

Laboratory Information	Sample Information	Practice Information
<b>CirrusDx, Inc</b> 77 Upper Rock Circle, 4 <sup>th</sup> Floor Rockville, MD 20850  CLIA# 21D2130541  Dr. Todd Myers, Lab Director 240-813-8801 or reports@cirrusdx.com	<b>Technician:</b> CWS  <b>Date Collected:</b> 8/6/2025 <b>Date Received:</b> 8/7/2025 <b>Date Reported:</b> 8/7/2025  <b>Reporting Method:</b> Email	<b>Name:</b> Smith County Center For Women's Health  <b>Provider:</b> Winesap MD, Roma <b>Address:</b> 24333 Suffix St Lebanon KS 66952 <b>Phone:</b> 243-555-5585 <b>Fax:</b> 243-555-5595 <b>Email:</b> Results@SCCWH.com

Test Information		
<b>Test Name:</b> Bacterial Vaginosis / Candida Vaginitis (BV/CV)	<b>Test Method:</b> Real-Time PCR (Molecular)	<b>Specimen Type:</b> Vaginal Swab

Overall Result	
<b>Bacterial Vaginosis (BV)</b>	<b>BV Significant Change Detected, see comment below.</b>
<b>Candida Vaginitis (CV)</b>	<b>Not Detected</b>

Beneficial Organisms	Detection Level
<i>Lactobacillus</i> spp.	Not Detected

Precursor Organisms	Detection Level
<i>Bacteroides fragilis</i>	Detected
<i>Prevotella bivia</i>	Not Detected

Bacterial Vaginosis Organisms	Detection Level
<i>Gardnerella vaginalis</i>	Detected (low level)
<i>Fannyhessea vaginae</i> (formerly <i>A. vaginae</i> )	Not Detected
Bacterial Vaginosis-associated Bacterium 2 (BVAB-2)	Detected (high level)
<i>Megasphaera</i> spp.	Not Detected
<i>Mobiluncus</i> spp.	Detected (high level)

Candida Organisms	Result
<i>Candida albicans</i>	Not Detected
<i>Candida glabrata</i>	Not Detected
<i>Candida krusei</i>	Not Detected
<i>Candida parapsilosis</i>	Not Detected
<i>Candida tropicalis</i>	Not Detected

General Comments
BV Significant Change Detected; significant changes to the vaginal microbiome were detected that indicates the presence of Bacterial Vaginosis.

**Notes:**

Questions including Clinical Consultation on Results: 240-813-8801 or reports@cirrusdx.com

**Organisms Tested (Reference Range):** Bacterial Vaginosis-associated Bacterium 2 (BVAB-2) ( $< 1 \times 10^3$ ), *Bacteroides fragilis* ( $< 1 \times 10^3$ ), *Candida albicans* ( $< 1 \times 10^3$ ), *Candida glabrata* ( $< 1 \times 10^3$ ), *Candida krusei* ( $< 1 \times 10^4$ ), *Candida parapsilosis* ( $< 1 \times 10^3$ ), *Candida tropicalis* ( $< 1 \times 10^3$ ), *Fannyhessea vaginae* (formerly *Atopobium vaginae*) ( $< 1 \times 10^4$ ), *Gardnerella vaginalis* ( $< 1 \times 10^4$ ), *Lactobacillus* spp. (inclusive of *L. crispatus*, *L. gasseri*, *L. insers*, *L. jensenii* and *L. vaginalis*) ( $< 1 \times 10^4$ ), *Megasphaera* spp. (inclusive of *M. lornae* and *M. hutchinsoni*) ( $< 1 \times 10^3$ ), *Mobiluncus* spp. (inclusive of *M. curisii* and *M. mulieris*) ( $< 1 \times 10^4$ ), *Prevotella bivia* ( $< 1 \times 10^4$ ).

**Detection Concentration:** Based on the calculation of genome equivalents. One genome equivalent is theoretically equal to one colony forming unit (cfu). The detection level "Low" is  $\leq 10^5$ . The detection level "High" is  $\geq 10^6$ .

**Bacterial Vaginosis Overall Result:** This result was determined by CirrusDx using the results from six Bacterial Vaginosis (BV) organisms. These BV organisms include *Lactobacillus* spp., *Gardnerella vaginalis*, *Fannyhessea vaginae* (formerly *Atopobium vaginae*), Bacterial Vaginosis-associated Bacterium 2 (BVAB-2), *Megasphaera* spp., and *Mobiluncus* spp.

A "Not Detected" result does not preclude a possible infection.

It is the physician's responsibility to interpret the results provided and determine the appropriate (if any) treatment options.

The assays were developed and their performance characteristics were determined by CirrusDx. They have not been cleared or approved by the US Food and Drug Administration. The FDA does not require these tests to go through premarket FDA review. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing.

This report has been reviewed and approved by:



Dr. Todd Myers, Laboratory Director.

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