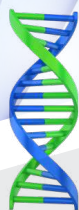




Breast Cancer Mutation Profiling



Highly Sensitive Detection of PIK3CA variants

PIK3CA is the most commonly mutated gene in HR+/HER2- advanced breast cancer and *PIK3CA* mutations are an indicator of poor prognosis. Determining *PIK3CA* variant status, especially during the initial stages of assessment, can inform clinical research studies of PI3Kα inhibitors that may result in a more positive response.

The ClearSEEK™ *PIK3CA* Panel targets a set of 20 variants in *PIK3CA* associated with response to targeted therapy, including the activating mutations recommended by the National Comprehensive Cancer Network Guidelines.¹

The Agena Bioscience® Solution

- Detect variants as low as 1% minor allele frequency.
- Utilize a variety of sample sources including formalin-fixed, paraffin embedded tissue with less than 10% tumor burden.²
- Obtain results quickly and at a low cost.

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

Genes & Mutations

Pre-designed panel for the identification of clinically relevant variants across *PIK3CA* for breast cancer clinical research.

Gene	Variants
PIK3CA	p.C420R
	p.E542K , p.E542Q
	p.E545K , p.E545Q, p.E545A , p.E545G , p.E545V, p.E545D (G>T and G>C)
	p.Q546K, p.Q546E , p.Q546P, p.Q546R , p.Q546L
	p.H1047N, p.H1047Y , p.H1047P, p.H1047R , p.H1047L
Total Variants:	20

Variants in bold are recommended in the NCCN guidelines for breast cancer.

ASSAY WORKFLOW

DNA to data in as little as 8 hours with minimal manual processing time enables greater lab efficiency. Simplified reporting with automated software generates clear results.

ORDERING INFORMATION

The assay panel set is available for use on the MassARRAY® System with Chip prep module in 96-format. The panel set contains assay specific primers and all the required reagents to process DNA samples on the MassARRAY system.

Catalog No.	Item	Sample Type	# Samples	Chip Format
13316F	ClearSEEK PIK3CA Panel Set – CPM (5x96)	Tissue	160	CPM-96

References

1. National Comprehensive Cancer Network (NCCN) Guidelines – Breast Cancer. Version 2.2022
2. AH Box et. al. Evaluation of a Mass Spectrometry-Based PIK3CA Mutation Assay for Predictive Breast Cancer Therapeutic Decision Making. Poster session presented at: Association of Molecular Pathology Annual Meeting; 2020

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Agena Bioscience, Inc.
4755 Eastgate Mall
San Diego, CA 92121
Phone: +1.877.443.6663

Order Desk: +1.858.202.9301
Order Desk Fax: +1.858.202.9220
orderdesk@agenabio.com
Website: www.agenabio.com

Online Support:
<https://support.agenabio.com>

