




Certificate of Analysis

SALSA® MLPA® Probemix P370 BRAF-IDH1-IDH2

Catalogue #	P370-025R, P370-050R, P370-100R	
Product name	Probemix P370 BRAF-IDH1-IDH2	
LOT	C1-0423	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: April 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 presence of the <i>BRAF</i> p.V600E, <i>IDH1</i> (p.R132H and p.R132C) and <i>IDH2</i> (p.R172M and p.R172K) point mutations, to determine the presence of genomic duplications leading to the <i>SRGAP3-RAF1</i> , <i>KIAA1549-BRAF</i> and <i>FGFR1-TACC1</i> fusion genes, and to determine DNA copy number of the <i>BRAF</i> , <i>CDKN2A/2B</i> , <i>FGFR1</i> , <i>MYB</i> and <i>MYBL1</i> genes, 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, SD054 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. Note: We observed two prominent peaks above the 25% threshold with lengths of approximately 161 nt and 165 nt in a No-DNA control in case the ligation reaction was performed at room temperature. 	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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SALSA MLPA Probemix P370-C1 BRAF-IDH1-IDH2 sample picture

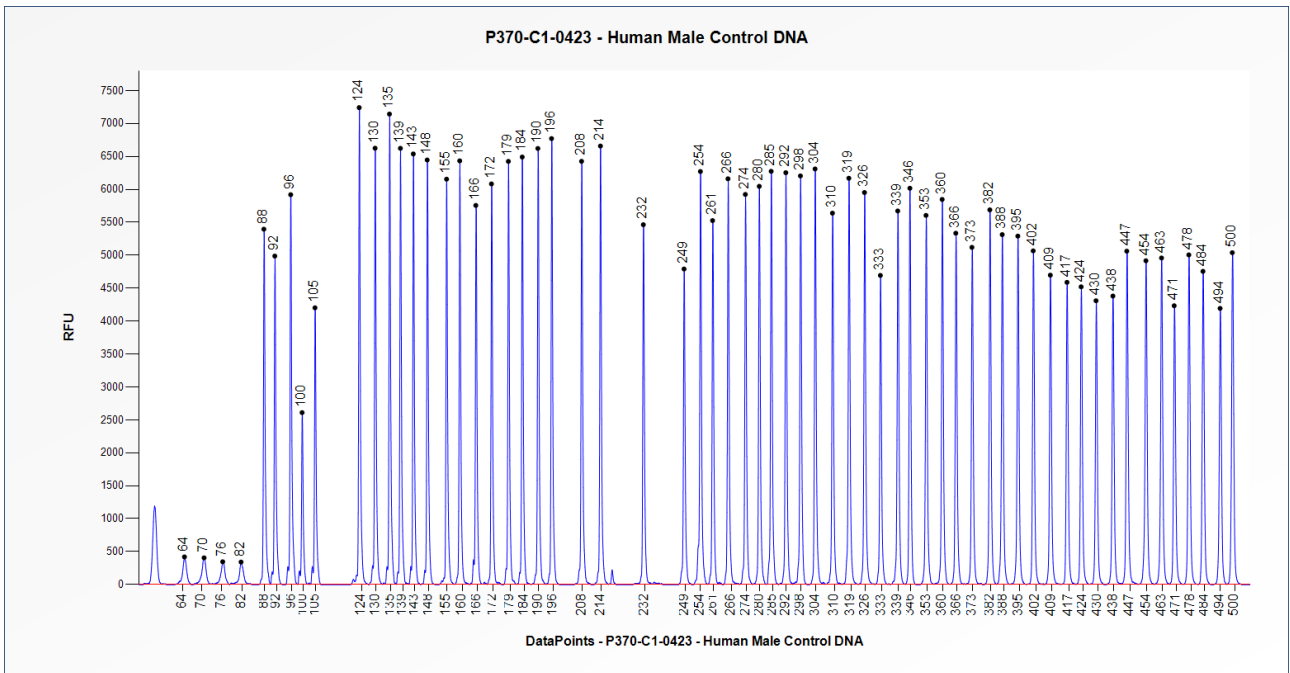


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P370 BRAF-IDH1-IDH2 (C1-0423).

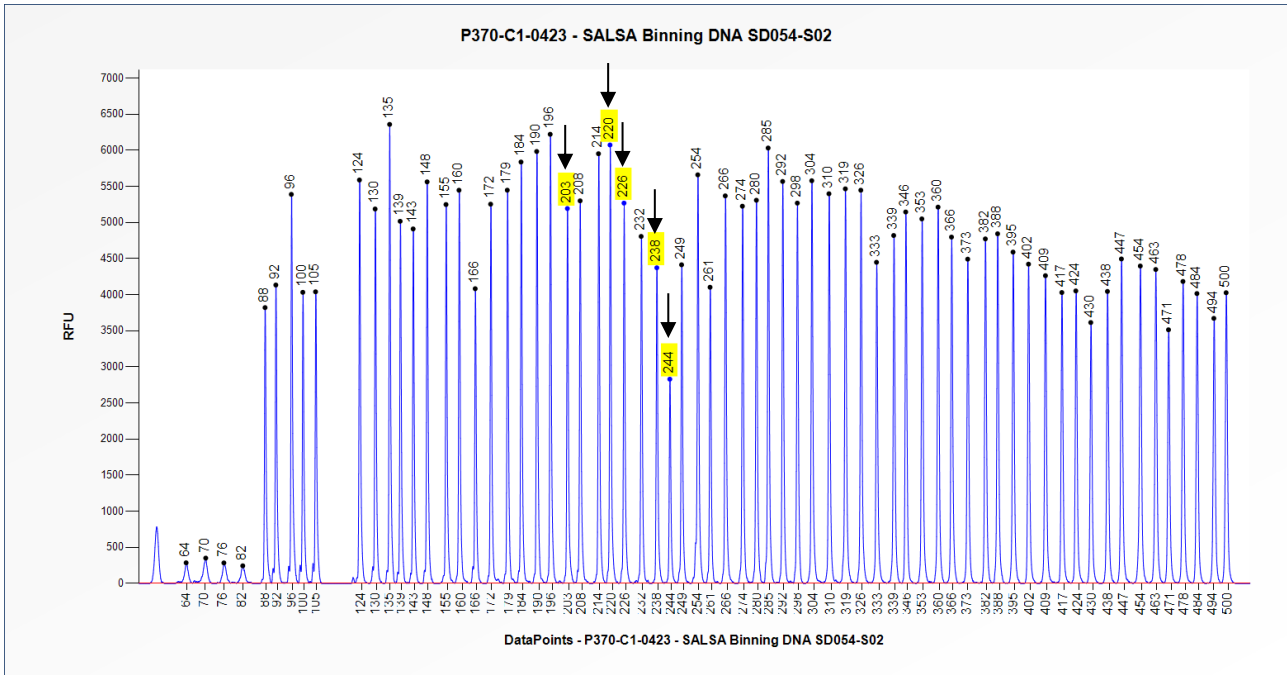


Figure 2. Capillary electrophoresis pattern from SALSA Binning DNA SD054-S02 (approximately 50 ng) analysed with SALSA MLPA Probemix P370 BRAF-IDH1-IDH2 (C1-0423). The location of the name of mutation specific probes *IDH1* p.R132H probe M19529-L16492 at 203 nt, *IDH1* p.R132C probe M14787-L16493 at 220 nt, *BRAF* p.V600E probe M08780-SP0039-L08904 at 226 nt, and *IDH2* p.R172K probe M20963-L29002 at 238 nt and *IDH2* p.R172M probe M20963-L29001 at 244 nt is indicated.

This lot was certified by MRC Holland on 16 November 2023.

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 – 20 November 2023 (6) - Not applicable, new document.