



Videssa® Breast: Frequently Asked Questions

The Basics of Videssa Breast

Q. What is Videssa® Breast?

- A. Videssa Breast is the first protein-based blood test that detects the presence or absence of breast cancer for women who receive abnormal mammogram results and/or have dense breasts. With a simple blood draw, Videssa Breast delivers:
- A more accurate “yes,” reducing the risk of a missed or delayed diagnosis
 - A high-confidence accurate “no,” reducing your chances of having a biopsy or additional imaging that could be avoided if you do not have cancer

Q. Who can Videssa Breast help?

- A. Women who receive abnormal mammograms and/or have dense breasts.

Q. What can the test tell me?

- A. Videssa Breast helps determine the absence or presence of breast cancer right now. This test is not like genetic tests, which are designed to determine the future risk of developing a disease. More importantly, results are not affected by breast density, allowing for earlier and more accurate detection of breast cancer.

Q. What results will my healthcare provider receive?

- A. Your blood test will provide one of two results:
- Low Protein Signature (No): likely indicates the absence of breast cancer. Your healthcare provider may use these results along with other available clinical data to determine with confidence if follow-up (additional imaging and/or biopsy) is needed.
 - High Protein Signature (Yes): may potentially indicate the presence of breast cancer. Your healthcare provider may use these results along with other available clinical data to determine with confidence if immediate follow-up (additional imaging and/or biopsy) is needed.*

Q. My Videssa Breast test came back as “low protein signature.” Does this mean I don’t have cancer?

- A. A low protein signature likely indicates that additional imaging or biopsy may not be needed to help your healthcare provider determine your diagnosis. Your healthcare provider will use Videssa Breast test results along with other clinical data to help guide next steps.

Q. My Videssa Breast test came back as “high protein signature.” Does this mean I have cancer?

- A. A high protein signature may potentially indicate that additional imaging and/or a biopsy is warranted to help your healthcare provider determine your diagnosis. Your healthcare provider will use Videssa Breast test results along with other clinical data to decide on next steps. Only a biopsy can definitely diagnose the presence of breast cancer.

Q. How reliable are Videssa Breast test results?



- A. Provista Diagnostics has determined the overall accuracy of Videssa Breast by conducting two large research studies. The results have shown that:
- Videssa Breast can dramatically reduce the total number of biopsies. When utilizing Videssa Breast the number of false positive biopsies also significantly decreases.
 - Videssa Breast can more accurately identify patients who need a biopsy. One of every three biopsies recommended by Videssa Breast resulted in a cancer diagnosis, whereas imaging caught cancer in only one out of six that were biopsied.
 - When Videssa Breast results are combined with imaging, 100 percent of cancers were caught.

Q. How can Videssa Breast help my healthcare providers make informed decisions about my care?

- A. Videssa Breast provides information that when combined with imaging results, allow your healthcare provider to make informed decisions on your treatment options. Mammogram results provide a visual interpretation of your breasts while Videssa provides biological evidence of the presence or absence of cancer. By combining imaging with Videssa Breast, your healthcare provider can have a more complete assessment of your breasts thus, improving early and accurate breast cancer detection.
- Low Protein Signature (No): likely indicates the absence of breast cancer. Your healthcare provider may use these results along with other available clinical data to determine with confidence if follow-up (additional imaging and/or biopsy) is needed.
 - High Protein Signature (Yes): may potentially indicate the presence of breast cancer. Your healthcare provider may use these results along with other available clinical data to determine with confidence if immediate follow-up (additional imaging and/or biopsy) is needed.

Q. Does this test replace my regular mammography screening?

- A. No, you should maintain your regular breast cancer screening as recommended by your healthcare provider. Videssa Breast is recommended for patients with abnormal or unclear mammogram results and/or with dense breasts.

Q. I've been told I have dense breasts. I know that mammography is not very accurate in women with dense breasts. Can I skip the mammogram and go straight to using this test?

- A. Dense breast tissue can reduce the overall accuracy of mammograms. However, Videssa Breast is meant to be used after imaging, to bring clarity for unclear imaging results. The combined approach of imaging and Videssa Breast increases overall detection of breast cancer.

Q. I'm at high risk of breast cancer because of family history or I have genetic mutations, (such as BRCA 1 or 2). Can I get this test done regularly instead of a mammography?

- A. No. Videssa Breast should always be used in combination with mammograms or other imaging under the guidance of your healthcare provider.

Q. I was told I need further tests to determine if I have cancer. Can I use Videssa Breast instead of other imaging tools like breast ultrasound, tomosynthesis or MRI?

- A. Only your healthcare provider can make decisions on treatment options available including if Videssa Breast test is right for you. Discuss with your healthcare provider to decide if Videssa Breast can provide additional information to decide on next steps.

Q. Is this covered by insurance?

A. For patients with health insurance, including Medicare, Provista will file an insurance claim on your behalf. Insurance providers may pay for all or a portion of the test based on your health plan benefit level. If you need support to pay for related out-of-pocket costs, Provista offers patients financial assistance to those who qualify, as well as, convenient, interest-free payment plans. Contact ClientServices@ProvistaDx.com or 1-855-552-7439 for more information.

Q. I've had abnormal mammograms in the past and I'm worried about getting breast cancer. How often can I have this test done?

A. As with any type of treatment decision or diagnostic test, it is important to talk to your healthcare provider about the frequency of follow-up and if Videssa Breast is right for you.

Q. I've been diagnosed and treated for breast cancer. Will this test tell me if my cancer has come back?

A. Videssa Breast is only meant for women who have not yet been diagnosed with breast cancer. Videssa has not yet been studied in patients previously diagnosed with breast cancer, and therefore is not intended to be used to monitor for breast cancer recurrence.

Q. Can I use this test if I'm pregnant?

A. Videssa Breast is not intended for patients who are pregnant at the time of testing.

Q. Will birth control or hormone replacement therapy affect my Videssa Breast results?

A. No, women using birth control or hormone replacement therapy may use Videssa Breast.

Q. What will my healthcare provider do if the test comes back with a "high protein signature" but imaging can't find a tumor?

A. A "high protein signature" may potentially indicate the presence of breast cancer; however, the test can also have a false positive result—similar to imaging. Talk about your test result with your healthcare provider to find out if additional testing or more frequent follow-up is needed.

Q. My doctor told me that because my mammogram was abnormal, I should come back in six months for another mammogram. If my Videssa test is negative, do I really need to come back in six months?

A. Only your healthcare provider can make decisions on your health. While an abnormal or unclear mammogram can be a source of stress and anxiety over the six months between appointments, a negative Videssa Breast test result indicates that likelihood of being diagnosed with cancer is low. However, it is important that you continue regular follow-up as recommended by your healthcare provider to confirm the absence of breast cancer.

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* A High Protein Signature does not necessarily mean a patient has cancer; this test result does not diagnose cancer, only a biopsy can diagnose and confirm the presence or absence of breast cancer.