PROVIDE Health Care

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Organization Providence Health Care

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Initial version

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Supervisor	9/29/2020	1.1	Patricia Weigand	
Approval	Lab Director	8/25/2020	1.0	Carmen L. Wiley Carmen Wiley, PhD	
Approval	Lab Director	12/10/2019	1.0	Joseph Schappert, MD	
Approval	Format Review	12/10/2019	1.0	Tawny Arensmeyer	
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Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	12/9/2019	12/10/2019	Indefinite

PROVIDENCE Health Care

Anatomic Pathology Collection Manual

Table of Contents

1. INTRODUCTION

1.1 Purpose and Objective

This manual is designed for the purpose of providing a simple and easy-to-follow guideline for collection, transport and submission of specimens for cytological and histological analysis.

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

The goal of Providence Sacred Heart Medical Center (PSHMC) in providing this manual is to maintain a high quality of patient care by obtaining specimens in their most preserved state, receiving the most complete and accurate patient information, and reporting back to the clinician with minimal turnaround time.

1.2 Turnaround Time

Gynecological Specimens:	3 – 5 days
Non-Gynecological Specimens:	1 – 2 days
Routine Surgical Specimens (i.e., biopsies):	24 – 48 hours
Complex Surgical Specimens:	72 – 96 hours

2. LICENSURE

2.1 Quality Assurance

All testing at PSHMC is conducted in accordance with current laws and government regulatory guidelines. The current quality control (QC) procedures are designed to not only meet, but also surpass the Clinical Laboratory Improvement Act (CLIA) requirements. Review of this program is under the direction of the laboratory Medical Director and the Technical Supervisors. In general, two types of activity are monitored:

2.1.1 Quality of Service Provided

- Specimen handling
- Data processing
- Reporting results
- Delivery of supplies (to clients)
- Dissemination of information (to clients)

2.1.2 Quality of Analytical Results

- Internal quality control program (QC review of slides)
- External quality control program (CAP inter laboratory comparison and ASCP Proficiency Testing)
- Voluntary accreditation by the College of American Pathologists (CAP)

2.2 Proficiency

The CAP and ASCP perform annual proficiency and intradepartmental comparison testing on all applicable staff. In addition, all applicable staff is required to participate in ongoing educational teleconferences offered through the American College of Clinical Pathologists (ASCP).

2.3 Confidentiality

The Health Information Portability and Accountability Act (HIPAA) require the development and implementation of policies and procedures to protect patient rights. Access to patient information is strictly controlled. A copy of PSHMC Privacy Practices is found in the Appendix.

2.4 Accreditation and Licensing

CAP-LAP# 2484601
Health Care Financing Administration (HCFA)-CLIA #50D0661616

2.5 Contact

PSHMC Laboratory Client Services – 509-474-3065.

3. POLICIES AND PROCEDURES

3.1 Returned Specimens (Unlabeled/Mislabeled/Expired)

- Specimens without proper patient identifiers (unlabeled, mislabeled) (see section 5.2.1) will be returned to the submitting clinician with a letter explaining the reason for the return. Irretrievable samples will be retained until a "Client Authorization Form" is filled out and returned to the lab, by the submitting clinician. Unlabeled specimens received from within the hospital will be retained until the appropriate personnel return to the lab to properly label all samples and requisitions.
- Specimens sent with no requisition or submitted on broken slides that cannot be reconstructed will be rejected.
- Specimens will be returned if the labeling (names and numbers) on the requisition and on the sample do not correspond.
- Specimens that are placed in expired SurePath™ or ThinPrep® vials will not be processed.

3.2 Tracking and Handling

To provide a documented tracking system for specimens submitted to the laboratory from remote sites, and to ensure that all specimens are actually received. Documentation should include date and time of dispatch and receipt, as well as documentation of any issues with the condition of specimens upon receipt.

1. Label the requisition and specimen container(s)/slide with the patient's name and a second identifier (e.g., birth date). Place these into a sealed specimen bag.
2. Fill out the specimen manifest, including all areas that are not shaded. Be careful to accurately tally the number of specimens at the bottom of the manifest. Keep the second copy of the manifest for your records. Place the individual specimen bags into the large tamper-proof bag. Do not overfill. Seal the bag. Place the top copy of the completed manifest in the outer pocket of the tamper-proof bag with the bar-coded tracking number visible. If you need to use more than one of the large bags, be sure to include a separate manifest for each one.
3. Keep a copy of the manifest for your records. Additional forms and/or baggies can be obtained by calling, 509-474-4437.

3.3 Obtaining Supplies

Supplies (brushes, brooms, spatulas, fixative, formalin, tracking manifests, transport bags) may be obtained by calling, 509-474-4437.

4. CYTOLOGY

4.1 Bethesda Reporting System (GYN Only)

PSHMC Cytology uses the Bethesda 2001 Reporting system for all GYN samples. The following outline is a brief reference to the information that will be contained in the Cytology Report.

4.1.1 Diagnosis / General Category

- Negative for Intraepithelial Lesion or Malignancy
- Epithelial Cell Abnormality: See Diagnosis/Specific ('squamous' or 'glandular' as appropriate)
- Other: See Diagnosis/Specific (e.g. endometrial cells in a woman > 40 years of age)

4.1.2 Diagnosis / Specific

- **NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY**
  - When there is no cellular evidence of neoplasia, this will be stated in the General Categorization above and/or in the Diagnosis section of the report, whether or not there are organisms or other non-neoplastic findings
- **OTHER NON-NEOPLASTIC FINDINGS** (Optional to report; list not inclusive)
  - Reactive cellular changes associated with:
    - Inflammation (includes typical repair)
    - Radiation
    - Intrauterine contraceptive device (IUD)
    - Glandular cells status post hysterectomy
    - Atrophy
    - Bacteria
  - **OTHER**
  - Endometrial cells (in a woman > 40 years of age)
  - Specifying if negative for 'squamous intraepithelial lesion'
- **EPITHELIAL (SQUAMOUS) CELL ABNORMALITIES**
  - Atypical squamous cells of undetermined significance (ASC-US)
  - Atypical squamous cells of undetermined significance cannot exclude HSIL (ASC-H)
  - Low grade squamous intraepithelial lesion (LSIL) encompassing:

- Mild dysplasia/CIN I
  - High grade squamous intraepithelial lesion (HSIL) encompassing:
- Moderate and severe dysplasia
- CIN II and CIN III/CIS
  - High grade squamous intraepithelial lesion (HSIL) with features suspicious for invasion (if invasion is suspected)
  - Squamous cell carcinoma

- **EPITHELIAL (GLANDULAR) CELL ABNORMALITIES**
  - Atypical endocervical cells (NOS or specified in comments)
  - Atypical endometrial cells (NOS or specified in comments)
  - Atypical glandular cells (NOS or specified in comments)
  - Atypical endocervical cells, favor neoplastic
  - Atypical glandular cells, favor neoplastic
  - **ENDOCERVICAL ADENOCARCINOMA IN SITU**
  - **ADENOCARCINOMA**
    - Endocervical
    - Endometrial
    - Extrauterine
    - Not Otherwise Specified (NOS)
- **OTHER MALIGNANT NEOPLASTMS (specified)**

4.1.3 Specimen Adequacy

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

4.1.4 Description

- Specimen Type (Conventional smear (Pap smear) vs. liquid based vs. other)
- Automated Review (If the case is examined by an automated device, the device will be specified with the result.)
- Pathologist's Review
- Quality Control Review
- Organisms
- Trichomonas vaginalis
- Fungal organisms morphologically consistent with Candida spp
- Shift in flora suggestive of bacterial vaginosis
  - Bacteria morphologically consistent with Actinomyces spp
  - Cellular changes consistent with Herpes simplex virus

- Comment
  - Educational Notes and Suggestions (optional)
  - Suggestions will be concise and consistent with clinical follow-up guidelines published by professional organizations (references to relevant publications maybe included).
  - Ancillary Testing
  - A brief description of the test methods will be provided and the result reported so that it is easily understood by theclinician.

5. GYNECOLOGICAL SPECIMENS

5.1 Requisition Required Information

Note: Patient information and pertinent clinical history must be included on the requisition to ensure accurate and timely results.

5.1.1 Physician Information

- Ordering physician's full name and identification code number
- Physician's office address, phone and FAX number

5.1.2 Patient Information

(Two patient identifiers must be provided in order to perform the test.)

- REQUIRED INFORMATION
  - Patient's full legal name – last, first and middle if available. Also include previous or maiden name if available
  - Date of birth
  - ABN – if Medicare
- OPTIONAL INFORMATION
  - Social security number
  - Gender
  - Address
  - Phone number
  - Patient's complete insurance information, including insurance name and address, policy number and policyholder's name. A photocopy of the patient's insurance card, front and back may be attached in lieu of completing the insurancesection

5.1.3 Specimen Information

- REQUIRED INFORMATION
  - Collection date
  - Specimen source: cervical, endocervical, and/orvaginal
  - Specimen type: SurePath™, ThinPrep® Pap or conventional slide Pap smear (to include the number of slides submitted)

5.1.4 Pap Test Order information

- Select the appropriate risk assessment level for the patient: screening or diagnostic. If diagnostic please indicate patient's signs, symptoms or history.
- ICD.10 code (required).
- Both the low-risk and high-risk levels are defined by Medicare to be screening tests. For Medicare patients receiving these screening tests, a signed Advanced Beneficiary Notice (ABN) should be submitted with the requisition. (See appendix for sample).

5.1.5 Clinical Information

- Please provide any applicable clinical information including:
  - Date of last menstrual period (LMP)
  - Pregnant
  - Postpartum, nursing
  - Menopausal
  - Hysterectomy
  - Hormone therapy
  - Clinical indications/risk factors
  - IUD
  - DES Exposure
  - Date of last pap and/or biopsy
  - Previous abnormal results and treatments including dates.

5.1.6 HPV Testing

HPV testing can be ordered on Pap (cervical/vaginal) specimens collected in a SurePath™ vial, or ThinPrep® PreservCyt® Solution. HPV testing will be resulted and will be billed separately.

Note: HPV testing on cervical/vaginal specimens collected in liquid is FDA approved only if performed within 3 weeks of collection. HPV testing will not be performed if the specimen is outside the three-week date parameter.

5.2 GYN Specimen Required Information

5.2.1 Identifiers

PSHMC does not accept unlabeled specimens. All specimens submitted to the laboratory must be individually labeled and must include two patient identifiers:

- The patient's first and last name as it appears on the requisition – do not use nicknames or initials.
- A second identifier, either the patient's date of birth, social security number or a unique patient identification number.

Note: For conventional smears the patient identifier must appear in pencil on the frosted label end of the slide. For SurePath™ and ThinPrep® Pap vials this information must be labeled on the vial itself not on the vial cap.

5.2.2 Vial Expiration

Specimens collected in SurePath™ solution and ThinPrep® PreservCyt® solution must be collected and processed before the expiration date on the vial. Specimens received in an expired vial will not be processed.

5.2.3 Transport Bag

Specimens must be submitted one specimen and requisition per bag. The specimen should be sealed inside the bag and the requisition placed securely in the outer pocket.

5.2.4 Test Order Information

PAP, LIQUID BASED (no HPV) – LAB12010
PAP, LIQUID BASED, AND HPV, HIGH RISK – LAB13425
PAP, LIQUID BASED, REFLEX HPV (if ASCUS) – LAB23708
PAP, LIQUID BASED, REFLEX HPV (if other than ASCUS) – LAB12010
PAP, CONVENTIONAL, SCREEN – LAB5
HPV, HIGH RISK, AND GENOTYPE 16 AND 18 – LAB23707

Please note: If you order PAP, LIQUID BASED, REFLEX HPV (if other than ASCUS) and the pap interpretation is other than ASCUS, you MUST order HPV, HIGH RISK, AND GENOTYPE 16 AND 18 – LAB23707.

5.3 Gynecological (Pap Smear) Collection

5.3.1 Patient Preparation

It is recommended that patients not use vaginal lubricants, vaginal medications, vaginal contraceptives, or douches within 48 hours before the exam. The patient should not engage in sexual activity 24 hours before the smear is collected. In menstruating women the optimal time for cell collection is at ovulation. Patients should not be scheduled during their menstrual cycle. Bleeding or a heavy exudate may make a specimen unsatisfactory for evaluation of epithelial cell abnormality.

SurePath
Option 1:

SurePath™ Sample Collection with Broom-Type Device with Detachable Head

1. Record the patient's first and last name and one other identifier on the vial.
2. Complete a laboratory requisition form with complete patient information and medical history. *Clients submitting computer-generated requisitions must include patient's full name, date of birth, date of collection, specimen source, client and physician information.*
3. Insert the cervix-brush into the endocervical canal. Apply gentle pressure until the bristles form against the cervix. Maintaining gentle pressure, hold the stem between the thumb and forefinger. Rotate the brush five times in a clockwise direction.
4. Place your thumb against the back of the removable collection device tip and disconnect the entire tip from the stem and place in the SurePath™ preservative vial.
5. The collection device tip should be transferred in the vial. Up to three different collection devices can be left in the SurePath™ vial. Place the cap on the vial and tighten. Shake the container vigorously to remove cells from collection device.
6. Place the vial and requisition in a specimen bag for transport to the laboratory.

Option 2:

SurePath™ Sample Collection with Combination Brush/Plastic Spatula Device with Detachable Heads

1. Record the patient's first and last name and one other identifier on the vial.
2. Complete a laboratory requisition form with complete patient information and medical history. *Clients submitting computer-generated requisitions must include patient's full name, date of birth, date of collection, specimen source, client and physician information.*
3. Insert the contoured end of the plastic spatula and rotate 360° around entire exocervix.
4. Snap the device handle and drop the detachable head of the device into the SurePath® vial.
5. Insert Cytobrush into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate ¼ to ½ turn in one direction. To reduce unnecessary bleeding, do not over-rotate brush.
6. Snap the device handle and drop the detachable head of the device into the SurePath® vial. Place the cap on the vial and tighten. Shake the container vigorously to remove cells from collection device.
7. Place the vial and requisition in a specimen bag for transport to the laboratory.

5.3.2 THINPREP

Option 1:

Endocervical Brush/Spatula Protocol

1. Record the patient's first and last name and one other identifier on the vial.
2. Clients submitting computer-generated requisitions must include patient's full name, date of birth, date of collection, specimen source, client and physician information.
3. Obtain an adequate sampling from the exocervix using a plastic spatula.
4. Rinse the spatula as quickly as possible into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.
5. Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into cervix until only the bottommost fibers are exposed. Slowly rotate one-fourth or the one-half turn in one direction. Do not over-rotate.
6. Rinse the brush as quick as possible in the PreservCyt® Solution by rotating the device in the solution 10 times while pushing against the PreservCyt® vial wall. Swirl the brush vigorously to further release material. Discard the brush.
7. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
8. Place the vial and requisition in a specimen bag for transport to the laboratory.

Option 2:

Broom-Like Device Protocol

1. Record the patient's first and last name and one other identifier on the vial.
2. Complete a laboratory requisition form with complete patient information and medical history. *Clients submitting computer-generated requisitions must include patient's full name, date of birth, date of collection, specimen source, client and physician information.*
3. Obtain an adequate sampling from the exocervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.

4. Rinse the broom as quickly as possible into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.
5. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
6. Place the vial and requisition in a specimen bag for transport to the laboratory.

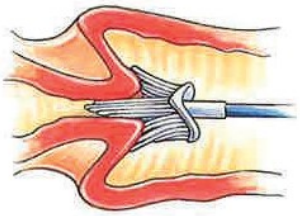
5.3.3 PAP-PAK® Conventional Smear

Pap Smear Specimen Collection Using Fast Smear Technique

1. Print the first and last name of the patient on the frosted end of the slide (use
2. #2 pencil) and one other unique identifier.
3. Clients submitting computer-generated requisitions must include patient's full name, date of birth, date of collection, specimen source, client and physician information.
4. Obtain cervical material from exocervix and squamo-columnar junction by rotating the spatula 360 degrees while scraping vigorously.
5. Place cervical material on slide near the labeled end as a thick drop. Do not smear.
6. Obtain endocervical sample using a cytobrush. Do not use cytobrush if the patient is pregnant; in this case follow step 2.
7. Mix on the slide with the exocervical sample drop. Do not smear.
8. Holding the slide with thumb and forefinger smear the sample with one lengthwise stroke of the spatula. Do not use circular or zigzag motion, as this would increase the chance of air-drying.
9. Immediately spray slide with fixative.
10. Note: Be careful to coat the slide until wet with fixative. However, do not spray the fixative so closely that cells are displaced or frozen.
11. Only one specimen from one patient per package. Please label package with patient's name and one other identifier (birth date).

SurePath™ test pack

FOUR SIMPLE STEPS



1. Cervical Sample Collection

Insert the Rovers Cervex-Brush® into the endocervical canal. Apply gentle pressure until the bristles form against the cervix. Maintaining gentle pressure, hold the stem between the thumb and forefinger.

NOTE: ROTATE BRUSH FIVE TIMES

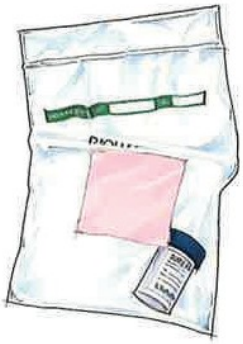
Rotate the brush five times in a clockwise direction.

2. Preserve the entire sample

Placing your thumb against the back of the brush pad, simply disconnect the entire brush from the stem into the SurePath™ preservative vial.

3. Cap and label vial

Place the cap on the vial and tighten. Label the vial and lab requisition form with patient name and/or number, physician name and date if desired.



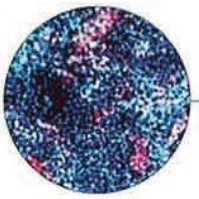
4. Send vial to your lab

Place the vial and requisition into a specimen bag and send to the laboratory.

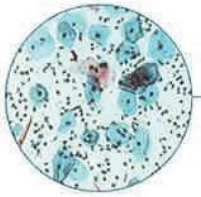
ONE CLEAR RESULT

In clinical trial studies, cervical samples were taken and first smeared onto slides. Residual cells from the conventional smear were used in the PrepStain™ process. *In each case, the same patient sample, with very different results.*

1.

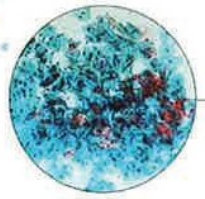


Conventional
Conventional smear, dense with blood, mucus, and inflammation is diagnosed as an unsatisfactory specimen, and the patient is called back in for another sample.



SurePath™ slide
The same sample was processed by PrepStain™, which eliminated the obscuring material for a sample easily diagnosed as "within normal limits."

2.



Conventional
The conventional smear, although diagnosed as "within normal limits" can be considered "limited" with the cells hidden by excessive cell clumping.

SurePath™ slide
The same sample, using residual material from the smear and processed by the PrepStain™ allows for diagnosis with no questions or concern.

ROVERS MEDICAL DEVICES BV

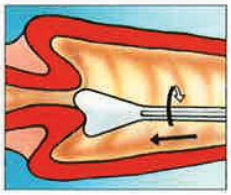
CERVEX-BRUSH™ *is a registered trademark of Rovers BV, OSS, Netherlands*

TRIPATH care technologies™

TriPath Imaging, Inc.
780 Plantation Drive
Burlington, NC 27215 USA

ThinPrep® Pap Test™ Quick Reference Guide

Endocervical Brush/Spatula Protocol

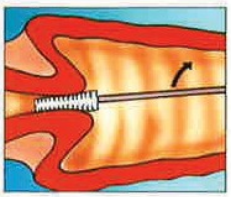


Obtain…

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

Rinse…

…the spatula as quickly as possible into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.



Obtain…

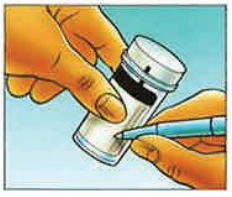
…an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. DO NOT OVER-ROTATE.

Rinse…

…the brush as quickly as possible in the PreservCyt Solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the brush.

Tighten…

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



Record…

…the patient's name and ID number on the vial.

…the patient information and medical history on the cytology requisition form.

Place…

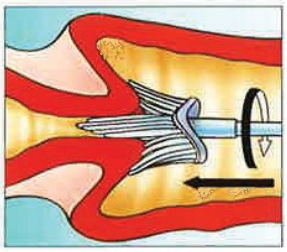
…the vial and requisition in a specimen bag for transport to the laboratory.

THE ThinPrep® PAP TEST

The clear choice.

ThinPrep® Pap Test™ Quick Reference Guide

Broom-Like Device Protocol



Obtain…

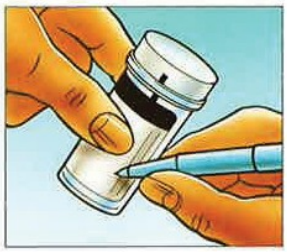
…an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.

Rinse…

…the broom as quickly as possible into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.

Tighten…

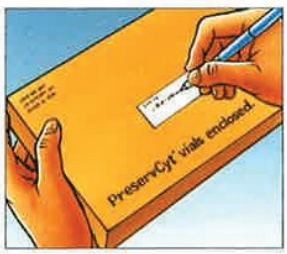
…the cap so that the torque line on the cap passes the torque line on the vial.



Record…

…the patient's name and ID number on the vial.

…the patient information and medical history on the cytology requisition form.



Place…

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

THE ThinPrep® PAP TEST

www.cytyc.com

The clear choice.

5.4 ThinPrep® Imaging System (ThinPrep® Specimens)

ThinPrep® Imaging System, manufactured by Hologic, is a system for imaging and analyzing ThinPrep® cervical cytology sample slides. Cells of interest are highlighted for the cytotechnologists' review, helping him/her to better focus his/her interpretive skills.

Currently at PSHMC all ThinPrep® specimens are analyzed by the ThinPrep® Imaging System and screened by a qualified cytotechnologist. A notation is made on the final report that the slide was screened by an automated intelligence device.

6. NON-GYN SPECIMENS

6.1 Requisition Required Information

Note: Patient information and pertinent clinical history must be included on the requisition to ensure accurate and timely results.

6.1.1 Physician Information

- Ordering physician's full name and identification code number
- Physician's office address, phone and FAX number

6.1.2 Patient Information

- REQUIRED INFORMATION
  - Patient's full name – last, first and middle if available. Also include previous or maiden name if available
  - Date of birth
  - Gender
- OPTIONAL INFORMATION
  - Social security number
  - Address
  - Phone number
  - Patient's complete insurance information, including insurance name and address, policy number and policyholder's name.
  - A photocopy of the patient's insurance card, front and back, may be attached in lieu of completing the insurance section.

6.1.3 Specimen Information (Required)

- Collection date
- Specimen type: i.e. FNA breast, pleural fluid, urine (voided or catheterized), bronchial washing, etc.
- Specimen source or location: i.e. right breast, left ureter, left lower lobe of lung, etc.

6.1.4 Clinical Information

- Please provide any applicable clinical information including recent related infections or illnesses and signs or symptoms experienced.
- Also indicate any applicable patient history: i.e. history of thyroid nodule, history of melanoma, history of bladder lesions, previous hysterectomy, etc. Please be as specific as possible
- Indicate clinical diagnosis with signs and symptoms.
- If requesting special stains please indicate this on the requisition.

6.1.5 Test Order Information

All non-GYN specimens are ordered using LAB13 (Medical Cytology).

6.2 Non-GYN Required Information (Specimen)

6.2.1 Identifiers

PSHMC Cytology does not accept unlabeled specimens. All specimens submitted to the laboratory must be individually labeled and must include two identifiers:

- The patient's first and last name as it appears on the requisition – do not use nicknames
- A second identifier, either the patient's date of birth, social security number or a unique patient identification number.

Note: For specimens submitted on a slide, label the frosted end of the slide using a #2 pencil. For specimens submitted in cytology fixative or other specimen container, this information should be written in permanent ink on the container itself not on the container cap.

6.2.2 Accepted and Processed

All specimens must be submitted to the laboratory using the collection procedures and the specimen requirements included in this manual in order to be accepted and processed. Any questions or concerns related to these criteria should be directed to the laboratory.

6.3 Non-Gynecological Collection

Note: Samples for microbiological and/or hematological studies should be provided in separate sterile containers.

Note: Formalin should never be used for cytology specimens as this renders the specimen unsatisfactory for cytology processing.

6.3.1 Body Cavity Fluid (Aspirated) including Pleural Fluid, Peritoneal Fluid, Pericardial Fluid

1. Collect specimen in a clean/sterile container that is labeled with the patients first and last name and a unique patient identifier.
2. If at all possible, at least 50 cc of fluid should be collected for proper cytological preparation. The volume need not exceed 200 mL of fluid.
3. Do not add fixative. If transport to the lab will be delayed, the specimen should be refrigerated or kept on ice. If a delay in processing beyond 24 hours is anticipated, the specimen should be mixed with an equal amount of CytoLyt® fixative.
4. Send specimen and completed requisition to Cytology.

6.3.2 Body Cavity Fluid (Washings) including Pelvic/Peritoneal, gutter, etc.

1. Normal saline is the recommended washing fluid.
2. Collect specimen in a clean/sterile, container that is labeled with the patients first and last name and a unique patient identifier.
3. If at all possible, at least 50 cc of fluid should be collected for proper cytological preparation. The size of the sample need not exceed 200 mL of fluid.
4. Do not add fixative. If transport to the lab will be delayed, the specimen should be refrigerated or kept on ice. If a delay in processing beyond 24 hours is anticipated, the specimen should be mixed with an equal amount of CytoLyt® fixative.

5. Send specimen and completed requisition to Cytology.

Note: Formalin should never be used for cytology specimens as this renders the specimen unsatisfactory for cytology processing.

6.3.3 Bronchial/Bronchoscopy Specimens

1. Collect specimen in a clean/sterile, container that is labeled with the patients first and last name and a unique patient identifier.
2. Do not add fixative. If transport to the lab will be delayed, the specimen should be refrigerated or kept on ice. If a delay in processing beyond 24 hours is anticipated, the specimen should be mixed with an equal amount of CytoLyt® fixative.
3. Send specimen and completed requisition to Cytology.

6.3.4 Bronchial Brushings

Slides

1. Roll the contents of the brush onto a clean, labeled glass slide and fix immediately with spray fixative (within one to two seconds) or, immediately drop slide(s) into a Coplin jar containing 95% alcohol.
2. Send specimen and competed requisition to Cytology.

Container

1. Rinse the brush in fixative (CytoLyt®) solution by rotating the brush in the solution 10 times while pushing against the vial wall. Swirl the brush vigorously in solution to further release cells.
2. Note: Saline may be used in place of fixative if transport to the lab is immediate; however, this is not recommended. Formalin should never be used for cytology specimens as this renders the specimen unsatisfactory for cytology processing.
3. Cut off brush leaving approximately one and one-half inches of wire and drop brush into the tube of cytology fixative obtained from the laboratory.
4. Replace cap tightly and label container with patient name and another identifier (birth date).
5. Send specimen and completed requisition to Cytology.
6. Note: Specimens submitted for culture studies, molecular studies, and other special studies must be submitted in separate sterile containers.

6.3.5 Bronchoalveolar Lavage

1. Collect specimen in a clean/sterile, container that is labeled with the patients first and last name and a unique patient identifier.
2. Do not add fixative. If transport to the lab will be delayed, the specimen should be refrigerated or kept on ice. If a delay in processing beyond 24 hours is anticipated, the specimen should be mixed with an equal amount of CytoLyt® fixative.
3. Send specimen and competed requisition to Cytology.

Note: Fixative may be added to the specimen if a delay in transport is expected. Cytology fixative (CytoLyt®) may be obtained from the laboratory. Fixative is added to BAL samples upon arrival to the lab. Formalin is never used as a cytology fixative.

6.3.6 Sputum

Note: Fresh sputum samples must be sent immediately to the laboratory refrigerated. Fixed sputum samples have no transport time limit.

6.3.6.1 Inpatient sputum

1. For the most adequate sputum specimen, be sure specimen collected is an early morning, deep cough specimen (preferably before breakfast) and not saliva.
2. Have patient cough into a clean, labeled specimen container. Do not add fixative.
3. Send specimen with completed cytology requisition to the laboratory.

6.3.6.2 Outpatient sputum

1. Specimen must be collected in labeled container with CytoLyt® fixative.
2. Be sure specimen collected is an early morning, deep cough specimen (preferably before breakfast) and not saliva.
3. After patient expectorates into container, replace lid and shake container to distribute fixative.
4. Send specimen with completed cytology requisition to the laboratory.

6.3.6.3 Post-bronchoscopy sputum (24-hour post-bronchial sputum)

1. Collect ONE good, deep cough specimen at any time during the 24 hours following bronchoscopy. Pooled 24-hour continuously collected sputa are not suitable for cytology.
2. Send specimen with completed cytology requisition to the laboratory.

6.3.6.4 Induced Sputum

1. A heated aerosolized solution of 15 percent NaCl and 20 percent Propylene Glycol is inhaled by the patient for 20 minutes.
2. Have patient cough into a clean, labeled specimen container. Do not add fixative.
3. Send specimen with completed requisition to the laboratory.

6.3.7 Cerebrospinal Fluid

1. Collect specimen in a clean/sterile container that is labeled with the patients first and last name and a unique patient identifier.
2. Fill out requisition indicating site of tap (lumbar, ventricle, omaya reservoir) and relevant clinical information.
3. Send specimen **refrigerated** and completed requisition to Cytology.

Note: If transport to the lab will be delayed, the specimen should be refrigerated or kept on ice. Fixative is not added to CSF.

6.3.8 Fine Needle Aspiration (Superficial Sites)

Aspiration of superficial, generally palpable, lesions of the breast, thyroid, salivary gland, lymph node, subcutaneous, skin, or other site can be performed in a doctor's office or patient room. Lymph node aspirates for flow cytometry require RPMI fixative available from Cytology or Histology. If you would like to arrange for a Cytotechnologist to assist within the hospital, please call 509-474-4437.

6.3.8.1 General Procedure for Superficial Sites

1. Label two or more clean glass slides or label cytology collection bottle (tube) with the patient's first and last name and a unique patient identifier.
2. Wipe the skin over the lesion with an alcohol swab. Local anesthetic is not usually needed.
3. Attach a 22 gauge (or 25 gauge in certain sites such as thyroid) needle to a 10-20 cc syringe.

4. If possible, fix the lesion in place using the thumb and forefinger of the left hand (if right handed).
5. Pass the needle through the skin and into the lesion.
6. After the needle is in the lesion, draw back the plunger of the syringe to create suction (negative pressure). Move the needle back and forth several times in the lesion. A "jack hammer" motion is often effective.

Note: With solid lesions, material should be aspirated only into the needle and not into the syringe. Once material appears in the hub of the needle, aspiration should be discontinued. Blood is undesirable. In the case of cystic lesions, the syringe may be filled with fluid. This fluid may be submitted for cytological examination.

7. Once aspiration is completed, release the plunger and allow it to fall back to a "neutral" position.
8. Remove the needle and syringe from the patient.

6.3.8.2 To Make Slides

1. Remove the needle from the syringe.
2. Draw air into the syringe.
3. Replace the needle onto the syringe.
4. With the bevel pointed down, express the material in the needle onto the center of a slide using firm but not excessive pressure on the plunger. Only one or two drops of fluid are necessary.
5. Immediately place a second slide over the slide with the sample.
6. Allow the sample to spread between the two slides without any smearing motion (other smearing methods can be used but require experience).
7. Immediately fix the slides using a spray fixative or by placing the slide in 95% alcohol.

Note: Alternatively, Allow only one slide to air dry particularly with suspected lymphoma or hematopoietic cancer (label it as 'air dried'). Air-dried slides have no time limit on transport. However, rinsed material should be transported immediately or fixed if a delay in transport is expected. Cytology fixative (CytoLyt®) may be obtained from the laboratory.

8. The remainder of the material in the needle can be expressed into a clean, labeled tube by drawing up sterile saline and forcing it back out until the spray is dry.
9. The procedure may be repeated several times.
10. Apply pressure to the aspirated site to minimize hematoma.

6.3.8.3 To send in a Container (No Slides)

1. Specimens with needles attached are not accepted and should not be transported. If transporting specimen in a syringe (not recommended), the needle should be removed and the syringe should be capped. It is recommended that if no slides are being smeared at the time of collection, the sample be expressed from the syringe to a clean, labeled container (cytospin tube) using sterile saline.
2. Obtain the sample using the general procedure.
3. Draw up sterile saline into syringe.
4. Force the saline out into the tube through the needle until the spray is dry.

5. The procedure maybe repeated several times.
6. Note: Rinsed material should be transported immediately. If a delay in transport is expected, the specimen should be fixed. Cytology fixative (CytoLyt®) may be obtained from the laboratory.
7. Cap the tube for transport.
8. Apply pressure to the aspirated site to minimizehematoma.
9. Dispose of the syringe and needle in the proper container.

6.3.9 Fine Needle Aspirations (Deep Sites)

Deep sites are aspirated under radiological guidance using a technique similar to that for superficial sites (see above). The radiologist expresses the sample onto a sterile slide or rinses the specimen with saline into a collection device (tube or cup). A pathologist, cytotechnologist, or technician spreads the sample between two slides and fixes and/or air-dries the slides.

If no slides are being made, the pathologist, cytotechnologist, or technician caps the collection device for transport. Fixed slides have no time limit on transport. Air-dried slides have no time limit on transport. However, rinsed material should be transported immediately or fixed, if a delay in transport is expected.

Slides can be immediately stained and interpreted for adequacy. The procedure can be repeated if inadequate material is obtained. Cytocentrifuge preparations, SurePath™ Slides, and cellblock can be prepared from needle and tube washings.

Cores of tissue can be fixed for histologic sectioning. Immunohistochemistry (for estrogen receptor, prostate specific antigen, leukocyte common antigen, keratin, etc.) can be performed on cellblock and cores of tissue. Particles can be saved for electron microscopy. Lymph node aspirates for flow cytometry require RPMI fixative available from Cytology or Histology.

If you would like to arrange for a Cytotechnologist to assist within the hospital, please call 509-474-4437.

6.3.10 Most Common Deep Sites

- Breast
- Liver
- Lung
- Lymph Node
- Pancreas
- Salivary Gland
- Thyroid
- Mediastinum
- Kidney
- Adrenal Gland
- Soft tissue

6.3.11 Gastrointestinal Brushings

Slides

1. Roll the contents of the brush onto a clean, labeled glass slide and fix immediately with spray fixative (within one to two seconds). Alternatively, slides may be placed into a bath of 95% alcohol for transport.
2. Send immediately to Cytology Lab with completed requisition.

Container

1. Rinse the brush in fixative solution by rotating the brush in the solution 10 times while pushing against the vial wall. Swirl the brush vigorously in solution to further release cells.
2. Cut off the brush and drop it in the fixative.
3. Replace cap tightly and label container.
4. Send immediately to Cytology Lab with completed requisition.

6.3.12 Nipple Discharge

1. Express secretion by gently compressing the full circumference of the areola between thumb and index finger. When a mass is palpable, the area between the mass and nipple may be compressed.
2. Smear secretion on a clean, labeled, glass slide. If secretion is scanty, the slide may be touched to the nipple. If secretion is thick, it may be smeared between two slides.
   Spray fix slide(s) immediately (hold aerosol spray four to six inches from slide and apply for one to two seconds). (Alternatively, place the slide immediately into a bath of 95% alcohol to fix cells.)
3. Place slides in carrier and send to Cytology Lab with completed requisition.

6.3.13 Skin (Tzanck Smear)

1. Identify a fresh typical vesicle.
2. Unroof the vesicle.
3. Scrape the margin of the vesicle with a scalpel blade.
4. Spread the cells and debris adherent to the blade on a clean, labeled, glass slide.
5. Fix immediately with spray fixative (Hold aerosol spray four to six inches from slide and apply for one or two seconds.) or place the slide into a bath of 95% alcohol.
6. Place slides in carrier, and send slides and requisition to the laboratory.

6.3.14 Urine, Renal Pelvic Washings & bladder Washings

Urine specimens without fixative should be sent directly to the laboratory or refrigerated if any delay is anticipated. Unfixed refrigerated urine is suitable for cytological examination for 24 hours. If specimens cannot be refrigerated or if a long delay in transport is anticipated, the specimen should be collected in an equal volume of cytology fixative (CytoLyt®) available from the Laboratory.

6.3.14.1 Voided Urine

1. Patient collects specimen. Be sure all specimens are collected "clean catch" and in properly labeled containers. **Make sure to note that specimen is voided urine.**
2. For optimal cytological evaluation of urine, **first-voided morning specimens should not be used.**
3. Send immediately to the cytology laboratory with completed requisition. If specimen cannot be sent immediately to the cytology laboratory, please refrigerate.
4. An alternative (especially if a delay in transport to the laboratory is anticipated) is to collect the specimen in an equal volume of cytology fixative (CytoLyt®). **Formalin is never an appropriate cytology fixative.**

6.3.14.2 Catheterized Urine

1. Specimen is collected by physician or nursing staff in a clean, properly labeled container and sent immediately to the Cytology Laboratory with completed requisition. **Make sure to note that specimen is catheterized urine.**
2. An alternative (especially if a delay in transport to the laboratory is anticipated) is to collect the specimen in an equal volume of cytology fixative (CytoLyt®). **Formalin is never an appropriate cytology fixative.**

6.3.14.3 Renal Pelvic and Bladder Washings

1. Using normal saline, the washing specimen is collected by a physician in a clean specimen container.
2. Label container with name, and body site (specifically designate right or left pelvic washing).
3. Send immediately to the laboratory with a completed requisition. Indicate that the specimen is a washing.
4. If a delay in transport is expected, add an equal volume of CytoLyt® to the specimen. **Formalin is never an appropriate cytology fixative.**

7. HISTOLOGY

7.1 Muscle/Nerve Biopsies

Muscle and nerve biopsies may be performed in the workup of suspected neuromuscular diseases. Correct interpretation of these biopsies is strongly dependent on the clinical setting; therefore, clinical history, including medications, must accompany the specimen. Specimens without history will be evaluated by H&E staining only. These studies are performed at the University of Iowa.

7.1.1 Frequency:

Due to the logistics required in sending fresh tissue to Iowa:

- Muscle and nerve biopsies may be performed Monday through Thursday, except when the day following surgery is a holiday.
- The biopsies must be scheduled with Histology/Pathology at least one day prior to the surgery.

- The specimen must arrive in Histology no later than 12:00 noon.

7.1.2 Requirements:

Muscle Biopsy:

At least 1 clamped biopsy, measuring at least 0.5 cm in diameter and 0.8 cm in length (2 are preferred), wrapped in normal saline moistened gauze.

Nerve Biopsy:

At least 4-6 cm long, already separated by surgery, into 2.5% buffered Isosmolar Glutaraldehyde and 10% Neutral Buffered Formalin.

- The specimen in Glutaraldehyde should be allowed to fix overnight in an upright position with the tension from the weight.
- The Glutaraldehyde specimen should also be refrigerated during the initial fixation and during storage prior to shipment.

7.1.3 Specimen Submission to Histology:

- Deliver to Histology as soon as possible.
- If delivery will be delayed by more than 10 minutes, cool the specimen under a plastic bag of wet ice.
- DO NOT allow the specimen to freeze.

7.2 Renal Biopsies

Prior to sending Renal Biopsies, please notify PSHMC Histology by calling, 509-474-4106.

7.2.1 Requirement

- A minimum of two, 1 cm renal cores of cortex are desirable.
- Using a 16-18 gauge biopsy gun to collect the core, immediately examine each core under the dissecting microscope, keeping the specimen moist with normal saline.
- Confirm ti presence of cortex by identifying the punctate blush of glomeruli, as opposed to parallel stacks of tubules of the medulla. The cortical tissue must be divided for light microscopy, immunofluorescence, and electron microscopy in order of decreasing importance.
- If necessary, a single core of tissue should be divided perpendicular to the axis of the specimen.
- It is extremely important to use clean forceps, rinsing in between steps to avoid fixative contamination.
    a. For **light microscopy**, place approximately one half of the cortical tissue in 10% neutral buffered formalin (approximately 1.0 cm). Label the container with a minimum of two patient identifiers.
    b. For **immunofluorescence,** place 4-5 mm of cortex tissue in Zeus media, being careful not to contaminate tissue with formalin. Label the container with a minimum of two patient identifiers.
    c. For **electron microscopy,** place one to two 2 mm segments of cortex tissue in Glutaraldehyde, depending upon the amount of cortex in the original specimens. If scant renal cortex is available, electron microscopy is usually of low priority, especially in kidney transplant and diabetic specimens. Label the container with a minimum of two patient identifiers.
- Rush all 3 specimens, with paperwork, by courier, to PSHMC Histology.
- Outside hospitals may choose to send the renal tissue in chilled saline to be divided at

PSHMC. If this option is chosen, the specimens must be sent by taxi directly to PSHMC STAT as courier service is too slow. Please notify Histology that the specimen is in saline.

7.3 Breast Biopsies

7.3.1 Requirement

1. Label an appropriately sized specimen container with addressograph or computer stamped patient label that contains a minimum of 2 patient identifiers, the tissue type, location, and specimen part (i.e., A, B, C, D….).
2. Complete a Histology requisition and Breast Specimen Clinical Data Form.
3. Place the tissue into the labeled formalin container and close the lid tightly, without cross-threading to prevent leakage in transit. *Please note: For proper fixation, specimens should be submitted in enough formalin or fixative to equal ten times the volume of tissue.*
4. Specimens should not be bent or folded by the container or proper fixation will not occur. Please contact Histology if larger containers are needed.

7.4 Amputations

7.4.1 Requirement

1. Label an appropriately sized specimen container with addressograph or computer stamped patient label that contains a minimum of 2 patient identifiers, the tissue type, location, and specimen part (i.e., A, B, C, D….).
2. Complete a Histology requisition.
3. Smaller specimens that will fit in a specimen container may be submitted in formalin. Ensure that the container is labeled with FORMALIN.
4. Place the amputation into a large heavy duty red biohazard bag and seal tightly (double bag, if possible). Affix the previously made specimen label to the outside of the bag in a visible location. **DO NOT STICK THE SPECIMEN LABEL AROUND THE STRING HOLDING THE BAG CLOSED.**

   Ensure that NO sharp bones are sticking out of the bag that could cause potential injury to caregivers transporting or receiving the specimen.

7.5 Skin Biopsies for Immunofluorescence

7.5.1 Requirement

1. Label an appropriately sized specimen container with addressograph or computer stamped patient label that contains a minimum of 2 patient identifiers, the tissue type, location, and specimen part (i.e., A, B, C, D….).
2. Complete a Histology requisition.
3. Place the tissue in the specimen container filled only with Saline. If delivery is going to be delayed, place in Zeus media.
4. Replace the lid tightly, without cross-threading to prevent leakage in transit.

7.6 Fetus and Stillborn Infants

7.6.1 Requirement

For infants who die in utero, prior to 20 weeks gestation:

1. Fetal remains are to be sent to the laboratory in formalin or fresh. If cytogenetics studies are requested, the specimen must be fresh and labeled as such.
2. No birth or death certificate is required.
3. Fetal remains will be processed as surgical specimens.
4. If parents wish to have a memorial service, the laboratory must be notified and will release fetal remains ONLY to a funeral home following histological examination.
5. If parents wish, remains can be buried at Holy Cross Cemetery.

For infants who die in utero, after 20 weeks gestation but before birth (stillborn infants):

1. Twenty (20) weeks gestation is equivalent to a fetus weighing 500 mg or measuring 25 cm crown-to-heel in length.
2. Chaplaincy (474-4716) handles the following:
    a. A death certificate is required and will be issued by the funeral home.
    b. Burial/cremation is required.

7.7 Heart Biopsies

7.7.1 Requirement

1. Label an appropriately sized dry specimen Saline container and a 10% Neutral Buffered Formalin specimen container with addressograph or computer stamped patient label that contains a minimum of 2 patient identifiers, the tissue type, location, and specimen part (i.e., A, B, C, D….).
2. Complete a Histology requisition.

7.7.2 Specimen Submission to Histology:

1. Specimens for Immunofluorescence studies:
    - Place the tissue in the appropriated labeled dry specimen container filled with Saline. Be sure that the lid to the container is tight and not cross-threaded to prevent leakage in transit Label the container as **SALINE**.

2. Specimens for Light Microscopy:
    - Place the tissue into a labeled formalin container and close the lid tightly, avoiding cross-threading to prevent leakage in transit. Label the container as **FORMALIN.**
    - *Please note: For proper fixation, specimens should be submitted in enough formalin or fixative to equal ten times the volume of tissue.*

7.8 Lymph Nodes for Lymphoma Triage

7.8.1 Requirement

1. Label an appropriately sized dry specimen Saline container and a 10% Neutral Buffered Formalin specimen container with addressograph or computer stamped patient label that contains a minimum of 2 patient identifiers, the tissue type, location, and specimen part (i.e., A, B, C, D….).
2. Complete a Histology requisition.
3. Collect fresh, unfixed tissue OR submit in RPMI media (specimens received in formalin cannot receive Lymphoma Triage).
4. Close the lid tightly, avoiding cross-threading to prevent leakage in transit.

8. APPENDIX

Patient Name: **Identification #:**

Advance Beneficiary Notice of Non coverage (ABN)

Note: If Medicare doesn't pay for Test/s below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **Test/s** below.

Test/s	Reason Medicare May Not Pay	Estimated Cost

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the Test/s listed above.
  Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this

OPTIONS: Check only one box. We cannot choose a box for you.

Option 1. I want the Test/s listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I **can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

Option 2. I want the Test/s listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not b i l l e d .**

Option 3. I don't want the Test/s listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

Additional Information: This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY**: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

Signature:	**Date:**

Form CMS-R-131 (03/11) Form Approved OMB No. 0938-056 6 _ABNEN_0001

8.1 Privacy Information

Providence Sacred Heart Medical Center is committed to protecting the confidentiality of your medical information and is required by law to do so.

Our privacy policy is available on our website which describes how we may use and disclose your protected health information to carry out treatment, payment, and health care operations, and for other purposes that are permitted or required by law. It also describes your rights to access and control your protected health information. We encourage you to go to our website to read our privacy policies.

Providence Sacred Heart Medical Center & Children's Hospital

Notice of Privacy Practices
http://washington.providence.org/senior-care/mount-st-vincent/notice-of-privacy-practices/

PROVIDENCE
Sacred Heart
Medical Center &
Children's Hospital