

## **Certificate of Analysis**

## SALSA® MS-MLPA® Probemix ME012 MGMT-IDH-TERT

Catalogue #	ME012-025R, ME012-050R, ME012-100R	
Product name	Probemix ME012 MGMT-IDH-TERT	
LOT	B1-1022	
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: October 2027, when stored at recommended condition should not be frozen/thawed more than 25 times.	ns. This product
Purpose	This probemix is developed to be used for <i>MGMT</i> promoter region methylation and copy number status determination. This probemix also allows detection of six point mutations: <i>IDH1</i> p.R132H=c.395G>A and p.R132C=c.394C>T, <i>IDH2</i> p.R172K=c.515G>A and p.R172M=c.515G>T and <i>TERT</i> promoter C228T and C250T. This probemix is designed for use only in combination with SALSA MLPA reagent kits, SALSA Binning DNA SD094, 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> <li>Standard deviation of each individual probe ≤0.10, when tested on 23 different DNA samples of healthy individuals, extracted by various methods.</li> <li>Each individual probe meets reaction-specific criteria when tested on a single DNA sample under various experimental conditions.</li> <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. Note: We observed one peak around the 25% threshold with a length of approximately 133 nt in a No-DNA control.</li> </ul>	Test result PASS

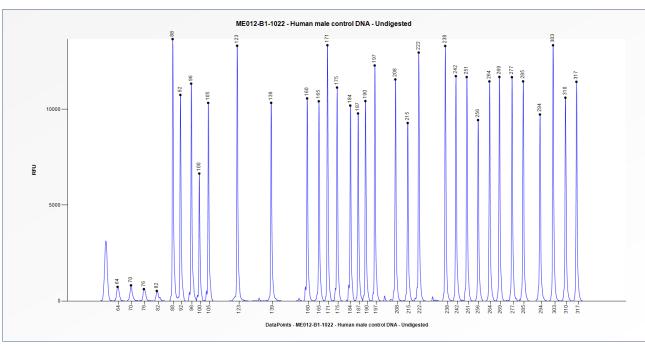
None of the ingredients are derived from humans, animals, or pathogenic bacteria. Based on the concentrations present, none of the ingredients are hazardous as defined by the Hazard Communication Standard. A Safety Data Sheet (SDS) is not required for these products: none of the preparations contain 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.



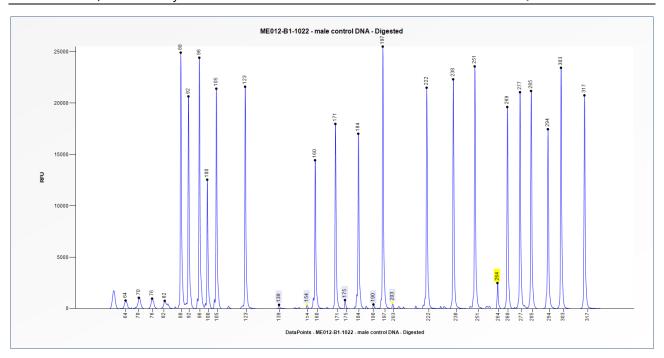
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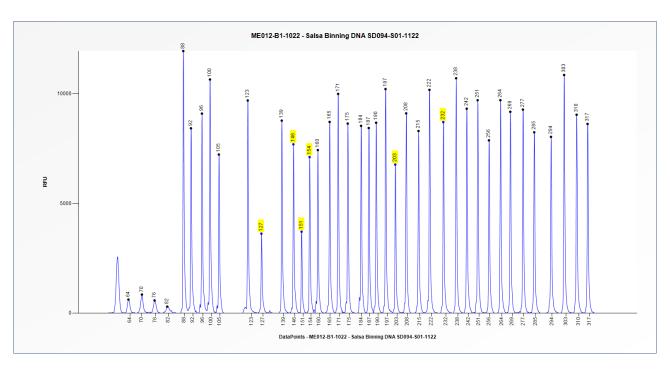
# SALSA MS-MLPA Probemix ME012-B1 MGMT-IDH-TERT sample picture



**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 ME012 MGMT-IDH-TERT (B1-1022) 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 ME012 MGMT-IDH-TERT (B1-1022) to determine the methylation status. The MS-MLPA probes at 139, 175, 190 and 264 nt are not completely digested in DNA samples derived from blood, and thus might have 5-15% background signal.



**Figure 3**. Capillary electrophoresis pattern from SALSA Binning DNA SD094-S01 (approximately 50 ng) analysed with SALSA MS-MLPA Probemix ME012 MGMT-IDH-TERT (B1-1022). The location of the *TERT* C250T, *TERT* C228T, *IDH2* p.R172K=c.515G>A, *IDH2* p.R172M=c.515G>T, *IDH1* p.R132H=c.395G>A and *IDH1* p.R132C=c.394C>T mutation-specific probes at 127, 146, 151, 154, 203 and 232 nt, respectively, are indicated.

#### This lot was certified by MRC Holland on 02 May 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 - 02 May 2023(4)

- Not applicable, new document.