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	**B1-0723**

Σ	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: July 2028 when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Purpose	This product has been developed to determine the DNA deletions or duplications in the human *GATA2, TERC, TERT, CEBPA* and *RUNX1* genes, and GATA2 p.R398W (c.1192C>T), GATA2 p.T354M (c.1061C>T) and TERT p.A1062T (c.3184G>A) point mutations 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, SD070 and Coffalyser.Net analysis software as described in the MLPA General Protocol.	
Quality control specifications	- 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. Note that standard deviation for the mutation specific probes is not determined because they either do not generate a signal or that the signal under the threshold on DNA from healthy individuals. - 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.

More information: www.mrcholland.com; www.mrcholland.eu	
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Certificate of Analysis
SALSA MLPA Probemix P437-B1 Familial MDS-AML sample picture

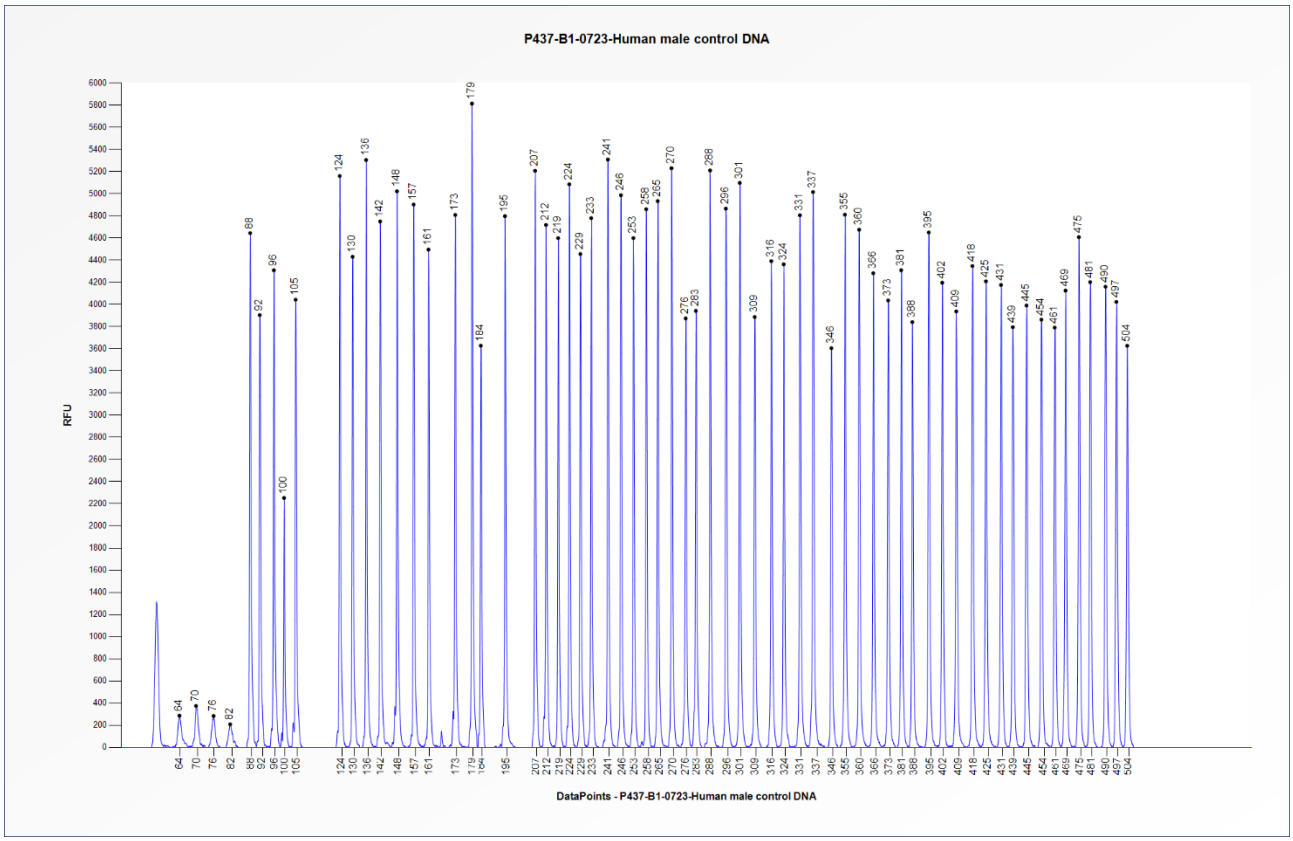

Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P437 Familial MDS-AML (B1-0723). Please note that in some healthy control samples without the *GATA2* c.1192C>T=p.R398W mutation, a low background signal (max. 5 % of the median peak height of all reference probes) at 168 nt in the electropherogram may appear, which indicates absence of this mutation.

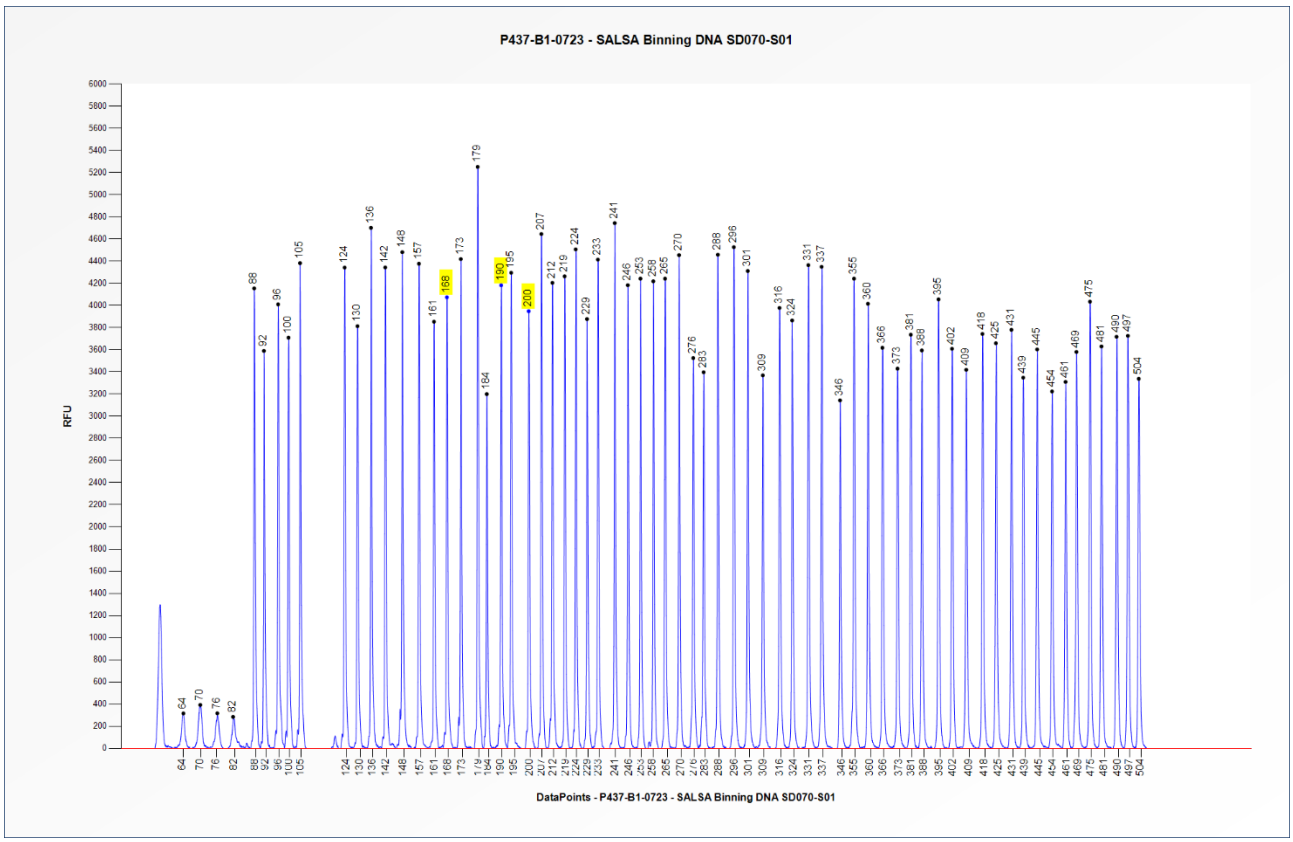

Figure 2. Capillary electrophoresis pattern from SALSA Binning DNA SD070-S01 (approximately 50 ng) analysed with SALSA MLPA Probemix P437 Familial MDS-AML (B1-0723). The location of the *GATA2* probe (p.R398W=c.1192C>T) at 168 nt, *GATA2* probe (p.T354M=c.1061C>T) at 190 nt and *TERT* probe (p.A1062T=c.3184G>A) at 200 nt is indicated.

This lot was certified by MRC Holland on 15 May 2024.

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 – 16 May 2024 (6) - Not applicable, new document.