The disease has a high infection rate, and catalytic activity is commonly produced from vaginal bacterial pathogens (Gardnerella vaginalis, Peptostreptococcus spp., Prevotella spp., Bacteroides spp., and others). The enzyme sialidase is designed for qualitative detection of sialidase catalytic activity in female vaginal secretions. This enzyme is commonly produced from vaginal bacterial pathogens. Failure to promptly identify and treat the disease can lead to further complications.

**DIAGNOSTIC SIGNIFICANCE**

Bacterial vaginosis (BV), also known as non-specific vaginitis, is a common infectious disease in women of childbearing age. The disease has a high infection rate, common occurrence of reinfection, and is easily transmitted (both sexually, and non-sexually). BV also predisposes women to an increased risk of premature delivery, endometriosis, pelvic inflammatory disease, vaginal cellulitis, and other reproductive tract infections. Failure to promptly identify and treat the disease can lead to further complications.

As such, the presence of sialidase activity is diagnostically relevant for detecting a potential BV infection.

**DETECTION PRINCIPLES**

Sialidase enzyme activity detection:

The BV test cassette has a sample pad that contains 5-bromo-4-chloro-3-indolyl-α-DN-acetylneuraminic acid. This compound, in the presence of sialidase, causes a catalytic hydrolysis reaction to occur. The reaction product in the presence of the subsequently added coloring solution causes the development of a red or purple coloration on the sample pad. This color indicates the presence of sialidase in the sample, and the depth of the color is proportional to the level of sialidase activity.

**EXPECTED USAGE**

This kit is designed for qualitative detection of sialidase catalytic activity in female vaginal secretions. This enzyme is commonly produced from vaginal bacterial pathogens. Failure to promptly identify and treat the disease can lead to further complications.

**SAMPLE COLLECTION AND STABILITY**

Sample Requirements:
The kit is designed for use with swabs taken from the vaginal cavity. As such, the following should be avoided 24 hours prior to the test.

- Sexual intercourse
- Bathing
- Vaginal lavage
- Douching
- Prescription medication (if possible)

Samples that are not compatible with the test kit:

- Samples during a menstrual period
- Purulent samples
- Bloody samples

Sample Isolation:
The kit is designed to test vaginal swabs for sialidase activity. Samples swabs should be taken from the lower third of the vaginal wall. Swabs should be rotated for 10-20 seconds in the vaginal vault, with visual confirmation of the presence of vaginal secretions upon isolation.

Sample Preservation:
Samples should be run immediately if possible. If not possible, store the collected swab in a collection pouch at 2-8°C. Detection should be completed within 12 hours of collection.

**TESTING METHODS**

1. Before testing, read the manual completely.
2. Ensure kit and sample have been stored as stated in the manual.
3. Take out enough individual foil bags as needed for the samples on hand.
4. Bring each individual the BV Detection Cassette foil bag to room temperature.
5. Open the foil bags and take out the cassette.
6. Using a 1.5mL or larger test tube, add 0.5mL of Sample Diluent.
7. Place the sample swab in the test tube.
8. Gently press the swab repeatedly against the side of the test tube wall to extract the secretions from the sample.
9. Add 1 drop (40uL) of the sample material to the sialidase reaction well in the BV test cassette.
10. Add 1 drop (40uL) of the color reagent to the reaction well.
11. Place the cassette in a 37°C incubator for 15 minutes to develop the color.
12. Evaluate the results.

**KIT COMPONENTS**

<table>
<thead>
<tr>
<th>Components</th>
<th>SIZE</th>
</tr>
</thead>
<tbody>
<tr>
<td>BV Detection Cassette</td>
<td>20 individual cassettes</td>
</tr>
<tr>
<td>Sample Diluent</td>
<td>1 bottle, 20mL *</td>
</tr>
<tr>
<td>Coloring Reagent</td>
<td>1 bottle, 3mL **</td>
</tr>
<tr>
<td>Instruction Manual</td>
<td>1</td>
</tr>
<tr>
<td>Color Card</td>
<td>1</td>
</tr>
</tbody>
</table>

- **Special Note:** The components of different lot numbers are not interchangeable

The sample diluent and coloring solution require the addition of water prior to use.

- Add 20mL of deionized water to the Sample Diluent bottle
- Add 3mL of deionized water to the Coloring Solution bottle

**Additional Materials Required:**

- Precision pipettes
- Cotton swabs for vaginal sample isolation
- Distilled or deionized water
- 1.5mL or larger volume test tube
- 37°C incubator

**STORAGE AND STABILITY**

Store kit and individual packages at 2–8°C centigrade, away from moisture, and away from light. Avoid freezing. Overall kit and individual cassettes are good for 12 months.

The Sample Diluent is good for 10 days after reconstitution. The individual cassette packages should only be opened when detection begins, and the cassette is only good for 4 hours after being opened.
• EVALUATION OF TEST RESULTS

Color Interpretation:
The testing cassette should be read immediately following the 15-minute incubation at 37°C. The presence or absence of sialidase in the sample is determined by the coloration of the sample pad.

Negative ( - )

Positive ( + )

Results are determined as follows:
• Negative result: No color or a yellow color on the sample pad indicates the absence of sialidase in the sample material.
• Positive result: Red or Purple coloring on the pad indicates the presence of sialidase in the sample. Additionally, the depth of the color indicates the level of the sialidase present.

Limitations of the Assay:
• This kit is only used to assist in the diagnosis of bacterial vaginosis, and is a qualitative assay.
• The qualitative results of this kit are interpreted by the naked eye, and are subjective in nature.
• The results should be combined with clinical microscopic examination to confirm the results.

Performance characteristics:
• Minimum detection limit: 0.01 U / mL of sialidase.
• Positive reference rate: The positive rate of the positive reference was ≥ 95%.
• Negative reference rate: The negative rate of the negative reference was ≥ 95%.
• Repeatability: 10 test cards were evaluated simultaneously. A positive reference sample was tested on these cards, and all cards showed a positive coloring result.
• Inter-assay Precision: Three different lots of kits were used to test a positive reference material simultaneously. All cards from all batches were shown to have a positive coloring result.

• SAFETY MEASURES

Warning statements:
• This kit is an in vitro diagnostic test kit.

• Please read this manual carefully before use to ensure you are familiar with the procedure.
• The kit can be manually operated, and the results can be measured accurately by the naked eye.
• This kit can be used in conjunction with a vaginal bacterial detector.
• Clearly label the identity of the test card once it is opened for both the assay, and the patient ID.
• The coloring reagent is for use only after the sample has been added to the sample pad.
• In the patient file, please note the patient’s name, ID number, and the test results.
• In the patient file, also note the lot number, and expiration date of the BV test kit for future records.
• Purulent samples, bloody samples, and viscous samples may result in a brown color reaction. This coloring change is non-specific and is not a valid result for the assay. Please do not use these sample types.
• The test cassette must be used within 4 hours after opening the foil bag.
• The sample must be read within 12 hours of sample collection.
• Swabs that cannot be read immediately must be stored at 2 – 8°C following collection.

Waste treatment:
• This reagent is a disposable product. Please dispose of the used product according to your Medical Waste Management Regulations.
• Dispose of medical waste after using of this product in accordance with local regulations.
• Following use, this product contains human-derived substances that may be contaminated. There are no known methods to fully ensure the presence of non-infectious substances. All completed cassettes should be treated as infectious agents.

• REFERENCES

Version: V1.0        Date:2018, March-30