





Certificate of Analysis

SALSA[®] MLPA[®] Probemix ME033 TNDM

Catalogue #	ME033-025R, ME033-050R, ME033-100R	
Product name	Probemix ME033 TNDM	
 LOT	B1-0424	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: April 2029, 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 a differentially methylated region located in the <i>PLAGL1</i> gene (<i>PLAGL1</i> :alt-TSS-DMR), as well as the DNA copy number of the 6p22, 6q24 and 11p15 chromosomal regions, 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 HhaI 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 HhaI 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. - 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. Note: We observed one prominent peak above the 25% threshold with a length of approximately 134 nt in a No-DNA control. 	Test result <p style="text-align: center; margin: 0;">PASS</p>

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 ME033-B1 TNDM sample pictures

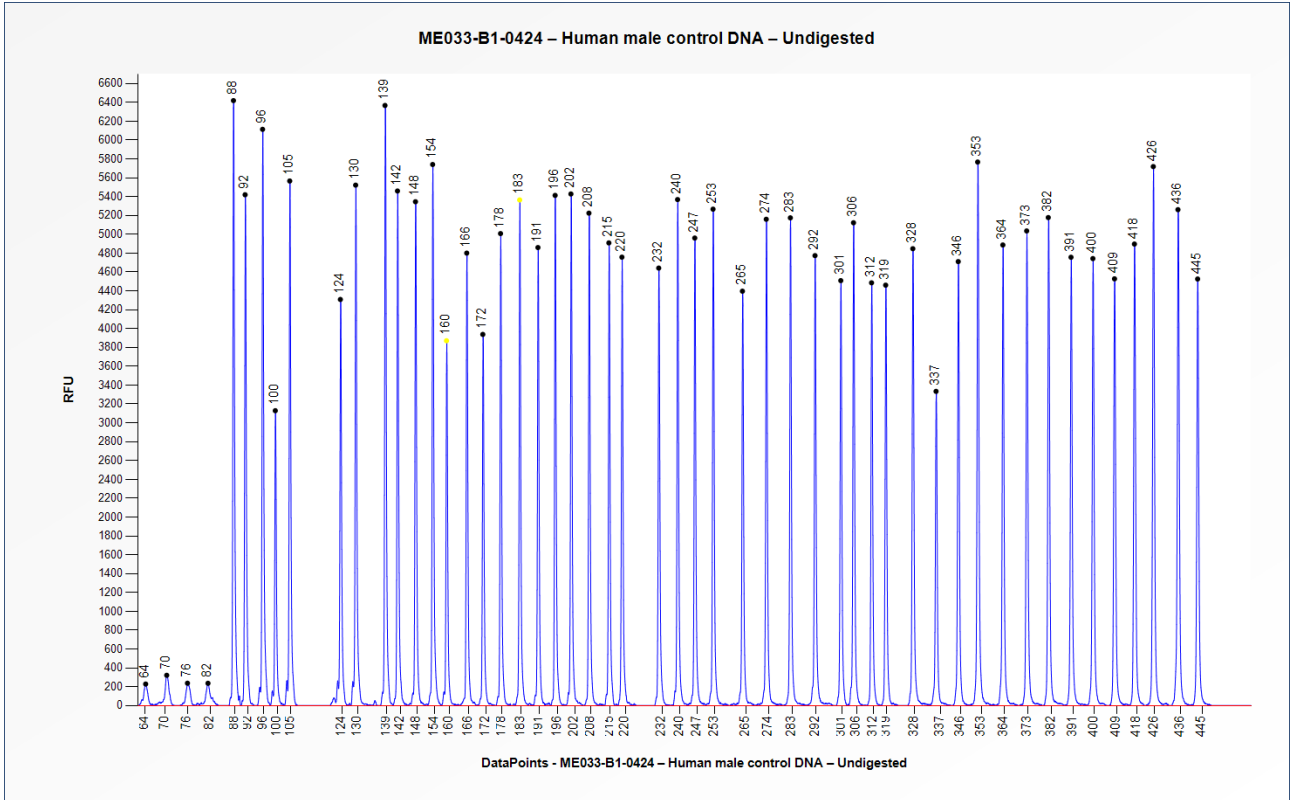


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng undigested human male control DNA analysed with SALSA MLPA Probemix ME033 TNDM (B1-0424) for the quantification of copy numbers.

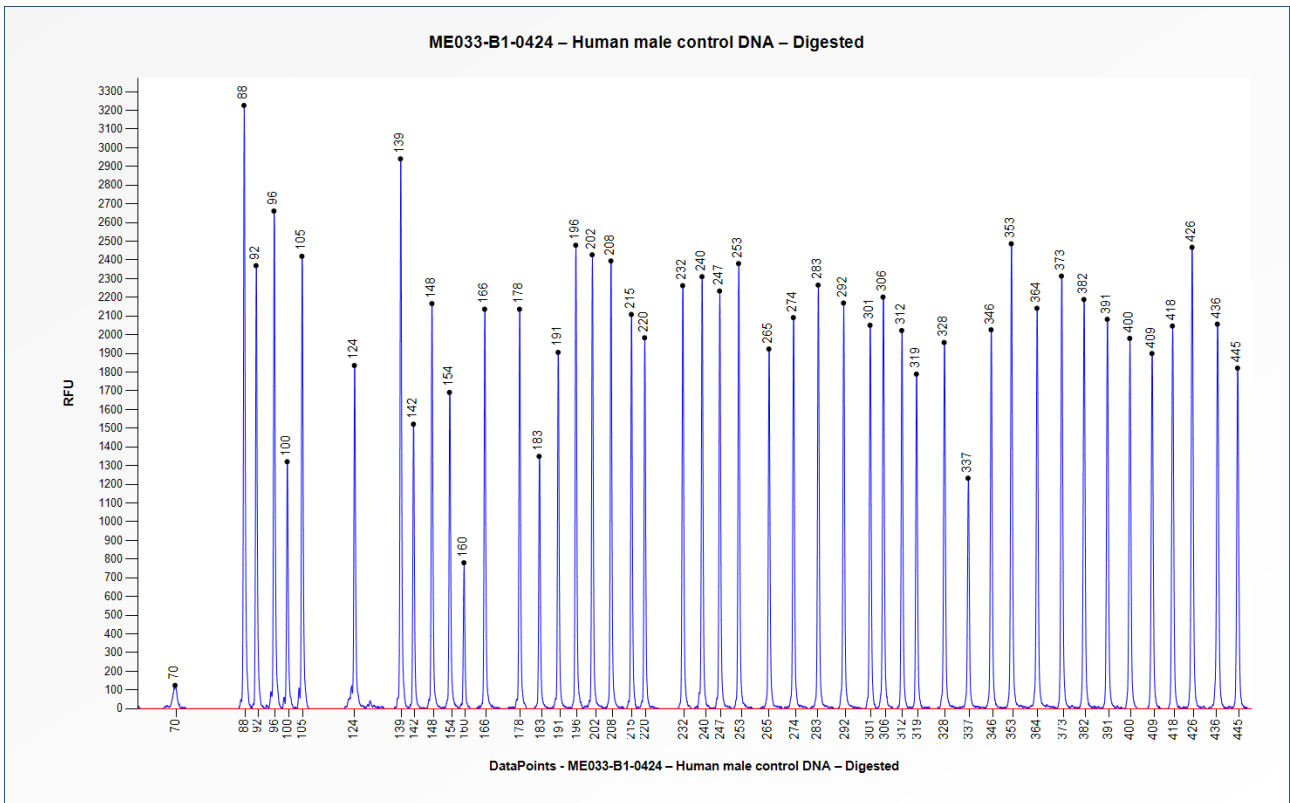


Figure 2. Capillary electrophoresis pattern from a sample of approximately 50 ng digested human male control DNA analysed with SALSA MLPA Probemix ME033 TNDM (B1-0424) to determine the methylation status.

This lot was certified by MRC Holland on 21 November 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 – 21 November 2024 (4) - Not applicable, new document.