

## Certificate of Analysis SALSA<sup>®</sup> MLPA<sup>®</sup> Probemix P315 EGFR

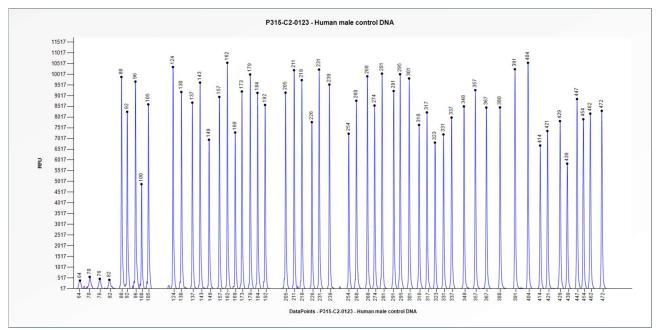
Catalogue #	P315-025R, P315-050R, P315-100R	
Product name	Probemix P315 EGFR	
LOT	C2-0123	
Σ	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
X	Store upon arrival between -25°C and -15°C.	
	Expiration date: January 2028 when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Purpose	This product has been developed to detect copy number alterations and two point mutations in the human <i>EGFR</i> gene, as described in table 1 and 2 of the product description. This probemix is designed for use only in combination with SALSA MLPA reagent kits, SD006 Binning DNA and Coffalyser.Net analysis software as described in the MLPA General Protocol.	
Quality control specifications	<ul> <li>Sufficient distance between peaks, absence of extra or shoulder peaks, and completeness of hybridisation of each individual probe, as tested on Applied Biosystems and Beckman/SCIEX GeXP sequencers.</li> <li>Standard deviation of each individual probe ≤0.10, when tested on 23 different DNA samples of healthy individuals, extracted by various methods.</li> <li>Each individual probe meets reaction-specific criteria when tested on a single DNA sample under various experimental conditions.</li> <li>No-DNA controls result in only five major peaks shorter than 121 nucleotides (nt): four Q-fragments at 64, 70, 76 and 82 nt, and one peak in the range of 0-40 nt corresponding to the unused portion of the fluorescent PCR primer. Non-specific peaks longer than 121 nt AND with a height &lt;25% of the median of the four Q-fragments are not expected to affect MLPA reactions when sufficient (50-250 ng) sample DNA is used.</li> </ul>	Test result PASS

None of the ingredients are derived from humans, animals, or pathogenic bacteria. Based on the concentrations present, none of the ingredients are hazardous as defined by the Hazard Communication Standard. **A Safety Data Sheet (SDS) is not required for these products**: none of the preparations contain dangerous substances (as per Regulation (EC) No 1272/2008 [EU-GHS/CLP] and amendments) at concentrations requiring distribution of an SDS (as per Regulation (EC) No 1272/2008 [EU-GHS/CLP] and 1907/2006 [REACH] and amendments). If spills occur, clean with water and follow appropriate site procedures.

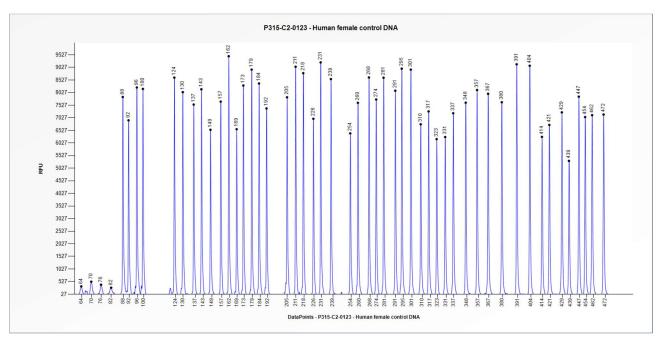
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## Certificate of Analysis SALSA MLPA Probemix P315-C2 EGFR sample pictures

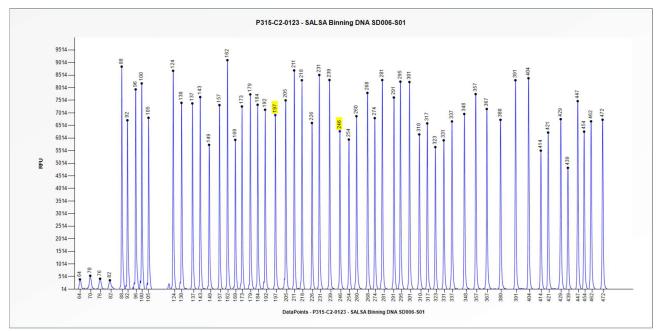


**Figure 1.** Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P315 EGFR (C2-0123).



**Figure 2.** Capillary electrophoresis pattern from a sample of approximately 50 ng human female control DNA analysed with SALSA MLPA Probemix P315 EGFR (C2-0123).





**Figure 3.** Capillary electrophoresis pattern from SALSA Binning DNA SD006-S01 (approximately 50 ng) analysed with SALSA MLPA Probemix P315 EGFR (C2-0123).The location of the c.2369C>T= p.T790M and c.2573T>G= p.L858R *EGFR* mutation-specific probes at 198 and 246 nt are indicated.

## This lot was certified by MRC Holland on 31 January 2023.

This certificate is a declaration of analysis at the time of the manufacturing process. All assays were run in compliance with manufacturer's instructions for use.

## Implemented changes in the COA Version 01 – 31 January 2023 (6) - Not applicable, new document.