Rancho Los Amigos National Rehabilitation Center
OUTPATIENT SERVICES: MOBILE CLINIC POLICY AND PROCEDURE

SUBJECT:	**Womens' Health Procedure:**	**Policy No.:**	**404**
		Supersedes:	**New**
	PAP (Papanicolaou) Smear Procedure Vaginal	**Revision Date:**	**February 9, 2022**
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1. PURPOSE

1.1 To provide guidance and describe the workflow process in performing PAP (Papanicolaou) Smear Procedure in the mobile clinic according to DHS – LA County Standard of Care.

2. POLICY

2.1 The mobile clinic collects GYN specimens using liquid based preparations – *ThinPrep Pap Test.* In rare situations, conventional pap smear preparations will be processed if collected.
2.2 Medical Provider will perform the procedure of PAP Smear with a chaperone.
2.3 Provide instructions and answers all patients' questions before the procedure is perform.
2.4 RN, LVN & CMA can help set-up and assist the medical provider in PAP Smear procedure.
2.5 Provide & maintain patient privacy while PAP Smear is performed.
2.6 Discussion of the procedure with patient shall be documented in the medical records.

3. DEFINITION

3.1 The PAP smear was developed in the early 1940's by Dr. George Papanicolaou and has proven to be the most effective means of detecting dysplastic and cancerous conditions of the female genital tract. It can also detect abnormalities of the vagina, endocervix, uterus or metastatic disease.

4. INDICATION

4.1 Screening for cervical cancer:
4.1.1 Clinicians are advised to consider guidelines in relation to the patient population they serve and refer to those screening guidelines.
4.1.2 Note: Pap smear is not diagnostic. If abnormality is seen or palpated at the time of pelvic exam, such as a raised or friable lesion or one that looks like a condyloma, it should be examined with colposcope and biopsied.

5. CONTRAINDICATION

5.1 Active vaginitis or cervicitis
5.2 Pelvic inflammatory disease (PID)

6. SPECIMEN COLLECTION

The importance of proper specimen collection and submission cannot be overemphasized.
The majority of false negatives are a result of patient conditions present at the time of sample collection and submission and the skill and knowledge of the individual who obtains the specimen. The laboratory provides feedback on sample adequacy via individual reports regarding patient sampling. *The ThinPrep Method* of liquid based evaluations has helped to eliminate many of the unsatisfactory specimens. *Reflex HPV* testing is also available on the remaining portion of the in cases of ASCUS. This service is available through an approved contract laboratory.

7. EQUIPMENTS

7.1 Examination table appropriate for placing the patient in the lithotomy position.
7.2 A warm, well-lit examination room.
7.3 Drape
7.4 Nonsterile examination gloves
7.5 Water-soluble lubricant (e.g., K-Y Jelly), warm water, or normal saline solution.
7.6 Bivalve vaginal speculum (metal or plastic, disposable). Select a speculum of the appropriate size.
7.7 Types of speculums include:
  7.7.1 Graves (metal)
  7.7.2 Pederson (metal)
  7.7.3 Plastic, disposable (Welch Allyn, Inc; Durr-Fillauer Medical, Inc.)
  * If the speculum has a light source, ensure that it's functioning properly. Inspect all equipment and supplies. If a product is expired, is defective, or has compromised integrity remove it from patient use, label it as expired or defective and report the expiration or defect as directed by your facility.
7.8 Cervical sampling devices (plastic spatula or broom and endocervical brush, such as Cytobrush® or Cervex-Brush®)
7.9 Vial of preservative solution (such as PreservCyt® solution)
7.10 Large swabs for gently blotting excess discharge.
7.11 Specimen label.
7.12 Laboratory biohazard transport bag.
7.13 Optional: Adjustable lamp (if the speculum is without a light source), laboratory request forms, large cotton swabs.
7.14 Culture or transport media and swabs as necessary for detection of gonorrhea, chlamydia, herpes, and fungal infection, and KOH/wet mount.
7.15 Materials and solutions for liquid-based Pap smears (e.g., ThinPrep).

8. PRE-ANALYTIC REQUISITES CONSIST OF

8.1 Patient Preparation
8.2 Electronic Health Record Orders
8.3 Collection of the Sample
8.4 Labeling the Specimen
8.5 Computer Procedures
8.6 Specimen/slide and requisition verification
8.7 Procedures for Transport to contract laboratory

9. PATIENT PREPARATION

9.1 The patient should understand the reason for performing the Pap smear.
9.2 The Pap smear is best performed during midcycle. In most instances the examination should be rescheduled if the patient is actively menstruating. Ideally, 10-18 days after the first day of the last menstrual period.
9.3 The patient should avoid douching, vaginal medications, and intercourse for 24 hours prior to the procedure.
9.4 The patient should void before undressing for the examination.
9.5 Question the patient regarding her concerns. Not infrequently, women are hesitant to discuss symptoms related to the genitals, such as vaginal dryness, itchiness, or discharge, unless the clinician asks.
9.6 The clinician should explain each step of the pelvic examination prior to proceeding. Inform the patient of the mechanisms that you use to follow up on test results (Pap smear, cultures, etc.).

10. ELECTRONIC HEALTH RECORD ORDERS

10.1 Orders must contain the following information as required by CLIA 88 for specimens submitted as applicable:

- Name of Patient
- Date of Birth and Age
- Menstrual status (LMP, Hysterectomy, Postpartum, or on Hormone Therapy.
- History of previous abnormal cytology, previous treatment, biopsy, or surgical procedure.
- Source of Specimen, e.g. Cervical or Vaginal.
- Relevant Clinical Findings such as abnormal bleeding, grossly abnormal cervix or visible cervical lesions.
- History of hormone or contraceptive use.

11. COLLECTION OF THE SAMPLE

11.1 The collection of the sample is performed with the patient in the dorso-lithotomy position. A sterile bivalve speculum is inserted into the vagina with lubrication. Warm water may be used to facilitate insertion of the speculum. The position of the speculum should allow for complete visualization of the cervix and endocervix.

11.2 The transformation zone is the site for most cervical neoplasia and should be the focus of cytology specimen collection. Location of the T-zone may vary from patient to patient. It is important to sample the transformation zone and the endocervix using the endocervical brush or broom. If the patient has had a hysterectomy, a vaginal sample is sufficient, with attention with the sampling vaginal cuff.

11.3 **Endocervical Brush/Spatula Protocol:**

11.3.1 Obtain an adequate sampling from the ectocervix using a plastic spatula. The use of

lubricant is not recommended during PAP Testing. Rinse the spatula as quickly as possible into the PreserveCyt solution by swirling the spatula vigorously in the vial 10 times. Discard the spatula.

11.3.2 Obtain an adequate sampling from the endocervix using an endocervix brush device. Insert the brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate ¼ or ½ turn in one direction. DO NOT OVER-ROTATE. Rinse the brush as quickly as possible in the PreserveCyt solution by rotating the device in the solution 10 times while pushing against the PreserveCyt 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.

11.4 **Broom-Like Device Protocol:**

11.4.1 Obtain an adequate sampling from the cervix using a broom-like device. The use of lubricant is not recommended during PAP Testing. 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 PreserveCyt solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristle apart. As a final step, swirl the broom vigorously to further release the material. Discard the collection device. Tighten the cap so that the torque line on the cap passes the torque line on the vial. Specimens are stable room temperature for 7 days following collection.

11.4.2 Conventional smear collection using the endocervical brush and spatula. The ectocervix should be sampled before the endocervix using the spatula. The tip of the spatula corresponding to the contour of the cervix is rotated 360 degrees around the circumference of the cervix retaining the sample on the upper surface of the spatula. The endocervical brush is then inserted into the endocervical canal and rotated 45 to 90 degrees. The spatula is smeared into half the labeled slide and then brush is removed and is gently rolled onto the same slide. The collected sample is immediately placed into 95% alcohol fixative. Alternatively, the slide may be sprayed fixed. Smears may be prepared using the broom device.

12. LABELING THE SPECIMEN

12.1 Specimen must be labeled with at least two patient unique identifiers, such as first and last name and medical record number or date of birth. Glass slides must be labeled with patient name, initials (in case with long names), and ID# written with a solvent resistant pencil on the frosted end of the slide.

13. COMPUTER PROCEDURES

13.1 The following information is entered into the computer and the PAP Log maintained in Histopathology prior to sending specimens to the contract lab for processing and interpretation.

a. Pap No.
b. Name of Patient

c. MRN Number
d. Date of Birth
e. Date of Pap
f. Date specimen received
g. Clinic
h. Physician
i. Date results received
j. Interpretation

14. SPECIMEN/SLIDE AND REQUISITION VERIFICATION

14.1 Verify the name on specimen and requisition to make sure that it matches.
14.2 Specimen will be rejected if slides or specimen is unlabeled.
14.3 Check the requisition for all the needed information.
14.4 Check the requisition for NAME, DATE OF BIRTH, MRN#, PHYSICIAN, PATIENT'S AGE, LMP (Last Menstrual Period), SPECIMEN SOURCE AND DATE SPECIMEN WAS TAKEN.
14.5 Prepare the specimen to be sent out to the contract laboratory, using universal precautions.
14.6 Remove slides from jar, tap end of slide(s) on a paper towel to remove excess alcohol, place in slide folders let slides dry and discard solution and jars in proper containers. Thin prep specimens should be capped tightly to prevent leakage.
14.7 All specimens are accessioned in the Co-Path system. A copy of the accession log is sent with specimen and requisitions to the Contract Lab.
14.8 Keep second copy of contract laboratory form and log information in Pap logbook.

15. PROCEDURES FOR TRANSPORT TO CONTRACT LABORATORY

15.1 The specimens and requisition forms (See copy attached) are packed and sent by courier to the contract laboratory for staining and reading as per contract.

16. ANALYTICAL AND POST-ANALYTIC REPORTING COMPONENT AT AN APPROVED CONTRACT LABORATORY

16.1 Contract Laboratory Procedure

16.1.1 The results are reported by the contract laboratory according to the Modified Bethesda Format and final printed reports will be returned within the stipulated turn-around-time of seven (7) working days.
16.1.2 Critical Values, such as high-grade dysplasia or carcinoma, reported by telephone from the contract laboratory is documented in the computer and Pap logbook. The Histotech must inform a Pathologist who will notify the physician of record. The date and time of the telephone call or email/fax verification of receipts of results will be documented in the logbook and computer system.

16.2 Upon receipt of the final report from the laboratory, the following information is recorded in the computer:

16.2.1 Interpretation is entered by using standardized codes set-up in coordination with the contract laboratory. (For example, within Normal Limits or Benign Cellular Change).

16.2.2 The report is canned as an image and final result verified as **"SEERPT" which notified the provider/designee to see the scanned image for the detailed Cytology Report from reference laboratory.**

16.2.3 Pap smears are correlated with the biopsy findings by the Pathologist at the time of Surgical Pathology specimen verification (release of biopsy final result).

16.2.4 Cases that show discrepancies between the cytology-histology correlations are investigated by the Pathologist and appropriate corrective action implemented.

REFERENCES

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6. Lippincott (2021, May. 21). *Papanicolaou (PAP) Test (Advanced Practice).* Retrieved on December 3, 2021, from https://procedures.lww.com/lnp/view.do?pId=6762309&hits=ecg,electrocardiogram,ecgs&a=false&ad=false&q=ekg.