



Precipio, Inc.

Instructions for Use

**EGFR Exon 12 Mutation Analysis using ICE COLD-PCR for
Detection with Sanger Sequencing**

Table of Contents

Manufacturer	2
Intended Use	2
Reagent Preparation	2
Kit Components and Storage Conditions	2
Reagents Required but not Supplied	3
Optional Reagents not Supplied	3
Primary Sample Collection, Handling and Storage	3
Notes for this Assay	4
ICE COLD-PCR Protocol	5
Thermal Cycler Program for ICE COLD-PCR	8
Quality Control of ICE COLD-PCR Products (OPTIONAL)	8
Sanger Sequencing of the ICE COLD-PCR products using the ABI 3730xl DNA Analyzer	8
Technical Support/Questions	9

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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 12 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.

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 EGFR Exon 12 Kit contains the components to perform ICE COLD-PCR amplification for mutation enrichment as well as single direction Sanger sequencing 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**.