




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	
	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	<p>This probemix is developed to be used for methylation and copy number status determination of the promoter regions of the <i>MLH1</i>, <i>MSH2</i>, <i>PMS2</i> and <i>MSH6</i> genes and for detection of the <i>BRAF</i> p.V600E point mutation. In addition, this assay can be used to detect deletions or duplications in the 3' region of the <i>EPCAM</i> gene.</p> <p>This probemix is designed for use only in combination with SALSA MLPA reagent kits, SALSA HhaI, SALSA Binning DNA SD086 and Coffalyser.Net analysis software as described in the MS-MLPA General Protocol.</p>	
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. 	<p>Test result</p> <p>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.

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

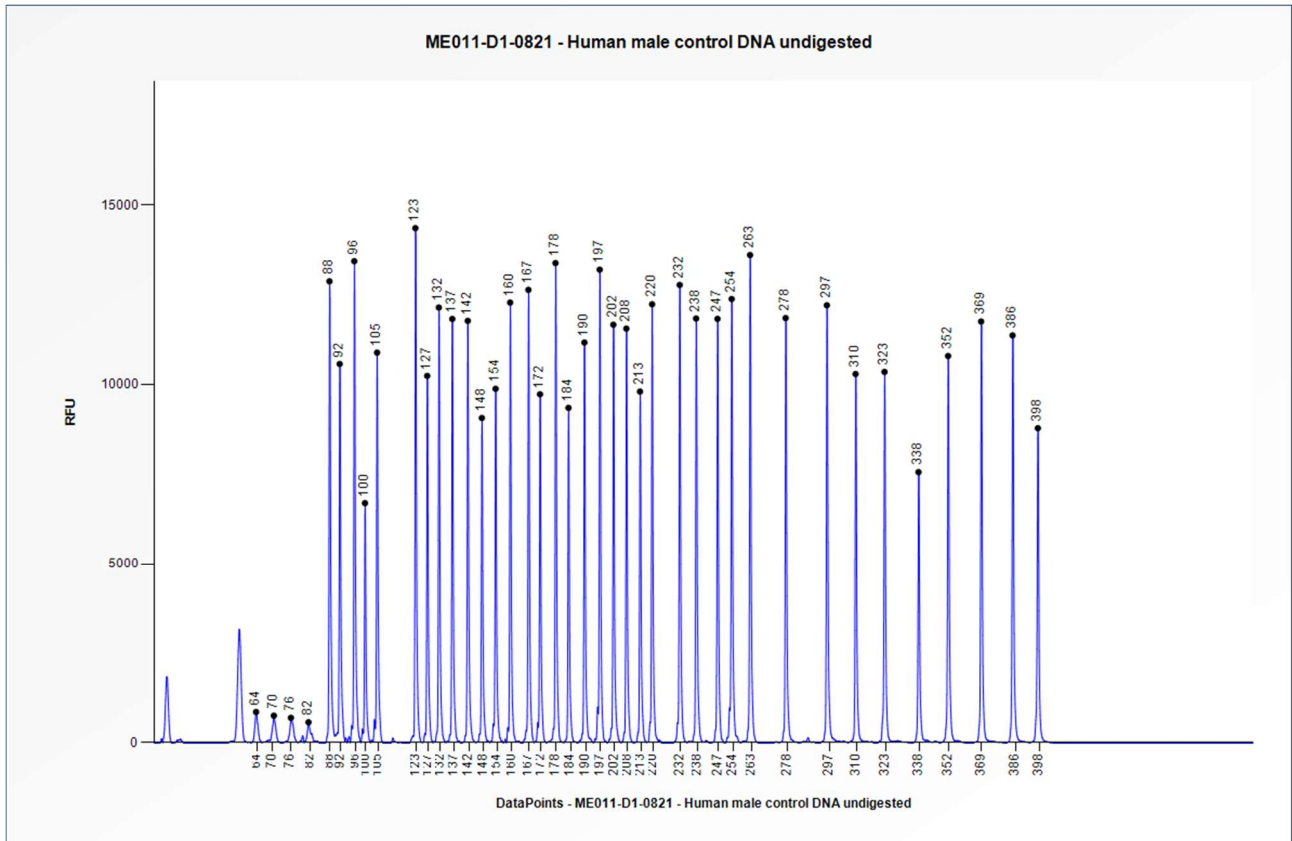


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng undigested human male control DNA analysed with SALSA MS-MLPA Probemix ME011 Mismatch Repair Genes (D1-0821) for the quantification of copy numbers.

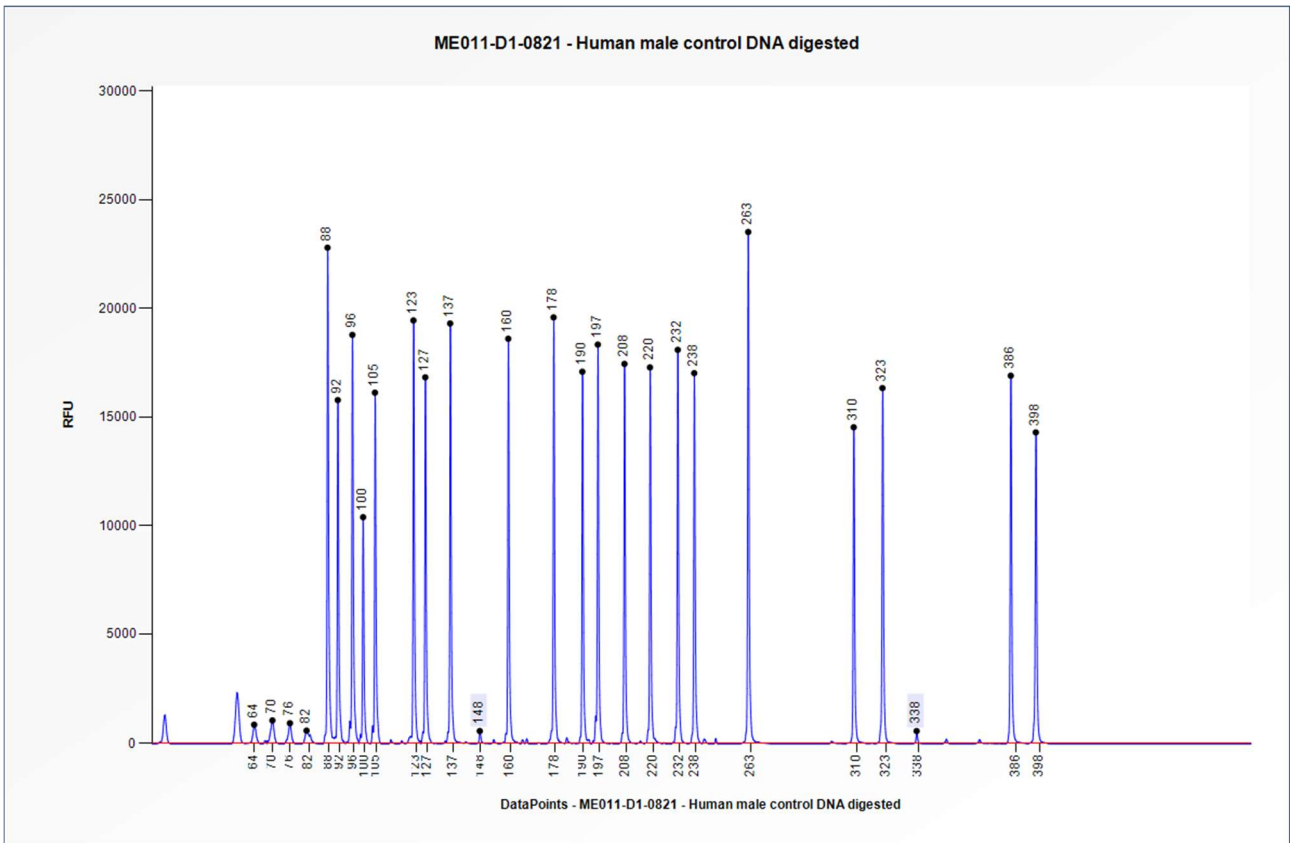


Figure 2. Capillary electrophoresis pattern from a sample of approximately 50 ng digested human male control DNA analysed with SALSA MS-MLPA Probemix ME011 Mismatch Repair Genes (D1-0821) to determine the methylation status. The MS-MLPA probes at 148 and 338 nt are not completely digested in DNA samples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

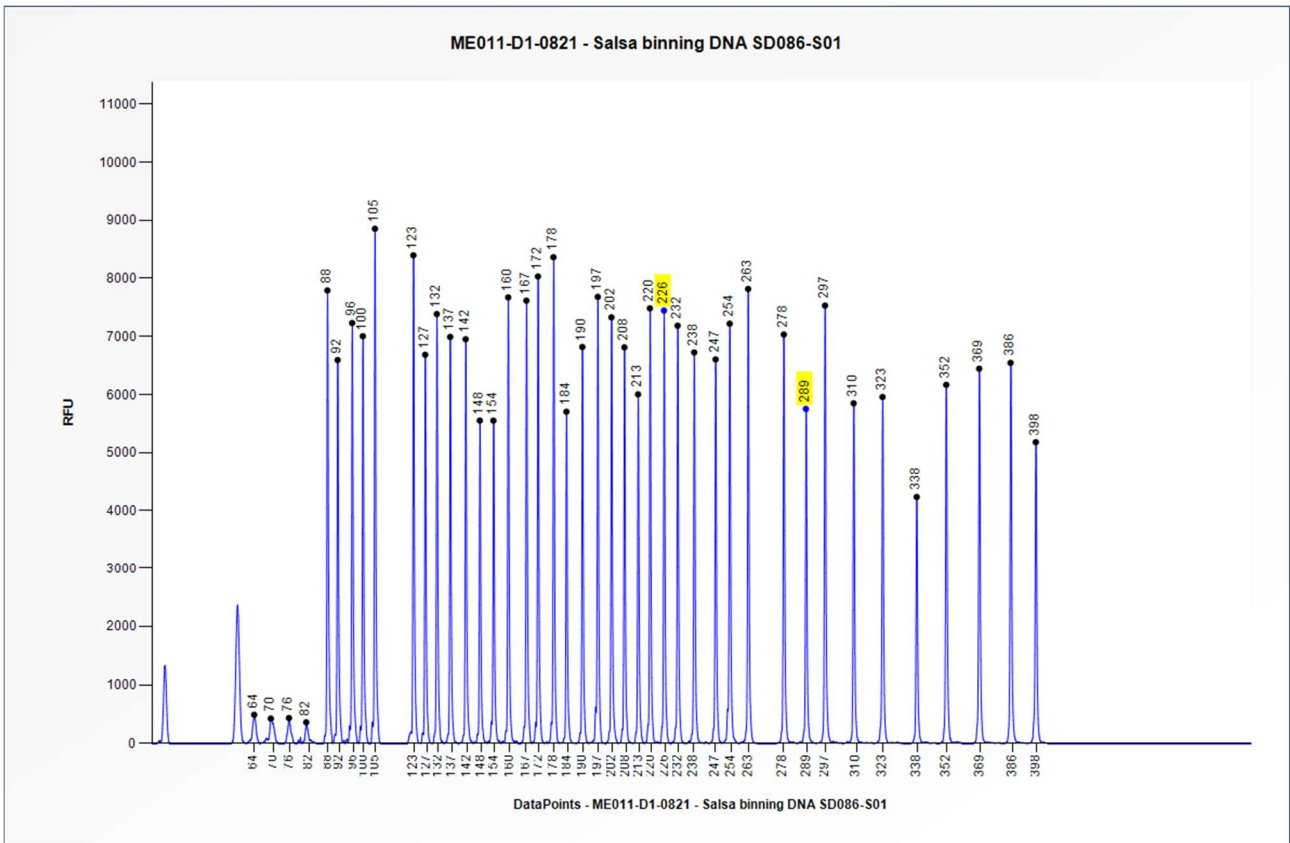


Figure 3. Capillary electrophoresis pattern from SALSA Binning DNA SD086-S01 (approximately 50 ng) analysed with SALSA MS-MLPA Probemix ME011 Mismatch Repair Genes (D1-0821). The locations of the *BRAF* p.V600E mutation- and rs104894994 SNP-specific probes at 226 and 289 nt are indicated.

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 01 – 19 September 2022 (4) - Not applicable, new document.