

Warning: Read the Directional Insert prior to performing the test.

For clinics in the US: A CLIA Certificate of Waiver is needed to perform testing in waived settings. Read all instructions carefully before use. If a laboratory modifies the following test instructions including Quality Control the test will be considered High Complexity and no longer considered Waived.

WARNINGS AND PRECAUTIONS:

- For In Vitro diagnostic use only.
- Do not use after the expiration date printed on the kit.
- Do not store the kit at temperatures above 26°C (79°F).
- Do not store the kit in strong light.
- Follow your laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens.
- Used tests should never be re-used.
- This product is intended for vaginal fluid use only.

STORAGE AND STABILITY:

Store the kit at controlled temperature, 2°–26°C (36°–79°F), out of direct sunlight. Store vessels inside the box. Kit contents are stable until the expiration date printed on the outer box.

LIMITATIONS OF THE PROCEDURE:

- Do not use samples from the cervix.
- Patients may have mixed infections. The BVBLUE test shows that sialidase enzyme is active in the sample. The BVBLUE Test does not show if other organisms such as yeast and parasitic organisms are present in the sample.
- Test results should be considered in conjunction with other clinical and patient information.
- Test operators must follow all instructions to a) collect the sample, b) store the sample, and c) use the test procedure properly. If the instructions are not followed, the BVBLUE test may not give correct results.

QUALITY CONTROL:**1. Internal Quality Controls**

The BVBLUE Test contains two types of internal quality control with each test run. For daily quality control, Gryphus Diagnostics recommends documenting these controls on each day of testing:

- Type 1 Control: Before adding a patient specimen, inspect the Test Vessel. It should contain a colorless liquid without precipitates (sediment).

If the testing vessel contains a precipitate, the test is invalid. Do not use the Test Vessel.

- Type 2 Control: The BVBLUE Test has a two-color result format: blue/green is positive, yellow is negative. After running the test according to the instructions for use, the appearance of either 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.

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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 the Type 1 Control or the Type 2 Control does not produce expected results.

2. External Quality Controls

External Controls (manufactured by Gryphus Diagnostics, LLC) are used to test that the reagents are working properly. Also use the Controls to test that you are able to correctly perform the test procedure.

- A Control Kit that contains a positive control and a negative control may be purchased separately, Catalog No. S751.
- Refer to the Control Kit Directional Insert for instructions on how to interpret the results of the control.

If QC testing fails:

- Check expiration dates of the test kit and controls
- Ensure the instructions for testing were followed
- Repeat the test

If the controls still do not perform as expected contact Technical Support at 1-800-924-4195.

You should follow the manufacturer's guidelines for QC testing. Gryphus Diagnostics recommends that external controls be run with each new lot, each new shipment and with each new untrained operator.

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INSTRUCTIONS FOR USE:

Allow the kit to come to room temperature before running the test.

STEP 1

Remove one BV Test Vessel and the Developer Solution Bottle from the kit prior to use. Remove the cap from the BV Test Vessel.

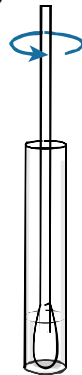
STEP 2

Collect a vaginal fluid sample with a swab. Contact the swab with the lower one-third of the vaginal wall. Collect as much fluid as possible.

NOTE: Do not use samples from patients who have used vaginal cream products within 72 hours before testing. Do not touch or collect fluid near the cervix.

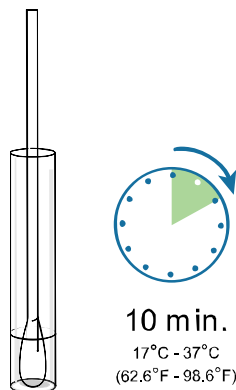
STEP 3

Put the swab into the BV Test Vessel. Gently swirl the mixture.



STEP 4

Let the BV Test Vessel containing the swab stand for 10 minutes between 17 and 37°C.

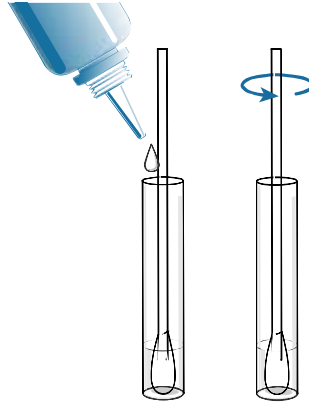


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STEP 5

Add one drop of Developer Solution to the BV Test Vessel containing the swab. Gently swirl the mixture. Read the results immediately.

CAUTION: The Developer Solution is a dilute alkaline solution. This may cause skin and eye irritation. If the solution comes in contact with the skin or eyes, flush with large volumes of water.



INTERPRETATION OF TEST RESULTS:

There are two possible results: (a) positive result or (b) negative result.

- a) Positive Result: A blue or green color in the BV Test Vessel or on the head of the swab.
- b) Negative Result: A yellow color in the BV Test Vessel.

NOTE: You may need to remove the swab to read the test results.

A Positive Result shows a high level of sialidase activity. A Negative Result shows a normal level of sialidase activity.

Interpretation of Results

