

A Note from our Medical Director

HealthTronics Laboratory Solutions is a specialty laboratory offering comprehensive Anatomic Pathology testing. We strive to maintain excellence in laboratory services and to provide you with the best professional assistance in the field of Laboratory Medicine.

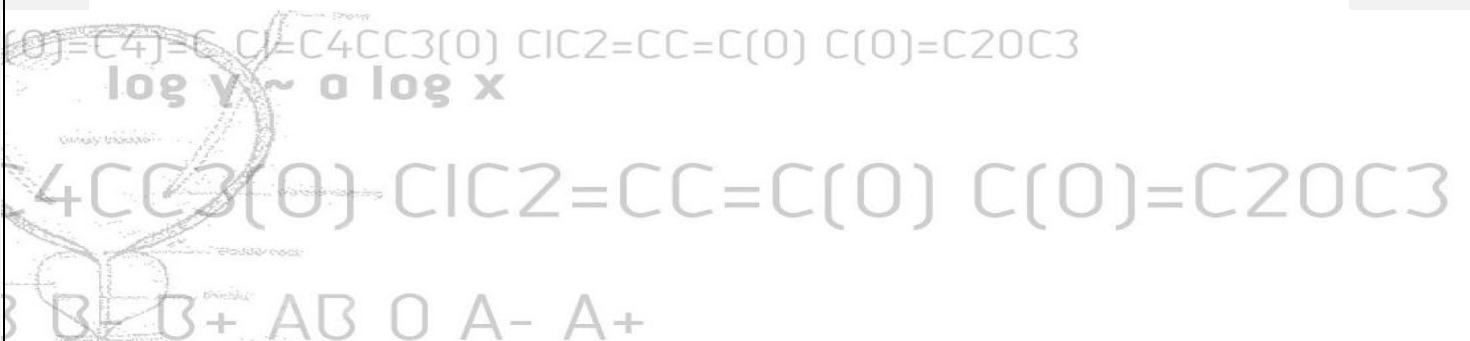
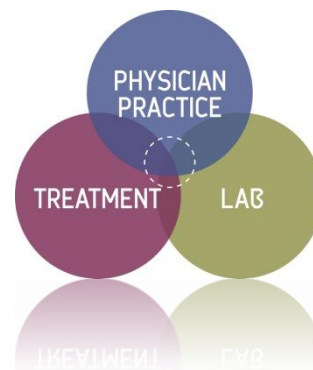
Our laboratory employs highly trained professionals, Technologists and Support Staff. State-of-the-art instrumentation, techniques, and data processing advancements enable us to deliver sophisticated laboratory services backed by extensive quality assurance programs.

This Laboratory Service Manual represents the efforts of Pathologists, Managers, Supervisors, Technologists, and Support Staff to develop a comprehensive and practical guide to our laboratory services. We trust that our services will exceed your expectations and truly enhance the care you provide to your patients.

Respectfully yours,



*Jeremy S. Miller, MD
Pathologist and Medical Director*





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ACCREDITATIONS OF HEALTHTRONICS LABORATORY SOLUTIONS

HealthTronics Laboratory Solutions is acknowledged as a high quality laboratory and is accredited as follows:

- CLIA
- Centers for Medicare and Medicaid Services (CMS)
- Georgia Department of Human Resources
- College of American Pathologists (CAP)
- New York State

BILLING INFORMATION

OUR commitment is to maintain customer satisfaction. We look forward to helping you with your billing questions.

For any questions regarding billing, please call **877.743.3338 option 2**

CLIENT CONSULTATION SERVICES

Our Pathologists are available for medical and technical consultation on laboratory test results and/or clinical conditions. Our supervisors and technical staff are also available whenever needed to resolve problems or answer questions, either by telephone or personal visit.

CLIENT SERVICES

Our commitment is to maintain open communication with our customers, patients and co-workers to better understand their needs and concerns with emphasis on building trust in order to maintain a long-term relationship.

Questions or Problem Resolution: 877.743.3338 (toll free)

Faxing Orders: 706.434.2639

REPEAT TESTING

Repeat determinations will be performed at no charge if, in the opinion of the referring physician, a distinct variance exists between the clinical picture and the laboratory result.

SUPPLY REQUESTS

HealthTronics Laboratory Solutions provides all requisition and supplies necessary for the collection and transport of patient samples. All supplies necessary are available in our specimen collection kits. Please contact Client Services if there are any problems with the collection kits

COMPLETING THE REQUISITION

For your convenience, HealthTronics Laboratory Solutions provides a Cytology / Pathology requisition in each specimen collection kit. The forms are pre-accessioned with a unique number matching the enclosed pre-accessioned specimen collection vials or cassettes also found in the kit. If these numbers do not match **DO NOT USE THE KIT** and notify Client Services immediately

1. Clearly print the patient's name, address, sex, date of birth and social security number in the provided spaces on the requisition.
2. Circle the physician name if pre-printed or print the physician name in the space provided.
3. Add the collection date and time.
4. Write the applicable ICD-9 code in the space provided.
5. Check the proper method of billing (Bill Patient, Bill Insurance, Bill Client).
6. Write in the primary and secondary insurance provider and authorization # if applicable or make a copy of the patient's insurance card to submit with the requisition.
7. Select all tests to be performed as well as all applicable clinical information.

SPECIMEN INTEGRITY CRITERIA

As part of our active quality assurance program and as part of requirements of various certifying agencies, we have developed the following list of specimen integrity criteria. These criteria were developed with the intention of ensuring accurate patient results.

- 1) Unsatisfactory Information
 - ❖ Specimens submitted for testing from outreach clients are identified by a unique accession number and matching barcode. The requisition should include a matching unique accession number and should also include the patient name birth date, sex, date and time of collection, specimen type, specimen source and name of requesting physician. The patient name must also be placed on the specimen transport containers.
 - ❖ Discrepancies must be resolved before processing.
- 2) Inadequate Specimen Due to Collection and Transportation Problems
 - ❖ Specimen collected in improper container or transport medium.
- 3) Inadequate Specimen Volume
 - ❖ All specimens are examined upon receipt by the laboratory to ensure suitability for analysis. If the specimen volume is insufficient or if the specimen has been improperly handled, the reliability of test results could be compromised and the specimen will not be processed. The client will be contacted.

Laboratory test results are dependent on the quality of the specimen submitted. If there is any doubt or question regarding the type of specimen that should be collected, please do not hesitate to contact our Client Services at 877.743.3338 (opt 2) to clarify the order and sample requirements.

CYTOPATHOLOGY AND FLUORESCENT IN-SITU HYBRIDIZATION (FISH) SPECIMEN COLLECTION AND TRANSPORT

GENERAL INSTRUCTIONS FOR FLUID COLLECTION

Fluids are commonly evaluated using cytology and fluorescent in-situ hybridization (FISH) for the detection of urologic malignancies. Urine may be evaluated both cytologically and by fluorescent in-situ hybridization (FISH) techniques for the detection and characterization of some renal diseases. Method of specimen collection as well as time of collection will affect the evaluation in many instances. Possible sources include *Voided Urine, Bladder Washings, Urethral Washings, Ureteral Washings, Renal Pelvis Washings*

VOIDED / CATHETERIZED URINE

Indications

Detection and characterization of malignant cells and other urologic abnormalities in symptomatic (usually hematuria) patients; screening for malignancy in selected individuals at high risk for the development of urologic malignancy; detection and characterization of some non-neoplastic renal diseases in symptomatic (usually hematuria) patients.

Specimen Required

30 mL – 60 mL of an appropriately collected voided or catheterized urine specimen

Supplies

- ✓ Clean collection container of appropriate size.
- ✓ Standard catheterization equipment (for catheterized urine)
- ✓ Pre-filled vial containing CytoLyt® fixative
- ✓ Urine Cytology/UroVysion™Kit
- ✓ HealthTronics Laboratory Solutions Requisition

Collection Procedure

For purposes of obtaining the greatest yield of diagnostic material, a morning voided urine specimen should be obtained, if possible. A midstream, clean-catch specimen is recommended to avoid vaginal contamination in female patients. A midstream specimen, not necessarily clean catch, is recommended for male patients. If the patient must be catheterized to obtain the specimen, this should be noted on the test request form as catheterization can lead to artifacts which may be misinterpreted without the knowledge that the specimen was catheterized. The pre-filled vial containing the CytoLyt® fixative is pre-accessioned with a unique accession number and matching barcode that link it with the matching label on the patient's requisition. The empty container (beaker) should be labeled with a unique patient identifier. Add 30 mL – 60 mL of urine sample to the vial containing the CytoLyt® fixative and tightly seal the container. Submit the specimen via the Kit along with the completed Claripath Requisition (See “Specimen Handling Instructions”).

OTHER UROLOGIC SPECIMENS

Indications

Detection of suspected malignancy utilizing lavage and brushing specimens obtained cystoscopically (bladder washing, renal pelvis washing/brushing, ureteral washing/brushing or urethral washing); staging of urologic malignancies.

Specimen Required

30 mL – 60 mL of an appropriately-collected, cystoscopically-derived specimen

Supplies

- ✓ Standard cystoscopy equipment
- ✓ Clean collection container of appropriate size
- ✓ Pre-filled vial containing CytoLyt® fixative
- ✓ Urine Cytology/ UroVysion™ Kit
- ✓ HealthTronics Laboratory Solutions Requisition

Collection Procedure (Washing)

Using standard cystoscopy technique, obtain washing specimens, carefully denoting specific specimen sites for each specimen on the test request form. Please label the pre-filled vial containing the CytoLyt® fixative with the patient's name. Add 30 mL – 60 mL of the specimen to the vial containing the CytoLyt® fixative and tightly seal the container. Submit the specimen via the Kit along with the completed HealthTronics Laboratory Solutions Requisition (See "Specimen Handling Instructions").

Collection Procedure (Brushing)

Using standard cystoscopy technique, identify the lesion in question and obtain a brushing sample of the lesion.

Note: It is important to brush the edges of an ulcer, as well as the floor, in order to obtain diagnostic material. Upon withdrawing the brush, agitate the brush vigorously in the vial of CytoLyt® fixative. **DO NOT APPLY THE BRUSH DIRECTLY TO SLIDES.** If possible, detach the brush and leave it in the vial (brush may be cut using sturdy scissors). There is no need to label the pre-filled vial containing the CytoLyt® fixative with the patient's name or date of birth because the pre-filled vial containing the CytoLyt® fixative is pre-accessioned with a unique accession number and matching barcode that links it to the corresponding label on the requisition. Submit the specimen via the Kit along with the completed HealthTronics Laboratory Solutions Requisition.

LABELING SPECIMENS

Specimen containers and requisitions are pre-labeled with a unique accession number and matching barcode that links the specimen with the corresponding label on the patient requisition. Please label the specimen vial with the patient name as needed.

SPECIMEN HANDLING INSTRUCTIONS

When utilizing the HealthTronics Laboratory Solutions Urine Cytology / UroVysion™ Collection Kit:

- 1) Collect the urine sample in the container that has a pour spout and no lid.
- 2) After collection of the specimen, pour the sample to the top line in the container with pre-filled fixative.
- 3) **Tightly seal** the container and place back in the kit.
- 4) Close the kit and place it in a provided biohazard bag and seal it.
- 5) Complete the patient requisition provided with the kit (this requisition has the accession number and bar code matching the accession number and barcode on the specimen container) with the appropriate information (see "Completing the Requisition").
- 6) Place the biohazard bag containing the specimen back in the kit along with the requisition.
- 7) Close the kit and place the provided seal over the tab.
- 8) The sealed biohazard bag containing the kit and the requisition should be placed in the provided pre-addressed lab pak (more than one kit may be mailed in the lab pak) and sealed.
- 9) The package is now ready for delivery by FedEx or UPS.



HISTOPATHOLOGY SPECIMEN COLLECTION AND TRANSPORT

INTRODUCTION

A full spectrum of surgical pathology and consultative services are available through HealthTronics Laboratory Solutions. All pathologists affiliated with HealthTronics Laboratory Solutions are board certified by the American Board of Pathology. All requests for histopathologic examination and diagnosis are viewed as a request for consultation by another physician and, as such, you are welcome to contact our pathologists concerning their findings.

LABELING

Specimen containers and requisitions are pre-labeled with a unique accession number, matching barcode and specific site location. Please label the specimen transport containers with the patient name.

SPECIMEN SUBMISSION REQUIREMENTS

All tissue biopsy specimens should be placed in a tightly secured container with 10% neutral buffered formalin. Do not allow the specimen to dry out. All specimens must be accompanied by an appropriate Pathology requisition. Biopsies from different sites should be separately identified.

SPECIMEN HANDLING INSTRUCTIONS

When utilizing the HealthTronics Laboratory Solutions Traditional Prostate Collection Kit containing multiple formalin-filled specimen containers:

- 1) Do not crush the specimen with forceps, hemostats, or other instruments during collection. Avoid using cautery.
- 2) Select correct vial for biopsy location
- 3) If biopsy site is different from pre-labeled vial, please provide correct site information on the vial and requisition
- 4) Place the biopsies in correct vials according to biopsy location
- 5) Be sure each vial cap is screwed tightly in place and return vial to kit
- 6) Please remove and dispose of unused vials – they cannot be used for other cases.
- 7) Complete the requisition in its entirety to include total number of vials submitted and method of billing
- 8) Seal the enclosed kit in the biohazard bag and insert the requisition in the biohazard bag pocket.
- 9) Place the biohazard bag containing the kit and requisition in the provided specimen shipping pack



When utilizing the HealthTronics Laboratory Solutions SimplifID™ kit containing multiple pre-labeled specimen cassettes and two formalin-filled specimen containers:



- 1) Check to ensure accession numbers for the requisition, bottles and cassettes are a match
- 2) Select the cassette that matches the site being biopsied
- 3) Open the cassette lid
- 4) Transfer the biopsy from the needle gun to the cassette using the foam pad if necessary
- 5) **Immediately** place the foam pad and the biopsy in the cassette and close the cassette securely until it clicks shut.
- 6) Place the left sided biopsies in the “Left” fixative container and the right sided biopsies in the “Right” fixative container.
- 7) Close each specimen container, making sure the lid on each is secure and tight
- 8) Seal the biohazard bag that encloses the specimen containers.
- 9) Close the kit and ship using the enclosed shipping materials

REPORTING

REPORTS

Reports are generated on a daily basis. Our Lab Information System has the ability to automatically transmit lab reports to client office facsimile (fax) machines and/or printers. In order to expedite quality patient care, HealthTronics Laboratory Solutions automatically transmits completed patient reports throughout the day as they are completed. Please provide us with your fax number and other relevant instructions.

We also have the capability of providing results via web access; please contact your Sales Executive or Client Services Department to obtain a user name and password.

