

Certificate of Analysis

SALSA® MLPA® Probemix P088 Oligodendroglioma 1p-19q

Catalogue #	P088-025R, P088-050R, P088-100R
Product name	Probemix P088 Oligodendroglioma 1p-19q
LOT	D1-1119

25, 50, or 100 reactions.	
Dry ice or cooling elements.	
Store upon arrival between -25°C and -15°C.	
Expiration date: November 2024, when stored at recommended of product should not be frozen/thawed more than 25 times.	conditions. This
This product has been developed to determine the DNA copy number status of chromosome arms 1p and 19q, <i>CDKN2A</i> and <i>CDKN2B</i> , and the presence of somatic point mutations in <i>IDH1</i> (p.R132C and p.R132H) and <i>IDH2</i> (p.R172K and p.R172M), 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, SALSA Binning DNA SD079 and Coffalyser.Net analysis software as described in the MLPA General Protocol.	
 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 	Test result PASS
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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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Certificate of Analysis SALSA MLPA Probemix P088-D1 Oligodendroglioma 1p-19q sample pictures

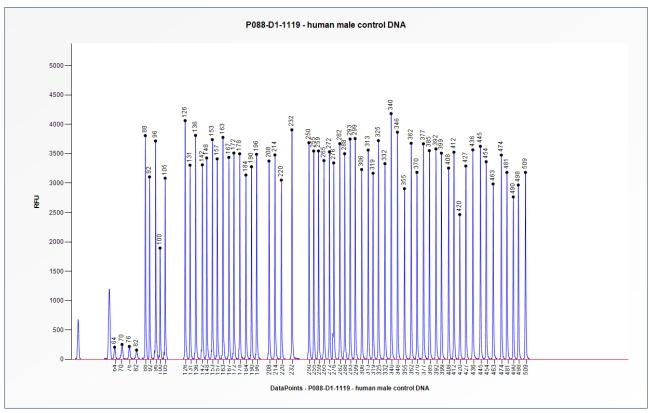


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P088 Oligodendroglioma 1p-19q (D1-1119).



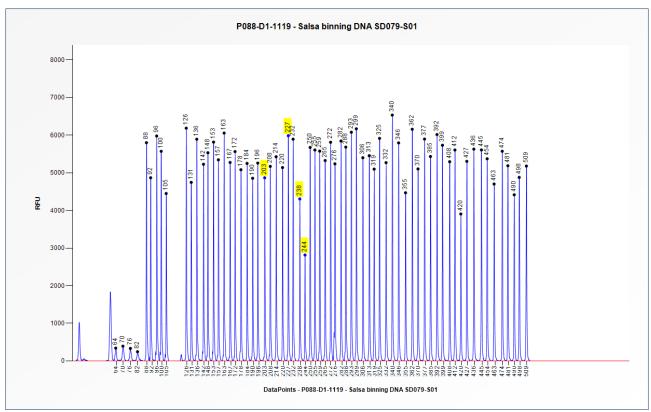


Figure 2. Capillary electrophoresis pattern from SALSA Binning DNA SD079-S01 (approximately 50 ng) analysed with SALSA MLPA Probemix P088 Oligodendroglioma 1p-19q (D1-1119). The locations of the IDH1 p.R132H, IDH1 p.R132C, IDH2 p.R172K and IDH2 p.R172M mutation specific probes at 203 nt, 227 nt, 238 nt and 244 nt, respectively, are indicated.

This lot was certified by MRC Holland on 23 April 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 03 - 26 April 2023 (6)

- Capillary electrophoresis pattern pictures corrected.

Version 02 - 28 March 2023 (6)

- COA restructured and adapted to a new template.

Version 01 - 23 April 2020 (04)

- Not applicable, new document.