
Specimen Collection Manual

Version 09 | Summer 2011

Toll Free **1.866.UniPath (864.7284)**



Vision Statement

Pathology at the Next Level

Mission Statement

A focused team dedicated to integrating the legacy of caring with the innovative diagnosis of disease

Core Values

Compassion – Compassion in our interactions with those we serve and whom we work

Quality – Dedicated to the quality of work with pride and professionalism

Integrity – Integrity is the basis of everything we say and do

Excellence – Achieving excellence through personal and professional growth

Patience – Patience is appreciating the diversity of others in developing sincere relationships

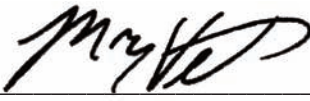
Consistency – Consistent high standards that are met day in and day out

General Statement

UniPath, LLC is a professional anatomic pathology laboratory offering diagnostic services in histology, cytology, molecular pathology and immunochemistry. All services can be reached by calling the main receptionist (303) 512-0888. The professional and technical functions of the laboratory depend on trained histotechnologists, cytology prep technologists, certified cytotechnologists and board certified pathologists. Billing and result entry operations are coordinated by trained and dedicated individuals who operate in accordance with accepted business and reporting standards. UniPath maintains CMS (CLIA) accreditation via the College of American Pathologists. UniPath also observes standards and guidelines from HIPAA, OSHA, state and city regulations and statutes and observes fair labor standards and regulations.



I, Michael Venrick, M.D., Medical Director of UniPath, LLC, hereby approve the contents of this Specimen Collection Manual, Version 09.

Medical Director Signature: 

Date: 10 Jun 2011



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Company Information

Toll Free **1.866.UniPath (864.7284)**



Company Information

Address

6116 East Warren Avenue
Denver, Colorado 80222-5703

Website Address

www.unipathdx.com

Phone Numbers

Toll Free Number	1-866-UniPath (864-7284)
Main Receptionist	303-512-0888
General Information	
Report Requests	
Specimen Pick-Ups	
Pathologists	
Reporting, Transcription & Medical Records	
Main Fax Number	303-512-2288
Client Relations	303-512-2210
Report Requests	
Account Setup Request	
Specific Questions, Comments & Concerns	
Supply Hotline	303-512-2216
Digene® Testing	303-512-0888
HPV and CT/NG Add-on Test Requests	
Flow Cytometry Hotline	303-512-2236
Cytology Technical Information	303-512-2221
Histology Technical Information	303-512-2220
Sales and Marketing	303-512-2240
Managed Care/Contracting/Compliance	303-512-2274

Note: Many extensions are equipped with voicemail, but you always have the option of speaking with one of our many dedicated and courteous employees who will help resolve your questions or problems. If you feel that your needs are not being satisfied, please ask for a member of the administrative staff or the pathology Medical Director.



Company Information

Billing Information

UniPath partners with Pathology Service Associates, Inc (PSA) to perform the majority of our billing functions. PSA has a website (see below) where patients can go to make secure payments, update their demographic or insurance information, and submit a question electronically. Alternately, patients may call the number on their statement or the customer service number listed below with any questions or concerns. Clinicians and their office staff can also contact PSA to update patient demographic or insurance information.

Please contact the Billing Coordinator at the number listed below if PSA is unable to resolve an issue.

Phone Numbers

Billing – Customer Service.....	877-268-0407
Billing Coordinator.....	303-512-2283
Billing Coordinator Fax.....	303-692-6061

PSA Website

www.psabilling.com

Payment Address

APP-UniPath, LLC
c/o PSA, Inc
PO Box 30309
Charleston, SC 29417

Patient Information Updates

To update patient demographics, insurance information, or diagnosis coding for a patient's specimen, please complete the Patient Information Update Form found in Appendix A-7 of this manual. Please fax the completed form to 303-692-6061, Attn: Billing Coordinator. We will convey the updated information to PSA for proper billing.



Pathology Introduction

...Pathology is the Study of Disease

The goal of anatomic and clinical pathology is to examine specimens collected from the patient to help make diagnoses about various disease states. A correct diagnosis will allow the clinician to correctly treat and manage the patient. In this regard, the laboratory, pathologist physician and laboratory professionals are partners with the clinician providing competent, complete and up-to-date medical care to the patient. UniPath's goal is to provide the clinician with support in the diagnosis and management of patient illnesses and disease processes.

Because patient specimens referred to the laboratory are only a representative portion of the whole person, it is vital that they are collected, transported, processed and interpreted with the utmost care and consideration. Any break in protocol may result in compromise of the specimen and/or effect the final report and diagnosis. Such occurrences may lead to inconvenience for the direct care provider and the patient, or worse, they have potential to result in incorrect interpretation and diagnosis, a situation of increased risk for dire consequences or outcomes.

To maximize the benefit of pathologic examination of patient specimens, this handbook was designed to provide up-to-date and helpful information for the collection and preparation of patient specimens. This handbook deals with cytology and tissue pathology only. Those seeking information dealing with blood, serum and plasma specimens should refer to manuals provided by your clinical reference laboratory. The information provided here is specific to our laboratory; however, many of the basic concepts will be applicable to other labs as well.

Providing dependable and clinically relevant information is of paramount importance to our physicians and staff; however, just as important is the timeliness and accessibility of reporting. UniPath not only provides pathologic diagnoses but also has the capability to generate other information and reports as needed to both support the individual patient as well as populations of patients. We actively review our own statistics and in many cases can provide you and your practice with individualized statistics about your patients.

Note: If you have any questions not resolved by this manual please call us. Questions resolved by use of this manual or by direct communication with us, prior to collection of the specimen will avoid problems that may compromise the specimen.



About UniPath

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About UniPath

Pathologists

UniPath's physicians are board-certified specialists in Pathology with comprehensive experience and training in all aspects of tissue diagnosis and analysis.

Pathologist	Specialty
Mitchell A. Bitter, M.D.	Anatomic Pathology Clinical Pathology Hematopathology
J. Daniel Brooke, M.D.	Anatomic Pathology Clinical Pathology
Shalini Chahal, M.D.	Anatomic Pathology Clinical Pathology
Aruna Dash, M.D.	Anatomic Pathology Clinical Pathology
Diane D. Heasley, D.O.	Anatomic Pathology Clinical Pathology Dermatopathology
W. Jeff Hodges, M.D.	Anatomic Pathology Clinical Pathology
Sharon Kelly, D.O.	Anatomic Pathology Clinical Pathology Blood Banking/Transfusion Medicine
Walter E. Madsen, M.D.	Anatomic Pathology Clinical Pathology
Cristina Smith McLaughlin, M.D.	Anatomic Pathology Clinical Pathology Hematopathology



About UniPath

Pathologist	Specialty
Sarah Culkin Mengshol, M.D.	Anatomic Pathology
Thomas A. Merrick, M.D.	Accreditation Consultation Clinical Pathology Clinical Consultation Medical Microbiology
Mark E. Miller, M.D.	Anatomic Pathology Clinical Pathology Hematopathology
Joseph W. Olivere, M.D.	Anatomic Pathology Clinical Pathology Dermatopathology
Ernest Sartorio, Jr., M.D.	Anatomic Pathology Clinical Pathology
Paul M. Scheele, Jr., M.D.	Anatomic Pathology Clinical Pathology
Karim E. Sirgi, M.D.	Anatomic Pathology Clinical Pathology Cytopathology
James M. Small, M.D., Ph.D.	Anatomic Pathology Clinical Pathology Medical Microbiology
Andrea Kathleen Sotelo, M.D.	Anatomic Pathology Clinical Pathology
Philip T. Stoffel, M.D.	Anatomic Pathology Clinical Pathology Renal Pathology



About UniPath

Pathologist	Specialty
R. Weslie Tyson, M.D.	Anatomic Pathology Clinical Pathology Renal Pathology
Michael G. Venrick, M.D.	Anatomic Pathology Clinical Pathology Cytopathology
Elaine D. Wagner, M.D.	Anatomic Pathology Clinical Pathology Cytopathology
Gordon V. Webb, M.D.	Anatomic Pathology Clinical Pathology

Doctoral Scientist	Specialty
Deborah Payne, Ph.D., DABMM, DABCC	Molecular Diagnostics Medical and Public Health Microbiology
Hong Lin, Ph.D.	Hematopathology



About UniPath

History

UniPath is the largest provider of anatomic pathology services in the Rocky Mountain Region. The Professional Corporation (PC) was created in January of 1998 by the merger of Denver Aurora Pathology Associates and Pathology Services, P.C. Prior to the merger, Denver Aurora Pathology Associates had practiced together for 12 years and Pathology Services, P.C. for more than 17 years. Rocky Mountain Pathology Services strategically merged into UniPath in 2001, adding additional talent and expanding the company's reach. UniPath's pathologists have medical staff privileges and provide services at the following medical facilities: *Avista Adventist Hospital, Centennial Medical Center, Kit Carson County Memorial Hospital, Lincoln Community Hospital, Littleton Adventist Hospital, North Suburban Medical Center, Parker Adventist Hospital, Platte Valley Medical Center, Porter Adventist Hospital, Presbyterian/St. Luke's Medical Center, Select Specialty Hospital, and The Medical Centers of Aurora.*

UniPath's pathologists hold subspecialty board certifications and fellowships in the following:

- Blood Banking/Transfusion Medicine
- Cytopathology
- Dermatopathology
- Gynecologic Pathology
- Hematopathology
- Laboratory Management
- Medical Microbiology
- Medical & Public Health Microbiology
- Molecular Diagnostics
- Pediatric Pathology

Furthermore, UniPath's pathologists have many years of extensive experience in the following clinical and anatomic pathology areas:

- Breast Pathology
- Clinical Chemistry
- Coagulation
- ENT Pathology
- Flow Cytometry
- Gastrointestinal Pathology
- Genitourinary Pathology
- Immunohistochemistry
- Laboratory Management
- Liver Pathology
- Medical & Public Health Microbiology
- Molecular Diagnostics
- Orthopedic Soft Tissue
- Renal Pathology
- Surgical Pathology
- Transfusion Medicine
- Transplant Pathology



About UniPath

Quality

UniPath operates a freestanding, independent laboratory and pathology practice that continually pursues a higher standard of quality. Prompt and accurate handling of biopsies and Pap tests is the foundation of our practice. Because of our reputation for quality, UniPath partners in-patient care with Denver-area medical centers and clinicians' offices, rural hospitals and practices, and provides consultative interpretations of cases referred by Colorado and out-of-state practitioners.

UniPath incorporates extensive quality control and quality assurance during all phases of operation. Interdepartmental process evaluation is conducted regularly and improvements are implemented as identified. UniPath has developed departmental committees to interpret statistics, recommend new monitors, discuss resolution of and follow-up on identified problems, and explore ways of improving quality, efficiency, and cost effectiveness.

Laboratory Accreditation

The following agencies accredit UniPath at its various sites:

- College of American Pathologists (CAP)
- Colorado State (CLIA)

UniPath's physicians hold current licenses in many states. A complete listing can be found in Appendix A-9 of this manual.



General Company Information

Toll Free 1.866.UniPath (864.7284)



General Company Information

Hours of Operation

Monday through Friday, 7:00 a.m. to 7:00 p.m. (Mountain Standard Time)

Test Turn-Around Time

UniPath endeavors to provide the most rapid turn-around-time possible without compromising quality. In general, tissue biopsies and critical cytology specimens are given priority, due to their serious nature. Pathology reports will typically be generated within 48 hours of receipt of the specimen. Routine Pap screening cytology reports will be available within 4-5 working days after receipt of the specimen. STAT processing and reporting are also available for special circumstances.

Specimen Pick-Up

UniPath Couriers and STAT Pickups – UniPath has a local courier system servicing the I-25 Corridor, with the ability to provide services across the state of Colorado, reaching into Arizona and Nevada. Arrangements for special or ‘STAT’ specimens may be made by contacting Courier Services at (303) 512-0888.

Contingency Plan For Specimen Pick-up When Weather Conditions or Other Problems Prohibit Routine Courier Transportation – On rare occasions weather or other conditions prohibit routine courier transportation of specimens. If the specimen has been fixed in formalin, alcohol or air-dried, it can be stored until routine courier systems resume. Body fluid specimens under 100 ml should be fixed with CytoLyt®, ethyl or methyl alcohol (1:1) and stored until routine courier systems resume. Body fluid specimens over 100 ml should be stored in a refrigerator until routine courier systems resume.



General Company Information

Items Supplied to Referring Physicians

UniPath provides specimen collection and preservation supplies to its clients. The following are some of the supplies provided directly to referring physicians. For information on other available supplies, please contact UniPath Customer Service at (303) 512-0888.

- Cytology spatulas
- Cytology brushes
- Cytology slides
- Cytology slide cardboard folders
- Cytology spray fixative
- SurePath® and ThinPrep™ Pap Tests™ – collection vials and cytobrush or broom
- Surgical Biopsy Collection Vials – biopsy containers are available in 7.5mL, 20mL, 40mL, and 60mL sizes with 10% neutral buffered formalin
- UniSwab
- “GBS by UniPath” swab and transport media (Group B Streptococcus)

Supply Order Form found in Appendix A-8 of this manual.



General Company Information

Medical Records Release

UniPath is required by law to ensure that private health information (PHI) is kept private, but may release records under the following circumstances:

1. Patient requested release of medical records (Colorado law [C.R.S. 25-1-802]): Upon receipt of a patient's written, HIPAA compliant, signed authorization to release medical records, UniPath may release patient records, original and/or re-cut slides to the person(s) or medical facility named on the release form for treatment and health care operations. Please allow forty-eight hours for preparation and send-out directly to the physician/pathologist or medical facility. Additional consultative expenses will be the responsibility of the patient or his/her insurance carrier. If a patient insists on retrieving the report, slide(s) or block(s), they will be required to arrive at UniPath in person, sign a release form and provide a current picture I.D.
2. Physician requested release of medical records: UniPath may release the patient's records directly to another accredited health care facility for further treatment and health care operations. Please allow forty-eight hours for preparation and send-out. Additional consultative expenses will be the responsibility of the patient or his/her insurance carrier.
3. Attorney requested release of medical records: Attorney requests for patient medical records must be accompanied by a patient's written, HIPAA compliant, signed and dated authorization to release medical records. Release of blocks and/or slides requested by legal counsel requires a court-ordered subpoena and will only be released to another physician or accredited health care facility. Colorado regulation C.C.R. 1011-1, Chapter 2, Part 5.2.3.4., allows UniPath to charge the requesting attorney's office for copying and mailing of patient records requested in this manner.

Note: Because this list is not exhaustive, not every use or disclosure is listed. Should you have any questions, please contact UniPath.



General Company Information

Monthly Statistical Reports

Monthly reports specific to your practice are available upon request. Reports such as diagnostic statistics specific to your practice and lists of patients with diagnostic information are two examples of reports we can provide. Please contact Client Relations at (303) 512-2274 for more information.

Pathology-Directed Consultations

Occasionally, a specific case may require a second opinion from outside UniPath's pathology group. UniPath reserves the right to select the experts used for consultative services. Additional consultative expenses will be the responsibility of the patient or his/her insurance carrier.

Slide Re-cut Program

Extra slides on cases may be requested by clinicians for study, second opinion or retention in your own files. Slides will be re-cut on request and sent along with the completed pathology report. A nominal fee may be assessed. For more information call Customer Service at (303) 512-0888.

Infectious Material

UniPath is an anatomic, cytology and molecular diagnostic laboratory only. Group B Streptococcus testing is the only test that requires culturing prior to molecular testing. Specimens for routine culturing should be referred to a clinical reference laboratory specializing in microbiology. Specimens for KOH preps or wet mounts should also be directed to a clinical microbiology laboratory.

Medical Legal Testing

UniPath does not perform testing for medical legal purposes.

Specimen Processing Service

Surgical specimen processing without diagnosis is available. UniPath can provide specimen gross examination, tissue processing, slide preparation and labeling. This service is exceptionally useful to dermatologists who have specialty training in Dermatopathology and wish to microscopically examine and diagnose their own patient's specimens.



Specimen Labeling and Submission

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Specimen Labeling and Submission

Prudent medical-legal practice and our laboratory accrediting agencies have strict guidelines for specimen labeling and submission. They also mandate rejection of improperly completed requisitions or incorrectly identified slides or specimens. For example, some specimens cannot be analyzed because of improper collection, preservation or degradation in transit. Other specimens may have prolonged turn-around-times because of lack of necessary patient information. Still other specimens will, by necessity, be rejected because of inaccurate or absent specimen and/or requisition labeling. You will be notified of rejected or problem specimens upon receipt. To avoid delayed diagnoses and potential specimen rejection, please observe the following requirements:

Surgical Specimens

Requisition:

1. Patient last, first name
2. Date of birth
3. Collection date
4. Physician and clinic name and address
5. Insurance and/or billing information including name of insured, subscriber number, group number, name and address of insurance company, and IPA group (if applicable) – copy of insurance card preferred
6. Reason for testing/ICD-9 code
7. Test Order
8. Site and type of biopsy
9. Brief clinical history
10. Requests for any special stains or studies

Specimen container:

1. Patient last name, first name (last name and first initial are acceptable)
2. Second identifier such as date of birth, chart number, SS# or other unique identifier is required
3. Specimen type and/or location (i.e. skin lesion, left shoulder etc.)



Specimen Labeling and Submission

Cytology Specimens

Requisition:

1. Patient last name, first name
2. Date of birth
3. Physician and clinic name and address
4. Insurance and/or billing information
5. Collection Date
6. Reason for testing/ICD-9 code
7. Type of Specimen
8. Brief clinical history including last menstrual period (LMP) or menstrual history
9. Request for any special stains or studies (i.e. HPV, CT/NG, Molecular Tests)

Vials/Non-Gyn Slides:

1. All Pap test and Non-Gyn vials and submitted Non-Gyn cytology smears must be legibly labeled with the patient's name (last name and first initial are acceptable) matching that on the requisition slip. Minimally, the last name must be legible and correctly spelled. Including the patient's first name or first initial on the slide is encouraged. Second identifier such as date of birth, chart number, SS# or other unique identifier is required
2. A #2 lead pencil is recommended for slides. Markers and ballpoint pens are unacceptable for slides because of wash off during processing. Also, a name written on top of fixative will wash away with the fixative during processing. All smears will be processed as air-dried. If no liquid based fixative is available, a fixed smear is acceptable. Write "Fix" on fixed smears.



Specimen Labeling and Submission

Molecular Diagnostic Specimens

Requisition:

1. Patient last, first name
2. Date of birth
3. Collection date
4. Physician and clinic name and address
5. Insurance and/or billing information including name of insured, subscriber number, group number, name and address of insurance company, and IPA group (if applicable) – copy of insurance card preferred
6. Reason for testing/ICD-9 code
7. Test Order
8. Site of collection
9. Brief clinical history

UniSwab™ vials:

1. Patient last name, first name (last name and first initial are acceptable)
2. Second identifier such as date of birth, chart number, SS# or other unique identifier is required
3. Specimen type and/or location (i.e. skin lesion, left shoulder etc.)

GBS swab and Transport media:

1. Patient last name, first name (last name and first initial are acceptable)
2. Second identifier such as date of birth, chart number, SS# or other unique identifier is required
3. Specimen type



Specimen Labeling and Submission

Flow Cytometry / Hematopathology Specimens

Requisition:

1. Patient last, first name
2. Date of birth
3. Collection date and time
4. Physician and clinic name and address
5. Insurance and/or billing information including name of insured, subscriber number, group number, name and address of insurance company, and IPA group (if applicable) – copy of insurance card preferred
6. Reason for testing/ICD-9 code
7. Test Order
8. Type and collection site of specimen
9. Brief clinical history
10. Requests for any special stains or studies

Bone Marrow/Peripheral Blood Slides:

All bone marrow/peripheral blood slides submitted must be legibly labeled with the patient's name (last name and first name initial are acceptable) matching with that on the requisition form. Minimally, the last name must be legible and correctly spelled. Second identifier such as date of birth, chart number, SS# or other unique identifier is required.

Specimen Containers:

1. Patient last name, first name (last name and first initial are acceptable)
2. Second identifier such as date of birth, chart number, SS# or other unique identifier is required
3. Specimen type and collection site (i.e. skin lesion, left shoulder etc.)



Specimen Preservation

Toll Free 1.866.UniPath (864.7284)



Specimen Preservation

Note: This is a general information section. For detailed and specific information regarding specific preservation guidelines for particular types of biopsies and cytological collections, please see the sections in this handbook relative to the procedure in which you are interested. If you have any questions, please contact UniPath at (303) 512-0888.

Biopsy Specimens

1. Most biopsy specimens should be submitted in 10% neutral buffered formalin with enough fixative to cover the specimen. UniPath will provide containers filled with 10% neutral buffered formalin to our clients.
2. The following specimens should be submitted immediately and may require special processing
 - Frozen sections (submit fresh or in saline)
 - Cytogenetics (submit in saline or RPMI)
 - Lymph nodes (submit in saline or RPMI)
 - Limbs (must be refrigerated)
 - Muscle biopsy (submit in saline soaked gauze and refrigerate)
 - Kidney biopsy (one biopsy in Glutaraldehyde for electron microscopy and one biopsy in 10% formalin)
 - Electron microscopy only (must be submitted in glutaraldehyde)
 - Urate crystals (gout) specimens (must be submitted fresh or in 100% alcohol)
 - POC (products of conception) for genetic or chromosomes studies, send in a sterile container with no fixative, refrigerate
 - Toenails or fingernails for fungus send in formalin and maybe sent with routine courier
 - Skin biopsy for immunofluorescence, send one biopsy in Michel's (Zeus) fixative and one biopsy in 10 % formalin. Specimen maybe sent with routine courier.
 - Liver biopsy for hemachromatosis (quantitative iron, Fe or Iron) send with no fixative in a metal free container and refrigerate
 - Calculi/stones for analysis, send dry
 - Nerve biopsy, clinician should speak with a pathologist
3. It is best to confer with a pathologist concerning requests out of the ordinary prior to submission of the specimen

Note: Prior to submission of these specimens, The Courier Department should be contacted during business hours to arrange for an unscheduled pick-up (303) 512-0888.



Specimen Preservation

Group B Streptococcus Swab (should be collected in vial containing transport media and must be refrigerated)

1. Aseptically remove sterile swab from package
2. Collect specimen
3. Aseptically remove cap from vial
4. Place swab in transport medium
5. Replace cap to vial - Close tightly
6. Fill out vial label with patient information
7. Refrigerate immediately - Specimen must be delivered to the laboratory within 48 hours

UniSwab™ Specimens

1. Aseptically remove sterile swab from package
2. Collect specimen by vigorously swabbing site for 30 seconds
3. Aseptically remove cap from vial
4. Place swab in transport medium and break off swab against rim of the tube
5. Replace cap to vial-Close tightly
6. Fill out vial label with patient information

Non-Gyn Prepared Smears

Either alcohol-fixed or air dried smears are acceptable for processing and interpretation. It is vitally important that you communicate to the laboratory which type of fixation you have used so we may determine the proper processing and staining procedure. In general, air-dried smears are preferable because of ease of preparation and decreased cell loss. Write “air-dried” or “AD” on frosted end of air-dried smears. Write “Fixed” or “F” on fixed smears. All smears that are unspecified will be processed as air-dried.



Specimen Preservation

Fluid specimens

1. The following fluids are best fixed with an equal volume of 50% methyl or ethyl alcohol, CytoLyt®:
 - Thyroid or other cyst fluid
 - Breast cyst fluid
 - Ovarian cyst fluid
 - Urine
 - Bronchial wash fluid and lavage fluid
2. The following fluids are best refrigerated without fixation and transported to the laboratory as soon as possible to prevent cellular degradation. Please contact Courier Services at (303) 512-0888 to arrange for an unscheduled pick-up.
 - Pleural and abdominal fluid
 - Pelvic wash fluid
 - Spinal fluid

Note: We have discovered that formalin fumes are extremely detrimental to cytology specimens. Many Pap smears have been compromised because of exposure to formalin. This exposure often occurs during transportation when Pap smears are shipped in the same bag with cervical biopsies. We recommend shipping cytology and surgical specimens in separate specimen bags to minimize this potential problem.

Patient Preparation: In general, no special patient preparation is needed for biopsies, fine needle aspiration or body fluid cytology. See special patient preparation notes for Gyn cytology (Pap test) and urine cytology.



Surgical Pathology

Toll Free **1.866.UniPath (864.7284)**



Biopsy – Bone Marrow

Materials Required:

1. Special Hematopathology requisition forms (call UniPath for these), with labels for patient name, specimen designation, time specimen was collected, and biohazard bags
2. B-Plus fixative
3. Three purple top (EDTA) tubes – one plastic capped tube for aspirate, one rubber stopper tube for peripheral blood, and one marrow aspirate for molecular testing (if requested)
4. Two with 3 to 6 ml of aspirate for cytogenetics
5. One yellow top tube with 3-5 ml blood or 1 ml marrow for flow cytometry
6. Extra EDTA tube 2-3 ml for molecular genetic studies
 - May use ACD for flow
 - ACD for STR studies (transplant patients)

Procedure:

1. Label the collection containers (not the lid) with the patient's name and specimen identification
2. Complete hematopathology requisition form including tissue type, patient name, complete address, birth date, date of service, and billing data, as well as any other physician who need copies of the report
3. Request studies in the test menu
4. After preparing 5 touch imprints, the bone marrow core biopsy should be immediately placed in the B-Plus fixative and note the time of fixation on the requisition form
5. Express bone marrow aspirate material into a purple top tube
6. The peripheral blood specimen should be placed in a purple top tube.
7. If chromosome or flow cytometry studies are required, aspirate material must be submitted in separate tubes (as above) or yellow (ACD) for flow. If marrow aspirate is not obtained, a 10mm bone core sample may be submitted in sterile RPMI fixative.
8. Place all the specimen tubes and the requisition form in a biohazard bag
9. If you are in the Denver Metro area, contact UniPath Client Services and they will immediately dispatch a courier for optimal specimen handling. If you are outside the Denver Metro area, send the specimen to UniPath with your local courier system.

Note: Bone marrow biopsy specimens are performed for a variety of reasons ranging from evaluation of anemia to the diagnosis of metastatic carcinoma and leukemia. Complete history including whether the patient is receiving growth factors. Complete patient history, as well as documentation of any supporting details is vital to the complete and accurate interpretation of the material. It is of particular importance to include information as to growth factor therapy.



Biopsy – Routine Cervical, Endocervical and Endometrial

Materials Required:

1. Collection container with 10% formalin
2. Requisition form

Procedure:

1. Label the body of the collection container (not the lid) with the patient's name and tissue identification
2. Complete requisition form including tissue type, patient name, complete address, birth date, date of service, and billing data
3. Provide clinical history, i.e. last menstrual period, prior biopsies or Pap smear information, and any history of hormone use including birth control pills on the requisition form
4. Immediately place the specimen in the fixative container, tightly close container lid and forward to laboratory with requisition

Note: Use of gauze pads to hold or place endometrial and endocervical samplings is discouraged because portions of the specimen are absorbed into the coarse weave and lost. Telfa is acceptable; placing the specimen directly into formalin is preferred.

Biopsy – Cone and Leep Conization of Cervix

Materials Required:

1. Collection container with 10% formalin
2. Requisition form

Procedure:

1. Label the collection container with the patient's name, and tissue identification.
2. Complete requisition form including tissue type, patient name, complete address, birth date, date of service, and billing data.
3. Include on the requisition a history of prior Pap smear or biopsy results.
4. Orient cone specimen with surgical suture material is preferred.
5. Immediately place the specimens in the fixative container, tightly close container lid and forward to laboratory with requisition.



Biopsy – Endoscopic (esophagus, gastric, small and large intestine, lung, etc.)

Materials Required:

1. Collection container with 10% formalin
2. Telfa
3. Requisition form

Procedure:

1. Label the body of the collection container (not the lid) with patient's name and tissue identification.
2. Complete requisition form including tissue type, patient name, complete address, birth date, date of service, and billing data.
3. Place specimen directly into formalin, close lid tightly and forward to laboratory.
4. If you chose to use Telfa, gently orient and place tissue on Telfa, mucosal surface up with submucosal surface in contact with the Telfa. Slowly enter the Telfa with attached tissue into the formalin, tightly close lid and forward to laboratory with the requisition.

Note: Use of gauze pads to hold or place endoscopically obtained specimens is discouraged because portions of the specimen are absorbed into the coarse weave and lost. Telfa is acceptable; placing the specimen directly into formalin is preferred.



Biopsy – Skin Excisions

Materials Required:

1. Collection container with 10% formalin
2. Requisition form

Procedure:

1. Label the collection container (not the lid) with the patient's name and tissue identification
2. Complete requisition form including tissue type, patient name, complete address, birth date, date of service, and billing data
3. Include on the requisition form any clinical history, a gross description of lesion, and history of prior biopsies if available
4. Indicate if specimen is a shave, a punch or an excision
5. Orient specimen as necessary using description or surgical suture material. Immediately place the specimen in the fixative container.
6. Tightly close the container and forward to laboratory with requisition

Biopsy – Lymph Node

Materials Required:

1. Sterile screw top container
2. Sterile isotonic saline
3. Completed requisition form
4. Ice

Procedure:

1. Label the collection container (not the lid) with the patient's name and identification
2. Place the lymph node in the container and moisten with saline. **DO NOT SUBMIT IN FORMALIN.**
3. Fill out requisition and include name of primary care physician or oncologist
4. Place container in biohazard bag filled with ice
5. Call UniPath Courier Services at (303) 512-0888 for STAT pick-up. Specimen should be received within 30 minutes of excision for optimal results.



Biopsy – Prosthetic Breast Implants

Materials Required:

1. Collection containers for implants (submitted without fixative) and containers for fibrous tissue capsules submitted in 10% formalin
2. Completed requisition form

Procedure:

1. Label the collection containers (not the lid) with the patient's name and specimen identification
 - a. The prosthetic breast implants must be submitted in separate containers without fixation
 - b. The fibrous tissue capsules may be submitted separately in 10% formalin
2. Complete requisition form to include tissue type, patient name, date of birth, date of service, and billing insurance data
3. Indicate on the requisition the presence or absence of prosthetic rupture or leakage
4. Tightly close container lids and forward to laboratory with requisition

Note: Please indicate if these specimens are to be returned to you or the patient. A signed release form from the patient must accompany the request for return of specimen for medical legal purposes.



Immunohistology, Cytochemistry, Molecular Pathology and Flow Cytometry

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Immunohistology

Principle:

Immunohistology employs highly specific monoclonal antibodies to detect protein antigens in pathologic material to demonstrate specific types of cellular differentiation. Molecular pathology uses specific DNA probes to identify genetic material, to associate a disease process with an infectious agent or rearrangement of genetic material. Cytochemistry employs specific chemical reactions to demonstrate sub-cellular organelles or enzymes, which might be associated with certain types of cellular differentiation. These special studies are useful in establishing the correct diagnosis for a wide variety of pathologic conditions. These studies are also useful in determining a patient's prognosis for a given tumor, such as status of estrogen and progesterone receptors for breast carcinoma. Finally, these studies are also useful in helping the pathologist to determine if a given histologic pattern represents a malignancy, such as demonstration of basement membrane epithelium in prostate needle biopsies.

Materials Required:

1. Collection container filled with 10% buffered formalin for specimens not suspected of being lymphoma or leukemia (see next line). The pathologist will determine if these special studies are needed.
2. Sterile collection container lined with saline soaked gauze for cases suspected of lymphoma
3. Glass Slides with frosted end for cytology specimens such as Fine Needle Aspirations or bone marrow aspirates
4. A completed requisition form with proper patient identification, history and source of biopsy

Procedure:

1. Label the collection container (not the lid) with the patient's name and tissue identification
2. Submit routine biopsy material in 10% buffered formalin unless lymphoma or leukemia is suspected. The pathologist will determine if special studies are required after studying the routine preparation.
3. For suspected lymphomas, place the fresh tissue in a clean container, which does not contain any fixative material. The tissue should be placed on gauze dampened with saline. Contact UniPath Courier Services at (303) 512-0888 to arrange for a STAT pick up.



Immunohistology, Cytochemistry, Molecular Pathology and Flow Cytometry

4. Let smears air dry at room temperature. Place them in a plastic slide box. If you do not have a box, simply wrap the slides up in paper towel or tissue paper and secure with tape.
5. Complete requisition form to include patient name, date of birth, date of service, and billing data. The pathologist will determine if additional studies are needed after initial examination of the specimen.
6. Please note that we can accept specimens Monday through Friday only, from 7:00 a.m. to 4:00 p.m. Advanced warning about specimens being sent fresh for Lymphoma work-ups ensures the specimen will be properly processed upon receipt at the laboratory. If unsure of proper submission please call prior to biopsy excision.

Molecular Oncology

Principle:

Molecular Oncology uses molecular methods to characterize genetic material, or to detect infectious agents. These special studies are useful in helping the pathologist determine what translocation occurred or what gene amplified, deleted, etc.

Testing is currently performed to evaluate:

1. Breast cancer Her2Neu status
2. Jak 2 quantitative Polymerase Chain Reaction
3. Human papillomavirus High risk detection
4. Various genetic rearrangement in hematologic malignancies

Tissue Biopsies:

Materials Required for Testing:

1. A tissue specimen that has been processed and is in a paraffin block. Or unstained slides cut from a paraffin block.
2. A completed pathology request form with insurance information or copies of insurance information attached.

Blood:

5 to 10ml blood specimens should be collected in EDTA containing tube or purple top. Heparin samples are not acceptable.



Chromosomal Studies

Currently, UniPath does not perform chromosomal studies on tissue or fluid specimens. If requests for chromosome studies are received, we will forward them to an appropriate reference laboratory. Specimens for Chromosomal analysis (i.e. Products of Conception) must be submitted fresh in saline or RPMI (without formalin) in an appropriately labeled contained and accompanied by a completed requisition form requesting Chromosomal Analysis.

Flow Cytometry

Principle:

Flow cytometry measures physical and chemical properties of the cells. The cells pass the flow cytometric analyzer in a fluid, single-cell stream. The laser beams interrogate each cell and indicate the cell size, internal complexity and the antigens present on cell surface or in the cytoplasm.

Methodology:

Each specimen is manually processed. A smear (peripheral blood or bone marrow) or touch prep (tissue) slide is made from the original specimen. A cytospin slide is made from the final cell suspension. The slides are stained and evaluated by the hemapathologist. Every specimen for flow cytometric analysis is manually processed. Panels of surface/intracellular markers are chosen to stain the cells based on morphology and clinical history. After the cells are stained, they are acquired and analyzed with flow cytometer.

Our immunophenotyping panel configurations are carefully considered based on state-of-art scientific references, consensus, and the experiences of our hemapathologists. The combinations of antibodies allow for the identification of normal and abnormal populations of cells within a specimen. Our antibody panes cover acute leukemia, chronic leukemia, T and B cell lymphoma, multiple myeloma, myeloid disorders and others.

Performed: Monday – Friday, STAT on-call available weekends

Turnaround Time: Verbal results available within 24 hours of specimen receipt.



Specimen Requirements:

Bone Marrow:

1. 2-7mL ACD (yellow) bone marrow
2. Specimen may be inoculated into a sodium heparin tube (dark green), or EDTA tube
3. Deliver to lab immediately (within 12 hours) and transport at room temperature (20-25°C). Do not refrigerate.
4. For overnight or weekend storage, the specimen may be inoculated into a 50mL conical tube containing RPMI media. Refrigerate (2-8°C) and transport on “wet” ice. Do not send on dry ice and DO NOT FREEZE.

Peripheral Blood:

1. 10-20mL collected in ACD tube. Sodium heparin & EDTA accepted.
2. Deliver within 24 hours of collection
3. Transport at room temperature (20-25°C). Do not refrigerate.

Solid Tissue/FNA:

1. 5mm solid tissue specimen cut aseptically into small pieces and placed in RPMI media and stored at (2-8°C).
2. FNA specimen placed in RPMI media and stored at (2-8°C).
3. Transport on “wet” ice. Do not send on dry ice and DO NOT FREEZE.

Body Fluids:

1. Volume required for testing depends on the cell count of the specimen. Specimen handling varies depending on the specimen type. Please call the laboratory for details.



Process and Holds:

Occasionally a physician may submit a specimen for possible immunophenotyping, depending on the results of permanent sections expected at a later time. In these cases, "Process and Hold" is written on the requisition. The specimen will be held for 2-3 days, during which time the physician must contact the laboratory to request immunophenotyping. A specimen may also be sent with a diagnosis that does not warrant flow cytometry testing (Hodgkin's lymphoma, carcinoma, etc.). These specimens are held until reviewed by the pathologist. If no further testing is requested, "CANCELLED by (pathologist name)" will be written on the requisition in red ink with the date and technologist initials. The paperwork is placed in the file cabinet. The specimen is kept for one week and then discarded.

Specimen Rejection:

A specimen may be rejected if it is frozen or fixed, too old, or if it is hemolyzed or clotted. All specimens MUST be labeled with the at least the patient's name and date of collection. Other identifying information is useful, such as hospital number.

Specimen Requisition:

There are two specific requisitions for Flow specimens. The one used for BMA Morphology/Flow is titled "Comprehensive Hematopathology Requisition". Please note on the requisition that Morphology is requested for Peripheral Blood (PB) and/or Bone Marrow Aspirate (BMA) and indicate the type of tubes which are sent. For BMA morphology, please include the PB and/or a CBC count and smear. Patient history and treatment is needed along with Approval for Special Studies, if deemed necessary by UniPath Hematopathologist.

The second requisition is used for Flow specimens such as tissues, FNA, and other body fluids (other than PB/BMA). It is important to indicate the diagnosis under consideration and the indication for flow testing.



The following information must be completed on each requisition.

1. Patient Name
2. Date and time of collection
3. Specimen source or type (i.e. Bone marrow, left cervical lymph node, etc.)
4. Physician and contact phone number
5. Hospital Number or Accession Number (if available)
6. Patient's date of birth
7. Social Security Number (if available)
8. Thorough clinical history
9. All insurance information must be included to ensure proper billing

Electron Microscopy

Currently, UniPath does not perform “in-house” Electron Microscopy on tissue or fluid specimens. If Electron Microscopy is requested or required to complete a diagnosis, we will refer to an appropriate reference laboratory. Specimens for Electron Microscopy must be submitted in Gluteraldehyde. Generally electron microscopy is clinically necessary only for complete evaluation of medical kidney disease. Coordination of preparation and submission of specimen can be accomplished best by contacting the pathologist at the appropriate medical facility prior to collecting the specimen.



Genetic Testing

Toll Free **1.866.UniPath (864.7284)**



Genetic Testing

UniPath partners with Kimball Genetics to provide genetic testing for a number of diseases and conditions. The tests offered have been proven to provide 100% positive predictive value for these particular disorders. Specimen types vary by test, but most disorders can be tested for using a buccal (cheek cell) swab. See the procedures below, and feel free to contact a UniPath representative for information on ordering these tests, or for supplies.

Materials Required:

1. Cheek cell (buccal) swab, Kimball Genetics cheek cell collection kit
2. UniPath/Kimball Genetics special requisition form

Procedure:

1. Label specimen collection container with appropriate information (including patient name, collection date, etc.)
2. Collect specimen using cheek cell (buccal) collection method; follow instructions accompanying collection kit
3. Submit to UniPath with completed requisition form (use both the UniPath requisition and the special UniPath/Kimball requisition if ordering other tests besides genetic testing)



Infectious Disease Testing

Toll Free 1.866.UniPath (864.7284)



Infectious Disease Testing

UniPath now offers infectious disease testing using the UniSwab™. These primarily gynecologic tests aid in the detection, diagnosis, and treatment of viral, fungal, and bacterial infections. UniPath performs nucleic acid testing using polymerase chain reaction (PCR), direct probe detection and hybrid capture methodologies providing high levels of sensitivity in testing for the presence of these organisms. Consult your UniPath requisitions, representatives or website for the most up-to-date information on available tests.

Tests offered using the UniSwab™ collection device can be found in Appendix A-2 of this manual.

UniSwab™ Collection

Purpose:

1. For female patients, collection of cervical, vaginal, and rectal specimens, including lesions
2. For male patients, collection of discharge from urethra or lesions

Procedure:

1. For HSV samples – please use UniSwab™ for specimen collection.
 - a. For crusted lesions, pre moisten the swab with either saline or sterile water
 - b. De-roof the crust, and swab the lesion firmly working from outer base of lesion to interior
 - c. Place swab into transport media, break off handle and recap transport vial

UniSwab™ Specimens

1. Aseptically remove sterile swab from package
2. Collect specimen by vigorously swabbing site for 30 seconds
3. Aseptically remove cap from vial
4. Place swab in transport medium and break off swab against rim of the tube
5. Replace cap to vial-Close tightly
6. Fill out vial label with patient information

Note: Specimen is stable at room temperature for up to 10 days



Group B Streptococcus Swab

A separate collection device is required for the molecular diagnostic test for Group B Streptococcus. Per the recommendations by the Centers for Disease Control (2010), molecular tests for GBS should be performed from specimens enriched by bacterial media, refrigerated and transported in order to obtain maximal sensitivity.

GBS Collection (should be collected in vial containing transport media and must be refrigerated)

Purpose: For female patients, collection of vaginal, and rectal specimens

Materials provided: GBS collection device and transport media

GBS Specimens

1. Aseptically remove sterile swab from package
2. Collect specimen
3. Aseptically remove cap from vial
4. Place swab in transport medium
5. Replace cap to vial-Close tightly
6. Fill out vial label with patient information
7. Refrigerate immediately per recommendation from Centers for Disease Control
8. Specimen must be delivered to the laboratory within 48 hours



Cytopathology (Non-Gyn)

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Cytopathology (Non-Gyn)

Cytology – Induced Sputum and Bronchial Washings for Pneumocystis Pneumonia

Materials Required:

1. Leak proof specimen container
2. Requisition form

Collection Procedure:

1. Label specimen containers (not the lid) with precise identification of specimen site (i.e. right upper lobe of lung, etc.). Add patient name and second unique identifier such as date of birth or social security number.
2. Complete requisition form including patient name, date of birth, date of service, and billing data. Include requests for “Pneumocystis jirovecii” (formerly carinii) pneumonia (R/O PCP).
3. Enter washings into specimen container
4. If brushings are performed concurrently, rotate brush gently over slide to apply material, allow to air dry
5. Place brush in a CytoLyt® container
6. Submit to laboratory with completed requisition form

Note: Specimens may be submitted “fresh” without fixative. If delay is anticipated, add equal amounts of 50% methyl or ethyl alcohol, or CytoLyt®. or refrigerate if specimen delivery is delayed. Only induced sputums or bronchial lavage/wash specimens are acceptable for ruling out PCP. Routine sputums to “rule out PCP” are rarely sensitive enough to yield reliable results.



Cytopathology (Non-Gyn)

Cytology – Bronchial, Colonic, Esophageal and Gastric Washings

Materials Required:

1. Leak proof specimen container
2. Preservative fluid (50% methyl or ethyl alcohol, or CytoLyt®)

Note: Do not use SurePath™ Pap test vials

3. Slides with frosted ends (if brushings obtained concurrently)
4. Requisition form

Procedure:

1. Label specimen containers (not the lid) with precise identification of specimen site (i.e. right upper lobe of lung, etc.). Add patient name and second unique identifier such as date of birth or social security number.
2. Label slides with patient's name
3. Complete requisition form including patient name, birth date, date of service, and billing data. Include requests for special stains or studies (i.e. Pneumocystis jiroveci (formerly carinii) or fungus).
4. Enter washings into specimen container Add equal volumes of preservative fluid to each specimen. Close specimen container tightly.
5. If brushings are performed concurrently, rotate brush gently over slide to apply material, allow to air dry
6. Place brush in a CytoLyt® container
7. Submit to laboratory with completed requisition form



Cytopathology (Non-Gyn)

Cytology – Sputum

Materials Required:

1. Leak-proof plastic container with CytoLyt® fixative
2. Requisition form

Procedure:

1. Label collection container (not the lid) with patient's name and second unique identifier such as date of birth or social security number
2. Complete requisition form including patient name, birth date, date of service, and billing data
3. If the specimen is one of a series of samples taken, indicate position in series (i.e. 1/3 if it is the first of three samples)
4. Have patient rinse mouth prior to collection
5. Give collection container to patient
6. Instruct patient to breathe deeply for 3 minutes
7. Instruct patient to cough deeply from the diaphragm, with effort to expectorate material into collection container
8. At short intervals, repeat the coughing attempts three more times with collection of all coughed up material
9. Add equal volumes of specimen to fixative fluid and shake vigorously (make sure that the container lid is tightly sealed before shaking)
10. Forward specimen to the laboratory with the completed requisition form

Comments:

1. Deep (cough from the diaphragm) specimens are necessary to provide information regarding the lower respiratory tract. The laboratory will determine adequacy of specimen by the presence of alveolar macrophages within the specimen.
2. A series of three sputum samples should be collected on three consecutive days, preferably first thing in the morning with hard, productive coughing is recommended. Morning collections take advantage of the accumulation of secretions during the night. Avoid collecting right after meals to avoid contamination with food particles.
3. If there is difficulty in producing a specimen, collections may be facilitated by the moisture and steam of a preceding, long hot shower. For patients unable to produce sputum with repeated attempts, consider aerosol induced coughing and specimen collection.



Cytopathology (Non-Gyn)

4. Post bronchoscopy sputums may be productive with diagnostic material even with negative bronchial washings, brushings and biopsies.
5. Specimen consisting of saliva or nasal pharyngeal drainage will be reported as lacking alveolar macrophages, metaplastic cells or bronchial columnar cells. These specimens are inadequate for lesions of the lower respiratory tract and will not be considered as true negative studies.
6. With sputum samples positive for malignant cells, a primary of the head and neck region should be considered as well as malignancies of lung. Up to 10% of positive sputums may reflect malignancies of the head and neck.
7. Specimens requiring culture must be separately submitted in sterile containers without fixative. The culture specimens must be submitted to a laboratory specializing in microbiologic culturing.
8. Specify the need for asbestos body examination. Studies will include examination of Papanicolaou and Prussian blue stained smears.
9. Specify the need for identification of pneumocystis jiroveci (formerly carinii). Specimens will include examinations of Papanicolaou, Diff Quick and GMS as needed. The specimens submitted for pneumocystis should be submitted fresh without fixative.



Cytopathology (Non-Gyn)

Cytology – Body Fluids

Materials Required:

1. Collection containers, leak proof
2. Completed requisition form

Procedure:

1. Label the collection container (not the lid) with the patient's name and second unique identifier such as date of birth or social security number, and specimen source.
2. Complete requisition form. Include patient name, date of birth, date of service, and billing data.
3. Close container tightly, then forward specimen to laboratory with the requisition form.
4. Fixation is not necessary if shipped expeditiously. Refrigerate specimen if delivery is delayed.

Comments:

1. Body fluids to be processed in this manner include pleural fluid, ascitic fluid, cul-de-sac fluid, pelvic gutter washing, and pericardial fluid
2. The entire collected specimen should be submitted for cytologic processing after allocating-off specimens for other studies (i.e. culturing, cell count and protein analysis). It is our opinion that the yield and diagnostic sensitivity is increased when the entire specimen is received for cytologic preparation and interpretation.



Cytopathology (Non-Gyn)

Cytology – Urine

Materials Required:

1. Leak proof collection containers
2. Appropriate fixative (50% ethyl or methyl alcohol, or CytoLyt®)
3. Completed requisition form

Procedure:

1. Label collection container (not the lid) with patient's name and second unique identifier such as date of birth or social security number
2. Complete requisition form, including patient name, date of birth, date of service, and billing data. Patient's history of prior kidney or bladder abnormalities should also be noted.
3. Patient Preparation: Instruct the patient to void and discard the first morning specimen. The patient should drink a quart of water an hour or so prior to collecting the urine specimens.
4. Mix an equal amount of fixative with the urine specimen. Forward specimen to laboratory with completed requisition form. Separate specimens should be collected and dated for three consecutive days.

Comments:

1. Urine should be identified as to type of sample (i.e. voided, catheterized, right or left ureteral or bladder irrigation fluid).
2. For detection of cancer of ureters or kidneys, a serial collection of specimens spaced over three days has proven to increase diagnostic sensitivity and yield.
3. Sensitivity and yield of urine specimens has also been shown to increase with optimal collection and preservation of specimen.
4. Unpreserved urine results in the rapid degeneration of exfoliated cells and may become useless for diagnosis.



Cytopathology (Non-Gyn)

Cytology – Nipple Secretions, Smears

Materials Required:

1. Slides with frosted ends
2. Physiologic saline
3. Cotton swab
4. Requisition form

Procedure:

1. Label slide with patient's name and site from which sample obtained. Example: R or L Breast, and allow to air-dry.
2. Complete requisition form, including patient name, birth date, date of service, and billing data. Also include any pertinent history on the requisition (especially if pregnant or lactating).
3. If there is no nipple erosion or ulceration, gently "strip" the area of the breast below the nipple and areola with a motion from beneath the areola towards the nipple surface. Do not massage the entire breast. The stripping motion will propel accumulated secretions within the ampulla of the larger excretory ducts.
4. With appearance of fluid on the nipple surface, touch a slide to the drop of fluid and draw the slide quickly across the nipple
5. Using a separate slide, repeat this process for the opposite breast
6. If there is nipple erosion or ulceration, touch a slide to this area three times, with a different part of the slide in contact each time. This is conveniently done, starting with a contact position close to the hand holding the slide and then moving the application area of the slide further with your hand for the next two samplings.
7. Following touch preparation (#6) of the ulcerated area, try to express fluid (#3) and prepare slides if fluid obtained
8. If no fluid can be expressed, a swab may be dipped in saline and gently rolled and rotated on the ulcerated surface, and applied to a glass slide
9. Place slides in slide container and forward to the laboratory with the completed requisition

Note: We recommend completely air-drying smears to avoid incomplete fixation artifact.



Cytopathology (Non-Gyn)

Cytology – Cerebral Spinal Fluid

Materials Required:

1. Leak proof container
2. Requisition form
3. RPMI (if hematopoietic disease suspected)

Procedure:

1. Label specimen container/s (not lid) with precise identification of specimen site, patient name, and an additional unique identifier such as date of birth or social security number.
2. Complete requisition form, including patient name, date of birth, date of service, and billing data, etc. Include all pertinent history, especially suspected hematopoietic disease.
3. If hematopoietic disease is suspected, place up to 2mL in separate RPMI container. Submit remaining fluid fresh (unfixed) in leak proof container.
4. Place in refrigerator while waiting for transport
5. Call courier department for a 'STAT' pick up



Cytopathology (Fine Needle Aspiration)

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Cytopathology (Fine Needle Aspiration)

Principle:

Fine needle aspiration (FNA) provides a prompt, cost effective, safe, means of evaluating a mass through cytologic diagnosis. The procedure is generally well tolerated by patients. FNA is often used as an alternative to surgery and may provide a definitive diagnosis that will determine therapy and/or assist in a planned surgical approach with effective utilization of operating room time. In general, any palpable mass can be evaluated by aspiration techniques. With ultrasound guidance, fluoroscopy and CT, most deep-seated lesions may also be sampled. Lesions that are commonly sampled include thyroid, breast, salivary glands and lymph nodes. Although the technique is relatively simple, it does require some practice and understanding of principles of aspiration.

Materials Required:

1. Hand grip syringe holder of preference
2. Syringe, screw lock, disposable, 10mL or 20mL plastic with tight fitting barrel
3. Needles of size preference. Most aspirates may be obtained with a needle no larger than 21 gauge. Most highly vascular structures (i.e. thyroid) are best sampled with a 23 or 25 gauge needle.
4. Frosted end labeled slides
5. Specimen container with appropriate fixative as needed for needle washings (CytoLyt®)
6. Alcohol or iodine solutions for sterilization of skin
7. Cotton swabs for sterilization of skin
8. Sterile gauze
9. Adhesive tape
10. Band-Aids
11. Requisition form
12. RPMI for Lymph Node flow

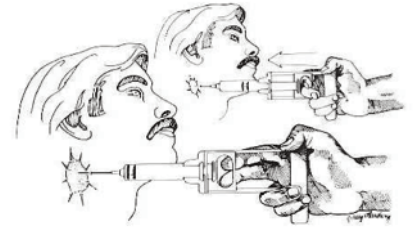
Procedure:

1. Using a pencil (ink or markers wash off during staining) label slides and specimen containers with the patient's name and precise site of aspiration. Add second unique identifier such as date of birth or social security number on the container.
2. Place labeled slides in rows of four slides, each row for use with a "pass". Open container with fixative for needle washings.
3. Set-up a sterile field including preparation of syringe and syringe holders for initial and repeat passes



Cytopathology (Fine Needle Aspiration)

4. Select needles and syringes to be used for the procedure
5. Confirm the identity of the patient by asking their name and comparing it with available requisition, insurance documents, etc.
6. Confirm the site and side which the procedure is to be performed on through review of the requisition and patient history
7. Place patient in a comfortable sitting or reclining position that allows easy access and aspiration of the lesion
8. Palpate the mass to identify the depth of the target and its relationship to surrounding structures
9. Assemble the syringe equipment
10. Clean the skin over the aspiration site with an alcohol swab
11. Immobilize the mass with the thumb and index finger of one hand or between two fingers of one hand
12. Take the syringe equipment in the opposite hand and use a one handed withdrawal and release manipulation of the syringe plunger
13. Place the needle against the skin at a determined puncture site and insert it into the mass area with a single quick motion without negative pressure on the syringe
14. Once the needle is in the desired area, retract the plunger of the syringe to create negative pressure in the syringe and needle lumen. Minimal negative pressure is needed for highly vascular organs such as the thyroid while more negative pressure is needed for dense fibrous organs like the breast.
15. Move the needle back and forth several times directing it in the same plane. Gently redirect the direction of the needle to increase the field of sampling but avoid vigorous redirection of the needle, as this tends to produce unnecessary hemorrhage in the lesion.
16. When material appears in the hub of the needle, the aspiration has been completed. Excess blood in the material will dilute the specimen rendering it unsuitable for microscopic diagnosis. One drop of material can usually produce 4 -6 smears.
17. Release the pressure in the syringe by releasing the syringe plunger
18. Gently withdraw the needle from the lesion and apply pressure to the puncture site with sterile gauze





Cytopathology (Fine Needle Aspiration)

Smear Preparation:

1. After the needle has been removed from the mass, detach the needle from the syringe using a surgical clamp or other appropriate instrument, fill the syringe with air, and reattach the needle to the syringe
2. Place the bevel of the needle against a glass slide and express a small drop of aspirated material onto the slide
3. If too much material is expressed onto the slide, either re-aspirate a portion of the material by withdrawing the syringe plunger slightly, or spread the material out among additional slides
4. If the cellular material is semi-solid, place a second slide on top of the material and pull the slides gently and quickly apart as the material spreads from the weight of the slide
5. If the aspirated material is diluted by fluid or by blood, use the same smear technique as for blood smears
6. Place a second slide onto the drop of material allowing it to spread. Gently pull the two slides apart.
7. Allow smears to air-dry for Diff Quick staining. Write "air dried" on the end of the smears.
8. Rinse the needle and syringe into the Cytolyt® vial for monolayer preparation
9. If staining and immediate evaluation is available, have the patient remain while adequacy of the aspiration pass is determined and repeat the procedure until the operator is satisfied with the adequacy of the material
10. Complete requisition form. Include patient name, birth date, date of service, and billing data. Provide the exact site of the lesion (i.e. parotid, thyroid, lymph node, etc.).

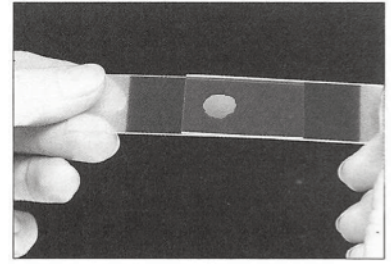


Figure 13. Place a second slide on top of drop.

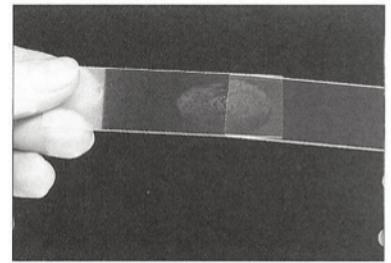


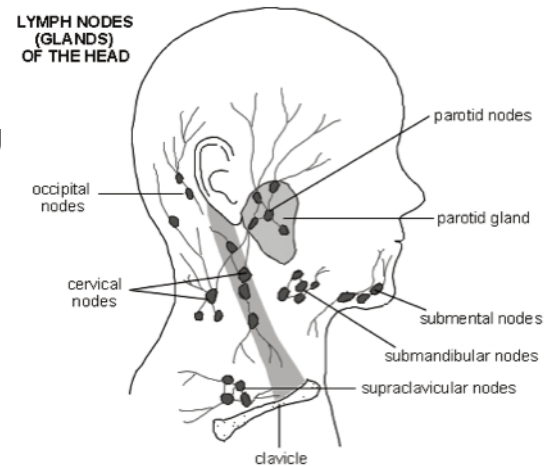
Figure 14. Pull slides gently and quickly apart.



Cytopathology (Fine Needle Aspiration)

Comments:

1. When the lesion is composed of solid tissue, the needle tip functions as a cutting instrument. As it is moved back and forth through the tissue, tiny tissue fragments become dislodged and collect inside the needle. When suction is added to this procedure the previously dislodged fragments are sucked into the needle and the tip of the attached syringe.
2. The needle should never be removed while any negative pressure is in the syringe. Such pressure may force aspirated material from the needle into the syringe. This may make preparation of smears difficult and may start air-drying of the material.
3. It is important not to dilute the cellular material with fluid or blood
4. If a cyst is encountered during the aspiration, evacuate all fluid from the cyst and perform a second aspiration on any residual mass. Express the fluid from the cyst into CytoLyt®, or 50% methyl or ethyl alcohol.
5. If blood is aspirated into the syringe, stop the procedure and prepare slides. Express residual bloody fluid into CytoLyt®, or 50% methyl or ethyl alcohol.
6. If pus is encountered, withdraw as much of the material as possible and perform a repeat aspiration in an adjacent area. (When an infectious process is included in the differential diagnosis, a culture of the aspirated material is often desirable).
7. Necrosis generally occurs in the center of large lesions because of an inadequate blood supply. If the first sample yields only necrotic debris, another sample obtained tangentially to the edge of the mass should be secured.
8. Local anesthesia is rarely required, as the discomfort caused by its application is about the same as the aspiration. Its use is dependent on the lesion location, the discomfort of the patient and the judgment of the operator
9. Passing through layers of muscle while inserting the needle adds significantly to the discomfort of the patient, while making needle placement more difficult and uncertain. Also, small fragments of muscle may plug the needle, jeopardizing subsequent sampling of the target. The muscle and lesion may sometimes be manipulated so that aspiration technique does not involve the muscle.
10. The nipple and the areola of the breast are the areas most sensitive to pain from a needle stick. These areas should be avoided whenever possible. Masses in these areas can sometimes be pushed away from the nipple, immobilized and sampled through adjacent skin.





Cytopathology (Fine Needle Aspiration)

11. When a mass is located close to the chest wall, there is a possibility that the needle may penetrate and cause a pneumothorax. This can be avoided by moving the mass sideways so it rests on a rib. This not only prevents penetration of the chest wall but also provides good support for immobilization of the target.
12. Complications can vary as to the site of aspiration and cannot all be listed. The aspirator should be aware of these prior to aspiration and communicate them to the patient.
13. When completing the requisition slip it is vital to provide the exact site of the lesion (i.e. Thyroid, lymph node, parotid gland, etc). “Neck Mass” provides insufficient information for the cytopathologists to provide a reasoned diagnosis.
14. For thyroid aspirations, it is important to provide further information. Is there one nodule or several? Is the nodule “cold” or “hot” (if a scan has been performed)?
15. For lymph node aspirations, history of prior malignancy, antibiotic treatment, etc are important. Flow cytometry can be performed on FNA’s of lymph nodes if the specimen is properly collected and stored. Please call UniPath for specific instructions if a lymphoma is under consideration. Prior planning can often alleviate the need for a repeat aspiration or biopsy.

Note: We perform FNAs at many of our covered hospitals. The results are generally available the next business day.

Thyroid Fine Needle Aspiration – Thyroglobulin Assay Option

Background:

UniPath, in conjunction with UCHSC Laboratories, now offers Thyroglobulin assays on needle rinsed FNA material. Some patients, status-post thyroidectomy for differentiated (functioning) thyroid carcinomas are often followed using serum thyroglobulin (Tg) as a marker of tumor recurrence. Patients with elevated serum thyroglobulin levels are often further evaluated by use of ultrasound, radioactive iodine scans, or PET/CT scans. Enlarged lymph nodes or nodules in the bed of the thyroid can often be sampled by fine needle aspiration making use of cytology as well as the newly available direct thyroglobulin levels on the aspirate material. The assay is useful in those cases where residual/recurrent disease is suspected, but cytology specimen is negative. To take advantage of this added, sensitive technique of detecting recurrent disease, the following procedure is detailed.



Cytopathology (Fine Needle Aspiration)

Collection Procedure:

1. Identify areas of suspicion, including enlarged lymph nodes or nodules in the bed of the resected thyroid. These can be sampled under ultrasound guidance via fine needle aspiration (FNA).
2. Prepare Cytologic preparations utilizing only direct smears (2 smears per aspirate)
3. Rinse the remaining needle aspirate material rinsed into normal saline (1 cc). Additional aspirates of the targeted lesion may be pooled in this saline rinse. See Fine Needle Aspiration section
4. Additional aspirates for routine cytology can also be collected in CytoLyt®, but is not required in these particular situations
5. After collection of the specimen, contact UniPath for pick-up of the smears and needle rinse material. If pick-up is delayed more than 2 hours, the needle rinse material should be frozen.

At the laboratory:

1. UniPath will prepare the cytologic smears for interpretation. In the event no metastatic carcinoma is identified, the saline rinse material will be forwarded to UCHSC for thyroglobulin testing.
2. Results of the thyroglobulin testing will be added to the original cytology interpretation report as an addendum/consolidated report.

Patient Management information:

The presence of thyroglobulin (> 1.0 ng per milliliter) in the aspirate material of athyrotic patients is presumptive evidence of metastatic disease even in the absence of cytologic finding of metastatic disease. The estimated sensitivity of this procedure is 100% with specificity of 96.2%. Billing for this procedure will be assigned to your patient's insurance per usual custom. Saline collection devices can be obtained through UniPath. For more information or to set up the additional reflex testing, please call (303) 512-0888, or speak with your customer service representative.



Cytopathology (Gyn)

Toll Free 1.866.UniPath (864.7284)



Cytology – ThinPrep® Pap Tests™ by Hologic®, formerly Cytoc

Principle:

Automation and new methodologies are dramatically changing gynecological cytology, particularly the Pap test. The FDA has approved the Hologic® ThinPrep® Pap Test™ as a replacement for the conventional Pap Smear. Studies indicate that it is more accurate than the conventional Pap smear in detecting premalignant and malignant lesions. The advantages of a monolayer slide include:

1. Reduction of obscuring inflammation and blood
2. Elimination of air drying artifact provided the specimen is placed in the fixative immediately after sampling
3. A more uniform and representative sampling of the collected specimen
4. Residual sample available to perform additional testing as needed
5. Lowering of the ASCUS rate since air-drying and obscuring inflammation are not present
6. Increased sensitivity in detecting HIGH GRADE DYSPLASIAS due to the greater ease in recognizing dysplastic cells on the ThinPrep® Pap Test™ monolayer slide

Materials Needed:

1. The collection kit includes a cervix brush with a spatula or broom, and a collection vial of PreservCyt®
2. Completed requisition form

UniPath is equipped to provide this test to you. Contact UniPath to obtain supplies and detailed instructions.

Procedure:

1. Patient Preparation
 - a. Schedule patient for sample collection mid cycle (obscuring blood from menstrual smears is a major source of less than optimal smears)
 - b. Instruct patient in advance not to douche for at least 24 hours prior to examination
2. Label PreservCyt® vial with the patient's name and second unique identifier such as date of birth or social security number



Cytopathology (Gyn)

3. Complete requisition form including patient name, birth date, date of service, and billing data. Include on the form all clinical information (LMP, hormone use, prior Pap smear and biopsy results).
4. Prior to specimen collection, clean away any visible blood, mucus and/or discharge from the cervix
5. Obtain a vaginal smear from secretions in the posterior fornix. This material, along with the ectocervical scrape should be placed immediately in the PreservCyt® vial and agitated to dislodge the collected cells. Shake vigorously.
6. Sample from the endocervix with a cytobrush or broom. If the brush is used the ectocervix is sampled with the spatula.
7. The brush/spatula or broom is placed into the vial of PreservCyt® and agitated up and down against the bottom of the container to collect as much material as possible. After agitation, discard collection device.
8. Close the vial tightly, and place it with a requisition form into a specimen bag and ship it to the laboratory

Note: Although formal maturation indexes (M.I.) cannot be performed on the ThinPrep® Pap Test™ specimen, estimated estrogen effect can be performed which may provide clinically useful information.

Due to the significantly higher cost of the ThinPrep® Pap Test™ kit, we are asking you to use the kits we provide only on patients whose specimens will be sent to our lab for processing. If you need more information on this test, please call the Customer Service Department at (303) 512-0888 for more information.

Cytology – SurePath™ Pap Tests by BD Diagnostics, formerly TriPath Care Technologies™

Note: SurePath™ vials should NOT be used for Non-Gyn specimens.

Principle:

Automation and new methodologies are dramatically changing gynecological cytology, particularly the Pap test. The FDA has approved SurePath™ Pap Test as a replacement for the conventional Pap Smear and as an alternative to the Hologic® ThinPrep® Pap Test™. Studies indicate that it is more accurate than the conventional Pap smear in detecting premalignant and malignant lesions. The advantages of this technology include:

1. Reduction of obscuring inflammation and blood



Cytopathology (Gyn)

2. Elimination of air drying artifact provided the specimen is placed in the fixative immediately after sampling
3. A more uniform and representative sampling of the collected specimen
4. Residual sample available to perform additional testing as needed
5. Lowering of the ASCUS rate since air-drying and obscuring inflammation are not present
6. Increased sensitivity in detecting High Grade Dysplasias due to the greater ease in recognizing dysplastic cells on the SurePath™ Pap Test slide.

Materials Needed:

1. The collection kit includes a Rovers Cervix-Brush®, and a SurePath™ preservative vial.
2. Completed requisition form

UniPath is equipped to provide this test to you. Contact UniPath to obtain supplies and detailed instructions.

Procedure:

1. Patient Preparation
 - a. Schedule patient for sample collection mid cycle (obscuring blood from menstrual smears is a major source of less than optimal smears)
 - b. Instruct patient in advance not to douche for at least 24 hours prior to examination
2. Label vial with the patient's name and second unique identifier such as date of birth or social security number
3. Complete requisition form including patient name, birth date, date of service, and billing data. Include on the form all clinical information (LMP, hormone use, prior Pap smear and biopsy results).
4. Prior to specimen collection, clean away any visible blood, mucus and/or discharge from the cervix
5. Insert Rovers Cervix-Brush® into the endocervical canal
6. Rotate brush 5 times in a CLOCKWISE direction
7. Disconnect the entire head of brush from stem and drop into SurePath™ preservative vial
8. Close the vial tightly, and place it with a requisition form into a specimen bag and ship it to the laboratory

Note: Although formal maturation indexes (M.I.) cannot be performed on the SurePath™ Liquid-Based Pap Test specimen, estimated estrogen effect can be performed which may provide clinically useful information.



Cytopathology (Gyn)

Due to the significantly higher cost of the SurePath™ Liquid-Based Pap Test kit, we ask that you use the kits we provide only on patients whose specimens will be sent to our lab for processing. If you need more information on this test, please call the Customer Service Department at (303) 512-0888 for more information.

Cytology – Human Papillomavirus (HPV) DNA testing

Principle:

UniPath has the technology to test for Human Papillomavirus (HPV). Testing is done directly from ThinPrep® Pap Test™ PreservCyt® sample vial, SurePath™ preservative vial, or Digene specimen transport medium, using the Digene Hybrid Capture II HPV DNA Assay.

The National Institutes of Health have concluded that HPV is present in at least 93 percent of cervical cancers. Using the Digene HPV Assay will help you rapidly categorize women diagnosed with ASCUS (Atypical Squamous Cells of Undetermined Significance) Pap Tests into those who should proceed directly to colposcopy, and those who may be good candidates for more conservative follow-up.

This Single Sample System provides:

1. Convenience: simplifying HPV risk assessment for ASCUS patients. The Digene HPV Assay is performed from the same sample collected for a Liquid Based Pap test.
2. Efficiency: providing rapid, objective HPV analysis of ASCUS patients, leading to fewer follow up procedures and office visits.
3. Peace of Mind: assuring you of optimal patient care while using the latest cervical cancer detection technologies.
4. Tests for: Low Risk Genotypes: 6, 11, 42, 43 and 44

High Risk (oncogenic) Genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68

Procedure:

You can now order the Digene HPV Assay every time a patient presents with an ASCUS from a Liquid Based Pap test without having to schedule the patient for a return office visit. Following the patient's diagnostic report, you will receive an HPV Assay request form that can be signed and faxed/mailed to us. This request must be received within 21 days of original specimen collection.



Cytopathology (Gyn)

Cytology – DNA and Pap Test™

Principle:

Extensive data show that HPV DNA is a sensitive marker for women at risk of neoplasia and that HPV DNA testing may be considered as an adjunct to cervical cytology in cancer prevention programs. HPV DNA testing has greater sensitivity than cytology for detecting clinically relevant lesions. The combination of the ThinPrep® Pap Test™ and HPV DNA Test result in a very sensitive and specific means for assessing a woman's risk of cervical cancer.

Based on ongoing and completed clinical trials, The American Cancer Society as well as the American College of Obstetrics and Gynecology has endorsed the following new recommendations for women over 30:

- The combined use of a cervical cytology test and an FDA-approved test for high-risk types of HPV
- With this option, the patient would receive both a cervical cytology test and a test that checks for certain high-risk types of the human papillomavirus (HPV) known to cause cancer
- Once women test negative on both tests they could be re-screened with the combined tests no more frequently than every 3 years

Procedure:

1. You can order the DNA and Pap Test™ on patient's 30 years or older. The test may be requested by completing the UniPath requisition form and checking the box "DNA and Pap Test™".
2. The specimen can be collected in either the ThinPrep® vial or the SurePath™ vial. (See above for gynecologic specimen collection procedure). Alternatively, a second collection in Digene Specimen Transport Media may be collected in addition to the cytologic collection. This dual collection will result in reduced possibility of a "quantity not sufficient" error.

Interpretation: (see table on next page)

1. All DNA and Pap™ requests will be processed for both cytology and HPV DNA regardless of cytologic diagnosis
2. An integrated report with both findings will be issued along with interpretation and management guidelines



Cytopathology (Gyn)

	Negative for Intraepithelial Lesion	ASCUS	LSIL, HSIL, Suspicious and Positive
HPV DNA Negative	Women who are high-risk HPV DNA negative and have a cervical cytology result of “Negative for intraepithelial lesion or Malignancy” need not be re-screened before three years.	Women who are High-Risk HPV DNA negative and have a cytology result of ASCUS can be followed-up with repeat cytology testing in 12 months.	Women who are High-Risk HPV negative and have a cytologic epithelial cell abnormality of Atypical Squamous Cell – cannot exclude high grade intraepithelial lesion, low-grade intraepithelial lesion, high-grade intraepithelial lesion, suspicious or Positive for malignant cells should undergo a colposcopic examination.
HPV DNA Positive	Women who are High-Risk HPV positive but have a cervical cytology result of “Negative for intraepithelial lesion or malignancy should repeat both cervical cytology and HPV DNA testing in 6 – 12 months	Women who are High-Risk HPV DNA positive and have a cytology result of “Atypical Squamous Cells of Undetermined Significance” should undergo a colposcopic examination.	Women who are high-risk HPV DNA positive and have a cytologic epithelial cell abnormality of Atypical Squamous –cannot exclude high-grade intra-epithelial lesion, low-grade intraepithelial lesion, high-grade intraepithelial lesion, suspicious or Positive for malignant cell should undergo a colposcopic examination.

Reference:

Wright TC Jr, Schiffman M, Solomon D, et al: Interim Guidance for the Use of Human Papillomavirus DNA Testing as a Adjunct to Cervical Cytology for Screening. The Am Col of OB and GYN, vol 103 (2), 2004, p304-309



Cytopathology (Gyn)

Cytology – Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG)

Principle:

UniPath also provides testing for Chlamydia trachomatis (CT) and Neisseria gonorrhoea (NG). Testing is done directly from the ThinPrep® Pap Test™ PreservCyt® sample vial, SurePath™ preservative vial, Digene specimen transport medium and the UniSwab™ using the Digene Hybrid Capture II HPV DNA Assay.

Using the Hologic®'s ThinPrep® Pap Test™ PreservCyt® vial, SurePath™ preservative vial, or Digene specimen transport medium. UniPath is able to provide 6 tests:

- Pap
- CT
- NG
- High and Low Risk HPV (if Pap is ASCUS)
- DNA with Pap™

Additional tests can be ordered from the vial but may be more dilute when compared with the sample collected using the UniSwab™. These tests can be found in Appendix A-2 of this manual.



Cytopathology (Gyn)

Procedure:

Order the CT/NG at the time of examination in the space provided on the UniPath requisitions. The testing must be requested within 21 days of specimen collection.

Cytology – Pap Smears for D.E.S. Evaluation

Conventional Method

Materials Required:

1. Frosted end glass slides, 5
2. Speculum
3. Gauze packs
4. Saline
5. Spatula and or other collection device
6. Requisition form

Procedure:

1. Label slides in pencil with the patient's name and site of sampling
2. Complete requisition form. Include patient name, birth date, date of service, and billing data. Include on the form history of DES exposure and all clinical information (LMP, hormone use, prior Pap smear and biopsy results).
3. Clear cervix and OS of all mucus. Using saline moistened gauze packs, swab clear the vagina including the fornix.
4. Cover the cervix with a gauze pack
5. Scrape the two lateral walls with the spatula and prepare two smears labeled right and left lateral walls. Spray fix smears immediately.
6. Scrape the entire anterior and posterior walls and prepare each labeled appropriately. Spray fix smears immediately.
7. Collect an endocervical smear on a labeled slide and fix it immediately
8. Place slides in slide containers and forward them to the laboratory with the attached requisition form

Note: Particular attention should be paid to the anterior wall of the vagina, as this is the site of most significant lesions associated with DES exposure.



Liquid Based Method

Materials Required:

1. Liquid Based Cytology collection vials, 5
2. Speculum
3. Gauze packs
4. Saline
5. Spatula and or other collection device
6. Requisition form

Procedure:

1. Label vials with the patient's name and second unique identifier such as date of birth or social security number and site of sampling
2. Complete requisition form. Include patient name, birth date, date of service, and billing data. Include on the form history of DES exposure and all clinical information (LMP, hormone use, prior Pap smear and biopsy results).
3. Clear cervix and OS of all mucus. Using saline moistened gauze packs, swab clear the vagina including the fornix.
4. Cover the cervix with a gauze pack
5. Scrape the two lateral walls with the spatula or other collection device and transfer into vials labeled right and left lateral walls. Spray fix smears immediately.
6. Scrape the entire anterior and posterior walls and transfer into appropriately labeled vials
7. Repeat process for endocervical smear
8. Forward vials to the laboratory with the attached requisition form

Note: Particular attention should be paid to the anterior wall of the vagina as this is the site of most significant lesions associated with DES exposure.



The Bethesda²⁰⁰¹ System for Reporting Cervical / Vaginal Cytologic Diagnoses

Toll Free 1.866.UniPath (864.7284)



The Bethesda²⁰⁰¹ System for Reporting Cervical / Vaginal Cytologic Diagnoses

The Bethesda System (TBS) for Reporting Cervical/Vaginal Cytologic diagnoses was developed at a National Cancer Institute (NCI) - sponsored workshop in December 1988 to provide uniform diagnostic terminology that would facilitate communication between the laboratory and the clinician. The System was revisited and modified in April 1991 and most recently in September 2001. The classification used in TBS is not a histogenetic one, but rather a nomenclature designed to facilitate categorization and reporting of cytologic diagnoses. UniPath adheres to the Bethesda System with minor modifications.

Specimen Type

Indicate conventional smear (Pap smear) vs. liquid based vs. other

Specimen Adequacy

1. Satisfactory for evaluation (describe presence or absence of endocervical/transformation zone component and any other quality indicators, e.g., partially obscuring blood, inflammation, etc.)
2. Unsatisfactory for evaluation ... (specify reason)
 - a. Specimen rejected/not processed (specify reason)
 - b. Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of (specify reason)

General Categorization (optional)

1. Negative for Intraepithelial Lesion or Malignancy
2. Epithelial Cell Abnormality: See Interpretation/Result (specify 'squamous' or 'glandular' as appropriate)
3. Other: See Interpretation/Result (e.g. endometrial cells in a woman > 40 years of age)

Automated Review

If case examined by automated device, specify device and result.



The Bethesda²⁰⁰¹ System for Reporting Cervical / Vaginal Cytologic Diagnoses

Ancillary Testing

Provides a brief description of the test methods and report the result so that it can be easily understood by the clinician.

Interpretation/Result

Negative for Intraepithelial Lesion or Malignancy: (when there is no cellular evidence of neoplasia, state this in the General Categorization above and/or in the Interpretation/Result section of the report, whether or not there are organisms or other non-neoplastic findings).

1. Organisms
 - a. Trichomonas vaginalis
 - b. Fungal organisms morphologically consistent with Candida spp
 - c. Shift in flora suggestive of bacterial vaginosis
 - d. Bacteria morphologically consistent with Actinomyces spp.
 - e. Cellular changes consistent with Herpes simplex virus
2. Other Non-Neoplastic Findings (Optional to report; list not inclusive)
 - a. Reactive cellular changes associated with
 - i. inflammation (includes typical repair)
 - ii. radiation
 - iii. intrauterine contraceptive device (IUD)
 - b. Glandular cells status post hysterectomy
 - c. Atrophy

Other: Endometrial cells (in a woman > 40 years of age)
(Specify if 'negative for squamous intraepithelial lesion')



The Bethesda²⁰⁰¹ System for Reporting Cervical / Vaginal Cytologic Diagnoses

Epithelial Cell Abnormalities:

1. Squamous Cell
 - a. Atypical squamous cells
 - i. of undetermined significance (ASC-US)
 - ii. cannot exclude HSIL (ASC-H)
 - b. Low grade squamous intraepithelial lesion (LSIL) encompassing HPV/mild dysplasia/CIN 1
 - c. High grade squamous intraepithelial lesion (HSIL) encompassing moderate and severe dysplasia, CIS/CIN2 and CIN3
 - i. with features suspicious for invasion (if invasion is suspected)
 - ii. Squamous cell carcinoma
2. Glandular Cell
 - a. Atypical
 - i. endocervical cells (NOS or specify in comments)
 - ii. endometrial cells (NOS or specify in comments)
 - iii. glandular cells (NOS or specify in comments)
 - b. Atypical
 - i. endocervical cells, favor neoplastic
 - ii. glandular cells, favor neoplastic
 - c. Endocervical adenocarcinoma in situ
 - d. Adenocarcinoma
 - i. endocervical
 - ii. endometrial
 - iii. extrauterine
 - iv. not otherwise specified (NOS)

Other Malignant Neoplasms: (specify)

Educational Notes and Suggestions: (optional)

Suggestions should be concise and consistent with clinical follow-up guidelines published by professional organizations (references to relevant publications may be included).



Pap Smear Comments - The Bethesda²⁰⁰¹ System

Toll Free 1.866.UniPath (864.7284)



Specimen Adequacy Statements

By the Bethesda System 2001 each Pap smear report is given a statement of adequacy. Two categories of adequacy have been defined:

Satisfactory for evaluation describes the presence or absence of endocervical/transformation zone component and any other quality indicators, e.g., partially obscuring blood, inflammation, etc.)

Unsatisfactory for evaluation... (specify reason)

Note: The quality category of “Satisfactory but limited by...” has been discontinued however, the report will continue to contain information that might limit the overall all quality of the specimen (i.e. partially obscuring inflammation, no endocervical component, etc.) There was general agreement at the recent American Society for Colposcopy and Cervical Pathology (ASCCP) Clinical Management Meeting that negative satisfactory Paps lacking transformation zone component or exhibiting partial obscuring factors should have an annual repeat Pap Test. An early repeat (6 – 12 months) may be considered in women with insufficient screening history or previous abnormalities. Unsatisfactory Paps should be repeated early (generally 2 – 4 months) as such Paps are unreliable for detection of epithelial abnormalities.

Definitions and Criteria for Specimen Adequacy

“**Satisfactory for evaluation**” indicates that the specimen has all of the following:

- Appropriate labeling and identifying information
- Relevant clinical information
- Adequate numbers of well-preserved and well-visualized squamous epithelial cells

“**Unsatisfactory for evaluation...**” is used for a diagnosis if any of the following apply:

- Lack of patient identification on the specimen and/or
- A technically unacceptable slide defined as: one that is broken and cannot be repaired, cellular material that is inadequately preserved,
- scant squamous epithelial component (well-preserved and well-visualized squamous epithelial cells spread over less than 10% of the slide surface, or for liquid based pap smears, less than 5000 squamous cells), obscuring blood, inflammation, thick areas, poor fixation, air-drying artifact, contamination, etc. which precludes interpretation of approximately 75% or more of the epithelial cells.

Note: The “Unsatisfactory....” Designation indicates that the specimen is unreliable for the detection of cervical epithelial abnormalities. Specimen adequacy is evaluated in all cases. However, any epithelial abnormality is of paramount importance and must be reported regardless of compromised specimen adequacy. If abnormal cells are detected, the specimen is never categorized as Unsatisfactory, Such cases may be considered Satisfactory, while describing any limiting factors.



Pap Test Interpretation Statements

By the Bethesda System 2001 each satisfactory Pap Test report is given an interpretative statement. There are three broad “general” categories:

- Negative for Intraepithelial Lesion or Malignancy
- Epithelial Cell Abnormality: See Interpretation/Result
- Other (i.e. endometrial cells in postmenopausal woman)

Negative for Intraepithelial Lesion or Malignancy:

This term will replace the category of “Within Normal Limits” and other negative terms. The “Benign Cellular Changes” category is now included in this negative category with descriptors included for organisms and reactive changes (i.e. radiation, inflammation, repair, etc.).

Epithelial Cell Abnormality

Squamous Cell Abnormality:

There are modifications to the category “Atypical Squamous Cells of Undetermined Significance (ASCUS). The new general category is “Atypical Squamous Cells”. The two subcategories are “of undetermined significance”, and “cannot exclude HSIL”. Most experts recommend colposcopy for the “cannot rule out HSIL” subcategory. For the “Atypical Squamous Cells of Undetermined Significance” subcategory a variety of management options are available including HPV DNA testing, repeat Pap Test or colposcopy. The subcategory “Atypical squamous cells, favor reactive” is eliminated. Please see summary in the Clinical Management Guidelines section of this handbook or visit www.asccp.org.

Note: The terminology for squamous intraepithelial lesions is unchanged (LGSIL, HGSIL)



Glandular Cell Abnormality:

The term “Atypical Glandular Cells of Undetermined Significance (AGUS)” is eliminated and replaced by terms such as “Atypical Endocervical Cells” or “Atypical Glandular Cells”. Some cases will be subcategorized as “favor neoplastic” and a few cases may be classified as “Endocervical Adenocarcinoma in situ” if cytologic criteria are met. The category “Atypical Glandular Cells, favor reactive” is eliminated. The “favor reactive” categories were eliminated for both squamous and glandular abnormalities as they provided mixed messages, and some patients did not receive adequate follow-up.

Endometrial Cells:

The presence of endometrial glandular cells will be mentioned if the woman is age 40 or older. Given the increasing use of hormonal therapy, the laboratory generally cannot determine whether endometrial cells indicate any abnormal finding, so clinical correlation is suggested. The likelihood of significant endometrial pathology is very low in women younger than age 40; therefore bland endometrial cells will not be reported.

Hormonal Status Evaluation

The vaginal/cervical squamous epithelium responds to systemic levels of estrogen by progressively “maturing”. This observation is the basis of the old “Maturation Index”. The maturation index however, is not particularly sensitive or specific and has largely been supplanted by serum hormonal assays. Furthermore, the maturation index may only be performed on specimens obtained directly from the lateral vaginal walls (not cervix). Because the vast majority of Pap Test specimens are from cervical sampling and many are liquid based, a general statement about “estrogen effect” may be given, if indicated, rather than a formal maturation index:

- “Estrogen effect consistent with patient age and/or history”
- “Low estrogen effect for patient age and/or history”
- “High estrogen effect for patient age and/or history”

Formal maturation index readings will continue to be available only on specimens specifically collected from the vaginal walls for the purpose of maturation index calculation.



Infectious Agent Comments

Unless cellular atypia or dysplasia is seen, those specimens with clinically significant infectious agents will be classified as “Negative for Intraepithelial Lesion or Malignancy” with a separate listing of any agents present.

The term “Shift in flora suggestive of bacterial vaginosis” will be used for those cases showing bacteria with features of Gardnerella, Mobiluncus, Peptostreptococcus and Streptococcus.

Clinical Management Guidelines

For detailed recommendations by the American Society for Colposcopy and Cervical Pathology (ASCCP), please visit www.asccp.org.

A summary of guidelines developed at the 2001 ASCCP-Sponsored Consensus Conference follows:

The management of women with atypical squamous cells (ASC) depends on whether the Pap is subcategorized as ASC-US (undetermined significance) or as ASC-H (cannot exclude high grade squamous intraepithelial lesion). Patients with ASC-US should be managed with a program of 2 repeat cytology tests, immediate colposcopy, or DNA testing for high-risk types of human papillomavirus (HPV). Testing for HPV DNA is the preferred approach when liquid-based cytology is used. In most instances, patients with ASC-H, low-grade squamous intraepithelial lesion, HSIL, and atypical glandular cells should be referred for immediate colposcopic evaluation.



Appendix

Toll Free **1.866.UniPath (864.7284)**



Immunohistochemical Panels

Panel	Reagents	Comment
Breast	Her2 IHC, Her2 FISH, Her2 IHC with reflex FISH testing, ER, PR, Ki-67, H&E	Quantitative analysis of therapeutic and prognostic markers
Microsatellite Instability	IHC, PCR	Quantitative analysis of therapeutic and prognostic markers
EGFR	Analysis	EGFR

UniSwab™ Collection

Tests offered using the UniSwab™ collection device include:

- Candida albicans
- Candida tropicalis
- Candida glabrata
- Candida parapsilosis
- Gardnerella vaginalis
- Mobiluncus curtisii
- Mobiluncus mulieris
- Bacteroides fragilis
- Herpes simplex virus 1
- Herpes simplex virus 2
- Trichomonas vaginalis
- Chlamydia trachomatis (CT)
- Neisseria gonorrhoeae (NG)

Vial Collection

Additional tests can be ordered from the vial but may be more dilute when compared with the sample collected using the UniSwab™.

- Candida albicans
- Candida tropicalis
- Candida glabrata
- Candida parapsilosis
- Gardnerella vaginalis
- Mobiluncus curtisii
- Mobiluncus mulieris
- Bacteroides fragilis
- Herpes simplex virus 1
- Herpes simplex virus 2
- Trichomonas vaginalis



Appendix

Special Stains

UniPath, LLC utilizes a variety of special stains to assist the pathologist with either the diagnosing or confirmation of a diagnosis. For more information on these services, see below or call (303) 512-0888.

Special Stains available:

Acid Fast Bacteria.....	Ziehl-Nielson AFB
Acid Fast Bacteria/Nocardia.....	Fite's
Amyloid.....	Congo Red
Bacteria.....	Gram stain
Basement Membrane.....	Jones
Bone Marrow.....	Giemsa (Done at P/SL)
Carbohydrates.....	Alcian Blue
Connective Tissue.....	Trichrome
Connective Tissue/Muscle.....	Pentachrome
Copper.....	Rhodanine
Elastic.....	Verhoeff's Elastic
Fat.....	Oil Red O
Fungus.....	Grocott's Methenamine silver
Fungus.....	Periodic Acid-Schiff reaction for Fungus
Glycogen.....	Periodic Acid Schiff's
Diatase Digestion (or)	
Glycogen Removal.....	PAS with Diatase
Iron.....	Gomori's
Colloidal Iron.....	Muller's Iron
Melanin.....	Fontana Masson
Melanin removal.....	Melanin Bleach
Mast Cells.....	Giemsa, Toluidine Blue or Dominicie's Method
Mucin.....	Mayer's Mucicarmine
Myelin.....	Luxol Fast Blue / PAS
Neurofibrillary and senile plaques (Alzheimer's disease).....	Bielschowsky Method
Reticulin Fibers.....	Gomori's Retic
Spirochetes.....	Warthin-Starry and Steiner
Acid mucosubstance and neutral polysaccharides.....	AB / PAS
Calcium.....	VonKossa's Calcium
Hyaluronidase.....	Digestion
Cresyl.....	Violet
Crystal.....	Violet
Uric.....	Acid



ChromaVision's Automated Cellular Imaging System

UniPath now offers truly quantitative Estrogen, Progesterone, and Ki-67 (proliferative marker) using the Automated Cellular Imaging System (ACIS III). ACIS is a novel hardware and software imaging system incorporating automated microscopy and an advanced color recognition technology.

Estrogen and Progesterone Receptors result of <9% stained nuclei is unfavorable and >19% stained cells is favorable*

The Ki-67 (proliferative marker) result of <19% is prognostically favorable.

As part of our reporting you will receive a separate result including a color photograph of a representative field for each marker for which the tumor was analyzed.

If you have any questions please feel free to contact Michael G. Venrick, M.D., Medical Director at (303) 512-0888.

*Reference for ER/PR scoring scheme: JM Harvey, GM Clark, DC Allred. Estrogen receptor status by immunohistochemistry is superior to the ligand-binding assay for predicting response to adjuvant endocrine therapy in breast cancer. *J. Clinical Oncology* 17: 1474-1481, 1999.

Comments on the Maturation Index and Other Estrogen Effect Indicators

The relationship between hormonal cycles and maturation of squamous cells of the vagina was first noted by Rameriz, and later by Papanicolaou in the 1920's. Papanicolaou's basic research was on the hormonal cycles of the female genital tract and he only incidentally discovered the usefulness of exfoliative cytology in detection of cervical cancer. The ability to perform a Maturation Index (MI) is based on the assumption that sex hormones (estrogen, progesterone and androgens) induce maturation sequences in squamous cells that can be detected by cytological examination.



Appendix

The MI is a ratio obtained by performing a random cell count of the three major cell types shed from the squamous epithelium - parabasal cells, intermediate cells and superficial cells. This count is then given as a percentage (MI=%parabasals, %intermediate, % superficial). Parabasal cells show the least maturity, therefore indicating no estrogen or progesterone stimulation. Intermediate cells show partial maturation and are stimulated by progesterone. Superficial cells show the most maturity, indicating estrogen stimulation.

MI's vary from patient to patient, and day to day in an individual patient. The only two absolute cell patterns are: 1.) Predominance of parabasal cells indicating absence of estrogen stimulation; and 2.) Predominance of superficial cells indicating estrogen stimulation. Intermediate cell patterns have minimal usefulness.

A meaningful MI must be taken as a gentle scrape along the lateral wall of the upper vagina at the level of the cervix. The cells from this area accurately reflect the hormonal balance present at a given time. It should be free of inflammation and endocervical contamination, which can falsely elevate the MI. Many factors can influence the accuracy of the MI including endocervical cell contamination, presence of microorganisms or large numbers of inflammatory cells. Patient history, especially menstrual status, and information about medications that the patient is taking at the time of the Pap smear, is very important in providing an accurate hormonal evaluation.

Because gynecologic cytology specimens are almost invariably obtained from the cervix (in those patients with cervixes) a formal maturation index is not appropriate and will not be performed on these specimens. Valuable information however can be obtained by evaluating the overall degree of maturation and correlating it with the patient's age and history and expressed as an "Estrogen Effect" statement.

- Estrogen effect consistent with Patient age/history
- Estrogen effect high for Patient age/history
- Estrogen effect low for Patient age/history

Formal Maturation Index will only be performed upon specific request and on specimens collected from the vaginal wall not showing confounding inflammation, atypical cells or endocervical contamination.



6116 Warren Avenue, Denver, CO 80222 Phone:303-512-0888

LABORATORY TESTING ADD / CHANGE REQUEST

SECTION I

Change requested by:		Fax:	
Form completed By:		Date:	
Referring Physician:		UniPath Accession # (if applicable)	
Practice Name:			
Patient Name:		Patient D.O.B.	

SECTION II

Changes requested (to be completed by UniPath. Physician representative may change information below if necessary, but please be sure to initial any such changes).

<input type="checkbox"/> HPV (circle one below): High risk High & Low risk (off liquid-based Pap)	<input type="checkbox"/> Chlamydia trachomatis (off liquid-based Pap)	<input type="checkbox"/> Neisseria gonorrhoea (off liquid-based Pap)	<input type="checkbox"/> Herpes (Types 1 & 2) (off liquid-based Pap)	<input type="checkbox"/> Liquid-based Pap Test (SurePath or ThinPrep)
<input type="checkbox"/> MDL PCR Testing (must have collected OneSwab or UroSwab specimen)				
MDL Test Number: _____ MDL Test Name _____				
<input type="checkbox"/> Other (please specify in space below; this section is <u>also</u> to be used for test cancellations and ICD-9 changes)				

Please sign below and fax back to 303-512-2288 promptly to avoid further specimen processing delays.

By signing below, I hereby authorize UniPath to make the changes noted above, and I acknowledge that I am authorized to request that these changes be made.

Signature

Print Name

Date

Confidential: The information contained in this transmission is intended solely for the addressee(s) named above and is privileged and/or confidential. If the reader of this message is not the intended recipient or the person responsible to deliver it to the intended recipient, you are prohibited from reading or disclosing the information contained in this transmission. Any examination, use, dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by phone for instructions.

Last Updated: 06/21/2010



Appendix



Patient Information Update Form

Please fax completed form to:

UniPath Billing Coordinator
Fax: 303-692-6061

ACCESSION _____

DATE OF UPDATE _____

CASE DETAILS

Client				
Clinician				
Patient		DOB		DOS

Please complete only the sections below that are pertinent to the information being updated

CHANGE BILLING STATUS

<input type="checkbox"/> Bill Uninsured Patient	<input type="checkbox"/> Bill Client	<input type="checkbox"/> Bill Insurance
---	--------------------------------------	---

DIAGNOSIS CODE UPDATE

Codes V70.0 and V22.2 are not appropriate for UniPath billing

New Code(s)	
Authorized By	

PATIENT DEMOGRAPHIC INFORMATION

Please provide a copy of the patient information sheet

Address		Home Phone	
		Work Phone	

PATIENT INSURANCE INFORMATION

Please provide a copy of all insurance cards or the patient information sheet

	Primary Insurance	Secondary Insurance
Company Name		
Policy Holder Name and DOB		
ID Number		
Group Number		
Claims Address		

The information contained in this facsimile transmission is intended solely for the addressee(s) named above and is privileged and/or confidential. If the reader of this message is not the intended recipient or the person responsible to deliver it to the intended recipient, you are prohibited from reading or disclosing the information contained in this transmission. Any examination, use, dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone for instructions.
 UniPath ♦ 6116 E Warren Ave., Denver, CO, 80222 ♦ Phone: (303) 512-2283 ♦ Fax: (303) 692-6061



Appendix

Supply Order Form

Revised 02.10.11



UniPath™
Pathology at the Next Level

UniPath - 6116 E Warren Avenue - Denver, CO 80222 - 303.512.0888 - 1.866.UniPath (864.7284) - Fax 303.512.2246 - www.unipathdx.com

CLINICIAN INFORMATION

Practice/Clinician: _____ Contact Name: _____
 Address: _____ Contact Number: _____
 City/State/Zip: _____ Date Ordered: _____

UNIPATH REQUISITIONS (Please Indicate Quantity)

Breast: _____ Dermatopathology: _____ FNA: _____ Hematopathology: _____
 Tissue: _____ Urology: _____ Cytology/Histology: _____ Tissue/Gyn NonGyn Cyto: _____

UNIPATH PREMIUM TEST KITS (Please Indicate Quantity)

Diagnostic Boxes: _____ Prostate Pathology: _____ UroVysion: _____ Bone Marrow/Periph.Blood: _____

UNIPATH SPECIMEN HANDLING BAGS (Please Indicate Quantity)

Specimen Bags (100/package): _____ GBS Transport Cylinder: _____

FORMALIN CONTAINERS (Please Indicate Quantity - 32 per box, 256 per case)

20mL: _____ 40mL: _____ 60mL: _____ 20mL (empty): _____

FNA AND BONE MARROW SUPPLIES (Please Indicate Quantity)

Green Top Tubes (100/tray): _____ Frosted End (72/box): _____ B+ Fixative-20mL (32/box): _____
 Purple Top Tubes (100/tray): _____ Plastic - 5 slide holders (25 each): _____ Cytolyt Fixative-30mL (20 each): _____
 Yellow Top Tubes (100/tray): _____ Cardboard - 2 slide holders: _____

MOLECULAR TESTING (Please Indicate Quantity)

UniSwab: _____ OneSwab (25/box): _____ UroSwab (Individual): _____
 25/pack: _____
 10/pack: _____ NasoSwab (Individual): _____ GBS by UniPath (individual): _____
 5/pack: _____

SUREPATH/THINPREP (Please Select Method and Indicate Quantity)

SurePath

ThinPrep

Fixative Vials (25/tray): _____

Fixative Vials (25/tray): _____

CytoBrooms (25/bag): _____

CytoBrooms (25/bag): _____

Purple CytoBrushes and Clear Spatulas (25 each/bag): _____
(Packaged together, cannot be ordered separately)

Purple CytoBrushes and Clear Spatulas (25 each/bag): _____
(Packaged together, cannot be ordered separately)

White Handle CytoBrushes Only (100/bag): _____

White CytoBrushes Only (100/bag): _____

CombiBrooms (25/bag): _____

ADDITIONAL REQUESTS



Pathologist Licensure

UniPath's physicians hold current licenses in the following states:

- Arizona
- California
- Colorado
- Kansas
- Minnesota
- Montana
- Nevada
- New Mexico
- New York
- North Carolina
- Oregon
- South Dakota
- Texas
- Utah
- Virginia
- Wyoming