

ddPLEX *ESR1* Mutation Detection Kit

Sensitive, Multiplexed Quantification of Plasma and FFPE Samples



The defined role of the *ESR1* gene in driving resistance to endocrine therapies highlights the critical nature of analyzing mutations within this target for advancing clinical research in breast cancer. The ddPLEX *ESR1* Mutation Detection Kit delivers highly sensitive detection and absolute quantification of seven key *ESR1* markers multiplexed in a single well.

Developed on the QX600™ Droplet Digital™ PCR (ddPCR™) System and powered by its streamlined workflow, this kit provides expedited results in less than a day. It was created to provide reproducible and simultaneous discrimination of mutations in either plasma or formalin-fixed paraffin-embedded (FFPE) tissue samples. The assay expands your laboratory's *ESR1* analysis capabilities to support precision oncology-based translational and clinical research studies. Discover how the ddPLEX *ESR1* Mutation Detection Kit can enhance your lab's breast cancer analysis potential.

High Analytical Sensitivity



Sensitivity as low as 0.01%

Plasma or FFPE Tissue



High-performance liquid biopsy analysis when tissue is unavailable

Cost-Effective Mutation Detection



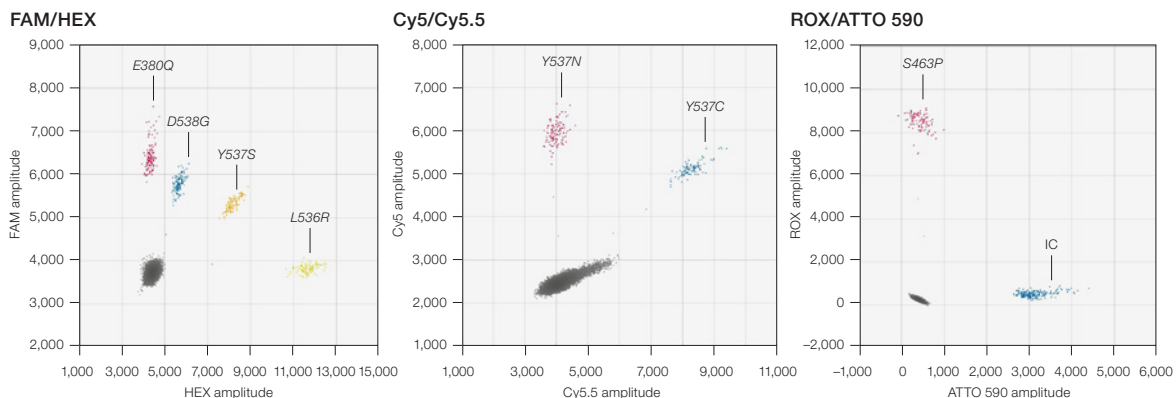
Multimarker analysis at a fraction of the cost of sequencing

Same Day Results



Sample to answer in a single work shift

Mutant Assay Demonstrating Discrimination of Seven ESR1 Variants



Discrimination of variants. Sample consisting of synthetic DNA with each of the seven *ESR1* variants at a frequency of 1% (50 copies per reaction) in a background of wild-type DNA was tested. Figure shows three wells overlaid using QX Manager Software. Wild-type assay data are not shown. IC, internal control.

Targeted ESR1 Biomarkers

Exon Number	Wild-Type Assay Allele	Mutant Assay Allele
5	380-WT	E380Q (c.1138G>C)
7	463-WT	S463P (c.1387T>C)
8	53X-WT	L536R (c.1607T>G)
		Y537C (c.1610A>G)
		Y537N (c.1609T>A)
		Y537S (c.1610A>C)
		D538G (c.1613A>G)

Summary of Limit of Detection (LOD) Results for the ESR1 Mutant Assay*

Target	Limit of Detection (variant allele frequency), %	Limit of Detection (mutant copies in 40,000 total)
E380Q	0.025	10
D538G	0.01	4
Y537S	0.025	10
L536R	0.025	10
Y537N	0.025	10
Y537C	0.025	10
S463P	0.025	10

* Samples consisting of synthetic DNA with each of the seven *ESR1* variants at frequencies of 0.5, 0.2, 0.1, 0.05, 0.025, and 0.01% in the background of wild-type DNA were tested. LOD was determined as the lowest variant allele frequency at which all eight replicates were above the predetermined limit of blank.

ddPLEX ESR1 Mutation Detection Kit Contents

Catalog Number	Component (also available separately)	Quantity
12019648	ddPLEX <i>ESR1</i> Mutation Detection Assay <ul style="list-style-type: none"> ddPLEX <i>ESR1</i> Mutant Assay, 60 reactions ddPLEX <i>ESR1</i> Wild-Type Assay, 60 reactions ddPLEX Enhancer ddPLEX Internal Control 	1
12019606	ddPLEX <i>ESR1</i> Positive Control	1
12005909*	ddPCR Multiplex Supermix	2
12012171	Dithiothreitol (DTT)	1

* Other ddPCR Multiplex Supermix packaging options are also available (catalog #12005910 and 12005911).

Ordering Information

Catalog #	Description
17009501	ddPLEX <i>ESR1</i> Mutation Detection Kit



Visit [bio-rad.com/ESR1](https://www.bio-rad.com/ESR1) for more information.

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