



Delphi Diagnostics Announces New Publication in the European Journal of Cancer

Peer-reviewed manuscript demonstrates the Endocrine Activity Index™ Recurrence Risk (EAI_{RR}) enhances risk stratification beyond Recurrence Score® and is predictive of endocrine therapy benefit

May 6, 2026, Houston, TX — Delphi Diagnostics today announced the publication of new clinical data in the *European Journal of Cancer* validating EAI_{RR}, as a significant independent predictor of outcomes in patients with hormone receptor-positive, node-positive breast cancer. The publication titled, “Combination of predicted sensitivity to endocrine therapy (SET_{2,3} index) and the Recurrence Score in node-positive breast cancer: Independent validation in the PACS-01 trial.” EAI is known as SET_{ER/PR} in scientific literature, and EAI_{RR} is known as SET_{2,3}.

The study, which analyzed 659 patient samples from the PACS-01 clinical trial, demonstrates that EAI_{RR} provides meaningful prognostic and endocrine-predictive information beyond the 21-gene Recurrence Score (RS).

Key Highlights

- Confirms that EAI_{RR} adds statistically significant prognostic information to RS.
- Both EAI and EAI_{RR} were independently prognostic from RS.
- Second independent prospective clinical trial validating that EAI_{RR} refines prognostic risk stratification in patients with node-positive HR+ breast cancer beyond RS, establishing level 1B evidence.
- The study included premenopausal women and patients with ≥ 4 positive lymph nodes, confirming that EAI/EAI_{RR} is prognostic in these patient groups.
- EAI strongly predicted benefit from adjuvant endocrine therapy (ET), compared to a subset of patients who did not receive ET ($p_{\text{interaction}} < 0.001$)

These findings position EAI as a differentiated biomarker that captures endocrine biology—an increasingly important driver of long-term outcomes in breast cancer and that the EAI_{RR} adds independent prognostic information to inform management decisions in breast cancer patients.

“This publication provides strong independent validation of EAI_{RR}, establishing Level 1B evidence that it adds prognostic information, and underscores its ability to provide clinically actionable biological information that is not captured by existing assays,” said Federico A. Monzon, MD, Chief Medical Officer of Delphi Diagnostics. “In addition, data showed that EAI added endocrine-predictive information, identifying which patients are

truly sensitive to endocrine therapy; thus, EAI and EAI_{RR} have the potential to further personalize treatment selection for breast cancer patients.”

1. Penault-Llorca F, et al. Combination of predicted sensitivity to endocrine therapy (SET_{2,3} index) and the Recurrence Score® in node-positive breast cancer: independent validation in the PACS-01 trial. *Eur J Cancer* (2025). DOI:<https://doi.org/10.1016/j.ejca.2025.116152>

About EAI

Delphi Diagnostics' Endocrine Activity Index® (EAI™) test can provide actionable information for prognosis and prediction of dose-intense taxane-based chemotherapy benefit in stage II-III, HR+HER2- breast cancer. The EAI measures endocrine activity in a breast tumor, and for prognostic use, the Index Score is adjusted for baseline prognosis using molecular subtype genes (RNA4) and clinical factors such as tumor size and regional lymph node involvement. The EAI test has been shown in various studies to be a consistent prognostic indicator for long-term outcomes in stage II-III breast cancer patients, to be independent of other prognostic tests, as well as to be predictive for response to dose-dense chemotherapy.

About Delphi Diagnostics

Delphi Diagnostics Inc. is a Texas-based company focused on advancing clinically valid tests for the prognosis and prediction of breast cancer treatment. Delphi Diagnostics, Inc. holds an exclusive license from The University of Texas MD Anderson Cancer Center in Houston, TX to commercialize the Endocrine Activity Index, a technology that was developed by the laboratory of Dr. W. Fraser Symmans**. The Endocrine Activity Index (EAI) test measures endocrine activity in stage II-III, HR+HER2- breast cancer. Delphi's vision is to make the EAI test available to breast cancer patients and open new pathways for personalized breast cancer treatment. To learn more, visit www.delphi-diagnostics.com.

**Dr. Symmans has a personal financial relationship with Delphi that has been identified as a conflict of interest with this research and is managed by MD Anderson's Conflict of Interest Committee.

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