SERVICE MANUAL

Patient Preparation and Specimen Collection, Labeling, Fixation, Handling, Transportation

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CONTACT US

CLIENT SERVICES: Monday through Friday, 8:00 AM – 6:30 PM EST

Phone: 800-325-PATH (7284)
Phone: 617-401-4027
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COURIER SERVICES:

Phone: 781-541-7054
EMAIL: courieremails@pathsrv.com

SAFETY DATA SHEETS:

Safety Data Sheets (SDSs) for current specimen collection chemicals sent to your office are available through our website for your convenience and reference twenty-four hours a day, seven days a week: http://stratadx.com/msds.html.

Please contact Client Services at 800-325-7284 if you have questions or to request a hardcopy version of a SDS.

SERVICE MANUAL TABLE OF CONTENTS

SCOPE OF SERVICES

Diagnostic Services and Consultation:

- Anatomic Pathology Service
- Surgical Pathology
- Cytopathology
- Dermatopathology
- Gastrointestinal Pathology
- Genitourinary Pathology
- Gynecologic Pathology
- Breast Pathology
- Hematopathology
- Molecular Pathology: in situ hybridization and FISH Technology
- Immunohistochemistry
- Flow Cytometry

Accurate test results are the result of the entire process of patient preparation, specimen collection, handling and transportation, as well as performance of test procedures and the interpretation and reporting of results.

Specific specimen requirements are provided in this Service Manual. Specimen collection containers and fixatives are available from StrataDx. Please contact a Client Service Representative at 800-325-7284 with questions, for additional information, or to place a supply request.

COMPLETING TEST REQUISITION FORMS DERMATOLOGY & PODIATRY

The information required is essential to assure positive patient identification, improve diagnostic accuracy, compare clinical information, and to compare the current findings with other test results.

Pathology specimens must be labeled in the room where the procedure is performed

Please ensure to write legibly. Any missing or indiscernible information will result in a call to your office for verification, which in can hold up a case and affect turnaround time.

The histology requisition requirements are as follows (in chronologic order of filling in requisition):

Blue Italic text = Required Information

1. *Attending physician's name and address* and consultants' names and addresses.
2. *Date of Procedure/Date of collection* and time (**Time of collection must be entered for breast tissue** due to regulations regarding proper fixation time).
3. *Date of birth* (vital for positive patient identification).
4. *Sex of patient.*
5. *The patient's full legal name* (first and last, no nicknames). If prior specimens have been submitted with another name within the past ten years, please include this information in parentheses.
6. *Patient's address, to include City, State, Zip* and *phone number.*
7. *Insurance information* for billing to include Insurance Company, Member ID, Group #, Insured name.
8. *Procedure Type* please ensure you check a box.
9. *Biopsy Site.*
10. *Clinical Impression* to include any pertinent medical history, previous pathology or clinical information when appropriate.
11. Physician Signature.
12. Pre-labeled stickers filled out with *Patient Name, DOB* and Site. Stickers should be adhered to corresponding specimen container/bottle.
13. If applicable, CC physician first & last name, address, phone and fax number (<u>if not all information is provided we will send the copy directly to you to disperse</u>).

Additional cytology requisition requirements are as follows:

1. The *source of the specimen* is essential when assessing specimen adequacy of Pap smears (i.e. vaginal, cervix, endocervix, vaginal cuff, cervical stump). The specimen source must also be provided for non-gynecological specimens.
2. If ancillary testing and/or special stains are required on non-gynecological specimens, specify the type under "other".
3. *Applicable clinical information* and the *LMP* (last menstrual period).
4. *High risk factors for gynecological cancer.*
5. *Previous abnormal Pap(s), treatment, or gynecological biopsies*. (This includes chemotherapy and radiation and history of cancer).

6. *Any pertinent patient history or clinical information when appropriate*.

SPECIMEN LABELING

Accurately labeling patient specimens will help prevent patient care errors due to specimen mislabeling.
Improving the accuracy of patient identification requires two identifiers on each patient specimen.

Please note:

1. Specimens not labeled according to the requirements below will not be accepted for testing by our laboratory.
2. A client service representative will notify your office concerning any specimen labeling issues.
3. Irretrievable specimen labeling issues will be referred to a pathologist for consultation with the ordering provider.

Before collection, verify the patient's identity by checking at least two unique identifiers. Avoid distractions and interruptions. Concentrate solely on the labeling and handling process. **Label all specimens** at the time of collection. If submitting multiple specimens, each specimen container must be labeled. **Always label samples at the time of collection in the presence of the patient**. **Print legibly** and always label with indelible ink. Alternately, a computer generated label printed with the required information may be affixed to each specimen container. Complete all paperwork at the time the specimen is obtained from the patient.

SPECIMEN LABELING REQUIREMENTS

Each primary specimen container must be labeled with:

1. **Patient's full legal name (first and last).**
2. **A second unique identifier.**
   Acceptable second identifiers include date of birth or a unique random identifier (such as patient medical record number or accession number).

It is also suggested to include the following:

3. Date of collection (and time of collection, when applicable).
4. Specimen site/source.
5. Submitting clinician.

If submitting multiple specimens from the same patient, each container must be marked to identify the correct site.

All information on specimen container(s) should match information provided on requisition.

SLIDE LABELING

Submitted slides must be labeled with the patient's full legal name (first and last) or another unique identifier. Labeling slides with two unique identifiers is recommended for patient safety. Labeling of cardboard/plastic slide holder IS NOT acceptable labeling; be sure that each slide is labeled.

REQUIREMENTS FOR CONSULTATIONS

1. Fill out a requisition or compose a letter of request with the following information:
   Patient's full legal name Source of specimen

Your Case # All required billing information

2. Place the paraffin filled block(s) and/or slide(s) in a transport bag with requisition/letter and a copy of the pathology report.

SPECIMEN TRANSPORTATION

A. FEDEX SHIPPING

StrataDx is pleased to provide complimentary specimen pickup service by FedEx. We provide your office with pre-printed FedEx return labels (with you as the sender and StrataDx as the recipient), along with the shipping materials.

1. Verify each specimen container has 2 unique forms of ID and place container(s) into a plastic biohazard specimen bag. The completed requisition should be folded and put into the outer document sleeve. Seal the biohazard bag.

2. Place the bag into a shipping box along with some absorbent material, such as paper towel or gauze. Please ensure NO patient information is visible, as this is in direct violation of HIPAA (Do not write on the shipping box or label the box with patient identifying information.)

3. Close the box and put it into a FedEx Clinical Pak. Seal the Clinical Pak.

4. Detach a FedEx return label for the package. The return labels are preprinted with all of the necessary shipping information.

5. Call FedEx at 1-800-463-3339 (1-800-GoFedEx) for a pickup. You may schedule daily pickups with FedEx at a time that is convenient for your office.

   **Please note: StrataDx is not open for deliveries on Saturday and Sunday.*
   Selecting Saturday delivery may result in significant delay of delivery.

6. If you are dropping your package at a FedEx box, we recommend recording your tracking number before dropping your box for tracking purposes and your records.

All packages must meet IATA regulations.

B. COURIER SERVICES

StrataDx is pleased to offer routine and STAT courier service to our regional clients. Our department of courier services provides door-to-door transportation of your specimens. Locally, our in-house couriers are assigned regular routes for pick up, designed to meet your practice and patient needs. In other locales, we contract with local providers to offer the same level of reliable and patient friendly service.

All drivers and operations team members are educated on OSHA, HIPAA, DOT, FAA and IATA regulations to ensure compliance in the handling of blood-borne pathogens and diagnostic specimens.
For more information, to inquire if courier service is available in your area, or to request a specimen pick up, please call Courier Services at 781-541-7054.

If STAT service is requested, please inform the representative. The representative will record your request along with the patient's name, date of birth and the site of the biopsy. Your request will be expedited accordingly.

SURGICAL PATHOLOGY

TEST AVAILABILITY	Monday – Friday.
TIMELY RESULTS	Evaluation of specimens usually within 24 hours of receipt. Special studies may require additional time.
STATS	Contact the laboratory
USE OF TEST	Diagnosis of surgical tissue
LIMITATIONS	Specimen Integrity
REJECTION	Unlabeled specimen or inappropriate fixative
METHOD	Microscopic examination by pathologist

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all histology specimens is according to the instructions specified by the patient's physician, unless otherwise specified in the procedure for each specimen type.

SPECIMEN LABELING

1. Identify tissue specimens by clearly labeling the specimen containers with patient's first and last name and a second unique identifier (such as Date of Birth or Medical Record Number). Identifiers must also be documented on the requisition. SEE SPECIMEN LABELING REQUIRMENT SECTION.
2. The specimen site should be identified on the container. Multiple containers must be identified with the specimen source on the container and the corresponding information on the requisition.

COLLECTION, HANDLING, FIXATION AND TRANSPORTATION

NOTE: Unfixed specimens and/or specimens held overnight should be refrigerated.

A. Gross and Microscopic Examination

1. Surgical specimens for routine gross and microscopic examination are submitted in 10% neutral buffered formalin (NBF). The amount of 10% formalin should be 10 times the amount of tissue.
2. DO NOT ADD 10% formalin to cytology specimens, flow specimens, cytogenetics, frozen section specimens, cultures, or specimens tested by another methodology that may require another fixative or no fixative.
3. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and seal the completed requisition in the outer section and submit to the laboratory.

B. Frozen Section

TIMELY RESULTS	Evaluation of routine specimens within 20 minutes of receipt
USE OF TEST	Diagnosis of tissue pathology while surgery is being performed
REJECTION	Formalin fixation, unlabeled specimen

1. When possible schedule 1-3 days prior to surgery by calling pathologist.
2. The pathologist must be notified before removal of tissue.
3. If transported to the lab, place the tissue in a saline-filled container without fixative.

4. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory immediately.
5. Notify the laboratory that a specimen for stat frozen section is being transported.

C. Gross Only Examination

A gross and microscopic examination is performed on all tissue specimens. A gross only examination is performed only on the following types of specimens:

Prosthesis	Stones
Pacemaker	Foreign Bodies
Teeth	Breast Implants (without tissue)

1. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.
2. Specimens cannot be released to the patient without their signature and proper identification.
3. Additional specimen sources may be ordered as "gross only," if in agreement with laboratory policy.

D. Bone Marrow Aspiration and Biopsy

TIMELY RESULTS	Evaluation of specimens usually within 24 hours of receipt. Special studies may impose delays of variable length (i.e. flow cytometry, cytogenetics)
STATS	Evaluation can usually be made within 24 hours upon request
USE OF TEST	Diagnosis of tissue pathology
METHOD	Microscopic examination by pathologist
REJECTION	Unlabeled specimen or inappropriate handling

1. Immediately place the bone marrow biopsy in a container of 10% formalin.
2. Make a minimum of six smears from the aspirate; Label smear with patient's name. It is recommended to write a second unique patient identifier.
3. If flow cytometry is requested, place 1 cc of bone marrow aspirate in a sodium heparin (green top) tube.
4. For cytogenetics, place 1 cc of bone marrow aspirate in a sodium heparin (green top) tube.
5. Allow the aspirate to clot and then place in a container of 10% formalin.
6. Submit at least 2 peripheral blood smears; label with patient's name. It is recommended to write a second unique patient identifier.
7. Copy of most recent CBC results and pertinent clinical information.
8. Label specimen according to labeling instructions, complete requisition according to requirements.
9. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory immediately.

E. Breast Tissue

TIMELY RESULTS	Evaluation of specimens usually within 48 hours of receipt. Special studies may impose delays of variable length

STATS	Evaluation can usually be made within 12 –24 hours upon request
USE OF TEST	Diagnosis of tissue pathology
METHOD	Microscopic examination by pathologist
REJECTION	Unlabeled specimen or inappropriate handling

1. Time of collection must be clearly written on the requisition for proper fixation. Regulations require a minimum of 6 hours and a maximum of 48 hours fixation for valid results.
2. Surgical specimens for routine gross and microscopic examination are submitted in 10% neutral buffered formalin (NBF). The amount of 10% formalin should be 10 times the amount of tissue.
3. DO NOT ADD 10% FORMALIN to cytology specimens, flow specimens, cytogenetics, frozen section specimens, cultures, or specimens tested by another methodology that may require another fixative or no fixative.
4. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and seal the completed requisition in the outer section and submit to the laboratory.

F. Immunofluorescent Examination, Tissue

TIMELY RESULTS	48 hours after receipt of specimen.
USE OF TEST	Diagnostic study of ultrastructure.
REJECTION	Unlabeled specimen, specimen not submitted in normal saline or Michel's fixative.
METHOD	Immunofluorescent Microscopy Examination

1. Immediately immerse the specimen in Michel's fixative. If no Michel's fixative is available, sterile saline may be used as long as the specimen can be rapidly transported to the laboratory (within 6 hours).
2. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

G. Muscle Biopsy

TIMELY RESULTS	2-3 weeks after receipt of the specimen
USE OF TEST	Diagnostic study of cellular and tissue ultrastructure
REJECTION	If not collected and submitted according to instructions. Unlabeled specimen
METHOD	Light, Electron, and Immunofluorescent Microscopy Examination

1. Notify the laboratory one working day in advance of biopsy.
2. Dampen 2 gauze sponges (4X4's) with normal saline, wring out to remove excess saline.
3. Place gauze sponges in a clean, dry container.
4. Remove 1 - 3 muscle tissue specimens. Each specimen should be approximately 1 cm in length and 0.5 - 0.1 cm in diameter.
5. Do not clamp or traumatize specimen.
6. Place the muscle biopsies between the wet gauze sponges in the container.
7. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag

and the completed requisition in the outer section and submit to the laboratory immediately on wet ice. A special courier can be arranged.

H. Nerve Biopsy

TIMELY RESULTS	2 weeks after receipt of the specimen
USE OF TEST	Diagnostic study of cellular and tissue ultrastructure
REJECTION	If not collected and submitted according to instructions. Unlabeled specimen.
METHOD	Light, Electron, and Immunofluorescent Microscopy Examination.

NON-GYNECOLOGICAL CYTOLOGY

TEST AVAILABILITY	Monday – Friday
TIMELY RESULTS	Evaluation of smears usually within 48 hours.
STATS	Smears: within 12 hours of receipt. Block examinations: within 48 hours. Cell Blocks: 12-24 hours. (PLEASE INDICATE ON REQUISITION)
USE OF TEST	Evaluation of cells for malignancy.
LIMITATIONS	Specimen Integrity
REJECTION	Broken slide, unlabeled or leaked specimen, inappropriate fixative
METHOD	Microscopic examination.

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all non-gynecological specimens is according to the instructions specified by the patient's physician, unless otherwise specified in the collection, fixation, handling and transportation procedure for each specimen type.

SPECIMEN LABELING

A. Smears on Glass Slides

1. Write the patient's first and last name on the frosted end of a glass slide with a #2 lead pencil or Statmark® pen. LABELING THE SLIDE HOLDER IS NOT PROPERLY LABELING THE SPECIMEN, since it is discarded upon receipt in the laboratory. SEE SPECIMEN LABELING REQUIRMENT SECTION.
2. If smears are taken from different anatomic sites (i.e., right and left), identify the site on the frosted end of the slide with the corresponding information on the requisition.
3. Refer to fixation instructions. Indicate AIR or FIX on the frosted end of the slide.
4. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

B. Specimen Containers

1. Identify fluid specimens by clearly labeling the specimen containers with patient's first and last name and second unique identifier or affix a printed label with 2 unique patient identifiers. SEE SPECIMEN LABELING REQUIRMENT SECTION.
2. Multiple containers must be identified with the specimen source on the container and the corresponding information on the requisition.
3. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

COLLECTION, HANDLING, FIXATION AND TRANSPORTATION FOR NONGYNECOLOGICAL SPECIMENS

A. Smears on glass slides

Option 1: Spray Fixation

1. Immediately spray fix smear with cytology spray fixative.
2. Do not spray fix smears for Diff Quik staining.
3. Allow specimen to dry before closing slide holder.
4. Close cover and secure with rubber band.
5. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

Option 2: Air Dry

1. Allow freshly prepared smear to dry completely.
2. Close slide cover and secure with rubber band.
3. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

B. Gout (Fine Needle Aspirations, Fresh Sample, Tissue Biopsy)

Joint Aspiration: Fluid

- If specimen is for gout crystals ONLY to rule out pseudo-gout OR for both routine cytology and gout crystals:
- Send in 100% / Absolute Alcohol

OR

- Send fresh in sterile container
- Send ASAP, as a delay in processing compromises the exam for crystals.*

PLEASE NOTE: DO NOT SEND FRESH SPECIMEN SAMPLES ON FRIDAY AS THE SPECIMEN WILL NOT BE PROCESSED UNTIL THE FOLLOWING MONDAY, COMPROMISING SPECIMEN INTEGRITY.

Biopsy: Tissue

- Tissue must be submitted in 100% / Absolute alcohol.

C. Bodily Fluids and Non-Gout Fine Needle Aspirations (FNA's), Needle Rinse and Urine

*****DO NOT SUBMIT NEEDLE WITH SPECIMEN – SPECIMEN WILL BE REJECTED*****

1. Use only CytoLyt fixative (for all fluid specimens other than the Pap Test) or PreservCyt (for urine, pap tests and superficial skin smears such as Tzanck smears).
2. If CytoLyt or PreservCyt is not available, DO NOT add any other type of fixative.
3. If you do not have CytoLyt, call the lab for fixation instructions.
4. DO NOT ADD FIXATIVE TO SPECIMENS THAT MAY REQUIRE SPECIALIZED TESTING (i.e. flow cytometry, urinalysis, cultures,).
5. For Needle Rinses ensure to rinse the needle and discard – DO NOT SUBMIT.

COLLECTION, HANDLING, FIXATION AND TRANSPORTATION FOR MICROBIOLOGIC TESTING

A. Body Cavity Fluids, Joint Fluids (For cerebrospinal fluid refer to procedure below.)
Specimen is collected by percutaneous aspiration or intraoperative suctioning by a physician.

1. To prevent clotting fluids should be collected in a container with 3 units of Heparin per ml. of anticipated fluid. Clots may entrap abnormal cells.
2. Body cavity fluids such as pleural fluids and synovial fluids can be refrigerated. Do not submit more than 200 ml. DO NOT ADD FIXATIVE.
3. Tighten lids securely to prevent leakage. (This is very important)
4. Clearly label specimens according to labeling instructions, complete requisition noting all pertinent clinical history and submit to the laboratory in a biohazard bag.
** If a delay in processing is anticipated (more than 8 hours), refrigerate specimen.
5. Do not add a fixative; cultures and flow may be performed on fluid submitted.

B. Breast Fluids

The specimen is obtained from a mammary nipple discharge or a mammary aspirate.

1. Squeeze tissue to express fluid from nipple. Make a touch preparation on a glass slide.
2. Immediately place slide in a container of 95% alcohol or spray fix. Do not let the slide air-dry.
3. If aspirated, collect a minimum of 2 ml and place in a CytoLyt vial.
4. Tighten lid securely to prevent leakage.
5. Clearly label specimen according to labeling instructions, complete requisition noting all pertinent clinical history. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

C. Brushings

Brushings include, but not limited to, bronchial, esophageal, gastric, and ureteropelvic sites. A brush is used to collect a cellular material for cytologic examination by moving the brush against any suspicious areas.

1. When the brush is withdrawn, place it in a container of CytoLyt fixative.
2. If desired, smears may be made by rapidly rotating the brush on a slide.
3. SPRAY FIX SMEARS IMMEDIATELY or place in a container of 95% alcohol. Do not let the slides air dry.
4. If obtaining multiple specimens, please use one container per site and be sure to label each container with the site from which the brushing was obtained.
5. Clearly label specimen according to labeling instructions, complete requisition noting all pertinent clinical history. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

D. Cerebrospinal Fluids

When cytopathology is used in conjunction with flow cytometry and other immunological techniques, a more accurate diagnosis is obtained for: 1) classification of leukemia's and lymphomas in cerebrospinal fluids, 2) cryptococcus, and 3) metastatic tumors to the central nervous system.

1. Collect 2-5 ml.
2. If several samples are obtained, the second or third should be submitted for cytology.
Add specimen for cytology to a small vial of CytoLyt. DO NOT ADD FIXATIVE TO SPECIMENS THAT MAY REQUIRE MICROBIOLOGIC TESTING OR FLOW ANALYSIS.
3. Tighten lids securely to prevent leakage.

4. Label specimen according to labeling instructions, complete requisition noting all pertinent clinical history. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

E. Fine Needle Aspirations (FNA's)

Fine Needle procedures are used to aspirate the thyroid, salivary gland, breast, lymph nodes and organs such as the liver and lung by a physician.

1. After aspiration expel a small droplet at one end of the slide opposite the frosted end.
2. Place another slide over the drop and quickly pull the top and bottom slides apart as the drop spreads. Prepare no more than 4-6 slides.
3. For some specimens (i.e., thyroid and lymph nodes) label 2 smears for Diff Quik staining and do not spray fix. Allow to air dry. (Diff Quick Only)
4. SPRAY FIX SMEARS IMMEDIATELY using cytology spray fixative and allow to dry.
5. Rinse remaining material from syringe in a small container of CytoLyt for a thin layer preparation and/or cell block, discard needle – DO NOT SUBMIT.
6. Tighten lids securely to prevent leakage.
7. Label specimen according to labeling instructions, complete requisition noting all pertinent clinical history. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

F. Urine

Patient Preparation:

1. Patient cooperation is necessary to get as clean a specimen as possible.
2. Speak to the patient in terms he/she will understand, avoiding the use of medical terms and abbreviations.
3. Instruct patient to wash hands well with soap and water.
4. Tell the patient not to touch the inside of the cup or cap.
5. Take the cap off of the cup and place it on the counter.
6. Have the patient cleanse themselves with the enclosed towelette and collect urine specimen.

NOTE: Second morning midstream urine specimen is most adequate.

Female

1. Sit comfortable on the toilet seat with your knees as far apart as possible.
2. Spread labia with one hand and wipe inner fold from front to back. Discard towelette and repeat with second and third.
3. Keeping labia separated, begin to pass the urine into the toilet.
4. Without stopping flow, collect urine into cup.
5. Finish voiding into toilet.
6. Replace cap tightly on cup, making sure not to touch inside the rim of cup.

Male

1. Wipe head of penis in a single motion with first towelette.
2. Repeat with second towelette. If not circumcised, hold foreskin back before cleansing.
3. Urinate a small amount into toilet.

4. Without stopping flow, collect urine into cup.
5. Finish voiding into toilet.
6. Replace cap tightly on cup, making sure not to touch inside of rim of cup.

G. Urine Specimen for Fluorescence in situ Hybridization (FISH)

Patient Preparation:
1. Collect patient urine in a routine manner; see patient preparation procedure listed in Strata Pathology Services Inc. Service Manual, Section F, above.
NOTE: Second morning midstream urine specimen is most adequate.
2. Collect as much urine as possible, up to 70mL, if urine volume exceeds 70mL pour off the excess.
NOTE: A minimum of 33mL of urine is required to perform the urine bladder cancer FISH assay. Volumes less than 33mL may cause an "insufficient" FISH result.
3. After the urine is collected, carefully pour PreservCyt solution into specimen cup containing urine. If using the specimen collection cup with Boritex® tablet proceed to next step.
4. Tightly secure cap on specimen cup to prevent leakage.
5. Make sure the lid is tightly closed and write or label the container with patient's first name, last name, and second unique identifier. See labeling requirements listed in Strata Pathology Services Inc. Service Manual.
6. Complete requisition according to requirements listed in Strata Pathology Services Inc. Service Manual and note all pertinent clinical history.
7. Place specimen cup into the large section of a biohazard bag making sure the bag is then properly sealed. Place the completed requisition into the outer pocket of the biohazard bag.
8. Return specimen/bag to the foam insert. Close the box and submit to the laboratory.
Note: Store specimen between 4°C to 25°C (39° to 77° Fahrenheit), refrigeration is preferred. Specimen must be processed within 72 hours.

H. Sputum
Sputum is usually used for microbiological investigations of respiratory infections.

Patient Preparation:
1. Instruct patient that sputum is the result of a spontaneous deep cough bringing up material from the small bronchi and alveoli and that saliva or sinus drainage is of no diagnostic value. Post bronchoscopy sputums are more likely to contain diagnostic material.
2. Instruct patient to expectorate sputum directly into the container.
3. Morning specimens resulting from overnight accumulation of secretia yield the best diagnostic results.
4. Collect one specimen a day, on 3 consecutive days to ensure a maximum of diagnostic accuracy.

Specimen Preparation:
1. Add CytoLyt to the specimen (cover specimen). Do not use CytoLyt if microbiology tests are ordered. (Do not add any other type of fixative).
2. Tighten lids securely to prevent leakage.

3. Label specimen according to labeling instructions, complete requisition noting all pertinent clinical history. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

I. Tzanck Smear

Smears are made from lesions to identify viral inclusions associated with Herpes virus.

1. Scrape lesion with a wooden spatula or tongue blade and spread cellular material obtained on a glass slide. Label patient name on the slide with a lead pencil.
2. SPRAY FIX SMEARS IMMEDIATELY with cytology spray fixative.
3. Place slide in a cardboard cover and allow to dry before closing cover.
4. Label specimen according to labeling instructions, complete requisition noting any pertinent clinical history. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

J. Washings

Washings may include, but are not limited to, specimen sources of bronchial, esophageal, gastric and ureteropelvic sites.

1. Washings should be collected in a sterile container.
2. DO NOT ADD FIXITIVE TO SPECIMENS FOR MICROBIOLOGY.
3. Label each container according to labeling requirements, complete requisition noting any pertinent clinical history. Multiple containers must be identified with the specimen source on the container and the corresponding information on the requisition.
4. Tighten lids securely to prevent leakage. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

GYNECOLOGICAL CYTOLOGY

Pap Test AVAILABILITY	Monday – Friday
TIMELY RESULTS	Evaluation of smears usually within two to three days
STATS	Evaluation usually within 24 hours, unless additional testing is required and/or requested
USE OF TEST	To diagnose reactive/reparative changes, atypical cells, pre-malignant conditions, malignancy, certain organisms and infectious processes, or to diagnose cells negative for intraepithelial lesions or malignancy.
LIMITATIONS	Specimen integrity, insufficient specimen volume
REJECTION	Broken slide, unlabeled or leaked specimen, inappropriate fixative
METHOD	Microscopic examination

Universal Precautions Required

PATIENT PREPARATION

For an optimal Pap test the patient should be instructed to:

1. Schedule the appointment at mid-cycle. Ideally the smear should be obtained at mid cycle because morphology is most easily interpreted at this time, although is not essential.
2. Not use vaginal medication, vaginal contraceptives, or douches for 24-48 hours prior to appointment and avoid the use of lubrication jellies. These materials significantly obscure cellular detail.
3. Not have intercourse for 24 hours before the appointment.

Note: A gynecologic slide or a Pap smear shall not result in a diagnostic report if:

1. The apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested.
2. It has been collected, labeled, preserved or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen.
3. The slide is broken to such extent that it cannot be repaired adequately so that cells are not obscured or lost.
4. It contains insufficient cells or the cells are obscured by inflammation, blood, or lubricating ointment, so that an accurate diagnosis cannot be made.

SPECIMEN LABELING

Liquid Based Methodology

1. Identify specimen by clearly labeling the specimen vial with patient's first and last name and unique second identifier or affix a printed label with two unique patient identifiers. SEE SPECIMEN LABELING REQUIRMENT SECTION.

SPECIMEN COLLECTION, FIXATION, TRANSPORTATION - LIQUID BASED METHODOLOGY

Spatula and Cervical Brush Combination and Transportation

A. Pap Test Specimen Collection Using ThinPrep® Pap Test® Method with Brush / Spatula
(Note: Cervical brushes are not approved for use on pregnant patients or inflamed tissue.)

1. Obtain an adequate sampling from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant sparingly applied to the posterior blade of the speculum can be used if necessary.[1] Select contoured end of plastic spatula and rotate it 360 degrees around the entire exocervix while maintaining tight contact with exocervical surface.

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. Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate 1/4 or 1/2 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. Discard the brush.

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 ID number on the vial, and the patient information and medical history on the cytology requisition form.

7. Place the vial and requisition in a specimen bag for transport to the laboratory.

B. Pap Test Specimen Collection Using ThinPrep® Pap Test® Method with Broom-like Device

1. Obtain an adequate sampling from the cervix using a broom-like device. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant sparingly applied to the posterior blade of the speculum can be used if necessary.[1] 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.

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 ID number on the vial, and the patient information and medical history on the cytology requisition form.

5. Place the vial and requisition in a specimen bag for transport to the laboratory.

C. Pap Smear Specimen Collection Using SurePath™ Method

Option 1: SurePath™ Sample Collection with Broom-Type Device with Detachable Head

1. Insert the cervix-brush into the endocervical canal. Apply gentle pressure until the bristles form against the cervix. Maintaining gentle pressure, hold the stem between the thumb and forefinger. Rotate the brush five times in a clockwise direction.
2. Place your thumb against the back of the removable collection device tip and disconnect the entire tip from the stem and place in the SurePath™ preservative vial.
3. The collection device tip should be transferred in the vial. One to three different sampling tips can be left in the SurePath™ vial. Place the cap on the vial and tighten.
4. Clearly label vial with patient's first and last name and second unique ID. See specimen labeling requirements.
5. Complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

Option 2: SurePath™ Sample Collection with Combination Brush/Plastic Spatula Device with Detachable Heads

1. Insert the contoured end of the plastic spatula and rotate 360 degrees around entire exocervix.
2. Snap the device handle and drop the detachable head of the device into the SurePath™ vial.
3. Insert Cytobrush into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate one-fourth to one-half turn in one direction. To reduce unnecessary bleeding, do not over-rotate brush.
4. Snap the device handle and drop the detachable head of the device into the SurePath™ vial. Place the cap on the vial and tighten.
5. Clearly label vial with patient's first and last name and second unique ID. See specimen labeling requirements.
6. Complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

HPV HIGH RISK OR HPV 16/18 GENOTYPING

AVAILABILITY	Monday – Friday
TIMELY RESULTS	Runs are batched daily, 1-2 times per day TAT.
STATS	Not available
TESTS INCLUDED	HPV High Risk & HPV 16/18 Genotyping
USE OF TEST	HPV Screening.
STABILITY	ThinPrep Vial: 21 days.
LIMITATIONS	Specimen integrity, insufficient specimen volume
REJECTION	Mislabeled, unlabeled or leaked specimen, inappropriate fixative
METHOD	Roche Cobas 4800: HPV High Risk HPV 16 and HPV 18 Test

Universal Precautions Required

PATIENT PREPARATION

For optimal Pap and HPV High Risk, HPV 16 and HPV 18 testing, the patient should be instructed to:

1. Schedule the appointment at mid-cycle. Ideally the smear should be obtained at mid cycle because morphology is most easily interpreted at this time, although is not essential.
2. Not use vaginal medication, vaginal contraceptives, or douches for 24-48 hours prior to appointment and avoid the use of lubrication jellies. These materials significantly obscure cellular detail.
3. Not have intercourse for 24 hours before the appointment.

SPECIMEN COLLECTION AND FIXATION

Collect a Pap specimen according to instructions for liquid based methodology in the gynecological cytology section of this manual.

SPECIMEN LABELING, ORDERING, HANDLING, AND TRANSPORTATION

1. Identify specimen by clearly labeling the specimen vial with patient's first and last name and a unique second identifier. SEE SPECIMEN LABELING SECTION. A printed label with the required 2 forms of patient identification can be affixed to the vial.
2. Complete requisition according to requirements. Clearly marking site (Cervical, Endocervical, Vaginal or Unspecified).
3.Indicate if any additional testing is requesting. All HPV testing includes High Risk HPV & HPV 16/18 Genotyping.
4. Reflex orders for HPV testing on all ASCUS, ASCUS/Low Grade Paps can be requested.
5. Orders for HPV testing can also be requested post signout, up to three weeks after initial specimen receipt.
6. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

INTENDED USE
The **cobas**® HPV Test is a qualitative *in vitro* test for the detection of Human Papillomavirus in patient specimens. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV16 and HPV18 while concurrently detecting the rest of the high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).
The **cobas®** HPV Test is indicated:
(a) To screen patients 21 years and older with ASC-US (Atypical squamous cells of undetermined significance) cervical cytology test results to determine the need for referral to colposcopy.

(b) To be used in patients 21 years and older with ASC-US cervical cytology results, to assess the presence or absence of high-risk HPV genotypes 16 and 18. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. The results of this test are not intended to prevent women from proceeding to colposcopy.

(c) In women 30 years and older, the **cobas**® HPV Test can be used with cervical cytology to adjunctively screen to assess the presence or absence of high risk HPV types. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.
(d) In women 30 years and older, the **cobas**® HPV Test can be used to assess the presence or absence of HPV genotypes 16 and 18. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

Cervical specimens that may be tested with the **cobas®** HPV Test include the following liquid based collection media and collection device:
• ThinPrep® Pap Test PreservCyt® Solution
• Endocervical Brush/Spatula

WARNING

This test is not intended for use as a screening device for women under age 30 with normal cervical cytology.

The **cobas**® HPV Test is not intended to substitute for regular cervical cytology screening.
The **cobas**® HPV Test is not intended for use in determining the need for treatment (i.e. excisional or ablative treatment of the cervix) in the absence of high-grade cervical dysplasia. Patients who are HPV16/18 positive should be monitored carefully for the development of high-grade cervical dysplasia according to current practice guidelines.

The use of this test has not been evaluated for the management of women with prior ablative or excisional therapy, hysterectomy, who are pregnant or who have other risk factors (e.g. HIV+, immunocompromised, history of STI).

The **cobas**® HPV Test is designed to enhance existing methods for the detection of cervical disease and should be used in conjunction with clinical information derived from other diagnostic and screening tests, physical examinations, and full medical history in accordance with appropriate patient management procedures.

CLINICAL SIGNIFICANCE/SUMMARY AND EXPLANATION OF THE TEST
Persistent infection with human papillomavirus (HPV) is the principal cause of cervical cancer and its precursor cervical intraepithelial neoplasia (CIN)[1-3]. The presence of HPV has been implicated in greater than 99% of cervical cancers, worldwide[3]. HPV is a small, non-enveloped, double-stranded DNA virus, with a genome of approximately 8000 nucleotides. There are more than 118 different types of HPV[4,5], and approximately 40 different HPV that can infect the human anogenital mucosa[6,7]. However, only a subset of approximately 14 of these types is considered high-risk for the development of cervical cancer and its precursor lesions[3,8-13]. In this document “HPV” means “high risk HPV,” except where otherwise noted.

Although persistent infection with high-risk (HR) HPV is a necessary cause of cervical cancer and its precursor lesions, a very small percentage of infections progress to these disease states.
Sexually transmitted infection with HPV is extremely common, with estimates of up to 75% of all women experiencing exposure to HPV at some point[14]. However, almost all of infected women will mount an effective immune response and clear the infection within 2 years without any long term health consequences[15-20]. An infection with any HPV type can produce cervical intraepithelial neoplasia (CIN) although this also usually resolves once the HPV infection has been cleared[21].

In developed countries with cervical cancer screening programs, the Pap smear has been used since the mid-1950s as the primary tool to detect early precursors to cervical cancer. Although it has decreased the death rates due to cervical cancer dramatically in those countries, the PAP smear and subsequent liquid based cytology methods require interpretation by highly trained cytopathologists and have a high rate of false negatives. Cytological abnormalities are primarily due to infection with HPV; however, various inflammatory or sampling variations can result in false positive cytology results. Triage of an abnormal cytology result involves repeat testing, colposcopy and biopsy. A histologically confirmed high-grade lesion must be surgically removed in order to prevent the development of invasive cervical cancer.

Papillomavirus is extremely difficult to culture *in vitro*, and not all patients infected with HPV have a demonstrable antibody response. Nucleic acid (DNA) testing by PCR is a non-invasive method for determining the presence of a cervical HPV infection. Proper implementation of nucleic acid testing for HPV may increase the sensitivity of cervical cancer screening programs by detecting high-risk lesions earlier in women 30 years and older with NILM cytology and reducing the need for unnecessary colposcopy and treatment in patients 21 and older with ASC-US cytology.

GONORRHEA & CHLAMYDIA

TEST AVAILABILITY	Monday – Friday
TIMELY RESULTS	Runs are batched daily, 1-2 per day turnaround time
STATS	Not available
TESTS INCLUDED	GC- Neisseria Gonorrhea & CT-Chlamydia Trachomatis
LIMITATIONS	Specimen Integrity
REJECTION	Mislabeled, unlabeled or leaked specimen, inappropriate fixative
METHOD	Roche Cobas 4800

Universal Precautions Required

PATIENT PREPARATION

For optimal Pap and GC/Chlamydia testing, the patient should be instructed to:

1. Schedule the appointment at mid-cycle. Ideally the smear should be obtained at mid cycle because morphology is most easily interpreted at this time, although is not essential.
2. Not use vaginal medication, vaginal contraceptives, or douches for 24-48 hours prior to appointment and avoid the use of lubrication jellies. These materials significantly obscure cellular detail.
3. Not have intercourse for 24 hours before the appointment.

SPECIMEN COLLECTION AND FIXATION

A. Liquid based Pap smear collection

1. Collect a Pap specimen according to instructions for liquid based methodology in the gynecological cytology section of this manual.

2. One aliquot from the vial will be used for the Pap test and another for the Gonorrhea and Chlamydia test.

B. Roche vaginal swab specimen (patient collected)

1. Please review ideogram on collection kit before proceeding.
2. Remove the collection tube and swab packet from the collection kit.
3. Partially peel open the swab packet revealing the plastic shaft of the swab. (see ideogram on swab packet)
4. Position: hold the swab in one hand and with the other hand separate the fold of the skin around the vaginal opening (labia). **DO NOT TOUCH THE SWAB TIP OR LAY IT DOWN**. If you touch the tip or lay the swab down, use extra swab provided in the swab packet.
5. Collection: Insert the swab about 5cm (2 inches) into the vaginal opening. Gently turn the swab for about 30 seconds while rubbing the swab against the wall of the vagina. Remove the swab carefully. DO NOT TOUCH THE SWAB TO ANY SURFACE BEFORE PLACING IT INTO THE COLLECTION TUBE.
6. Open tube: while holding the swab in the same hand remove the yellow cap from the collection tube provided.
7. Align: Lower the swab into the tube until the visible dark line on the swab shaft is lined up with the tube rim. The tip of the swab should be just above the liquid in the tube.
8. Break: Carefully lean the swab against the tube rim to break the swab shaft at the dark line; discard the top portion of the swab.
9. Close: Tightly close the yellow cap on the collection tube provided.
10. Wash your hands after collection. Return the sample to your healthcare provided as instructed.

C. Roche Male Urine Specimen (patient collected)

NOTE: PATIENT SHOULD NOT URINATE 1 HOUR PRIOR TO SAMPLING

A. Collecting a urine specimen
   1. Position the urine cup to collect the beginning of the urine stream.
   2. Begin urinating. Please direct the patient to provide first-catch urine (approximately 10 to 50 mL of the initial urine stream) into a urine collection cup.
      NOTE: ***Collection of larger volumes of urine may reduce the test sensitivity**
   3. Close lid of the urine cup securely.

B. How to transport samples for testing

1. Immediately transfer urine into the collection tube provided using the provided disposable pipette.
2. The correct volume of urine has been added when the fluid level is between the two back lines on the tube.
3. Tightly close the yellow cap on the collection tube provided.
4. Invert the tube 5 times to mix. The specimen is now ready to transport.

SPECIMEN LABELING, ORDERING, HANDLING, AND TRANSPORTATION

1. Identify specimen by clearly labeling the specimen vial with patient's first and last name and a unique second identifier. SEE SPECIMEN LABELING SECTION. A printed label with the required 2 forms of patient identification can be affixed to the vial.
2. Complete requisition according to requirements. Additionally, under COLLECTION METHOD, indicate the collection method and under ADDITIONAL TESTING REQUESTED, indicate if testing is for GCCL only or in addition to other testing.
3. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

NOTE: Swab specimens must be transported to the laboratory in the swab specimen transport medium. Specimens must be transported to the laboratory at 2°C to 30°C and tested within 60 days of collection. Urine specimens can be transported to the laboratory at 2°C to 30°C in either the primary collection device (urine cup) or in the urine specimen transport tube. Urine specimens must be transferred into the Cobas urine specimen transport tube within 24 hours of collection and before being assayed. After transfer, urine specimens can be stored at 2°C to 30°C for up to 30 days after collection. Vaginal swab specimens collected with the **cobas**® PCR Female Swab Sample Kit and male urine collected with the **cobas**® PCR Urine Sample Kit may be stored at 2-30°C for up to 12 months once the specimens have been stabilized in **cobas**® PCR Media. Neat male urine is stable at 2-30°C for up to 24 hours.

FLOW CYTOMETRY

Flow cytometry utilizes the most up to date instrumentation available to sort and analyze cells from peripheral blood, bone marrow, tissue specimens, body fluid and cerebral spinal fluid.

Cell surface markers present in suspected leukemia/lymphoma cases may aid in identifying the tumor lineage for diagnostic and prognostic purposes. Identification of cell types present can give an adequate assessment of a patient's immune status.

Specimens for flow cytometry will be received and accessioned by Strata Pathology Services and forwarded to NeoGenomics for technical preparation only.

NeoGenomics Laboratories
6 Morgan Street, Suite 150
Irvine, CA 92618
CAP# 7197542 CLIA# 05D1065194

To learn more about NeoGenomics and the scope of services offered please call NeoGenomics at 866-776-5907 or visit their website: www.neogenomics.com.

Flow cytometry supplies can be ordered from Strata Pathology Services by contacting a Client Service Representative at 800-325-7284.

TEST AVAILABILITY	Monday – Friday
TIMELY RESULTS	Evaluations are usually available within 48 hours of receipt.
USE OF TEST	Evaluation for hematopoietic abnormalities.
LIMITATIONS	Specimen Integrity.
STABILITY	Up to 48 hours post collection if specimen is stored at ambient (room) temperature.

REJECTION	Clotted, refrigerated, hemolyzed, frozen, wrong anticoagulant, collected > 48 hours, unlabeled or leaked specimen, inappropriate fixative
METHOD	Flow Cytometry

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all flow cytometry specimens are according to the instructions specified by the patient's physician and may vary by site.

SPECIMEN LABELING, COLLECTION, HANDLING, FIXATION AND TRANSPORTATION

1. Identify specimen by clearly labeling the specimen vial with patient's first and last name and a unique second identifier. SEE SPECIMEN LABELING SECTION. A printed label with the required two forms of patient identification can be affixed to the vial.
2. Requisitions must include patient's name and a second unique identifier. Refer to the requisition requirements for Histopathology requisition. In addition to the date collected, include the time of collection.
3. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.
4. For additional specimen-specific collection, handling, fixation and transportation requirements please refer to chart below.

SPECIMEN	REQUIRED VOLUME	CONTAINER	TEMPERATURE
Blood	≥ 0.5ml	lavender top or yellow top tube	Ambient. DO NOT FREEZE.
Tissue Aspirate	at least one dedicated pass	RPMI or sterile saline	Ambient. DO NOT FREEZE.
Tissue	≥ 0.5 cm cube	RPMI or sterile saline	Ambient. DO NOT FREEZE.
Bone Marrow	1 ml minimum	Green top tube	Ambient. DO NOT FREEZE.
Cerebral Spinal Fluid	≥ 1.5 ml		Ambient. DO NOT FREEZE.
Body Fluid	≥ 10 ml		Ambient. DO NOT FREEZE.

MOLECULAR PATHOLOGY

Fluorescence in-situ Hybridization (FISH) is a branch of cancer genetics that focuses on detecting and locating the presence or absence of specific DNA sequences on chromosomes. FISH is also referred to as Molecular Cytogenetics.

To perform FISH, cells are fixed onto the surface of a slide, and then the slide is treated so that the chromosomal DNA is denatured into single strands.

Special fluorescently labeled DNA probes are then applied onto the slide. The DNA probes are small pieces of single stranded DNA with a sequence from the gene of interest. Probes are only able to hybridize with their complimentary sequence, which is the gene or locus of interest on a particular chromosome. The DNA probes are allowed to hybridize with the denatured chromosomal DNA and any excess probes are washed away.

After the excess probes are washed away, the slide is then viewed under a fluorescence microscope. The fluorescently labeled molecules reveal the physical location of the gene or locus of interest. Pathologists will then use specified cut off values to assess the results of the FISH test.

A. **ProStrata™ FISH**

ProStrata™ FISH is an eight-probe FISH assay that enhances diagnostic understanding of the unique biology of prostate cancer. ProStrata™ tests for ERG Fusion and PTEN deletion.

TEST AVAILABILITY	Tuesday and Thursday
TIMELY RESULTS	Evaluation of specimens usually within 3 to 5 days of receipt
STATS	Contact the laboratory
USE OF TEST	Aid in the diagnosis of prostate cancer
LIMITATIONS	Specimen Integrity
REJECTION	Unlabeled specimen or inappropriate fixative

METHOD	Molecular Cytogenetics

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all histology specimens is according to the instructions specified by the patient's physician, unless otherwise specified in the procedure for each specimen type.

SPECIMEN LABELING, COLLECTION, HANDLING, FIXATION AND TRANSPORTATION

1. Surgical specimens for routine gross and microscopic examination are submitted in 10% neutral buffered formalin (NBF). The amount of 10% formalin should be 10 times the amount of tissue.
2. Identify specimen by clearly labeling the specimen vial with patient's first and last name and a unique second identifier. SEE SPECIMEN LABELING SECTION. A printed label with the required 2 forms of patient identification can be affixed to the vial.
3. Requisitions must include patient's name and a second unique identifier. Refer to the requisition requirements for Histopathology requisition. In addition to the date collected, include the time of collection.
4. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

B. **MelanoSITE™ FISH**
MelanoSITE™ is a four-probe FISH assay that enhances diagnostic discrimination between nevi and melanoma. Specimens for MelanoSITE™ FISH will be received and accessioned by Strata Pathology Services and forwarded to NeoGenomics for technical preparation.

TEST AVAILABILITY	Monday – Friday
TIMELY RESULTS	Evaluation of specimens usually within 3 to 5 days of receipt.
STATS	Contact the laboratory
USE OF TEST	Aid in the diagnosis of melanoma
LIMITATIONS	Specimen Integrity
REJECTION	Unlabeled specimen or inappropriate fixative
METHOD	Molecular Cytogenetics

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all histology specimens is according to the instructions specified by the patient's physician, unless otherwise specified in the procedure for each specimen type.

SPECIMEN LABELING, COLLECTION, HANDLING, FIXATION AND TRANSPORTATION

1. Surgical specimens for routine gross and microscopic examination are submitted in 10% neutral buffered formalin (NBF). The amount of 10% formalin should be 10 times the amount of tissue.

2. Identify specimen by clearly labeling the specimen vial with patient's first and last name and a unique second identifier. SEE SPECIMEN LABELING SECTION. A printed label with the required 2 forms of patient identification can be affixed to the vial.
3. Requisitions must include patient's name and a second unique identifier. Refer to the requisition requirements for Histopathology requisition. In addition to the date collected, include the time of collection.
4. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

C. **OneSwab**

TEST AVAILABILITY	Monday – Friday
TIMELY RESULTS	Evaluation of specimens usually within 3 to 5 days of receipt.
STATS	Contact the laboratory
USE OF TEST	Assist in the detection, diagnosis, evaluation & treatment of viral, fungal and bacterial infections
LIMITATIONS	Specimen Integrity
REJECTION	Unlabeled specimen or missing swab
METHOD	PCR

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all molecular specimens is according to the instructions specified by the patient's physician, unless otherwise specified in the procedure for each specimen type.

SPECIMEN LABELING, COLLECTION, HANDLING, FIXATION AND TRANSPORTATION

1. Aseptically remove sterile swab from package.
2. Collect specimen by vigorously swabbing site involved for 10 to 30 seconds.
3. Aseptically remove cap from vial.
4. Break swab and insert into medium.
5. Place cap on vial and secure tightly.
6. Fill out vial label with patient information.
7. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the pouch on the outer section and submit to the laboratory.

D. UroSwab

TEST AVAILABILITY	Monday – Friday
TIMELY RESULTS	Evaluation of specimens usually within 3 to 5 days of receipt.
STATS	Contact the laboratory

USE OF TEST	Assist in the detection, diagnosis, evaluation & treatment of viral, fungal and bacterial infections
LIMITATIONS	Specimen Integrity
REJECTION	Unlabeled specimen or missing swab
METHOD	PCR

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all molecular specimens is according to the instructions specified by the patient's physician, unless otherwise specified in the procedure for each specimen type.

SPECIMEN LABELING, COLLECTION, HANDLING, FIXATION AND TRANSPORTATION

1. Urine collection should be at least one hour between voids.
2. Collect a urine sample in a urine collection container.
3. Open UroSwab kit, remove cap from vial and dip the sponge into the urine.
4. Place the sponge into the vial and tightly cap the vial.
5. Fill out vial label with patient information.
6. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the pouch on the outer section and submit to laboratory.

K. PCA-3

TIMELY RESULTS	2 weeks after receipt of the specimen
USE OF TEST	to follow up an indeterminate PSA result
REJECTION	Specimens not collected in PCA3 urine collection tubes. Urine is not within fill area window in each tube. Storage/Transport Temperature guidelines are not followed. Specimen is unlabeled
METHOD	Transcription-Mediated Amplification/Hybridization Protection Assay.

Urine Collection Procedure:

****NOTE: TWO URINE TUBE SPECIMENS ARE REQUIRED PER PATIENT****

1. Perform attentive DRE by applying firm pressure from the base to apex and from the lateral to midline of prostate. Three strokes per lobe. Firm pressure is enough pressure to depress the surface approximately 1 cm.

2. Collect 20-30mLs of first-catch patient urine in a collection cup immediately following the DRE.
3. Immediately pipette patient urine to the fill area window of each specimen tube.
4. Replace tube lid and invert 5 times. Do not shake or vortex.

Storage/Transport Temperature**:**

1. Unprocessed urine specimens, if not immediately processed, must be maintained at 2°C to 8°C or kept on ice. The chilled, unprocessed urine specimen must be transferred into the urine specimen transport tube within 4 hours of collection. Otherwise, the specimen must be rejected and the urologist must collect a new specimen. Do not freeze unprocessed urine specimens.
2. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory immediately on wet ice. A special courier pickup can be arranged.

MICROBIOLOGY

Select specimens for microbiology will be received and accessioned by Strata Pathology Services and forwarded to Microbiology Dx for testing. Dr. Joseph D. Musto is President of Microbiology DX

Microbiology Dx
19A Crosby Drive, Suite 215
Bedford, MA 01730
Phone: 781-276-4956 Fax: 781-275-6236

Microbiology Dx is licensed by the Federal Government [CLIA# 22D2089996].
For more information about Dr. Joseph D. Musto, Microbiology Dx, and the scope of services offered by, please call 781-276-4956 to speak with a Client Service Representative please visit their website: www.microbiologydx.com.

Microbiology supplies can be ordered from Strata Pathology Services by contacting a Client Service Representative at 800-325-7284.

PATIENT PREPARATION

Patient preparation for all microbiology specimens is according standard to the instructions specified by the patient's physician, unless otherwise specified in the procedure for each specimen type.

SPECIMEN LABELING, HANDLING AND TRANSPORTATION

1. Identify specimen by clearly labeling the specimen vial with patient's first and last name and a unique second identifier. SEE SPECIMEN LABELING SECTION. A printed label with the required 2 forms of patient identification can be affixed to the vial.
2. Complete requisition according to requirements. SEE COMPLETING A REQUISITION. Additionally,

please indicate all special tests requested.
3. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.
4. Please see additional specimen-specific handling and transportation requirements below.

Universal Precautions Required

MICROBIOLOGY COLLECTION DEVICES AND SPECIMEN REQUIREMENTS:

Universal Precautions Required

ANAEROBIC CULTURES

Specimen Requirements: Blood, tissue, bone marrow, biopsy material, body fluids other than urine, exudates, pus, from wounds and deep lesions, transtracheal aspirates, suprapubic aspirate of bladder urine.

Procedure: Submit in ANAEROBIC Culturette ONLY!

DO NOT REFRIGERATE. ROOM TEMPERATURE.

Unacceptable sites: Those containing normal anaerobic flora or likely to be contaminated with such flora, sputum, bronchial washings, nasotracheal or tracheal aspirate, feces, gastric contents, vaginal and cervical swabs, superficial wounds, voided or catheterized urine.

Specimens unlikely to contain anaerobes include: Corneal scrapings, Cerebrospinal fluid

BODY FLUIDS

Specimen Requirements: CSF or aspirates (most body fluids are sterile).

Procedure: Submit in sterile, screw top container or plain RED top Vacutainer.
Also see NON-GYNECOLOGICAL CYTOLOGY SPECIMENS: COLLECTION, HANDLING, FIXATION AND TRANSPORTATION FOR MICROBIOLOGIC TESTING.

ROOM TEMPERATURE

BORDETELLA PERTUSSIS

Specimen Requirements: Nasopharyngeal (not throat) swab.

Procedure: Submit in SPECIAL TRANSPORT MEDIA. Contact laboratory for appropriate media.

ROOM TEMPERATURE.

CERVICAL CULTURE

Specimen Requirements: Cervix or endocervix

COLLECTION, FIXATION, TRANSPORTATION Procedure:
l. Visualize cervix using speculum without lubricant.
2. Wipe cervix clean of vaginal secretions.
3. Gently compress the blades on the speculum and use a rotating motion with the swab(s)* to obtain exudate.
*If smear is requested, submit an additional inoculated culturette, if possible.
4. Transport in culturette with ampule broken.
5. Also see GYNECOLOGICAL CYTOLOGY SPECIMENS.

ROOM TEMPERATURE

Interpretation of Reported Results:

NORMAL FLORA - Sensitivities not performed:

Anaerobic gram positive cocci
Diphtheroids Lactobacillus
Staphylococcus epidermidis
Small concentrations of:
Enterococcus (Group D Strep)
Escherichia coil
Gardnerella vaginalis
Gram negative fecal organisms
Yeast

PATHOGENS

Candida albicans - detected by wet prep, KOH prep, gram stain or culture
Neisseria gonorrhea - Beta lactamase tested only
Trichomonas vaginalis - detected by wet prep only

Overgrowth of the following organisms will be reported:

Gardnerella vaginalis - sensitivities not performed
Listeria monocytogenes - sensitivities not performed
Staphylococcus aureus - sensitivities performed upon request
Streptococcus agalactiae (Group B) - sensitivities not performed

CERVICAL CULTURE (GROUP B STREP ONLY)

Specimen Requirements: Cervix or endocervix

Procedure: Submit in culturette with broken ampule
Also see GYNECOLOGICAL CYTOLOGY SPECIMENS.

NOTE: Routine genital cultures always include a screen for Group B Strep.

ROOM TEMPERATURE

CHLAMYDIA CULTURE or CHLAMYDIA DNA PROBE

SEE HPV HIGH RISK & HPV 16/18 GENOTYPING & GONORRHEA/CHALAMYDIA

CMV CULTURE (Cytomegalovirus)

Specimen Requirements: Blood (5 ml heparinized blood), lung biopsy, liver biopsy, throat, urine

Procedure: Submit biopsies in sterile, screw top container.

REFRIGERATE

CORNEBACTERIUM DIP THERIA

Specimen Requirements: Throat or nasopharynx

Procedure: Submit on transport swab with charcoal media.

EAR CULTURE

Specimen Requirements: Ear exudate

Procedure: Submit 1 culturette with ampule broken

ROOM TEMPERATURE

NOTE: SPECIMEN SOURCE ON REQUISITION

Interpretation of Reported Results:

NORMAL FLORA of external ear - sensitivities not performed

Staphylococci epidermis
Diphtheroids
Bacillus Sp.
Saprophytic fungus

PATHOGENS:

Enterobacteriaceae - sensitivities performed
Haemophilus influenzae - beta lactamase reported, sensitivities performed on request
Moraxella catarrhalis - beta lactamase replied, sensitivities not performed
Pseudomonas aeruginosa - sensitivities performed
Staphylococcus aureus - sensitivities performed
Streptococcus pneumoniae - sensitivities not performed
Streptococcus pyogenes (Group A) - sensitivities not performed

EYE CULTURE

Specimen Requirements: Eye exudate

Procedure: Submit 1 culturette with ampule broken. It is recommended to culture both eyes when questioning infection.

ROOM TEMPERATURE

NOTE: SPECIMEN SOURCE ON REQUISITION

Interpretation of Reported Results:

NORMAL FLORA - sensitivities not performed

Staphylococcus epidermidis
Diphtheroids
Veri dans streptococcus

PATHOGENS:

Haemophilus influenzae - Beta lactamase reported.
Pseudomonas aeruginosa - sensitivities performed
Staphylococcus aureus - sensitivities performed
Streptococcus pneumoniae - sensitivities not performed
Streptococcus pyogenes (Group A) - sensitivities not performed
Other gram negative rods - sensitivities performed

FUNGUS

Specimen Requirements: Tissue, biopsies, skin scrapings, sputum, exudates, body fluids except urine. SWABS NOT ACCEPTED.

Procedure: Submit in sterile, screw top container. Acceptable collection includes cleansing periphery of lesion with antiseptic and running 5 -10 cc sterile saline over region. Submit saline washing.

SWAB EXCEPTION: When disseminated candidiasis is suspected, submit urine (10cc), rectal swab and nasopharyngeal (use culturette and break ampule). All three specimens must be submitted for proper analysis.

ROOM TEMPERATURE

NOTE: SPECIMEN SOURCE ON REQUISITION

G.C. SCREEN CULTURE or G.C. DNA PROBE

See HPV HIGH RISK & HPV 16/18 GENOTYPING & GONORRHEA/CHLAMYDIA

GENITAL

See CERVICAL VAGINAL OR URETHRAL

GENITAL STREP SCREEN (Group B Strep Only)

Specimen Requirements: Cervix or endocervix

Procedure: Submit in culturette with ampule broken

NOTE: Routine genital cultures always include a screen for Group B Strep

ROOM TEMPERATURE

HERPES CULTURE

Specimen Requirements: CSF, body fluids, biopsy specimens

Procedure:
1. Collect specimen from a fresh non-crusted vesicle.
2. Use Viral transport media for transport.
3. Insert swab into transport media and break swab below vial lip.
4. Also see NON-GYNECOLOGICAL CYTOLOGY SPECIMENS: COLLECTION, HANDLING, FIXATION AND TRANSPORTATION FOR MICROBIOLOGIC TESTING.

REFRIGERATE

HUMAN PAPILLOMAVIRUS SCREEN (HPV SCREEN)

See HPV HIGH RISK & HPV 16/18 GENOTYPING & GONORRHEA/CHLAMYDIA

LEGIONELLA CULTURE

Specimen Requirements: Pleural fluid, bronchial washings, sputum

Procedure: Submit in sterile screw top container.
Also see NON-GYNECOLOGICAL CYTOLOGY SPECIMENS: COLLECTION, HANDLING, FIXATION AND TRANSPORTATION FOR MICROBIOLOGIC TESTING.

REFRIGERATE

MYCOPLASMA PNEUMONIA

Specimen Requirements: Pleural fluid, bronchial washings, sputum or lung tissue.

Procedure: Available by special arrangement. Call Laboratory.

MYCOPLASMAIUREAPLASMA UREALYTICUM

Specimen Requirements: Urethral, endocervix or urine

Procedure:

1. Thaw vial of transport media.
2. Obtain epithelial cells from infected site (e.g. insert and rotate a culturette 2-3 cm into urethra (male) or endocervix (female).
3. Extract swab in warmed media.
4. Discard swab.
5. Tightly cap vial.

ROOM TEMPERATURE

NASOPHARYNGEAL/NOSE CULTURE

Specimen Requirements: Nasopharynx, nostril

Procedure: Use culturette swab with ampule broken.

ROOM TEMPERATURE

Interpretation of Reported Results:

NORMAL FLORA - Sensitivities not performed

- Alpha hemolytic streptococcus
- Diphtheroids
- Gram negative rods (in small numbers)
- Haemophilus sp. (in small numbers)
- Nonpathogenic Neisseria sp.
- Staphylococcus epidermidis
- Streptococcus pneumoniae (in small numbers)

PATHOGENS:

- Candida albicans - sensitivities not performed
- Haemophilus influenzae - Beta lactamase only
- Neisseria meningitidis - cultured only by special request
- Pasteurella sp. - sensitivities not performed
- Staphylococcus aureus - sensitivities performed
- Streptococcus pneumoniae -sensitivities not performed
- Streptococcus pyogenes - sensitivities not performed

PARAINFLUENZA

SEE VIRAL CULTURE

RSV CULTURE (Respiratory Syncytial Virus)

Specimen Requirements: Nasal washing only

Procedure: Using a respiratory suction device or plastic disposable infant feeding tube attached to a small sterile syringe, aspirate specimen from nose or nasopharynx. A saline washing of approximately 3 ml is recommended. Submit aspirate in original collection device or in sterile, screw top container.

REFRIGERATE TE up to 24 hours. FREEZE if longer.

SPUTUM CULTURE

Specimen Requirements: 5-10 ml "TRUE" sputum (a.m. specimen collected before brushing teeth.) Saliva not acceptable.

Procedure: Submit in sterile, screw top container.
Also see NON-GYNECOLOGICAL CYTOLOGY SPECIMENS: COLLECTION, HANDLING, FIXATION AND TRANSPORTATION FOR MICROBIOLOGIC TESTING.

REFRIGERATE

Interpretation of Reported Results:
Gram stains are routinely performed on all sputum.

PATHOGENS:

Candida - sensitivities not performed
Gram negative rods - sensitivities performed
Haemophilus influenzae - sensitivities not performed
Beta-Lactamase only
Staphylococcus aureus - sensitivities performed
Streptococcus pneumoniae -sensitivities not performed

STREP SCREEN (Group A Strep)

Specimen Requirements: Throat or nasopharynx (Detects beta-hemolytic Group A strep only)

Procedure: Submit in culturette with ampule broken.

NOTE: Routine throat culture always includes a screen for Group A Strep.

ROOM TEMPERATURE

THROAT CULTURE

Specimen Requirements: Throat swab

Procedure: Submit in culturette with ampule broken.

ROOM TEMPERATURE

Interpretation of Reported Results:

NORMAL FLORA - Sensitivities not performed

Alpha hemolytic streptococcus
Nonpathogenic Neisseria sp.
Diphtheroids
Gram negative rods (in small numbers)
Haemophilus sp (in small numbers)
Staphylococcus epidermidis
Streptococcus pneumoniae (in small numbers)

PATHOGENS:

Group A beta hemolytic streptococcus - sensitivities not performed
Group C and Group G (infrequently) – sensitivities not performed
Neisseria gonorrhea by special request

TRICHOMONAS V VAGINALIS

See WET PREP

UREAPLASMA UREALYTICUM (Includes Mycoplasma)

See MYCOPLASMAJUREAPLASMA UREAL YTICUM

URETHRAL CULTURE

Specimen Requirements: Urethral

Procedure:

1. Wipe exudates form urethral orifice.
2. Collect discharge with swab(s). If discharge cannot be obtained, pass a swab at least 2 cm into urethra.
3. Transport in culturette with ampule broken. If smear is requested, submit a well labeled smear or an additional inoculated culturette.

ROOM TEMPERATURE

NOTE: SPECIMEN SOURCE ON REQUISITION

Interpretation of Reported Results:

NORMAL FLORA- MALE - Sensitivities not performed

Staphylococcus epidermidis
Diphtheroids

PATHOGENS - MALE

Neisseria gonorrhea - Beta lactamase tested only
Trichomonas vaginalis - detected by wet prep only.

Overgrowth of the following organisms will be reported:

Gardnerella vaginalis - sensitivities not performed.
Staphylococcus aureus - sensitivities performed
Streptococcus agalactiae (Group B) - sensitivities not performed.

URINE CULTURE

Specimen Requirements: 2 ml urine for culture only.
15 ml for complete urinalysis and urine culture.

Procedure:

1. Cleanse external genitals.
2. Collect specimen using midstream protocol.
3. Submit in sterile, screw top container. If catheter specimen obtained, note on requisition.
4. Also see NON-GYNECOLOGICAL CYTOLOGY SPECIMENS: COLLECTION, HANDLING, FIXATION AND TRANSPORTATION FOR MICROBIOLOGIC TESTING.

REFRIGERATE

Interpretation of Reported Results:

Urine is NORMALLY STERILE. Any organism in pure culture can be a potential pathogen especially in urine containing significant white blood cells and rare epithelial cells.
Mixed flora consists of 3 or more organisms.
Organism Identification and sensitivities will be performed only upon request.

VAGINAL CULTURE

Specimen Requirements: Vaginal

Procedure:

1. Wipe away any excess secretions.
2. Swab mucosa high in vaginal canal with swab(s).

3. Transport in culturette with ampule broken. If smear is requested, submit a well labeled smear or an additional inoculated culturette.
4. Also see GYNECOLOGICAL CYTOLOGY SPECIMENS.

ROOM TEMPERATURE

Interpretation of Reported Results:

NORMAL FLORA - FEMALE - Sensitivities not performed:

Anaerobic gram positive cocci Diphtheroids
Lactobacillus
Staphylococcus epidermidis
Small concentrations of:
Enterococcus (Group D Strep)
Escherichia coli
Gardnerella vaginalis
Gram negative fecal organisms
Yeast

PATHOGENS - FEMALE

Candida albicans - detected by wet prep, KOH prep, gram stain or culture
Neisseria gonorrhea - Beta lactamase tested only
Trichomonas vaginalis - detected by wet prep only

Overgrowth of the following organisms will be reported:

Gardnerella vaginalis - sensitivities not performed
Gram negative fecal organisms - sensitivities will be performed upon request
Listeria monocytogenes - sensitivities not performed
Staphylococcus aureus - sensitivities performed upon request
Streptococcus agalactiae (Group B) - sensitivities not performed

VIRAL CULTURE

Specimen Requirements: Blood, sputum, urine, cerebrospinal fluid

Procedure:

BLOOD: Collect 5 ml heparinized blood
SPUTUM: Submit in sterile, screw top container
BIOPSY SPECIMENS: Submit in sterile, screw top container
SWAB SPECIMENS: Use viral culturette
URINE: 2 m1 in sterile, screw top container
CSF: 2 m1 in sterile, screw top container
Also see NON-GYNECOLOGICAL CYTOLOGY SPECIMENS: COLLECTION, HANDLING, FIXATION AND TRANSPORTATION FOR MICROBIOLOGIC TESTING.

REFRIGERATE ALL SPECIMENS

NOTE: SPECIMEN SOURCE ON REQUISITION

WET PREP (Trichomonas and Candida)

Specimen Requirements: Vaginal or urethral

Procedure: Vaginal or urethral swab submitted in sterile saline Submit inoculated saline within 12 hours of collection.

ROOM TEMPERATURE

WOUND CULTURE

Specimen Requirements: Wound exudate

Procedure: Submit 2 culturettes with ampules broken.

NOTE: SPECIFY SITE ON REQUISITION AND SAMPLE

Interpretation of Reported Results:

Superficial wounds cultured by swab method may yield skin flora, such as corynebacteria (diphtheroids) and Staphylococcus epidermidis. These are not considered significant.

ROOM TEMPERATURE

TICK IDENTIFICATION AND TESTING

Tick Identification and testing services for the detection of B. burgdorferi (Lyme disease spirochete) and B. microti (Babesia parasite) by polymerase chain reaction (PCR) is performed by IMUGEN. This testing is performed on Ixodes scapularis ticks only.

IMUGEN
315 Norwood Park South
Norwood, MA 0206
CLIA# 22D0650196

If you have any questions about tick testing services or would like additional information about IMUGEN, please contact an IMUGEN Customer Service Representative at 800-246-8436 or visit their website: www.imugen.com/tick_testing.html.

Supplies for transporting ticks can be ordered from Strata Pathology Services by contacting a Client Service Representative at 800-325-7284.

TEST AVAILABILITY	Runs are once per week.
TIMELY RESULTS	Up to 15 days from receipt
STATS	Not available
TESTS INCLUDED	Identification, Assessment for Lyme Disease, Babesiosis and Anaplasmosis

Universal Precautions Required

SPECIMEN COLLECTION, LABELING, HANDLING, ORDERING, FIXATION AND TRANSPORTATION

1. Properly remove embedded ticks as soon as possible.

How to Remove a Tick:

1. The Centers for Disease Control and Prevention (CDC) suggests that you grab the tick with fine-tipped tweezers as close to the skin as possible.
2. Slowly, gently and firmly, pull STRAIGHT up until all parts of the tick are removed. Do NOT twist or rock the tick while removing it.
3. After removing the tick, swab the bite site with alcohol.

2. Place tick in a Ziplock bag or crushproof container. Do not submit the tick on tape.

PLEASE NOTE: TICKS SHOULD BE SUBMITTED DRY - DO NOT SUBMIT THE TICK IN FORMALIN.

3. Identify specimen by clearly labeling the specimen vial with patient's first and last name and a unique second identifier. SEE SPECIMEN LABELING SECTION. A printed label with the required 2 forms of patient identification can be affixed to the vial.
4. Complete requisition according to requirements. See completing a requisition. Additionally, please indicate if the specimen is for Identification (ID) Only or for Polymerase Chain Reaction (PCR) Testing.
5. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.

PLEASE NOTE: The Massachusetts Department of Public Health offers the following advice with regard to tick test results:

Tests performed on the ticks are not perfect and they do not test for all infections ticks may be carrying. Therefore, even with a negative result, people should still monitor themselves for the appearance of rash, fever or other unusual symptoms and immediately seek the advice of a health care provider should any symptoms occur.

If someone has been infected by a tick bite, symptoms may begin to occur even before the results of tick testing are available. People should not to wait for tick testing results before seeking additional medical advice should any symptoms develop.

A positive test on a tick is not an automatic indication that treatment is needed. A positive test indicates that the tick was infected but not that the tick was successful in spreading the infection to the person bitten. The longer a tick is attached, the greater the chance that it will spread infection.

We are so pleased you chose StrataDx!
We thank you, look forward to working with you, and truly appreciate your business.

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