Standardizing Biomarker-Based Assessments for Risk of Recurrence in Early Breast Cancer

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Recognizing the heterogeneity of recurrence risk profiles in eBC helps guide appropriate care[1]

- Patients with early breast cancer (eBC) exhibit diverse risk of recurrence profiles influenced by multiple factors, including tumor size, grade, lymph node involvement, and other molecular characteristics[1-3]
- The risk of recurrence can persist for years, making accurate risk stratification critical for management[4,5]
  - The risk of recurrence is present in all patients with HR+ eBC, even those with stage II or III disease with no to low nodal involvement[5,6]
- Differentiating between patients at high, intermediate, and low risk for recurrence is essential to tailor treatment strategies[1]

Gene expression profile (GEP)–based risk-of-recurrence assessments inform decisions regarding the necessity and intensity of adjuvant therapies, aiming to optimize benefit while minimizing unnecessary interventions[1-3]

Lack of GEP testing standardization and inconsistencies in clinical risk-of-recurrence definitions may lead to variability in management approaches in practice[1,2,7,8]

According to National Comprehensive Cancer Network® (NCCN®) and ASCO guidelines, high-risk features may include:

	NCCN[3]			ASCO[6,9,10,a]									
Positive nodes	≥4	1-3	1-3	≥4	1-3	1-3	1-3	1-3	1-3	1-3	0	0	0
Tumor grade		3			3			3	2	1	3	2	1
Tumor size, cm			≥5			≥5		Any	Any	2.1-5	1.1-5	2.1-5	3.1-5
Ki-67 index							≥20%						

Adopting uniform risk-of-recurrence definitions into the clinical workflow may help ensure that patients receive appropriate GEP testing and subsequent therapies[1,8]

NCCN and ASCO recommend the use of genomic assays to determine prognosis and prediction of benefit to guide decisions on adjuvant systemic therapy[2,3]

Integrating GEP assay results with clinicopathological risk features early is essential to obtain a comprehensive and individualized assessment of a patient's risk of recurrence[1,2]

ASCO, American Society of Clinical Oncology; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; HR, hormone receptor.
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[a]For ER+/HER2- breast cancer.[9,10]

Gene Expression Assays for Consideration of Adjuvant Systemic Therapy[2,3]

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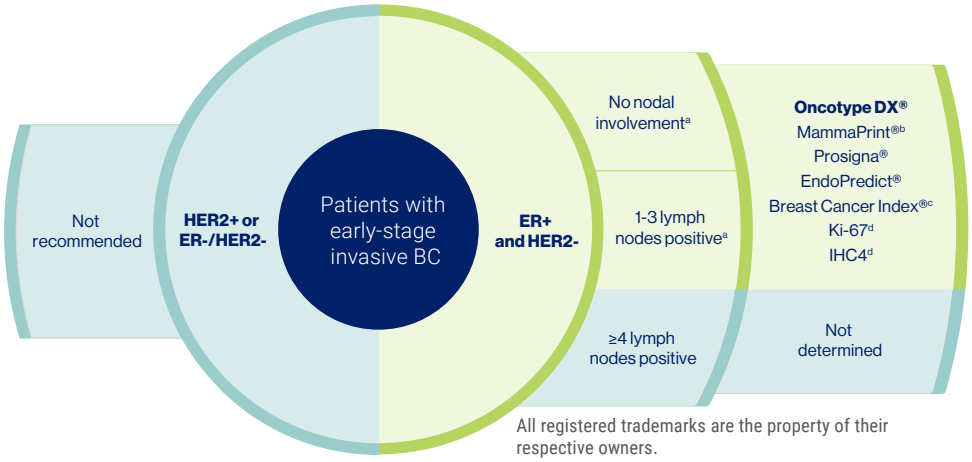

IHC4, immunohistochemistry 4.
Bold text designates high quality of evidence/strong strength of recommendation.[2]
[a]Recommendations differ based on menopausal status (premenopausal vs postmenopausal) and age (≤50 years vs >50 years). For patients who are premenopausal or ≤50 years of age, Oncotype DX is the only recommended test for node-negative disease, and there is insufficient evidence to recommend a biomarker for use for 1 to 3 positive nodes. Prosigna is only recommended for node-negative patients who are postmenopausal or >50 years of age.[2] [b]Only in patients with high clinical risk per MINDACT categorization.[2] [c]May also be offered to patients who received 5 years of endocrine therapy without evidence of recurrence.[2] [d]Only if locally validated and together with other parameters in patients who do not have access to genomic tests.[2]

Implementing standardized risk-of-recurrence assessment protocols can ensure all patients receive the appropriate evaluation and help identify those who may benefit from biomarker testing[1,8]

PULSE CHECK

How does your institution or practice integrate standardized biomarker testing into clinical practice for ER+/HER2- eBC?

Practical Considerations for Standardizing GEP-Based Assessments for Risk of Recurrence in Early Breast Cancer

- Identify patients with HR+/HER2- eBC who meet guideline criteria for GEP testing[2,3]
- Ensure timely testing to facilitate treatment planning[11]
- Understand the implications of test results to inform treatment decisions effectively[1-3]
  - ASCO recommends incorporating age, menopausal status, and nodal status when considering GEP test result interpretation[2]

Establish a comprehensive assessment of each patient's risk of recurrence by combining clinical and genomic features, enabling informed doctor-patient discussions on individual risk and treatment options to guide optimal care[2,12-14]

Provide all your patients with the right test by standardizing risk-of-recurrence assessments in eBC and discuss all treatment options

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MINDACT, Microarray In Node negative Disease may Avoid ChemoTherapy.

References: 1. Zambelli A et al. *Crit Rev Oncol Hematol*. 2023;191:104104. doi:10.1016/j.critrevonc.2023.104104 **2.** Andre F et al. *J Clin Oncol*. 2022;40(16):1816-1837. doi:10.1200/JCO.22.00069 **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.4.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed April 22, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. **4.** Early Breast Cancer Trialists' Collaborative Group. *Lancet*. 2024;404(10461):1407-1418. doi: 10.1016/S0140-6736(24)01745-8 **5.** Pan H et al. *N Engl J Med*. 2017;377(19):1836-1846. doi:10.1056/NEJMoa1701830 **6.** Amin MB et al, eds. *AJCC Cancer Staging Manual*. 8th ed. Springer Cham; 2017. **7.** Acs B et al. *Cancers (Basel)*. 2021;13(5):1166. doi:10.3390/cancers13051166 **8.** Paige JS et al. *J Gen Intern Med*. 2023;38(11):2584-2592. doi:10.1007/s11606-023-08043-4 **9.** Henry LN et al. *J Clin Oncol*. 2019;37(22):1965-1977. doi:10.1200/JCO.19.00948 **10.** Freedman RA et al. *J Clin Oncol*. 2024;42(18):2233-2235. doi:10.1200/JCO.24.00886 **11.** Snow S et al. *Curr Oncol*. 2024;31(3):1359-1375. doi:10.3390/curroncol31030103 **12.** Janz NK et al. *Breast Cancer Res Treat*. 2017;161(3):525-535. doi:10.1007/s10549-016-4076-5 **13.** Hawley ST et al. *Breast Cancer Res Treat*. 2017;161(3):557-565. doi:10.1007/s10549-016-4082-7 **14.** Lillie SE et al. *Cancer Epidemiol Biomarkers Prev*. 2007;16(2):249-255. doi:10.1158/1055-9965.EPI-06-0525

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