



Precipio, Inc.

# Instructions for Use

**PIK3CA Exon 9 Mutation Enrichment using ICE COLD-PCR**

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## Manufacturer

This Kit was manufactured by Precipio, Inc. at 8813 F Street, Omaha, NE 68127, USA.  
USA Telephone 1-203-787-7888

## Intended Use

**For professional use only.** Precipio's ICEme Kit offerings are *in vitro* diagnostic assays that enrich clinically actionable somatic mutations in a target of interest. This kit is specifically designed to enrich for mutations in Exon 9 of the PIK3CA gene that are of clinical relevance. This kit is designed to be used in a clinical diagnostic laboratory by suitably trained personnel testing DNA extracted from formalin-fixed paraffin embedded tissues or from plasma.









## Reagent Preparation

All reagents supplied with this kit are ready to use. Some components will need to be thawed, vortexed and/or spun in a microcentrifuge before use; check details in Assay Procedure below. Reagents do need to be combined to produce Master Mixes and reaction mixtures; full details are given in the procedure below.

## Kit Components and Storage Conditions

The PIK3CA Exon 9 Kit contains the components to perform ICE COLD-PCR amplification for mutation enrichment for 24 total samples with controls. Enough reagents, including controls, are present to accommodate 4 batches of 6 samples. Recommended storage conditions are listed in **Table 1**.

**Table 1:** Kit components with recommended storage conditions.

Reagent, ICE COLD-PCR	Lid Color	Color of Label	Number of Tubes	Volume Total (μL)	Storage (°C)
10X Primer/RS-Oligo Mix			1	290	-20
2X Polymerase Master Mix			4	360	-20
Wild-Type Control			1	66	-20
1% E545K Control			1	66	-20

This kit was designed specifically to enrich the following mutations:

1. c.3140A>G; p.E545K
2. c.1624G>A; p.E542K
3. c.1634A>G; p.E545G