OncoStem
CanAssist Breast®
predicts risk of recurrence

Patient Name	: XXXX XXXX			**Age / Gender**	: XX Years / F
Block ID	: XXXX/XX-2C	**Lab. ID**	: CAN/XXXXX/XX	**Received On**	: DD-MM-YYYY
Ref. Doctor	: Dr. XXXX XXXX			**Accepted On**	: DD-MM-YYYY
Ref. Hospital	: XXXX Hospital			**Reported On**	: DD-MM-YYYY

SAMPLE DESCRIPTION

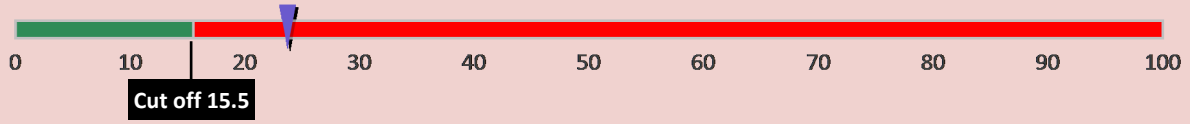
Received 2 block/s bearing number XXXX/XX 2B and 2C along with histopathology & IHC report.
Clinico-pathologic parameters mentioned below have been extracted from patient's histopathology & IHC report.

Diagnosis	: Invasive Ductal Carcinoma of Right Breast				
Tumor Size	: 2.4 x 2.3 cms.	**Pathological Stage**	: T2N0(sn)M0	**Grade**	: 3
Receptor Status	**ER** : Positive	**PR** : Positive	**HER2/neu** : Negative		

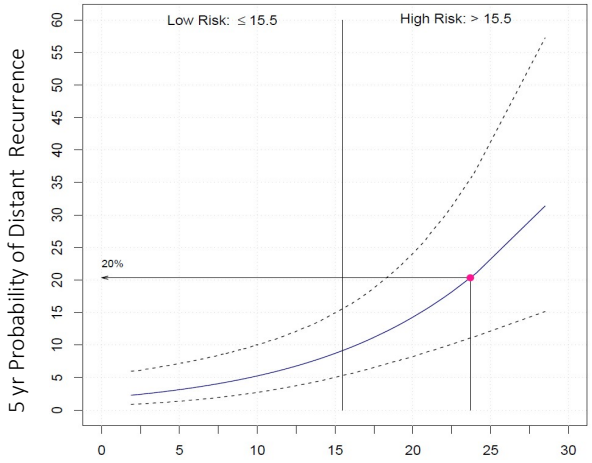
Patient referred for prognostic assessment by CanAssist Breast Test to aid treatment planning.

TEST RESULT

CanAssist Breast Risk Score: 23.7 **Risk Category: High Risk of Recurrence**



5 YEAR PROBABILITY OF DISTANT RECURRENCE



CanAssist-Breast risk score

5 Year Probability of Distant Recurrence with Hormone Therapy and Prescribed Local Radiotherapy

20 %

Probablity of distant recurrence derived from 800+ samples validation study [2] is reprensented in the graph.

TEST INFORMATION

CanAssist Breast is an IHC-based test that uses 5 biomarkers and 3 clinical parameters (tumor size, node status, and grade) to generate a risk score through a proprietary machine learning algorithm.[1] Using a cut-off of 15.5 out of 100, the test stratifies patients into low/high-risk for distant recurrence within 5 years from diagnosis. The test has been analytically and clinically validated on ~4000 samples in retrospective studies and provides superior prognostic information.[2,3] The low-risk patients have a 4.7% probability (95% CI: 3-6.4%) and high-risk patients have a 15.6% probability (95% CI:10.5-20.7%) of distant recurrence within 5 years (not accounting for any covariates).[2] The CanAssist Breast test has been shown to achieve a comparable performance to Oncotype DX.[4] For the first time, real-world data from ~6,000 patients using the CanAssist Breast test have been published, highlighting its clinical usage.[5] **CAB is included in AGOS, ISMPO and ABSI Breast Cancer Treatment Guidelines.[6,8]**

MINIMUM PERFORMANCE CRITERIA

CanAssist Breast can be performed in patients with Stage I / II, HR+ & HER2- Invasive Breast Carcinoma. The FFPE block must have at least 30% tumor content and any deviation is subject to pathologist review and acceptance.

Test performed by OncoStem Diagnostics Private Limited, No.4, Raja Ram Mohan Roy Road, Aanand Tower, 2nd Floor, Bangalore 560027.
Website www.oncostem.com **Telephone** +91 80 2224 0034 **Mobile** +91 96866 96505 **Email** info@oncostemdiagnostics.com

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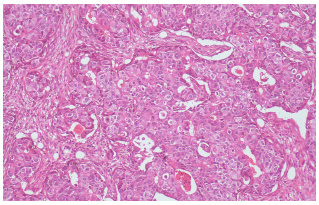
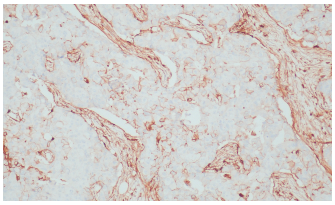
HISTOPATHOLOGY & IHC FINDINGS

Tumor content : 60%

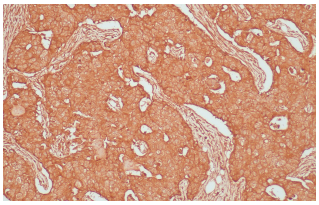
H&E



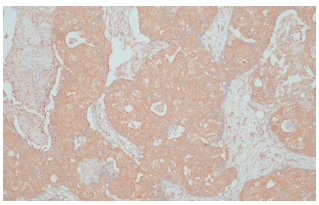
CD44



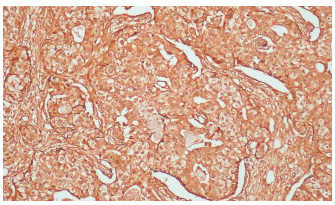
ABCC4



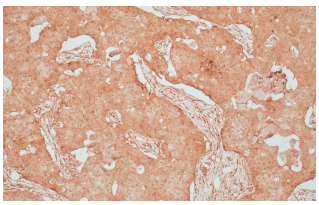
ABCC11



N-Cadherin



Pan-Cadherin



Representative IHC images from the CanAssist Breast test. All IHCs were assessed quantitatively to derive the CanAssist Breast risk score. The reported tumor cell percentage and pathology comments serves as a quality control for CanAssist Breast test and should not be viewed as a diagnosis of the malignancy.

PATHOLOGY / ADDITIONAL COMMENTS

Cold ischemia and formalin fixation time are indeterminate. Batch and internal controls show appropriate reactivity.

Pathologist

Panel of Pathologists

Pathologist 1 Pathologist 2 Pathologist 3 Pathologist 4

1. Ramkumar, C., et al. Biomarker insights (2018) 13, 1177271918789100. doi: 10.1177/1177271918789100
2. Bakre, M.M., et al. Cancer medicine (2019) 1-10. doi: 10.1002/cam4.2049
3. Durgekar, T.D., Ghosh, S., Clin. Breast Cancer (2025). doi: 10.1016/j.clbc.2025.08.022
4. Sengupta, A.K., et al. Cancer Medicine (2020). doi: 10.1002/cam4.3495
5. Durgekar, T.D., et al. Scientific Reports (2025). doi:10.1038/s41598-025-15736-9
6. Parikh, P., et al. BMC Cancer (2023). doi: 10.1186/s12885-023-11121-9.
7. Singh, R., et al. Ind J Med Paediatr Oncol (2025). DOI https://doi.org/10.1055/s-0044-1786517.
8. Somashekhar, S.P., et al. Indian J Surg Oncol (2025). https://doi.org/10.1007/s13193-025-02429-y

All IHC tests were performed on the Automated IHC staining platform at OncoStem Diagnostics,Bengaluru.This IVD is restricted to sale on the order of a physician. CanAssist Breast is a Laboratory-developed test. CanAssist Breast is an aid in estimating the risk of recurrence in patients with Breast Cancer. Treatment decisions should not be based solely on CanAssist Breast results, but rather on the independent medical judgment of the treating physician taking all the clinical-pathological variables and family history into account in accordance with accepted standard of care. More information can be found on www.oncostem.com, or email us at helpdesk@oncostemdiagnostics.com
Specific Testing information: Cold ischemia time, fixative and processing: Specimen should be placed in neutral buffered formalin within 1 hour of removal from the patient and fixed for a minimum of 6 hours but not in excess of 72 hours. Inappropriate fixation and processing may give erroneous results. Repeat testing may be considered on a different tissue or block if available.

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