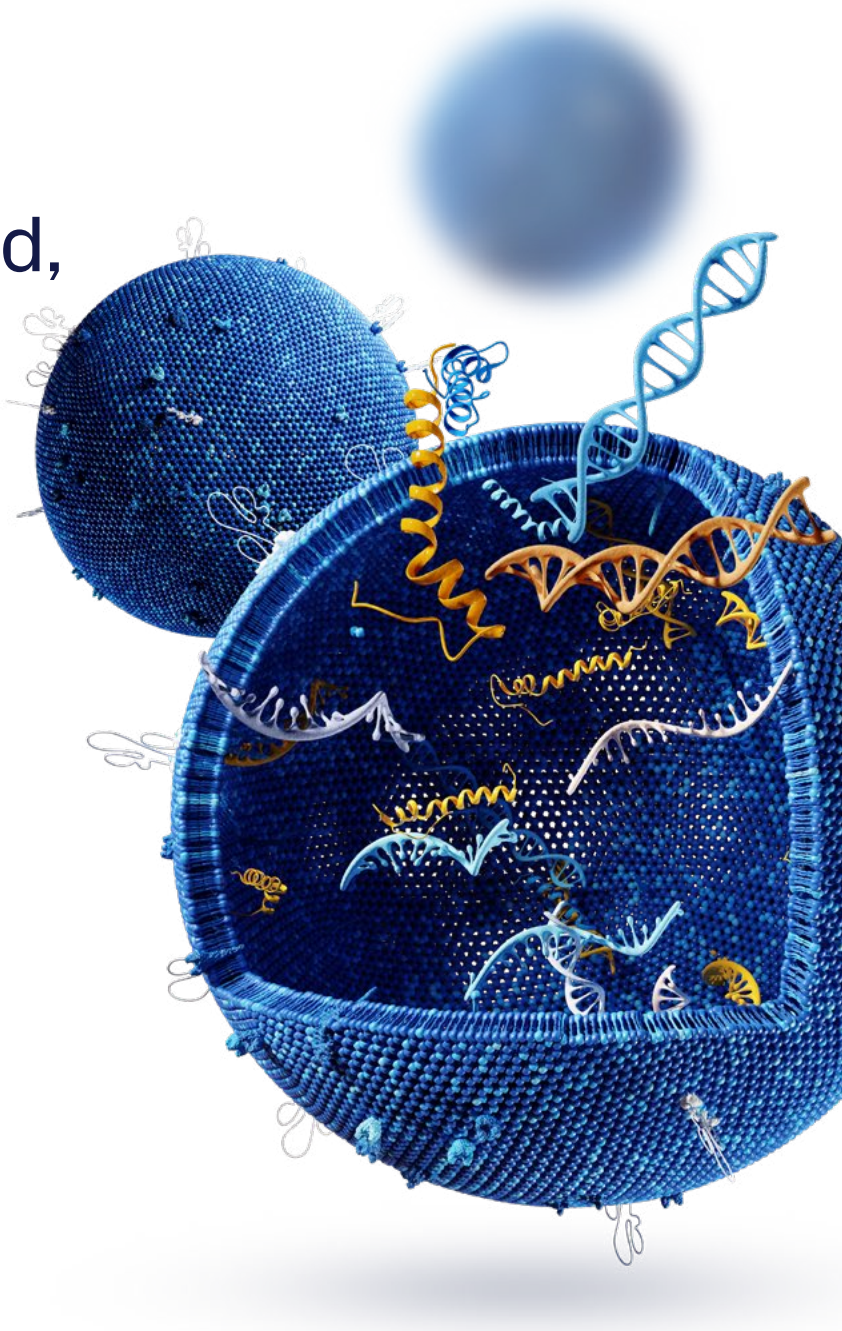
biotechne® / Asuragen®

Bringing Exosome-Powered, High-Sensitivity *ESR1* Mutation Testing to qPCR



QuantideX®
qPCR *ESR1* exoMutation Kit*

ExoLution™ Plus cfDNA + exoRNA Isolation Kit*

The Quantidex® qPCR *ESR1* exoMutation Kit is the first multi-analyte liquid biopsy assay tailored for detecting *ESR1* mutations. Designed to provide highly sensitive detection in 11 of the most prevalent *ESR1* variants in plasma, the kit offers a novel approach to achieving more meaningful breast cancer insights.

Streamlining cfDNA + exoRNA Co-Isolation

The QuantideX qPCR *ESR1* exoMutation Kit is paired with the ExoLution™ Plus cfDNA + exoRNA Isolation Kit, leveraging proprietary chemistries to co-isolate cfDNA + exoRNA in a single workflow. ExoLution Plus includes all necessary reagents and consumables for high-quality, multi-analyte isolation to power downstream mutation detection.

	Sample Preparation	ExoLution™ Plus	Reverse Transcription	PreAmp PCR	qPCR	Data Analysis	Total
Hands-On Time	10 min	30 min	10 min	5 min	10 min	2 min	67 min
Instrument Time	30 min	30 min	90 min	25 min	75 min	1 min	251 min

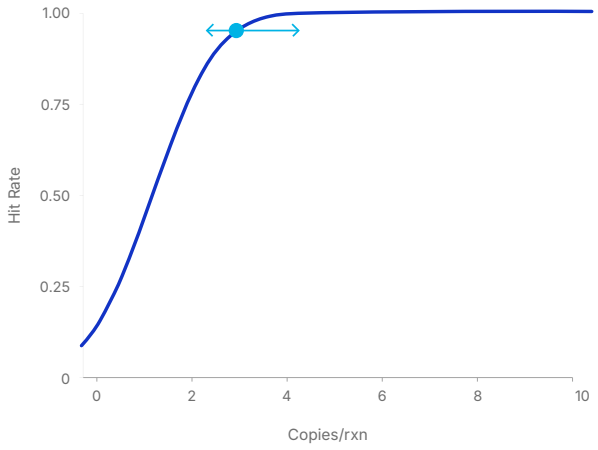
Note: Hands-on time will vary depending on the number of samples being run. Above is based on 6 samples.

Controls Included in the QuantideX qPCR *ESR1* exoMutation Kit

	Controls Provided with QuantideX qPCR *ESR1* exoMutation Kit	
Within Sample Control (IC1, IC2 & IC3)	Internal Controls	An **Internal Control (IC)** is included in all 3 mixes (A,B & C) Because we don't require users to quantitate their qPCR input, the IC informs the user if they have added adequate sample into each testing well, removing the requirement to quantitate starting input.
Batch Controls	Positive Control	The **Positive Control (CONP)** is a DNA based control for 6 of the 11 targeted mutations. Each mix contains 2 mutations as a positive control and the internal control. • Mix A: D538G & S463P • Mix B: Y537X & E380Q • Mix C: L536X & V422del The Positive Control demonstrates successful qPCR via positive signal in all 3 mixes across 2 mutant channels and in the internal control channel.
	Negative Control	The **Negative Control (CONN)** is an RNA based negative control. It acts as: • A batch contamination control • Demonstrates a successful Reverse Transcriptase (RT) reaction within the RT-qPCR workflow via positive signal in all 3 mixes in the internal control channel.

Limit of Detection Demonstrates High Sensitivity

Probit analysis of synthetic DNA (0, 1, 3, 5, 10 copies/rxn, 20 replicates of each) titrated in a background of presumed normal DNA (10,000 total copies).



Target	LOD (%VAF)*	Company A (qPCR)	Company B (dPCR)
D538G	0.082%	0.4%	0.01%
S463P	0.066%	0.08%	0.025%
Y537S	0.025%	0.1%	0.025%
Y537C	0.028%	0.4%	0.025%
Y537N	0.025%	0.2%	0.025%
Y537D	0.030%	-	-
E380Q	0.028%	1.0%	0.025%
L536R	0.028%	0.7%	0.025%
L536H	0.041%	0.8%	-
L536P	0.028%	0.9%	-
V422del	0.030%	-	-

*ABI QuantStudio 5 Dx

High Analytical Specificity Observed Across Both K_2EDTA, PAXgene Tubes

Evaluation of target analytical specificity (exclusivity) was determined on plasma procured from presumed normal samples.

- Utilized ExoLution Plus cfDNA + exoRNA Isolation Kit workflow for nucleic acid isolation
- Support of multiple collection tubes provides more flexibility to accommodate nuances across laboratory operations

Blood Collection Tube	Specificity based on Negative Percent Agreement (NPA)
K_2EDTA	97.1%
PAXgene Blood ccfDNA Tube	97.7%

Achieve more meaningful breast cancer insights today

*For Research Use Only. Not for use in diagnostic procedures.
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