

Indigenously developed early-stage breast cancer detection blood test gets USFDA 'Breakthrough Designation'

19 November 2021 | News

It is the first blood test able to detect early-stage Breast Cancer with high accuracy in women above the age of 40 years

Datar Cancer Genetics, serving cancer patients in India, UK, European Union, United States, GCC, has announced that the US Food and Drug Administration (FDA) has granted 'Breakthrough Designation' for its blood test to detect early-stage Breast Cancer.

The blood test uses a proprietary technology developed by the company to detect Circulating Tumor Cells and Clusters specific to Breast Cancer with very high accuracy. Data from clinical trials has shown that the test can detect Stage 0 (DCIS) and Stage 1 Breast Cancers with accuracy of better than 99% without any false positives. The test has been validated on more than 20,000 women comprising healthy and cancer patients. The test requires only 5 ml blood and does not involve exposure to any radiation or discomfort associated with mammography.

"This is for the first time that women above the age of 40 can obtain a Breast Cancer specific blood test in consultation with their physician from the convenience and privacy of their home or office", said Rajan Datar, Chairman of the Company.

The test is already available in Europe and is CE marked. The test will be available in India shortly as 'EasyCheck' and will be reasonably priced. The company is in discussions with several leading healthcare providers for ready accessibility. The company has also validated a blood test to detect multiple cancers including several extremely lethal malignancies such as Lung, Pancreas and Ovaries and will be available next year.