COMMUNITY PATHOLOGY
Laboratory

SPECIMEN COLLECTION MANUAL

COMMUNITY PATHOLOGY LABORATORY, LLC

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CAP, CLIA AND STATE LICENSE NUMBERS

CAP Certification #: 3102001
CLIA License #: 44D0316108
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SPECIMEN TRANSPORT PROTOCOL

INTRODUCTION

Quality anatomic pathology testing is highly dependent on proper collection, handling and transport of the specimen that is submitted for interpretation. Correct patient preparation, proper specimen collection, adequate specimen packaging and transportation are all essential factors.

HEALTH AND SAFETY PRECAUTIONS

All specimens must be properly sealed and placed in specimen bags prior to transportation. All supplies necessary for proper collection of specimens are provided to clients by Community Pathology Laboratory. Only specimens in proper containers may be transported to the laboratory.

All healthcare workers are required by OSHA to follow an "exposure control plan." All CPL couriers are trained in and will follow Community Pathology's Bloodborne Exposure Control Plan when handling specimens for transport.

TRANSPORTATION OF SPECIMENS

Bagged specimens collected from each client should be placed into the transportation tote at the appropriate temperature for the specimen type.

SPECIMEN TRACKING

All specimens transported by CPL couriers are tracked using courier log sheets and accession logs. The courier documents the type of specimen (i.e., Thin Prep, tissue or other), the number of each type, and time of pick up. These log sheets are compared to the accession logs to verify the number of each specimen received from each location.

RESULT REPORTING

Testing results are transmitted to the appropriate parties via courier, fax or electronic delivery as determined by individual client preference. The referring physician must give written permission to CPL to release results to another physician, institution or the patient themselves (per Tennessee law).

BILLING

Community Pathology, LLC accepts billing assignments when as a provision of the service subject to reimbursement by governmental payers including Medicare, Medicaid or other third party payers. All billing is done in accordance with Center for Medicare and Medicaid (CMS) guidelines. CPL also bills private pay patients and performs monthly account billing.

To ensure proper and timely billing the following demographic information is required:

- Patient's Name
- Mailing Address
- Telephone Number
- Date of Birth
- Social Security Number
- Insurance carrier name, address, identification number, group number and telephone number
- Diagnosis
- ICD-10 code
- Authorization Number
- Employer's Name
- Referring physician's full name and UPIN number
- Indicate clinic (eg. IP, OP, physicians office)

A copy of the patient's insurance information (front and back) must accompany the appropriate requisition. By receiving the correct information initially, CPL will not need to call your facility to obtain missing information and eliminate unnecessary patient billing.

TEST REQUISITION

Community Pathology has two types of test requisitions. The following information is required for both. The outline below details each area of the test requisition and the importance of including all the requested information.

- **PATIENT INFORMATION**
  1. The patient name should be written clearly and spelled correctly.
  2. Clearly write the patient's address. This will assist our staff with insurance requirements.
  3. The patient's social security information is required for billing purposes and is also used to identify any previous testing performed by CPL.
  4. The date of birth is another means of identifying a patient.
  5. The physician's name is required by law, but it is also important for the pathologists to have the ability to discuss the case with the referring physician. This information is also required for billing purposes.
  6. Our billing department when billing third parties needs a physician UPIN number. This includes insurance companies.

- **SPECIMEN**
  Please mark the sample type and source. Different specimen types require different processing.

- **PATIENT HISTORY/COMMENTS**
  Community Pathology does not have access to the Patient's Medical Record. Please include any patient history or comments that may aid in the analysis of the specimen and the reporting of results.

- **ICD-10 CODE**
  Please include the appropriate ICD-10 code as it reflects the patient's diagnosis. This information is required for billing purposes.

- **ADVANCED BENEFICIARY NOTICE (ABN)**
  An ABN signed by the patient must be provided for any non-covered diagnosis or test for all Medicare patients. It notifies the patient that Medicare may not cover the test, and that they are willing to pay the bill.

For more information concerning billing requirements please refer to the billing section.

To order requisitions please refer to the supply section.

SUPPLIES

All supplies necessary to collect specimens are provided to clients as part of our service.

Specimen collection devices supplied by CPL are to be used only for the collection of specimens for processing by CPL. Such supplies are not to be used to store or dispose of biological materials, including sharps, or for any activity not connected with the collection of specimens.

Small quantities of reagents will be provided to clients for CPL testing purposes. A copy of the Material Safety Data Sheet (MSDS) on the active ingredients of the reagent or the reagent itself will be provided to the client upon request. You will be provided a CPL Supply Requisition Form for obtaining collection supplies, reagent and test requisitions.

Community Pathology Laboratory
Pathology and Cytology Supply Request Form

COMMUNITY PATHOLOGY Laboratory

115 N Peachtree Ave
Cookeville, TN 38556
ph. 931.528.2836
fx. 931.528.8204

FROM:_____
***Required (Name of person ordering, phone #, and name of Hospital or Dr.'s office)**

DATE:_____

Gyn Cytology Supplies	**QTY:**
□ ThinPrep Pap Tests (Vials)	_____
□ Pap Brushes and Scrapers	_____
□ Pap Brooms	_____

Forms	**QTY:**
□ Surgical Pathology Request Forms	_____
□ Cytology Request Forms	_____
□ Specimen Transport Logs	_____

Other Cytology Supplies	**QTY:**
□ CytoLyt Solution (for use with breast FNAs **ONLY**)	_____
□ FNA Kits (Slides, CytoRich-Red)	_____
□ Urine CytoPreserv (30 ml prefill)	_____
□ RPMI (for Flow Cytometry **ONLY**)	_____

Formalin

□ 20 ml Formalin Prefills (10% NBF)	_____
□ 120 ml Formalin Prefills (10% NBF)	_____
□ Gallon Jug of Formalin (10% NBF)	_____

Empty Containers	**QTY:**
□ 60 ml	_____
□ 120 ml	_____
□ 16 oz	_____
□ 32 oz	_____
□ 85 oz (placenta)	_____
□ 172 oz (colon)	_____

Misc.	**QTY:**
□ Slide mailers/folders	_____
□ Specimen Labels for Containers	_____
□ Biohazard bags □Large _____ □Small_____	

SPECIMEN LABELING

All specimens must be properly labeled in order to be received by CPL. All specimens should include the following minimum information:

1. Patient First and Last Name
2. Patient Date of Birth
3. Physician Name
4. Specimen anatomic site
5. Medical Record Number (if applicable)
6. Collection Date and Time

SPECIAL CONSIDERATIONS FOR BREAST SPECIMENS

In addition to the above labeling requirements, breast specimens (including needle core biopsies, lumpectomies and mastectomies) require additional information to ensure compliance with CAP/ASCO guidelines for testing of breast prognostic actors (ER, PR and HER-2):

1. **Collection time**
2. **Time into formalin**

Special breast specimen labels for documenting the above information will be provided by CPL.

SPECIMEN REJECTION POLICY

As part of our quality control program, and in order to comply with Federal, state, and College of American Pathologists guidelines, we cannot accept any specimen that is received unlabeled or with discrepant identification on the specimen and/or requisition form.

Proper specimen identification and handling are essential to obtain valid, timely laboratory results. All requisitions and specimens must meet the defined criteria for processing. If any specimen does not meet the criteria, the physician, resident, or nursing staff with be notified immediately so corrective action can be taken.

Criteria for Rejection
Inadequately labeled specimens
1. **Unlabeled**
Any specimen is considered unlabeled if the specimen container does not have the patient first and last name and type of specimen directly affixed to the specimen.

2. **Mislabeled**
A specimen is mislabeled when the patient name or type of specimen differ from the name or type of specimen on the requisition form.

3. **Improperly/Incompletely Labeled**

4. **Corrective Action**
All specimens that are unlabeled, mislabeled, or improperly/incompletely labeled without exception will be sent back to the submitting office/location with a Specimen Rejection Form, and corrected and/or verified by the staff involved. The staff will sign the rejection form accepting responsibility of the misidentified specimen allowing the laboratory to proceed with processing.

FROZEN SECTION

PURPOSE

Frozen section tissue analysis is an intraoperative surgical pathology procedure intended to give the surgeon pertinent information in order to guide surgical intervention. The frozen section process produces a slide that can be interpreted by the pathologist who then directly reports the results to the surgeon. Turnaround time is less than 20 minutes.

HEALTH AND SAFETY

Universal precautions should be used for all fresh tissue specimens that are brought to the laboratory for frozen section analysis.

All instruments and countertops used during the grossing or freezing of tissue must be disinfected with a hospital-approved disinfectant.

- If tissue is confirmed to be contaminated (TB) and a frozen was performed, the cryostat must be decontaminated with OCIDE 2 before being used again.
- All contaminated disposable items should be placed in red biohazard bags
- Contaminated sharps go into designated puncture resistant containers.
- The interior of the cryostat should be disinfected periodically with OCIDE 2.

PROCEDURE

1. Schedule frozen section with pathologist secretary (931-783-5777).
2. When scheduling provide:
    - Specimen type
    - Patient's age and sex
    - Surgeon
3. Before the scheduled time for the frozen section check the stains and the cryostat.
4. Upon receipt of the specimen place the appropriate specimen label on the formalin container.
5. Label each slide and tissue cassette with patient's first and last name, date and frozen section number (i.e. FSA1, etc.).

6. Once the tissue is frozen take a 5 micron section on a slide and stain for examination by the pathologist.
7. After the pathologist has examined the specimen and slides to his or her satisfaction and relayed his findings to the surgeon, be sure that the pathologist signs the frozen section report and records the case in the frozen section logbook.
8. Ensure that the frozen section report is immediately returned to the O.R.
9. Place the frozen tissue section in the cassette and drop the cassette in the formalin container along with the remainder of the specimen.

FROZEN SECTION STAINING PROCEDURE

1. After the tissue is mounted to the slide, IMMEDIATELY rinse the slide in Alcohol Formalin for 10 dips.
2. Stain slides in Hematoxylin solution for 60 sections.
3. Rinse in tap water for 10 seconds or until clear.
4. Fix slides in Bluing solution for 10 dips.
5. Stain slides in Eosin solution for 10-20 seconds
6. Rinse in tap water.
7. Dehydrate slides in two changes of 95% alcohol.
8. Dehydrate slides in two changes of 100% alcohol.
9. Clear slides in two changes of xylene.
10. Coverslip slides with mounting media.

FROZEN SECTION STOCK REAGENTS

Alcohol Formalin

95% ethanol

100% ethanol

Hematoxylin

Eosin

Xylene

Bluing Solution

OCT compound

Freeze spray

Mounting Media

FROZEN SECTION KIT SUPPLIES

1 bottle OCT compound
1 can of freeze spray
3 cryo molds (chucks)
1 ruler
1 scalpel holder
2 non-sterile scalpel blades
1 pair forceps
1 set of marking dyes (red, yellow, orange, black, green and black)
1 dozen long cotton tip applicators
1 small container of vinegar
Pen and pencil
1 box microscope slides
Slide holders
1 dozen tissue cassettes with lids
1 bottle alcohol formalin
1 bottle hematoxylin
1 bottle bluing solution
1 bottle eosin
1 bottle 70% alcohol
1 bottle 100% alcohol
1 bottle Xylene
1 bottle mounting media
1 box coverslips

DATE CHECKED_____

CHECKED BY_____

ROUTINE SURGICAL PATHOLOGY

FORMALIN-FIXED TISSUE SPECIMENS

1. Immediately place the tissue in a tightly secured container of 10% neutral buffered formalin. Do not allow the specimen to dry out.
    - We suggest only one specimen per container. If multiple specimens must be submitted in one container, please designate by size or suture marking.
    - Do not crush the specimen with forceps, hemostats or other blunt instruments. Avoid using cautery when possible. Do not freeze formalin fixed specimens.
    - Do not force a large specimen into a small container. Formalin must surround the tissue for proper fixation. Formalin volume : specimen ratio should be 10:1.

2. Appropriately label the specimen bottle
    - Patient name
    - Physician name
    - Specimen type/anatomic site
    - Collection time
    - Time into formalin (for breast specimens)

3. Fill out the appropriate pathology requisition:
    - Patient name
    - Patient age
    - Patient social security number
    - Patient date of birth
    - Insurance/billing information
    - Specimen collection date/time
    - Physician's name
    - Pre-op/post-op diagnosis
    - Type of tissue/anatomic site
4. Only one requisition form is needed for multiple specimens from the same patient.
5. Place all paperwork in a plastic biohazard bag along with the labeled specimen container.
6. Send specimens to Community Pathology Laboratory, 115 N Peachtree Ave. Cookeville, TN 38501 via the courier designated for your location.

GUIDELINES FOR RETENTION AND STORAGE OF PATHOLOGY RECORDS AND MATERIALS

SURGICAL PATHOLOGY/AUTOPSY MICROSCOPIC SLIDES

Surgical pathology and autopsy slides are labeled with the patient's name and CPL accession number. The slides are filed in a metal slide file cabinet. **Surgical pathology and autopsy slides are retained for a minimum of 10 years as required by law.**

SURGICAL PATHOLOGY/AUTOPSY PARAFFIN BLOCKS

Surgical pathology and autopsy paraffin blocks are labeled with a CPL accession number and stored in cardboard paraffin block filing boxes in a climate controlled environment. **Surgical pathology and autopsy blocks are retained for a minimum of 10 years as required by law.**

WET TISSUE/SPECIMENS

Surgical tissue and Cytology specimens are retained for two weeks after the final report is issued in compliance with College of American Pathologists guidelines. Autopsy tissue is retained for three weeks after the final report is issued in compliance with College of American Pathologists guidelines.

GYNECOLOGICAL SLIDES

Gyn-Cytology slides are labeled with the patient's name and CPL accession number. The slides are filed in a metal slide file cabinet. **Gyn-Cytology slides are retained for a minimum of 5 years as required by law.**

NON-GYNECOLOGICAL SLIDES

NonGyn Cytology slides are labeled with the patient's name and CPL accession number. The slides are filed in a metal slide file cabinet. **NonGyn-Cytology slides are retained for a minimum of 10 years as required by law.**

SURGICAL PATHOLOGY, CYTOLOGY, & AUTOPSY REPORTS

Surgical pathology and autopsy reports are retained on the laboratory's file server indefinitely. Paper copies of reports are stored on the premises of the laboratory. **We retain surgical pathology and autopsy paper reports for 10 years.**

ACCESSION LOGS

Accession logs are filed and retained for 2 years in the laboratory.

MAINTENANCE RECORDS

Maintenance records are retained for 2 years in the laboratory.

CYTOLOGY SPECIMEN COLLECTION AND SUBMISSION

GENERAL INFORMATION

Exfoliative specimens may yield surface epithelial cells either by surface abrasion or from accumulation in body fluids. These cells may reveal evidence of a malignant process, inflammation or other conditions. Because these exfoliated cells degenerate rapidly when exposed to air, cytology specimens must be properly collected, promptly fixed and submitted to the laboratory as soon as possible after collection. Please refer to the general collection and handling procedures for all cytology specimens below and to the instructions for specific cytology specimens on the following pages.

CYTOPATHOLOGY ORDERING INFORMATION

Complete a cytopathology test requisition.

- Patient name
- Patient sex
- Patient date of birth
- Patient social security number
- Patient billing/insurance information
- Pertinent clinical history and appropriate ICD-10 code*
- Check proper box for specimen(s) submitted
- Source of specimen

Label all slides specimen containers and slides with the patient's first and last name and collection date.

Fix all fluids immediately following specimen collection.

Close all specimen containers securely and place specimen in plastic biohazard bag with accompanying requisition.

Please bag cytology specimens separate from surgical pathology specimens.

*The referring physician must designate all **Pap smears** in one of the following categories:

- Screening - low risk
- Screening - high-risk
- Diagnostic

An appropriate ICD-10 code must be submitted to indicate the medical necessity of the Pap smear.

Call the cytology department at (931) 528-2836 for questions regarding cytology specimen collection, fixation or reporting.

CYTOLOGY SPECIMEN REJECTION POLICY

- Non-gynecologic fluid specimens will be rejected and a new specimen requested whenever the specimen has completely dried or spilled during transport.
- Non-gynecologic fluid specimens will be rejected whenever a specimen container is received with a needle attached.
- Gynecologic and non-gynecologic slides will be rejected whenever the slides are received broken beyond repair.
- Gynecologic and non-gynecologic slides and fluid specimens will be rejected whenever the slide(s) and/or fluid container (s) are received without being properly labeled with the patient's name and/or identifying number or if the information received on either the container or specimen slide does not match the specimen requisition. (See Specimen Rejection Policy pg.12)
- Clients will be notified immediately of any rejected changes.

CYTOLOGY REPORTS

Cytology reports are transmitted to the appropriate parties via courier, fax or electronic delivery as determined by individual client preference. The referring physician must give written permission to CPL to release results to another physician, institution or the patient themselves (per Tennessee law).

CYTOLOGY SUPPLIES

Please refer to the supplies section of the manual (pg. 9-10)

GYNECOLOGIC CYTOLOGY SPECIMEN PROCEDURES

PATIENT PREPARATION

- Ideal sampling date is 14 days after the first day of the last menstrual period.
- Patient should not use douches, vaginal medication, or vaginal contraception for 48 hours prior to sampling.
- The speculum should be introduced with no lubricant.

NOTE: Lubricants increase the risk of contaminating or obscuring the cellular sample with both conventional pap smears and all liquid-based methods. The Clinical and Laboratory Standards Institute (CLSI; formerly the NCCLS) recommends that lukewarm water be used to lubricate and warm the speculum. If a lubricant must be used due to patient discomfort or other circumstances, it should be applied sparingly on the outer portion of the speculum *with great care to avoid the tip*, using a water-based lubricant such as Astroglide®. *http://www.thinprep.com/hcp/specimen_collection/common_questions.html*

CONVENTIONAL PAP SMEAR

CERVICAL/ENDOCERVICAL

1. Using a lead pencil, label the frosted end of slide with patient's first and last name.
2. Complete requisition with all patient information.
3. Tear open fixative pouch or place fixative bottle beside slide.
4. Rotate cervical scraper around ectocervix and spread material evenly in the middle section of the glass slide.
5. Insert endocervical brush into endocervical canal until only the bottommost fivers are exposed. Rotate brush 90 – 180 degrees. Gently remove brush and spread material from brush evenly onto slide on the end farthest from the frosted end (endocervivcal brush should not be used on pregnant patients).
6. Fix smear immediately by flooding entire slide with pouch fixative or spraying evenly and completely with fixative.
7. When slide is dry, secure Pap Pak and place Pap Pak in specimen back with accompanying requisition.

VAGINAL

1. Using a #2 lead pencil, label frosted end of glass slide with patient's first and last name.
2. Complete a requisition with all the patient's information.
3. Tear open fixative pouch, or place spray fixative bottle beside slide.
4. Take vaginal smear with spatula end of cervical scraper and spread evenly in center of the slide. (NOTE: If maturation index is requested, the lateral vaginal wall must be scraped and "Maturation Index Requested" must be written on the requisition.
5. Fix smear immediately by flooding the entire slide with pouch fixative or spraying evenly and completely with spray fixative.
6. When slide is dry, secure in Pap Pak and place Pap Pak in specimen bag with accompanying requisition.

THINPREP PAP TEST

Endocervical Brush/Spatula Protocol

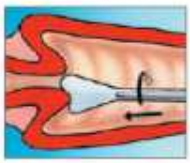
1. Label the ThinPrep vial with patient's first and last name and ID number.
2. Complete requisition with all patient information , medical history, and ICD code.
3. Obtain an adequate sampling from the **ectocervix** using a plastic spatula.
4. Rinse the spatula as quickly as possible into the PreservCyt Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.
5. Obtain an adequate sampling from the **endocervix** using an endocervical brush device. Insert the brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate ¼ or ½ turn in one direction. DO NOT OVER-ROTATE.
6. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
7. Place the vial and requisition in a specimen bag for transport to the laboratory.

Broom Collection Device Protocol

1. Label the ThinPrep vial with patient's first and last name and ID number.
2. Complete requisition with all patient information , medical history, and ICD code.
3. 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 endocervix. Push gently, and rotate the broom in a clockwise direction five times.
4. 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.
5. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
6. Place the vial and requisition in a specimen bag for transport to the laboratory.

ThinPrep® Pap Test Quick Reference Guide

Endocervical Brush/Spatula Protocol

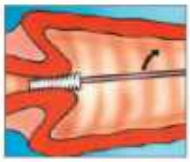


Obtain…

…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 bottom-most 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.

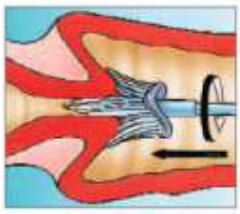
Place…

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

THE ThinPrep PAP TEST

ThinPrep® Pap Test Quick Reference Guide

Broom-Like Device Protocol



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.

THE ThinPrep® PAP TEST

HUMAN PAPILLOMA VIRUS (HPV)

HPV testing utilizing the Hybrid Capture II System for HPV DNA detection is offered on the ThinPrep Pap Test specimen.

ThinPrep Pap Test

1. Collect the ThinPrep pap smear as previously described.
2. Complete the requisition with all the patient's information, ID Number, and ICD code.
3. Mark the ThinPrep Pap Test box and the HPV High-Risk box on the Cytology Requisition if HPV is requested regardless of the pap results,
    a. or mark the HPV if ASCUS or above if HPV is requested only if the pap results are abnormal.
    b. If HPV only and no pap is requested, mark the HPV High-Risk box and do not mark the ThinPrep Pap Test box.
4. Place the vial and requisition in a specimen bag for transport to the laboratory.

GONORRHEA/CHLAMYDIA TESTING

Gonorrhea/Chlamydia Testing is sent to a reference laboratory (based on insurance requirements).

GENETIC ASSAYS
A Molecular Diagnostics Laboratory

CT/NG Chlamydia/Gonorrhea by PCR - Qualitative

GA Test Code	**3333/0180** ***Note***: GA recommends ordering these assays together because patients infected with *C. trachomatis* may be co-infected with *N. gonorrhoeae*.
Method	***FDA-approved*** Abbott RealTime in vitro polymerase chain reaction (PCR)
Specimens	**ThinPrep**: 2.0 mL (1.0 mL), store and ship ambient (up to 3 months). **SurePath**: 1.0 mL (0.5 mL), store and ship ambient (14 days). **G Swab:** G Swab kits are provided by GA. Collect vaginal specimen with swab and place in tube with liquid media. Break-off swab (pre-scored) and seal tube for transport. Sample is stable for 90 days at room temperature (15-30°C). **G Swab - Urine:** G Swab kits include a urine collection pipette. Use pipette to add 1.0 mL **only** of first catch urine to red fill line on media tube. Sample is stable for 90 days at room temperature (15-30°C). **Swab**: from any site, place in 1-2 mL viral transport medium, store/ship ambient or refrigerated (14 days). If longer storage is needed, store frozen (90 days). **Urine**: 10.0 mL (5.0 mL). Collect first-catch (not mid-stream) urine in sterile, leakproof container. The patient should not have urinated for 2 hours prior to collection. Immediately refrigerate urine and ship within 24 hours on cold pack. *Note*: The presence of blood, mucus, some spermicidal agents, feminine powder sprays, and treatments for vaginal conditions such as yeast infection may interfere with nucleic acid test based assays.
Causes for Rejection	Quantity not sufficient (QNS); time and/or temperature instructions not followed; G Swab urine filled above 3 mL (red line).
Reference Range	Not Detected
Turnaround Time	24-48 hours
CPT Code	87491, 87591

Description

The Abbott RealTime CT/NG assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae*. The assay uses PCR technology with homogeneous real-time fluorescence detection.

Clinical Utility

The CT/NG assay is used for the dual detection of the sexually transmitted disease pathogens, *C. thrachomatis* and *N. gonorrhoeae*. Cell culture used to detect *C. trachomatis* has been replaced by more sensitive nucleic acid tests. Since a specific diagnosis of chlamydia may improve treatment compliance and enhance partner notification, the use of these highly sensitive and specific tests is strongly recommended. Culture is commonly used for the detection of *N. gonorrhoeae*. Presumptive diagnosis of gonorrhea is based on the morphological examination, Gram stain, and oxidase measurement of the culture isolate. Nucleic acid tests are widely available for definitive identification of *N. gonorrhoeae*.

Performance characteristics of the Abbott RealTime CT/NG assay were established in a multi-center clinical study. The overall sensitivity and specificity for CT was 95.2% and 99.3%, respectively. The overall sensitivity and specificity for NG was 97.5% and 99.7%, respectively.

Sexually transmitted diseases treatment guidelines, 2010. *MMWR*, December 17, 2010/Vol. 59/No. RR-12, 44-55.

Chlamydia Trachomatis (CT), Qualitative by Aptima CC

Test Code

CT

Associations

The CDC recommends that all sexually active adolescent women be screened for chlamydia trachomatis at least once a year. Close to half of chlamydia cases (46%) occur in women ages 15-19 and another 33% of infections occur in females between 20 and 24. Of all reported neisseria gonorrhoeae cases, 75% occur in individuals between 15 and 29 years of age.

Methodology

Transcription-Mediated Amplification (TMA)

Turnaround Time

1-3 days

Specimen Requirements

3.0 mL ThinPrep® PAP or SurePath™ Test Pack
1.0 mL liquid cytology media (ThinPrep or SurePath) media
One cervical or urethral swab collected with APTIMA Unisex Swab Specimen Collection (WHITE) Kit
20.0-30.0 mL (first catch) urine collected in preservative-free urine collection cup or 2.0 mL urine transferred to APTIMA urine specimen transport (YELLOW) tube

Specimen Stability

ThinPrep/SurePath - 14 days from collection
Swabs - 60 days from collection
Urine - 24 hours from collection; 30 days after transfer to APTIMA urine transport (YELLOW) tube

Storage & Handling

Transport and store all specimens at 2-30°C

Causes for Rejection

Insufficient specimen volume
No swab in transport tube
Urine specimens >24 hours old unless transferred to APTIMA urine transport (YELLOW) tube

Reference Range

Detected/Not Detected

Description

Intended for use as a screening test for evidence of Chlamydia trachomatis infection.

References

1. Welch DF (2007). Screening for Chlamydial and Gonorrheal infections: Current laboratory applications. Infect Med. 24:266-278.
2. Chernesky M et al. (2006). High analytical sensitivity and low rates of inhibition may contribute to detection of Chlamydia trachomatis in significantly more women by the APTIMA Combo 2 assay. J Clin Micro. 44:400-405.
3. GEN-PROBE APTIMA Combo 2 Assay.

Trademarks

Neisseria Gonorrhoeae (NG) Qualitative by Aptima COM

Test Code

NG

Methodology

Transcription mediated amplification (TMA)

Turnaround Time

1-3 days

Specimen Requirements

3.0 mL ThinPrep® PAP solution or SurePath™ Test Pack solution
1.0 mL liquid cytology media (ThinPrep or SurePath)
One cervical or urethral swab collected with APTIMA Unisex Swab Specimen Collection (WHITE) Kit
20-30 mL (first catch) urine collected into a preservative-free urine collection cup or 2.0 mL urine transferred to APTIMA urine specimen transport (YELLOW) tube

Specimen Stability

ThinPrep/SurePath atable at 2-30°C for 14 days from collection
Swabs stable at 2-30°C for 60 days from collection
Urine stable at 2-30°C for 24 hours from collection; 30 days after transfer to APTIMA urine transport (YELLOW) tube

Storage & Handling

Transport and store all specimens at 2-30°C.

Causes for Rejection

Insufficient specimen volume
No swab in transport tube
Urine specimens >24 hours old unless transferred to APTIMA urine transport (YELLOW) tube

Reference Range

Detected/Not Detected

Description

Intended for use as a screening test for evidence of Neisseria gonorrhoeae infection.

References

1. GEN-PROBE APTIMA Combo 2 Assay (http://www.gen-probe.com/prod_serv/std_aptima.asp)
2. Welch DF (2007). Screening for chlamydial and gonorrheal infections: current laboratory applications. Infect Med. 24:266-278.

Trademarks

NON-GYNECOLOGICAL SPECIMEN COLLECTION

Source	Acceptable Collection Media	Submission Requirements
Bladder Washings	**Saline, CytoPreserv**	Use saline or a balanced salt solution for bladder washings. Label specimen with patient name and specimen source. Place in clean container or in appropriate amount of CytoPreserv.
Body Cavity Washings	**Saline**	When washing out a body cavity, saline or a balanced salt solution is recommended. Label specimen container with the patient's name and specimen source.
Breast Cyst Aspiration	**Smear Slides, Cytolyt**	If aspiration is scanty, fluid may be smeared one drop at a time on clean, dry slides and immediately fixed. If aspirate is abundant, mix material with an equal volume of cytology fixative. Label slide or specimen container with the patient's name and source of specimen.
Breast Secretion (Nipple Discharge)	**Smear slides**	Label slide with the patient's name and source of the specimen. Smear drops of fluid from the nipple directly onto a clean glass slide(s) and fix immediately with spray fixative or immerse 95% alcohol.
Bronchial Brushings	**Smear slides, Saline**	Label slide with the patient's name and source of the specimen. Roll brush over a clean, dry slide. Fix immediately with spray or immerse in a container of cytology fixative. The brush used to prepare the slides may be rinsed in a container of saline to dislodge additional specimen. Submit slides and liquid specimen together with one requisition.
Bronchial Washings	**Saline, Cytolyt**	Label specimen container with the patient's name and specimen source. Specimen should be received fresh in saline, or fixed with an equal volume of cytology fixative.
Bronchoalveolar Lavage (BAL	**Saline, Cytolyt**	Label specimen container with the patient's name and specimen source. Specimen should be received fresh in saline, or fixed with an equal volume of cytology fixative.
Cerebrospinal Fluid	**Fresh, RPMI**	Label specimen container with the patient's name and specimen source. For optimal cellular preservation and diagnostic viability, submit specimen to Laboratory immediately. If clinically suspicious of lymphoproliferative disorder (leukemia/lymphoma), it is recommended that 2-5 cc of fluid be placed in RPMI for flow cytometry.
Endometrial Washings	**Saline, Cytolyt**	Label specimen container with the patient's name and specimen source. Specimen should be received fresh in saline, or fixed with an equal volume of cytology fixative.
Esophageal Brushings	**Saline, Cytolyt**	Label specimen container with the patient's name and specimen source. Specimen should be received fresh in saline, or fixed with an equal volume of cytology fixative.
Esophageal Washings	**Saline, Cytolyt**	Label specimen container with the patient's name and specimen source. Specimen should be received fresh in saline, or fixed with an equal volume of cytology fixative.
FNA		See FNA collection section of manual
Gastric Brushings	**Saline, Cytolyt**	Label specimen container with the patient's name and

		specimen source. Specimen should be received fresh in saline, or fixed with an equal volume of cytology fixative.
Gastric Washings	**Saline, Cytolyt**	Label specimen container with the patient's name and specimen source. Specimen should be received fresh in saline, or fixed with an equal volume of cytology fixative.
Lesions Scrapings	**Slides**	Label slide(s) or specimen container with the patient's name and specimen source. Remove crust or some from lesion. Scrape ulceration with a moistened tongue blade or cotton swab. Spread material on slides(s). Spray-fix immediately or immerse in a container of 95% alcohol. Do not allow drying of smears before fixing. Do not use aerosol fixative.
Serous Fluids (Pleural, Peritoneal, Pericardial).	**Fresh**	Label specimen container with the patient's name and specimen source. Collect fluid in heparinized evacuated container or other clean collection device.
Sputum		To obtain cells from an upper respiratory tract lesion, collection of a sputum specimen is recommended. Sputum is also useful in the diagnosis of fungal, viral, and parasitic infections. **Submission:** Label specimen with the patient's name. Submit early morning deep-cough specimen prior to any food ingestion. Have patient rinse mouth with plain water. Place sputum specimen directly into clean container. Collect separate specimens on 3 consecutive mornings.
Urine	**CytoPreserv**	Label specimen container with patient's name. Fix material by adding an equal amount of PreservCyt. Mark requisition: "**Voided**" or "**Catheterized**" as appropriate. **Voided urine:** Instruct patient to drink three 8-oz. glasses of water before bedtime. Provide patient with an appropriate volume of CytoPreserv. Have patient collect the **second** AM urine specimen and mix an equal volume with the fixative. **Do not submit a 24-hour urine for cytological evaluation.** **Catheterized urine:** Place the catheterized urine in a appropriate volume of CytoPreserv.

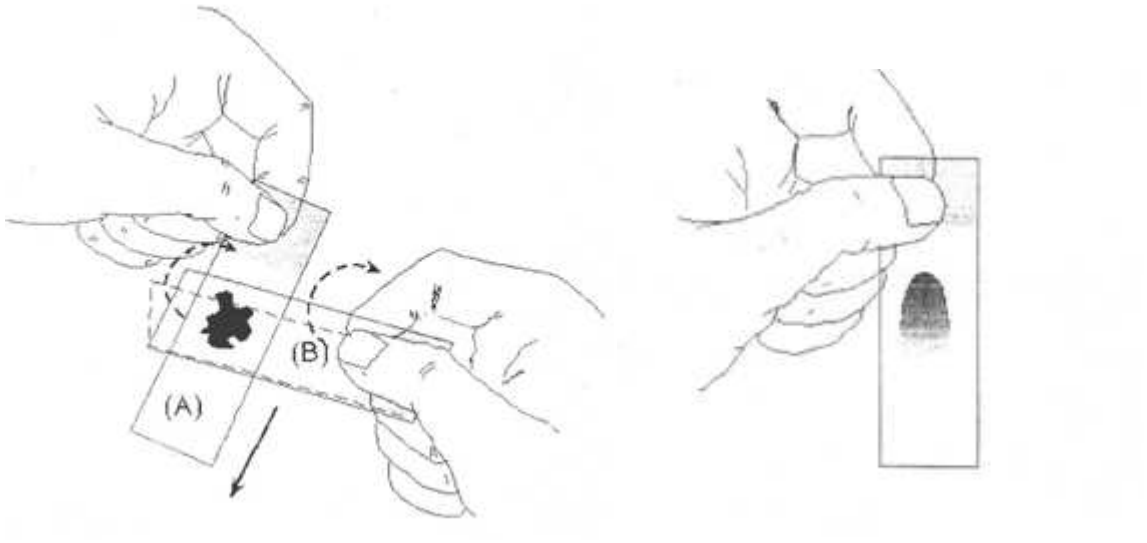
Fine Needle Aspiration (FNA) Collection

Objective: Fine needle aspiration is commonly utilized in the diagnosis of mass lesions. Obtaining a good diagnostic specimen requires adequate aspiration technique as well as proper handling of the material obtained. It is highly desirable that several direct smears be prepared (most of which should be air-dried with a few fixed in 95% ethanol) for all fine needle aspiration specimen submitted to the cytopathology laboratory.

Procedure:

1. Slides and CytoRich Red container are labeled with the patient's name and collection date.
2. After the cellular harvest has been obtained, a small amount (no larger than the size of a pencil eraser) of the specimen is deposited near the label end of a glass slide.
    a. If a larger volume of material is present in the needle for a given pass, additional slides should be prepared as opposed to placing excessive material on a single slide.
3. While holding the slide firmly in the left hand, a second clean glass slide is laid gently across the first slide in a perpendicular orientation (see figure below).
4. While applying very gentle pressure the second slide is moved downward while maintaining full contact with the first slide. (**Do not "pop" slides apart.**
5. The slide is then placed in the provided slide holder (for air dried slides) or immediately placed in the provided pre-filled alcohol containers (for alcohol fixed slides).
6. The needle is then rinsed in the provided CytoRich-Red solution for preparation of a cell block and special stains. (A dedicated pass or two deposited directly into CytoRich-Red is often helpful to ensure adequate cell block material for ancillary studies).
7. The procedure is repeated for each pass and usually results in several (4-6) air-dried slides and a few (2-3) alcohol-fixed slides. (Slides can be re-hydrated in the lab for alcohol fixation, if none are provided).
8. The slide containers, CytoRich-Red container, and specimen requisition are placed in a biohazard bag and submitted to the cytopathology laboratory in the provided FNA kit box.

One-Step Method



Hold stationary slide (A) firmly in one hand. With the other hand rest edge of spreader slide (B) that is closer to operator on stationary slide and tilt spreader slide until the aspirated material is beginning to spread. Then move spreader slide toward you, applying slight pressure to aspirated material. Do no lift either end of spreader slide until smear preparation is complete.

Bone Marrow Biopsy/Aspiration Procedure

The bone marrow aspiration and biopsy procedure is performed by a physician with the assistance from a laboratory personnel. The test is done to evaluate a possible hematologic disorder, metastatic tumor, nutritional deficiency, or drug/toxic effect on the marrow.

Equipment For Procedure Tray

1. Alcohol and betadine swabsticks
2. Sterile gloves for physician
3. Sterile towel pack
4. 18 and 21 gauge 1 ½ inch needles
5. 1% Lidocaine solution
6. 1-2 packs sterile gauze pads
7. Sterile lancets
8. (2) 10 ml syringes, (3) 20 ml syringes, (2) 5 ml syringes
9. Jamshidi needle
10. (2) 7 ml red top tubes with 1 ml 10% EDTA (available from Community Pathology).
11. Heparinized green top tubes
12. Container of 10% formalin
13. Optional – Pediatric blood culture bottles and/or tissue culture fluid
14. Alcohol preps
15. Op-site bandage or band aid

NOTE: A disposable bone marrow tray may be used.

Procedure at Bedside

1. Assist the physician in placement of the patient and preparation of a sterile field.
2. Observe precautions in maintaining a sterile field and supply physician with necessary implements for the procedure.
3. After the physician aspirates the marrow, quickly dispense it into red top tubes that contain EDTA and heparin.
4. Cap and invert immediately to mix anticoagulants.
5. Marrow particles will adhere to the sides of the glass tube and are easily visible. Report presence or absence of particles to the physician.
6. A second aspirate may be obtained for special studies and needs to be immediately placed in the proper anticoagulant, preservative, or sterile container.
7. Place uncapped vial of formalin on the table near the physician's bone marrow aspirate tray. Make sure it is out of the sterile field. He/she will deposit the biopsy into the vial.
8. Make a peripheral blood smear from a fingerstick, if request.
9. OR draw a purple top tube for a CBC and a reticulocyte count, if applicable.

Procedure in the Laboratory

1. Particles will rise to the top of the EDTA specimen of aspirated particles. With a 9" Pasteur pipette, pick up a few particles and place on a slide. Place another slide on top (do not press) and pull apart. Alternatively, draw the particles out into a smear like preparing a peripheral smear. Make 8-10 slides. Stain 2 slides 2 times on the stainer.
2. Prepare slides, 2 stained aspirate smears and 4-6 unstained aspirate smears, bone marrow EDTA and heparin tubes, peripheral blood tube, and biopsy to be sent to AP Laboratories.
3. In some cases, flow cytometry, cytogenetics, or cultures may be requested on the bone marrow or peripheral blood. Use a green-top heparin tube for flow cytometry or cytogenetic studies. Cultures are placed in pediatric blood culture bottles, ACD solution, or sterile tube depending upon the type of culture requested, and taken to microbiology.

NOTE: All parts of the specimen must be properly identified. When packing, keep the formalin fixed and non-formalin fixed smears and fluid specimens in separate plastic bags since formalin fumes can cause changes in the cell morphology of the other specimens.

Histopathology Ordering Information:

Complete a histopathology test requisition. Be sure to include the following:

- Date specimen was collected
- Patient's first and last name
- Patient's date of birth
- Social security number
- Name of requesting physician

Complete billing information or attached hospital face sheet or copies of insurance cards.

Operative Procedure
Clinical History and Clinical Diagnosis

NOTE: Provide copies of pertinent clinical history and laboratory results, especially complete blood count with indices and differential.

Bone Marrow Specimen Submission Guidelines

Peripheral Blood

Purple-top tube should be performed within 24 hours prior to bone marrow procedure. If smears are prepared, send copy of peripheral blood workup sheet along with the smear. Label with patient's name and specimen type.
Optimum Amount – 5 ml
Minimum Amount – 2 ml

Bone Marrow (Particles)
10% EDTA tube, store at room temp; expiration date is 6 months from date of preparation as long as 10% EDTA is within expiration date and the 5 ml red-top tube is within expiration date.
Optimum Amount – 2 ml
Minimum- Pathologist Dependent

Bone Marrow (Smears)
If smears have been prepared, they must be packaged in a tightly wrapped plastic container/bag. Smears exposed to the formalin liquid or vapors will not stain properly.

Bone Marrow Core Biopsy
Place in a 10% buffered-neutral formalin container. Label container with the patient's name and specimen name. Indicate right or left, if applicable. Keep at room temperature. If bone marrow aspirate is clotted, place the clot in a formalin container.

Bone Marrow Particles for Cultures
Yellow-top tube containing ACD (acid citrate dextrose), pediatric blood culture bottle, or sterile container, specimen obtained by pathologist. Label with patient's name and specimen type. Kept at room temperature.
Optimum Amount – 2 ml
Minimum Amount- 1 ml

Bone Marrow for Cytogenetic
Green-top heparin tube. Label with patient's name and specimen type. Keep at room temperature.
Optimum Amount – 2 ml
Minimum Amount – 1 ml

Bone Marrow for Leukemia/Lymphoma
Green-top heparin tube. Label with patient's name and specimen type. Keep at room temperature.
Optimum Amount – 2 ml
Minimum Amount – 1 ml

Bone Marrow Specimen Submission Guidelines

Peripheral Blood for Leukemia/Lymphoma
Green-top heparin tube. Label with patient's name and specimen type. Keep at room temperature.
Optimum Amount – 2 ml
Minimum Amount – 1 ml

SPECIMENS FOR GOUT

In order to maximize accurate results for Pathology, the collector of the original specimen should:

Pre-label a 100% ETOH (alcohol) Container with the Patient's Name, Collection Date, and Collection Site.

- This specimen **MUST NOT BE SUBMITTED INTO FORMALIN**.
- This specimen MAY be SUBMITTED FRESH.

Insert the specimen into the container. Close the container and tighten the lid.

According to the facility's courier set-up, call for a pick-up or wait for the scheduled pick-up time.

Specimen Preparation for Chromosome Analysis

In order to maximize accurate results for Chromosome Analysis, the person collecting and handling the original Product(s) of Conception (POC) specimen should:

Pre-label an empty dry biopsy container with the Patient's Name, Collection Date, Collection Time and Collection Site.

Monday-Thursday

1. Moisten a piece of gauze with saline.
2. Wrap the piece of gauze very loosely around the specimen.
   These specimens are to be kept moist with saline-soaked gauze.
   DO NOT SUBMERGE IN SALINE.
3. Insert the specimen into the specimen container.
4. Seal the container and insert it into a specimen transport bag.
5. Fill out a Patient Surgical Requisition and insert it into the side pocket of the specimen transport bag.
6. Hold the specimen in a 4° Celsius refrigerator until the courier arrives for pick-up.
7. Call Community Pathology at 931.528.2836 for a "STAT" pick-up and let them know you have a FRESH Specimen for Cytogenetics. If an out-of town pick-up time is missed, hold the specimen in the refrigerator until the next day pick-up.
8. This specimen **MUST NOT BE SUBMITTED IN FORMALIN**.

Friday - Sunday

Cover the specimen in RPMI and follow steps 3- 8 above.

* Products of Conception/Fetal Tissue for general histology processing can be submitted in formalin. Hold for courier pick-up.

SPECIMEN FOR FLOW CYTOMETRY

In order to maximize accurate results for Flow Cytometry, the person collector of the original specimen should:

1. Pre-label a container of RPMI with the Patient's Name, Collection Date, Collection Time, and Collection Site.
2. Insert the specimen into the pre-labeled container.
3. Seal the container and insert it into a specimen transport bag with a cold (not frozen) pack.
4. Fill out a Patient Surgical Requisition and insert it into the side pocket of the specimen transport bag.
5. Hold the specimen in a 4° Celsius refrigerator until the courier arrives for pick-up.
6. Call Community Pathology Laboratory at 931-528-2836 for a "STAT" pick-up and let them know you have a FRESH Specimen in RPMI for Flow Cytometry.

*This specimen **MUST NOT BE SUBMITTED INTO FORMALIN**.

RPMI

Molecular Specimen Requirements – (CSI Laboratories)

(ship specimens with refrigerated cold pack)

Flow Cytometry	Peripheral Blood	3 ml in sodium heparin (green top) - preferred or 3 ml in EDTA (purple top)
	Bone Marrow Aspirate	1-2 ml in sodium heparin (green top) - preferred or 1-2 ml in EDTA (purple top)
	Fresh Tissue	Multiple 2-3 mm pieces of tissue in RPMI transport media (optimum RPMI to tissue ratio is 15:1)
	Body Fluids	Mix 1:1 in RPMI transport media
	PNH Profile	3 ml peripheral blood in EDTA (purple top) preferred, should be processed within 24 hours of collection
Cytogenetics	Peripheral Blood	5 ml in sodium heparin (green top)
	Bone Marrow Aspirate	2-3 ml in sodium heparin (green top)
	Cord Blood	2-5 ml in sodium heparin (green top)
	Fresh Tissue	Multiple 2-3 mm pieces of tissue in RPMI transport media (optimum RPMI to tissue ratio is 15:1)
FISH	Peripheral Blood	3 ml in sodium heparin (green top) - preferred or 3 ml in EDTA (purple top)
	Bone Marrow Aspirate	2-3 ml in sodium heparin (green top) - preferred or 3 ml in EDTA (purple top)
	Fresh Tissue	Multiple 2-3 mm pieces of tissue in RPMI transport media (optimum RPMI to tissue ratio is 15:1)
	Voided Urine or Bladder	Minimum of 33mL voided urine or bladder washing mixed 2:1 with preservative (Preservcyt©)
	Formalin-fixed Paraffin-Embedded tissue	
	FISH TESTING ON PARAFFIN-EMBEDED TISSUE FOR GENE LOSS OR GAIN IN HEMATOLYMPHOID NEOPLASIA REQUIRES	
	HER2 (C+FISH, Tech Only)	3 unstained positively charged slides and 1 marked H&E slide (all at 4-5 microns) MUST CIRCLE AREA OF INTEREST ON H&E SLIDE 1 paraffin block with 1 marked H&E slide MUST CIRCLE AREA OF INTEREST ON H&E SLIDE
PCR	Peripheral Blood	5 ml in EDTA (purple top) - preferred; ACD (yellow top) acceptable
	Bone Marrow Aspirate	1-2 ml in EDTA (purple top) - preferred; sodium heparin (green top) and ACD (yellow top) acceptable
	Fresh Tissue	Minimum of 250 mg tissue in RPMI transport media
	Formalin-fixed Paraffin-Embedded tissue	