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| Origination | N/A | Owner | Colleen Turtenwald: Technical Specialist |
| Last Approved | N/A | Area | Microbiology - Molecular |
| Effective | Upon Approval | Applicability | Community Physician |
| Last Revised | N/A | | |
| Next Review | 2 years after approval | | |

# Xpert Xpress MVP Real Time PCR Assay



## SCOPE

This procedure provides instruction for testing of the MVP test on the Cepheid GeneXpert Xpress starting on the planned go-live date at the following laboratories.

- Moorland Reserve
- Drexel Town Square
- North Hills Health Center
- Town Hall Health Center
- Mequon Health Center
- West Bend Health Center.
- Tosa Health Center

This procedure is for Beaker Test Code LAB6189 - Bacterial Vaginosis, Candida Vaginitis, and Trichomonas Nucleic Acid Amplified Test (NAAT).

## PRINCIPLE:

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. 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 assays. 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.

The Xpert Xpress MVP test includes reagents for the detection of DNA from BV organisms, Candida species, and Trichomonas vaginalis from vaginal swab samples. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert System instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the PCR reaction. The SPC also ensures that the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

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.

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

The Xpert Xpress MVP test is a waived test method when performed on the GeneXpert Xpress analyzer following manufacturer instructions.



# SPECIMEN:

## *SPECIMEN COLLECTION:*

**Vaginal Swab**:

1. Vaginal swabs can be collected by a clinician or by the patient using the Cepheid Xpert Swab Specimen Collection Kit.
2. Refer to the attached Xpert Swab Specimen Collection kit Instructions for Use for collection instructions

## *SPECIMEN TRANSPORT:*

**Vaginal Swab:**

1. Transport specimens at 2-28°C.
2. Stability: 42 days at 2-28°C.

## *SPECIMEN ACCEPTABILITY:*

1. Acceptable: Vaginal swab in Xpert Swab Specimen Collection kit
2. Rejection Criteria:
    a. Non-vaginal specimen sources
    b. Sample collected using large woven cleaning swab included in Xpert Swab Specimen Collection kit (only smaller flocked swab packaged with pink capped reagent tube is acceptable)
    c. Specimens collected in alternative collection kits (eg. Eswab, UTM, dry swabs)
3. The following comment should be added to unacceptable specimens when applicable: " Incorrect swab specimen submitted."

# MATERIALS:

## *KIT:*

**Xpert Xpress MVP Kit (10 cartridges):**

- Included in one cartridge:

  Bead 1, Bead 2, Bead 3 and Bead 4: 1 each
  Lysis Reagent (Guanidinium thiocyanate): 1.3 mL
  Sodium Hydroxide: 0.44 mL
  Binding Reagent: 1.5 mL
  Wash Reagent: 0.48 mL
  Elution Reagent: 2.0 mL
- Transfer pipette (Approx. 600uL): 10 each/kit



The above kit (XPRSMVP-10) is purchased commercially from Cepheid.
Store at 2-28ºC in original box to protect from light.
Expiration: See manufacturer's expiration date.

## *CONTROLS:*

**NATtrol Vaginal Positive Control (Zeptometrix NATVPOS-6C)**

Contains purified, intact *Atopobium vaginae, Escherichia coli* containing BVAB2 (recombinant), *Candida albicans, Candida glabrata,* and *Trichomonas vaginalis*.

**NATtrol Vaginal Negative Control (Zeptometrix NATVNEG-6C)**

Contains purified, intact *Lactobacillus acidophilus*.

Store at 2-8ºC.
Expiration: See manufacturer's expiration date.

# QUALITY CONTROL:

## *INTERNAL QC* :

Each test includes a Sample Processing Control (SPC) and Probe Check Control (PCC). A test will be flagged as invalid if the SPC or PCC does not pass the validated acceptance criteria.

1. **Sample processing control (SPC)—** Ensures the sample was correctly processed. The SPC verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR test, ensures that the PCR conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria.
2. **Probe check control (PCC)—** Before the start of the PCR reaction, the GeneXpert Xpress System measures the fluorescence signal from the probes to monitor bead rehydration, reaction-tube filling, probe integrity, and fluorophore stability. The PCC passes if it meets the validated acceptance criteria.

## *EXTERNAL QC:*



External Quality Control must be run:

- Before a new lot/new shipment of Xpert Xpress MVP test kits is used for resulting patient specimens.
- By each new operator trained on the GeneXpert Xpress.

External Quality Control Procedure

A. Verify the Assay Definition File (ADF) is current and uploaded to the GeneXpert software. The ADF version is printed on the CD accompanying each test kit box. If the version printed on the CD is different than that in the Xpert software notify Technical Specialist before performing New Lot/New Shipment QC testing.

B. A positive and negative external control must be tested with each new lot and new shipment of test kits.
    1. Order QC in Beaker. Ensure that the lot number of control matches the lot number in Beaker. If it is a new lot, refer to Beaker Quality Control Documentation and Material Maintenance for instructions on how to set up new lot of control.
    2. External controls come ready to use in a single use vial.
    3. Refer to the Testing procedure below for proper preparation of the cartridge.

C. The QC parameters must pass as described. Review the results in Beaker. If any of the parameters are out of control, repeat the testing and notify a manager or technical specialist.

# PROCEDURE:

## *TESTING:*

1. Preparing the work surface
    a. Before and after each test run, prepare the testing work area by sanitizing/ disinfecting the work area with a disinfecting wipe.
    b. In the event a specimen contaminates the work surface, the spill must be cleaned using a three step process: 1) Wipe with a 10% bleach wipe, 2) Wipe with a paper towel saturated in water, 3) Wipe with alcohol based disinfecting wipe (Sani-cloth disinfectant wipe)

2. Prepare the cartridge
   **NOTE:** Start the test within 15 minutes of adding the reagents to the cartridge.
   **NOTE:** Prepare one cartridge at a time. Do not set up multiple cartridges at a time. Proper cleaning must take place between processing multiple samples.
    a. Remove the Xpress MVP test cartridge from the package.
    b. Mix by rapidly inverting the specimen tube or external control for 5 seconds.
    c. Using the kit-suppled pipette, squeeze the top bulb of 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 specimen transport tube or external control vial.
        i. **NOTE:** Use only one of the transfer pipettes included with the Xpert Xpress MVP assay kit. Do not use a pipette included in the COV and/or COV/Flu/ RSV assay kits as the volume is insufficient.
    d. Open the cartridge lid.
    e. To transfer the sample to the cartridge, squeeze the top bulb of the transfer pipette completely until it is fully flat to empty the contents of the pipette into the large opening (Sample Chamber) in the cartridge.
    f. Close the cartridge lid.
    g. Refer to the GeneXpert Xpress Instrument Operation and Maintenance for proper loading of the instrument.
    h. If the test did not pass internal QC, repeat the test immediately using a new Xpert Xpress MVP test cartridge.



# RESULT INTERPRETATION:

The results are interpreted by the GeneXpert Xpress System and are clearly shown in the **Results** screen. The possible results and interpretations are shown in table 1

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

| Result | Interpretation |
|---|---|
| BV NEGATIVE | Negative test for bacterial vaginosis (BV). |
| Candida group NOT DETECTED | Candida group (*C. albicans* and/or *C. tropicalis* and /or *C. parapsilosis* and /or *C. dubliniensis*) target DNA is not detected. |
| Candida glab-krus NOT DETECTED | *Candida glabrata* and/or *Candida krusei* target DNA is not detected |
| TV NOT DETECTED | *Tricomonas vaginalis* (TV) target DNA is not detected. |
| BV POSITIVE | Positive test for bacterial vaginosis (BV).<br>Indicator DNA target(s) related to BV organisms is/are detected in one of the four BV Positive algorithms shown in Table 2. |
| Candida group DETECTED | Candida group (*C. albicans* and/or *C. tropicalis* and /or *C. parapsilosis* and /or *C. dubliniensis*) target DNA is detected |
| Candida glab-krus DETECTED | *Candida glabrata* and/or *Candida krusei* target DNA is detected |
| TV DETECTED | *Tricomonas vaginalis* (TV) target DNA is detected. |
| NO RESULT-REPEAT TEST | If the result is NO RESULT-REPEAT TEST, then retest with a new cartridge using a new transfer pipette. If retest is **NO RESULT - REPEAT TEST**, contact Cepheid technical support and notify manager and tech specialist.. |
| INSTRUMENT ERROR | Result is an instrument error. Touch CLEAR ERROR and follow the on-screen instructions. When the home screen appears, repeat the test using a new cartridge and a new transfer pipette.If the repeat test is **INSTRUMENT ERROR,** contact Cepheid technical support and notify manager and tech specialist. |



**Table 2 - BV Results Algorithm**

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

## *RESULTS WILL BE REPORTED AS:*

Bacterial Vaginosis NAAT: Detected / Not Detected
*Candida species, excluding C. glabrata/krusei* NAAT: Detected / Not Detected
*Candida glabrata/krusei* NAAT: Detected / Not Detected
*Trichomonas vaginalis* NAAT: Detected / Not Detected

The following test comment will be reported with all results:
The Xpert Xpress MVP test is an in vitro diagnostic test for detection of DNA targets from bacteria associated with bacterial vaginitis, *Candida* species associated with vulvovaginal candidiasis, and *Trichomonas vaginalis*. The *Candida* species target detects, but does not differentiate, *C. albicans, C. tropicalis, C. parapsilosis*, and *C. dubliniensis*. The organism targets for *Candida* and BV results may be commensal organisms in women and results should be considered in conjunction with other clinical information to determine disease status.

# REPORTING RESULTS:

1. Following completion of a test, view the test results from the "Test Completed Screen" or press RESULTS on the home screen to see all completed patient results.
2. The GeneXpert Xpress instruments are interfaced; valid patient results will autoverify through the interface to Beaker.
3. For external controls, valid results and lot number will interface to Beaker. Operator will need to enter lot expiration date and verify result.



# LIMITATIONS:

1. The Xpert Xpress MVP assay targets three anaerobic organisms associated with bacterial vaginosis. Other organisms that have been reported to be associated with BV are not detected by this assay.
2. A positive *Candida* group result can be due to the presence of one or multiple *Candida* species.
3. False negatives can occur if the organism are present below the level of detection.
4. No correlation can be drawn between the Ct value and the number of cells present in the sample.

A full listing of assay limitations can be found in the Xpert Xpress Instruction for Use.

# REFERENCES:

1. **Cepheid** Xpert Xpress MVP Instructions for Use. 302-6886, Rev A, November 2023..
2. **Cepheid,** GeneXpert Xpress User guide. 302-5609, Rev. D, August 2023.

## Attachments

MVP Self Collect Instructions.pdf

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| CP Managers and Director | Tina Bognar: CP Director | Pending |
| CP Managers and Director | Emery Smith: Lab Manager | 07/2024 |
| CP Managers and Director | Mary M Cypert: Lab Manager | 07/2024 |
| CP Managers and Director | Karen Kundinger: Lab Manager | 07/2024 |
| Technical Specialists | Carolyn Webb: Heme Technical Specialist | 07/2024 |
| Technical Specialists | Colleen Turtenwald: Technical Specialist | 07/2024 |
| Policy Owner | Colleen Turtenwald: Technical Specialist | 07/2024 |



## Applicability

Community Physician

## Standards

No standards are associated with this document