

BRACAnalysis® Large Rearrangement Test (BART™)

Large genomic rearrangements occur in a small percentage (<1%) of all patients tested for hereditary breast and ovarian cancer. In August 2002, Myriad launched an enhancement to the BRACAnalysis test to detect five common large rearrangements. The BRACAnalysis Rearrangement Test, or BART, launched in August 2006, is designed to detect large rearrangements beyond these five.

For patients who meet the defined clinical criteria outlined below, BART will automatically be performed *concurrently* with the sequence analysis of Comprehensive BRACAnalysis®. The defined clinical criteria are as follows:

Patient affected with:	Additional Family History Required:
Breast cancer before age 50	2 or more diagnoses of breast cancer before age 50 ¹ and/or ovarian cancer at any age ²
Ovarian cancer at any age	2 or more diagnoses of breast cancer before age 50 ¹ and/or ovarian cancer at any age ²
Male breast cancer at any age	2 or more diagnoses of breast cancer before age 50 ¹ and/or ovarian cancer at any age ²
Breast cancer at or after age 50 and ovarian cancer at any age	1 or more diagnosis of breast cancer before age 50 ¹ and/or ovarian cancer at any age ²
Breast cancer before age 50 and ovarian cancer at any age	No additional relatives required

¹ Male breast cancer qualifies at any age

² At least one relative must be a first or second degree relative and qualifying cancers must be on the same side of the family

Note: For this criteria, “breast cancer” includes ductal carcinoma in situ (DCIS) and invasive breast cancers.

BRACAnalysis® Rearrangement Test (BART™) Frequently Asked Questions

1. *For patients that meet the clinical criteria, how do I order BART?*

Completely fill out the clinical history section of the Test Request Form (TRF). If the clinical criteria are met, BART will automatically be performed concurrently with Comprehensive BRACAnalysis.

2. *What if I do not include my patient’s clinical information on the Test Request Form (TRF)?*

This information must be provided on the TRF in order to determine if your patient is eligible for BART to be performed concurrently.

3. *How will I be notified of my patient’s BART Test result?*

Results for Comprehensive BRACAnalysis and BART will be included in a single result report sent to you.

4. *Is a different informed consent required for BART?*

No, the standard informed consent is appropriate.

5. *How much is BART?*

For samples received from patients who meet the clinical criteria, there is no charge for this additional analysis. For patients who had Comprehensive BRCA*Analysis* prior to August 2006 or who do not meet the criteria, the charge is \$700.

6. *If my patient was previously tested and meets the criteria can they be tested?*

Yes, contact your Customer Service Specialist to initiate the process. Please note there will be a charge of \$700 for the test.

7. *If my patient does not meet the stated criteria can I order BART?*

Yes, by selecting “Other” and writing in “BART” on the TRF. There will be a charge of \$700 for the test for these patients. Please note that Comprehensive BRCA*Analysis* results and BART results will be reported separately for these patients.

8. *Will there be insurance coverage for BART?*

If a patient does not meet the defined medical criteria or has previously been tested, there will be a \$700 charge for BART. At this time, BART is not a contracted service and therefore may not be covered under a patient’s healthcare plan. While Myriad will attempt to receive insurance coverage for the test, patients will be responsible for non-covered services or any unpaid balance.

9. *What is the turn around time for BART?*

A combined result report for both Comprehensive BRCA*Analysis* and BART will be available within two weeks from the day the sample is released to the laboratory. Release may be delayed if samples arrive with incomplete TRFs or missing required information for insurance cases.

10. *Has BART been validated?*

Yes, the test has been validated and is performed in our CLIA certified, CAP accredited laboratory.

11. *How were the clinical criteria for BART determined?*

Published literature on the rate of BRCA large rearrangements were reviewed and these clinical criteria are consistent with this published literature.

12. *Will the criteria be expanded?*

The criteria are reviewed periodically. Based on various factors these criteria may be revised.

Please feel free to contact your Myriad Genetic Laboratories Patient Services Coordinator at 800-469-7423 if you have additional questions.