MRC-Holland

COA Version 01; Issued 14 December 2018

Certificate of Analysis SALSA[®] MLPA[®] Probemix P419 CDKN2A/2B-CDK4

Catalogue #	P419-025R, P419-050R, P419-100R	
Product name	Probemix P419 CDKN2A/2B-CDK4	
LOT	B1-1118	
Σ	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
\square	Expiration date: November 2023, when stored at recommended conditions. should not be frozen/thawed more than 25 times.	This product
Use	This product has been developed to determine the DNA copy number of all exons of the human <i>CDKN2A</i> , <i>CDKN2B</i> and <i>CDK4</i> genes, as described in tables 1 and 2 of the product description. Moreover, this probemix can be used to determine the presence of the <i>MITF</i> p.E318K (c.952G>A) point mutation and status of <i>CDK4</i> codon 24, as described in tables 1 and 2. This probemix is designed for use only in combination with SALSA MLPA reagent kits and Coffalyser.Net as described in the MLPA General Protocol.	
Quality control specifications	 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. 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 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. 	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.mlpa.com; www.mlpa.eu		
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Certificate of Analysis

SALSA MLPA Probemix P419-B1 CDKN2A/2B-CDK4 sample picture

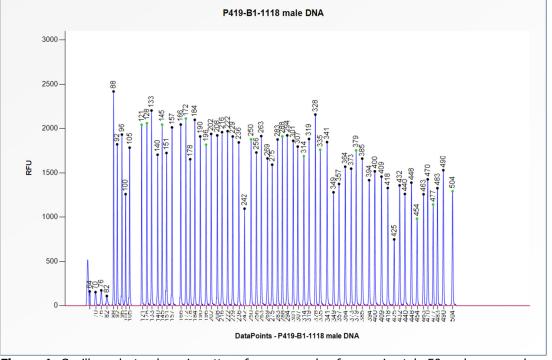


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P419 CDKN2A/2B-CDK4 (B1-1118).

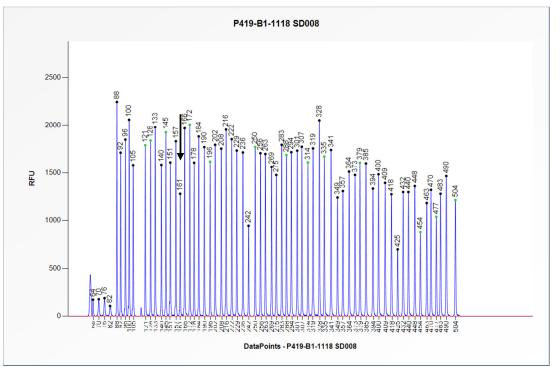


Figure 2. Capillary electrophoresis pattern from SALSA Binning DNA SD008-S01 (approximately 50 ng) analysed with SALSA MLPA Probemix P419 CDKN2A/2B-CDK4 (B1-1118). The location of the MITF p.E318K (c.952G>A) point mutation specific probe at 161 nt is indicated.



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This lot was certified by MRC-Holland on 14 December 2018.

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 – 14 December 2018 (04) - Not applicable, new document.