**SUBJECT: Xpert Xpress MVP**
**INSTRUMENT: Cepheid GeneXpert Xpress and GeneXpert Infinity System**
**DEPARTMENT: Microbiology**

## 1.0 PURPOSE/PRINCIPLE

1.1 The most common causes of vaginosis and vaginitis are: 1) proliferation of one or more anaerobic bacterial species in the vaginal tract leading to vaginal discharge without inflammation (22–50% of symptomatic women), known as bacterial vaginosis; 2) vulvovaginal candidiasis (17–39%); and 3) trichomoniasis (4–35%).1 Symptoms in undiagnosed women may be caused by a broad array of non-infectious conditions, including atrophic vaginitis, aerobic vaginitis, various vulvar dermatologic conditions, and vulvodynia. Abnormal vaginal discharge has a broad differential diagnosis, and successful treatment typically requires an accurate diagnosis.

1.2 The Xpert Xpress MVP test is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis, or trichomoniasis.

1.3 The Xpert Xpress MVP test is designed for use with the following specimens collected from symptomatic individuals: self-collected vaginal swabs (collected in a clinical setting) and clinician-collected vaginal swabs. The swab transport reagent included in the Xpert Swab Specimen Collection Kit is designed to collect and preserve patient specimens to allow transport to the laboratory prior to analysis with the Xpert Xpress MVP test.

1.4 The specimen is briefly mixed by vigorously shaking the collection tube 3 to 4 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress MVP cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time PCR for the detection of DNA. Summary and detailed test results are obtained within 60 minutes and are displayed in tabular and graphic formats.

1.5 The Xpert Xpress MVP test is an automated in vitro diagnostic test for qualitative detection of DNA targets from anaerobic bacteria associated with bacterial vaginosis, Candida species associated with vulvovaginal candidiasis, and Trichomonas vaginalis, the agent of trichomoniasis. The Xpert Xpress MVP test is performed on GeneXpert Instrument Systems.

1.6 The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR tests. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized.

1.7 For contamination and monitoring refer to *Cepheid Contamination and Monitoring* SOP.

## 2.0 SCOPE

2.1 This policy applies to employees of the UPMC Hanover Microbiology Lab.

## 3.0 SPECIMEN

3.1 This procedure applies to human vaginal swab specimens using tubes containing Xpert Swab Transport Reagent (pink cap).

3.2 Vaginal swab specimens can be stored up to 42 days at 2-28°C in the Xpert Swab Transport Reagent (pink cap) prior to testing with the Xpert Xpress MVP test.

## 4.0 SUPPLIES, EQUIPMENT AND REAGENTS

4.1 Cepheid GeneXpert Xpress and GeneXpert Infinity System
4.2 560uL disposable sterile transfer pipette
4.3 Xpert Swab Transport Reagent Tube (pink cap)
4.4 10% bleach
4.5 70% ethanol
4.6 NATtrol Vaginal Negative Control (Cat. # NATVNEG-6C)
4.7 NATtrol Vaginal Positive Control (Cat. # NATVPOS-6C)

## 5.0 QUALITY CONTROL

5.1 External Controls
- 5.1.1 Positive and Negative controls are purchased from ZeptoMetrix.
  - 5.1.1.1 Negative control (Cat. # NATVNEG-6C)
  - 5.1.1.2 Positive control (Cat. # NATVPOS-6C)

5.2 Testing External Quality Control Samples (Negative and Positive)
- 5.2.1 Put on a clean pair of gloves.
- 5.2.2 Open a Xpert Xpress MVP test cartridge by lifting the front of the cartridge lid.
- 5.2.3 Check that the external control sample tube cap is closed. Vigorously shake the external control sample 3 to 4 times. Open the cap on the external control tube.
- 5.2.4 Taking a 560 uL disposable transfer pipette, squeeze the top bulb completely until the top bulb is fully flat. Place the pipette into the external control tube.
- 5.2.5 Release the top bulb of the pipette slowly until the pipette is filled with sample. Excess sample may be seen in the overflow reservoir bulb. That is okay. Make sure there is no bubbles.
- 5.2.6 Place the pipette into the large opening on the lower right corner of the cartridge. Squeeze the top bulb of the transfer pipette completely until it is fully flat to empty the contents.
- 5.2.7 Discard the pipette.
- 5.2.8 Close the cartridge lid.

## 6.0 TESTING PROCEDURE

6.1 Preparing the Cartridge
- 6.1.1 Open the cartridge by lifting the front of the cartridge lid.
- 6.1.2 Check that the specimen transport tube cap is closed. Vigorously shake the specimen transport tube 3 to 4 times. Open the cap on the specimen transport tube.

6.1.3 Remove the 560uL transfer pipette from the wrapper.

6.1.4 Squeeze the top bulb on the transfer pipette completely until the top bulb is fully flat. While continuing to hold the bulb fully flat, place the pipette tip in the transport specimen tube.

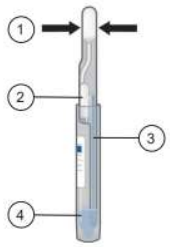


**Figure 7. Transfer Pipette**

| Number | Description |
|---|---|
| 1 | Top Bulb (Squeeze here until fully flat) |
| 2 | Overflow Reservior Bulb (Do Not Squeeze) |
| 3 | Pipette |
| 4 | Sample |

6.1.5 Keeping the pipette below the surface of the liquid, release the top bulb of the pipette slowly until the pipette is filled with sample before removing it from the tube. Excess sample may be seen in the overflow reservoir bulb of the pipette. That is okay. **Make sure the pipette does not contain bubbles.**

6.1.6 Place the pipette into the large opening on the lower right corner of the cartridge. Sample Chamber. Squeeze the top bulb of the transfer pipette completely until it is fully flat to empty the contents.


**Figure 8. Xpert Xpress MVP Cartridge (Top View)**

6.1.7 Continue to hold the top bulb fully flat and do not release until the pipette is removed from the cartridge. Do not reuse a pipette. Dispose of the pipette when finished.

6.1.8 Close the cartridge lid.

6.2 Starting the Test

6.2.1 GeneXpert Dx:

6.2.1.1 In the **GeneXpert System** window, click **Create Test**. The **Create Test** window displays. The **Scan Patient ID barcode** dialog box displays.

6.2.1.2 Scan or type in the Patient ID. If typing the Patient ID, make sure the Patient ID is typed correctly. The Patient ID is associated with the test results and displays in the **View Results** window and all the reports. The **Scan Sample ID barcode** dialog box displays.

6.2.1.3 Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly. The Sample ID is associated with the test results and displays in the **View Results** window and all the reports. The **Scan Cartridge Barcode** dialog box displays.

6.2.1.4 Scan the barcode on the cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and Expiration Date.

6.2.1.5 Click **Start Test**. In the dialogue box that displays, type your password if required.

6.2.1.6 Open the instrument module door with the blinking green light and load the cartridge.

6.2.1.7 Close the door. The test starts and the green light stops blinking. When the test is finished the light turns off.

6.2.1.8 Wait until the system releases the door lock before opening the module door, then remove the cartridge.

6.2.1.9 Dispose of the used cartridges in the appropriate specimen waste container.

6.2.2 GeneXpert Infinity:

6.2.2.1 In the **Xpertise Software Home** workspace, click **Orders** and in the Orders workspace, click **Order Test**. The **Order Test - Patient ID** workspace displays.

6.2.2.2 Scan or type in the Patient ID. If typing the Patient ID, make sure the Patient ID is typed correctly. The Patient ID is associated with the test results and displays in the **View Results** window and all the reports.

6.2.2.3 Enter any additional information required by your institution and click the **CONTINUE** button. The **Order Test - Sample ID** workspace displays.

6.2.2.4 Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly. The Sample ID is associated with the test results and displays in the **View Results** window and all the reports.

6.2.2.5 Click the **CONTINUE** button.

6.2.2.6 The **Order Test - Assay** workspace displays.

6.2.2.7 Scan the barcode on the cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and Expiration Date.

6.2.2.8 After the cartridge is scanned, the **Order Test - Test Information** workspace displays.

6.2.2.9 Verify that the information is correct and click **Submit**. In the dialog box that displays, type your password, if required.

6.2.2.10 Place the cartridge on the conveyor belt. The cartridge automatically loads, the test runs, and the used cartridge are placed into the waste container.

## 7.0 INTERPRETATION OF RESULTS

7.1 The results are interpreted automatically by the GeneXpert Xpress and Infinity System. The results will display in the **Results** screen. The possible results and interpretations are shown in **Table 1**. **Table 2** presents the BV algorithm and expected results.

**Table 1. Xpert Xpress MVP Results and Interpretations**

| Result | Interpretation |
|---|---|
| **BV NEGATIVE**<br>**Candida group NOT DETECTED**<br>**Candida glab-krus NOT DETECTED**<br>**TV NOT DETECTED** | Indicator DNA target(s) related to bacterial vaginosis (BV) organisms is/are not detected (see Table 2); Candida group (*C. albicans* and/or *C. tropicalis* and/or *C. parapsilosis* and/or *C. dubliniensis*) target DNA is not detected; Candida glab-krus (*Candida glabrata* and/or *C. krusei*) target DNA is not detected; and *Trichomonas vaginalis* (TV) target DNA is not detected.<br>• SPC: PASS; SPC has a Ct within the valid range and endpoint above the threshold setting.<br>• PCC: PASS; all probe check results pass. |
| **BV POSITIVE**<br>**Candida group DETECTED**<br>**Candida glab-krus DETECTED**<br>**TV DETECTED** | Indicator DNA target(s) related to bacterial vaginosis (BV) organisms is/are detected (see Table 2); Candida group (*C. albicans* and/or *C. tropicalis* and/or *C. parapsilosis* and/or *C. dubliniensis*) target DNA is detected; Candida glab-krus (*Candida glabrata* and/or *C. krusei*) target DNA is detected; and *Trichomonas vaginalis* (TV) target DNA is detected.<br>• BV, Candida group, Candida glab-krus, and TV: Ct values are within the valid range.<br>• SPC: NA (not applicable); SPC signal is not part of the result interpretation algorithm if the target DNA is detected since SPC signal may be suppressed due to competition with BV, Candida group, Candida glab-krus, and TV targets.<br>• PCC: PASS; all probe check results pass. |
| **INVALID** | Presence or absence of the target DNA cannot be determined.<br>• BV, Candida group, Candida glab-krus, and TV: one or more of the analyte results is INVALID.<br>• SPC: FAIL or NA.<br>• PCC: PASS; all probe check results pass.<br>**Note** If SPC shows NA, the INVALID may be caused by a test parameter failure. |
| **ERROR** | Presence or absence of BV, Candida group, Candida glab-krus, and TV target DNA cannot be determined<br>• BV, Candida group, Candida glab-krus, and TV: NO RESULT<br>• SPC: NO RESULT<br>• PCC: FAIL; all or one of the probe check results fail.<br>**Note** If the probe check passes or shows NA, the error may be caused by the maximum pressure limit exceeding the acceptable range, insufficient sample volume or by a system component failure. |

| | |
|---|---|
| **NO RESULT** | Presence or absence of BV, Candida group, Candida glab-krus, and TV target DNA cannot be determined. A **NO RESULT** indicates that insufficient data were collected. For example, cartridge integrity test failed, the operator stopped a test that was in progress or a power failure occurred.<br>• BV, Candida group, Candida glab-krus, and TV: NO RESULT<br>• SPC: NO RESULT<br>• PCC: NA (not applicable)*<br>**Note** If the probe check shows NA, the error may be caused by the maximum pressure limit exceeding the acceptable range and terminates the run prior to probe check. |

**Table 2. BV Results Algorithm[a]**

| BV Organisms | | | BV Result |
|---|---|---|---|
| *Atopobium* spp.[b] | *Megasphaera*-1 | BVAB2 | |
| + | + | - | **BV Positive** |
| + | - | + | **BV Positive** |
| + | + | + | **BV Positive** |
| + (high concentration) | - | - | **BV Positive** |
| - | +/- | +/- | **BV Negative** |

[a] Algorithm results are either BV positive or BV negative.
[b] *Atopobium vaginae* and/or *Atopobium* novel species CCUG 55226.

## 8.0 REPORTING RESULTS

8.1 Interfaced Resulting

8.1.1 If the instrument result is Positive (Detected) or Negative (Not Detected) the result will go straight from the Cepheid into Sunquest with no user involvement.

8.1.2 All results of Error, No Result, and Invalid will be held on the instrument and will not cross to the LIS.

8.1.3 Repeat testing once if the result is Error, No Result, or Invalid.

8.1.4 If the result is of Error for the second time that means the specimen is invalid.

8.1.4.1 Result as **INVALID**

8.1.4.2 **NOTE:** Do not credit results

8.2 Manual Resulting

8.2.1 Refer to:

8.2.1.1 LSC Cepheid Molecular Testing GeneXpert Dx System

8.2.1.2 LSC Cepheid Molecular Testing GeneXpert Infinity System

## 9.0 LIMITATIONS

9.1 The Xpert Xpress MVP test has only been validated with vaginal swabs collected with the Xpert Swab Specimen Collection Kit.

9.2 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.

9.3 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 in this Instructions for Use and the Xpert Swab Specimen Collection Kit instruction documents are necessary to avoid erroneous results.

9.4 The Xpert Xpress MVP test performance has been evaluated in patients 14 years of age and older (including pregnant women).

9.5 Possible interfering substances include microbial interference, competitive interference, potentially interfering substances, and carry-over contamination.

## 10.0 REFERENCE

10.1 Cepheid (2022-2023). Xpert Xpress MVP Package Insert. Sunnyvale, California.