WCP LABORATORIES, INC.

CYTOLOGY SPECIMEN COLLECTION AND HANDLING PROTOCOL

INTRODUCTION

WCP Laboratories, Inc. is committed to providing the highest quality laboratory services in the industry. In doing so a well defined and easy to follow specimen collection protocol is vital. Procedures related to specimen procurement, transport, and accessioning are critical for obtaining accurate testing results.

Guidelines for submitting specimens to the cytology laboratory were developed to encompass all activities, from removal of the specimen to its acceptance by the laboratory. WCP Laboratories, Inc. only accepts specimens referred from licensed physicians or licensed organizations.

PREPARATION

CYTOLOGY SPECIMENS SHOULD BE SENT TO THE LABORATORY AS SOON AS POSSIBLE AFTER THEY ARE OBTAINED.

SPECIMEN TYPE	SPECIMEN PREPARATION	TYPE OF FIXATIVE
Vaginal & Cervical Conventional Collection	See Following Section – Page 4	Spray fixative, or fixative Provided in Pap Pak
Vaginal & Cervical Thin Prep Collection	See Following Section – Page 6	PreservCyt™ Solution Vial.
Sputum	See Following Section – Page 7	Cytolyt
Bronchial Brushing Smears	See Following Section – Page 8	Spray fixative or alcohol.
Bronchial Washes	See Following Section – Page 8	Cytolyt
Gastric Brushing Smears	See Following Section – Page 9	Spray fixative or alcohol.
Gastric Washes	See Following Section – Page 9	Cytolyt
Urine	See Following Section – Page 10	Cytolyt
Body Cavity Fluids	See Following Section – Page 11	Cytolyt
Cerebrospinal Fluid	See Following Section – Page 12	None
Fine Needle Aspiration	See Following Section – Page 13	Cytolyt
Oral Smear	See Following Section – Page 14	Spray Fixative
Nipple Discharge	See Following Section – Page 15	Spray Fixative
Cyst Aspiration Fluid	See Following Section – Page 16	Cytolyt
Oral Brushing Specimen	See Following Section – Page 17	PreservCyt™ Solution Vial.

NEVER add formalin, absolute alcohol or saline to a cytology smear. Reagant grade alcohol is an acceptable fixative (100% or 95%).

If presented with a specimen that you cannot find on the above list, or that you are unfamiliar with, please call the Manager of Cytology at (314) 991-4313 x216.

SPECIMEN PROCUREMENT, TRANSPORT, AND ACCESSIONING

The procurement of specimens for cytology evaluation consists of the following elements:

1. Correct identification and integrity of identification
2. A completed laboratory requisition
3. Fixation or special handling appropriate to the specimen
4. Prompt delivery of the specimen to the laboratory
5. Proper accessioning

The initial responsibility for proper specimen collection & handling, including preservation and labeling, lies with the submitting physician. In general, the submitting physician is responsible for ensuring specimens are collected and labeled appropriately, are correctly preserved and comply WCP Laboratories, Inc. requirements for submission. While the laboratory cannot be responsible for the material until it is accepted, WCP Laboratories, Inc. works very closely with our clientele to train and provide to them the proper guidelines for submitting and preserving cytology specimens. Our laboratory's main responsibility is to ensure adequate material for proper diagnosis. Any specimen referrals for special procedures or research will be done through the direction of our laboratory director and/or pathologists. In general, the timing of such procedures will take into account the work schedule for our laboratory personnel and internal policies.

CORRECT IDENTIFICATION OF SUBMITTED SPECIMENS

Correct identification and integrity of identification from specimen removal to accessioning within WCP Laboratories, Inc. is essential. Proper identification should be on the specimen container and include at the minimum:

1. Patient's full name
2. Unique Identifying number (hospital number, accession number, etc.)
3. Age (date of birth)
4. Date obtained
5. Type of Specimen and Source
6. Name of Submitting Physician or location (hospital, etc.)

*NOTE: All specimens should be presumed to be infectious. Universal safety precautions are followed in handling all specimens. If a specimen presents a known or suspected biohazard, the container should be marked to indicate such. This identifying information should match the information on the specimen requisition form. Best method is to place identification on the body of the container rather than the top, as the top may be inadvertently transferred.

The laboratorian (technician/clerk) who accessions the specimen into the laboratory computer should not accept specimens that are either improperly labeled, incompletely labeled, or without proper accompanying specimen requisition. If any of these items are not met, the accessioning personnel will follow the specimen rejection protocol within this manual. Criteria for specimen acceptance or rejection are specifically listed in that protocol and are monitored for compliance and internal efficiency. The laboratory manager/QC coordinator on a monthly basis reviews these forms and any educational or other follow up with the submitting client is recorded.

WCP Laboratories, Inc. has developed methods for obtaining and assuring correct identification in sample submission. These methods include timely follow up with the client to assure a correctly labeled specimen is obtained or resubmitted to the laboratory. WCP Laboratories, Inc. uses a "Specimen Rejection Form" to document and monitor improper specimen received in the lab. (Please see Attachment A).

REQUISITION FORM

A properly completed specimen requisition form is mandatory for all testing of samples at WCP Laboratories, Inc. The following information is required on the form for the sample to be accepted for testing:

1. Patient's full name
2. Unique identifying number (Social Security Number, hospital number, etc.)
3. Date of birth
4. Name of submitting and/or attending physician
5. Date of specimen collection
6. Site of specimen
7. Type of specimen (incisional, excisional, resection, etc.)
8. Brief clinical history (if applicable)
9. Clinical Diagnosis
10. Appropriate billing identifiers (CPT code, ICD-9, etc.)
11. Insurance information

All identifying information on the requisition form should match that on the specimen container and/or slide. All accessioning personnel are responsible for checking for compliance in this area. If a specimen presents a known or suspected biohazard, this information should also be placed on the specimen and requisition form.

A requisition form MUST accompany all specimens. Patient identification data should be correct and legible. Requisition forms MUST be retained for the regulatory amount of time depending on the sample, etc. (Please see records retention protocol within this manual). Quarterly, the Requisitions Form Problem Log (please see Attachment B for Requisition Form Problem Log) is reviewed and any follow up with clients is documented by the appropriate personnel and reviewed by the supervisor/manager of the laboratory.

FIXATION

Specimens may be submitted without fixative if they are delivered to the surgical pathology laboratory promptly enough or if frozen section is requested. When a fixative is used, it should be one that is acceptable by WCP Laboratories, Inc. Please see above for specific fixative per specimen type. This information is documented on WCP Laboratories, Inc. "Fixative Problem Log", (please see Attachment C). Again these logs are reviewed on a periodic basis and follow up performed with the client.

PROMPTNESS OF DELIVERY TO THE LABORATORY

In general, specimens should be delivered to the laboratory as soon as possible after they are obtained. WCP Laboratories, Inc. follows a courier pickup system where specimens are picked up from our clients on a periodic basis. If a specimen is referred to as a "stat", a special pickup is performed at an additional charge.

Fixation or refrigeration of specimens is required if deliver to the laboratory is delayed. In order to monitor specimens delivered to the laboratory, the date of accessioning MUST be matched against the date of surgery, or sample collection date; which is a date required on the requisition.

Title: COLLECTION OF VAGINAL OR CERVICAL CONVENTIONAL PAP SMEAR

PURPOSE: The primary purpose of obtaining a sample of cells from the cervix (Pap Smear) is to detect cervical cancer, its precursors, and other abnormalities of the reproductive tract. Preferably, the woman should be tested 2 weeks after the first day of her last menstrual period and definitely not when she is menstruating.

MATERIALS NEEDED:

1. Sterilized bivalve speculum.
2. Pap-Pak or frosted-end glass slides, cervical brush, wooden spatula.
3. Requisition
4. #2 Pencil
5. Cytology Spray Fixative
6. Biohazard Bag

PROCEDURE:

1. Label frosted-end of the glass slide with the patient's name.
2. Insert speculum, which may be slightly moistened with water. No other lubricant should be used
3. Choose the contoured end of spatula. Rotate the spatula around at least 360° of the cervical Os and ectocervix. Hold the spatula between fingers of the nonsampling hand with specimen face -up.
4. Insert the cervical brush into the OS. With gentle pressure, rotate the brush only 90 to 180° to minimize bleeding.
5. It is important to obtain a smear that is not obscured by blood, mucus, or inflammatory exudate.
6. Spread the material collected on the spatula evenly over the glass slide with a single, smooth stroking motion. Roll the brush across the glass slide by twirling the handle. **To avoid air drying artifact, transfer the material from both sampling instruments to the slide within a few seconds and fix immediately**. Use spray fixation, holding the container 12 inches from the slide.
7. Spray-fixed or liquid-coated slides must be allowed to dry before packaging for transport.

8. Fill out requisition for Gynecological Specimen completely and accurately. **ALL** pertinent requested information should be completed. It is within the authority of the laboratory receiving the specimen to reject it because of insufficient or inaccurate patient information (discrepancy between patient name on slide and requisition)

9. Place in biohazard bag and send to WCP Laboratories, Inc.

Reference

NCCLS Infobase 99, GP15-a Papanicolaou Technique; Approved Guideline.

Title: COLLECTION OF VAGINAL OR CERVICAL THIN PREP PAP SMEAR

PRINCIPAL: Correct collection of Thin Prep Pap Smear for good patient care.

MATERIALS NEEDED:

1. Thin Prep Pap Kit or
2. Plastic Spatula
3. Endocervix Brush/Broom Device
4. PreservCyt™ Vial
5. Requisition
6. Biohazard Bag

PROCEDURE:

1. Obtain...an adequate sampling from ectocervix using a plastic spatula.

2. Rinse...the spatula into the PreservCyt™ Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.

3. Obtain---an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate ¼ to ½ turn in one direction. DO NOT OVER-ROTATE.

4. Rinse...the brush 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.

5. Tighten...the cap so that the torque line on the cap passes the torque line on the vial.

6. Record...the patient's name and I.D. number on the vial.
   Record...the patient's information and medical history on the cytology requisition form.
7. Place...the vial and requisition in a specimen bag for transport to the laboratory.

8. Fill-out requisition with **printed patient's name**, date of birth, date of service, last menstrual period (if applicable), client and/or physician's name, patient's history, and insurance information.

Title: COLLECTION OF SPUTUM

PRINCIPAL: Correct collection of Sputum for good patient care.

MATERIALS NEEDED:

1. Small Container
2. Cytolyt fixative
3. Requisition

PROCEDURE:

1. Obtain...early morning collection with deep cough in small container.
2. Write...name of patient, source of specimen, date and time collected on container.
3. Add...one part Cytolyt fixative to three parts of sputum.
4. Fill-out requisition with **patient's printed name**, date of birth, date of service, source of specimen, client and/or physician's name, patient's history, and insurance information.
5. Place in biohazard bag and send to laboratory.
6. For optimal sensitivity, repeat sputum cytology on two additional mornings.

Title: COLLECTION OF BRONCHIAL BRUSHINGS AND WASHINGS

PRINCIPAL: Correct collection of bronchial brushings and washings for good patient care.

MATERIALS NEEDED:

1. Small container
2. Frosted-end glass slides
3. Cytolyt fixative
4. Spray fixative / 95% reagent alcohol
5. #2 Pencil
6. Requisition
7. Biohazard bag

PROCEDURE:

1. After collection of bronchial brushing/washing, smear brush on slides and spray fixative **immediately.** Write name of patient on frosted-end of glass slide using the #2 pencil. Place in holder.

2. Place fluid from washings in small container and add one-part Cytolyt to three-parts fluid. Write name of patient and source of specimen on container.

3. Fill-out requisition with **printed patient's name**, date of birth, date of service, client and/or physician's name, patient's history, and insurance information.

4. Place in biohazard bag and send to laboratory.

* In the event spray fixative is not available, drop the slide in 95% reagent alcohol.

Title: COLLECTION OF GASTRIC BRUSHINGS AND WASHINGS

PRINCIPAL: Correct collection of gastric brushings and washings for good patient care.

MATERIALS NEEDED:

1. Small container
2. Frosted-end glass slides
3. Cytolyt Fixative
4. Spray fixative / 95% reagent alcohol
5. #2 Pencil
6. Requisition
7. Biohazard bag

PROCEDURE:

1. After collection of gastric brushing/washing, smear brush on slides and spray fixative **immediately.** Write name of patient on slide end with #2 pencil. Place in holder.

2. Place fluid from washing in small container and add one-part Cytolyt to three-parts fluid. Write name of patient on container and source of specimen.

3. Fill-out requisition with **printed patient's name**, date of birth, date of service, client and/or physician's name, patient's history, and insurance information.

4. Place in biohazard bag and send to laboratory.

* In the event spray fixative is not available, drop the slide in 95% reagent alcohol.

Title: URINE COLLECTION

PRINCIPAL: Correct collection of urine for good patient care.

MATERIALS NEEDED:

1. Small urine container
2. Cytolyt Fixative
3. Requisition
4. Biohazard bag

PROCEDURE:

1. Collect urine in small urine container.
2. Write name of patient on container and source of specimen.
3. Add one-part Cytolyt to three-parts urine.
4. Fill-out requisition with **printed patient's name**, date of birth, date of service, client and/or physician's name, patient's history, and insurance information.
5. Place in biohazard bag and send to laboratory.

Title: BODY CAVITY FLUID COLLECTION

PRINCIPAL: Correct collection of body cavity fluids for good patient care.

MATERIALS NEEDED:

1. Small container.
2. Cytolyt Fixative
3. Requisition
4. Biohazard bag

PROCEDURE:

1. Aliquot 60 ml. of fluid into small container.

2. Write name of patient on container and source of specimen.

3. Add one-part Cytolyt to three-parts fluid:

   Example:
   20 ml. of Cytolyt to 60 ml. of fluid or
   10 ml. of Cytolyt to 30 ml. of fluid

4. Fill-out requisition with **printed patient's name**, date of birth, date of service, client and/or physician's name, patient's history, and insurance information.

5. Place in biohazard bag and send to laboratory.

Title: CEREBROSPINAL FLUID COLLECTION

PRINCIPAL: Correct collection of cerebrospinal fluid (CSF) for good patient care.

MATERIALS NEEDED:

1. Small container
2. Requisition
3. Biohazard bag

PROCEDURE:

1. Collect cerebrospinal fluid (CSF) in small container.
2. Write name of patient on container and source of specimen.
3. Refrigerate; **DO NOT ADD ANYTHING TO THE FLUID.**
4. Fill-out requisition with **printed patient's name**, date of birth, date of service, client and/or physician's name, patient's history, and insurance information.
5. Place in biohazard bag and send to laboratory as soon as possible.

Title: COLLECTION OF FINE NEEDLE ASPIRATION

PRINCIPAL: Correct collection of fine needle aspiration for good patient care.

MATERIALS NEEDED:

1. Frosted-end glass slides
2. Spray fixative / 95% reagent alcohol
3. Small container, if applicable
4. #2 Pencil
5. Cytolyt for cell block
6. Requisition
7. Biohazard bag

PROCEDURE:

1. Make 2-4 smears per pass; spray fixative **immediately**.
2. If applicable, rinse needle in small container, adding 1 part Cytolyt to 3 parts fluid, and submit for cytospin.
3. Write name of patient on frosted-end of glass slide smears with #2 pencil and place in holder. Write name of patient on container and source of specimen.
4. Fill-out requisition with **printed patient's name**, date of birth, date of service, client and/or physician's name, patient's history, and insurance information.
5. Place in biohazard bag and send to laboratory.

* In the event spray fixative is not available, drop the slide in 95% reagent alcohol.

Title: COLLECTION OF ORAL SMEAR

PRINCIPAL: Correct collection of oral smear for good patient care.

MATERIALS NEEDED:

1. Frosted-end glass slides
2. Spatula
3. Spray fixative / 95% reagent alcohol
4. #2 Pencil
5. Requisition
6. Biohazard bag

PROCEDURE:

1. Make a thin smear using a spatula scraping oral cavity and smearing on a frosted-end slide. Spray fixative **immediately.** Write name of patient on frosted-end of slide with #2 pencil. Place in holder.

2. Fill-out requisition with **printed patient's name**, date of birth, date of service, client and/or physician's name, patient's history, and insurance information.

3. Place in biohazard bag and send to laboratory.

* In the event spray fixative is not available, drop the slide in 95% reagent alcohol.

Title: COLLECTION OF NIPPLE DISCHARGE

PRINCIPAL: Correct collection of nipple discharge for good patient care.

MATERIALS NEEDED:

1. Frosted-end glass slides
2. Spray fixative / 95% reagent alcohol
3. #2 Pencil
4. Requisition
5. Biohazard bag

PROCEDURE:

1. Make thin smear and spray fixative **immediately.** Write name of patient on frosted-end of slide with #2 pencil. Place in holder.

2. Fill-out requisition with **printed patient's name**, date of birth, date of service, client and/or physician's name, patient's history, and insurance information.

3. Place in biohazard bag and send to laboratory.

* In the event spray fixative is not available, drop the slide in 95% reagent alcohol.

Title: COLLECTION OF CYST ASPIRATION FLUID

PRINCIPAL: Correct collection of cyst aspiration fluid for good patient care.

MATERIALS NEEDED:

1. Small container
2. Cytolyt
3. Requisition
4. Biohazard bag

PROCEDURE:

1. Collect fluid in small container, add 1 part Cytolyt to 3 parts fluid. Write name of patient and source of specimen on container.

2. Fill-out requisition with **printed patient's name**, date of birth, date of service, client and/or physician's name, patient's history, and insurance information.

3. Place in biohazard bag and send to laboratory.

WCP LABORATORIES, INC.

Cytology Specimen Collection Manual

Title: COLLECTION OF ORAL BRUSHING SPECIMENS

PRINCIPAL: Correct collection of Oral brushing specimens for good patient care.

MATERIALS NEEDED:

1. PreservCyt™ Vial
2. Rovers® Orcellex®Oral Collection Brush
3. Requisition
4. Biohazard Bag

PROCEDURE:

1. Obtain…an adequate sampling from the oral cavity by using the Rovers® Orcellex®Oral collection brush. Place the brush perpendicular onto the mucosa to be sampled. Press the brush gently into the lining mucosa so that it makes firm contact and displaces the mucosa. Rotate the brush through ten complete turns in one direction for each site to be sampled. At least five rotations should be used for the floor of the mouth and ideally ten if tolerated, maintaining the pressure on the lining mucosa.
   Note: The Rovers® Orcellex® collection brush is for single use only and a new brush and vial must be used for each location examined.

2. Rinse…the brush in the PreservCyt™ Solution by rotating the device in the solution 10 times while pushing against the PreservCyt™ vial wall. Continue to swirl the brush vigorously until all of the collected material has been released into the vial solution. Discard the brush. (Remember…the more material collected, the better the results!)

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

4. Record…the patient's name and D.O.B. on the vial.

5. Record…the patient's information and medical history on the oral pathology requisition form. Fill-out the requisition with **printed patient's name**, date of birth, date of service, client and/or physician's name, patient's history, and insurance information.

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

ATTACHMENT A

Submitting Location or Physician_____ Accession#_____

Date Received_____ Received From_____

REASON FOR REJECTED/UNSATISFACTORY SPECIMEN

_____No Client or Physician Identified on Requisition or Container

_____Container Not Labeled with Complete Patient Name

_____Container Not Labeled at All

_____Patient's Age/DOB Not on Requisition

_____No Date of Service (Specimen Taken) Given

_____Incorrectly Labeled (Container vs. Requisition)

_____All Specimen Container(s) Not Indicated/Labeled as per Requisition

_____No Fixative or Improper Fixative for Test

_____No Specimen Identified in Container

_____Specimen Received Broken Beyond Repair

_____No Sites Listed on Requisition on Container(s)

_____Multiple Accession Numbers for Same Patient

_____Other (Please Describe under Comment Section below)

COMMENTS:

_____

_____

_____

Reviewed by _____ Date _____

ATTACHMENT B

REQUISITION FORM PROBLEM LOG

Case No.	Patient Identification	Client Number or Name	Source of Tissue	Clinical Information	Pre-/Post- Operative Diagnosis	Biohazard Notation

Reviewed by _____ Date _____

ATTACHMENT C

FIXATIVE PROBLEM LOG

Date	Patient Name	Client Name or Number	Problem	Follow-up

Reviewed by _____ Date _____