



Optimizing Early Breast Cancer Care With Reflex Gene Expression Profiling Testing Workflows

Benefits of Gene Expression Profiling

Gene expression profiling (GEP) tests provide predictive and prognostic information to help guide treatment decisions in early breast cancer (eBC)^{1,2}

- By integrating **GEP test results with clinical risk features**, health care professionals can make a **comprehensive and individualized assessment** of a patient's risk of recurrence^{3,4}

The National Comprehensive Cancer Network® (NCCN®) and the American Society of Clinical Oncology (ASCO) **recommend GEP testing to determine the likelihood of benefit on adjuvant systemic therapy**^{2,4}

Adopting uniform risk definitions based on tools integrating GEP test results and clinicopathological risk features may help **ensure that patients receive appropriate therapies**³⁻⁵

GEP testing may help improve patient outcomes



GEP test users had **~60% to 80% lower risk** of breast cancer (BC)-related death relative to non-users⁶

The Impact of Delayed Testing – Missed Opportunities

Delayed BC therapy initiation may lead to:

Increased mortality risk

Patients who initiated adjuvant chemotherapy >60 days after surgery had a



19% increase in the risk of death

vs those who initiated within 30 days⁷

Unnecessary chemotherapy

Genomic testing delays may lead to unnecessary chemotherapy,

increasing toxicity risks^{8,9}

In some settings, GEP testing can lead to treatment delays

>7-fold
increase in delays

Patients may be **more than 7 times more likely to have an unacceptable delay** in adjuvant treatment initiation vs those who did not receive GEP testing¹⁰

Inefficient processes may lead to a:

2.2-week
treatment delay

Patients may have a **2.2-week increase in the time to initiation** of adjuvant treatment¹¹

PULSE CHECK



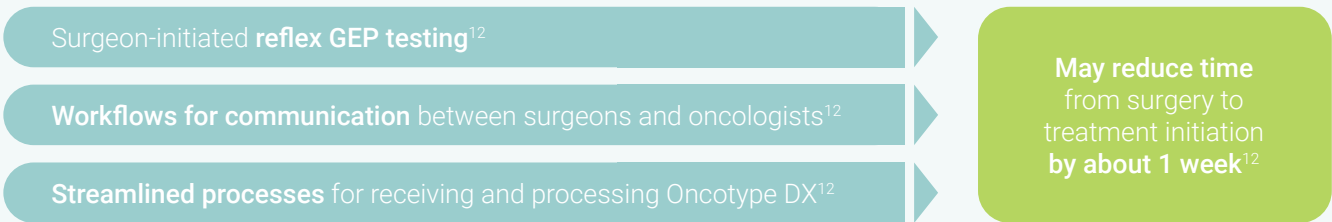
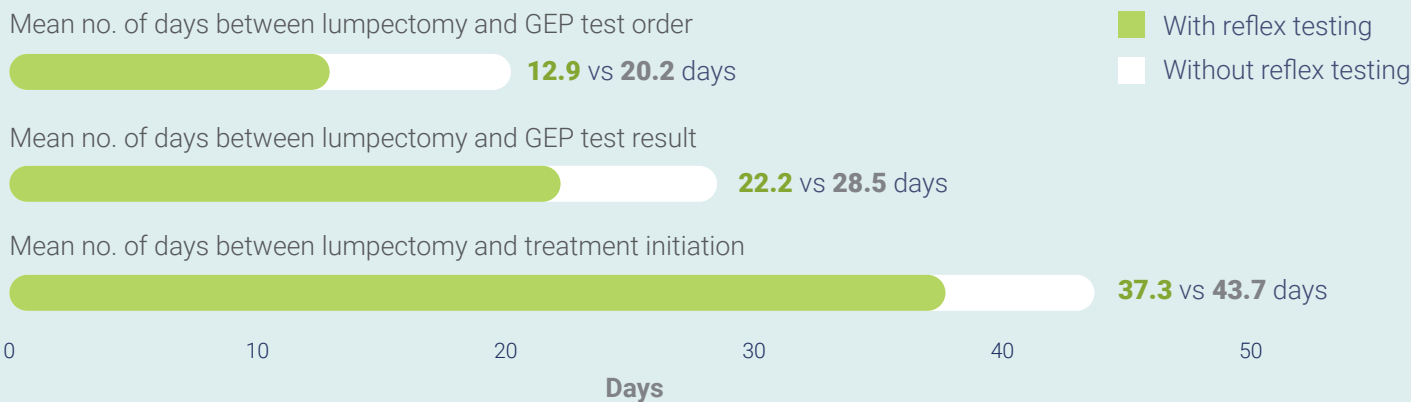
Does your institution have any of these inefficiencies in testing?

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Reflex Testing – A Game Changer: Faster Time to Therapy, Better Patient Outcomes¹²⁻¹⁴

Reflex testing—automatic testing in the standard operating procedures by pathologists or surgeons in certain situations—helps streamline biomarker analysis^{12,15}

Turnaround Time (TAT) for GEP Testing With and Without Reflex Testing^{12,16,17}



In a large community practice setting, **reflex testing reduced the TAT from surgery to treatment plan finalization from 90 days to 12.6 days¹³**



Reflex testing prevents patients from missing out on the potential benefits of early GEP results¹³

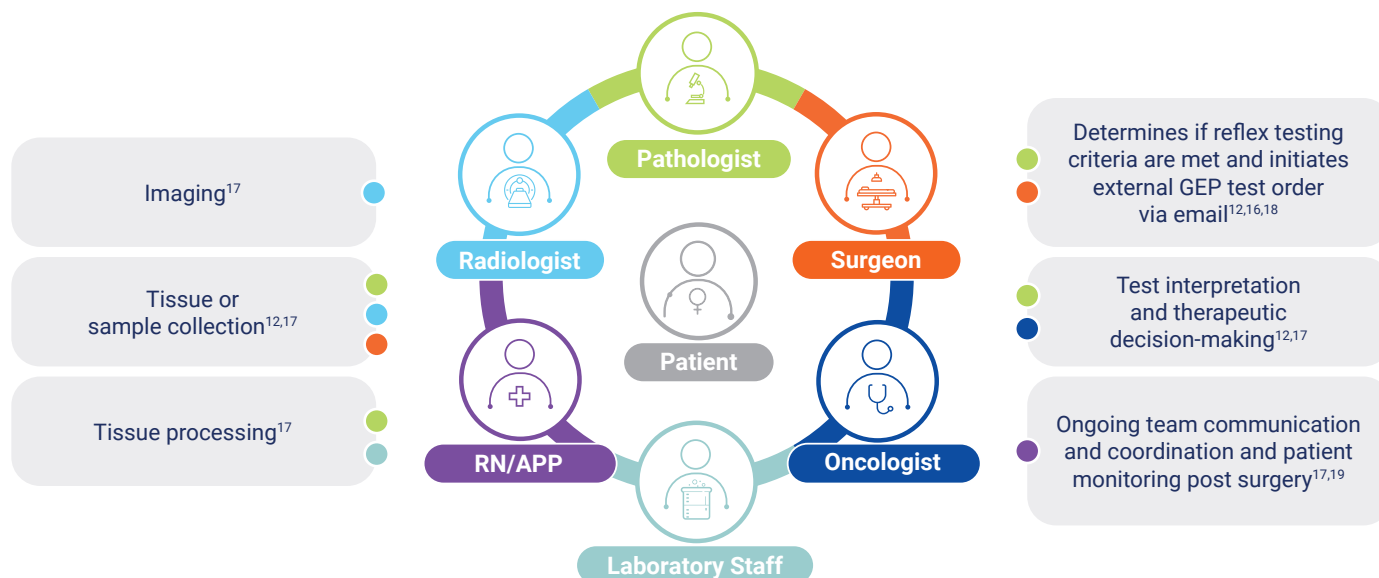
Without early GEP testing, a patient deemed at low risk of recurrence but found to be at high risk based on GEP testing might receive tamoxifen alone or require treatment interruption for subsequent chemotherapy¹³



Increasing efficiency and developing criteria for reflex ordering of GEP testing may help ensure timely care¹¹

The Importance of an MDT Approach in eBC

GEP Reflex Testing Roles and Responsibilities



The multidisciplinary team (MDT) approach ensures standardized, evidence-based decision-making^{12,17}

Pathologists and BC surgeons play critical roles in streamlining patient journeys^{12,20}

- Reflex testing should be ordered by BC surgeons or pathologists to shorten TAT^{12,20}
- Having a centralized email address for all reflex testing streamlines the pathology system for receiving and processing requests¹²

Criteria to initiate reflex testing for stage I or II invasive eBC may include^{12,20,21}

Age (Years)	Receptor Status	Nodal Status	Tumor Size (cm)	Tumor Grade
≤65	ER+/HER2-	Node-negative	1 to 2	2 or 3
			2 to 5	1 or 2
		1 to 3 positive nodes	Up to 2	
			2 to 5	

PULSE CHECK

☐

Has your institution initiated a reflex testing protocol for automatic GEP test ordering by surgeons and/or pathologists?

APP, advanced practice provider; ER+, estrogen receptor–positive; HER2-, human epidermal growth factor receptor 2–negative; HR+, hormone receptor–positive; RN, registered nurse.

Patient Perspective: The Potential Impact of Reflex Testing



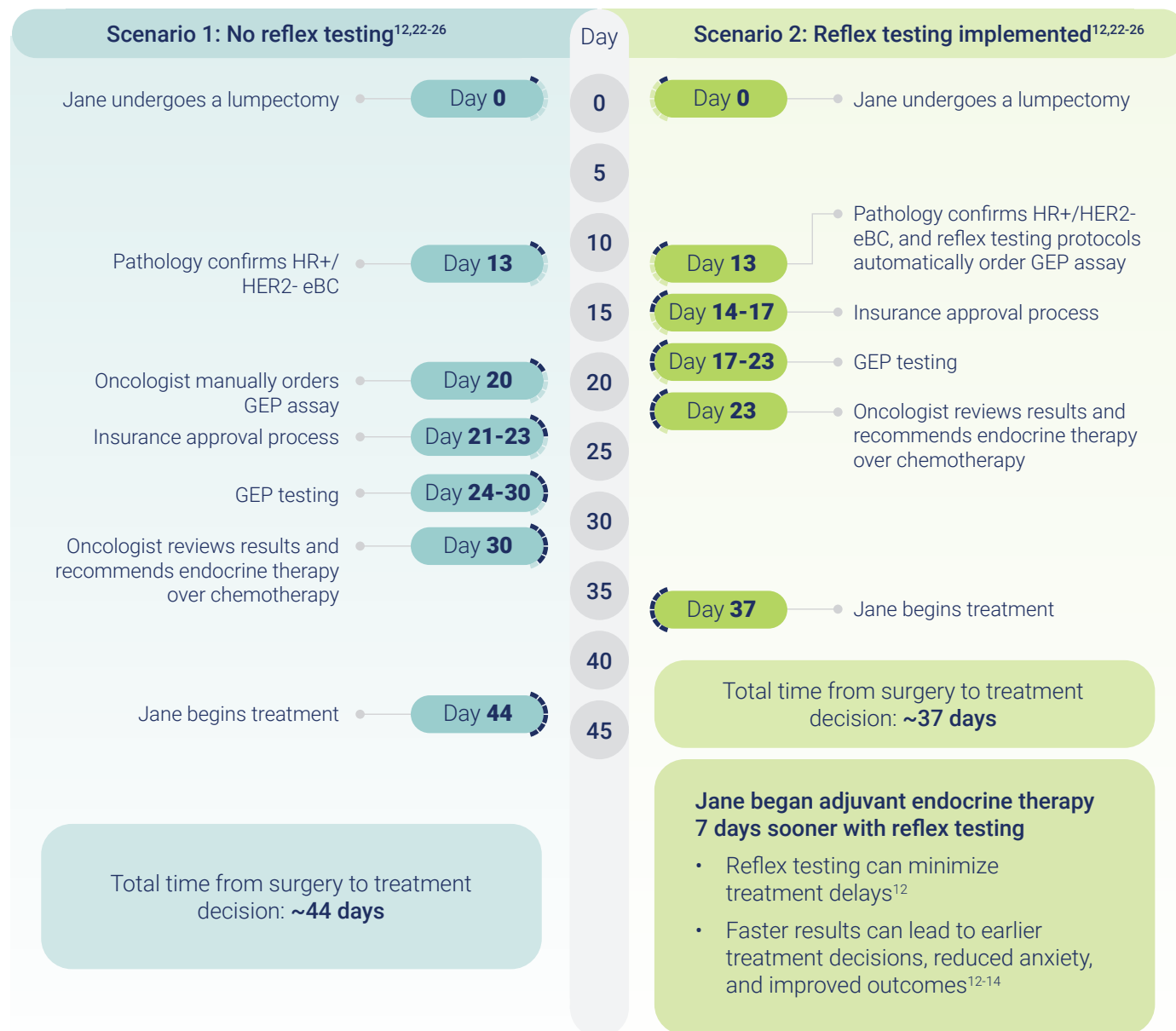
Patient Background

Name: Jane Doe; **Age:** 52 years

Medical history: Recently diagnosed with HR+/HER2- eBC

Initial symptoms: Routine mammogram detected a suspicious lesion; biopsy confirmed malignancy

First clinical visit: Surgical oncologist and medical oncologist consulted for treatment planning



Integrating GEP testing early ensures faster decision-making and personalized treatment strategies^{12,26}

References: 1. Freeman JQ, Huo D. *Cancer Epidemiol Biomarkers Prev.* 2024;33(5):635-637. doi:10.1158/1055-9965.EPI-24-0231 2. 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. 3. Zambelli A, Gallerani E, Garone O, et al. *Crit Rev Oncol Hematol.* 2023;191:104104. doi:10.1016/j.critrevonc.2023.104104 4. Andre F, Ismaila N, Allison KH, et al. *J Clin Oncol.* 2022;40(16):1816-1837. doi:10.1200/JCO.22.00069 5. Paige JS, Lee CI, Wang PC, et al. *J Gen Intern Med.* 2023;38(11):2584-2592. doi:10.1007/s11606-023-08043-4 6. Schaafsma E, Zhang B, Schaafsma M, et al. *Breast Cancer Res.* 2021;23(1):74. doi:10.1186/s13058-021-01453-4 7. Gagliato Dde M, Gonzalez-Angulo AM, Lei X, et al. *J Clin Oncol.* 2014;32(8):735-744. doi:10.1200/JCO.2013.49.7693 8. Sparano JA, Gray RJ, Makower DF, et al. *N Engl J Med.* 2018;379(2):111-121. doi:10.1056/NEJMoa1804710 9. National Institute for Health and Care Excellence. Accessed April 10, 2025. <https://www.nice.org.uk/news/articles/new-tests-could-spare-people-with-early-breast-cancer-from-unnecessary-chemotherapy> 10. Losk K, Vaz-Luis I, Camuso K, et al. *J Natl Compr Canc Netw.* 2016;14(12):1519-1526. doi:10.6004/jnccn.2016.0163 11. Vandergrift JL, Niland JC, Theriault RL, et al. *J Natl Cancer Inst.* 2013;105(2):104-112. doi:10.1093/jnci/djs506 12. Losk K, Freedman RA, Lin NU, et al. *J Oncol Pract.* 2017;13(9):e815-e820. doi:10.1200/JOP.2017.023788 13. Seidman AD, Amjadi DK, De La Melena T, et al. *Popul Health Manag.* 2017;20(4):252-254. doi:10.1089/pop.2016.0133 14. Piening B, Bapat B, Weerasinghe RK, et al. *J Clin Oncol.* 2023;41(suppl 16): Abstract 6622. doi:10.1200/JCO.2023.41.16_suppl.6622 15. Murphy MJ. *Ann Clin Biochem.* 2021;58(2):75-77. doi:10.1177/0004563221993153 16. Cree IA, Deans Z, Ligtenberg MJL, et al. *J Clin Pathol.* 2014;67(11):923-931. doi:10.1136/jclinpath-2014-202404 17. De Las Casas LE, Hicks DG. *Am J Clin Pathol.* 2021;155(6):781-792. doi:10.1093/ajcp/aqaa212 18. Smith A, Farrah K. *Ottawa (ON): Canadian Agency for Drugs and Technologies in Health;* April 18, 2019. 19. The American Society of Breast Surgeons. Accessed May 7, 2025. https://www.breastsurgeons.org/management/practice/app_toolkit 20. Pruner G, Lorenzini D, Mastropasqua MG, et al. *NPJ Breast Cancer.* 2023;9(1):3. doi:10.1038/s41523-023-00506-5 21. Amin MB et al, eds. *AJCC Cancer Staging Manual.* 8th ed. Springer Cham; 2017. 22. Rakha EA, Pinder SE, Bartlett JMS, et al. *J Clin Pathol.* 2015;68(2):93-99. doi:10.1136/jclinpath-2014-202571 23. Breast Cancer Now. Accessed April 10, 2025. <https://breastcancernow.org/about-breast-cancer/diagnosis/her2> 24. Labcorp. Accessed April 10, 2025. <https://www.labcorp.com/tests/480277/estrogen-receptor-progesterone-receptor-er-pr-immunohistochemical-paraffin-block> 25. Centers for Medicare & Medicaid Services. Accessed April 10, 2025. <https://www.cms.gov/newsroom/press-releases/cms-finalizes-rule-expand-access-health-information-and-improve-prior-authorization-process> 26. Genomic Health. Accessed April 10, 2025. <https://www.oncotypeiq.com/-/media/Project/PrecisionOncology/OncotypeIQ/Files/about-the-test/ghi10010-0616-invasive-patient-brochure.pdf?rev=a8c5604d2dd04eb2b20d7383e4b4b040>

Summary

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) and ASCO recommend the use of GEP tests to guide adjuvant therapy decisions^{2,4}

However, GEP testing delays may lead to unnecessary chemotherapy and late treatment initiation that can increase BC mortality risk⁷⁻¹¹

GEP reflex testing may result in faster time to therapy and better patient outcomes¹²⁻¹⁴

Integrating GEP reflex testing in the MDT workflow ensures a timely individualized patient recurrence risk estimate and improved patient outcomes^{12-14,20}



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