**MICRO.KIT.8.0 BACTERIAL VAGINOSIS (BV) RAPID TEST**

# PRINCIPLE

Approximately 15-30% of the female population is affected by BV and reoccurring bouts of the disease are common. Although BV is the most common form of infectious vaginitis in adult women, it is the most benign in symptomology and is characterized by a relative lack of inflammatory response. When present, the main symptoms of BV are vaginal discharge and genital malodor; however, not all patients exhibit noticeable symptoms.

Complications associated with BV include salpingitis, endometritis, post-hysterectomy infections, and an increased risk of pelvic inflammatory disease and HIV. BV represents a serious danger in women due to its significant association with placental infection, premature rupture of membranes, and preterm birth as well as chorioamnionitis, amniotic fluid infections, post-partum endometritis and bacteremia. Other possible complications associated with untreated BV infections include adnexal tenderness and recurrent urinary tract infections.

The diagnostic methods currently adopted as the “Gold Standards” in evaluations of patient Samples for BV are Amsel Criteria and Gram’s stain. Amsel Criteria involves the assessment of four clinical criteria for each patient sample. These clinical criteria include the following:

1. a milky homogenous vaginal discharge
2. a vaginal pH of greater than 4.5,
3. the presence of clue cells (i.e., epithelial cells with adherent coccobacilli).

Although the use of these clinical criteria is the most widely used method of diagnosing patients with BV, numerous published studies have reported on the subjectivity of the method. Gram’s stain involves an objective identification and scoring of morphotypes present in patient vaginal fluid samples.

The OSOM BVBlue Test is a test that detects sialidase activity in vaginal fluid specimens. Sialidase is an enzyme produced by the causative bacterial agents of *BV, Gardnerella* *vaginalis, Bacteroides* spp., *Prevotella* spp., and *Mobiluncus* spp.

The OSOM BVBlue Test contains a chromogenic substrate of bacterial sialidase, IBX-4041. The chromogenic substrate is provided in each of the BVBlue tests as a solution containing 0.25 mg IBX-4041 in 0.5 ml. aqueous potassium acetate solution (49 mg/ml.; 0.5 M; pH5.5-6.0). When the solution containing the solubilized chromogenic substrate is exposed to bacterial sialidase, the substrate undergoes a chemical reaction to yield sialic acid and IBX-4050. Upon the addition of one drop of the Developer Solution (an aqueous sodium hydroxide solution (40 mg/ml.; 1.0M; pH>11.0)), IBX-4050 exhibits an intense blue color. In the absence of bacterial sialidase, the chromogenic substrate does not undergo the aforementioned chemical reaction and exhibits a yellow color upon the addition of one drop of the Developer Solution.

# OWNERS

Supervisor, Regional Microbiology

Microbiology Best Practice Team

# RELATED DOCUMENTS

MICRO.KIT.8.1 BV and TRICH Log

QA.QC.1.1 External QC Log Sheet

# SPECIMEN

**NOTE:** Specimens should be processed as soon as possible after collection. A separate swab must be used if a culture is requested.

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| Vaginal fluid swab  (from lower 1/3 of vaginal wall) | Dacron, rayon, or cotton tipped swab transported in sterile tube with no preservatives or swab in redcapped Liquid Stuarts culturette.  Swabs in saline are unacceptable. | |
| Storage requirement | If: | Then: |
| <48 hours | Room temperature (15-30ºC) |
| >48 hours – 7 days | Refrigerate (2º-8°C) |

# REAGENTS

Store test kit at 2-8C. Vessels should be stored inside the box and prolonged exposure to light should be avoided.

1. 25 Testing vessels each containing 0.25 mg IBX-4041 component in 0.5 ml. of an aqueous potassium acetate buffer solution (49 mg/ml.; 0.5M; pH5.5-6.0)
2. Developer Solution containing 10.0 ml. of an aqueous sodium hydroxide solution (40.0 mg/ml.;

1.0M; pH>11.0)

1. Sterile Swabs (Dacron, rayon, or cotton acceptable)
2. OSOM BVBlue Positive Control – aqueous solution containing 250U/mL sialidase enzyme, (neuraminidase) (not included with kit, must be purchased separately). Refrigerate at 2-8°C.
3. Timer

**Note:** The Developer Solution is a dilute alkaline solution, which may cause skin irritation. If contact with exposed skin results, rinse contacted area with water.

# QUALITY CONTROL

1. Parallel testing of New Lots is performed and documented prior to the release of the lots to the Network Laboratories. All tested lots are marked with a yellow sticker.
2. External QC must be performed with each New Lot or New Shipment, whichever is most frequent.
3. External QC may also be performed at the discretion of the technologist.

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| **Step** | **Action** |
| 1. | Remove the OSOM BVBlue Positive Control and Developer from the refrigerator and let stand at room temperature for 20 minutes. |
| 2. | Remove two testing vessels from the OSOM BVBlue Test kit immediately prior to use and bring to room temperature. Label one vessel positive and the other negative. Remove the caps. |
| 3. | Positive Control: Add one drop of the OSOM BVBlue Positive Control to the testing vessel that is labeled positive.  Negative Control: Vessel that is labeled negative (nothing added) |
| 4. | Immerse the head of a clean swab from the test kit into the solution in the testing vessel for each control. Gently swirl the swab. Let each testing vessel containing the swab stand at 17-37C for 10 minutes. |
| 5. | Continue with Test Procedure Step 3. |

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| Internal Control | *The OSOM BVBlue test has two types of internal control with each run.*    *Type 1 Control: The testing vessel should contain a colorless testing solution without the appearance of a flocculent (i.e., a precipitate) upon first inspection of the test and prior to the addition of a patient sample. If the testing vessel contains precipitate, the test is invalid. Do not use the BV test vessel.*    *Type 2 Control: The OSOM BVBlue Test has a two-color result format: Positive Control : Blue/green is positive Negative Control: Yellow is negative.*    *The appearance of a uniform yellow, blue, or green color in the testing vessel or a blue or green color on the swab assures proper mixing of the reagent and sample has occurred. If the test fails to provide either a blue, green, or a yellow color result the test is invalid. Do not report patient results if either type 1 or 2 control does not produce expected results.* |

# PROCEDURE

**NOTE**: Test performed by the Hospital-based Labs (Misys only)

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| **Step** | **Action** |
| 1. | Remove number of testing vessels needed for number of patients and the Developer Solution bottle from the test kit in the refrigerator and warm to room temperature at least 20 minutes. |
| 2. | Remove the cap from the testing vessel. |
| 3. | Immerse the head of the vaginal swab into the solution in the vessel. Gently swirl the mixture. |
| 4. | Let the testing vessel containing the swab stand at 17-37C for 10 minutes. |
| 5. | At the end of 10 minutes, add one drop of the Developer Solution to the testing vessel containing the swab. Gently swirl the mixture. |
| 6. | Interpret the results immediately after adding the Developer Solution using the criteria in Interpretation Of Results (below). |
| 7. | Return the Developer Solution to the refrigerator (2-8C). |

# INTERPRETATION OF RESULTS

**NOTE:** It may be necessary to remove the swab from the testing vessel to observe blue or green color.

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| Reaction: | Result: |
| The generation of a blue or green color in the testing vessel or on the head of the testing swab. | Positive |
| The generation of a yellow color in the testing vessel. | Negative |
| No visible yellow, green, or blue color change in the testing vessel or on the head of the swab. This could include color interference due to a bloody specimen. | Invalid  (repeat test , or recollect) |

# REPORTING RESULTS

POS: Positive

NEG: Negative – A negative result does not exclude the possibility of infection. Diagnosis should be made in conjunction with clinical symptoms.

Misys (all sites)

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| **IF** | **THEN** |  |
| Result is negative | a.  b.  c.  d. | Function MEM  <Enter> to worksheet prompt  At worksheet prompt, type site specific worksheet  <Enter> to accession prompt. Type accession number, and <enter> |
|  | e. | Type NEG at the BVR prompt, <enter>, and accept |
| Result is positive | a.  b.  c.  d. | Function MEM  <Enter> to worksheet prompt  At worksheet prompt, type site specific worksheet  <Enter> to accession prompt. Type accession number, and <enter> |
|  | e. | Type POS at the BVR prompt, <enter>, and accept |
| BVTRS (Bacterial vaginosis and  Trichomonas Screen) is requested | a.  b.  c.  d.  e. | Function MEM  <Enter> to worksheet prompt  At worksheet prompt, type site specific worksheet  <Enter> to accession prompt. Type accession number, and <enter>  Type appropriate response, POS or NEG, at each test prompt, <enter>, and accept |

# LIMITATIONS

1. Do not use cervical samples.

1. Mixed infections may occur. Therefore, a test indicating the presence of vaginal fluid sialidase activity does not rule out the presence of yeast, *Trichomonas vaginalis*, or other organisms.

1. OSOM BVBlue test results provide presumptive diagnostic information about the occurrence of BV and should be considered in conjunction with other clinical and patient information.

1. Failure to follow instructions for specimen collection, storage and/or proper test procedure may adversely affect the performance of the OSOM BVBlue Test.

# REFERENCES

1. Package insert for the OSOM® BVBlue Test, July 2008.
2. Technical Bulletin 7/28/08.