Lab Dept: Microbiology

Test Name: MULTIPLEX VAGINAL PANEL PCR

General Information

Lab Order Codes:	MVPP
Synonyms:	Vaginal Panel, Vaginal PCR, Bacterial Vaginosis PCR, Trichomonas PCR
CPT Codes:	0352U – All targets – Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2. *Atopobium vaginae,* and *Megasphera* type 1). Algorithm reported as detected or not detected and separate detection of Candida species (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*), Candida glabrata/Candida krusei, and *Trichomonas vaginalis*, vaginal-fluid specimen, each result reported as detected or not detected.
Test Includes:	Detection of bacterial vaginosis (BV), *Trichomonas vaginalis, Candida* species and *Candida glabrata*/*Candida krusei* in vaginal specimens. ***Candida* species included:** *Candida albicans, Candida tropicalis, Candida parapsilosis,* and *Candida dubliniensis.* These species are not differentiated.

Logistics

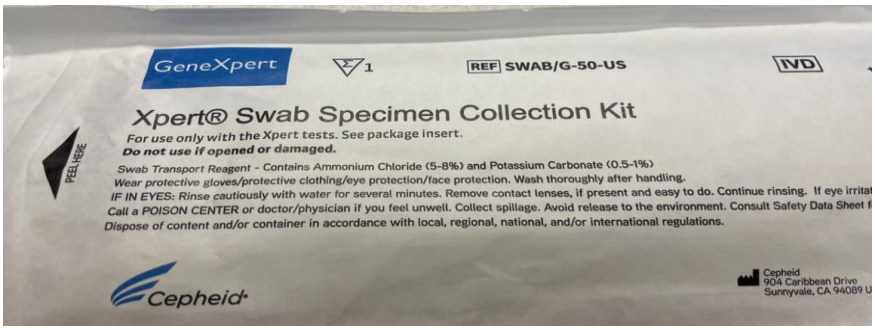
Test indications:	Detection of Bacterial Vaginosis (BV), *Trichomonas vaginalis, Candida* species and *Candida glabrata/Candida krusei* in vaginal specimens.
Lab Testing Sections:	Microbiology, performed on Minneapolis campus
Phone Numbers:	MIN Lab: 612-813-5866 STP Lab: 651-220-6555
Test Availability:	Daily, 24 hours
Turnaround Time:	3 hours from receipt in Minneapolis lab
Special Instructions:	This test is approved for vaginal swabs utilizing special collection kits obtainable on patient units. Specimen site, date/time of collection and collector's initials are required for processing.

Specimen

Specimen Type: Vaginal swabs

Container: CHC # 31654 Xpert Swab Specimen Collection Kit (SWAB/G-50-US)

A separate collection kit should be collected from the Chlamydia Gonorrhea collection when both are ordered.



Collection:

Vaginal Swab:
Supply # 31654 - Xpert Swab Specimen Collection Kit

1. Open the Xpert Swab Specimen collection kit.
2. Discard the large cleaning swab.
3. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and the individually wrapped collection swab. Set the tube aside before proceeding.
4. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Xpert Swab Specimen Collection Kit.
5. Insert collection swab about 5 cm past introitus and rotate gently for 30 seconds.
6. Immediately place collection swab into Xpert Swab Transport Reagent Tube (pink cap) provided in collection kit. Snap off swab at score line so swab fits into closed tube.
7. Cap tube securely and invert the tube 3-4 times to elute material from the swab. Avoid foaming.
8. Label the transport tube with the patient label including date of collection, specimen type and collector's initials.
9. Transport and store swab container at 2 to 28 degrees C (refrigerate is preferred temperature) within 3 days of collection.

● Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit.

● **Warning:** If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water.

Patient-collected Vaginal Swab:
Supply # 31654 - Xpert Swab Specimen Collection Kit

Caution: Do NOT expose swab to Xpert Swab Transport Reagent prior to collection.

STEPS FOR PATIENT TO PERFORM

Wash your hands before starting.

1. Open the outer peel pack (which contains the two-package kit), and identify the larger cleaning swab and discard it.
2. Open the package that contains the pink-capped Xpert Swab Transport Reagent tube and individually wrapped collection swab. Set the tube aside before beginning to collect sample.
3. Open the collection swab wrapper by peeling open the top of the wrapper.
4. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new collection kit.
5. Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the score line.
6. Carefully insert the swab into your vagina about 5 cm (two inches) inside the opening of the vagina and gently rotate the swab for 10 to 30 seconds.

Ensure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
7. Withdraw the swab carefully and continue to hold it in your hand.
8. While holding the swab in the same hand, unscrew the pink cap from the Xpert Swab Transport Reagent tube.
9. Do not spill the contents of the tube. If the contents of the tube are spilled, request a new collection kit.

● **Warning:** If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your doctor, nurse or care-provider if irritation develops. If the contents of the tube are spilled, your test result may be invalidated. Do not take internally.

10. Immediately place the specimen collection swab into the transport reagent tube.
11. Identify the score line on the collection swab shaft. Carefully break the swab shaft against the side of the tube at the score line and discard the top portion of the swab shaft.
12. Re-cap the swab transport reagent tube and tighten the cap securely.
13. Return the tube as instructed by your doctor, nurse, or care provider to complete the following steps.

STEPS FOR CAREGIVER TO PERFORM

14. Invert the tube 3-4 times to elute material from the swab. Avoid foaming.
15. Label the transport tube with the patient label including date of collection and specimen type.
16. Transport and store swab container at 2-28ºC (refrigerate is preferred temperature) within 3 days of collection.

Storage: Samples placed in transport media following collection can be stored for up to 42 days at 2-28ºC prior to testing with Xpert Xpress MVP test.

Sample Rejection: Large white swab included in Xpert Swab Specimen Collection Kit is for preparatory cleaning of the endocervix and is unacceptable for testing. Specimens in any transport media other than indicated above. Specimens in swab transport media without a swab. Specimen not submitted in appropriate transport container; improperly labeled specimen; midstream urine; Cath urine, vaginal drainage, urethral swabs; insufficient volume; external contamination; specimens exceeding acceptable transport time. If an unacceptable specimen is received, the physician or nursing station will be notified and another specimen requested before the specimen is discarded.

Interpretive

Reference Range: Negative for Bacterial Vaginosis

Negative for Trichomonas vaginalis

Negative for Candida species

Negative for Candid glabrata/Candida krusei

Unresolved results due to PCR inhibition are inconclusive. Consider repeat collection if clinically indicated.

Critical Values: None

Limitations:

- The Xpert Xpress MVP test has been validated using the procedures provided in this Instructions for Use only. Modification to these procedures may alter the performance of the test.
- The Xpert Xpress MVP test has been validated with vaginal swabs collected with the Xpert Swab Specimen Collection kit
- Testing of vaginal swab specimens with the Xpert Xpress MVP test is not intended to replace an exam by a clinician. Vaginal infections may result from other causes or concurrent infections may occur.
- As with many diagnostic tests, results from the Xpert Xpress MVP test should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
- Public health recommendations should be consulted regrading testing for additional sexually transmitted diseases for patients with a positive result for bacterial vaginosis (BV) or *T. vaginalis* with the Xpert Xpress MVP test.
- The Xpert Xpress MVP test targets three anaerobic microorganisms that are associated with BV. Other organisms that are not detected by the Xpert Xpress MVP test have also been reported to be associated with BV.
- A *Candid*a group positive results can be due to one or multiple *Candida* species.
- Candida species can be present as commensal organisms in women; the Xpert Xpress MVP positive results for Candida should be considered in conjunction with other clinical and patient information to determine the disease status.
- The BV organism target of the Xpert Xpress MVP test can be commensal in women; Xpert Xpress MVP positive results for bacterial vaginosis should be considered in conjunction with other clinical and patient information to determine the disease status.
- Erroneous test results might occur from improper specimen collection, technical error, sample mix-up, or because the number of organisms in the specimen is not detected by the test. Careful compliance with the Instructions for Use and to the Xpert Swab Collection Kit instructions document are necessary to avoid erroneous results.
- A negative test results does not exclude the possibility of infection because test results may be affected by improper specimen collection, technical error, sample mix-up, concurrent antibiotic

therapy, or the number of organisms in the specimen that may be below the sensitivity of the tests.

- False negative results may occur if the organism is present at levels below the analytical limit of detection or below the cut-off concentration.
- Mutations of other changes within the regions of the microbial genomes covered by the primers and/or probes in the Xpert Xpress MVP test may result in failure to detect the target organisms.
- The effects of other potential variable such as vaginal discharge, use of tampons, douching, and specimen collection variables have not been determined.
- The Xpert Xpress MVP test provides qualitative results. No correlation can be drawn between the magnitude of the Ct value and the number of cells in an infected sample.
- The Xpert Xpress MVP test performance has been evaluated in patients 14 years of age and older (including pregnant women).
    - A bridging study was performed to evaluate performance in patients <14 years of age. Results were satisfactory verifying this assay's performance in this age group. Clinical correlation is still recommended.
- The Xpert Xpress MVP test has not been validated for use with vaginal swab specimens collected by patients at home. The self-collected vaginal swab specimen application is limited to healthcare facilities where support/counseling is available to explain procedures and precautions.
- Five strains of *Candida albicans* evaluated in the Inclusivity Study were detected by the Xpert Xpress MVP test. Three of the strains were only detected at concentration higher than 3xLoD.
- Eleven strains of *Atopobium spp*. evaluated in the Inclusivity Study were detected by the Xpert Xpress MVP test. Four of the strains were only detected at concentrations higher than 3x near cut-off concentration.
- *Candida orthopsilosis*, a recently described species that has been grouped previously with C. parapsilosis, was found to cross-react with the Xpert Xpress MVP test at levels above $1x10^2$ CFU/mL. *Pentatrichomonas hominis* (a commensal of the large intestine) was found to cross-react with the Xpert Xpress MVP test at levels above $5x10^4$ cell/mL. *Trichomonas tenax* (a commensal of the oral cavity) was found to cross-react with the Xpert Xpress MVP test at level above 10 cells/mL.
- Interference with Xpert Xpress MVP test was observed in the presence of mucin (from porcine stomach).
- The analyte target may persist *in vivo*, independent of pathogen viability. Detection of the analyte does not imply that the corresponding pathogen is infectious, or is the causative agent of the clinical symptoms.
- The Xpert Xpress MVP test cannot be used to assess therapeutic success or failure since target nucleic acids may persist following antimicrobial therapy.

Methodology: Real time PCR performed on the Cepheid GeneXpert platform

References:	Xpert Xpress MVP Instructions for Use, 301-8994, Rev. E, October 2022. Sunnyvale, CA: Cepheid.
Updates:	Initial version 6/27/2023