Certificate of Analysis

SALSA® MS-MLPA® Probemix ME011 Mismatch Repair Genes

Catalogue #	**ME011-025R, ME011-050R, ME011-100R**
Product name	**Probemix ME011 Mismatch Repair Genes**
LOT	**D1-0821**

Σ	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: August 2026, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Purpose	This probemix is developed to be used for methylation and copy number status determination of the promoter regions of the *MLH1*, *MSH2*, *PMS2* and *MSH6* genes and for detection of the *BRAF* p.V600E point mutation. In addition, this assay can be used to detect deletions or duplications in the 3' region of the *EPCAM* gene. 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	- 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.	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.

More information: www.mrcholland.com; www.mrcholland.eu	
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SALSA MS-MLPA Probemix ME011-D1 Mismatch Repair Genes sample pictures

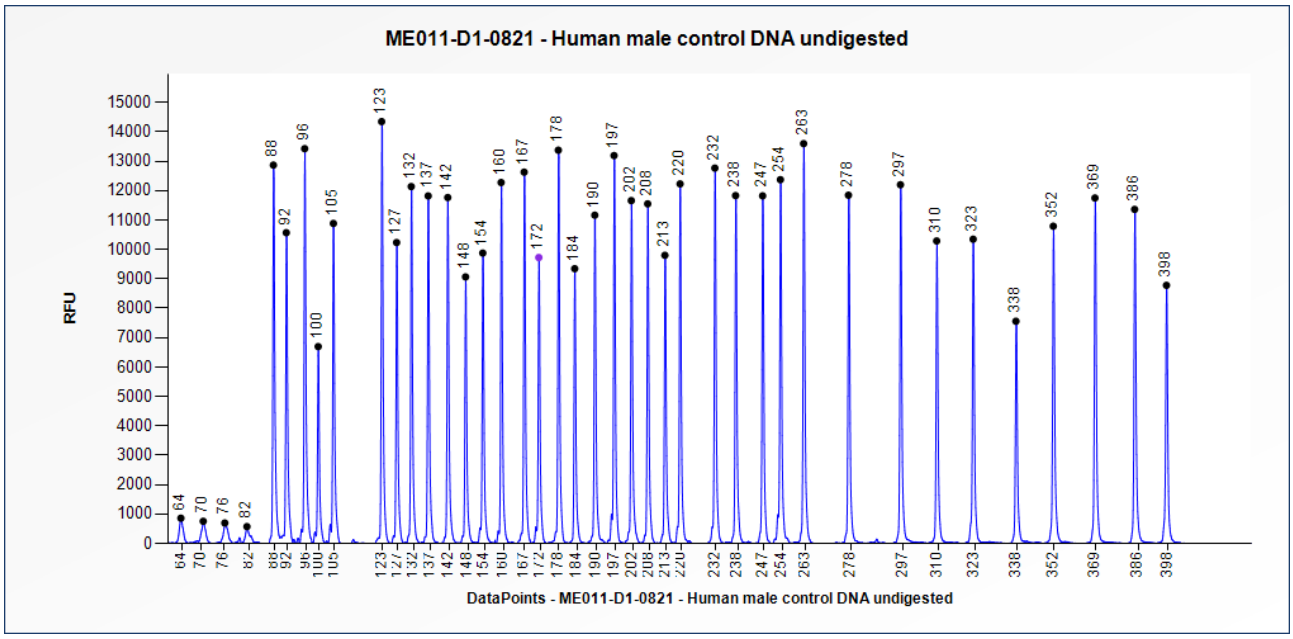

Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng undigested human male control DNA analysed with SALSA MS-MLPA Probemix ME011 Mismatch Repair Genes (D1-0821) for the quantification of copy numbers.

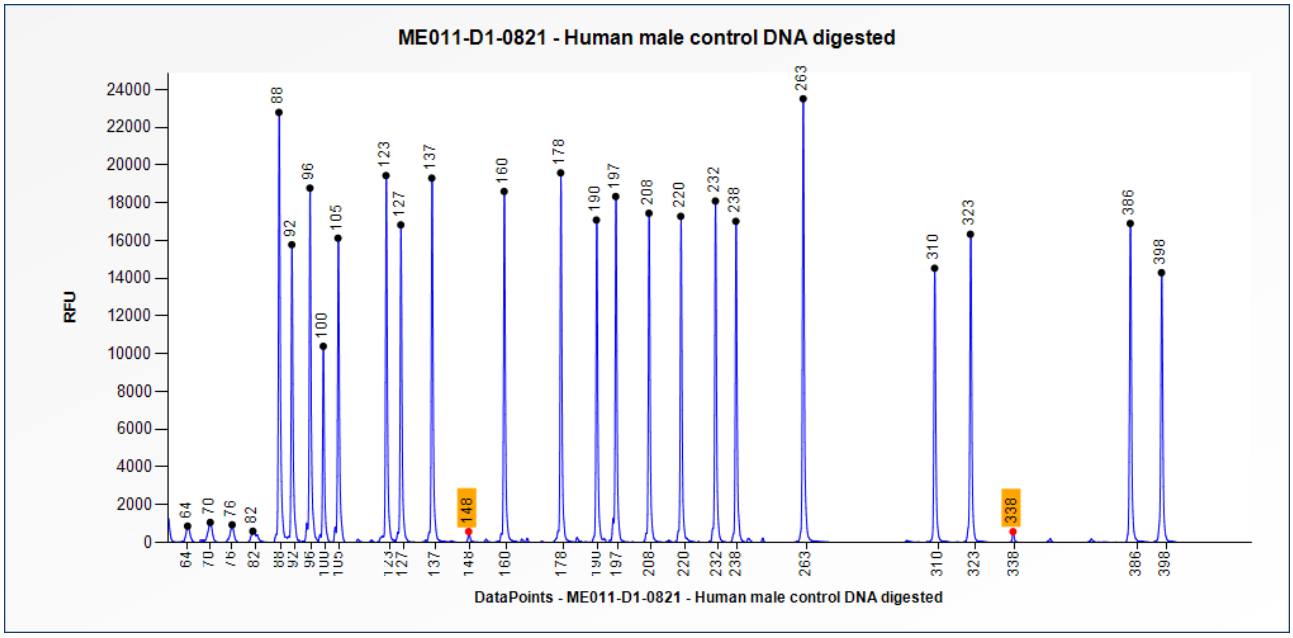

Figure 2. Capillary electrophoresis pattern from a sample of approximately 50 ng digested human male control DNA analysed with SALSA MS-MLPA Probemix ME011 Mismatch Repair Genes (D1-0821) to determine the methylation status. The MS-MLPA probes at 148 and 338 nt are not completely digested in DNA samples derived from blood, and thus might have 5-10% background signal.

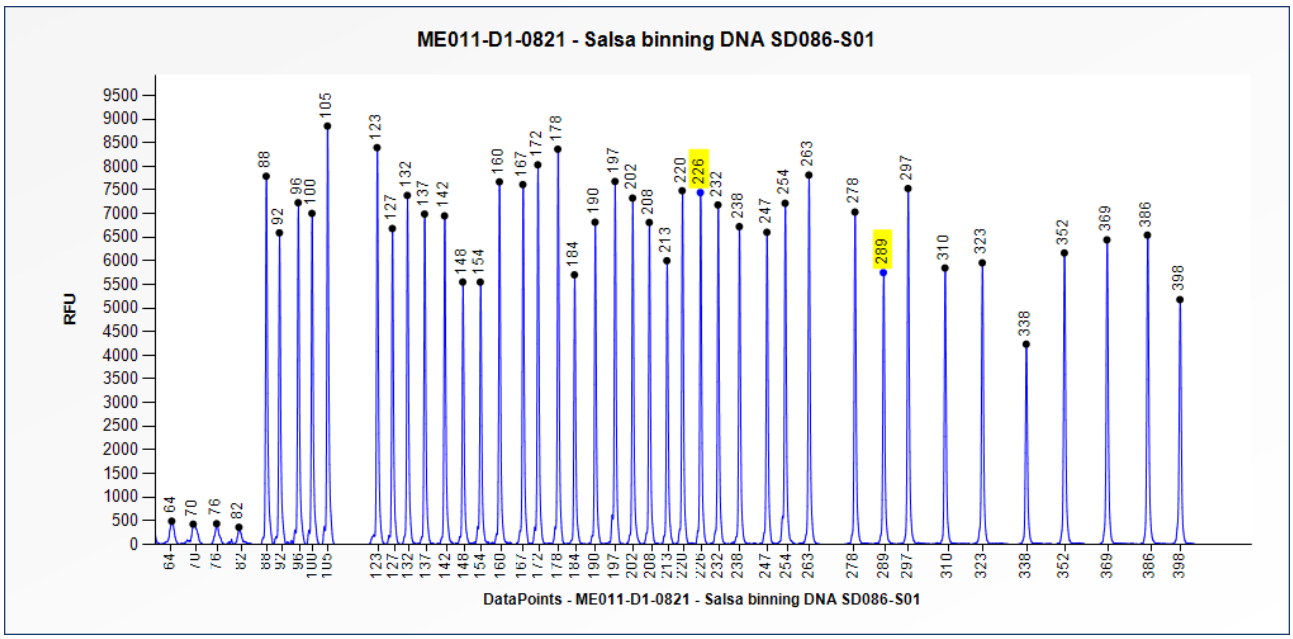

Figure 3. Capillary electrophoresis pattern from SALSA Binning DNA SD086-S01 (approximately 50 ng) analysed with SALSA MS-MLPA Probemix ME011 Mismatch Repair Genes (D1-0821). The locations of the *BRAF* p.V600E mutation- and rs104894994 SNP-specific probes at 226 and 289 nt are indicated.

This lot was certified by MRC Holland on 19 September 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 02 – 19 November 2024 (4) - SALSA Binning DNA SD086 removed from section Purpose. - Figure 1, 2 and 3 updated. Version 01 – 19 September 2022 (4) - Not applicable, new document.