

Certificate of Analysis

SALSA® MLPA® Probemix P056 TP53

Catalogue #	P056-025R, P056-050R, P056-100R	
Product name	Probemix P056 TP53	
LOT	D1-0321	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: March 2026, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Purpose	<p>This product has been developed to determine the DNA copy number of all exons of the human <i>TP53</i> gene, exons 8, 10 and 13 of the human <i>CHEK2</i> gene, and to detect the <i>CHEK2</i> 1100delC mutation, as described in Table 1 and 2 of the product description.</p> <p>This probemix is designed for use only in combination with SALSA MLPA reagent kits, SALSA Binning DNA SD067 and Coffalyser.Net analysis software as described in the MLPA General Protocol.</p>	
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 one prominent peak above the 25% threshold with length of approximately 404 nt in a No-DNA control in the case of room temperature ligation or addition of cold ligase mix. 	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 P056-D1 TP53 sample pictures

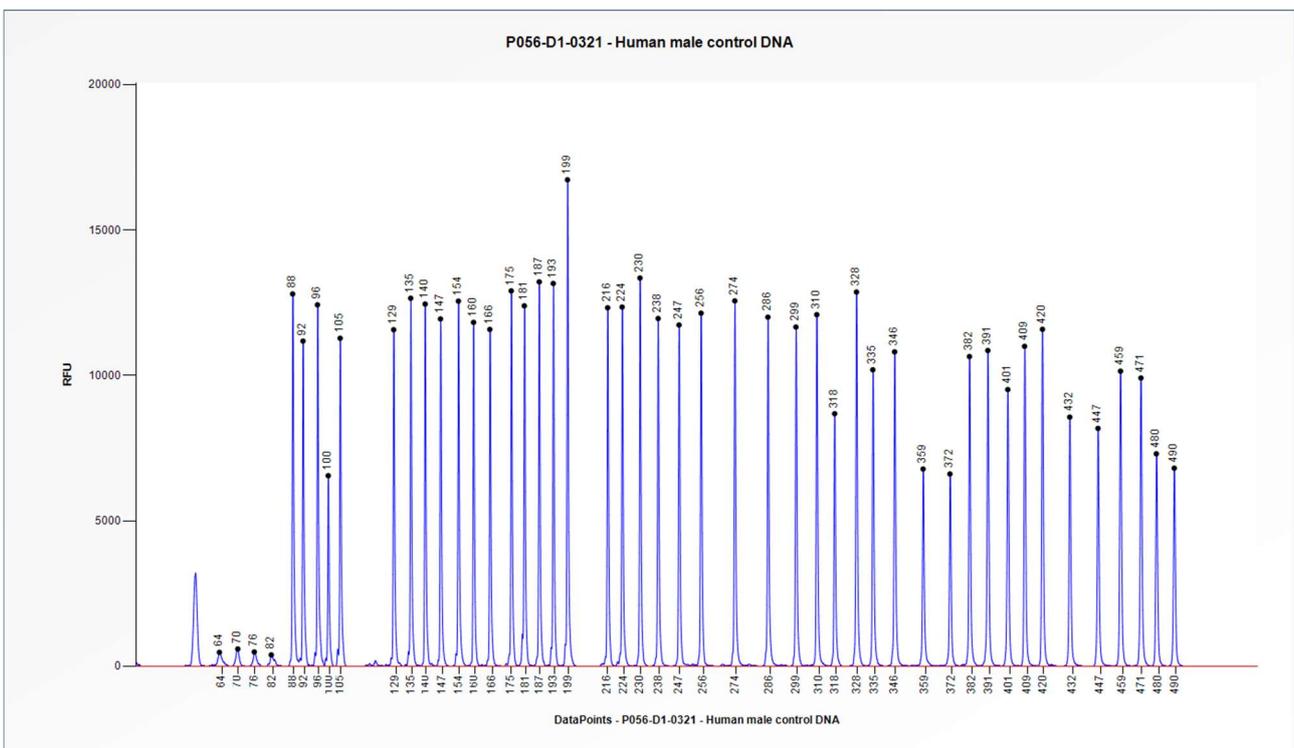


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P056 TP53 (D1-0321).

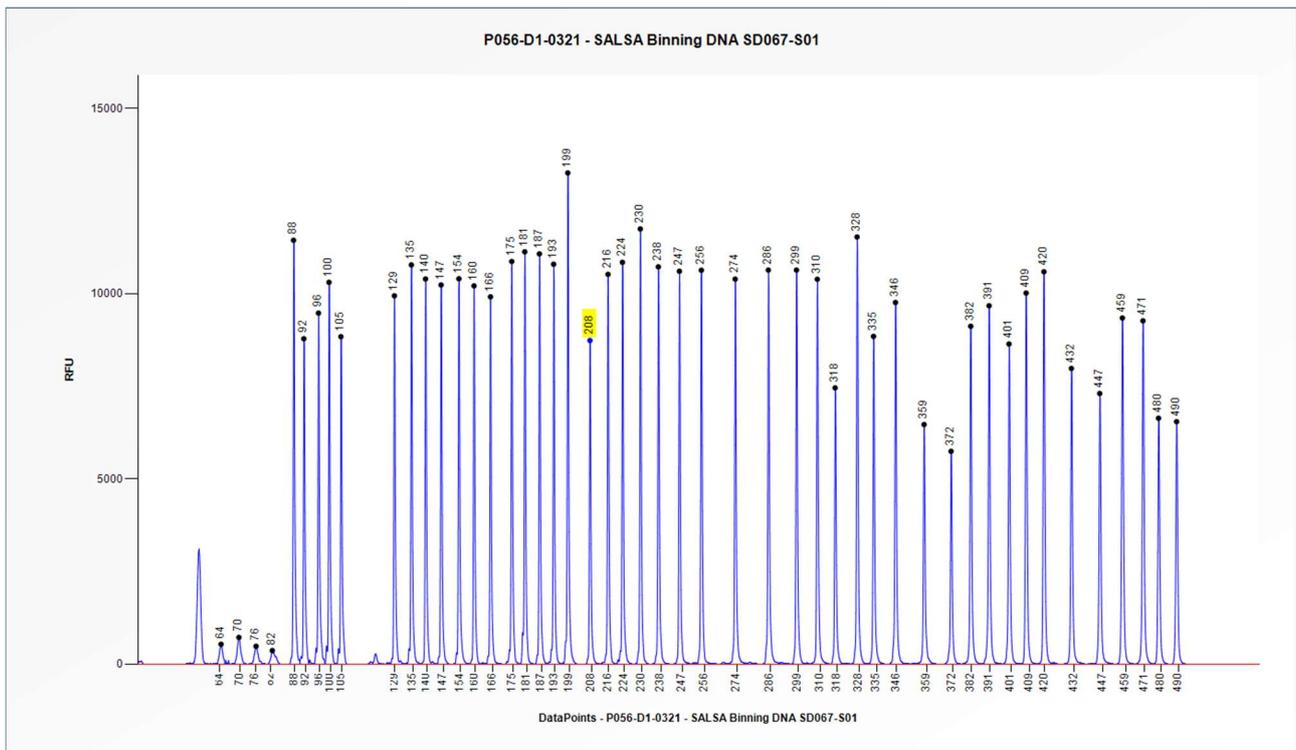


Figure 2. Capillary electrophoresis pattern from SALSA Binning DNA SD067-S01 (approximately 50 ng) analysed with SALSA MLPA Probemix P056 TP53 (D1-0321). The location of the *CHEK2* 1100delC mutation specific probe at 208 nt is indicated.

This lot was certified by MRC Holland on 22 March 2022.

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.

<p>Implemented changes in the COA</p> <p>Version 01 – 22 March 2022 (6) - Not applicable, new document.</p>
