biotechne® / Asuragen®

QuantideX®
qPCR *ESR1* exoMutation Kit*

Bringing Ultra High-Sensitivity to *ESR1* Mutation Detection

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 of the 11 most prevalent[1] *ESR1* variants in plasma. The kit utilizes both cfDNA and exosomal RNA, which are isolated using the ExoLution™ Plus cfDNA + exoRNA Isolation Kit*, provided with the *ESR1* exoMutation Kit. The kit offers a novel approach to achieving more meaningful breast cancer insights.

Complete QuantideX qPCR *ESR1* Workflow in a Single Day

QuantideX qPCR *ESR1* exoMutation Kit provides all the reagents including buffers, enzymes, and positive and negative controls necessary for 50 RT-qPCR reactions and 50 isolations of both cfDNA and exosomal RNA completed in less than 6 hours.

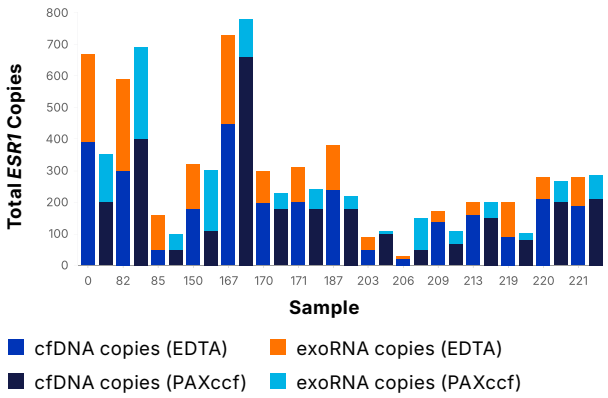
Variant detection as low as 0.025%VAF†

Synthetic DNA (0, 1, 3, 5, 10 copies/reaction) titrated in a background of presumed normal DNA (10,000 total copies).

Target	LOD (%VAF)†		
	Asuragen (qPCR)	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%	-	-

Note: If no %VAF is shown in either Company A or B, the associated variant is not supported by their product.

The Addition of Exosomal RNA (exoRNA) Boosts the Sensitivity of the *ESR1* Signal by ~60% Over cfDNA Alone



cfDNA and exoRNA distribution across 15 normal female plasma samples shows an increase in *ESR1* copies due to exoRNA using two different sample collection tubes.

Experimental Design

2 mL of plasma (K_2EDTA + PAXgene Blood ccfDNA Tubes) were collected from 15 presumed normal female subjects and underwent exoRNA and cfDNA co-isolation using ExoLution Plus Kit.

Samples were Split

- Reverse Transcription reaction **with enzyme** (+RT) using half of the eluate to quantify total nucleic acid contribution to *ESR1* copies (exoRNA & cfDNA)
- Reverse Transcription reaction **without enzyme** (-RT) using half of the eluate to quantify DNA contribution to *ESR1* copies (cfDNA only)

Balance High Sensitivity with High Analytical Specificity

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

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

Ordering Information

Part Number	Product Description	Number of Reactions
A01031	QuantideX® qPCR *ESR1* ExoMutation Kit*	50
A00669	QuantideX® ExoLution Plus Kit	50

Achieve more meaningful breast cancer insights today

	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. Time estimates above are based on 6 samples. Verified instruments: ABI 7500 Fast Dx, QuantStudio 5 Dx and QuantStudio 7 Pro Dx

*For Research Use Only. Not for use in diagnostic procedures. †ABI QuantStudio 5 Dx

1. PLoS One. 2020 May 6;15(5):e0231999.

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