

Certificate of Analysis SALSA[®] MS-MLPA[®] Probemix ME030 BWS/RSS

Catalogue #	ME030-025R, ME030-050R, ME030-100R	
Product name	Probemix ME030 BWS/RSS	
LOT	C3-0522	
Σ	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
X	Store upon arrival between -25°C and -15°C.	
	Expiration date: May 2027, when stored at recommended condition should not be frozen/thawed more than 25 times.	ns. This product
Purpose	This product has been developed to determine the DNA copy number and the presence of aberrant methylation of one or more sequences of the IC2 (KvDMR) and IC1 (H19DMR) domains in the 11p15 chromosomal region, as described in table 1 and 2 of the product description. Two probes are also included for the <i>NSD1</i> region. 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	 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. 	Test result
	 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. 	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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Certificate of Analysis SALSA MS-MLPA Probemix ME030-C3 BWS/RSS sample picture

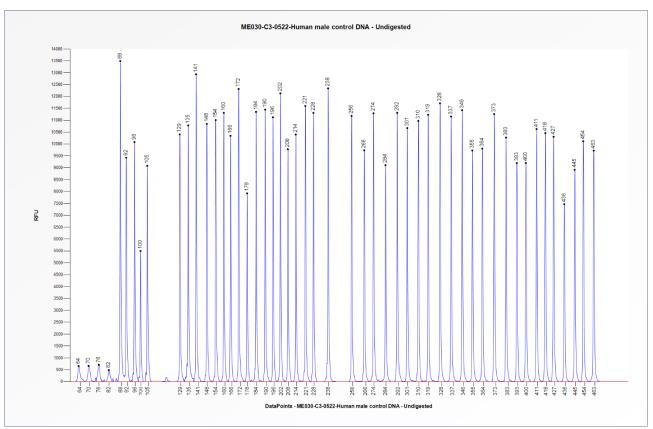


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng <u>undigested</u> human male control DNA analysed with SALSA MS-MLPA Probemix ME030 BWS/RSS (C3-0522) for the quantification of copy numbers.



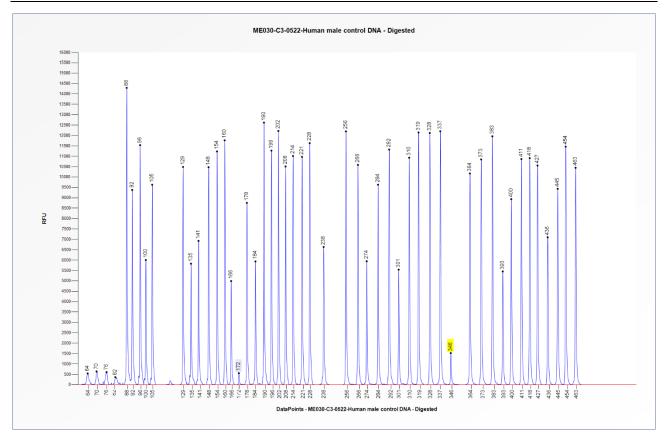


Figure 2. Capillary electrophoresis pattern from a sample of approximately 50 ng digested human male control DNA analysed with SALSA MS-MLPA Probemix ME030 BWS/RSS (C3-0522) to determine the methylation status.

This lot was certified by MRC Holland on 16 November 2022.

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 November 2022 (4) - Not applicable, new document.