Droplex

ESR1 Mutation Test

CE IVD

Cat No. CD009, CD015
Cancer Type Breast Cancer
Regulatory Status IVD(CD009), RUO(CD015)
Compatible Sample Type FFPE tissue(IVD)
FFPE tissue, Plasma(RUO)
Mutation Variants 16(19*)
2 well-reactions/test (24 tests/kit)
Storage Temp -20°C (+/-3°C)

OM1		OM2	
Codon 534/536/537/538	Internal Control	Codon 380	Codon 463

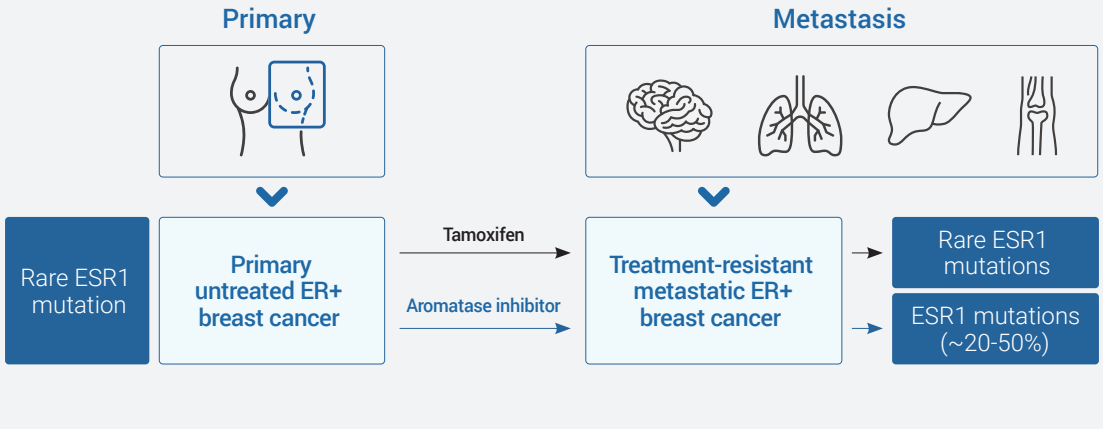
Mutaion Coverage

*The mutations included in the RUO product.

ESR1	Codon 380	Codon 463	Codon 534	Codon 536	Codon 537	Codon 538
	· E380Q	· S463P	· V534E	· L536P/R/Q/H · L536P/R/Q/H/G*/K*	·Y537S/C/N/H/D	· D538G · D538G/E*

ESR1 mutations are frequently found in advanced and metastatic breast cancer patients

ESR1 mutations rarely exist in primary tumors(~ 1%) but are relatively common(20~50%) in metastatic, endocrine therapy-resistant cancers and are associated with a shorter progression-free survival.



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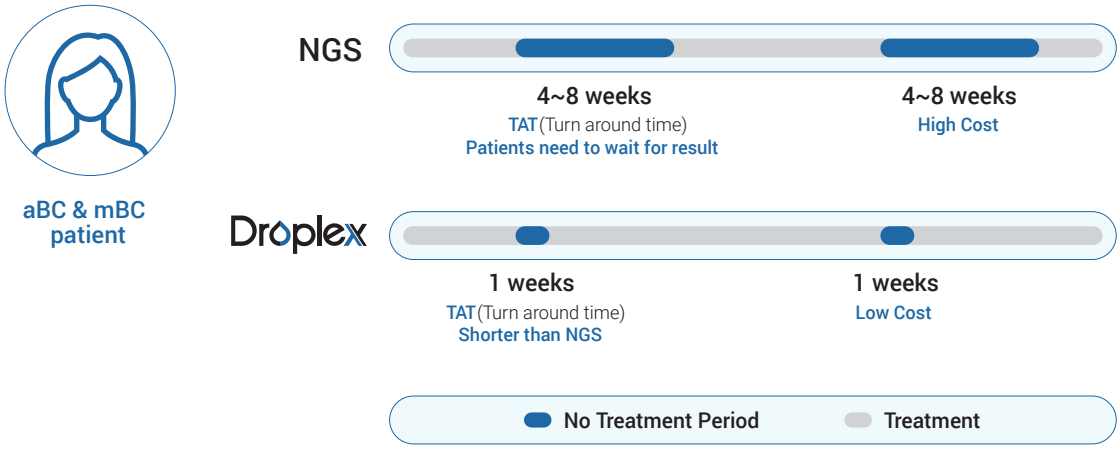
Droplex ESR1 Mutation Test

Why ddPCR for ESR1 mutation test?

There is **strong concordance** [ICC = 0.93] between ESR1 mutation allele frequency detected by **ddPCR** and **NGS**[1,2]

The **Droplex ESR1 Mutation Test** enables ESR1 mutation monitoring with a **shorter TAT(Turn around time)** and **lower cost** than NGS.

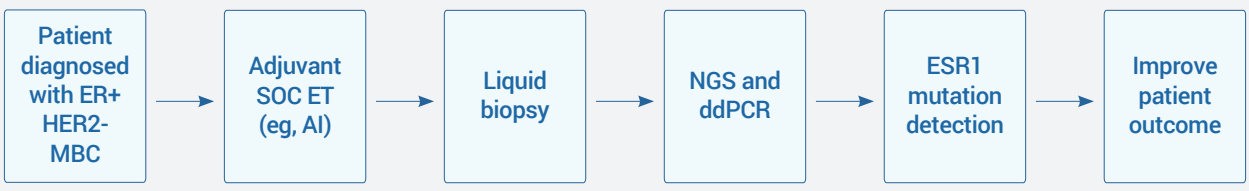
ESR1 mutation requires routine testing – NGS can be time consuming for multiple test for monitoring



Guidelines

Blood-based ctDNA liquid biopsy is preferred owing to **greater sensitivity** in detecting **ESR1-mut** status, as recommended by **ESMO, NCCN, and the ASCO guidelines**[3-7]

ASCO Expert Panel (2023) updates test the guideline to recommend routine testing for ESR1 mutations at disease recurrence or upon progression on endocrine therapy in this patient population.



1. Callens C et al. Anal Chem 2022; 2. Jeannot E et al. Oncogene 2020; 3. Lone SN et al. Mol Cancer 2022; 4. Pascual J et al. Ann Oncol 2022; 5. Burenstien HJ. J Clin Oncol 2023; 6. NCCN Guidelines Version 2.2023: Breast Cancer; 7. Spoerke JM et al. Nat Commun 2016

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