

## Certificate of Analysis SALSA<sup>®</sup> MS-MLPA<sup>®</sup> Probemix ME031 GNAS

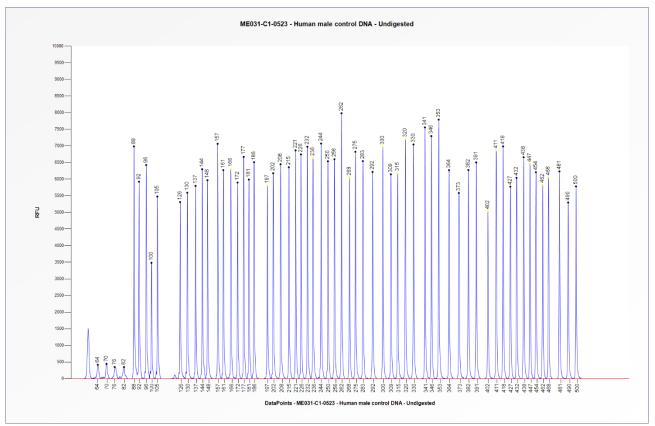
Catalogue #	ME031-025R, ME031-050R, ME031-100R	
Product name	Probemix ME031 GNAS	
LOT	C1-0523	
Σ	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
X	Store upon arrival between -25°C and -15°C.	
8	Expiration date: May 2028, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Purpose	This product has been developed to determine the DNA copy number and methylation status of the <i>GNAS</i> complex locus and the DNA copy number of the <i>STX16</i> gene, 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> <li>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.</li> </ul>	Test result
	<ul> <li>Standard deviation of each individual probe ≤0.10, when tested on 23 different DNA samples of healthy individuals, extracted by various methods.</li> </ul>	
	- Each individual probe meets reaction-specific criteria when tested on a single DNA sample under various experimental conditions.	PASS
	<ul> <li>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 &lt;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.</li> </ul>	

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 ME031-C1 GNAS 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 ME031 GNAS (C1-0523) for the quantification of copy numbers.



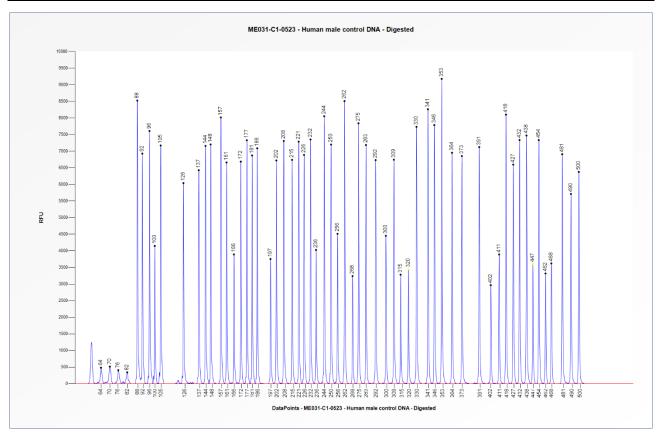


Figure 2. Capillary electrophoresis pattern from a sample of approximately 50 ng digested human male control DNA analysed with SALSA MS-MLPA Probemix ME031 GNAS (C1-0523) to determine the methylation status.

## This lot was certified by MRC Holland on 1 November 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 - 01 November 2023 (4) - Not applicable, new document.