




Certificate of Analysis

SALSA® MLPA® Probemix P038 CLL-2

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| Catalogue # | P038-025R, P038-050R, P038-100R | |
| Product name | Probemix P038 CLL-2 | |
| LOT | B2-1123 | |
|  | 25, 50, or 100 reactions. | |
| Shipping conditions | Dry ice or cooling elements. | |
|  | Store upon arrival between -25°C and -15°C. | |
|  | Expiration date: November 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 of several chromosomal regions and genes 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> c.7541-7542delCT (p.P2514Rfs*4), <i>SF3B1</i> c.2098A>G (p.K700E) and <i>MYD88</i> c.794T>C (p.L265P) point mutations 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, SD009 and Coffalyser.Net analysis software 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 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.

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| More information: www.mrcholland.com ; www.mrcholland.eu | |
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SALSA MLPA Probemix P038 CLL-2 sample pictures

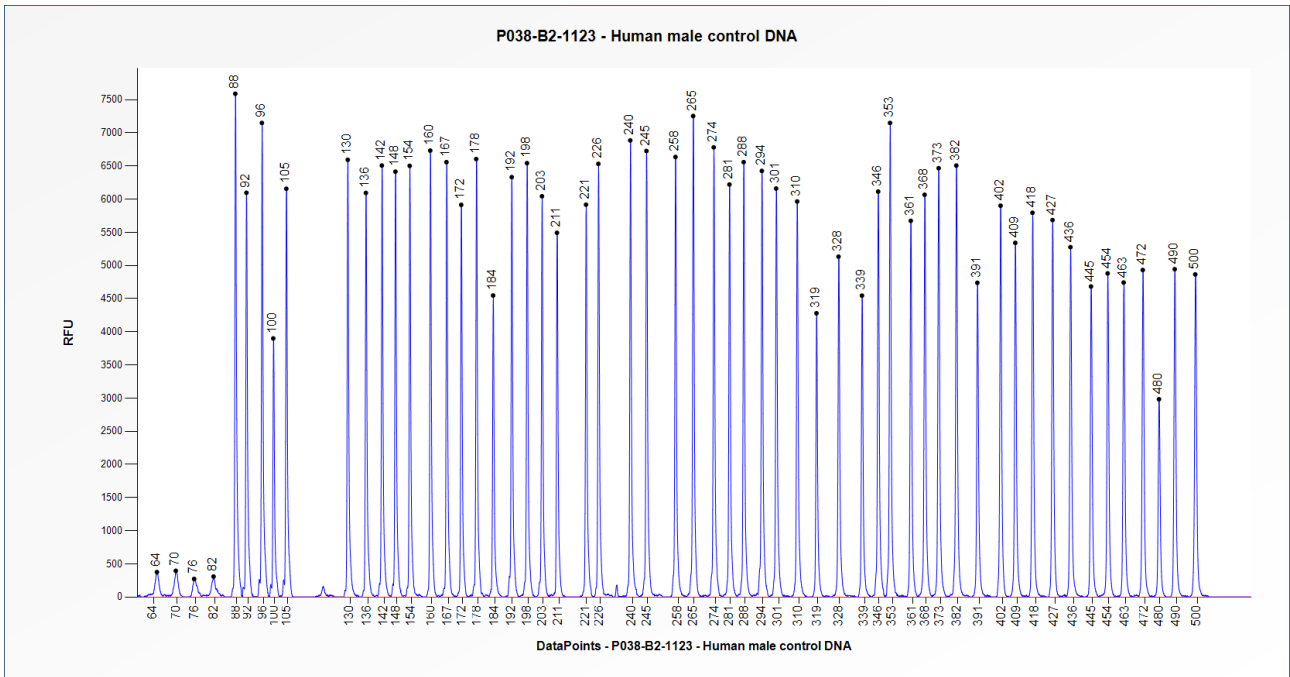


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P038 CLL-2 (B2-1123).

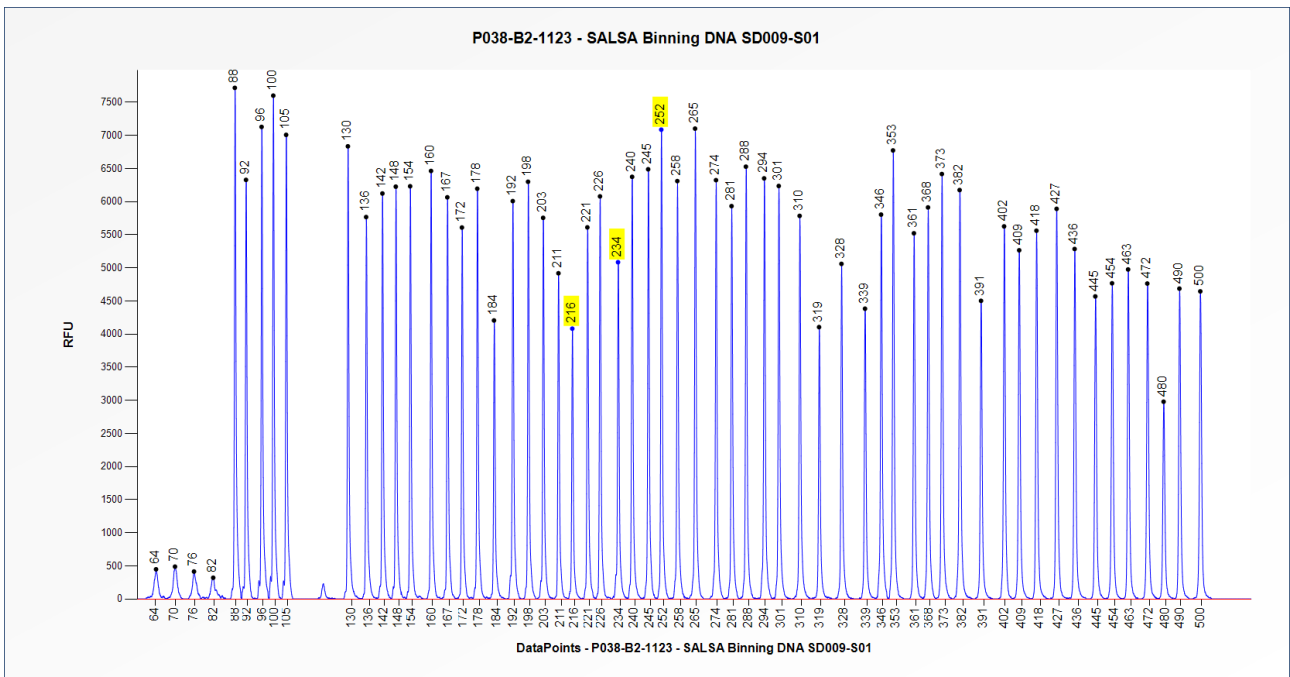


Figure 2. Capillary electrophoresis pattern from SALSA Binning DNA SD009-S01 (approximately 50 ng) analysed with SALSA MLPA Probemix P038 CLL-2 (B2-1123). The locations of the NOTCH1 c.7541-7542delCT (p.P2514Rfs*4), SF3B1 c.2098A>G (p.K700E) and MYD88 c.794T>C (p.L265P) mutation-specific probes at 216 nt, 234 nt and 252 nt, respectively, are indicated.

This lot was certified by MRC Holland on 16 January 2024.

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 |
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| Version 01 – 16 January 2024 (6) - Not applicable, new document. |