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ESR1 Mutation Test Results

Lab ID:	**Sample ID:**	**Job ID:**
Specimen ID:	**Collection Site:**	**Report Date:**
Clinical Indication:	**Collection Date:**	

RESULT: _[POSITIVE/NEGATIVE/INCONCLUSIVE]____

The following *ESR1* mutation(s) was/were identified: _____

Interpretation

A single activating mutation in the *ESR1* ligand-binding domain was detected in circulating nucleic acids. Such mutations commonly emerge under selective pressure from aromatase inhibitor–based endocrine therapy in ER+/HER2- metastatic breast cancer and are associated with acquired resistance to aromatase inhibitors.
Clinical trials have shown that *ESR1*-mutated tumors may retain sensitivity to selective estrogen receptor degraders (SERDs), and that detection of *ESR1* mutations in plasma can inform endocrine therapy selection and timing of treatment change.

The presence of this *ESR1* mutation supports the presence of an endocrine-resistant tumor subclone and may be relevant when considering subsequent endocrine therapy options (e.g., SERD-based or other non-AI endocrine strategies) in accordance with current guidelines and drug labels. Therapy selection should integrate this result with disease burden, prior therapies, radiographic findings, and patient factors.

Consider repeat testing at clinically relevant time points or at progression to monitor clonal evolution, if clinically indicated.

Digitally reviewed and approved by:

Assay Methodology/Limitations:

This laboratory developed test consists of qualitative *ESR1* mutation profiling of the genomic region _____. It covers the following activating mutations: _____. *ESR1* mutations outside of these regions will not be detected. The test cannot distinguish between mutations within a single codon. The presence of *ESR1* mutations below LOD will not be reported.

Total Nucleic Acid is extracted, reverse-transcribed, pre-amplified with a pool of primers, and then run on a QuantStudio 7 Real-Time qPCR instrument. The workflow and subsequent analyses were optimized for ____-collected plasma samples. This test has been validated on residual clinical samples sourced from breast cancer that were mutation positive and negative. The accuracy of the test ____. Acceptable sample types are _____.

Disclaimer: 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.