





Certificate of Analysis

SALSA® MLPA® Probemix P038 CLL-2

Catalogue #	P038-025R, P038-050R, P038-100R	
Product name	Probemix P038 CLL-2	
LOT	B1-0319	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: March 2024, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Use	The P038 CLL-2 is intended to be used for the detection of deletions or duplications in the genes/chromosomal implicated in B-cell chronic lymphocytic leukemia (B-CLL) such as: 10q23 (<i>PTEN</i>), 11q (<i>ATM</i>), chromosome 12, 13q14 (<i>RB1</i> , <i>DLEU1/2</i>), 14q, 17p13 (<i>TP53</i>) and chromosome 19. This probemix can also be used to detect the presence of <i>NOTCH1</i> p.P2514*fs, <i>SF3B1</i> p.K700E and <i>MYD88</i> p.L265P point mutations. This probemix is designed for use only in combination with SALSA MLPA reagent kits as described in the MLPA General Protocol.	
Quality control specifications	<ul style="list-style-type: none"> - Sufficient distance between peaks, absence of extra or shoulder peaks, and completeness of hybridisation of each individual probe, as tested on Applied Biosystems 3130 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. - 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 19 nt peak 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 style="text-align: center; font-weight: bold;">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.mlpa.com ; www.mlpa.eu	
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SALSA MLPA Probemix P038-B1 CLL-2 sample picture

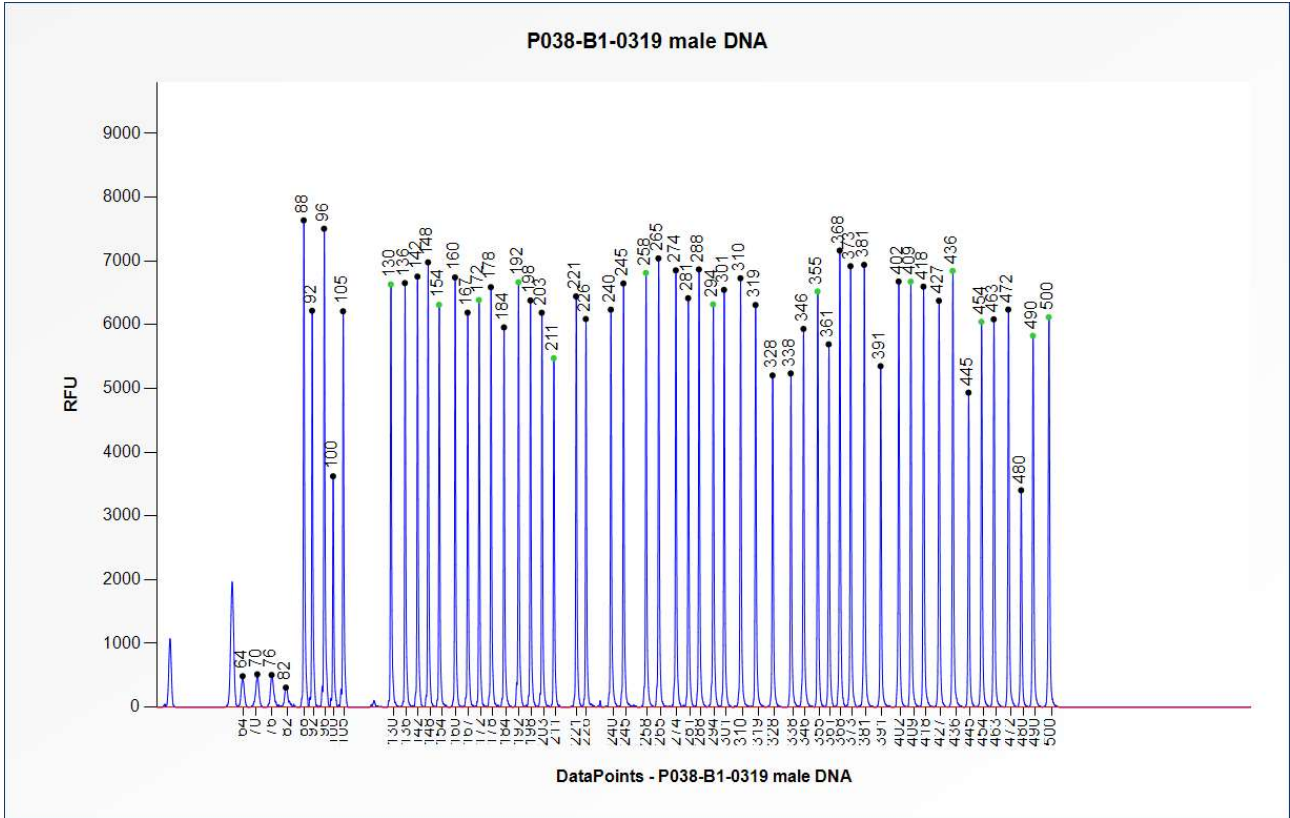


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P038 CLL-2 (B1-0319).

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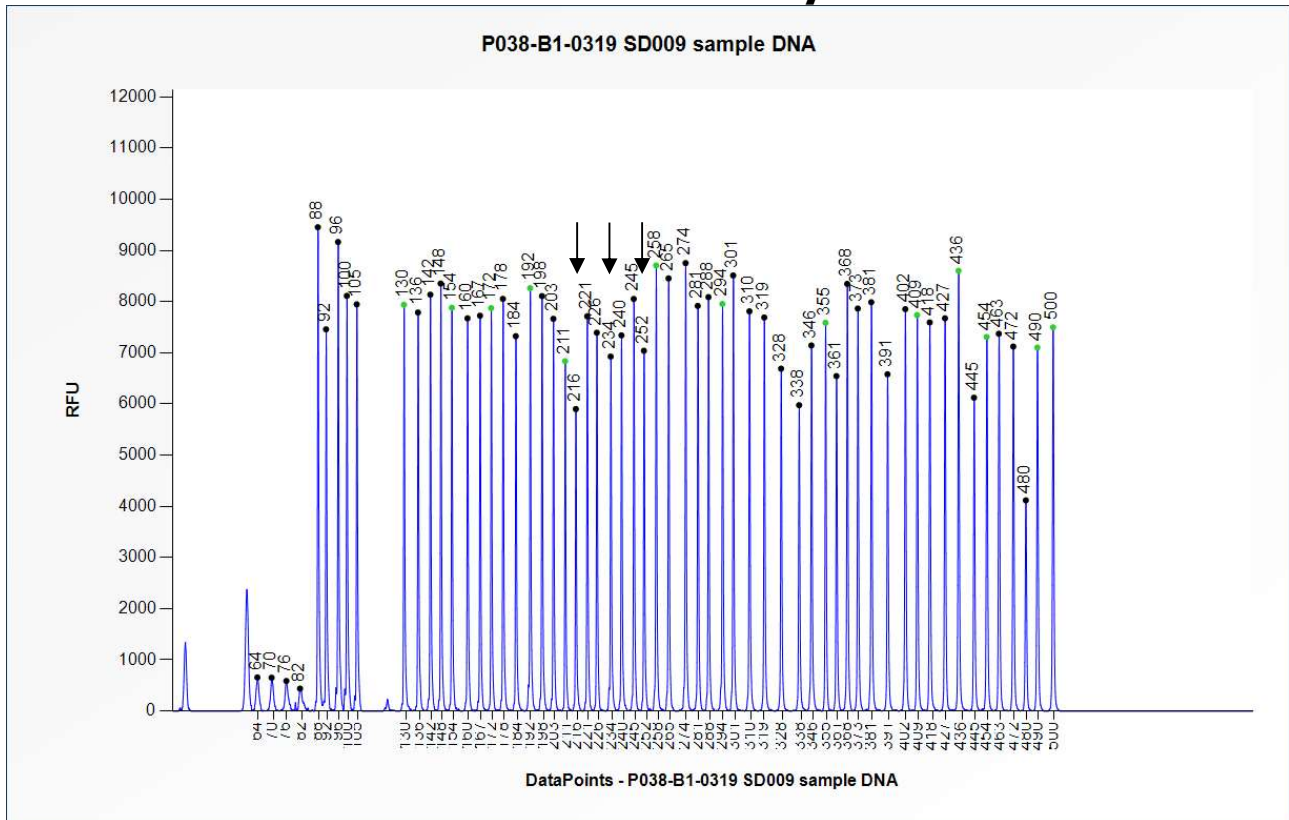


Figure 2 Capillary electrophoresis pattern from SALSA Binning DNA SD009-S01 (approximately 50 ng) analysed with SALSA MLPA Probemix P038 CLL-2 (B1-0319). Locations of the *NOTCH1* p.P2514*fs, *SF3B1* p.K700E and *MYD88* p.L265P mutation-specific probes at 216 nt, 234 nt and 252 nt, respectively, are indicated.

This lot was certified by MRC-Holland on 13 January 2020.

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- 13 January 2020 (04) - Not applicable, new document.