# SALINA PATHOLOGY LABORATORY

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SALINA PATHOLOGY LABORATORY
GENITAL CYTOLOGY
PAP TESTING

I. REQUISITION:

Salina Pathology Laboratory is a Clinical Laboratory Improvement Amendment (CLIA) certified laboratory. Our certification is your assurance of the highest possible testing standards.

In compliance with CLIA regulation, guidelines have been established for the acceptance or rejection of cytology specimens. Appropriately labeled specimens must be accompanied by a cytology requisition. Information appearing on the slide or Surepath vial and the requisition MUST match identically.

Complete a cytology requisition (yellow, Form 15) noting the following information:

1. PATIENT NAME: Patient name on the requisition must exactly match the patient name as it appears on the slide or SurePath vial label.

2. DATE OF COLLECTION

3. PATIENT’S DATE OF BIRTH

4. PATIENT ADDRESS: If the ordering physician/practitioner participates in the Pap Reminder system, patient address is needed to generate the patient reminder letter.

5. PHYSICIAN/PRACTITIONER NAME

6. SOCIAL SECURITY NUMBER/PATIENT ID: Please provide patient social security number or other patient identifier. It is helpful if you would advise the laboratory if you become aware of name changes.

7. PERTINENT CLINICAL INFORMATION: The following information is required by CLIA regulation for accurate interpretation of the specimen:

   a) Date of last menstrual period
   b) Source of material submitted (cervix, endocervix or vagina)
   c) Hormonal status (pregnant, post-partum, post-menopausal, etc)
   d) Exogenous hormone therapy (birth control pills, estrogen therapy, etc.)
   e) History of abnormal cytology
   f) Date of last gynecological testing and the diagnosis
   g) Any other pertinent history

II. SPECIMEN LABELING:

Using a Number 2 lead pencil, record the following on the frosted end of the slide. Ink may be used on the Surepath vial:

- Patient first and last name

IMPORTANT:

If the name on specimen requisition does not exactly match the name on the slide or SurePath vial, the specimen will be rejected and returned to the originating facility. Please correct the discrepancy and re-submit the specimen.
III. Pap Smear Specimen Collection

A. Patient Preparation

1. It is advisable for the patient to avoid using vaginal suppositories, creams or douches for twenty-four (24) hours prior to collection.

2. Water may be used to lubricate and warm the speculum; however, lubricant jellies should not be used. Position the speculum so that the entire face of the cervix appears at the end of the speculum. A sample from this area is necessary for adequate specimen collection.

B. Sample Collection

1. For a sample to be considered adequate, it is necessary to obtain a specimen from both the ectocervix and the endocervix. Successful collection requires careful inspection of the cervix and localization of the transformation zone.

2. To sample the endocervix, an endocervical brush is gently inserted into the endocervix, turned 360 degrees and withdrawn. The cytobrush is NOT recommended for use on pregnant patients. Vigorous scrubbing of the endocervix should be avoided as bleeding and patient discomfort may result.

3. It is important to obtain a smear that is not obscured by blood, mucus or inflammatory exudate. If there is mucus or other discharge present, gently remove with a swab. Discard swab. Do not clean the cervix by washing with saline as it may result in an acellular smear.
4. To sample the ectocervix, use a scraper to gently, but firmly scrape the transformation zone (squamocolumnar junction). Be careful to avoid removing pieces of tissue with the scraper.

C.

**PLACEMENT OF MATERIAL ON SLIDE**

**ONE SLIDE TECHNIQUE:**

1. Once both specimens have been collected, the endocervical brush should be rolled on the label half of the slide. The ectocervical scraping should be spread on the remaining half of the entire slide.

2. Fix the smear immediately using cytology spray fixative. Failure to fix smears immediately may result in smears that are unsatisfactory for evaluation.

**TWO SLIDE TECHNIQUE**

1. The endocervical brush and ectocervical scraping are each spread on individual slides as soon as they are obtained.

2. Fix the smears immediately using the cytology spray fixative. Failure to fix smears immediately may result in smears that are unsatisfactory for evaluation.

Care must be taken to fix the smear as quickly as possible. Air drying begins within seconds of applying the smear to the slide. Air drying produces artifacts, cellular distortion and may lead to misinterpretation of smears.

The fixative provided is 95% alcohol with carbowax added to prevent drying of the sample. The nozzle of the spraying apparatus should be held approximately twelve (12) inches from the slide. Adequate amounts of fixative should be applied to completely wet the surface.
### PAP SUREPATH SPECIMEN COLLECTION

Four Simple Steps.

<table>
<thead>
<tr>
<th>1. Cervical Sample Collection</th>
<th>2. Preserve the entire sample</th>
<th>3. Cap and label vial</th>
<th>4. Send vial to Peterson Laboratory Services</th>
</tr>
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<tr>
<td>Insert the Rover’s 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 and rotate the brush five times in a clockwise direction.</td>
<td>Placing your thumb against the back of the brush pad simply disconnect the entire brush from the stem into the CytoRich preservative vial.</td>
<td>Place the cap on the vial and tighten. Label the vial and lab requisition form with patient name, date of birth, physician name, and date.</td>
<td>Place the vial and requisition into specimen bag and send to Peterson Laboratory Services.</td>
</tr>
</tbody>
</table>
IV. INTERPRETATION OF PAP TESTING REPORTS

The following information specifically describes epithelial cell abnormalities.

A. ADEQUACY

Adequacy and diagnosis should be used in conjunction with clinical history to determine appropriate patient follow-up. The condition of the specimen received and the presence or absence of endocervical and/or squamous metaplastic cells is noted. The presence of excessive red blood cells, inflammation, scanty cellularity or poor fixation of cells is also noted. ADEQUACY IS NOT A DIAGNOSIS.

B. PATHOLOGIST REVIEW POLICY

Pap Smears with an atypical diagnosis will be reviewed by a pathologist. A separate charge will be made for the pathologist over-read.

C. HORMONAL EVALUATION

Hormonal evaluation is a qualitative cytohormonal evaluation of the patient. HORMONAL EVALUATION IS NOT A DIAGNOSIS! In compliance with Bethesda 2001 guidelines for reporting Pap testing, hormone evaluation is reported only if:

a) Estrogen effect is elevated for the patient age and/or history

b) Estrogen effect is decreased for the patient age and/or history

If no hormone evaluation is reported, you may assume that the estrogen effect is compatible with the patient’s age and history.

The results should be used in conjunction with the patient’s history.

D. INFECTIOUS DISEASE SCREENING

Specimens are screened for cytologic evidence of infectious diseases, such as trichomonas, herpes, candida and human papillomavirus (HPV).

HPV testing can be performed from the SurePath specimen vial. HPV testing will determine the presence of LOW-RISK and/or HIGH-RISK HPV factors.

LOW-RISK HPV types are generally associated with warts or low-grade dysplasia. Testing for low-risk HPV is not necessary nor recommended.

HIGH RISK HPV types are associated with warts, low-grade lesions and high-grade lesions (including cancer).

Guidelines developed by the American Society for Colposcopy and Cervical Pathology (ASCCP) recommend HPV high risk testing only be ordered on patients with atypical squamous cells of undetermined significance (ASCUS). The test must be ordered within 3 weeks of Surepath vial specimen collection.

Chlamydia trachomatis and Neisseria Gonorrhoeae testing by can also be performed from SurePath specimen collection vials. The Cytology Department must have a written request to run either HPV or CT/GC testing. If testing is desired, fax a request to 785-537-3592, attention CYTOLOGY.
V. Pap Reminder System

Salina Pathology Laboratory holds quality patient care to the highest standard. A patient reminder system if offered at no additional cost.

PAP PATIENT LETTER

Letters are prepared by and mailed directly from our facility to those patients with negative pap test results. The letters are addressed to the patient and appear as if they were sent from the office of the attending physician. The letter explains to the patient that their pap test has been interpreted as “normal.” The patient is instructed to telephone the attending physician’s office if they have questions or concerns. The name of the laboratory does not appear on the correspondence.

If there is a question whether a letter was sent to a patient or not sent to a patient, please refer to the patient report. A single asterisk (*) under the pathologist’s name on the left side indicates that a letter was sent. If no asterisk appears, it indicates that a letter was not sent.

PAP REMINDER LETTERS

Letters reminding patients that they are due for a repeat Pap test are prepared and sent to the physician’s office on a monthly basis. The letters are prepared with the physician name and telephone number for the patient to phone to make an appointment and make no reference to Salina Pathology Laboratory. The attending physician may use the reminder letters as they desire; however, double window envelopes are furnished with the letters to facilitate mailing.

The reminder letters are prepared nine (9) months following a negative report.
SUMMARY:
"Zelsmyr" Cytobrush is a sampling device specifically designed for the uterine endocervical canal. It is ten times more effective in collecting endocervical cells than the cotton swab. The cells are twice as well preserved...a major improvement over the cotton swab. "Zelsmyr" Cytobrush is the answer to accurate diagnosis of cervical and uterine pathology. With the "Zelsmyr" Cytobrush cytological abnormality can be detected early.

BACKGROUND:
Since the introduction of cervical cytologic screening by George Papanicolaou, M.D. in 1943, the Pap test has done more to eradicate invasive carcinoma of the cervix and lower the death rate from cancer in women than any other scientific contribution. Studies have shown that the age-adjusted incidence of invasive carcinoma decreased by 58% in the 20 years following the introduction of the Pap test. This decrease in the incidence of invasive cervical cancer is largely a result of early detection of precancerous lesions. The diagnosis of precancerous lesions is in turn a function of sampling.

Published estimates of false-negative rates from the Pap test range from 6-50%. The main explanation for these false-negative findings is sampling error. Cotton swabs are traditionally used for Pap smear sampling. Over the years, their effectiveness has been questioned. Slides prepared with the cotton swab often lack endocervical cells, a reflection of poor sampling. Rubio suggested that cells may be trapped in cotton swabs, never reaching the slide. Many cells may not even be picked up because of the relatively smooth surface of the cotton swabs.

"Zelsmyr" Cytobrush has been scientifically designed to improve the effectiveness of sampling. Results of recent studies demonstrate that "Zelsmyr" Cytobrush is more effective in collecting endocervical cells and the cells are better preserved than those (if any) obtained with the cotton swab. It is inexpensive and easy to use. With "Zelsmyr" Cytobrush significant improvement can be made in the sensitivity and specificity of cytologic diagnosis.

KEY BENEFITS:
• "Zelsmyr" Cytobrush is ten times more effective in collecting endocervical cells than the cotton swab
• The cells are twice as preserved.
• Early detection of abnormalities for timely therapeutic procedures and treatment.
• Cost effective. When cervical and uterine pathology is accurately diagnosed early, complications and higher costs can often be avoided.
• "Zelsmyr" Cytobrush is quick and easy to use. No special training or instruments are required.

WARNING:
Insufficient clinical data. DO NOT USE ON PREGNANT PATIENTS.

INSTRUCTIONS:
After sampling the vaginal fornix and portio in the usual manner, gently insert the "Zelsmyr" Cytobrush into the endocervix and rotate slowly one-half to one-turn. Remove the cytobrush from the endocervix and vagina. Prepare a Pap smear by rolling and twisting the cytobrush on a clean glass slide. Fix with alcohol or spray immediately. Discard the cytobrush in an appropriate container.
# Collection / Handling Procedures

The most accurate testing is achieved with highest quality specimens. Please submit at next courier pickup.

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<th>Source</th>
<th>Specimen Requirements</th>
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<tr>
<td><strong>Body Fluids</strong> (pleural, ascitic, etc.)</td>
<td>Fresh (no fixative required). Refrigerate. Submit the entire specimen.</td>
</tr>
<tr>
<td><strong>Breast Cyst Aspirate</strong></td>
<td>Fresh (no fixative required). Refrigerate.</td>
</tr>
<tr>
<td><strong>Bronchial Washings</strong></td>
<td>Fresh (no fixative required) or submitted in equal amounts of alcohol.</td>
</tr>
<tr>
<td><strong>Brushings</strong></td>
<td>Place brush(s) in small container with normal saline. Refrigerate.</td>
</tr>
<tr>
<td><strong>Cerebrospinal Fluid</strong></td>
<td>Fresh (no fixative required). Refrigerate.</td>
</tr>
<tr>
<td><strong>Fine Needle Aspirate</strong></td>
<td>Refer to following special collection procedure</td>
</tr>
<tr>
<td><strong>Sputum</strong></td>
<td>First morning deep-cough specimen is recommended. Generally three (3) separate specimens are collected. Equal volumes of carbowax fixative are added to the specimen.</td>
</tr>
<tr>
<td><strong>Urine</strong></td>
<td>Fresh (no fixative required). Refrigerate. DO NOT COLLECT FIRST MORNING SAMPLE. Indicate on requisition if sample is voided or catheterized, as appropriate.</td>
</tr>
<tr>
<td><strong>Bladder Washings</strong></td>
<td>Fresh (no fixative required). Refrigerate.</td>
</tr>
<tr>
<td><strong>Smears (including Tzanck)</strong></td>
<td>Spray fix immediately. If collected from the head/neck/lymph area, please submit 2 air-dried slides also.</td>
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A. LABELING

1. Label glass slides with the following information:
   a. Patient first and last name
   b. Date of collection
2. Label the container with the following information:
   a. Patient first and last name
   b. Anatomic location of specimen
   c. Date of collection
3. Indicate on the label that the specimen bottle contains NORMAL SALINE if used

B. REQUISITION:

1. Complete a Salina Pathology requisition with the following demographic information:
   a. Patient First and Last Name
   b. Physician
   c. Date of Birth
   d. SEX of patient
2. Additional required information on the request form:
   a. Anatomic Location of Specimen
   b. Pertinent medical history
   c. Diagnosis

C. HANDLING:

1. Place slides in slide folders
2. Place slide folders and specimen container in specimen transport bag
3. Fold requisition and place in side pocket of the specimen transport bag
4. Transport to Salina Pathology Laboratory

NOTE: Containers and spray fixative are furnished upon request. Please contact the laboratory if you require supplies or additional information.
II. FINE NEEDLE ASPIRATE

COLLECTION/HANDLING PROCEDURE

Fine needle aspirate specimens may be submitted fresh (no fixative required) or submitted as slides. Dependent upon volume of specimen obtained, specimens may be submitted in the syringe needle (draw up small amount of saline or alcohol to prevent drying) or the syringe itself. Larger volume specimens (e.g., breast cyst aspirates) may be expressed into a container for submission.

A. SLIDE SUPPLIES NEEDED:
   1. 22-25 gauge needle
   2. 20 mL syringe
   3. Clean glass slides with frosted ends
   4. Spray fixative or 95% alcohol
   5. Small screw-cap container containing normal saline
   6. Slide holder(s)

B. COLLECTION:
   1. The aspiration is usually performed under aseptic technique without local anesthesia. If local anesthesia is used, insert the needle adjacent to, but not into the lesion. Anesthetizing solution could dilute or distort the specimen.
   2. Attach a 22-25 gauge needle to the 20 mL syringe.
   3. Place the plunger of the syringe at the 5 mL mark. Secure the mass with one hand. Use the other hand to insert the needle into the mass.
   4. Draw negative pressure to the 20 mL mark, move needle in short stabbing motions, changing the angle of direction within the lesion.
   5. Return the plunger to the 5 mL mark to release the suction before withdrawing the needle. NEVER INJECT AIR!
   6. After withdrawing the needle, remove the needle from the syringe. Fill the syringe with air.
   7. Reattach the needle and carefully express one drop of specimen onto a glass slide. Use another glass slide or the needle tip to spread the specimen.
   8. Make two slides. IMMEDIATELY (within a few seconds) spray one slide with the fixative. Any delay will cause air drying and cellular distortion, thus rendering the specimen difficult to evaluate. Let the second slide air-dry.
   9. The contents of the syringe should be expressed into a container of normal saline or 95% alcohol. The needle and syringe should then be rinsed with the saline solution.
   10. Submit the glass slides and saline or 95% alcohol container for cytology studies.