




Certificate of Analysis

SALSA® MS-MLPA® Probemix ME033 TNDM

Catalogue #	ME033-025R, ME033-050R, ME033-100R	
Product name	Probemix ME033 TNDM	
LOT	A1-0923	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: September 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 methylation status of an alternative <i>PLAGL1</i> Transcription Start Site this is shared with the <i>HYMAI</i> gene, as well as the DNA copy number of the 6q24 and 11p15 region, 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, SALSA Hhal and Coffalyser.Net analysis software as described in the MS-MLPA General Protocol.	
Quality control specifications	<ul style="list-style-type: none"> - 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, extracted by various methods. - 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. Note: We observed one prominent peak above the 25% threshold with a length of approximately 207 nt in a No-DNA control. 	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 MS-MLPA Probemix ME033-A1 TNDM sample pictures

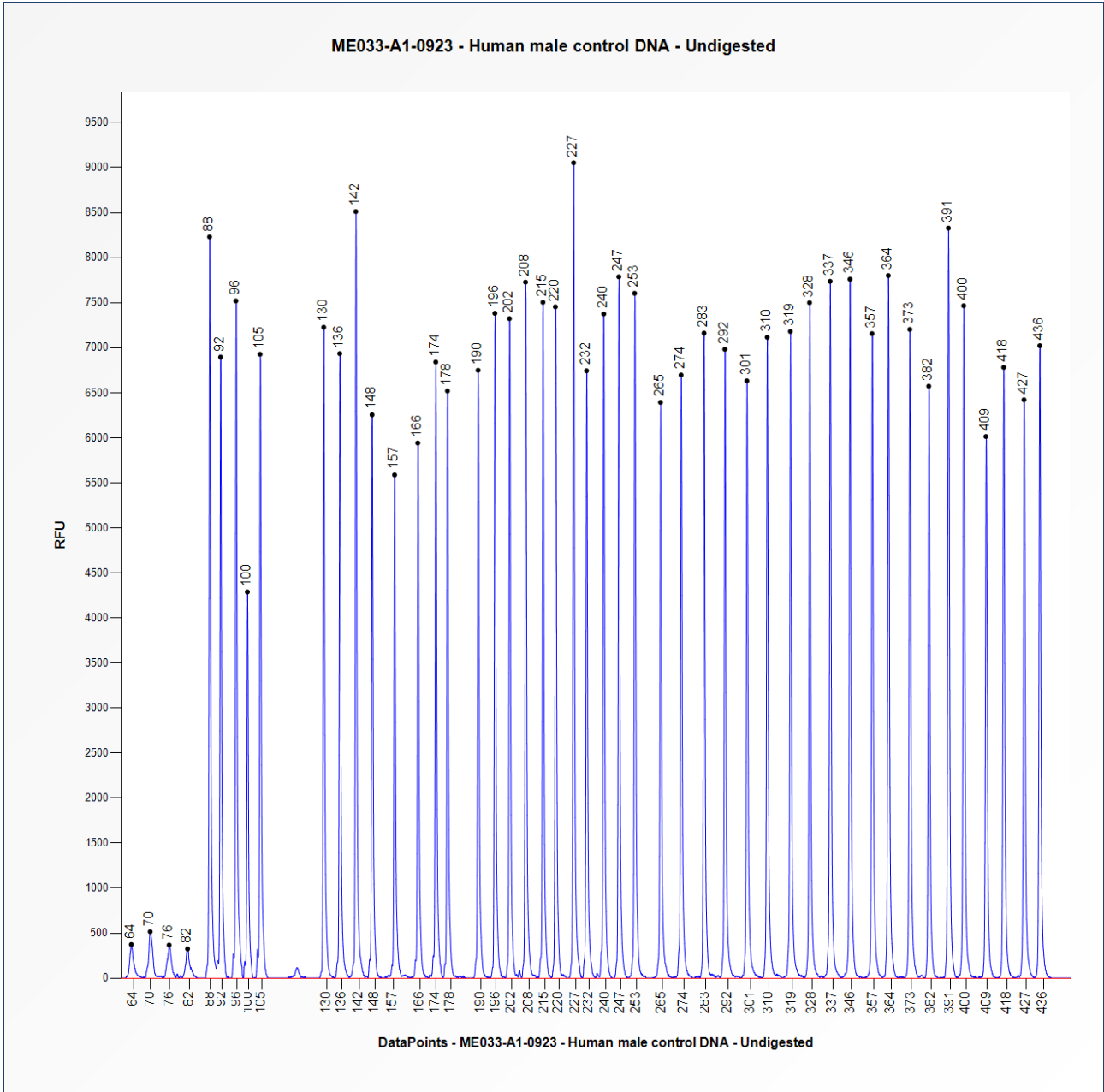


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng undigested human male control DNA analysed with SALSA MS-MLPA Probemix ME033 TNDM (A1-0923) for the quantification of copy numbers.

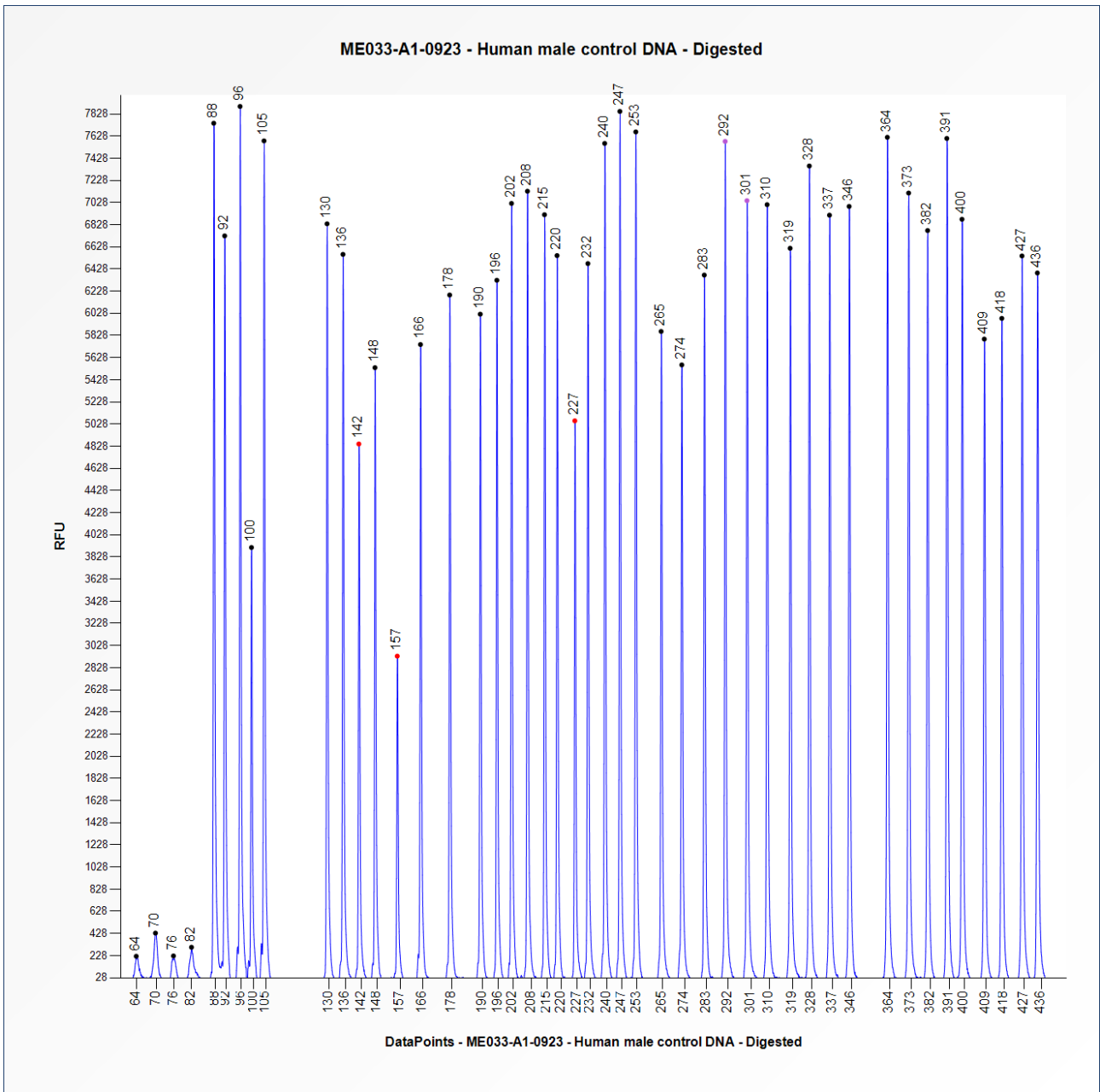


Figure 2. Capillary electrophoresis pattern from a sample of approximately 50 ng digested human male control DNA analysed with SALSA MS-MLPA Probemix ME033 TNDM (A1-0923) to determine the methylation status.

This lot was certified by MRC Holland on 12 December 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 – 12 December 2023 (4) - Not applicable, new document.