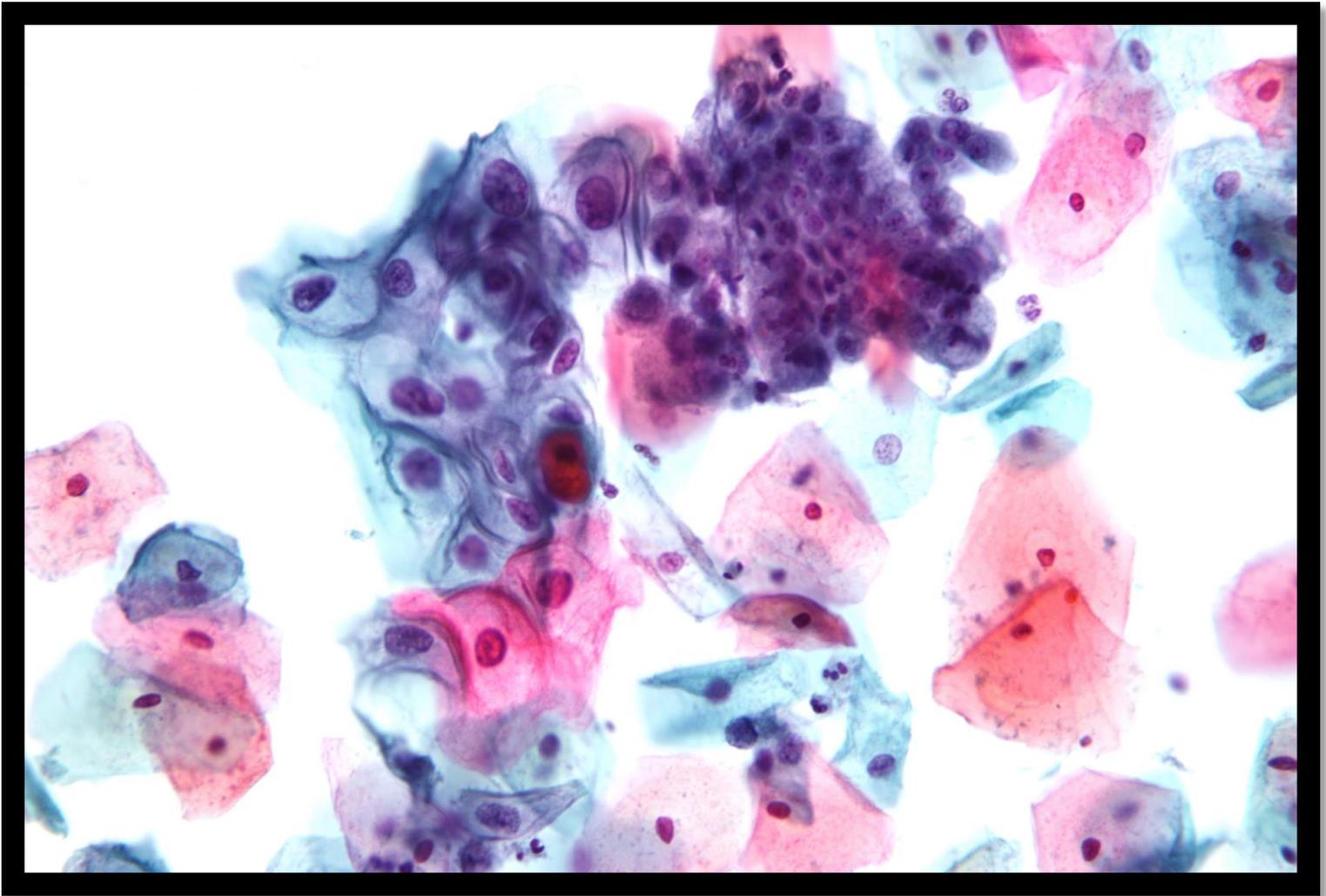




SKY LAKES

LABORATORY SERVICES

Cytology Reference Manual



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Laboratory Leadership and Personnel

Medical Director of Laboratories/Technical Supervisor/General Supervisor

Miguel Montes, M.D., FASCP, FCAP

541-274-6243

Pathologist

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541-274-6243

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 analysis.

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

The goal of Sky Lakes Medical Center 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 business days without pathologist's review and 3-8 business days with pathologist's review
- Non-Gynecological Specimens: 3-8 business days

1.3 Hours of Service

Cytology services are available Monday through Friday from 0600 to 1600.

1.4 Courier Services

Courier services are provided Monday through Friday within a radius of 5 miles from Sky Lakes Medical Center.

2. LICENSURE

2.1 Quality Assurance

All testing at Sky Lakes Medical Center 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. 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)
- Voluntary accreditation by the Joint Commission (JC)

2.2 Proficiency

CAP performs annual proficiency and intradepartmental comparison testing on all applicable staff. In addition, all applicable staff participates in ongoing educational activities to maintain accreditation.

2.3 Confidentiality

The Health Information Portability and Accountability Act (HIPAA) requires the development and implementation of policies and procedures to protect patient rights. Access to patient information is strictly controlled.

2.4 Accreditation and Licensing

College of American Pathologists -- 24546201

Health Care Financing Administration (HCFA)-CLIA -- 38D0628145

2.5 Contact

Sky Lakes Pathology Department at 541-274-6243

3. POLICIES AND PROCEDURES

3.1 Returned/Rejected Specimens (Unlabeled/Mislabeled/Expired)

The laboratory criteria for rejecting specimens include unlabeled slides or specimens, broken slides, specimens without a requisition, specimens with inappropriate fixative, and mismatch of names from specimen to requisition.

The requisition should include patient name (and/or unique identifier), date of birth, sex, specimen source, pertinent clinical information, requesting physicians or other authorized person's name, and date of specimen collection. For gynecological specimens, the date of last menstrual period should be included as well as the date of birth and pertinent history of previous abnormal reports, treatment or biopsy.

Non-GYN gross description of specimen (number of slides received, quantity and appearance of fluid specimens) is included with accessioning/processing procedures. A log of rejected/unsatisfactory specimens is maintained. The log includes submitting clinician or location, as well as type of specimen and reason for rejection. Clinicians are notified of rejected/unsatisfactory specimens. If the log shows an increased incidence from a certain physician or location, education on submission should occur and is documented.

3.2 Compromised Specimens

Compromised specimens are not returned. However, they are considered not optimal for evaluation. Factors that compromise the evaluation of the specimen will be noted in the final report. These factors include, but are not limited to:

- Specimen with no fixative
- Low fixative or wrong fixative
- Specimen for special studies not in preservative for prolonged time
- Specimen with prolonged ischemic time when relevant
- Insufficient specimen material

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

3.3 Tracking and Handling

PRINCIPLE:

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 pick up and receipt.

PROCEDURE:

Client's responsibility:

Complete the requisition and specimen container(s)/slide with the patient's name and a second identifier (i.e. birth date),



making sure all red mandatory areas are completed on requisition. Place specimen container(s)/slide into a sealed specimen bag and place the requisition in the side pocket of the specimen bag.

3.4 Obtaining Supplies

ThinPrep® supplies (brushes, brooms, spatulas, fixative, requisitions, transport bags) may be provided by contacting the receiving department at Sky Lakes Medical Center 541-274-6264.

3.4.1 ThinPrep®: is the preferred gynecological and non-gynecological collection method

SurePath™ supplies are not provided by Sky Lakes Medical Center.

3.4.2 SurePath™: gynecological collection is not supported by Sky Lakes Medical Center. Specimens will be sent to a reference laboratory for processing and interpretation.

Note: Non-GYN specimens without fixative must be transported within two hours to the laboratory.

3.5 Bethesda Reporting System (GYN Only)

The Bethesda 2001 Workshop, held April 30 - May 2, 2001, reviewed issues regarding terminology and reporting of cervical cytology. Over 400 Cytopathologists, cytotechnologists, clinicians, and patient advocates participated. Forty-five professional societies, including over 20 countries, sent representatives. Nine forum group sessions covered topics including specimen adequacy, non-neoplastic changes, ASCUS, AGUS, ancillary testing, endometrial cells, SIL, automated computer review, and recommendations. The meeting was characterized by energetic exchange of opinions and productive discussions. Sky Lakes Medical Center 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.

Caveat: Any abnormal cell is significant regardless of specimen adequacy.

The specimen containing abnormal cells must never be classified as unsatisfactory.

3.5.1 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)

3.5.2 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)

3.5.3 Interpretation/Result:

- **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
 - Intra-uterine 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: HPV/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
 - extra-uterine
 - not otherwise specified (NOS)
- OTHER MALIGNANT NEOPLASMS (specified)

3.5.4 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
- HPV-Sent for Testing (Liquid-Based only)
- 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

3.5.5 Comment/Recommendations

(Educational Notes and Suggestions) (optional)

- Suggestions will be concise and consistent with clinical follow-up guidelines published by professional organizations (references to relevant publications may be included).
- Ancillary Testing:
 - A brief description of the test methods will be provided and the result reported so that it is easily understood by the clinician.
 - Test type
 - Test Result
 - Test Description

4. GYNECOLOGICAL SPECIMENS

4.1 Requisition Required Information

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

4.1.1 Physician Information

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

4.1.2 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.
 - Date of birth
 - ABN - if Medicare
 - Includes Returned/Rejected patient data as stated above, see 3.1 above.

- 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.
- Primary provider

4.1.3 Specimen Information

- REQUIRED INFORMATION
 - Collection date
 - Specimen source: cervical, endocervical, and/or vaginal
 - Specimen type: Liquid based or conventional slide Pap smear (to include the number of slides submitted)

4.1.4 Pap Test Order information

- Select the appropriate risk assessment level for the patient: low-risk, high-risk or diagnostic. If diagnostic please indicate patient's signs, symptoms or history.
- 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).

4.1.5 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.

4.1.6 HPV Testing

- HPV testing can be ordered on Pap (cervical/vaginal) specimens collected in a SurePath™ vial, or ThinPrep® PreservCyt® Solution. HPV testing ordered in conjunction with the Pap test will be resultated on the same report and will be billed separately. HPV testing added after the Pap result has been released will be reported and billed separately.

HPV Reflexive Testing

- Performed only when the requisition is marked with reflex HPV.

HPV Non-Reflexive Testing

- Performed regardless of results.
 - To order, check the “Pap with HPV” on the requisition.

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

4.2 GYNECOLOGICAL Specimen Required Information

4.2.1 Identifiers

Sky Lakes Medical Center 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 and the patient’s date of birth as the second identifier.

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.

4.2.2 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.

4.2.3 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.

4.3 Gynecological (Pap Smear) Collection

4.3.1 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.

4.3.2 THINPREP® (Preferred Collection Method)

OPTION 1:

Endocervical Brush/Spatula Protocol

- Record the patient's first and last name and one other identifier on the vial.
- Obtain an adequate sampling from the exocervix 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 cervix until only the bottommost fibers are exposed. Slowly rotate one-fourth or the one-half turn in one direction. Do not over-rotate.
- 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 as the cells will attach to the brush if left in the fixative.

- Tighten the cap so that the torque line on the cap passes the torque line on the vial.
- Place the vial and requisition in a specimen bag for transport to the laboratory.

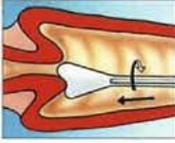
OPTION 2:

Broom-Like Device Protocol

- Record the patient's first and last name and one other identifier on the vial.
- Complete a laboratory requisition form with complete patient information and medical history.
- 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 exocervix. 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.
- Place the vial and requisition in a specimen bag for transport to the laboratory.

ThinPrep® Pap Test™ Quick Reference Guide

Endocervical Brush/Spatula Protocol



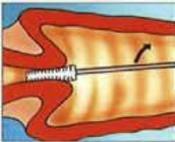
Obtain...

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



Rinse...

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



Obtain...

...an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate $\frac{1}{4}$ or $\frac{1}{2}$ 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.

SurePath™ referred to a reference laboratory for testing.

OPTION 1:

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

- Record the patient's first and last name and one other identifier on the vial.
- Complete a laboratory requisition form with complete patient information and medical history.
- 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.
- 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.
- 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.
- Place the vial and requisition in a specimen bag for transport to the laboratory.

OPTION 2:

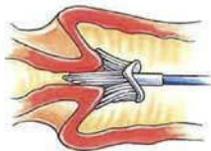
SurePath™ Sample Collection with Combination Brush/Plastic Spatula Device with Detachable Heads

- Record the patient's first and last name and one other identifier on the vial.
- Complete a laboratory requisition form with complete patient information and medical history
- Insert the contoured end of the plastic spatula and rotate 360° around entire exocervix.
- Snap the device handle and drop the detachable head of the device into the SurePath® vial.
- 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.
- 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.
- Place the vial and requisition in a specimen bag for transport to the laboratory.

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.



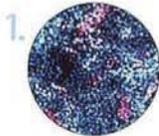
3. Cap and label vial
Place the cap on the vial and tighten. Label the vial and lab requisition form with patient name and/or number, physician name and date if desired.



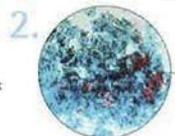
4. Send vial to your lab
Place the vial and requisition into a specimen bag and send to the laboratory.

ONE CLEAR RESULT

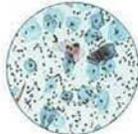
In clinical trial studies, cervical samples were taken and first smeared onto slides. Residual cells from the conventional smear were used in the PrepStain™ process. In each case, the same patient sample, with very different results.



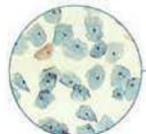
1. Conventional
Conventional smear, dense with blood, mucus, and inflammation is diagnosed as an unsatisfactory specimen, and the patient is called back in for another sample.



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



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



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

TRiPATH™
care technologies™

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

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4.4 HPV Testing

HPV testing can be made on adequate specimens collected only in liquid media (either SurePath™ or ThinPrep®). No additional collection methodology is necessary for HPV testing to be done. Please refer to the GYN required information (Requisition) for ordering instructions.

5. NON-GYNECOLOGICAL SPECIMENS

5.1 Requisition Required Information

Note: Patient information and pertinent clinical history must be included on the requisition to insure 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

- 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.

5.1.3 Specimen Information

- 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.

5.1.4 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

5.1.5 Test Order Information

- Indicate clinical diagnosis with signs and symptoms.
- If requesting special stains please indicate this on the requisition.

5.2 Non-GYNECOLOGICAL Required Information (Specimen)

5.2.1 Identifiers

Sky Lakes Medical Center 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 and the patient's date of birth as the second identifier.

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.

5.2.2 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.

All Non-Gyn cytology fluid specimens will have a cell block produced in addition to a Thin Prep slide for examination if sufficient tissue/cells are available.

5.3 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.

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

- Collect specimen in a clean/sterile container that is labeled with the patients first and last name and a unique patient identifier.
- 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.
- Do not add fixative. If transport to the lab will be delayed, the specimen should be refrigerated. If a delay in processing beyond 24 hours is anticipated, the specimen should be mixed with an equal amount of CytoLyt® fixative (available from Sky Lakes Medical Center Pathology department 541-274-6243.)
- Send specimen and completed order/requisition to Pathology.

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

- Normal saline is the recommended washing fluid.
- Collect specimen in a clean/sterile, container that is labeled with the patients first and last name and a unique patient identifier.
- 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.
- Do not add fixative. If transport to the lab will be delayed, the specimen should be refrigerated. If a delay in processing beyond 24 hours is anticipated, the specimen should be mixed with an equal amount of CytoLyt® fixative (available from Sky Lakes Medical Center Pathology department 541-274-6243).
- Send specimen and completed requisition to Pathology.

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

5.3.3 Bronchial/Bronchoscopy Specimens

- Collect specimen in a clean/sterile, container that is labeled with the Patient's first and last name and a unique patient identifier.

- Do not add fixative. If transport to the lab will be delayed, the specimen should be refrigerated. If a delay in processing beyond 24 hours is anticipated, the specimen should be mixed with an equal amount of CytoLyt® fixative (available from Sky Lakes Medical Center Pathology department 541-274-6243).
- Send specimen and completed requisition to Pathology.

5.3.4 Bronchial Brushings

Slides

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

Container

- 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.

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.

- 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.
- Replace cap tightly and label container with patient name and another identifier (birth date).
- Send specimen and completed requisition to Pathology.

Note: Specimens submitted for culture studies, molecular studies, and other special studies must be submitted in separate sterile containers.

5.3.5 Bronchoalveolar Lavage

- Collect specimen in a clean/sterile, container that is labeled with the patients first and last name and a unique patient identifier.
- Do not add fixative. If transport to the lab will be delayed, the specimen should be refrigerated. If a delay in processing beyond 24 hours is

anticipated, the specimen should be mixed with an equal amount of CytoLyt® fixative (available from the Sky Lakes Medical Center 541-274-6243).

- Send specimen and completed requisition to Pathology.

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.

5.3.6 Sputum

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

Inpatient sputum

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

Outpatient sputum

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

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

- 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.
- Send specimen with completed cytology requisition to the laboratory.

Induced Sputum

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

5.3.7 Cerebrospinal Fluid

- Collect specimen in a clean/sterile container that is labeled with the patients first and last name and a unique patient identifier.
- Fill out requisition indicating site of tap (lumbar, ventricle, Omayya reservoir) and relevant clinical information.
- Send specimen and completed order/requisition to Pathology.

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

5.3.8 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 delivery of the RPMI media, please call 541-274-6243.

General Procedure for Superficial Sites

- Label two or more clean glass slides or label cytology collection bottle (tube) with the patients first and last name and a unique patient identifier.
- Wipe the skin over the lesion with an alcohol swab. Local anesthetic is not usually needed.
- Attach a 22 gauge (or 25 gauge in certain sites such as thyroid) needle to a 10-20 cc syringe.
- If possible, fix the lesion in place using the thumb and forefinger of the left hand (if right handed).

- Pass the needle through the skin and into the lesion.
- 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.

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

To Make Slides

- Remove the needle from the syringe.
- Draw air into the syringe.
- Replace the needle onto the syringe.
- 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.
- Immediately place a second slide over the slide with the sample.
- Allow the sample to spread between the two slides without any smearing motion (other smearing methods can be used but require experience).
- Immediately fix the slides using a Cytology 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.

- 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.
- The procedure may be repeated several times.

- Apply pressure to the aspirated site to minimize hematoma.

To send in a Container (No Slides)

- 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 CytoLyt® container.
- Obtain the sample using the general procedure.
- 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.
- Close the container for transport.
- Apply pressure to the aspirated site to minimize hematoma.
- Dispose of the syringe and needle in the proper container.

5.3.9 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 RPMI 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.

Cytology fixative (CytoLyt®) may be obtained from the laboratory.

Slides can be immediately stained and interpreted for adequacy. The procedure can be repeated if inadequate material is obtained. Cyto centrifuge preparations, ThinPrep® 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 Pathology.

If you would like to arrange for delivery of RPMI media, please call 541-274-6243.

5.3.10 Most Common Deep Sites

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

5.3.11 Gastrointestinal Brushings

Slides

- 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.
- Send immediately to Pathology Lab with completed requisition.

Container

- 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.
- Cut off the brush and drop it in the fixative.
- Replace cap tightly and label container.
- Send immediately to Pathology Lab with completed requisition.

5.3.12 Nipple Discharge

- 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.
- 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 slide(s) with Cytology fixative 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.)

- Place slides in carrier and send to Pathology lab with completed requisition.

5.3.13 Skin (Tzanck Smear)

- Identify a fresh typical vesicle.
- Unroof the vesicle.
- Scrape the margin of the vesicle with a scalpel blade.
- Spread the cells and debris adherent to the blade on a clean, labeled, glass slide.
- Fix immediately with Cytology 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.
- Place slides in carrier and send slide(s) and requisition to the laboratory.

5.3.14 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 Sky Lakes Medical Center 541-274-6243.

Voided Urine

- 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.**
- For optimal cytological evaluation of urine, **first-voided morning specimens should not be used.**
- Send immediately to the cytology laboratory with completed requisition.
- If specimen cannot be sent immediately to the cytology laboratory, please refrigerate.

- 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®) available from the Sky Lakes Medical Center 541-274-6243.

Formalin is never an appropriate cytology fixative.

Catheterized Urine

- Specimen is collected by physician or nursing staff in a clean, properly labeled container and sent immediately to the Sky Lakes Laboratory with completed requisition. **Make sure to note that specimen is catheterized urine.**
- 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®) available from the Sky Lakes Medical Center 541-274-6243.

Formalin is never an appropriate cytology fixative.

Renal Pelvic and Bladder Washings

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

6. Advance Beneficiary Notice

Notifier:  **SKY LAKES** 2865 Daggett Avenue, Klamath Falls Oregon 97601
 MEDICAL CENTER Phone: 541-274-6221

Patient Name: _____ **Identification Number:** _____

**Advance Beneficiary Notice of Non-coverage
(ABN)**

NOTE: If Medicare doesn't pay for the item or service 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 item or service below.

Item or Services	Reason Medicare May Not Pay:	Estimated Cost
<input type="checkbox"/> Screening Pap	<input type="checkbox"/> Due To Frequency Conditions (once every two years)	\$ 161.00
<input type="checkbox"/> Screening HPV	<input type="checkbox"/> Due to age requirements, 30 – 50 years in conjunction with Pap test.	\$ 323.80
<input type="checkbox"/> Other: _____		

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 item or service 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.
<input type="checkbox"/> OPTION 1. I want the item or service 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.
<input type="checkbox"/> OPTION 2. I want the item or service 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 billed.
<input type="checkbox"/> OPTION 3. I don't want the item or service 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: _____
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6.1 Privacy Information

Sky Lakes Medical Center is committed to protecting the confidentiality of your medical information and is required by law to do so. See www.SkyLakes.org for the full privacy policy.