

Certificate of Analysis

SALSA® MS-MLPA® Probemix ME029 FMR1-AFF2

Catalogue #	ME029-025R, ME029-050R, ME029-100R	
Product name	Probemix ME029 FMR1-AFF2	
LOT	C1-0223	
Σ	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
*	Store upon arrival between -25°C and -15°C.	
	Expiration date: February 2028, when stored at recommended condition should not be frozen/thawed more than 25 times.	ons. This product
Purpose	This product has been developed to determine the DNA copy number of multiple exons of the human <i>FMR1</i> and <i>AFF2</i> genes, as described in table 1 and 2 of the product description. In addition, this probemix can be used for the analysis of the methylation status of the promoters of these genes in male samples only. The length of the trinucleotide repeats in these genes cannot be measured by MLPA. This probemix is designed for use only in combination with SALSA MLPA reagent kits (except the SALSA MLPA buffer), SALSA Hhal, SALSA Low pH MLPA buffer, 60 mM NaOH (not provided) and Coffalyser.Net analysis software as described in the MS-MLPA General Protocol and the ME029-C1 Product Description.	
Quality control specifications	 Sufficient distance between peaks, absence of extra or shoulder peaks, and completeness of hybridisation and Hhal digestion 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 from the same sex, 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.



More information: www.mrcholland.com; www.mrcholland.eu		
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Certificate of Analysis SALSA MS-MLPA Probemix ME029-C1 FMR1-AFF2 sample picture

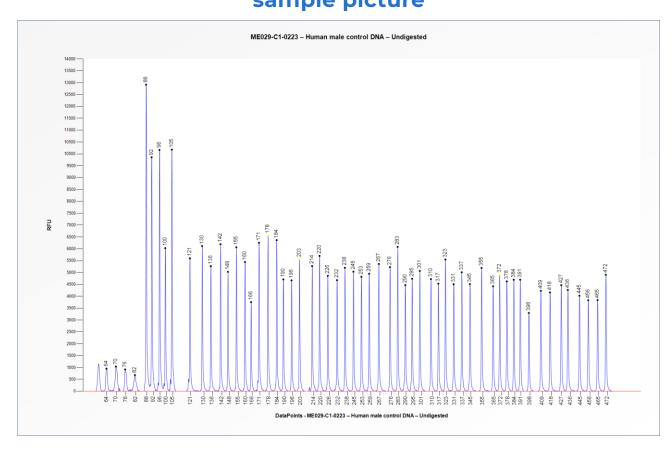


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng <u>undigested</u> human male control DNA analysed with SALSA MS-MLPA Probemix ME029 *FMR1/AFF2* (C1-0223) for the quantification of copy numbers.

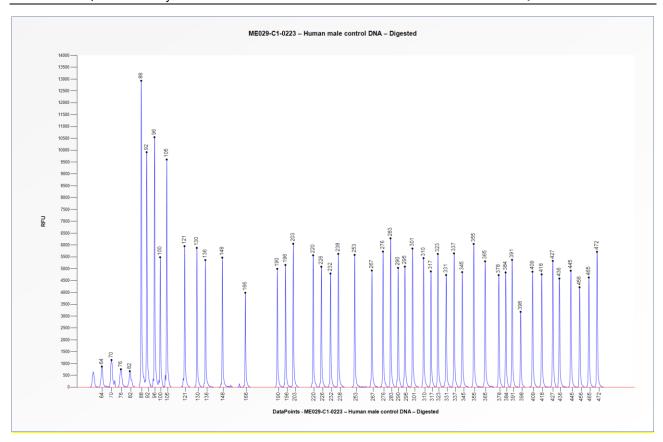


Figure 2. Capillary electrophoresis pattern from a sample of approximately 50 ng <u>digested</u> human male control DNA analysed with SALSA MS-MLPA Probemix ME029 *FMR1/AFF2* (C1-0223) to determine the methylation status.

This lot was certified by MRC Holland on 03 July 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 01-03 July 2023 (4)

- Not applicable, new document.