



Precipio, Inc.

Instructions for Use

**EGFR Exon 21 Mutation Analysis using ICE COLD-PCR for
Detection with Sanger Sequencing**

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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 21 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 21 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**.