




Certificate of Analysis

SALSA® MLPA® Probemix P437 Familial MDS-AML

Catalogue #	P437-025R, P437-050R, P437-100R	
Product name	Probemix P437 Familial MDS-AML	
LOT	B1-0520	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: May 2025, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Purpose	<p>This product has been developed to determine the DNA copy number of all exons of the human <i>GATA2</i>, <i>TERC</i>, <i>TERT</i>, <i>CEBPA</i> and <i>RUNX1</i> genes and the last exon of the human <i>EPCAM</i> gene, as described in table 1 and 2 of the product description.</p> <p>This probemix is designed for use only in combination with SALSA MLPA reagent kits, SD070 and Coffalyser.Net analysis software as described in the MLPA General Protocol.</p>	
Quality control specifications	<ul style="list-style-type: none"> - 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. - Standard deviation of each individual probe ≤ 0.10, when tested on 23 different DNA samples of healthy individuals, extracted by various methods. - Each individual probe meets reaction-specific criteria when tested on a single DNA sample under various experimental conditions. - 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 <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. 	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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SALSA MLPA Probemix P437-B1 Familial MDS-AML sample picture

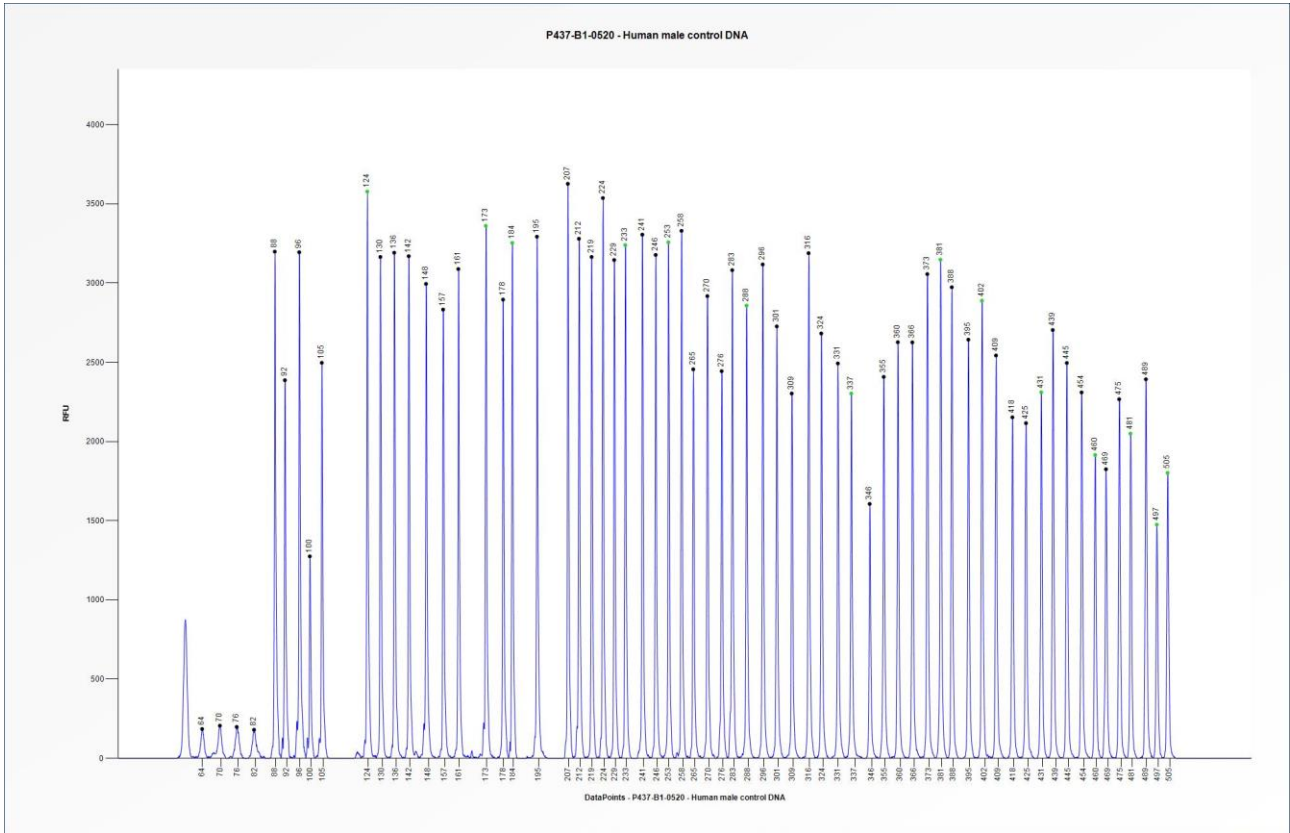


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P437 Familial MDS-AML (B1-0520).

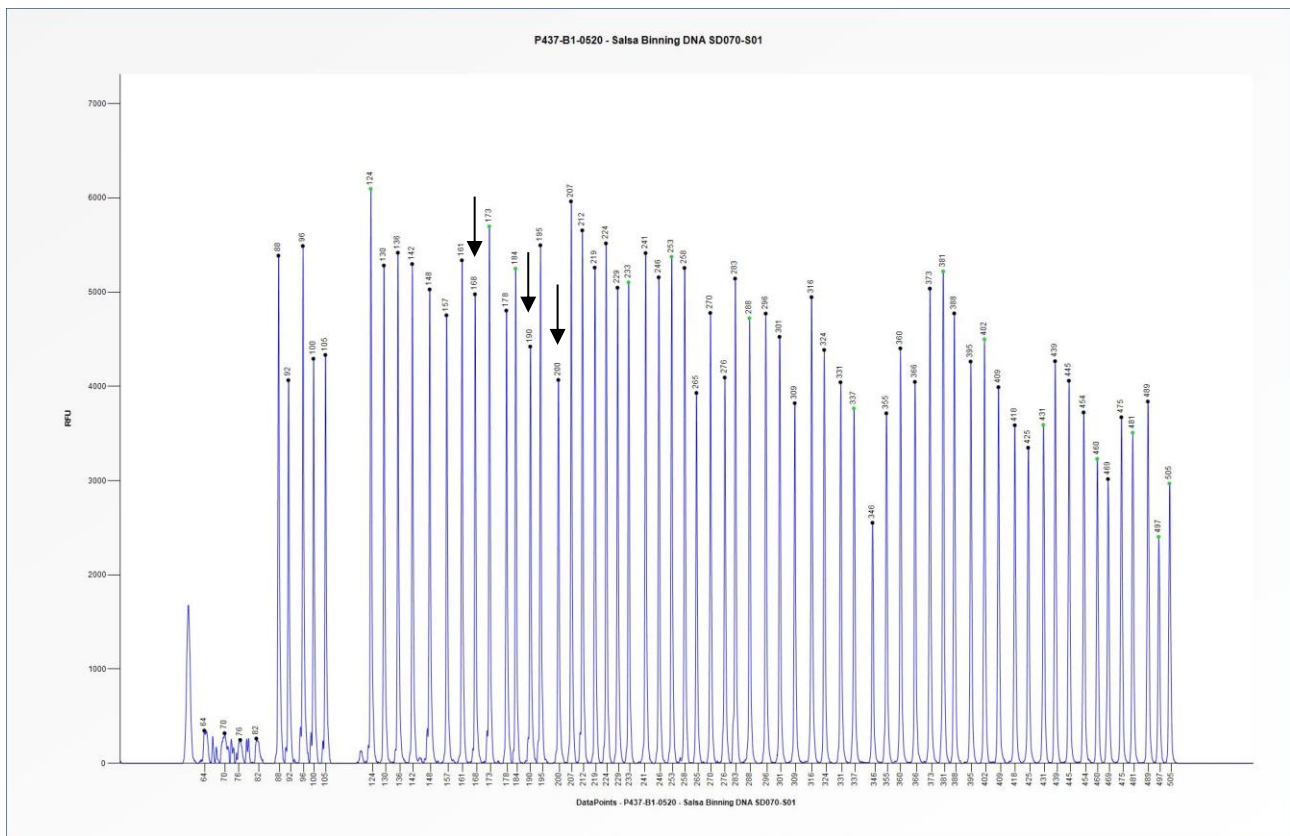


Figure 2. Capillary electrophoresis pattern from SALSA Binning DNA SD070-S01 (approximately 50 ng) analysed with SALSA MLPA Probemix P437 Familial MDS-AML (B1-0520). The locations of the *GATA2* (p.R398W, p.T354M) and *TERT* (p.A1062T) mutation specific probes at 168, 190 and 200 nt, respectively, is indicated.

This lot was certified by MRC Holland on 18 May 2021.

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 – 18 May 2021(6)
- Not applicable, new document.