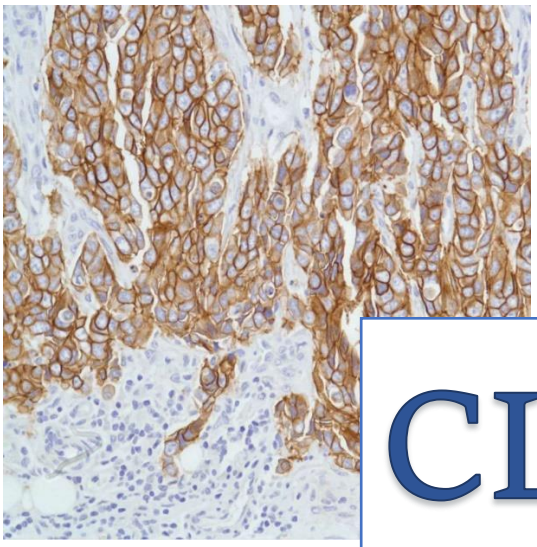
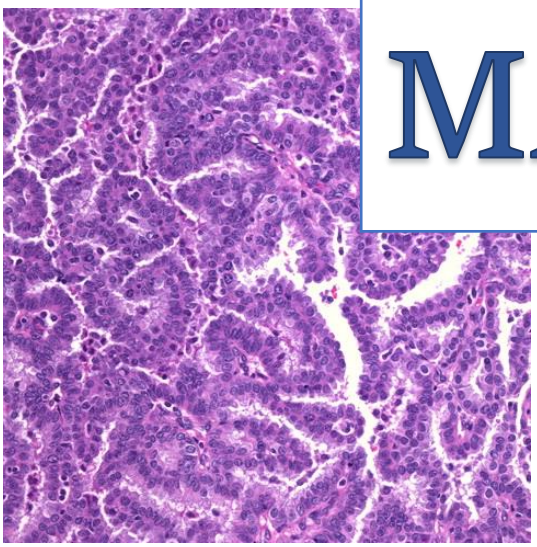
CLINICAL PATHOLOGY ASSOCIATES PA



CLIENT SERVICE MANUAL



1150 NORTH 18TH STREET • SUITE 102
ABILENE • TEXAS • 79601
p. 325-670-6527 www. clinicalpathologyassociates.com

CLINICAL PATHOLOGY ASSOCIATES

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Clinical Pathology Associates is a group of medical professionals who specialize in diagnosis and treatment for a wide number of diseases. We are the certified experts who can provide the testing and screening you need in our state-of-the-art pathology laboratory. We have been serving hospitals, clinics, and surgery centers in Abilene and West Texas for over 50 years, offering ThinPrep tests, women's health screening, and anatomic pathology services.

MEET OUR PHYSICIANS:

Jim Duff, M.D.

Undergraduate: McMurry University

Graduate Studies: Scholarship in Biochemistry, University of Kentucky

Medical School: University of Texas at San Antonio

Residency: Baptist Hospital Systems, San Antonio

Special Interests: Prostate Pathology, Genitourinary Pathology, Pathology Informatics, Administration

President: Clinical Pathology Associates, Abilene, TX

Karen Thomas, M.D.

Start Date: August 2024

Undergraduate: Baylor University

Medical School: Texas Tech University Health Sciences Center Paul L. Foster School of Medicine

Residency: Houston Methodist Hospital

Fellowships: Cytopathology at The University of Texas MD Anderson Cancer Center

Special Interest: Cytopathology

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David Stanley, M.D.

Undergraduate: Abilene Christian University

Medical School: UTMB at Galveston

Residency: Pathology at UTMB Galveston

Fellowships: Clinical Pathology, Surgical Pathology, UTMB at Galveston

Special Interests: Breast Pathology, Gastrointestinal Pathology, Genitourinary Pathology, Dermatopathology

Othon Almanza, M.D.

Undergraduate: Universidad de Monterrey

Medical School: Universidad Autonoma de Nuevo Leon

Residency: University of Massachusetts Medical Center

Fellowships: Surgical Pathology, Cytopathology at LSU in Shreveport, LA

Affiliations: Research projects with Texas Tech University

Special Interests: Gastrointestinal Pathology, Cytopathology

Priscilla R. Lyon, D.O.

Undergraduate: Baylor University, Waco, TX

Medical School: University of North Texas Health Science Center Texas College of Osteopathic Medicine

Residency: Baylor Scott and White Medical Center

Fellowships: Dermatopathology Fellowship Baylor Scott and White Medical Center, board certified in Anatomic and Clinical Pathology, and Dermatopathology

Special Interests: Dermatopathology, Soft tissue Surgical Pathology

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BILLING INFORMATION

BILLING INFORMATION

Insurance Billing

We participate with all third-party insurers and bill them directly for our services, relieving you and your patients of billing difficulties. Clinical Pathology Associates participates with many insurances Aetna, Blue Cross Blue Shield, Cigna, FirstCare, Medicare, Medicaid, United Health Care, PHCS, 1st Health, PHS Networks and many more.

Patient Billing

We have a patient-friendly billing practice and will work with your patients to resolve any billing concerns in a way that is best for them. Patients may also visit www.clinicalpathologyassociates.com for payment information.

Personal Attention

You will have access to our billing department by calling the following:

- Billing: 325-670-6500
- Toll Free: 1-800-478-9341

Medicare Technical Component for Hospitals

Medicare does not allow an outside laboratory to bill technical component on pathology specimens. Medicare requires the hospital to bill the technical component CPT charges to Medicare. The laboratory will then client bill these technical component charges to the hospital. Clinical Pathology Associates reports for Medicare split bill patients will be printed with the CPT codes at the top of the report to enable the Laboratory Manager an easy way to know what to bill Medicare. These charges will be a CPT code, followed by "TC", to make sure they are billed technical only. The hospital will need to be careful not to globally bill for the respective CPT code.

CLINICAL PATHOLOGY ASSOCIATES

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CLIENT SERVICES INFORMATION

Supplies

We supply all the necessary materials for cytology, histology, and pathology services. Supply cards are available upon request. A list of products can be found on our website, www.clinicalpathologyassociates.com/order-supplies

Special Stains

We use special stains and immunohistochemistry to demonstrate organisms and other structures when needed.

Report & Turn-Around-Time

A fully customized, comprehensive Pathology report on any type of anatomic surgical specimen is issued by a board-certified Pathologist within 24-48 business hours of receipt of specimen. If the case must be sent out for testing or requires additional testing at a reference facility the turn-around time will vary. A verbal report within 24 hours is available upon request.

Reports can be mailed, sent via courier, faxed, or sent electronically into an interfaced EHR (if available). A color photograph of the microscopic specimen can be provided in the report upon request at no additional cost.

Professional Consultation Services

Our board-certified Pathologists and technical specialists are readily available by telephone.

Personal Attention

You will have access to our client service and laboratory department by calling the following:

- Client Services: 325-670-6525
  325-670-6533
- Laboratory: 325-670-6527
- Courier Service: 325-670-4254

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

SURGICAL SPECIMEN

Proper identification of the specimen and its anatomic location is of utmost importance to assure accurate reporting of results. It is imperative that the Pathologist receive all the pertinent information regarding the lesion to be examined.

Tissue that is removed surgically must be properly preserved. This is necessary to obtain quality microscopic sections for the demonstration of morphological alterations. Do not allow the tissue to dry – place in the fixative immediately after removal, the fixative should completely cover the specimen. Clinical Pathology Associates provides all necessary supplies at no additional cost.

Note: Please use "Universal Precautions" with all specimens

A. Specimens must be delivered to the laboratory as soon as possible after collection, or they must be placed in fixative and/or refrigerated until delivery to the laboratory if possible. Individual specimen guidelines for delivery follow:
   1. 10% Neutral Buffered Formalin (10% NBF) container:
      a. Write patient's name, using a pen or marker, or place a patient identifier label on the 10% NBF container.
      b. The name on the bottle MUST be identical to the name on the requisition.
      c. Specimens that do not adhere to these requirements or containers that spill within the biohazard bag may be returned to the referring physician for completion or corrections. An Unacceptable Specimen Log will be submitted.
   2. Ziplock Bags and/or Containers for large specimens:
      a. Write patient's name, using a pen or marker, or place a patient identifier label on the bag/container.
      b. The name on the bottle MUST be identical to the name on the requisition.
      c. Place the specimen in an appropriately sized container, completely cover the specimen with 10% NBF.
         Ideal volume of 10% NBF is 10 to 15 times the volume of the specimen
      d. Specimens that do not adhere to these requirements or containers that spill within the biohazard bag may be returned to the referring physician for completion or corrections. An Unacceptable Specimen Log will be submitted.
   3. Specimen requiring Special Handling:
      a. Write patient's name, using a pen or marker, or place a patient identifier label on the bag/container.
      b. The name on the bottle MUST be identical to the name on the requisition.
      c. Follow the Special Handling Policies for specimen viability.
         i. Amputated Limbs
         ii. Frozen Sections
         iii. Enzyme Histochemistry (Muscle Biopsies)
         iv. Bone Marrows
         v. FLOW Cytometry
         vi. Immunofluorescence
         vii. Perinatal Loss
      d. Specimens that do not adhere to these requirements or containers that spill within the biohazard bag may be returned to the referring physician for completion or corrections. An Unacceptable Specimen Log will be submitted.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

ACCEPTABLE SURGICAL SPECIMEN CRITERIA

PURPOSE	To provide a list and instructions for specimens received in the laboratory.
SPECIMEN	All pathology specimens
LABELING	All specimens must be clearly labeled and contain at least two identifiers on the container. • Patient Name (mandatory) • Date of Birth • Social Security Number • Unique Random Identifier (patient medical record number) ***Note: Pathology Specimens****: Be sure to include the specimen site/anatomic location on the container.* ***Note:*** *Improperly labeled specimens will cause a delay in results and reporting.*
REQUISITIONS	All specimens must be accompanied by a requisition form. Please see, ***How To Complete A Histology Requisition***. **NOTE: All electronic forms and requisitions will be accepted as long as the information from "How to Complete a Histology Requisition" is included.**
STORAGE REQUIREMENTS	All histology fixative or media must be stored according to manufacturer guidelines. Unless specified the temperatures for storage are with and without the specimen. 1. 10% Neutral Buffered Formalin (10% NBF) a. Room Temperature (15-30°C) 2. RPMI a. Refrigerated Temperature (2-8°C) 3. Michel's a. Room Temperature (15-30°C) 4. Sterile Saline a. Without Specimen i. Room Temperature (15-30°C) b. With specimen i. Refrigerated Temperature (2-8°C)

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

PACKAGING

All specimens must meet the minimum packaging guidelines. The following are the minimum specimen packaging guidelines that should be followed when submitting specimens using one of our couriers.

1. Ensure that all specimen container caps and lids are properly tightened to prevent leakage.
2. Properly complete the requisition.
3. Collect the specimen(s) and transfer to a proper transport container, if needed.
4. Double check the specimen container to ensure that the device is not beyond its stated expiration date.
5. The specimen transport bag has two pouches. Insert the requisition into the front pocket. Place the specimen container(s) in the back pocket.
6. Make sure the specimen transport bag has been zipped properly. This will protect the test requisition from leakage and prevent separation of the requisition and specimen.
7. Any updates to these guidelines (or to the specimen transport supplies) will be communicated through our marketing representative.

HANDLING

All specimens will be handled, stored, and transported according to the manufacturer's guidelines.

Clinical Pathology Associates (CPA) contracts Hendrick Regional Laboratory couriers to handle and transport specimens. Specimen viability is of the utmost importance for CPA. To ensure correct handling and transport, a bi-annual transportation cooler verification is completed.

SPECIMEN TRANSPORT

After the specimens have been collected, the specimen jars are placed in a biohazard specimen bag along with the completed requisition. The specimen bag(s) should be collected and placed in a central location within the hospital/practice for transport to Clinical Pathology Associates (CPA).

It is recommended that the client complete a ***Specimen Inventory Log*** (see appendix I) for tracking purposes. The log should be submitted with the pathology specimens and a copy should be retained for your records. ***Specimen Inventory Logs*** are provided by CPA at the client's request.

Courier

If transporting via courier, the following must be completed:

- The courier should verify that the specimen(s) on the ***Specimen Inventory Log*** are picked up.
- The courier must initial and date the ***Specimen Inventory Log*** to ensure that the specimen(s) are accounted for.
- A copy of the ***Specimen Inventory Log*** should accompany the specimen and a copy should remain with the client.

- Please communicate the special handling and transport of the specimen to the courier so that they can handle and transport the specimens according to the manufacturer's guidelines.
- Upon receipt in the lab, lab personnel will verify that the specimen(s) were received.
    - For Specimen pickups please call the following:
        - Courier Services: 325-670-4254

**In the case of any missing specimen(s) both the courier and client will be contacted to locate the specimen(s) or resolve the discrepant information.*

CRITERIA FOR SPECIMEN REJECTION

All specimens must be submitted according to the client manual instructions. Laboratory personnel will contact the office for additional information on discrepant specimens.

Situations that may prevent Clinical Pathology Associates from processing specimens include but are not limited to:

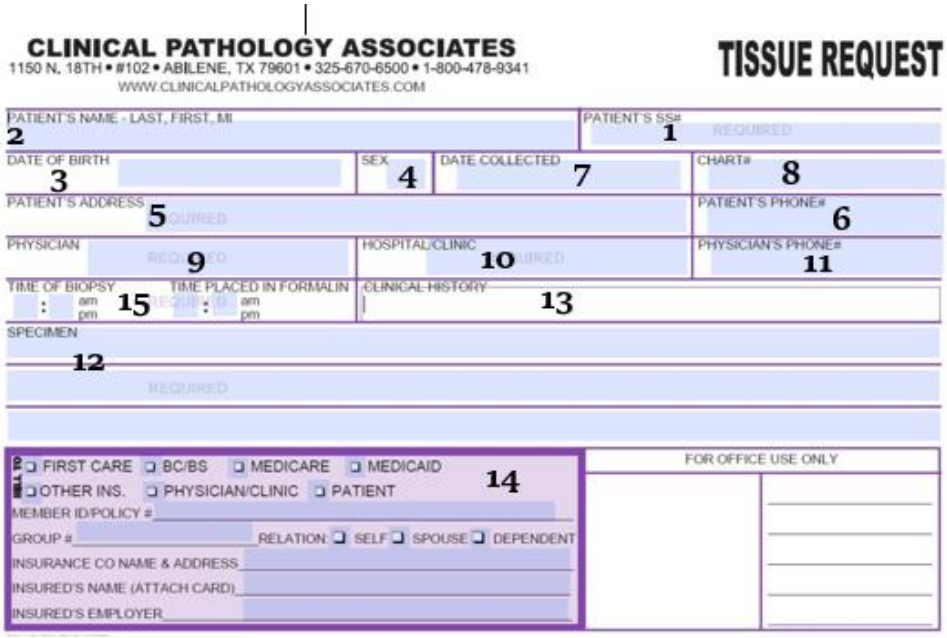
1. Specimen not accompanied by requisition
2. Inappropriate specimen type
3. Specimen not properly labeled
4. Insufficient volume for analysis
5. Requisition not accompanied by the specimen
6. Improper specimen transport
7. Specimen/requisition separated on receipt and is not properly identified to verify chain of custody
8. Specimen not properly preserved, and specimen has deteriorated
9. Patient identifier of requisition and specimen label differ
10. Specimen submitted in incorrect or expired transport media
11. Specimen leaked from container in transport
12. No referring provider
13. Requisition lacks proper patient identifiers or contains discrepant information (i.e. No test ordered, no referring provider, a specimen source is not provided)

Please see Appendix I for information on the ***Specimen Verification Form***.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

HOW TO COMPLETE A HISTOLOGY REQUISITION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WWW.CLINICALPATHOLOGYASSOCIATES.COM

TISSUE REQUEST

PATIENT'S NAME - LAST, FIRST, MI 2
PATIENT'S SS# 1
DATE OF BIRTH 3
SEX 4
DATE COLLECTED 7
CHART# 8
PATIENT'S ADDRESS 5
PATIENT'S PHONE# 6
PHYSICIAN 9
HOSPITAL/CLINIC 10
PHYSICIAN'S PHONE# 11
TIME OF BIOPSY 15
TIME PLACED IN FORMALIN
CLINICAL HISTORY 13
SPECIMEN 12
FIRST CARE BC/BS MEDICARE MEDICAID 14
OTHER INS. PHYSICIAN/CLINIC PATIENT
MEMBER ID/POLICY #
GROUP # RELATION SELF SPOUSE DEPENDENT
INSURANCE CO NAME & ADDRESS
INSURED'S NAME (ATTACH CARD)
INSURED'S EMPLOYER
FOR OFFICE USE ONLY

PATIENT DEMOGRAPHICS

1. Patient's Social Security Number
2. Patient's Last Name and First Name
3. Patient's Date of Birth
4. Patient's Gender
5. Patient's Address
6. Patient's Phone Number
14. Patient's Insurance Information

REFERRING PHYSICIAN & SPECIMEN INFORMATION

7. Date of Collection
8. Chart number or Patient ID for referring office
9. Physician's Name
10. Hospital or Clinic where specimen was obtained
11. Physician's Phone Number
12. Specimen
    - i. Anatomic Location
    - ii. Type of Specimen (i.e. Skin, Gallbladder)
13. Any pertinent patient clinical history
15. Fixation Times

NOTE: All electronic forms and requisitions will be accepted if all of the above information is included.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

SPECIAL HANDLING POLICY AND PROCEDURE

PURPOSE

To provide a list and instructions for specimens requiring special handling.

SPECIMEN

- Amputated Limbs
- Bone Marrows
- Enzyme Histochemistry (Muscle Biopsies)
- FLOW Cytometry
- Frozen Sections
- Immunofluorescence
- Perinatal Loss

LABELING

LABELING

All specimens must be clearly labeled and contain at least **TWO** identifiers on the container.

- Patient Name (Mandatory)
- Date of Birth
- Social Security Number
- Unique Random Identifier (patient medical record number)

Note: Pathology Specimens*: Be sure to include the specimen site/anatomic location on the container.*
Note: *Improperly labeled specimens will cause a delay in results and reporting.*

REQUISITION

REQUISITION

All specimens must be accompanied by a requisition form. Please see, ***How To Complete A Histology Requisition***.

NOTE: All electronic forms and requisitions will be accepted if the information from "How to Complete a Histology Requisition" is included.

AMPUTATED LIMBS

AMPUTATED LIMBS

To ensure the correct handling of amputated limb specimens for processing. Please see the following.

A. All amputated limbs must have an attached ***Disposal Permit***
   - Please see Appendix I for ***Disposal Permit***
B. Amputated limbs must be bagged in red biohazard bags and kept in the refrigerator until picked up by the courier.
C. For transporting purposes. Place the limb in a cardboard box.

D. Patients may request limb for burial. Limbs, with a ***Specimen Release Form***, are only released to a funeral home or the surgical facility for funeral home pickup.

BONE MARROWS

To ensure the correct handling of bone marrow specimens sent for processing. Please see the following.

A. Collection of Bone Marrow
   1. Supplies
      a. Two 10% Neutral Buffered Formalin (10% NBF) containers
      b. One EDTA (Lavender) tube for molecular diagnostics
      c. Two Sodium Heparin (Green) tubes for Cytogenetics and FLOW Cytometry
      d. 10 slides
         i. 2 Trephine Imprints (Optional)
         ii. 2 Peripheral Blood Smears
         iii. 6 Bone Marrow Aspirate Smears
   2. Bone Core Biopsy
      a. The marrow core should be collected first. It is recommended to obtain a length of 2 cm.
      b. Prepare two (2) air dried imprint slides from the fresh core first (Trephine Imprint- Optional).
      c. Place fresh core into a 10% NBF container and secure lid.
   3. Aspirate
      a. Marrow aspirate should be collected in two syringes
         i. Syringe One
            - Use for Slides and Aspirate Clot
            - Approximately 2-3 mL of marrow aspirate
               1) Bone Marrow Aspirate Smears
                  - Quickly squeeze aspirated bone marrow from syringe into watch glass.
                  - Quickly aspirate approximately 0.5 mL of marrow with a Pasteur pipette from the watch glass.
                  - Place a small drop of marrow on 6 individual slides.
                  - Spread using desired method.
                  - Remember to air dry quickly and completely. **DO NOT fix slides with any substance**
                  - Please see the illustration on the next page.

            Note: The bone marrow smear is ONE of the most critical specimens. For the best results smears should be made ASAP.

            Note: Slides must be packaged and sent in a separate biohazard bag from the 10% NBF.

               2) Bone Marrow Fixed Clot
                  - Once the remaining aspirate forms a clot on the watch glass it should be transferred to a 10% NBF container.

         ii. Syringe Two
            - Use for vacutainers

- Approximately 10 mL of marrow aspirate
- Be sure to use a sterile needle

1) Flow Cytometry Studies
   - Inject 3 mL of aspirate into a Sodium Heparin Tube (Green Top)
2) Cytogenetic Studies
   - Inject 3 mL of aspirate into a second Sodium Heparin Tube (Green Top)
3) Molecular Diagnostic Studies
   - Any remaining Aspirate should be injected into an EDTA Tube (Purple Top)

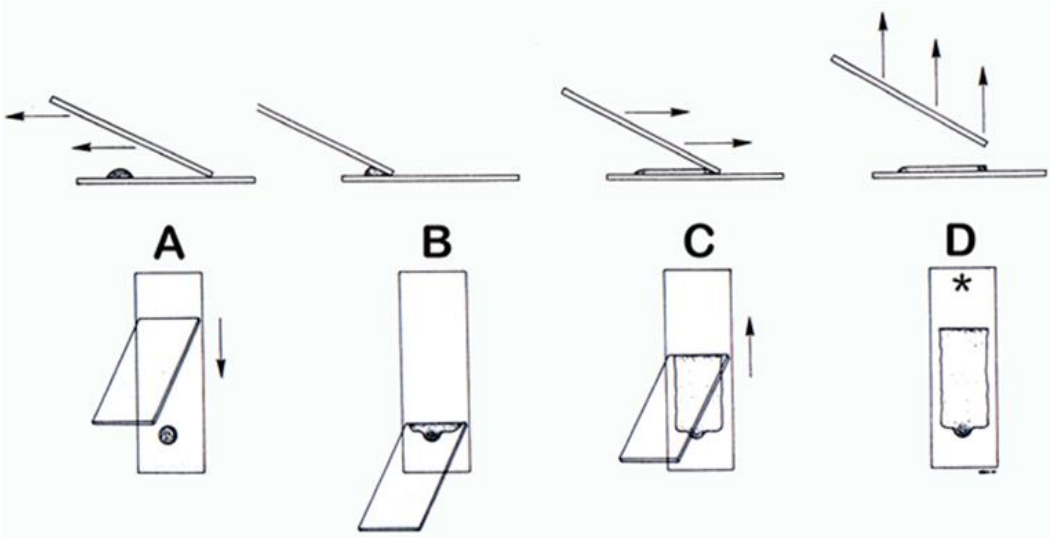
4. Peripheral Blood Smears
   a. Can be taken before or after marrow
   b. Fingerstick specimen is best
   c. Fresh EDTA Tube (Purple Top) <2 hours old
   d. Spread, dry, and handle just like the bone marrow aspirate smears.
5. CBC results and Clinical History or note.

B. Packaging and Transport

1. 10% NBF containers and smears must be bagged separately.
2. Smears can be placed in plastic slide holders (mailers)
3. To keep the patient specimens together please staple, tape, or rubber band the separate biohazard bags together.
4. Specimen should be received within 24 hours of procedure. (Please schedule and plan accordingly)

Note: The 10% NBF will distort the cellular morphology of the smears. For the patient care please bag the smears and 10% NBF separately.

C. Aspirate Smear Illustration



ENZYME HISTOCHEMISTRY

To ensure the correct handling of specimens sent for enzyme histochemistry. Please see the following.

A. Collection of surgical specimens for Enzyme Histochemistry
   1. Supplies
      a. Sterile Gauze
      b. Sterile Saline
      c. Sterile Specimen Container
   2. Specimen Instructions
      a. Obtain at least 2.0 cm of muscle or nerve.
      b. Wrap the muscle or nerve specimen in a lightly dampened piece of sterile gauze.
      c. Place the muscle or nerve specimen in a Sterile Specimen Container.
         i. Keep specimen refrigerated.
      d. Notify Clinical Pathology Associates (CPA) (325) 670-6527 that there is a muscle or nerve specimen on the way.
      e. The muscle or nerve specimen should be received by CPA on the same day the procedure was completed.

   Note: Due to the specimen deteriorating, it should be removed in the morning (AM) and be received by Clinical Pathology Associates by the afternoon (PM).

B. Packaging and Transport
   1. Place an ice pack in the biohazard bag with the specimen for transit.
   2. Inform the courier that the specimen needs to be refrigerated.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

FLOW CYTOMETRY

To ensure the correct handling of specimens sent for FLOW cytometry. Please see the following.

A. Collection of surgical specimens for FLOW Cytometry
   1. Supplies
      a. RPMI container
      b. Sterile Saline (If RPMI is not available)
   2. Specimen Instructions
      a. Place specimen in the proper container filled with RPMI, or sterile saline.
         i. Completely cover the specimen.
         ii. Keep specimen refrigerated.
         iii. Prefilled RPMI containers are provided through Clinical Pathology Associates (CPA).
      b. Notify CPA (325) 670-6527 that there is a FLOW Cytometry specimen on the way.
      c. The requisition MUST state “For FLOW Cytometry”.
      d. The FLOW Cytometry specimen should be received by CPA on the same day the procedure was completed.

   Note: RPMI is not a fixative it is a nutrient rich broth. Due to the specimen deteriorating, it should be removed in the morning (AM) and be received by CPA by the afternoon (PM).

B. Packaging and Transport
   1. Place an ice pack in the biohazard bag with the specimen for transit.
   2. If the specimen is split between 10% Neutral Buffered Formalin and RPMI place both containers within the same biohazard bag.
   3. Inform the courier that the specimen needs to be refrigerated.

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CLIENT SERVICE MANUAL

FROZEN SECTION – IN TOWN

FROZEN SECTION

To ensure the correct handling for specimens sent for in town frozen sectioning. Please see the following.

A. Scheduling
    1. For a timely procedure, it is highly recommended to call CPA at 670-6522 to schedule the Frozen Section in advance. A CPA representative will call the courier service to setup the pickup, and make sure that there are no other patients that may be having Frozen Section procedures done during this time. Calling the courier service 30 minutes before having the Frozen section ready, without prior notice, is risky and we do not recommend this.

B. Supplies
    1. Sterile Specimen Container

C. Packaging and Transport
    1. Frozen sections from a local physician's office or surgery center are to be completed at Hendrick Medical Center North, or South Campus.

****Note:** Please see ***Frozen Section Procedure*** for hospitals with an in-house frozen section lab. **

    2. Place the specimen in a Sterile Specimen Container (Specimen must be fresh with NO FIXATIVE or ADDITIVES)
    3. The requisition MUST include the best phone number to contact the provider/surgeon.
    4. Physician's office calls for a STAT courier pickup to be taken to HMC North, or South, for frozen section.

D. Chain of Custody
    1. Courier delivers specimen to HMC North, or South, Histology Department.
    2. HMC technician notifies Clinical Pathology Associates (CPA) of the following:
        a. Patient's name
        b. Specimen
        c. Physician name

E. CPA's technician records the information and pulls an accession number for the case.

F. The HMC pathologist will contact the provider/surgeon with the results.

G. HMC will complete the frozen sections and send the case back to CPA via courier for permanent sections.

IMMUNOFLUORESCENCE

To ensure the correct handling of specimens sent for Immunofluorescence. Please see the following.

A. Collection of surgical specimens for Immunofluorescence
   1. Supplies
      a. Michel's Solution
      b. RPMI container (If Michel's is not available)
      c. Sterile Saline (If RPMI is not available)
   2. Specimen Instructions
      a. Place specimen in the proper container filled with Michel's or the alternative solutions listed above.
         i. Completely cover the specimen.
         ii. If RPMI or Sterile Saline is being used, please keep the specimen refrigerated.
         iii. Prefilled Michel's and RPMI containers are provided through Clinical Pathology Associates (CPA).
      b. Notify CPA (325) 670-6527 that there is an Immunofluorescence specimen on the way.
      c. The requisition MUST state "For Immunofluorescence" or "DIF".
      d. The Immunofluorescence specimen should be received by CPA on the same day the procedure was completed.

   Note: Due to the specimen deteriorating we recommend receiving the specimen ASAP. The specimen should be removed in the morning (AM) and be received by CPA by the afternoon (PM).

C. Packaging and Transport
   1. If the specimen is split between 10% Neutral Buffered Formalin and RPMI place both containers within the same biohazard bag.
   2. If using RPMI or Sterile Saline place an ice pack in the biohazard bag with the specimen for transit.
   3. If using RMPI or Sterile Saline inform the courier that the specimen needs to be refrigerated.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

PERINATAL LOSS

PERINATAL LOSS

To ensure the correct handling of specimens regarding Perinatal Loss. Please see the following.

A. Miscarriage/Abortus
   1. A fetus weighing less than 350 grams is considered an abortus and will be treated as a surgical specimen.
      a. The parents may, if they desire, bury the fetus in the cemetery, after gross pathology has been performed.
         i. It is the responsibility of the parents to make arrangements with the funeral home.
         ii. It is the responsibility of the parents to notify the client hospital of desire to bury fetus.
      b. The client hospital must notify our laboratory of parent's desire to bury the fetus.
         i. A ***Specimen Release Form*** need to be completed by the client hospital and parents.
   2. Collection of Miscarriage/Abortus
      a. Genetic Testing
         i. If genetic testing is ordered, please send "fresh" (NO fixative)
         ii. Genetic testing cannot be completed if received in 10% Neutral Buffered Formalin (10% NBF).
         iii. Keep specimen refrigerated
      b. Routine Pathology
         i. For routine pathology, place in 10% NBF. Be sure to fully cover the specimen.
   3. Packaging and Transport
      a. Genetic Testing
         i. Place an ice pack in the biohazard bag with the specimen for transit.
         ii. Inform the courier that the specimen needs to be refrigerated.

   Note: Due to the specimen deteriorating we recommend receiving the specimen ASAP.

B. Fetal Death
   1. Per the Texas Health and Safety Code, a fetus that is above 350 grams or a fetal age of 20 weeks or greater (gestational age) a ***Fetal Death Certificate*** must be issued.
   2. At Clinical Pathology Associates (CPA), if we receive a fetus that has physical characteristics of a completed 20-week fetus
      a. Weighing 350 grams or more and/or a crown to heel length of 25.6 cm or more)
   3. CPA will consider the fetus to be of 20 completed weeks or more age.
      a. Pathology cannot be performed.
      b. Clinical Pathology Associates DOES NOT file death certificates.
      c. If an autopsy is desired, please contact the medical examiner or autopsy services of your choice.

C. Stillbirth
   1. "Stillbirth" means an unintended, intrauterine fetal death occurring in this state after a gestational age of not less than 20 completed weeks.
   2. At Clinical Pathology Associates, if we receive a fetus that has physical characteristics of a completed 20-week fetus
      a. Weighing 350 grams or more and/or a crown to heel length of 25.6 cm or more)
   3. CPA will consider the fetus to be of 20 completed weeks or more age.
      a. Pathology cannot be performed.
      b. CPA DOES NOT issue a "Certificate of birth resulting in stillbirth".
      c. If an autopsy is desired, please contact the medical examiner or autopsy services of your choice.

D. Neonatal Death
   1. A fetus that is of 20 weeks, or more, gestation age who is born alive and later expires prior to 90 days of age.
      a. Pathology cannot be performed.
      b. CPA DOES NOT issue death certificates.
      c. If an autopsy is desired, please contact the medical examiner or autopsy services of your choice.

Note: By state law any fetus that is 20 completed weeks and/or 350 grams, or more must have a death certificate. A fetal death certificate must be filed with the State Vital Statistics Unit (VSU). The funeral home will be responsible for the disposition of the remains.

Note: CPA accepts all fetus specimens less than 20 completed weeks of gestation and weighing less than 350 grams. CPA DOES NOT file death certificates and CANNOT accept Fetal Deaths, Stillborn, or Neonatal Deaths.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

CYTOLOGY SPECIMEN

This manual is intended to be used as a specimen collection guideline for cytology. Each separate area of concern is included in a different procedure. Therefore, items such as "transportation", "patient preparation", and "preservation required" may differ from procedure to procedure.

Compromising the diagnostic integrity of specimens is avoided when the client and the lab follow proper collection, preservation and reporting procedures. In addition, maintaining these guidelines will shorten turnaround time, preserve necessary patient information, and ensure safe, timely transport of the sample.

The goal of Clinical Pathology Associates in providing this manual is to maintain a high quality of patient care by obtaining specimens in their most preserved state, receiving the most complete and accurate patient information, and reporting back to the clinician with minimal turnaround time.

Criteria for Specimen Rejection

CRITERIA FOR SPECIMEN REJECTION

All specimens must be submitted according to the client manual instructions. Laboratory personnel will contact the office for additional information on discrepant specimens.

Each separate area will include additional rejection criteria based on manufacturer guidelines.

Situations that may prevent Clinical Pathology Associates from processing specimens include but are not limited to:

1. Specimen not accompanied by requisition
2. Inappropriate specimen type
3. Specimen not properly labeled
4. Insufficient volume for analysis
5. Requisition not accompanied by the specimen
6. Improper specimen transport
7. Specimen/requisition separated on receipt and is not properly identified to verify chain of custody
8. Specimen not properly preserved, and specimen has deteriorated
9. Patient identifier on requisition and specimen label differ
10. Specimen submitted in incorrect or expired transport media
11. Specimen leaked from container in transport
12. No referring provider
13. Requisition lacks proper patient identifiers or contains discrepant information (i.e., No test ordered, no referring provider, a specimen source is not provided)

Please see Appendix I for information on the ***Specimen Verification Form***.

CLINICAL PATHOLOGY ASSOCIATES

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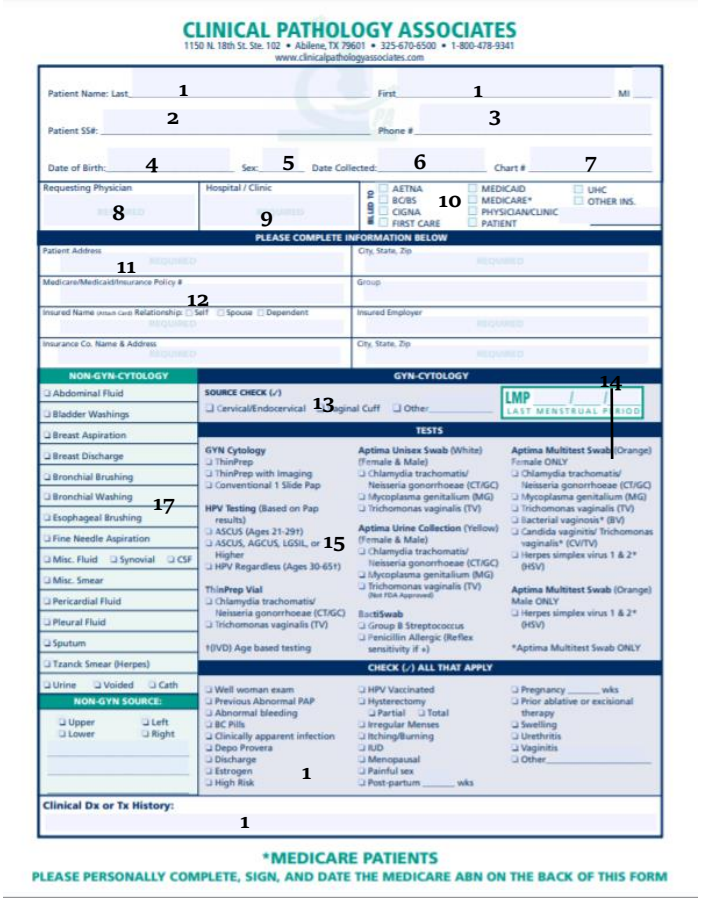
HOW TO COMPLETE A CYTOLOGY REQUISITION


CLINICAL PATHOLOGY ASSOCIATES
1150 N. 18th St. Ste. 102 • Abilene, TX 79601 • 325-670-6500 • 1-800-478-9341
www.clinicalpathologyassociates.com

Patient Name: Last 1 First 1 MI
Patient SS#: 2 Phone # 3
Date of Birth: 4 Sex: 5 Date Collected: 6 Chart # 7
Requesting Physician 8 Hospital / Clinic 9
BILL TO: AETNA, BC/BS, CIGNA, FIRST CARE, MEDICAID, MEDICARE*, PHYSICIAN/CLINIC, PATIENT, UHC, OTHER INS. 10
PLEASE COMPLETE INFORMATION BELOW
Patient Address 11 City, State, Zip
Medicare/Medicaid/Insurance Policy # 12 Group
Insured Name Relationship: Self Spouse Dependent Insured Employer
Insurance Co. Name & Address City, State, Zip
NON-GYN-CYTOLOGY: Abdominal Fluid, Bladder Washings, Breast Aspiration, Breast Discharge, Bronchial Brushing, Bronchial Washing, Esophageal Brushing 17, Fine Needle Aspiration, Misc. Fluid, Synovial, CSF, Misc. Smear, Pericardial Fluid, Pleural Fluid, Sputum, Tzanck Smear (Herpes), Urine, Voided, Cath
NON-GYN SOURCE: Upper, Lower, Left, Right
GYN-CYTOLOGY
SOURCE CHECK (✓): Cervical/Endocervical 13, Vaginal Cuff, Other
LMP 14 LAST MENSTRUAL PERIOD
TESTS
GYN Cytology: ThinPrep, ThinPrep with Imaging, Conventional 1 Slide Pap
HPV Testing (Based on Pap results): ASCUS (Ages 21-29†), ASCUS, AGCUS, LGSIL, or Higher 15, HPV Regardless (Ages 30-65†)
ThinPrep Vial: Chlamydia trachomatis/ Neisseria gonorrhoeae (CT/GC), Trichomonas vaginalis (TV)
†(IVD) Age based testing
Aptima Unisex Swab (White) (Female & Male): Chlamydia trachomatis/ Neisseria gonorrhoeae (CT/GC), Mycoplasma genitalium (MG), Trichomonas vaginalis (TV)
Aptima Urine Collection (Yellow) (Female & Male): Chlamydia trachomatis/ Neisseria gonorrhoeae (CT/GC), Mycoplasma genitalium (MG), Trichomonas vaginalis (TV) (Not FDA Approved)
BactiSwab: Group B Streptococcus, Penicillin Allergic (Reflex sensitivity if +)
Aptima Multitest Swab (Orange) Female ONLY: Chlamydia trachomatis/ Neisseria gonorrhoeae (CT/GC), Mycoplasma genitalium (MG), Trichomonas vaginalis (TV), Bacterial vaginosis* (BV), Candida vaginitis/ Trichomonas vaginalis* (CV/TV), Herpes simplex virus 1 & 2* (HSV)
Aptima Multitest Swab (Orange) Male ONLY: Herpes simplex virus 1 & 2* (HSV)
*Aptima Multitest Swab ONLY
CHECK (✓) ALL THAT APPLY
Well woman exam, Previous Abnormal PAP, Abnormal bleeding, BC Pills, Clinically apparent infection, Depo Provera, Discharge, Estrogen, High Risk 1, HPV Vaccinated, Hysterectomy (Partial, Total), Irregular Menses, Itching/Burning, IUD, Menopausal, Painful sex, Post-partum ____ wks, Pregnancy ____ wks, Prior ablative or excisional therapy, Swelling, Urethritis, Vaginitis, Other
Clinical Dx or Tx History: 1
*MEDICARE PATIENTS
PLEASE PERSONALLY COMPLETE, SIGN, AND DATE THE MEDICARE ABN ON THE BACK OF THIS FORM

PATIENT DEMOGRAPHICS

1. Patient's last name, first name, and middle initial

2. Patient's social security number

3. Patient's phone number

4. Patient's date of birth

5. Patient's gender

10. Bill to

11. Patient's address

12. Patient's insurance information

REFERRING PHYSICIAN & SPECIMEN INFORMATION

6. Date of collection
7. Patient's chart number
8. Referring physician
9. Physician's location
13. Source of specimen
14. Last menstrual period (only for GYN cytology)
15. Available testing
16. Any pertinant patient clinical history
17. Non-GYN cytology testing

* Medicare Patients must sign the ABN on the reverse side.

NOTE: All electronic forms and requisitions will be accepted if all of the above information is included.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

LABORATORY POLICY FOR ACCEPTING SPECIMENS

PRINCIPLE

Specimens received in the laboratory must be properly bagged, labeled, and accompanied by a completed laboratory requisition form.

NOTE: All electronic forms and requisitions will be accepted if the information from "How to Complete a Cytology Requisition" is included.

SPECIMEN

Cytology and Non-GYN cytology

QUALITY CONTROL

Document Discrepancies:
An ***Unacceptable Specimen Log*** will be submitted with the requisition.

PROCEDURE

Origin of Request:

A. Laboratory requisitions are received according to ordering locations as a:
   1. Manually completed requisition form
   2. Computer-generated request
B. By Federal Law, specimen requisition must contain the following:
   1. Patient name and identifying number
   2. Name and location of ordering physician
   3. Patient's sex and date of birth
   4. Source and type of specimen
   5. Date and time (if applicable) specimen was collected
   6. Pertinent clinical information
   7. Billing information
C. Specimen labels must contain the following:
   1. Patient name and identifying number.
   2. Ordering physician
   3. Date of specimen collection
   4. Time of specimen collection
   5. Solution (Fixative, Saline, fresh, etc.)
D. Specimen labels must be placed properly on the sample container, i.e.:
   1. Information or coded area is not obscured or damaged
   2. Label is placed on container, not lid.
   3. If specimen is placed in a non-transparent bag, a label is placed on the bag as well as the specimen container.

GYNECOLOGICAL SPECIMEN LABELING PROCEDURE

PRINCIPLE

To define proper labeling for gynecological cytology specimens

QUALITY CONTROL

Document Discrepancies:
An ***Unacceptable Specimen Log*** will be submitted with the requisition.

PROCEDURE

A. GYN Conventional Slides:
   1. Write patient's name on the frosted end of the slide ON THE SAME SIDE AS THE SMEAR using a graphite pencil or chemical resistant marker. No ink or magic marker.
   2. Place an identifying label on the outside of the mailer that contains the patient's demographics.
   3. The name on the slide and the outside of the mailer MUST be identical to the name on the requisition.
   4. Specimens that do not adhere to these requirements or slides received broken beyond repair may be returned to the referring physician for completion or corrections. An Unacceptable Specimen Log will be submitted.

B. ThinPrep Pap Test:
   1. Write patient's name, using a pen or marker, or place a patient identifier label on the Thin Prep Pap bottle.
   2. The name on the bottle MUST be identical to the name on the requisition.
   3. Specimens that do not adhere to these requirements or containers that spill within the biohazard bag may be returned to the referring physician for completion or corrections. An Unacceptable Specimen Log will be submitted.

GYNECOLOGICAL THINPREP PROCEDURE

PRINCIPLE

ThinPrep gynecological specimen collection instructions based on preferred collection devices (i.e.: Endocervical Brush/Spatula and Broom-Like Device)

HANDLING

Store and transport specimens at room temperature (15 to 30°C).
Specimen must be processed for testing within 21 days of collection.
Do NOT freeze

PATIENT PREPARATION

Patient should avoid douches 48 to 72 hours prior to examination.
Specimen should not be collected during or shortly after menstrual period.
Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination.
Note: Only minimal ThinPrep® approved lubricants should be used during collection.

Hologic Approved Lubricants	
Pap Test Lubricating Jelly	4-ounce (Multi use tube)
Surgilube Surgical Lubricant	3 g (Single use foil packet)

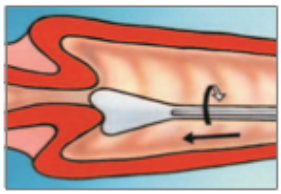
Clinical Pathology Associates provides ThinPrep® approved lubricants at no additional cost.

LIMITATIONS

Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation.
Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory pap results.

Endocervical Brush/Spatula Protocol

PROCEDURE

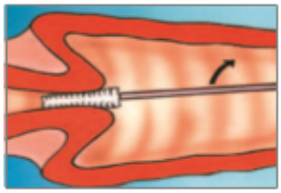


Obtain…

…an adequate sampling from the ectocervix using a *plastic* spatula.

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.



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.

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.

Tighten…

…the cap so that the torque line on the cap passes the torque line on the vial.

Record…

…the patient's name and ID number on the vial.
…the patient information and medical history on the cytology requisition form.

Place…

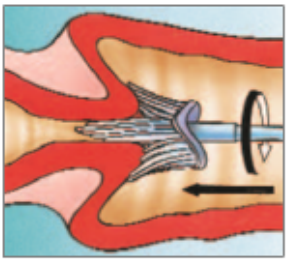
…the vial and requisition in a specimen bag for transport to the laboratory.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

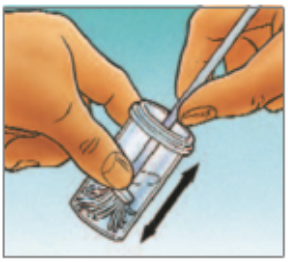
Broom-Like Device Protocol

PROCEDURE



Obtain…

…an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.



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.

Tighten…

…the cap so that the torque line on the cap passes the torque line on the vial.

Record…

…the patient's name and ID number on the vial.
…the patient information and medical history on the cytology requisition form.

Place…

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

ADDITIONAL GYNECOLOGICAL TESTING PROCEDURES

PRINCIPLE

To ensure the correct use of the Hologic ThinPrep and Aptima collection kits for additional testing.

AVAILABLE TESTING

I. Tests
   A. Bacterial vaginosis
   B. Candida vaginitis/Trichomonas vaginalis
   C. Chlamydia trachomatis/ Neisseria gonorrhea
   D. Herpes Simplex Virus 1 & 2
   E. Human Papillomavirus
   F. Mycoplasma genitalium
   G. Trichomonas vaginalis

II. Collection Methods
   A. Multitest
   B. ThinPrep Pap
   C. Unisex
   D. Urine

CLINICAL PATHOLOGY ASSOCIATES

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BACTERIAL VAGINOSIS

TEST

A. Bacterial vaginosis testing of the vulvovaginal area of women

SPECIMEN

A. Multitest Swab
- Orange Aptima Tube

PROCEDURE

A. Multitest Swab
1. Partially open swab package and remove the swab.
   a. Do not touch the soft tip or lay the swab down.
   b. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima vaginal swab specimen collection kit.
2. Hold swab, placing thumb and forefinger in the middle of the swab shaft covering the black score line.
   a. Do not hold the swab shaft below the score line.
3. Carefully insert swab into vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds.
4. Make sure the swab touches the vagina walls so that moisture is absorbed by the swab. Withdraw swab without touching the skin.
5. While holding the swab in hand, unscrew the tube cap.
   a. Do not spill tube contents.
   b. If the tube contents are spilled, discard and replace with a new Aptima vaginal swab specimen collection kit.
6. Immediately place swab into transport tube so the black score line is at the top of the tube.
7. Align the score line with the top edge of the tube and carefully break swab shaft.
   a. Swab will drop to bottom of the vial.
   b. Discard the top portion of the swab shaft.
8. Tightly screw cap onto tube.

STORAGE & HANDLING

A. Store collection kit at room temperature (15°C to 30°C).

LIMITATIONS OF PROCEDURE

A. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen.
B. Do not use the kit after its expiration date to collect specimens.
C. Multitest Tubes received without the designated pink swab will be rejected.
D. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens.
E. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers.
F. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
G. Specimen must adhere to the ***Acceptable Specimen Criteria***

CANDIDA VAGINITIS/ TRICHOMONAS VAGINALIS

TEST

A. Candida vaginalis and Trichomonas vaginalis testing of the vulvovagial area of women

SPECIMEN

A. Multitest Swab
- Orange Aptima Tube

PROCEDURE

A. Multitest Swab
1. Partially open swab package and remove the swab.
   a. Do not touch the soft tip or lay the swab down.
   b. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima vaginal swab specimen collection kit.
2. Hold swab, placing thumb and forefinger in the middle of the swab shaft covering the black score line.
   a. Do not hold the swab shaft below the score line.
3. Carefully insert swab into vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds.
4. Make sure the swab touches the vagina walls so that moisture is absorbed by the swab. Withdraw swab without touching the skin.
5. While holding the swab in hand, unscrew the tube cap.
   a. Do not spill tube contents.
   b. If the tube contents are spilled, discard and replace with a new Aptima vaginal swab specimen collection kit.
6. Immediately place swab into transport tube so the black score line is at the top of the tube.
7. Align the score line with the top edge of the tube and carefully break swab shaft.
   a. Swab will drop to bottom of the vial.
   b. Discard the top portion of the swab shaft.
8. Tightly screw cap onto tube.

STORAGE & HANDLING

A. Store collection kit at room temperature (15°C to 30°C).

LIMTATIONS OF PROCEDURE

A. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen.
B. Do not use the kit after its expiration date to collect specimens.
C. Multitest Tubes received without the designated pink swab will be rejected.
D. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens.
E. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers.
F. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
G. Specimen must adhere to the ***Acceptable Specimen Criteria***

CHLAMYDIA TRACHOMATIS & NEISSERIA GONORRHEA

TEST

A. Chlamydia trachomatis and Neisseria gonorrhea testing of the endocervical and vulvovaginal area of women and women's urine, throat or rectum.
B. Chlamydia trachomatis and Neisseria gonorrhea testing of the urethral area of men and men's urine, throat or rectum.

SPECIMEN

A. Multitest Swab
   - Orange Aptima Tube
B. ThinPrep Pap Vial
C. Unisex Swab
   - White Aptima Tube
D. Urine Collection Kit
   - Yellow Aptima Tube

PROCEDURE

A. Multitest Swab – Vaginal Testing

Note: Can ONLY be used on Women

Note: Must be from the vulvovaginal area

1. Partially open swab package and remove the swab.
   a. Do not touch the soft tip or lay the swab down.
   b. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima vaginal swab specimen collection kit.
2. Hold swab, placing thumb and forefinger in the middle of the swab shaft covering the black score line.
   a. Do not hold the swab shaft below the score line.
3. Carefully insert swab into vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds.
4. Make sure the swab touches the vagina walls so that moisture is absorbed by the swab. Withdraw swab without touching the skin.
5. While holding the swab in hand, unscrew the tube cap.
   a. Do not spill tube contents.
   b. If the tube contents are spilled, discard and replace with a new Aptima vaginal swab specimen collection kit.
6. Immediately place swab into transport tube so the black score line is at the top of the tube.
7. Align the score line with the top edge of the tube and carefully break swab shaft.
   a. Swab will drop to bottom of the vial.
   b. Discard the top portion of the swab shaft.
8. Tightly screw cap onto tube.

B. Multitest Swab, **throat** specimens

1. Partially open swab package and remove the swab.
   a. Do not touch the soft tip or lay the swab down.
   b. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima multitest swab specimen collection kit.

2. Hold swab, placing thumb and forefinger in the middle of the swab shaft covering the black score line.
   a. Do not hold the swab shaft below the score line.
3. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.
4. While holding the swab in hand, unscrew the tube cap.
   a. Do not spill tube contents.
   b. If the tube contents are spilled, discard and replace with a new Aptima vaginal swab specimen collection kit.
5. Immediately place swab into transport tube so the black score line is at the top of the tube.
6. Align the score line with the top edge of the tube and carefully break swab shaft.
   a. Swab will drop to bottom of the vial.
   b. Discard the top portion of the swab shaft.
7. Tightly screw cap onto tube.

C. Multitest Swab, **rectal** specimens

1. Partially open swab package and remove the swab.
   a. Do not touch the soft tip or lay the swab down.
   b. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima multitest swab specimen collection kit.
2. Hold swab, placing thumb and forefinger in the middle of the swab shaft covering the black score line.
   a. Do not hold the swab shaft below the score line.
3. Carefully insert the swab into the rectum about 1-2 inches (3-5 cm) past the anal margin and gently rotate the swab clockwise for 5 to 10 seconds. Withdraw the swab without touching the skin.While holding the swab in hand, unscrew the tube cap.
   a. Do not spill tube contents.
   b. If the tube contents are spilled, discard and replace with a new Aptima vaginal swab specimen collection kit.
4. Immediately place swab into transport tube so the black score line is at the top of the tube.
5. Align the score line with the top edge of the tube and carefully break swab shaft.
   a. Swab will drop to bottom of the vial.
   b. Discard the top portion of the swab shaft.
6. Tightly screw cap onto tube.

D. ThinPrep Pap Vial

Note: Can ONLY be used on Women

1. Follow the ***Gynecological ThinPrep Procedure*** for collection instructions on pages 26-28.

E. Unisex Swab

Note: Can be used on both men and women

Note: Follow the gender specific collection instructions

1. Female (Cervical/Endocervical)
    a. Use cleaning swab (white shaft swab with red printing) to remove excess mucus from cervical os and surrounding mucosa.
        i. Discard this swab.
    b. Insert collection swab (blue shaft swab with green printing) into endocervical canal.
    c. Gently rotate swab clockwise for 10 to 30 seconds to help ensure adequate sampling.
        i. Withdraw swab carefully; avoid any contact with vaginal mucosa.
    d. While holding swab in hand, unscrew the tube cap.
        i. Do not spill tube contents.
        ii. If the tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.
    e. Carefully break the swab shaft at the score line against the side of the tube.
        i. Discard top portion of swab shaft.
    f. Re-cap swab specimen transport tube tightly.
2. Male (Urethral)

    Note: Patient should not have urinated for at least 1 hour prior to specimen collection.
    a. Discard cleaning swab (white shaft with red print on label).
        i. The cleaning swab is NOT needed for male specimen collection.
    b. Insert specimen collection swab (blue shaft swab with green printing) 2 cm to 4 cm into urethra.
    c. Gently rotate swab clockwise for 2 to 3 seconds in urethra to help ensure adequate sampling.
        i. Withdraw swab carefully.
    d. While holding swab in hand, unscrew tube cap.
        i. Do not spill tube contents.
        ii. If tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.
    e. Carefully break the swab shaft at the score line against the side of the tube.
        i. Discard top portion of swab shaft.
    f. Re-cap swab specimen transport tube tightly.

F. Urine Collection Kit

Note: Can be used on both men and women.

Note: Patient should not have urinated for at least 1 hour prior to specimen collection.

1. Direct patient to provide first-catch urine (approximately 20 to 30 mL of initial urine stream) into urine collection cup free of any preservatives.
2. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.
    a. Female patients should not cleanse labial area prior to providing specimen.

3. Remove cap from urine specimen transport tube and transfer 2 mL of urine into urine specimen transport tube using the disposable pipette provided.
4. The correct volume of urine has been added when the fluid level is between the black fill lines on urine specimen transport tube label.
5. Re-cap urine specimen transport tube tightly.

STORAGE & HANDLING

A. Store collection kits at room temperature (15°C to 30°C).

LIMITATIONS OF PROCEDURE

A. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen.
B. Do not use the kit after its expiration date to collect specimens.
C. Excessive use of lubricating jelly can interfere with test results.
D. Multitest Tubes received without the designated pink swab will be rejected.
E. Urine must be transferred to the Aptima Urine Specimen Transfer Tube within 24 hours of collection.
F. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens.
G. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers.
H. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
I. Specimen must adhere to the ***Acceptable Specimen Criteria***

HERPES SIMPLEX VIRUS 1 & 2

TEST

A. Herpes Simplex Virus 1 & 2 testing of lesions in the anogenital area of men and women.

SPECIMEN

A. Multitest Swab
- Orange Aptima Tube

PROCEDURE

A. Multitest Swab

Note: Can be used on men and women

Note: Do not use disinfectants or cleaners on the lesion before the specimen is collected.

1. Partially peel open the swab package.
2. Remove the swab.
   a. Do not touch the soft tip or lay the swab down.
   b. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection kit.
3. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line.
   a. Do not hold the swab shaft below the score line.
4. If needed, expose the base of the lesion to access fluid.
5. Vigorously swab the base of the lesion to absorb fluid, being careful not to draw blood.
   a. Withdraw the swab without touching any other site outside the lesion.
6. While holding the swab in the same hand, unscrew the cap from the tube.
   a. Do not spill the contents of the tube.
   b. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection kit.
7. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
8. Carefully break the swab shaft at the score line against the side of the tube.
   a. Discard the top portion of the swab shaft.
9. Tightly screw the cap onto the tube.

STORAGE & HANDLING

A. Store collection kit at room temperature (15°C to 30°C).

LIMITATIONS OF PROCEDURE

A. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen.
B. Do not use the kit after its expiration date to collect specimens.
C. Multitest Tubes received without the designated pink swab will be rejected.

D. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens.
E. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers.
F. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
G. Specimen must adhere to the ***Acceptable Specimen Criteria***

HUMAN PAPILLOMAVIRUS

TEST

A. Human papillomavirus testing of the cervical and endocervical area of women.

SPECIMEN

A. ThinPrep Pap Vial

PROCEDURE

A. ThinPrep Pap Vial
Note: Can ONLY be used on Women
Note: Must be from the cervical/endocervical area
1. Follow the ***Gynecological ThinPrep Procedure*** for collection instructions on pages 26-28.

STORAGE & HANDLING

A. Store collection kits at room temperature (15°C to 30°C).

LIMITATIONS OF PROCEDURE

A. Test only the indicated specimen type. The Aptima HPV assay has only been validated for use with cervical specimens collected in PreservCyt Solution using a broom-type or cytobrush/spatula collection device.
B. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen.
C. Do not use the kit after its expiration date to collect specimens.
D. Excessive use of lubricating jelly can interfere with test results.
E. Specimens may be infectious. Use Universal Precautions when collecting the sample.
F. Avoid cross-contamination during the specimen handling steps. Ensure that specimen containers do not contact one another, and discard used materials without passing over open containers. Change gloves if they come in contact with specimen.
G. This assay is not intended for use as a screening device for women under age 30 with normal cervical cytology.
H. The Aptima HPV assay is not intended to substitute for regular cervical cytology screening.
I. Detection of HPV using the Aptima HPV assay does not differentiate HPV types and cannot evaluate persistence of any one type.
J. The use of this assay has not been evaluated for the management of HPV vaccinated women, women with prior ablative or excisional therapy, hysterectomy, who are pregnant, or who have other risk factors (e.g., HIV+, immunocompromised, history of sexually transmitted infection).
K. The Aptima HPV assay 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.
L. Specimen must adhere to the ***Acceptable Specimen Criteria***

MYCOPLASMA GENITALIUM

TEST

A. Mycoplasma genitalium testing of the endocervical and vulvovaginal area of women and women's urine.
B. Mycoplasma genitalium testing of the urethral area of men and men's urine.

SPECIMEN

A. Multitest Swab
   - Orange Aptima Tube
B. Unisex Swab
   - White Aptima Tube
C. Urine Collection Kit
   - Yellow Aptima Tube

PROCEDURE

A. Multitest Swab

Note: Can ONLY be used on Women

Note: Must be from the vulvovaginal area

1. Partially open swab package and remove the swab.
   a. Do not touch the soft tip or lay the swab down.
   b. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima vaginal swab specimen collection kit.
2. Hold swab, placing thumb and forefinger in the middle of the swab shaft covering the black score line.
   a. Do not hold the swab shaft below the score line.
3. Carefully insert swab into vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds.
4. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Withdraw swab without touching the skin.
5. While holding the swab in hand, unscrew the tube cap.
   a. Do not spill tube contents.
   b. If the tube contents are spilled, discard and replace with a new Aptima vaginal swab specimen collection kit.
6. Immediately place swab into transport tube so the black score line is at the top of the tube.
7. Align the score line with the top edge of the tube and carefully break swab shaft.
   a. Swab will drop to bottom of the vial.
   b. Discard the top portion of the swab shaft.
8. Tightly screw cap onto tube.

B. Unisex Swab

Note: Can be used on both men and women

Note: Follow the gender specific collection instructions.

1. Female (Cervical/Endocervical)
    a. Use cleaning swab (white shaft swab with red printing) to remove excess mucus from cervical os and surrounding mucosa.
        i. Discard this swab.
    b. Insert collection swab (blue shaft swab with green printing) into endocervical canal.
    c. Gently rotate swab clockwise for 10 to 30 seconds to help ensure adequate sampling.
        i. Withdraw swab carefully; avoid any contact with vaginal mucosa.
    d. While holding swab in hand, unscrew the tube cap.
        i. Do not spill tube contents.
        ii. If the tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.
    e. Carefully break the swab shaft at the score line against the side of the tube.
        i. Discard top portion of swab shaft.
    f. Re-cap swab specimen transport tube tightly.
2. Male (Urethral)

    Note: Patient should not have urinated for at least 1 hour prior to specimen collection.

    a. Discard cleaning swab (white shaft swab with red printing).
        i. The cleaning swab is NOT needed for male specimen collection.
    b. Insert specimen collection swab (blue shaft swab with green printing) 2 cm to 4 cm into urethra.
    c. Gently rotate swab clockwise for 2 to 3 seconds in urethra to help ensure adequate sampling.
        i. Withdraw swab carefully.
    d. While holding swab in hand, unscrew tube cap.
        i. Do not spill tube contents.
        ii. If tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.
    e. Carefully break the swab shaft at the score line against the side of the tube.
        i. Discard top portion of swab shaft.
    f. Re-cap swab specimen transport tube tightly.

C. Urine Collection Kit

Note: Can be used on both men and women.

Note: Patient should not have urinated for at least 1 hour prior to specimen collection.

1. Direct patient to provide first-catch urine (approximately 20 to 30 mL of initial urine stream) into urine collection cup free of any preservatives.

2. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.
   a. Female patients should not cleanse labial area prior to providing specimen.
3. Remove cap from urine specimen transport tube and transfer 2 mL of urine into urine specimen transport tube using the disposable pipette provided.
4. The correct volume of urine has been added when the fluid level is between the black fill lines on urine specimen transport tube label.
5. Re-cap urine specimen transport tube tightly.

STORAGE & HANDLING

A. Store collection kits at room temperature (15°C to 30°C).

LIMITATIONS OF PROCEDURE

A. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen.
B. Do not use the kit after its expiration date to collect specimens.
C. Excessive use of lubricating jelly can interfere with test results.
D. Multitest Tubes received without the designated pink swab will be rejected.
E. Urine must be transferred to the Aptima Urine Specimen Transfer Tube within 24 hours of collection.
F. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens.
G. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers.
H. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
I. Specimen must adhere to the ***Acceptable Specimen Criteria***

TRICHOMONAS VAGINALIS

TEST

A. Trichomonas vaginalis testing of the endocervical and vulvovaginal area of women and women's urine.
B. Trichomonas vaginalis testing of the urethral area of men and men's urine.

Note: We are not validated for testing on men, or urine. These will be sent out to a reference lab.

SPECIMEN

A. Multitest Swab
   - Orange Aptima Tube
B. ThinPrep Pap Vial
C. Unisex Swab
   - White Aptima Tube
D. Urine Collection Kit
   - Yellow Aptima Tube

PROCEDURE

A. Multitest Swab

Note: Can ONLY be used on Women

Note: Must be from the vulvovaginal area

1. Partially open swab package and remove the swab.
   a. Do not touch the soft tip or lay the swab down.
   b. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima vaginal swab specimen collection kit.
2. Hold swab, placing thumb and forefinger in the middle of the swab shaft covering the black score line.
   a. Do not hold the swab shaft below the score line.
3. Carefully insert swab into vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds.
4. Make sure the swab touches the vagina walls so that moisture is absorbed by the swab. Withdraw swab without touching the skin.
5. While holding the swab in hand, unscrew the tube cap.
   a. Do not spill tube contents.
   b. If the tube contents are spilled, discard and replace with a new Aptima vaginal swab specimen collection kit.
6. Immediately place swab into transport tube so the black score line is at the top of the tube.
7. Align the score line with the top edge of the tube and carefully break swab shaft.
   a. Swab will drop to bottom of the vial.
   b. Discard the top portion of the swab shaft.
8. Tightly screw cap onto tube.

B. ThinPrep Pap Vial

Note: Can ONLY be used on Women

1. Follow the ***Gynecological ThinPrep Procedure*** for collection instructions on pages 26-28.

C. Unisex Swab

Note: Can be used on both men and women

Note: Follow the gender specific collection instructions.

1. Female (Cervical/Endocervical)
   a. Use cleaning swab (white shaft swab with red printing) to remove excess mucus from cervical os and surrounding mucosa.
      i. Discard this swab.
   b. Insert collection swab (blue shaft swab with green printing) into endocervical canal.
   c. Gently rotate swab clockwise for 10 to 30 seconds to help ensure adequate sampling.
      i. Withdraw swab carefully; avoid any contact with vaginal mucosa.
   d. While holding swab in hand, unscrew the tube cap.
      i. Do not spill tube contents.
      ii. If the tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.
   e. Carefully break the swab shaft at the score line against the side of the tube.
      i. Discard top portion of swab shaft.
   f. Re-cap swab specimen transport tube tightly.
2. Male (Urethral)

Note: Patient should not have urinated for at least 1 hour prior to specimen collection.

   a. Discard cleaning swab (white shaft swab with red printing on label).
      i. The cleaning swab is NOT needed for male specimen collection.
   b. Insert specimen collection swab (blue shaft swab with green printing) 2 cm to 4 cm into urethra.
   c. Gently rotate swab clockwise for 2 to 3 seconds in urethra to help ensure adequate sampling.
      i. Withdraw swab carefully.
   d. While holding swab in hand, unscrew tube cap.
      i. Do not spill tube contents.
      ii. If tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.
   e. Carefully break the swab shaft at the score line against the side of the tube.
      i. Discard top portion of swab shaft.
   f. Re-cap swab specimen transport tube tightly.

D. **Urine Collection Kit
Up to a 3% lower sensisitivity

Note: Can be used on both men and women.
Note: Patient should not have urinated for at least 1 hour prior to specimen collection.
Note: Will be sent out to a reference lab for testing. Turnaround time will be delayed.

1. Direct patient to provide first-catch urine (approximately 20 to 30 mL of initial urine stream) into urine collection cup free of any preservatives.
2. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.
   a. Female patients should not cleanse labial area prior to providing specimen.
3. Remove cap from urine specimen transport tube and transfer 2 mL of urine into urine specimen transport tube using the disposable pipette provided.
4. The correct volume of urine has been added when the fluid level is between the black fill lines on urine specimen transport tube label.
5. Re-cap urine specimen transport tube tightly.

STORAGE & HANDLING

A. Store collection kits at room temperature (15°C to 30°C).

LIMITATIONS OF PROCEDURE

A. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen.
B. Do not use the kit after its expiration date to collect specimens.
C. Excessive use of lubricating jelly can interfere with test results.
D. Multitest Tubes received without the designated pink swab will be rejected.
E. Urine must be transferred to the Aptima Urine Specimen Transfer Tube within 24 hours of collection.
F. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens.
G. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers.
H. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
I. Specimen must adhere to the ***Acceptable Specimen Criteria***

MULTITEST COLLECTION TESTS

SPECIMEN

A. Multitest Swab
- Orange Aptima Tube

TESTING

A. A list of testing based on gender and collection
1. Women
   a. Vulvovaginal
      i. Bacterial vaginosis
      ii. Candida vaginitis
      iii. Chlamydia trachomatis and Gonorrhea neiserria
      iv. Trichomonas vaginalis
      v. Mycoplasma gentalium
      vi. Herpes simplex 1 & 2
   b. Anogenital
      i. Herpes simplex 1 & 2
   c. Throat
      i. Chlamydia trachomatis and Gonorrhea neiserria
   d. Rectal
      i. Chlamydia trachomatis and Gonorrhea neiserria
2. Men
   a. Penile
      i. Herpes simplex 1 & 2
   b. Anogenital
      i. Herpes simplex 1 & 2
   e. Throat
      i. Chlamydia trachomatis and Gonorrhea neiserria
   f. Rectal
      i. Chlamydia trachomatis and Gonorrhea neiserria

LIMITATIONS OF TESTING

A. Use the provided swab only. Failure to use the provided swab will result in specimen rejection.
B. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
C. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
D. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.

E. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Aptima Multitest Swab Specimen Collection Kit. Failure to use a new kit may invalidate the test results.
F. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
G. Do not use the kit after its expiration date to collect specimens.

UNISEX COLLECTION TESTS

SPECIMEN

A. Unisex Swab
   - White Aptima Tube

TESTING

A. A list of testing based on gender and collection
   1. Women
      a. Cervical/ Endocervical
         i. Chlamydia trachomatis and Gonorrhea neiserria
         ii. Mycoplasma genitalium
         iii. Trichomonas vaginalis
   2. Men
      a. Urethral
         i. Chlmaydia trachomatis and Gonorrhea neiserria
         ii. Mycoplasma genitalium
         iii. Trichomonas vaginalis

         Note: Unisex swabs for male trichomonas vaginalis will be sent to a reference lab.

LIMITATIONS OF TESTING

A. The performance of male urethral swab specimens has not been established for the Aptima Trichomonas vaginalis assay.
B. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
C. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
D. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
E. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Aptima Unisex Swab Specimen Collection Kit. Failure to use a new kit may invalidate the test results.
F. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
G. Do not use the kit after its expiration date to collect specimens.

URINE COLLECTION TEST KIT

SPECIMEN

A. Urine Collection Kit
   - Yellow Aptima Tube

TESTING

A. A list of testing based on gender and collection
   1. Women
      a. Chlamydia trachomatis and Gonorrhea neiserria
      b. Mycoplasma genitalium
      c. Trichomonas vaginalis
   2. Men
      a. Chlamydia trachomatis and Gonorrhea neiserria
      b. Mycoplasma genitalium
      c. Trichomonas vaginalis

Note: Men and women's urine collection kits for Trichomonas vaginalis will be sent to a reference lab.

Note: Turnaround time for results will be delayed.

LIMITATIONS OF TESTING

A. The patient should not have urinated for at least 1 hour prior to specimen collection.
B. Do not apply the transport medium directly to skin or mucous membranes or take internally.
C. Collection of larger volumes (above 30 mL) of urine may result in rRNA target dilution that may reduce test sensitivity.
D. Female patients should not cleanse the labial area prior to providing the specimen
E. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
F. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
G. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Aptima Urine Collection Kit. Failure to use a new kit may invalidate the test results.
H. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.
I. Do not use the kit after its expiration date to collect specimens.

FIXATION

I. Principle: A fixative alters tissue and cells by rendering their constituents insoluble with protein as the primary target for stabilization. This process prevents cell distortion and maintains true morphologic structure. Distortion due to improper fixation nearly always prevents proper and accurate evaluation of the cell population.

II. Specimen
- A. Glass slides
  1. Spread specimen evenly over the slide and fix immediately.
     - a. Spray Fixative
     - b. 95% Ethyl Alcohol (in spill proof slide holder)
- B. Fluid Specimen
  1. Fluid cytology specimens are fixed by adding an equal volume of CytoLyt fixative.

III. Procedure
- A. Types of fixatives:
  1. 95% Ethyl Alcohol (wet fixation) Fixative
     - a. 95% Ethyl Alcohol is widely accepted as an ideal cellular fixative for cytologic smears.
     - b. Freshly prepared smears are immersed immediately into fixative. Fixation occurs in 5 to 30 min.
  2. CytoLyt Solution
     - a. CytoLyt Solution is a methanol-based, buffered, preservative solution designed to lyse red blood cells, prevent protein precipitation, dissolve mucus, and preserve morphology of general cytology samples.
     - b. It is intended as a transportation medium and is used in specimen preparation prior to processing. It is not intended for complete inactivation of microbes.
     - c. It is the fixative of choice for fluid.
  3. Air Drying
     - a. Air drying is the absence of fixation
     - b. Air drying produces artifacts and cellular distortion and may lead to misinterpretation of smears.
     - c. Air dried smears may be used in certain types of specimens i.e., lymph node.
  4. Cytology Spray Fixative
     - a. Cytology Fixative spray is widely accepted as an ideal cellular fixative for cytologic smears.
     - b. Freshly prepared smears are immediately sprayed with the fixative.

ACCEPTANCE & REJECTION OF NON-GYNECOLOGICAL SPECIMENS

I. Principle: To define which specimens are acceptable for processing, to document specimens that are not acceptable, to identify sources of problems that render specimens unacceptable, and to seek solutions to these problems.

II. Specimen
   A. All NON-GYNECOLOGICAL specimens

III. Quality Control
   A. Document Discrepancies
      An ***Unacceptable Specimen Log*** will be submitted with the requisition.

IV. Procedure
   A. Specimens must be delivered to the laboratory as soon as possible after collection, or they must be placed in fixative and/or refrigerated until delivery to the laboratory. Individual specimen guidelines for delivery follow:

Specimen	Fresh	Fixative
Body cavity fluids	48 Hours	2 weeks
Bronchial Brushings/Washings	48 Hours	2 weeks
CSF (cerebrospinal fluid)	ASAP	ASAP
Gastrointestinal Brushings/ Washings	48 hours	2 weeks
Sputum	48 hours	2 weeks
Urine	48 hours	2 weeks

   B. All "**Fresh**" specimens will need to be refrigerated (2 to 8°C) to help preserve the specimen.
   C. Specimens not adhering to the above requirements may be returned to the submitting physician to be properly identified; for specimens received without proper prior handling, including prompt delivery, fixation, or refrigeration, the submitting physician is notified of the problem. An Unacceptable Specimen Log will be submitted and attached to the requisition.

Procedure Notes: Specimens for which multiple tests are ordered MUST be separated by collecting physician for each of the laboratories requiring a specimen. The lab is not responsible for separating specimens.

BODY FLUIDS

I. Principle

A. Collection of fluid from one of the three body cavities and cysts from other areas of the body to rule out metastatic or primary cancer.

II. Specimen

A. Body Fluids:
1. Pleural – Thoracentesis
2. Peritoneal Cavity – Ascites
3. Pericardium – Pericardial

III. Reagents and Supplies
Provided by Clinical Pathology Associates Laboratory to the ordering physician

A. CytoLyt fluid
B. 95% Ethyl Alcohol

IV. Quality Control

A. Specimen should be submitted immediately to the laboratory or an equal volume of CytoLyt fixative added to the fluid. Body fluids may be stored in the refrigerator for a short term (overnight) without fixative.

V. Procedure

A. Immediately fix the specimen with at least an equal volume of CytoLyt.
B. For larger volume specimens, a minimum of 50mL of the specimen should be submitted.
C. Tighten the cap and mix the contents thoroughly.
D. Package the specimen
E. Verify that the specimen is properly labeled, the requisition is complete, and package the specimen in a biohazard bag.

VI. Handling and Transport

A. CytoLyt Specimens
1. Must stay at room temperature (15 to 30°C).
2. Cells are only stable for 8 days after collection.
B. Fresh
1. Must be refrigerated (2 to 8°C) to help preserve the specimen.
2. Must be received ASAP

VII. Limitation of Procedure

A. Failure to immediately deliver specimen to the laboratory or to add CytoLyt fixative if specimen is delayed.
B. Failure to obtain sufficient fluid.
C. Failure to store the specimen in the correct temperature

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

BREAST SECRETIONS

I. Principle

A. Collection of fluid discharged from the breast to rule out cancer

II. Specimen

A. Breast Fluid

III. Reagents and Supplies
Provided by Clinical Pathology Associates Laboratory to the ordering physician

A. Glass slides
B. 95% Ethyl Alcohol
C. Cell Fixative Spray

IV. Quality Control

A. Proper collection technique
B. Immediate fixation of slide

V. Procedure

A. Secretion expressed at the nipple should be smeared lengthwise onto a labeled slide.
B. When the secretion is scanty, the slide is touched lightly against the nipple a few times making several touch preparations on one slide.
C. Fix immediately
    1. Submerging slide into 95% Ethyl Alcohol
    2. Spraying with Cytology Spray Fixative
D. Package the specimen
E. Verify that the specimen is properly labeled, the requisition is complete, and package the specimen in a biohazard bag.

VI. Handling and Transport

A. All fixed forms of specimen
    1. Must stay at room temperature (15 to 30°C).

VII. Limitation of Procedure

A. Broken slide
B. Failure to immediately spray fix slides
C. Failure to obtain adequate cell sample

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

BRONCHIAL BRUSHINGS

I. Principle

A. Collect bronchial brushing for cytological examination.

II. Specimen

A. Bronchial brushings are obtained and collected during endoscopic examination.

III. Reagents and Supplies
Provided by Clinical Pathology Associates Laboratory to the ordering physician

A. CytoLyt fixative
B. Glass Slides
C. 95% Ethyl Alcohol
D. Cell Fixative Spray

IV. Quality Control

A. Immediate fixation of prepared smears.
B. Specimen should be submitted immediately to the laboratory, or the brush must be submersed in CytoLyt fixative.
C. Fresh specimens MUST be stored in the refrigerator for a short term (overnight) without fixative.

V. Procedure

A. Label CytoLyt container or slides with the patient's first and last name
B. Direct Smear
    1. Roll the brush gently over 2/3 of the glass slides
    2. Spray and fix immediately
C. CytoLyt
    1. The brush is thoroughly washed in CytoLyt fixative, if the brush is disposable keep it in the container.
D. Package the specimen
E. Verify that the specimen is properly labeled, the requisition is complete, and package the specimen in a biohazard bag.

VI. Handling and Transport

A. All fixed forms of specimen
    1. Must stay at room temperature (15 to 30°C).
B. Fresh
    1. Must be refrigerated (2 to 8°C) to help preserve the specimen.
    2. Must be received ASAP

VII. Limitations of Procedure

A. If direct smears are made at the site of the procedure, special care must be taken to avoid air-drying and to fix promptly.

B. Failure to immediately deliver specimen to the laboratory or to add CytoLyt fixative if specimen is delayed.

BRONCHIAL WASHINGS

I. Principle

A. Collect bronchial washing specimens for cytological examination.

II. Specimen

A. Bronchial brushings are obtained and collected during endoscopic examination.

III. Reagents and Supplies
Provided by Clinical Pathology Associates Laboratory to the ordering physician

A. CytoLyt fixative
B. 95% Ethyl Alcohol

IV. Quality Control

A. Specimen should be submitted immediately to the laboratory or an equal volume of CytoLyt fixative added to the fluid.
B. Fresh specimens MUST be stored in the refrigerator for a short term (overnight) without fixative.

V. Procedure

A. Label the CytoLyt/Fixative container with the patient's first and last name
B. Immediately fix the specimen with at least an equal volume of CytoLyt or 95% ethyl alcohol.
C. Tighten the cap and mix thoroughly
D. Package the specimen
E. Verify that the specimen is properly labeled, the requisition is complete, and package the specimen in a biohazard bag.

VI. Handling and Transport

A. All fixed forms of specimen
   1. Must stay at room temperature (15 to 30°C).
B. Fresh
   1. Must be refrigerated (2 to 8°C) to help preserve the specimen.
   2. Must be received ASAP

VII. Limitations of Procedure

A. Failure to immediately deliver specimen to the laboratory or to add CytoLyt fixative if specimen is delayed.

CEREBROSPINAL FLUID

I. Principle

A. Collect Cerebrospinal fluid for cytological examination.

II. Specimen

A. Cerebrospinal fluid is a water cushion protecting the brain and spinal cord. The fluid is clear and colorless under normal conditions. Cerebrospinal fluid is obtained by a spinal puncture.

III. Reagents and Supplies
Provided by Clinical Pathology Associates Laboratory to the ordering physician

A. CytoLyt fixative
B. Fresh

IV. Quality Control

A. Specimens should be submitted immediately to the laboratory or an equal volume of CytoLyt fixative added to the fluid.
B. Fragile cells and diagnostic material may disintegrate in less than an hour and yield a false-negative assessment.
C. CytoLyt fixative is the better option if immediate processing is not possible.
D. Accurate patient history is vital.

V. Procedure

A. Label the “fresh” or CytoLyt container with the patient’s first and last name
B. Immediately fix the specimen with at least an equal volume of CytoLyt or 95% ethyl alcohol.
C. Tighten the cap and mix thoroughly
D. Package the specimen
E. Verify that the specimen is properly labeled, the requisition is complete, and package the specimen in a biohazard bag.

VI. Handling and Transport

A. All fixed forms of specimen
   1. Must stay at room temperature (15 to 30°C).
B. Fresh
   1. Must be refrigerated (2 to 8°C) to help preserve the specimen.
   2. Must be received ASAP

VII. Limitations of Procedure

A. Failure to immediately deliver specimen to the laboratory or to add CytoLyt fixative if specimen is delayed.
B. Failure to provide accurate patient history.
C. Contamination by a bloody tap or aspiration of solid material.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

FINE NEEDLE ASPIRATION

I. Principle

A. Cellular material is obtained by Fine Needle Aspiration of solid and cystic masses to be evaluated for malignancy and benign inflammatory conditions.

II. Specimen

A. Cellular material is obtained from a mass by negative pressure into a syringe and the aspirated sample is expelled into a fixative.

III. Reagents and Supplies
Provided by Clinical Pathology Associates Laboratory to the ordering physician

A. CytoLyt
B. 95% Ethyl Alcohol
C. Cytology Fixative Spray

IV. Quality Control

A. Specimen should be submitted immediately to the laboratory or an equal volume of CytoLyt fixative added to the fluid.
B. Fresh specimens MUST be stored in the refrigerator for a short term (overnight) without fixative. DO NOT submit the needle to the laboratory, discard according to regulations.

V. Procedure

A. Label the CytoLyt/Fixative container or slides with the patient's first and last name
   1. Direct Smear
      a. Place a drop of the fine needle aspirate onto the slide and smear/spread the material evenly over the slide.
   2. CytoLyt
      a. Express the obtained cellular material into the CytoLyt/Fixative. A "flushing or rinse" technique should be used to maximize the cellular richness of the specimen.
B. Package the specimen
C. Verify that the specimen is properly labeled, the requisition is complete, and package the specimen in a biohazard bag.

VI. Handling and Transport

A. All fixed forms of specimen
   1. Must stay at room temperature (15 to 30°C).
B. Fresh
   1. Must be refrigerated (2 to 8°C) to help preserve the specimen.
   2. Must be received ASAP

VII. Limitations of Procedure

A. Failure to immediately deliver specimen to the laboratory or to add CytoLyt fixative if specimen is delayed.
B. A negative diagnosis may reflect improper needle insertion and does not rule out a malignant neoplasm.

SPUTUM

I. Principle

A. Collection of deep lung material for cytological examination

II. Specimen

A. Sputum, spontaneously produced expectorates

III. Reagents and Supplies
Provided by Clinical Pathology Associates Laboratory to the ordering physician:

A. CytoLyt

IV. Quality Control

A. Specimen should be submitted immediately to the laboratory or an equal volume of CytoLyt fixative added to the fluid.
B. Fresh specimens MUST be stored in the refrigerator for a short term (overnight) without fixative.

V. Procedure

A. Label the CytoLyt container with the patient's first and last name
   1. The patient is given three wide-mouth specimen bottles.
      a. One container to be used each morning for three consecutive mornings.
      b. Patients are instructed to rinse their mouths out with water upon arising.
      c. Cough and expectorate into the specimen bottle a volume of 4 – 5 tablespoons of deep lung sputum.
B. Transfer specimen to conical tubes containing CytoLyt and agitate to distribute the fixative throughout the specimen.
C. The three specimens are returned to the laboratory for processing where they may be pooled into one.

Note: Non-coughing patients should be assisted with aerosol instrumentation.

D. Package the specimen
E. Verify that the specimen is properly labeled, the requisition is complete, and package the specimen in a biohazard bag.

VI. Handling and Transport

A. All fixed forms of specimen
   1. Must stay at room temperature (15 to 30°C).
B. Fresh
   1. Must be refrigerated (2 to 8°C) to help preserve the specimen.
   2. Must be received ASAP

VII. Limitations of Procedure

A. Failure to immediately deliver specimen to the laboratory or to add CytoLyt fixative if specimen is delayed.
B. Failure to obtain deep lung material

C. Obtaining materials from the tongue or nasal areas

TZANCK SMEAR

I. Principle

A. Collection of inflammatory/infectious process of the skin, for Cytology evaluation.

II. Specimen

A. Cellular material from lesions

III. Reagents and Supplies

Provided by Clinical Pathology Associates Laboratory to the ordering physician

A. Glass slides
B. Cytology Spray Fixative
C. 95% Ethyl Alcohol

IV. Quality Control

A. Proper collection technique
B. Immediate fixation of slide

V. Procedure

A. Unroof blister and lightly scrape blister base at the edges with a curette.
B. Smear specimen onto labeled slide.
C. Spray slide with spray fixative or place in 95% Ethyl Alcohol.
D. Fix immediately
    1. Submerging slide into 95% Ethyl Alcohol
    2. Spraying with Cytology Spray Fixative
E. A second slide may be touched lightly against the area several times, making several touch preparations on the slide.
F. Package the specimen
G. Verify that the specimen is properly labeled, the requisition is complete, and package the specimen in a biohazard bag.

VI. Handling and Transport

A. All fixed forms of specimen
    1. Must stay at room temperature (15 to 30°C).

VII. Limitation of Procedure

A. Broken slide
B. Failure to immediately spray fix slides
C. Failure to obtain adequate cell sample

CLIENT SERVICE MANUAL

URINE

I. Principle

A. Collecting either a “voided urine specimen” or a “catheterized urine specimen” for cytological examination; concentrating cells into a monolayer for the detection of cancerous or viral infections and conditions of the urinary tract.

II. Specimen

A. Urine:
B. Void urine (clean catch)
C. Catheterized urine
   1. Bladder
   2. Ureters
   3. Renal pelvis

III. Reagents and Supplies
Provided by Clinical Pathology Associates Laboratory to the ordering physician:

A. CytoLyt

IV. Quality Control

A. Voided Urine
   1. Proper collection technique to avoid contamination by cells from outside the urinary passages.
   2. Correct time of specimen collection to avoid cell degeneration.
   3. Prompt delivery of specimen to the laboratory for processing or immediate fixation in CytoLyt fixative.
B. Catheterized urine and Bladder wash:
   1. Instrumentation effect on the cells.

V. Procedure

A. Voided Urine
   1. The patient is given a wide-mouthed specimen bottle.
      a. Collection should be made approximately three hours after the initial morning void.
      b. The patient should increase their intake of water.
      c. Usually, 100-300 mL of urine will be submitted.
      d. Female patients should thoroughly clean the vulva area to assist in avoiding contamination from the vagina, cervix, and endometrium.
B. Catheterized Urine
   1. Involves an invasive procedure with attendant risk and is suitable for special situations.
C. Bladder irrigation specimens
   1. Obtained by vigorously irrigating the bladder lumen via a catheter with saline or similar solutions.
   2. Obtains a large number of well-preserved cells.
   3. Has the same disadvantage of catheterization technique.

VI. Handling and Transport

A. All fixed forms of specimen
   1. Must stay at room temperature (15 to 30°C).
B. Fresh
   1. Must be refrigerated (2 to 8°C) to help preserve the specimen.
   2. Must be received ASAP

VII. Limitation of Procedure

A. Voided Urine:
   1. Contamination by cells originating outside the urinary passages.
   2. Cells degenerated from prolonged exposure to urine.
   3. Sparse cellularity
   4. Failure to promptly submit specimen to the laboratory or to fix in CytoLyt.
B. Catheterized Urine
   1. Instrumentation effect on cells.
   2. Failure to promptly submit specimen to the laboratory or to fix in CytoLyt.
C. Bladder Irrigation:
   1. Instrumentation effect on cells
   2. Failure to promptly submit specimen to the laboratory or to fix in CytoLyt.

URINE SEND OUT FISH

I. Principle

Preparing either a "voided urine specimen" or a "catheterized urine specimen" for reference laboratory sent out for Fluorescent In-Situ Hybridization (FISH) examination.

II. Specimen

A. Urine:
B. Void urine (clean catch)
C. Catheterized urine
   1. Bladder
   2. Ureters
   3. Renal pelvis

III. Reagents and Supplies

Provided by Clinical Pathology Associates Laboratory to the ordering physician

A. Specimen Collection Cup
B. PreservCyt

IV. Quality Control

A. Voided Urine
   1. Proper collection technique to avoid contamination by cells from outside the urinary passages.
   2. Correct time of specimen collection to avoid cell degeneration.
   3. Prompt delivery of specimen to the laboratory for processing or immediate fixation in CytoLyt fixative.
B. Catheterized urine and Bladder wash:
   1. Instrumentation effect on the cells.

V. Procedure

A. You will need a minimum of 33mL of urine
B. Mix specimen thoroughly by inverting the specimen collection cup several times to ensure a homogenous solution
C. Immediately add PreservCyt in 2:1, urine to PreservCyt ratio (PreservCyt volume 30mL)
D. Decomposition of urine begins within 30 minutes.
E. Immediately store urine/preservative mixture in the refrigerator until ready for transport.

VI. Handling and Transportation

A. All fixed forms of specimen
   1. Must stay at room temperature (15 to 30°C).
B. Fresh
   1. Must be refrigerated (2 to 8°C) to help preserve the specimen.
   2. Must be received ASAP

VII. Limitation of Procedure

A. Specimen with no fixative needs to be refrigerated
B. Specimen needs to be received by the laboratory ASAP
C. Not all bladder cancers can be detected by the Urine FISH Panel.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

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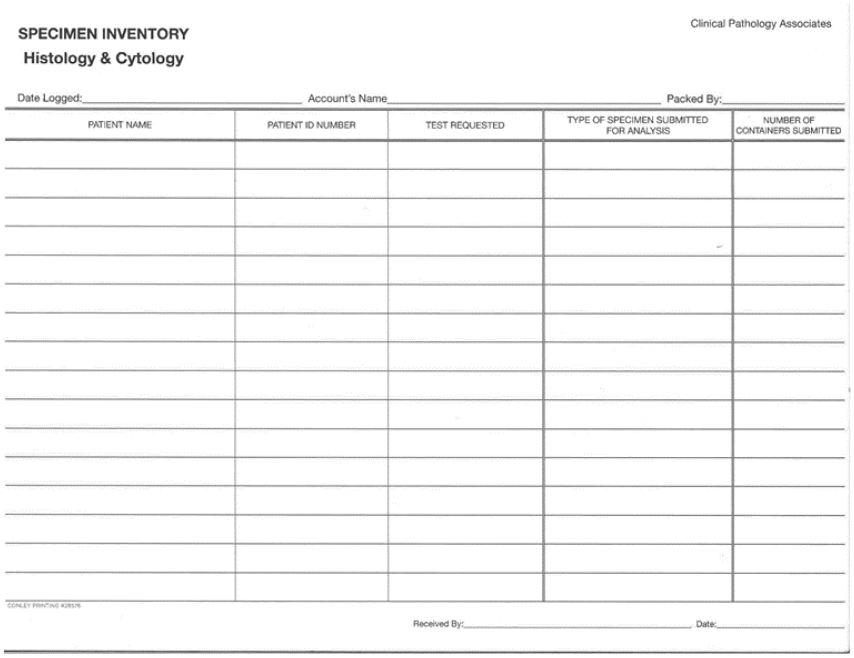
CLIENT SERVICE MANUAL

APPENDIX I

Specimen Inventory Log

SPECIMEN INVENTORY LOG



SPECIMEN INVENTORY
Histology & Cytology

Clinical Pathology Associates

Date Logged:_____ Account's Name_____ Packed By:_____

PATIENT NAME	PATIENT ID NUMBER	TEST REQUESTED	TYPE OF SPECIMEN SUBMITTED FOR ANALYSIS	NUMBER OF CONTAINERS SUBMITTED

CONLEY PRINTING #28576

Received By:_____ Date:_____

It is recommended that the client complete a ***Specimen Inventory Log*** for tracking purposes.

The log should be submitted with the specimens and a copy should be retained for your records.

Note: The Specimen Inventory Log has a carbon copy attached.

- White Copy- Client Copy
- Yellow Copy- Lab Copy
-

Specimen Inventory Logs are provided by Clinical Pathology Associates at the client's request.

Information needed on the ***Specimen Inventory Log***

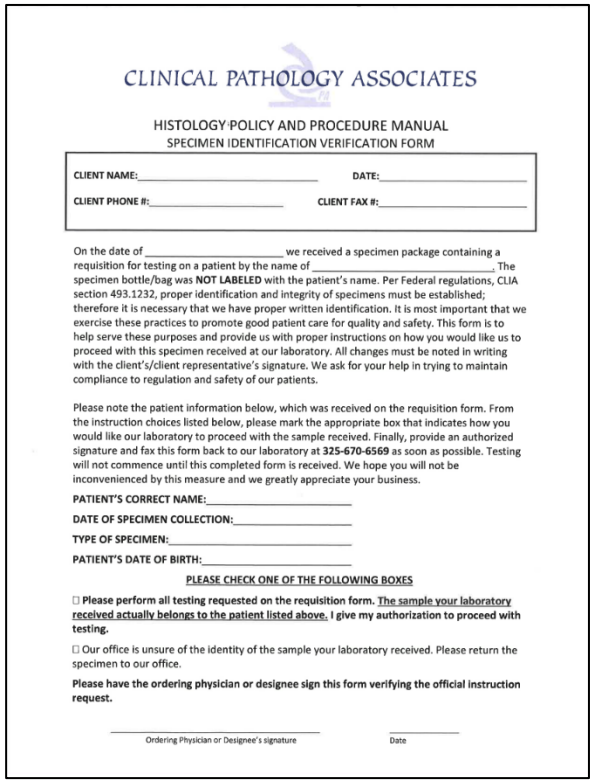
- Patient's name
- Patient's ID number (if applicable)
- Test requested
- Specimen
- Number of containers submitted

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

Specimen Identification Verification Form

SPECIMEN IDENTIFICATION VERIFICATION FORM



CLINICAL PATHOLOGY ASSOCIATES

HISTOLOGY POLICY AND PROCEDURE MANUAL
SPECIMEN IDENTIFICATION VERIFICATION FORM

CLIENT NAME:_____ DATE:_____

CLIENT PHONE #:_____ CLIENT FAX #:_____

On the date of _____ we received a specimen package containing a requisition for testing on a patient by the name of _____. The specimen bottle/bag was **NOT LABELED** with the patient's name. Per Federal regulations, CLIA section 493.1232, proper identification and integrity of specimens must be established; therefore it is necessary that we have proper written identification. It is most important that we exercise these practices to promote good patient care for quality and safety. This form is to help serve these purposes and provide us with proper instructions on how you would like us to proceed with this specimen received at our laboratory. All changes must be noted in writing with the client's/client representative's signature. We ask for your help in trying to maintain compliance to regulation and safety of our patients.

Please note the patient information below, which was received on the requisition form. From the instruction choices listed below, please mark the appropriate box that indicates how you would like our laboratory to proceed with the sample received. Finally, provide an authorized signature and fax this form back to our laboratory at **325-670-6569** as soon as possible. Testing will not commence until this completed form is received. We hope you will not be inconvenienced by this measure and we greatly appreciate your business.

PATIENT'S CORRECT NAME:_____

DATE OF SPECIMEN COLLECTION:_____

TYPE OF SPECIMEN:_____

PATIENT'S DATE OF BIRTH:_____

PLEASE CHECK ONE OF THE FOLLOWING BOXES

☐ **Please perform all testing requested on the requisition form. The sample your laboratory received actually belongs to the patient listed above. I give my authorization to proceed with testing.**

☐ Our office is unsure of the identity of the sample your laboratory received. Please return the specimen to our office.

Please have the ordering physician or designee sign this form verifying the official instruction request.

_____ _____
Ordering Physician or Designee's signature Date

The ***Specimen Identification Verification Form*** will be sent when specimens are not labeled by the client.

> Per Federal regulations, CLIA section 493.1232, proper identification and integrity of specimens must be established; therefore, it is necessary that we have proper written identification.

It is important that we exercise these practices to promote good patient care for quality and safety. This form is to help serve these purposes and provide us with proper instructions on how the client would like us to proceed.

Our laboratory personnel will notify the client of the discrepancy and request a valid fax number for the client.

The client will need to review the information and verify that specimen belongs to the patient.

The client will need to complete the following:

- Patient's Correct Name:
- Date of Specimen Collection:
- Type of Specimen:
- Patient's Date of Birth:

The client will need to check one of the following boxes:

☐ Please perform all testing requested on the requisition form. <u>The sample your laboratory received actually belongs to the patient listed above.</u> I give my authorization to proceed with testing.

☐ Our office is unsure of the identity of the sample your laboratory received. Please return the specimen to our office.

The client will need to sign, date, and fax the form back to Clinical Pathology Associates.

PERMITS AND RELEASES

DISPOSAL PERMIT

All extremity amputations must be released to Clinical Pathology Associates (CPA). The patient must consent to the relinquishment of said tissues. CPA will attempt to obtain the **Disposal Permit** by contacting the surgical facility or ordering provider. If the **Disposal Permit** is not received within 14 days of the final pathology report CPA reserves the right to return the extremity amputation to the surgical facility.

Due to the state guidelines of disposal for pathologic tissues (i.e., extremity amputations) and the lack of fixation on said tissues. All extremity amputations will be disposed of as soon as the final pathology report is issued.

The patient may request for the extremity amputation to be released to them. Requests for extremity amputations will not be honored unless for religious, cultural, or burial purposes because of the significant biological and chemicals hazards.

Please have the patient complete the **Specimen Release Form**.

Extremity amputations will **ONLY** be released to the funeral home and/or the surgical facility for funeral home pick up.

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

DISPOSAL OF EXTREMITIES PERMIT

I (we) hereby authorize Clinical Pathology Associates to dispose of:

_____

Removed by Dr._____ at _____ Hospital

On the date of _____

I (we) consent to the relinquishment of said amputated parts and the disposal of said amputated parts including but not limited to such parts as well as any other tissue removed during this operation. It is also understood that the parts removed will be disposed of by Clinical Pathology Associates according to state disposal regulations.

Patient signature:_____ Date:_____

Witness signature: _____ Date:_____

Or, in the event that the patient is not capable (whether physically or mentally) of signing for themselves:

Next of kin signature: _____ Date:_____

Witness signature:_____ Date:_____

SPECIMEN RELEASE

A patient may request to have their specimen or part of the specimen released to them. Requests for wet tissue will not be honored unless for religious, cultural, or burial purposes because of the significant biological and chemicals hazards.

I. Allowances for specimen release
   - A. Religious purposes
   - B. Cultural purposes
   - C. Legal purposes
   - D. Burial purposes
   - E. Manufacturer's request for medical devices
   - F. Hospital Risk Management requests
   - G. Gallstones
   - H. All other requests will not be honored due to significant biological and chemical hazards.

II. Procedure
   - A. Requests for specimen release must be submitted to Clinical Pathology Associates (CPA).
     1. A specimen release form must be completed and received by CPA within 14 days following the date of the surgery.
     2. If a release form is not received within 14 days, the request will be deemed informal.
     3. All informal requests (i.e., requests written on requisitions and verbal requests over the phone) will not be honored and the specimen may be disposed of per normal protocol.
   - B. If an informal request is made, a release form will be sent to the physician's office for completion.
     1. CPA is not responsible for directly contacting the patient

CLINICAL PATHOLOGY ASSOCIATES

CLIENT SERVICE MANUAL

SPECIMEN RELEASE FORM

RE: Release of _____

I understand that surgical specimens are the property of Clinical Pathology Associates (CPA), and that CPA will release the specimen listed above to me at their discretion. By signing this paper, I understand that I undertake all responsibility in the handling of this tissue/specimen. CPA cannot be held liable for any reason once the tissue specimen is under my control or the control of my designee.

I understand that the specimen has been exposed to 10% formalin which has the following caution:

- **FORMALDEHYDE:** Toxic by inhalation and if swallowed. Irritating the eyes, respiratory system, and skin. May cause sensitization by inhalation or skin contact. Risk of serious damage to the eyes. May cause cancer. Repeated or prolonged exposure increases the risk.
- I further understand that the specimen is considered a biohazard. Although the specimen has been disinfected in 10% formalin for a minimum of 72 hours there may still be a risk of infection.

Specimens may be retrieved from Clinical Pathology Associates 14 days after surgery. Please contact CPA at 325-670-6527 to ensure specimen is prepared for retrieval. CPA will **not** initiate contact with you to retrieve the specimen. CPA will hold the specimen up to 42 days after the date of surgery. Once the 42-day period elapses, the request for release will be voided and the specimen will be discarded per the appropriate protocol.

Designate who will retrieve the specimen:

- ❑ Patient will pick up
- ❑ Designee will retrieve specimen (Full name: _____)

Location:

- ❑ Clinical Pathology Associates
- ❑ Courier transport to provider location/client hospital
  (Facility's name: _____)
  (Courier name:_____)
- ❑ Funeral Home will pick up (Funeral Home: _____)

HIPAA DISCLOSURE: I have been fully advised of my rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and I intend for this authorization to satisfy the requirements of HIPAA. In regard that I certify that I consent to the release of my specimen (protected information) to any designee stated above.

I, _____(print), the patient requesting the specimen, have read and understand the above.

PATIENT SIGNATURE: _____DATE: _____

WITNESS: _____ DATE: _____

Return this form to Clinical Pathology Associates within 14 days following the surgical procedure or the specimen may be disposed of per normal protocol.
Please return to Clinical Pathology Associates via courier or fax: Fax: 325-670-6569

Signature upon receipt of specimen: _____ Date: _____

CLIENT SERVICE MANUAL