

**4.0**

**FAMILY PLANNING LABORATORY**

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## 4.0 INTRODUCTION

All laboratory procedures, quality assurance monitoring and recording must be performed according to current CLIA regulations. Refer to your clinic Laboratory Manual for specific guidelines.

Clinic staff should discuss recommended screening tests with the client using opt-out language. Following counseling about the importance of the recommended screening tests, if client chooses to decline or defer a service, this should be documented in their medical record. Counseling must include information about the possible health risks associated with declining or delaying preventive screening tests or procedures.

### SERVICE POPULATION

Uninsured or underinsured reproductive-age women and men who present for Title X reproductive health services in order to plan the size of their families and birth spacing of their children.

## 4.1. LABORATORY TESTS OVERVIEW

The following laboratory tests may be ordered by the clinician when clinically indicated:

### A. Cervical Cancer Screening (including Pap and/or HPV as indicated)

#### B. Chlamydia/Gonorrhea Test

- All Providers should screen:
  - All sexually active women aged <25 years for chlamydia annually, using opt-out language.
  - Females requesting IUD insertion, regardless of age.
- Chlamydia testing may also be provided for female and male FP clients who are <30 years old and are (one or more of the following):
  - Symptomatic
  - Those diagnosed with an STD in the last year
  - A known contact to an STD infected partner
- **PHO Providers:** for diagnostic testing of high-risk PHO clients, please refer to the STD Program Protocol for testing guidelines.
- **FP Provider Agreement Sites/Non-PHO Providers:** Any testing outside of these parameters is not covered by the FP Provider Agreement and the client must pay for this testing. **Also ensure that all clients who are tested under the FP Provider Agreement have the appropriate health history, counseling, and medical record documentation in order to qualify them as FP clients** (refer to Section 1).

#### C. Wet Prep Test

For asymptomatic clients with normal pelvic exam, the wet prep, pH, and amine test is not indicated. However, testing may be performed on asymptomatic clients when the clinician has clinical suspicion (e.g. abnormal discharge). If bacterial vaginosis (B.V.) or trichomonas is suspected or diagnosed, you may still insert IUD and start treatment on the same visit (US MEC 2).

#### D. Urine Pregnancy Test

Required for provision of specific methods of contraception.

**E. All other tests are done either on site or by referral:**

- Syphilis: For PHOs, refer to STD Program Protocol and addendum. For non-PHOs, refer to clinic treatment protocols and the New Mexico Public Health Order.
- HIV: For PHOs, refer to Section 1 of the FPP Protocol, Subsection 1.2.H.e STD Services. For non-PHO Title X clients, HIV testing is not covered in the FPP agreement.
- Rubella immunity status at the client's own expense for both PHOs and non-PHOs.

**4.2 LABORATORY RESULTS OVERVIEW**

- The clinic must have a tracking system in place for follow-up of abnormal/positive lab tests.
- There must be a designated person(s) that maintain the system.
- The system must include timely notifying a clinician of test results.
- The clinician will determine appropriate follow-up based on the test result report, clinical findings, and the client's ability to follow-up.
- Lab results requiring a clinician's (MD, CNM, CNP, PA) attention includes:

**Table 1: Laboratory Results Requiring Follow-Up by a Clinician**

Cervical Cytology/HPV	Unsatisfactory, ASC-US, ASC-H, AGC, LSIL or HSIL, +HPV, *invasive cancer
Chlamydia/Gonorrhea	Positive
Syphilis serology	Reactive or positive (*pregnant client and/or HIV positive)
TPPA	Positive
HIV	Positive
Hepatitis B	Hepatitis B carrier status in a pregnant woman

*\* Immediate attention required*

## 4.3 LABORATORY METHODOLOGY AND PROCEDURE

### A. Standing Order for Public Health Nurses to Collect Specimens for Chlamydia/Gonorrhea Testing

**Purpose:** Since their epidemiological profiles are similar, CT/GC testing recommendations are the same. **Testing should not substitute client counseling/education regarding correct and consistent condom use in STD prevention.**

*Chlamydia trachomatis* is the most common bacterial STD with the highest prevalence among young women under 25 years of age. Men, women and infants are affected but women bear an inordinate burden because of their increased risk for adverse reproductive consequences. It causes cervicitis, PID and infertility in women but is often asymptomatic. It causes urethritis and epididymitis in men.

In low-risk asymptomatic women 30 years of age and over, the rate of positive CT tests is generally low, which makes false positive tests more likely to occur. For this reason, the FPP does not recommend routine screening of low-risk asymptomatic women over 25.

#### **Subjective and objective nursing assessment:**

The PHN will interview clients to obtain:

1. History: Assess the client's RLP, complete medical history and sexual history as described in Section 1, Step 2 of sub-section 1.2.H.A. to include LMP, drug allergies in the medical record (BEHR).
2. Symptoms: to include fever, abnormal vaginal discharge, burning on urination, lower abdominal pain, abnormal vaginal bleeding, bleeding after sex, painful sexual intercourse

#### **Screening:**

1. **Women under 25:** Test all **sexually active** women under 25 years of age **annually**.
2. **Women seeking an IUD insertion** should be screened regardless of age.

**Procedure:** Follow the package insert and PHD Standard Operating Procedures (SOP) Manual.

#### **Nursing assessment of normal and abnormal findings requiring notification of a clinician**

1. Positive screen for symptoms listed above might indicate that the client has pelvic inflammatory disease (PID) and requires PHN to consult a clinician as soon as possible or a referral to PMD.
2. Positive Chlamydia and/or Gonorrhea lab results require a clinician's (MD, CNM, CNP, PA) attention. Clinician will need all the information listed under nursing assessment to make a decision whether the client needs to have a pelvic examination to rule out PID.

#### **Plan of care for client with either positive CT or GC lab result**

1. In an asymptomatic client without an IUD, the PHN will follow a PHD standing order or a clinician's order to provide counseling and administer appropriate antibiotic(s) to which the client is not allergic.
2. In a client with an IUD or in a female client with any symptoms listed above,
  - If a clinician is available on-site, consult the clinician to assess the client and rule out PID.
  - If a clinician is not available on-site, contact a clinician by phone to discuss the appropriate follow-up or to obtain permission to refer the client to ER or PMD as appropriate. If unsuccessful, contact a RHO.
3. Complete a NM Morbidity Report for Sexually Transmitted Diseases for clients with positive CT/GC.
4. Inform clients with positive tests to have all partners in the last 2 months come to the clinic for testing and treatment. If there were no partners in the past two months, then the most recent sexual partner should be tested and treated. If clients are unable to contact partner(s), refer to DIS (Disease Intervention Specialist).
5. Since re-infection with CT/GC is common in the months following an initial infection, women and men with a positive CT/GC test will be given an appointment to return for a re-test (regardless of whether the client believes that sex partners were treated) approximately 3 months following treatment.
  - If the client returns sooner than the appointment date and after 4 weeks, PHN can send a urine specimen for re-testing. Re-testing should not be performed prior to 4 weeks due to the likelihood of a false positive test due to the presence of dead organisms.
  - If the client missed the 3-month appointment but returns within 12 months following treatment, PHN can still send a urine specimen for re-testing.

## **TREATMENT (FOR CLINICIANS)**

For management of symptomatic women or laboratory-confirmed positive test results and their partners, please refer to the current CDC STD Treatment Guidelines <https://www.cdc.gov/std/treatment-guidelines/default.htm>.

Clients diagnosed with chlamydia that are treated with any of the recommended or alternative regimens do not need a test-of-cure (i.e., repeat testing 3-4 weeks after completing therapy).

Treatment of partners is vital to prevent re-infection of treated patients and to reduce onward transmission of infection. Counsel clients on the important role of partner services and offer clients available partner services.

## **NM MORBIDITY REPORT**

All Title X clinics are required to complete a NM Morbidity Report for Sexually Transmitted Diseases for clients with newly diagnosed HIV, syphilis, chlamydia or gonorrhea infections or clients with any STD who are pregnant. Since these are notifiable conditions in New Mexico, this will ensure that the NM law is followed and provides notification to a Public Health Office Disease Prevention Specialist (DPS).

## B. CERVICAL CANCER SCREENING

### 1. BACKGROUND:

Pap and or HPV testing provides a means of screening for pre-invasive and invasive cervical cancer. Educate all women about the risk factors for cervical cancer (HPV infection, multiple partners, tobacco use etc.) and importance of screening. The test report may include information about the identification of organisms causing cervicitis or vaginitis. Cervical cytology and HPV tests are screening tools, not diagnostic tools. Refer any woman with a clinically suspicious cervical lesion for colposcopy with biopsy as indicated per ASCCP Guidelines.

The most recent guidelines place an emphasis on a “Risk-Based Strategy” that makes equivalent recommendations for equivalent risk. For the general population, cytology every 3 years is acceptable and is the FPP’s preferred test.

For populations with a history of abnormal results, multiple factors go into this risk calculation including prior screening or histologic results, treatment history, HPV results if available, age and what specific tests were done. For this reason, the ASCCP has changed most of its algorithms into a dynamic application that will calculate the client’s risk. As such, many printed algorithms have been replaced by the new tools, the mobile app and web app.

The need for cervical cancer screening should not be the basis for the onset of gynecologic care. Sexually active adolescents (i.e., females younger than 21 years) should be counseled and tested for STDs and should be counseled regarding safe sex and contraception. These measures may be carried out without a cervical cytology test and, in the asymptomatic patient, without the introduction of a speculum.

**Table 2: FPP’s Cervical Cancer Screening Recommendations**

Age	Screening interval	Action/Comments
<21 years	No Screening	No Screening
21-24 years	Cytology alone every 3 years	HPV testing not recommended
25-65 years	Cytology every 3 years	Reflex HPV for ASCUS. Primary HPV testing may ONLY be done if indicated for management of previous abnormality.
Post-hysterectomy	No Screening	Applies to clients <i>without</i> a cervix who <i>do not have</i> a history of CIN2 or a more severe diagnosis in the past 25 years or cervical cancer ever.
HPV Vaccinated	Follow age-specific recommendations (same as unvaccinated clients)	
>65	No screening except: 1) continue surveillance for minimum 25 years after diagnosis of CIN 2+. Surveillance beyond 65 should continue indefinitely unless limited life expectancy 2) History of inadequate screening: needs 3 negative cytology every 3 years 3) Immunocompromised: every 3 years for life	
HIV Positive/ Immuno-compromised	Screen within 1 year of first intercourse or at 21, whichever comes first.  Cytology annually x3 years then every 3 years for life	

Intervals for routine cervical cytology screening in the New Mexico Family Planning Program are based on the 2018 USPSTF Screening Guidelines:  
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening>

Management of abnormalities is based on 2019 ASCCP Guidelines:  
[https://journals.lww.com/jlgt/Fulltext/2020/04000/2019\\_ASCCP\\_Risk\\_Based\\_Management\\_Consensus.3.aspx](https://journals.lww.com/jlgt/Fulltext/2020/04000/2019_ASCCP_Risk_Based_Management_Consensus.3.aspx)

**Additional Resources:**

ASCCP Website: <https://www.asccp.org/guidelines>

ASCCP Web App: <https://app.asccp.org/>

Web App User Guide: <https://www.asccp.org/userguide>

## 2. DEFINITIONS AND TYPES OF TESTING:

**Screening:** A screening test refers to the testing of asymptomatic healthy people without a prior abnormality. FPP uses cytology alone as its main screening modality in this population.

**Surveillance:** Surveillance refers to the ongoing management of someone with a past history of an abnormal result. Surveillance should be done with HPV-based test strategies, cytology alone is unacceptable where HPV testing is available.

**Pap Test (aka Cytology):** Pap tests can help identify cancerous or pre-cancerous abnormalities. They are FPP's primary method of screening in asymptomatic previously healthy clients. Cytology can also be useful in known HPV carriers.

**HPV-Based Testing:** This term is used in ASCCP guidelines as an umbrella term to describe the use of either co-testing or primary HPV testing.

**Primary HPV Test:** A Primary HPV test is approved by the FDA to be done in place of cytology, instead of in conjunction with it. In the literature it can refer to screening or surveillance. FPP's HPV test is an FDA approved Primary HPV test. These tests do not cross-react with low risk (non-oncogenic) strains. It is collected in the same manner as a pap. (FPP will be utilizing Primary HPV test for **surveillance only** at this time).

**HPV/Pap Co-Test:** A procedure where a Pap test and a human papillomavirus (HPV) test are done at the same time to check for cervical cancer. This means that the HPV test is done regardless of the Pap result. Co-testing should be performed when specifically recommended by ASCCP for surveillance.

**HPV Reflex Testing:** With reflex HPV testing, the test is performed only in response to an abnormal cytology result. The testing may be set up with the laboratory to occur automatically under some conditions (not currently available) or may require an additional order by a clinician following lab resulting.



### 3. HUMAN PAPILLOMA VIRUS (HPV) TESTING

- **Rationale for Recommendations**

Screening and surveillance allow for early detection of pre-cancerous and cancerous lesions and facilitates treatment of lesions before they become advanced. Cytology has long been a mainstay of cervical cancer screening and evaluates for cellular changes that may indicate dysplasia. HPV testing allows for risk stratification and gives additional information beyond cytology. It is particularly useful for ASCUS or for the surveillance of clients who have previously had abnormal pap tests. It is important to provide the correct tests at the correct interval in order to achieve the optimal benefit to the client.

- **Continued Screening Is Still Needed After HPV Vaccination**

Women who have received the HPV vaccine should be screened according to the same guidelines as women who have not been vaccinated:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening>

### 4. PROGRAM GUIDELINES FOR CERVICAL CANCER TESTING AND FOLLOW-UP

#### OVERVIEW

The US Preventive Services Task Force **recommended in 2018** Pap alone (every three years) for women 21-65 years of age with the option of using co-testing for screening women 30-65 years of age (every five years). Due to programmatic costs, FPP uses cytology alone and not co-testing for screening of asymptomatic healthy women. **American Cancer Society 2020 guidelines recommend Primary HPV screening beginning at age 25. These guidelines are under review by the Family Planning Program for future consideration.** FPP only uses **HPV-based testing for follow-up testing (surveillance)** where advised by the American Society for Colposcopy and Cervical Pathology **2019 guidelines ( [www.asccp.org/guidelines](http://www.asccp.org/guidelines)).** **Please utilize the Web App or Mobile App from ASCCP for management guidance.**

**Please note:** At times the ASCCP webtool does not specify testing modality for follow up of abnormalities. In this case, you may call the program medical director for consultation, review the guidelines publication, or see the table below.

If uncertain about the recommendations, contact the Regional Health Officer or Program. For complete guidelines and rationale regarding prevention and early detection of cervical cancer, please see links below:

ASCCP Website: <https://www.asccp.org/guidelines>

ASCCP Mobile App: <https://www.asccp.org/mobile-app>

HPV testing is covered by Family Planning Program whenever indicated by the ASCCP. For example:

- Add-on testing after ASC-US pap in  $\geq 25$  years old
- Follow up on known HPV infection
- Follow up after colposcopy or treatment
- Surveillance of prior abnormal pap

***Because of the complexity of new follow-up recommendations, this list is not exhaustive. Please refer to the ASCCP app for tailored recommendations for your client. Note that the web-tool may yield less specific guidance, contact the program when unsure of how to proceed.***

## I. Pap and HPV Testing

Please see the PHD Lab Standing Operating Procedures (SOPs - available at [http://intranet/PHD/clinical\\_protocols.html](http://intranet/PHD/clinical_protocols.html)) or other lab SOPs for detail on indications, contraindications, procedures, shipping, and results for Pap and HPV testing.

## II. Limitations for HPV Testing

Liquid-based cytology (LBC) samples are held for up to 21 days post collection by the CDD. Clinicians needing to add any add-on testing must request testing prior to the 21 days. Occasionally, a specimen that requires reflex testing may not have had a sufficient specimen. In this case, you will need to collect a new specimen and order only testing that should have reflexed (e.g. only cytology, or only HPV, as appropriate)

- a. Thin Prep (Pap only): use for routine screening in healthy clients
- b. Thin Prep with Reflex HPV: use only for ASCUS in women 25 and older - must be ordered by the clinician (automatic reflex testing by the lab is not available).
- c. Thin Prep with HPV (Co-Testing): use when HPV based test is recommended and Primary HPV test is not available, and for surveillance after AGC/AIS.
- d. HPV without Cytology: used if initial Pap positive and HPV testing indicated – may be ordered on original specimen, or on a new specimen if not ordered in time or specimen processing precluded testing original specimen.

## III. How to order HPV testing on a previously collected Pap

To add an order for HPV testing:

### 1. Order the Test in BEHR (PHO)

Open a new note (non-appointment) in BEHR and order the HPV test. Document the addition of the HPV test to the prior pap sample, including the prior visit's date for reference. Save and sign. The charge for the HPV test will be on a new encounter form. Go to the new encounter form and submit.

### 2. Implement the Order and Fax it to CDD

In AFTIS, go to the order and enter the Accession Number for the original liquid-based Pap into the HPV order:

- a. The nurse or clinician should complete Amendment Form and fax to CDD.
- b. Ordering Issues: If the previous accession number is not recognized by AFTIS, the nurse or clinician will need to complete the CDD Laboratory Test Amendment Form and fax it to CDD rather than calling CDD. It occasionally happens, and always happens when the clinician orders the HPV before the pap results are received back into BEHR.
- c. The accession number includes all the numbers except the year (for example 0149250080532019, do not enter the 2019) and the accession number should go through. If a clinician orders the HPV, she or he needs to make sure the nurse is aware (the lab will already have the pap liquid and it may cause some confusion if the nurse doesn't see a sample to stick a label on). Then put the label in the CLIA log, the bar code label should be added to the Laboratory Test Amendment Form prior to faxing it. The completed form can be faxed to 888-858-8664.

Call the Center for Disease Detection (CDD) at 1-888-858-8663, Extension 1 (Client Care), with any questions about the order.



# LABORATORY TEST AMENDMENT FORM

<b>(DO NOT USE THIS FORM FOR BILLING PURPOSES)</b> <b>PLEASE COMPLETE EACH SECTION AS INDICATED. FOR ANY QUESTIONS CALL 888-858-8663.</b>		
<b>1. SELECT APPLICABLE CATEGORY</b>		
<input type="checkbox"/> <b>Patient Details</b> <small>Examples: Date of Birth, I.D. #</small>	<input type="checkbox"/> <b>Test Details</b> <small>Examples: # of vials, source</small>	<input type="checkbox"/> <b>Add/Change Test</b> <small>Examples: HIV, TP-PA, RPR</small>
<b>2. EXPLAIN ORIGINAL ENTRY AND PROVIDE CORRECTION</b>		
<b>3. PROVIDE REQUIRED INFORMATION</b>		
<b>CLINIC INFORMATION</b>		
Account #:	Clinic Name:	
<b>PATIENT'S INFORMATION</b>		
Last Name:	First Name:	M.I.:
Accession Number:	Date of Birth:	Date of Service:
<b>REQUESTOR'S INFORMATION</b>		
Name:	Title:	Date:
Signature:	Phone #:	Alt. Phone #:
<b>4. USE THIS SECTION ONLY WHEN ADDING OR CORRECTING TESTS</b>		
Use the AFTIS computer program to complete patient entry. Select the correct lab test, print the barcode label, and place it in the space provided. Transmit patient data electronically.  <b>NOTE:</b> CDD retains specimens requiring correction provided the specimen meets test stability criteria.		<div style="border-left: 1px solid black; border-right: 1px solid black; border-bottom: 1px solid black; padding: 10px; margin: 0 auto; width: 80%;"> <p style="text-align: center; margin: 0;"><b>Place AFTIS</b></p> <p style="text-align: center; margin: 0;"><b>Barcode Label</b></p> </div>
<b>5. WHEN COMPLETED FAX THIS FORM TO 888-858-8664</b>		
<b>FOR CDD USE ONLY</b>		
Fax Receive Date:	Signature & Title:	
<b>REQUEST FOR ADDITIONAL TESTING</b>		
Date Specimen Received:	Rack:	Position:
Original Test Performed:	Original Test Accession #:	
New Test Requested:	New Test Accession #:	
<b>FOR LABORATORY USE ONLY (TEST COMPLETED)</b>		
Test Result Code:	Tech Initials:	Result Date:
Reviewed by:	Review Date:	
<input type="checkbox"/> REJECTED	Reason for Reject:	Site Notification date for rejection:

#### IV. Family Planning Program Abnormal Cervical Cancer Screening Guidance

- Always review the client's Pap and/or HPV history (past results).
- **Clinician must review all abnormal cytology tests, HPV tests, and unsatisfactory test results as soon as possible.**
- **Abnormal Cytology and/or HPV Results:** Manage as per ASCCP Web Tool/App. Note there have been significant changes to management of some abnormalities. Below is a quick reference guide that can be helpful but may lack precision in some circumstances. The ASCCP app guidance is preferable, but if it is not available, the chart below can assist with guiding testing modality.
- **For follow up testing after colposcopy/treatment, FPP will cover HPV-based testing for all clients 25 and older, or as recommended by ASCCP.**
- **For Management of Pregnant Women:** Should be managed as per Web Tool/App with the exception of the following pregnancy-related contraindications: endocervical sampling, endometrial sampling, and expedited diagnostic excisional procedure. Excisional procedures in pregnancy should only be performed if cancer is suspected in consultation with specialists.
- Any cervix with abnormal appearance, even if normal screening tests, should be referred for colposcopic evaluation.

<b>Table 3: Abnormal Pap Results and Recommended Follow-Up RESULTS</b>	<b>NEXT CERVICAL CYTOLOGY/ACTION</b>	<b>NEXT CERVICAL CYTOLOGY/ACTION</b>
<b>ASC-US</b> (Atypical Squamous Cells of Undetermined Significance)	<25 yrs: Cytology at 12 and 24 months. If negative cytology x 2, return to routine screening.	<p><b>At 12 months:</b></p> <ul style="list-style-type: none"> <li>• If ASC-US/LSIL: Repeat cytology in 12 months (i.e. at 24 months)</li> <li>• If ASC-H, AGC or HSIL: Colposcopy</li> </ul> <p><b>At 24 months:</b></p> <ul style="list-style-type: none"> <li>• If negative and the previous cytology was ASC-US/LSIL: Repeat cytology at 12 month intervals until <u>negative x 2 (e.g. at 24 and 36 months)</u> before returning to routine screening</li> <li>• If ≥ASC-US x2 (not including initial pap): Colposcopy</li> </ul>
	25 yrs and older: Add-on HPV	<p>If HPV positive: Colposcopy</p> <p>HPV negative: HPV based test in 3 years</p>
<b>LSIL</b> (Low Grade Squamous Intraepithelial Lesion encompassing HPV) Mild dysplasia	<25 yrs: Cytology at 12-month intervals. If negative cytology x 2, return to routine screening.	<p><b>At 12 months:</b></p> <ul style="list-style-type: none"> <li>• If ASC-US/LSIL: repeat cytology in 12 months (i.e. at 24 months)</li> <li>• If ASC-H, AGC or HSIL: Colposcopy</li> </ul> <p><b>At 24 months:</b></p> <ul style="list-style-type: none"> <li>• If negative and the previous cytology was ASC-US/LSIL: Repeat cytology at 12-month intervals until <u>negative x 2 (e.g. at 24 and 36 months)</u> before returning to routine screening</li> <li>• If ≥ASC-US: Colposcopy</li> </ul>
	25 yrs and older: Colposcopy	Follow as per ASCCP guidance using colposcopy results
<b>ASC-H</b>	Colposcopy	Follow up as per ASCCP guidance
<b>HSIL</b> (High Grade Squamous Intraepithelial Lesion) Moderate dysplasia Severe dysplasia/CIS	<25 yrs: Colposcopy	HPV based test 6 months after treatment if applicable
	25 yrs and older: Colposcopy or Excision	
<b>Unsatisfactory</b>	Repeat in 2-4 months	If Unsatisfactory x 2: Refer to colposcopy

**Table 4: Miscellaneous Pap Abnormalities and Recommended Follow-Up**

<b>RESULTS</b>	<b>NEXT ACTION</b>	<b>SUBSEQUENT ACTION</b>
<b>AGC (Atypical glandular cells) NOS, favor neoplasia, AIS (adenocarcinoma in situ)</b>	Refer for Colposcopy with endocervical sampling and endometrial sampling if ≥35 yrs or at risk for endometrial neoplasia.	If no pathology identified: Co-testing at 12 and 24 months
<b>Atypical Endometrial Cells</b>	Refer for endometrial and endocervical sampling	If no endometrial pathology: Refer for colposcopy
<b>Squamous Cell Cancer, Adenocarcinoma, Grossly Abnormal Appearing Cervix</b>	Refer to Gyn-Oncologist immediately	
<b>Benign Endometrial Cells</b>	If asymptomatic and premenopausal: no further action  If postmenopausal: refer for endometrial sampling	

**Table 5: Organisms Reported on Cytology Testing and Recommended Follow-Up**

<b>RESULTS</b>	<b>NEXT ACTION</b>
<b>Trichomonas</b>	Confirm clinically.  <ul style="list-style-type: none"> <li>• If the woman was treated when the test was taken and told that her partner needs treatment, no further action is needed.</li> <li>• If the woman was not treated, consider treatment based on the result.</li> <li>• Among women at risk for STIs, screen for GC and chlamydia if this was not already done.</li> <li>• Explain potential trichomoniasis complications and advise STD evaluation and treatment for her partner.</li> </ul>
<b>Bacterial Vaginosis</b>	The test is not an accurate test for B.V. If the woman is pregnant or trying to conceive and her cytology is positive for B.V, notify her and offer other testing (pH, wet prep and amine) prior to treatment. <b>Asymptomatic non-pregnant women do not require further action.</b>
<b>Candida</b>	If the woman is symptomatic and was not treated, consider treatment.
<b>Actinomyces</b>	See IUD in Section 2 for management.
<b>Herpes Simplex Virus</b>	If woman is aware of HSV infection, no immediate follow up needed. If she is not aware, contact for education and resources.

## V. Best Practice for Patient Education

Women who have received abnormal cervical results indicate that they experience adverse psychological reactions to their HPV diagnosis. Reactions to consider while counseling patients on HPV diagnosis include:

- Anxiety, anger, regret
- Fears of cancer
- Pregnancy related outcomes
- Concerns about negative reactions from friends, family or sexual partners
- Concerns about partner infidelity
- Hostility towards person believed to be the source of infection
- Changes in body image
- Decrease in physical intimacy activities
- Difficulty with understanding the differences between low and high-risk strains of HPV
- Confusion with how pap test results could be normal if HPV is present

Educational disparities and psychosocial concerns can decrease adherence for follow up. Research has shown that women desire information on transmission, prevention, detection, treatment and progression with treatment, and risk of cervical cancer (Anhang, Goodman, & Goldie, 2008, <https://onlinelibrary.wiley.com/journal/15424863>).

It is important to emphasize with the patient that HPV is very common, HPV is sexually transmitted, most women that have HPV will not develop cervical cancer, HPV can clear without treatment, the purpose of a Pap testing, the purpose of HPV testing, and a diagnosis with high-risk HPV may not indicate cervical cancer on further evaluation.

## VI. Additional Resource Links

For more information on lab SOPs, please see link below:

- [http://intranet/PHD/clinical\\_protocols.htm](http://intranet/PHD/clinical_protocols.htm)

For more information regarding sources of information for women about HPV and cervical cancer, please see links below:

- American Sexual Health Association (ASHA)  
[https://www.ashasexualhealth.org/human\\_papilloma\\_virus/](https://www.ashasexualhealth.org/human_papilloma_virus/)
- Centers for Disease Control and Prevention  
<https://www.cdc.gov/std/hpv/stdfact-hpv.htm>
- American Cancer Society  
<https://www.cancer.org/cancer/cervical-cancer.html>

For more information on best practices, please see link below:

- Anhang, R., Goodman, A., & Goldie, S. J. (2008). HPV Communication: Review of Existing Research and Recommendations for Patient Education. *CA: A Cancer Journal for Clinicians*, 54(5), 248-259. doi:10.3322/canjclin.54.5.248 @ <https://onlinelibrary.wiley.com/journal/15424863>

Guidelines and mobile app can be found at:

- Website: ASCCP@ <http://www.asccp.org/guidelines>
- Mobile App: Available for Android, iPhone, also available in Spanish. Go to the mobile app store, "ASCCP Mobile"
- BCC Program guidelines: <http://archive.cancernm.org/bcc/services.html>

#### 4.4 PROCEDURE FOR CONTACTING FAMILY PLANNING CLIENTS

This procedure is to be used when clinic staff has to contact a client to prevent adverse health outcomes if not addressed. The next steps use the framework of abnormal cytology follow up but can also be used for other notification such as positive/abnormal test results or medication recall.

##### Staff Roles

1. The nurse in charge of family planning in the clinic/PHO is responsible for the follow-up of all cytology tests. The clinician will determine appropriate follow-up based on the cytology report, clinical findings, and the woman's ability to follow-up. The following procedure is recommended:
  - In the PHO, cytology results will be tasked to the clinician that collected the specimen. Except in rare situations where the ordering clinician is not available, the clinician who performed the test should review the cytological findings, and 'verify' the results. A progress note should then be created outlining the findings and plan (including treatment, if applicable, and referral or follow-up), and the note tasked for review by the PHN.
  - In the FP provider agreement clinics, the Nurse will forward cytology results to the Family Planning clinic Physician, CNP, CNM, or PA. The clinician who performed the test should review the cytological findings.

This should be accomplished as promptly as possible and should never exceed 2 weeks from the time the result was reported. Any client with HSIL or invasive cancer is to be referred to a gynecologist as soon as possible, and this includes prompt notification of the result to the clinician. In no case should the clinician's notification of HSIL or invasive cancer result be delayed > 1 week. Reasons for exceptions to this must be recorded on the client's record.

2. The clinician's assessment and follow-up shall be based on the current 2019 ASCCP Guidelines, Web Tool, and App.
3. Using the client's preferred contact information; the nurse telephones or sends a letter to all clients with abnormal cytology results **that do not require referral out of the FP clinic (e.g. ASCCP recommends f/u pap or HPV)**. All attempts should be made to discreetly contact clients requesting "no mail" through whatever means appropriate without breaching confidentiality.
  - a. Record the abnormal test result in the Past Medical History, including prior abnormal pap results, biopsy results and next action item (if applicable) in the client's record. Consider adding an alert at the top of the chart noting abnormal history and next pap or co-test due date.
  - b. A note is made in client's record regarding the method of attempted contact and recommendations given.
  - c. The nurse will list the client on the abnormal test log (or card file), which is to be the record of clinic follow-up.
4. When the client returns to clinic, provide education about the abnormal cytology or any other condition requiring referral. **For clients who are referred out of the FP clinic,**
  - a. The client should sign the "Client Acknowledgment of Abnormal Medical Condition" form included in following pages, which should be filed in the client's record. If a client refuses treatment or referral for treatments, document client's refusal in the record.
  - b. The Referral Form should be sent to the physician or clinic along with a copy of the abnormal cytology test result(s). All HIPAA rules regarding release of client medial information must be followed.



- c. Refer clients needing colposcopy or expedited excisional procedure to the B&CCP if appropriate using the B&CC Program Manual for questions regarding eligibility criteria. You may also contact your Region B&CCP Nurse Coordinator or call 505-841-5860.
  - d. After referring a client to an outside provider, the nurse should document in the client's record that follow-up occurred before closing the case.
5. Once the recommended number of normal follow up test(s) has been obtained, if the diagnosis was CIN1 or less, the past medical history should note the resolution and that the client may return to routine screening. Indicate this on the client's record and the abnormal test log (or card file). A repeat episode of an abnormal cytology test at a later date is to be given a new entry. For clients with a diagnosis of CIN 2 or higher, the PMH should note the ongoing need for q3 year HPV-based test as per ASCCP recommendations.
  6. If the client does not respond or return to pick up referral paperwork, she should be contacted a second time within 2 weeks, and third time within 2 weeks after the second attempt. Document all three attempts made in the record and on the abnormal test log (or card file).
  7. In case of HSIL or invasive cancer, every effort should be made to locate the client. In addition to a telephone call, all letters sent to clients should be certified letters. The return receipt (or a copy of) should be placed in client's record. If the previous three attempts were unsuccessful within 8 weeks after cytology test result was received, consider a home visit from the nurse or other authorized staff.
  8. If a client's record lacks returned cytology results for more than 30 days, the nurse should contact the Lab for results and a copy of the report. The test should be repeated if results are not found within 2 weeks.

Clinics that cannot meet this standard need to present the problem in writing to the Family Planning Program.

**REFERRAL FORM:**

[http://intranet/PHD/documents/BEHR\\_ReferralForm\\_PHD\\_3000\\_English.pdf](http://intranet/PHD/documents/BEHR_ReferralForm_PHD_3000_English.pdf)  
[http://intranet/PHD/documents/BEHR\\_ReferralForm\\_PHD\\_3100\\_Spanish.pdf](http://intranet/PHD/documents/BEHR_ReferralForm_PHD_3100_Spanish.pdf)

The following information must be included:

1. On the "Clients Name" line, add Medicaid or private insurance coverage.
2. Please evaluate the client for: (Reason for referral)  
  
 Example: "For colposcopy – cervical cytology test of    (date)   , results (          ).  
 Previous abnormal (if any):  
   (date)   ,    (results)   ,    (treatment if any)   ).
3. Attach copies of all abnormal results
4. From Referral Source: request for information to be returned to us on:  
 colposcopy findings  
 biopsy/pathology report  
 treatment  
 surgery  
 recommended follow-up (orders must be signed by Colposcopist)

The information from the above records and forms can be utilized for documentation and follow-up in the abnormal test log (or card file).

### Client Acknowledgment of Abnormal Medical Condition

I acknowledge that I have been told by the Health Department that I have a medical condition called \_\_\_\_\_ that requires medical treatment. This service is not provided by the Health Department. I understand I must go see a private physician as soon as possible. The Health Department has given me a list of doctors in my area who handle my kind of medical problem.

\_\_\_\_\_  
Client's Signature

\_\_\_\_\_  
Date

---

### Documento firmado por el/la cliente mediante el cual reconoce que adolece de una problema de salud anormal

Por la presente reconozco que el personal del Departamento de Salud de Nuevo México me ha dicho que adolezco de una enfermedad identificada con el nombre \_\_\_\_\_ que requiere tratamiento por un médico. El Departamento de Salud de Nuevo México no provee ese tratamiento. Entiendo que tan pronto como sea posible tendré que consultar a un médico particular. El personal del Departamento de Salud de Nuevo México me proporcionó una lista de médicos particulares que tienen sus consultorios en la zona donde yo vivo que proveen tratamiento para el tipo de enfermedad identificada más arriba.

\_\_\_\_\_  
Firma del/la cliente

\_\_\_\_\_  
Fecha

#### 4.5 VAGINITIS: DIFFERENTIAL DIAGNOSIS FOR CLINICIANS

	NORMAL	BACTERIAL VAGINOSIS	CANDIDIASIS	TRICHOMONIASIS	ATROPHIC VAGINITIS	CHEMICAL OR ALLERGIC VAGINITIS	LACTO-BACILLOSIS	CYTOLYTIC VAGINITIS
Color of Discharge	Slate Gray/White/ Clear	Gray/White	White/Yellow	Yellow/Green Green/Gray/Yellow	Gray/Yellow	Normal	White	White
Odor of Discharge	Normal body odor	Fishy	None/Yeasty/Musty	Foul	Normal	Normal	Normal	Normal
Consistency of Discharge	-Thin Homogeneous -Mucoid	-Thin -*Homogeneous /Milky/Frothy	-Thick plaques, may be adherent to vaginal walls -Creamy/Thin/ Watery	-Thin/Frothy -May be non-frothy	-Watery Homogeneous/ Purulent -Serosanguinous -Sticky	Normal	Pasty	Pasty
Presenting Complaints	None	Odor, increased discharge, minimal or no pruritus, occasional irritation	Pruritus, burning, dyspareunia, external dysuria, increased discharge or dryness	Pruritus, burning, dyspareunia, external dysuria, increased discharge	Spotting, burning, dyspareunia. pruritus, external dysuria, increased discharge	Pruritus, tenderness/pain, burning, external dysuria, dyspareunia	Pruritus, burning, dyspareunia and cyclic increase in symptoms	Pruritus, dyspareunia, vulvar dysuria, and cyclic increase in symptoms
Physical Findings	Absence of abnormality	Absence of inflammation, pooling of discharge at introitus  *Positive whiff	Vulva: erythematous  Vagina: excoriations secondary to scratching, possible tissue friability	Erythema, petechiae (especially of cervix), cervical friability, occasional lower abdominal pain, inguinal lymphadenopathy	Pale/pink vaginal and cervical mucosa, absence of rugation, sparse/brittle pubic hair, inflammation, ecchymosis, petechiae, excoriation	Erythema, edema, vesicles or blisters, oozing, ulcerations, thickened skin, white patches, lymphadenopathy	Erythema Edema Normal	Erythema Edema Normal
pH	≤ 4.5	*≥ 4.5	≤ 4.5 or slightly ↑	5.2-7.0	5.5-7.0	≤ 4.5	3.6-4.7	3.6-4.7

	NORMAL	BACTERIAL VAGINOSIS	CANDIDIASIS	TRICHOMONIASIS	ATROPHIC VAGINITIS	CHEMICAL OR ALLERGIC VAGINITIS	LACTO-BACILOSIS	CYTOLYTIC VAGINITIS
Microscopic Findings	-Squamous epithelial cells -Lactobacilli -Few WBCs	-Rare WBCs -*Clue cells -Decreased lactobacilli -Increased bacteria, especially thin, curved, crescent-shaped rods	-Pseudohyphae -Yeast buds -WBCs -Lactobacilli	-Motile trichomonads with flagellae -WBCs	-Decreased lactobacilli -Increased WBCs and bacteria -RBCs -Absence of pathogens -Increased number of parabasal cells on maturation index	-Absence of pathogens and WBCs	-Lactobacilli are 6 times longer than normal -No fungi -Few WBCs  See page 20	-Evidence of cytolysis with bare intermediate nuclei -Overgrowth of lactobacilli, often adherent to epithelial cells  See page 20
Relationship of Symptoms to Menses	Increases around ovulation	Not applicable	Increased before menses. Relief with/after menses.	Increased during/after menses	Not applicable	Not applicable	Increased before menses	Increased before menses
Treatment	None	*3 out of 4 criteria should be present before treatment  Metronidazole 500 mg by mouth, twice a day for 7 days	Clotrimazole Cream OTC 1 applicator per vagina at bedtime for 7 days  OR Fluconazole by prescription 150 mg by mouth as a one-time dose	Metronidazole 2 g by mouth as a one-time dose  Partner needs treatment	Consider prescription for Estrogen Cream or refer to PMD to consider HRT	Remove culprit	Amoxicillin and Clavulanate by prescription 500 mg by mouth three times a day for 7 days*  D/C tampon use until symptom-free for 6 months	Doxycycline by prescription 100 mg by mouth twice a day for 7 days  Sodium Bicarbonate sitz baths 1 - 2 TBSP to 1 liter warm water 3 times in 1 week. Then weekly until symptom free.  OR D/C tampon use until symptom-free for 6 months

Table from Gynecology-Well-women Care by Ronnie Lichtman and Susan Papera with the added columns for lactobacillosis and cytolytic vaginitis

\*Horowitz BJ, Mardh PA, Nagy E, Rank EL. Vaginal lactobacillosis. American Journal Obstetrics Gynecology 1994;170:857-61

## Vaginitis Differential Diagnosis

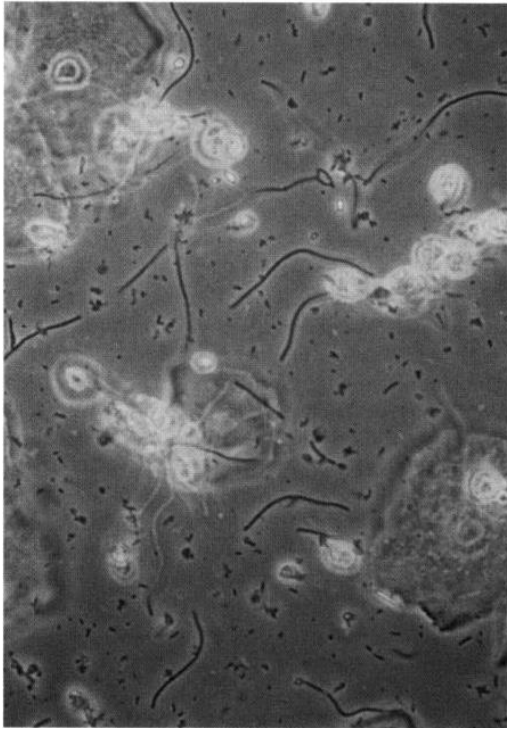


Figure 1 Lactobacillosis  
*Am J Obstet Gynecol.* 1994;170(3):857-61

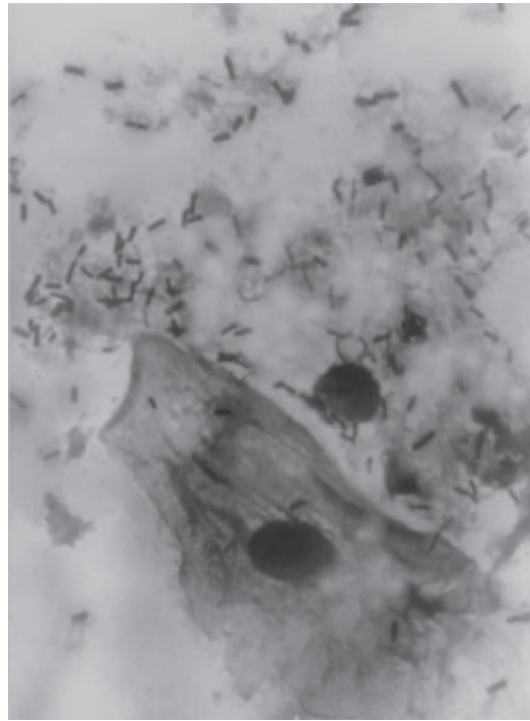


Figure 2 Cytolytic Vaginosis  
*Infect Dis Obstet Gynecol* 2004;12:13-16