

Sialidase Activity Detection Kit for Bacterial Vaginosis (BV)

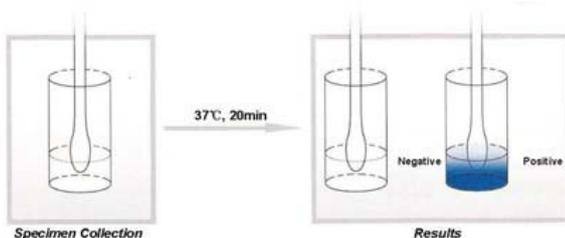
Cat. No. DTS035
Lot. No. (See product label)

INTENDED USE

This product is an enzyme activity test for use in the detection of vaginal fluid specimens for sialidase activity, an enzyme produced by bacterial pathogens associated with Bacterial Vaginosis (BV) such as *Gardnerella vaginalis*, *Bacteroides* spp, *Prevotella* spp., and *Mobiluncus* spp. Studies have shown elevated sialidase activities in women with BV and an increased risk for pre-term birth and low birth weight infants in patients exhibiting elevated sialidase activity. This product is designed to provide a clear, simple, rapid, sensitive and specific indication of elevated sialidase activity in patient vaginal fluid samples. This kit contains a chromogenic substrate of bacterial sialidase. The chromogenic substrate is provided in each of the testing vessels. When the testing solution is exposed to bacterial sialidase, the substrate undergoes a chemical reaction and exhibits a color from blue to purple to dark charcoal brown (upon the concentration of bacterial sialidase). In the absence of bacterial sialidase, the chromogenic substrate does not undergo the aforementioned chemical reaction and no color should be developed.

SPECIMEN COLLECTION AND PREPARATION

1. Collect a vaginal fluid sample from the side vaginal walls with a cotton swab. Collect as much fluid as possible.
2. Remove one test tube from the kit prior to use. Remove the cap from the testing vessel. Immerse the head of the sample swab into the test solution and gently swirl. Incubate the test tube containing the cotton swab at 37°C (98°F) for 20 minutes.



INTERPRETATION OF RESULTS

NEGATIVE

No color developed in the solution and the head of the cotton swab in 20 minutes.

POSITIVE

The development of color (from blue to purple to dark charcoal brown) of the test solution in the testing tube or on the head of the cotton swab within 20 minutes.

STORAGE AND STABILITY

The products should be stored at 4-8°C to ensure that the components of the test device remain stable until the expiration date printed on the package. Do not explore package at high temperatures, in strong light for extended periods.

PRECAUTION

1. Indication of instability: The chromogenic substrate is colorless to light yellow. Any appearance of other color in the testing solution without the presence of patient specimen, with or without the heat incubation, indicates the test kit is invalid.
2. Collected specimen should be stored at 4-8°C, not exceed 4 hours, if the test cannot be performed immediately. Immerse the swab in the testing solution for more than 10 minutes before the 37°C(98°F) incubation may adversely affect the performance of test.
3. The development of color within 20 minutes indicates a positive result, and the color should not fade within 1 hour. A negative result should not show color development in 20 minutes, and it should still be considered as negative results if there is color developed after 25 minutes.
4. Results should be read and determined within 3 minutes after the incubation period end. Failure to read result in time may affect the accuracy of test.
5. Do not use vaginal fluid specimens from patients who have been treated with vaginal cream products within 24 hours prior to testing.
6. Collect a vaginal fluid sample with the cotton swab from the lower onethird of the vaginal wall. Do not touch or collect vaginal fluid near the cervix.
7. Do not use the test after the expiration date printed on the package.
8. Avoid repeated freezing and thawing of reagents and specimens.
9. Grossly hemolyzed, icteric or lipemic specimens should be avoided.

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