	For detection of upper urinary tract lesions, catheterize ureters to pelvis for suspected renal or pelvic lesions. Repeat procedure using either ureter for control.
	For ureteral lesion, catheterize ureter to point just below level of suspected lesion. Catheterize other ureter for control. Collect urine for 30 minutes. Label appropriately as "right" and "left ureter" or "right" and "left pelvic" and document source on requisition.
	Immediately add equal amounts of cytology fixative (CytoLyt®) to each specimen.
	Label container: "Cytology Fixative added".
	Document specimen as "urine" on label and Cytology requisition, note: voided or catheterized.
Storage/Transport:	Room temperature.
Rejection Criteria:	Improper fixation.

Cytologic Studies, Washings	
Preferred Specimen:	Bronchial, colonic, duodenal, esophageal, gastric, pelvic, peritoneal, tracheal, and miscellaneous washings in plastic container with cytology fixative (CytoLyt®).
Minimum Volume:	2.0 mL
Collection:	Place washings or aspirates collected during endoscopic exam into a container and add equal volumes of cytology fixative (CytoLyt®).
	Label container: "Cytology Fixative added".
	After bronchial washings, collect postbrochoscopy sputum for cytologic studies as it may yield more diagnostic cells than are obtained during bronchoscopy.
	Document specimen source on labels and Cytology requisition.
Storage/Transport:	Room temperature.
Rejection Criteria:	Improper fixation.

^{**} If collecting a bronchial washing for cultures and cytology we can no longer split this specimen. Collect and submit two specimens, one for Cytology (SBMF) the other for cultures to be sent to your reference lab.



HER2(ERBB2) Analysis, IHC, Paraffin Block	
Test Type:	АР
Test Mnemonic:	PRFN HERCP
Order Number:	38521
Department:	Pathology
Performance Lab Name:	South Bend Medical Foundation
ABN:	Local Coverage Determination (LCD): Special Histochemical Stains and Immunohistochemical Stains (<u>L36805</u>)
CPT Code:	88360
Test Includes:	Immunohistochemistry Pathology interpretation Reflexive Testing: HER2 (ERBB2), IHC with reflex to FISH analysis if indicated. If reflex testing is indicated, FISH analysis will be performed when IHC result is equivocal or there are selected histopathologic features as specified by 2013 ASCO/CAP guidelines. 38553 HER2 (ERBB2) Analysis, FISH, Paraffin Block
Also Known As:	HER-2/neu by IHC; HER2 Protein Overexpression Assessment; HercepTest®

Specimen Type:	Tissue section.
Specimen Container:	Formalin-fixed paraffin-embedded (FFPE) tumor tissue.
Collection:	The appropriate specimen for testing is a properly fixed and processed tissue specimen embedded in a paraffin block.
	Neutral buffered formalin is the preferred fixative and tissues should be sectioned and fixed in neutral buffered formalin as soon as possible after surgery for best immunohistochemical staining properties.
	In selecting the paraffin block, submit the largest area of tumor available that show the least degeneration or necrosis and the least fibrous stroma.
	Preservation of nuclear detail can help assess quality of fixation.
Storage/Transport:	Room temperature.
	Avoid excessive heat (greater than 55°C) during transportation of specimen.
Stability:	Room temperature (20-30°C), indefinitely.
Methodology:	Immunohistochemistry (IHC)
Use:	HercepTest™ is a semi-quantitative immunohistochemical assay for determination of HER2 protein (c-erbB-2 oncoprotein) overexpression in breast cancer tissues routinely processed for histological evaluation and formalin-fixed, paraffin-embedded cancer tissue from patients with metastatic gastric or gastroesophageal junction adenocarcinoma. HercepTest™ specifically demonstrates overexpression of HER2 protein. Positive or negative results aid in the classification of abnormal cells/tissues and provide a basis for Herceptin® treatment selection. Decision regarding Herceptin® treatment should be made within the context of the patient's clinical history. HercepTest™ is indicated as an aid in the assessment of patients for whom Herceptin® (trastuzumab) treatment is being considered.



Estrogen/Progesterone Receptor (ER/PR) Assay, IHC, Paraffin Block	
Test Type:	AP
Test Mnemonic:	PRFN ERPR
Order Number:	38551
Department:	Pathology
Performance Lab Name:	South Bend Medical Foundation
ABN:	Local Coverage Determination (LCD): Special Histochemical Stains and Immunohistochemical Stains (<u>L36805</u>)
CPT Code:	88360x2
Test Includes:	Immunohistochemistry
	Pathology interpretation
Also Known As:	ER/PR

Specimen Type:	Tissue section.
Specimen Container:	Formalin-fixed paraffin-embedded (FFPE) tumor tissue
Collection:	The appropriate specimen for testing is a properly fixed and processed tissue specimen embedded in a paraffin block.
	Neutral buffered formalin is the preferred fixative and tissues should be sectioned and fixed in neutral buffered formalin as soon as possible after surgery for best immunohistochemical staining properties.
	In selecting the paraffin block, submit the largest area of tumor available that show the least degeneration or necrosis and the least fibrous stroma.
	Preservation of nuclear detail can help assess quality of fixation.
Storage/Transport:	Room temperature
	Avoid excessive heat (greater than 55°C) during transportation of specimen
Stability:	Room temperature (20-30°C), indefinitely
Methodology:	Immunohistochemistry (IHC)
Use:	A useful biochemical parameter in deciding which patients with breast cancer should be treated by endocrine therapy such as androgens, tamoxifen, or adrenalectomy.
Clinical Significance:	The hormone receptor assays lend predictive value to the patient's response to endocrine therapy. Evidence exists that the incidence of response is enhanced when progesterone receptor is also present. Meningiomas frequently contain progesterone receptors. Such assays are sometimes useful for female patients with metastatic adenocarcinoma of unknown primary site.



Hematopathology Consultation, Peripheral Blood Smear	
Test Type:	Hematology
Test Mnemonic:	CBC PR
Order Number:	25058
Department:	Pathology
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	85060
Also Known As:	Blood Smear Consult; Blood Smear with Interpretation

Specimen Type:	1 stained and 1 unstained slide
Specimen Container:	Slides
Preferred Volume:	1 stained slide, 1 unstained slide
Submit with Order:	Copy of patient's most recent CBC and differential report, along with the Pathology Peripheral Blood Smear Interpretation form .
Collection:	Standard phlebotomy procedure using EDTA tube. Mix by inverting tube 8 times. Prepare slides.
Storage/Transport:	Room temperature
Stability:	3 years
Remarks:	Reason for ordering the consultation must be documented on the test order form or electronic order.
Methodology:	Microscopic Examination
Use:	Determine qualitative and quantitative variations in white cell numbers and morphology, morphology of red cells and platelet evaluation.
	May be of use in the evaluation of anemia, leukemia, infections, inflammatory states, and other conditions.
Clinical Significance:	Evaluate hematological disorders.