



Precipio, Inc.

Instructions for Use

**EGFR Exon 19 Mutation Analysis using ICE COLD-PCR for
Detection with High Resolution Melting**

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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

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.















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 19 of the EGFR 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.

Kit Components and Storage Conditions

The EGFR Exon 19 Kit contains the components to perform ICE COLD-PCR amplification for mutation enrichment as well as High Resolution Melting 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	Clear 	Blue 	1	290	-20
2X Polymerase Master Mix	Clear 	Green 	4	360	-20
Wild-Type Control	Clear 	White 	1	66	-20
1% E19DEL Control	Clear 	Red 	1	66	-20
Reagent, HRM	Lid Color	Color of Label	Number of Tubes	Volume Total (μL)	Storage (°C)
HRM Primer Mix	Clear 	Yellow 	1	60	-20
2X HRM Master Mix	Black 	White 	1	960	-20
Sanger Sequencing Primer, 10 μM*	Clear 	Orange 	1	60	-20

* Can be used for uni-directional Sanger Sequencing confirmation.

This kit was designed specifically to enrich all insertions, deletions, and indels in Exon 19. The control for this kit is: c.2235_2249delGGAATTAAGAGAAGC; p.E746_A750del.

Reagents Required but not Supplied

1. Molecular Biology Grade Water: Thermo Fisher Catalog # AM9937