REVISION HISTORY				
Major or Minor ?	**VERSION**	**DATE**	**SUMMARY OF CHANGES**	**TRAINING REQUIRED ? YES OR NO**
	1.0	1/1/2001	New	
	1.1	6/10/10	SOP Format Change; New format, changed collection instructions for ThinPrep. Added procedure notes and limitations of procedure to include criteria for unsatisfactory paps. Added monitors.	No
	1.2	6/19/12	New SOP Format (revision table moved to top of procedure and elimination of numbering system)	No
Minor	1.3	4/6/18	Formatting change	No
	1.4	6/29/22	Change to system wide procedure to include Premier sites	No

EFFECTIVE DATES	
Applicable only to System Policies/SOPs. See iPassport for documentation of initial Medical Directors authorization.	
DATE	**LABORATORY SITE**
7/8/22	Atrium Medical Center
4/6/18	CompuNet Clinical Laboratory- Sandridge Core Lab
7/8/22	Miami Valley Hospital
7/8/22	Miami Valley Hospital South
7/8/22	Miami Valley Hospital North
7/8/22	Upper Valley Medical Center

I. Principle or Purpose:

The Pap smear is the microscopic examination of cells utilizing the Papanicolaou staining procedure. This procedure describes the preferred methods for collection of a pap smear from the cervical, endocervical, and vaginal areas of the female genital tract.

II. Responsibility:

The physician or qualified nurse practitioner is responsible for the proper collection of the Pap smear.

It is the responsibility of the Medical Director to approve the procedure and the technical manager to review biennially.

The Cytology Manager is responsible for assuring the laboratory accepts only those specimens that are properly labeled with patient's name on the frosted end of the glass slide or the ThinPrep specimen vial.

The Cytology processor is responsible for checking the name on each slide and specimen label to verify it matches with the name of the requisition.

III. Safety:

Universal precautions should be taken when handling pap specimens outside of their secondary containment (specimen bags).

IV. Specimen Requirements:

Thin Prep specimens – label the vial with 2 unique identifiers, including the patient's full last name, first name and one other identifier, e.g. date of birth or patient ID number. The name on the slide and the requisition must match for laboratory acceptance.

Conventional Pap smear specimens – label the frosted end of the glass slide with the patient's last name and first initial. The name on the slide and the requisition must match for laboratory acceptance.

V. Supplies and Equipment:

Thin Prep Pap Smear

Thin Prep vial
Broom *or* Brush/Spatula collection device(s)

Conventional Pap Smear

Pap Pak kit containing:

Slides
Fixative
Cervical scrapers or Cytobrush
Swab
Cardboard submission folder

VI. Quality Control:

Verify patient identification match on specimen and requisition.

Maintain record logs and other documentation of rejected specimens and specimens needing additional verification prior to testing.

VII. Procedure:

ThinPrep Collection (preferred)
Brush/Spatula collection

1. Take cervical smear by rotating the cervical scraper around ectocervix with special emphasis on the squamo-columnar junction.
2. Rinse immediately by vigorously swirling the spatula 10 times in the vial of fixative.
3. Take endocervical smear by gently inserting the cytology brush into endocervical canal, past the squamo-columnar junction. Rotate cytology brush one half turn (180°).
4. Gently remove cytology brush without touching vaginal surfaces.
5. Rinse immediately by vigorously swirling the brush 10 times in the vial of fixative while pressing it against the sides of the vial to dislodge material.
6. Cap vial so that the torque line on the cap passes the torque line on the vial.
7. Label the vial with the patient's last name, first name and other identifier, e.g. DOB
8. Place vial in plastic zip locked bag with requisition and send to the laboratory. (See attached pictorial instructions.)

Broom Collection

1. 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.
2. 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.
3. Cap vial so that the torque line on the cap passes the torque line on the vial.
4. Label the vial with the patient's last name, first name and other identifier, e.g. DOB

5. Place vial in plastic zip locked bag with requisition and send to the laboratory. (See attached pictorial instructions.)

Conventional Smear Collection

Prepare smears as illustrated on Pap Pak Kit:

1. Take cervical smear by rotating the cervical scraper around ectocervix with special emphasis on the squamo-columnar junction. Place specimen on portion of slide labeled “C”
2. Take endocervical smear by gently inserting the cytology brush into endocervical canal, past squamo-columnar junction. Rotate cytology brush one half turn (180°) in endocervical canal.
3. Gently remove cytology brush without touching vaginal surfaces.
4. Spread material evenly by rotating cytology brush back and forth over section “E”.
5. Take vaginal smear from posterior fornix with spatula and cervical scraper.
6. Spread material evenly on “V” slide.
7. Tear open fixative pouch and immediately fix all preparations.
8. Label frosted end of glass slide. Print patient’s name in pencil.
9. Label box with patient’s name in appropriate area.
10. Prepare Cytology/Pathology requisition and place in plastic zip locked bag for transport to the laboratory.

If a Pap Pak Kit is not available:

1. Prepare slide as explained above.
2. Spray or flood slide with cytology fixative.
3. Label frosted end of slide with patient’s name in pencil.
4. Place into cardboard or plastic slide transport holder.
5. Label slide holder with patient’s name.

VIII. Records or Reporting Results:

All pap tests are screened and resulted by certified cytotechnologists if negative and referred to pathologists for resulting if abnormal or unsatisfactory according to the 2014 edition of The Bethesda System for Reporting Cervical Cytology (TBS).

IX. Procedure Notes:

Detailed instructions are included in the CompuNet Directory of Services provided to all clients. Collection methods of gyn specimens are outlined in the section tab designated Cytology/Histology Tests and in each pap smear test code description.

X. Limitations of Procedure:

Satisfactory squamous cellularity as stated by The Bethesda System for Reporting Cervical Cytology (TBS) is "…an estimated minimum of approximately 8,000 to 12,000 well preserved and well-visualized squamous epithelial cells" for conventional pap smears, or "…an estimated minimum of at least 5,000 well-visualized/well-preserved squamous cells" for liquid based pap smears.
Pap smears collected using lubricant or during a patient's menstrual cycle may compromise the specimen adequacy and may be resulted as "Unsatisfactory" according to criteria stated in TBS. Refer to the Hologic ThinPrep Collection guide for proper collection techniques, approved lubricants, and other limiting factors.

XI. References:

- *The Bethesda System for Reporting Cervical Cytology,* Second Edition
- Pap Pak Kit – Medical Packaging Corporation
- ThinPrep vial – Hologic Corporation
- CompuNet Clinical Laboratories Directory of Services

XII. Monitor:

CoPath Specimen/Requisition Deficiencies for pap specimens provides documentation for specimens received with insufficient information/patient identifiers for processing pap smears.

Unsatisfactory Pap smear rates are monitored monthly for each physician and the lab total and compared with CAP standards. If unsatisfactory rates fall within the 5^{th} or 95^{th} percentile, an investigation of processes will be conducted with documentation of any findings.