

4.0

FAMILY PLANNING LABORATORY

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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 have a discussion on the importance of recommended screening tests with the client. 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.

METHODOLOGY

4.1 LABORATORY TESTS

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

- A. Cervical cytology test
- B. Chlamydia/Gonorrhea test

1. For PHO:

PHO Providers should screen:

- All sexually active women aged <25 years for chlamydia annually.
- Females requesting IUD insertion, regardless of age.

For diagnostic testing of high-risk PHO clients, please refer to the STD Program Protocol for testing guidelines.

2. Note that the following guidelines apply to clinic sites operated by FP Provider Agreement sites (outside of PHO):

Non-PHO Providers should screen:

- All sexually active women aged <25 years for chlamydia annually.
- 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:

- symptomatic, or
- those diagnosed with an STD in the last year, or
- a known contact to an STD infected partner.

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 optional. 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 is required for provision of specific methods of contraception.

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

- Syphilis – For both PHO and non-PHO, refer to STD Program Protocol.
- HIV- For PHO, refer to Section 1 of the FPP Protocol, Subsection 1.2.H.e STD Services. For non-PHO Title X clients, the HIV testing is not covered in the FPP agreement.
- Rubella immunity status at the client's own expense for both PHO and non-PHO.

4.2 LABORATORY RESULTS

- 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.
Lab results requiring a clinician's (MD, CNM, CNP, PA) attention includes:
Cervical cytology test unsatisfactory, ASC-US, ASC-H, AGC, LSIL or HSIL, *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*
- The clinician will determine appropriate follow-up based on the test result report, clinical findings, and the woman's ability to follow-up.

4.3 LABORATORY METHODOLOGY/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 asymptomatic women 30 years of age and over, the rate of positive CT tests is generally < 5% which makes false positive tests more likely to occur. For this reason, the FPP does not recommend screening of this population for CT and GC. Routine annual testing of low risk women over age 24 is also not recommended.

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 DPS.
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 <http://www.cdc.gov/std/tg2015/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 CYTOLOGY

1. PURPOSE:

The test 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 includes information about the identification of organisms causing cervicitis or vaginitis. Cervical cytology tests are screening tools, not diagnostic tools. Refer any woman with a clinically suspicious cervical lesion for colposcopy with biopsy as indicated or women who must have HPV testing (either alone or as a co-test) per ASCCP Guidelines.

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.

Intervals for routine cervical cytology screening in the New Mexico Family Planning Program are based on the 2012 ACS, ASCCP and ASCP Screening Guidelines for the Prevention and Early Detection of Cervical Cancer, <http://journals.lww.com/jlgttd/PublishingImages/ASCCP%20Guidelines.pdf>. Additional resources (ASCCP Mobile App, algorithms) can be found at <http://www.asccp.org/asccp-guidelines>.

Age	Screening interval	Action/Comments
<21 years	No Screening	HPV testing should not be used for screening or management of ASC-US in this age group.
21-24 years	Cytology alone every 3 years	HPV testing should not be used for screening or management of ASC-US in this age group.
25-menopause	Cytology alone every 3 years	Refer women who must have HPV testing (either alone or as a co-test) per ASCCP Guidelines.
Post hysterectomy	No Screening	Applies to women <i>without</i> a cervix and <i>without</i> a history of CIN2 or a more severe diagnosis in the past 20 years or cervical cancer ever.
HPV Vaccinated	Follow age-specific recommendations (same as unvaccinated women)	

2. PROCEDURE:

The procedure and standard to be followed in collection of the cervical cytology test sample will be found in the SOP manual. When taking the cytology test, be sure to obtain a good endocervical sample. If you wet the speculum with water and also plan to test the pH of vaginal secretions, be aware that this may alter the pH. The pH of water is approximately 7.

Staff making cytology test appointments should remind the woman not to put anything in her vagina for 48 hours before each test—that is, no intercourse, douching, tampons, or vaginal medications. Clients getting tested should not use vaginal creams for 1 week prior to their test, should not be having their menses at the time of their test, and should aim to have their test mid-cycle if possible.

3. THE ABNORMAL CERVICAL CYTOLOGY TEST

Detailed information for follow up of abnormal cervical cancer tests can be found at <http://www.asccp.org/Assets/405b4550-593f-40a7-ae25-0c783de95b0d/635912114192570000/asccp-updated-guidelines-3-21-13-pdf>.

EQUIPMENT

Cytology test report
Client record with appropriate entry on the Active Problem List
Abnormal cytology tests Follow-up Log
Client Acknowledgment of Abnormal Medical Condition Form
Referral Form

INTERPRETATION AND MANAGEMENT

Clinician must review all abnormal cytology test and unsatisfactory test results as soon as possible.

Family Planning Program Abnormal Cytology Test Algorithm

Always review the client's cytology history (past results)

	RESULTS	NEXT CERVICAL CYTOLOGY/ACTION	NEXT CERVICAL CYTOLOGY/ACTION
1	UNSATISFACTORY	Repeat in 2-4 months	Colpo is recommended if 2 consecutive unsatisfactory results.
2	NEGATIVE but with absent or insufficient endocervical cells/ transformation zone component	Routine screening.	
3	<p>NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY</p> <p>Organisms:</p> <p>Trichomonas</p> <p>Bacterial Vaginosis</p> <p>Candida</p> <p>Actinomyces</p> <p>Herpes Simplex Virus</p>	<p>Routine screening.</p> <p>Confirm clinically.</p> <ul style="list-style-type: none"> • If the woman was treated when the test was taken and told that her partner needs treatment, no further action is needed. • If the woman was not treated, consider treatment based on the result. • Among women at risk for STIs, screen for GC and chlamydia if this was not already done. • Explain potential trichomoniasis complications and advise STD evaluation and treatment for her partner. <p>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.</p> <p>If the woman is symptomatic and was not treated, consider treatment.</p> <p>See IUD in Section 2 for management.</p> <p>If woman is aware of HSV infection, no immediate follow up needed. If she is not aware, contact for education and resources.</p>	

	RESULTS	NEXT CERVICAL CYTOLOGY/ACTION	NEXT CERVICAL CYTOLOGY/ACTION
4	ASC-US (Atypical Squamous Cells of Undetermined Significance)	21-24 yrs Cytology at 12 month intervals. If negative cytology x 2, return to routine screening.	At 12 months: <ul style="list-style-type: none"> • If ASC-US/LSIL, repeat cytology in 12 months (i.e. at 24 months). • If ASC-H, AGC or HSIL, colpo. At 24 months: <ul style="list-style-type: none"> • 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. • If ≥ASC-US, colpo.
		25 yrs and older Cytology at 12 months. If negative cytology, routine screening.	If ≥ASC-US, colpo.
5	LSIL (Low Grade Squamous Intraepithelial Lesion encompassing HPV) Mild dysplasia	21-24 yrs Cytology at 12 month intervals. If negative cytology x 2, return to routine screening.	At 12 months: <ul style="list-style-type: none"> • If ASC-US/LSIL, repeat cytology in 12 months (i.e. at 24 months). • If ASC-H, AGC or HSIL, colpo. At 24 months: <ul style="list-style-type: none"> • 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. • If ≥ASC-US, colpo.
		25 yrs and older: Colposcopy	
6	ASC-H cannot exclude HSIL	Colposcopy	
7	HSIL (High Grade Squamous Intraepithelial Lesion) Moderate dysplasia Severe dysplasia/CIS	Colposcopy	
8	AGC (Atypical glandular cells) NOS, favor neoplasia, AIS (endocervico adeno carcinoma in situ)	Colposcopy with endocervical sampling, and endometrial sampling if ≥35 yrs or at risk for endometrial neoplasia.	
9	Atypical endometrial cells	Refer for endometrial & endocervical sampling	If no endometrial pathology, refer for colposcopy
10	Squamous cell cancer, Adenocarcinoma, Grossly malignant lesion	Refer to Gyn-Oncologist immediately.	

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 FPP Abnormal Cytology Test Algorithm and 2012 ASCCP Guidelines and algorithms, <http://www.asccp.org/asccp-guidelines>.
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., ASCUS)**. All attempts should be made to discreetly contact clients requesting "no mail" through whatever means appropriate without breaching confidentiality.
 - a. Record the abnormal cytology test result as an active problem in the client's record.
 - 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 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 cytology test(s) has been obtained, the "abnormal cytology test result" problem is "resolved." 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.
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:

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	LACTOBACILLOSIS	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.	Erythema of vulva. Vagina; Excoriations secondary to scratching; Possible tissue friability.	Erythema; Petechiae especially of cervix; Cervical friability. Occasional lower abdominal pain, inguinal lymphadenopathy	Pale, pink vaginal, 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/WBCs	Lactobacilli are 6 times longer than normal. No fungi. Few WBCs See page 12	Evidence of cytolysis with bare intermediate nuclei; overgrowth of lactobacilli, often adherent to epithelial cells See page 12
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 1applicator Per vagina at bedtime for 7 days OR Fluconazole by prescription 150 mg by mouth, as one time dose	Metronidazole 2 gms by mouth as 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 500mg 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

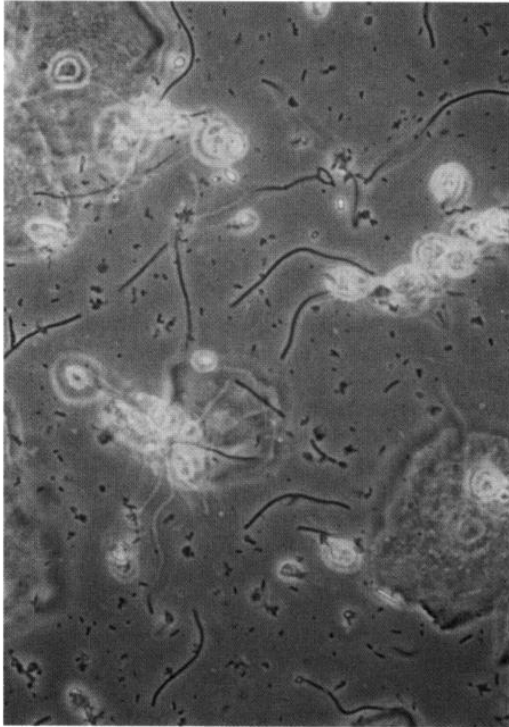


Figure 1 Lactobacillosis
Am J Obstet Gynecol. 1994;170(3):857-61

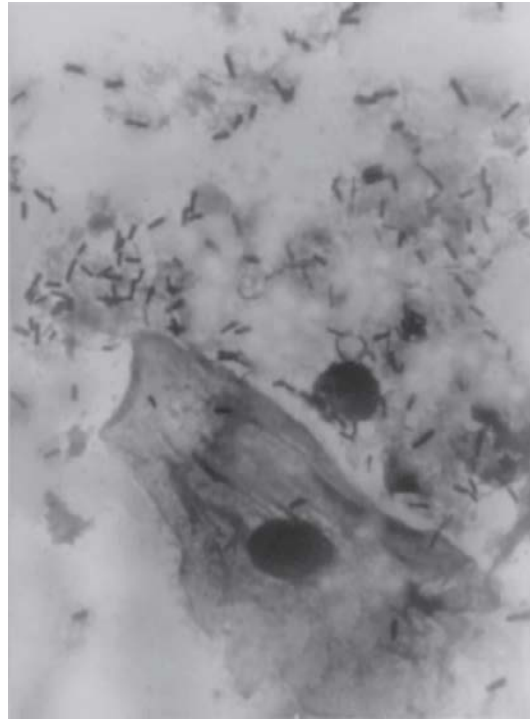


Figure 2 Cytolytic Vaginosis
Infect Dis Obstet Gynecol 2004;12:13-16