

ESR1 Mutation Surveillance is Coming.

Are You Ready?

ESR1 mutations are acquired in up to 40% of HR+/HER2- mBC patients with prolonged exposure to endocrine therapies such as aromatase inhibitors.¹ Emerging clinical data has shown that routine monitoring for *ESR1* mutations followed by early intervention of novel, effective therapies can help prolong progression-free survival and improve quality of life for these patients.^{2,3}

With *ESR1* surveillance still emerging but rapidly growing in clinical interest, laboratories may not be equipped to support your testing needs today. Until your partner laboratory is locally validated with a solution to support you in perpetuity, the Asuragen Clinical Laboratory is available to support your *ESR1* testing needs immediately with



ultra-sensitive, fast, and targeted testing for the most common, pathogenic variants in *ESR1*, providing greater confidence in your results. In the meantime, Asuragen can help support your partner laboratory through validation to help provide continuous and seamless *ESR1* testing services today and well into the future.

ESR1 Testing Process

1

Order Test via Laboratory Partner

Establish Lab Services Agreement to facilitate fast, simple ordering.



2

Collect/Process Blood Sample and Send to Asuragen Clinical Laboratory

Collect whole blood in 2x10 mL K₂EDTA or PAXgene ccfDNA tubes and isolate plasma according to manufacturer's instructions. Ship on dry ice.



3

ESR1 Testing at Asuragen Clinical Laboratory

Sample processing and ultra-sensitive *ESR1* mutation detection.



4

Sample Results

Reported within 7 business days of sample receipt.



Test Overview

Technology	RT-qPCR
Coverage	E380Q, V422del, S463P, L536H/P/R, Y537S/N/C/D, D538G
Sample	K ₂ EDTA: 2×10mL whole blood spun down to plasma within four hours. Store frozen until shipment. PAXgene: 2×10mL whole blood spun down to plasma according to manufacturer's instructions. Store frozen until shipment.
Assay Sensitivity	0.03–0.11% VAF
Turnaround	7 business days from receipt.
Shipping	Ship frozen overnight Mondays–Thursdays with dry ice.

Key Benefits



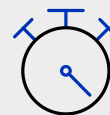
Focused Coverage

Screens for the most common *ESR1* ligand-binding domain mutations with known pathogenicity



Ultra-Sensitive

Detect variants earlier at ultra-low levels



Fast

Results within 7 business days from sample receipt

CONTACT US

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**Learn More About Our
ESR1 Testing Services**

1. BreastCancer.org. *Metastatic Breast Cancer*. Available at: <https://www.breastcancer.org/types/metastatic>. Last Accessed: 6 February 2026
2. Bidard FC, et al. *N Engl J Med* 2025;393:569–580
3. Bidard FC, et al. *The Lancet Oncology* 2022;23:11, 1367–1377

This test was developed and its performance characteristics determined by Asuragen Clinical Services. It has not been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.
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