



SERVICE MANUAL

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

StrataDx One Cranberry Hill, Suite 303, Lexington, MA 02421
Phone: 800-325-PATH (7284) Fax: 617-401-4032



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LEXINGTON LABORATORY
ONE CRANBERRY HILL, SUITES 104 & 303
LEXINGTON, MA 02421
CAP# 7193854
CLIA# 22D1043442

CONTACT US

ACCOUNT MANAGEMENT SERVICES:

Monday through Friday, 8:00 AM – 6:00 PM EST
Phone: 800-325-PATH (7284)
Phone: 617-401-4027
Fax: 617-401-4032

COURIER SERVICES:

Phone: 781-541-7054
EMAIL: CourierEmails@stratadx.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 Account Management Services at 800-325-7284 if you have questions or to request a hardcopy version of a SDS.



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SCOPE OF SERVICES

Diagnostic Services and Consultation:

- Surgical Pathology
- Dermatopathology
- Podiatric Pathology
- Oral Pathology
- Urologic Pathology
- Microbiology - cultures
- Immunohistochemistry

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 an Account Management Specialist at 800-325-7284 with questions, for additional information, or to place a supply request.

COMPLETING TEST REQUISITION FORMS - DERMATOLOGY, PODIATRY & ORAL PATHOLOGY

The information required is essential to insure 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 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. *Submitting Clinician's name and address* boxes checked off or written in.
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*. An attached copy of insurance card is preferred.
8. *Procedure Type* please ensure you check a box.
9. *Biopsy Site* please make sure site on req. matches site on bottle.
10. *Clinical Impression* to include any pertinent medical history, previous pathology or clinical information when appropriate. Necessary for billing purposes.
11. *Physician Signature*. PLEASE MAKE SURE YOU SIGN YOUR REQUISITION – THIS IS YOUR TEST ORDER.
12. Pre-labeled stickers filled out with *Patient Name, DOB* and *Site*. Stickers should be adhered to corresponding specimen container/bottle. NOTE THAT THE STICKERS ARE PRELABELED WITH A, B, C, etc.
13. If applicable, CC physician first name, last name and fax number.
 - a. **Please Note: If full physician name and fax number are not provided, we will not be able to send an additional copy to the requested provider.**

SPECIMEN LABELING

Accurately labeling patient specimens promotes patient care and eliminates 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. An Account Management Specialist 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 (FedEx, UPS & Courier)

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, the bottle lids or specimen bags are securely fastened 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 the necessary shipping information.
5. Call FedEx at 1-800-463-3339 (1-800-GoFedEx) for a pickup. You can set specific day or daily pickup schedules with FedEx at a time that is convenient for your office to eliminate having to call each time you need a pickup.

**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 that are designed to meet your practice and patient needs. In other locales, we contract with local services 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 the automated Courier Services line at 781-541-7054. Messages from this line are received, tracked and responded to in real time.

If STAT* service is requested, please state that in your message and your request will be expedited accordingly.

*STAT service is only available in areas local to StrataDx.

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 REQUIREMENT 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 should be refrigerated.

A. Gross and Microscopic Examination – Routine Dermatology, Podiatry (**non-culture specimens**), Oral, Urology (including urine), Gynecological tissue (biopsies only), ENT tissue.

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 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. Place the completed requisition in the outer pocket and submit to the laboratory.

B. Nail specimens for culture (speciation) - Podiatry & Dermatology

Biopsy: Nail, nail fragments

- Tissue must be submitted dry in provided nail bag or sterile, empty, not previously used container.

C. Gout (Tissue Biopsy ONLY)

***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.
- Or Fresh in a sterile, not-previously used container.

D. 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. 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 if the specimen will 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.

NON-GYNECOLOGICAL CYTOLOGY

A. 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 the cup and place it on the counter.
6. Have the patient cleanse themselves with the enclosed towelette and collect urine specimen.
7. If requesting culture and sensitivity in conjunction with any other tests, please provide two specimens (cups) of urine.

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.

MICROBIOLOGY

Select specimens for microbiology will be received and accessioned by Strata Pathology Services and forwarded to Winchester Hospital or Quest Diagnostics for testing.

Winchester Hospital
264 West Cummings Park
Woburn, MA 01801
Phone: 781-756-2329 Fax: 781-756-7659

Winchester Hospital licensed by the Federal Government [CLIA# 22D1057427].
Medical Director: Mark Zuckerman, MD.

Quest Diagnostics
200 Forest Street
3rd Floor
Marlborough, MA 01752
Phone: 774-369-3900

Quest Diagnostics licensed by the Federal Government [CLIA# 22D0076229].
Medical Director: Salim E. Kabawat, MD

Microbiology supplies can be ordered from Strata Pathology Services by contacting your Account Management Specialist at 800-325-7284.

PATIENT PREPARATION

Patient preparation for all microbiology specimens is according 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, seal the bag, place the completed requisition in the outer pouch on the bag 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:

CULTURES – Viral, Bacterial/Wound, Fungal

VIRAL CULTURE (Results Reported 3-14 days, with full viral panels taking up to 30 days):

Patient Preparation:

Collect: Eye swab, lesion, tissue, or urine.

Specimen Preparation:

Fluid: Transfer 3 mL specimen to a sterile container. (Min: 0.5 mL) Also acceptable: Transfer to 3 mL viral transport media

Swab or Tissue: Place in 3 mL viral transport media

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Calcium alginate, **eSwab**, dry, or wood swabs.

Stability: Ambient: 2 hours; Refrigerated: 72 hours; Frozen: Unacceptable

BACTERIAL/WOUND CULTURE (Results Reported within 3 days, final negative at 3 days):**Patient Preparation**

Collect: Bacti-Swab.

Specimen Preparation: Swab: Place in Bacti-Swab transport media

Storage/Transport Temperature: Room temperature.

Unacceptable Conditions: Syringes with needle attached. Dry swabs.

Remarks: Refrigerated specimens are not recommended for recovery of some fastidious organisms such as *Neisseriaspp*.

Stability: Sterile Container: Ambient: 24 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Eswab: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

FUNGAL CULTURE (Results Reported as soon as positive finding occurs, final negative within 30 days):**Patient Preparation**

Collect: Material from any bodily site – no fluids

Specimen Preparation: Material: Transfer to sterile container. A single specimen may be cultured for both bacteria and fungi. Place each specimen in an individually sealed bag or sterile container.

Storage/Transport Temperature: Cutaneous specimens (skin, hair, nails): Room temperature

Unacceptable Conditions:

Remarks: Additional information required: Specimen source. Notify laboratory if *Malassezia furfur* is suspected, special media must be used for the cultivation of this yeast.

Stability: Hair or Skin or Nail Scrapings: Ambient: 2 weeks; Refrigerated: Unacceptable Frozen: Unacceptable

URINE CULTURE**Patient Preparation**

Collect: Midstream urine. 2 ml urine for culture only, 15 ml for complete urinalysis and urine culture

Specimen Preparation: Transfer urine to a sterile container or boric acid transport tube. (Min: 1 mL).

Storage/Transport Temperature: Unpreserved: Refrigerated.

Unacceptable Conditions: Urine from catheter bag. Multiple (more than one in 24 hours), 24-hour, or pooled specimens. Foley catheter tips (syringe with needle attached). Delayed transport of unpreserved urine (greater than two hours at room temperature or greater than 24 hours refrigerated).

Remarks: Specimen source required.

Stability: Unpreserved: Ambient: 2 hours; Refrigerated: 24 hours; Frozen: Unacceptable.

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 (there is an underscore _ between tick and testing).

Supplies for transporting ticks can be ordered from Strata Pathology Services by contacting a Account Management Specialist 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 regarding 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 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.*

StrataDX | Strata Pathology Services, Inc.
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