





Certificate of Analysis

SALSA® MLPA® Probemix P473 CTNS

Catalogue #	P473-025R, P473-050R, P473-100R	
Product name	Probemix P473 CTNS	
LOT	A2-0620	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: June 2025, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Use	This product has been developed to determine the DNA copy number of the human <i>CTNS</i> gene and to detect the presence of the <i>CTNS</i> c.414G>A (p.Trp138Ter; W138X) point mutation, 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 and Coffalyser.Net 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 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. 	<p>Test result</p> <p style="text-align: center; font-weight: bold;">PASS</p>

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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SALSA MLPA Probemix P473-A2 CTNS sample pictures

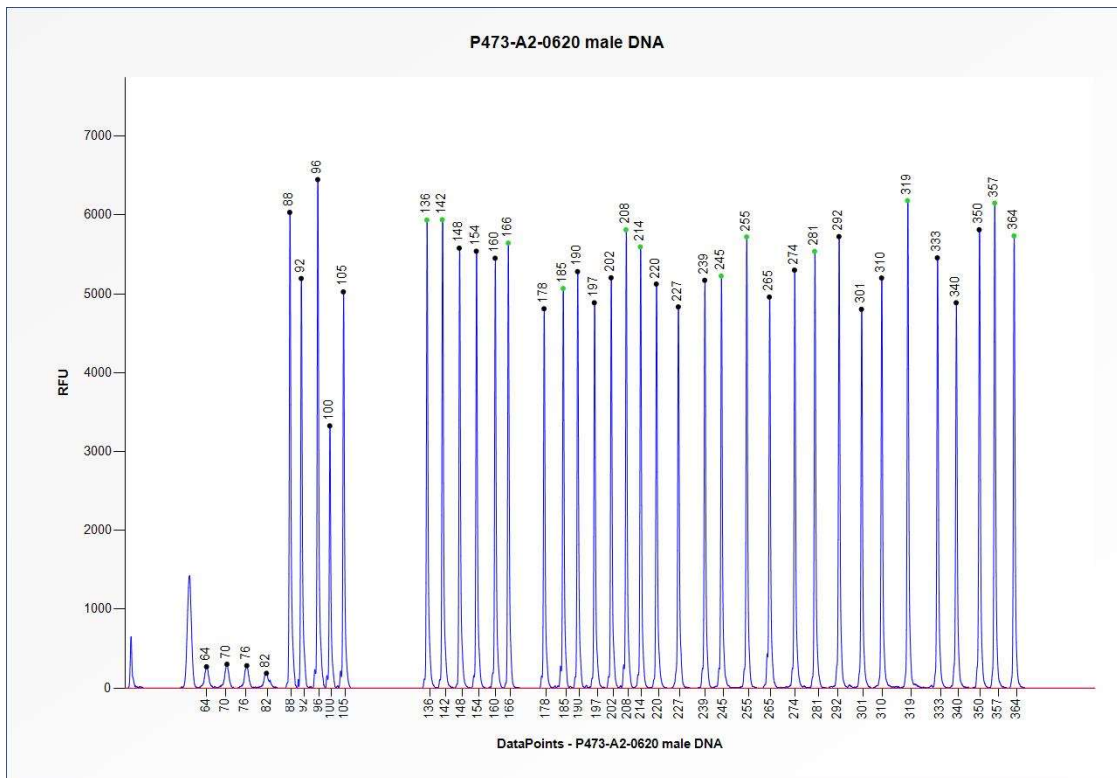


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P473 CTNS (A2-0620).

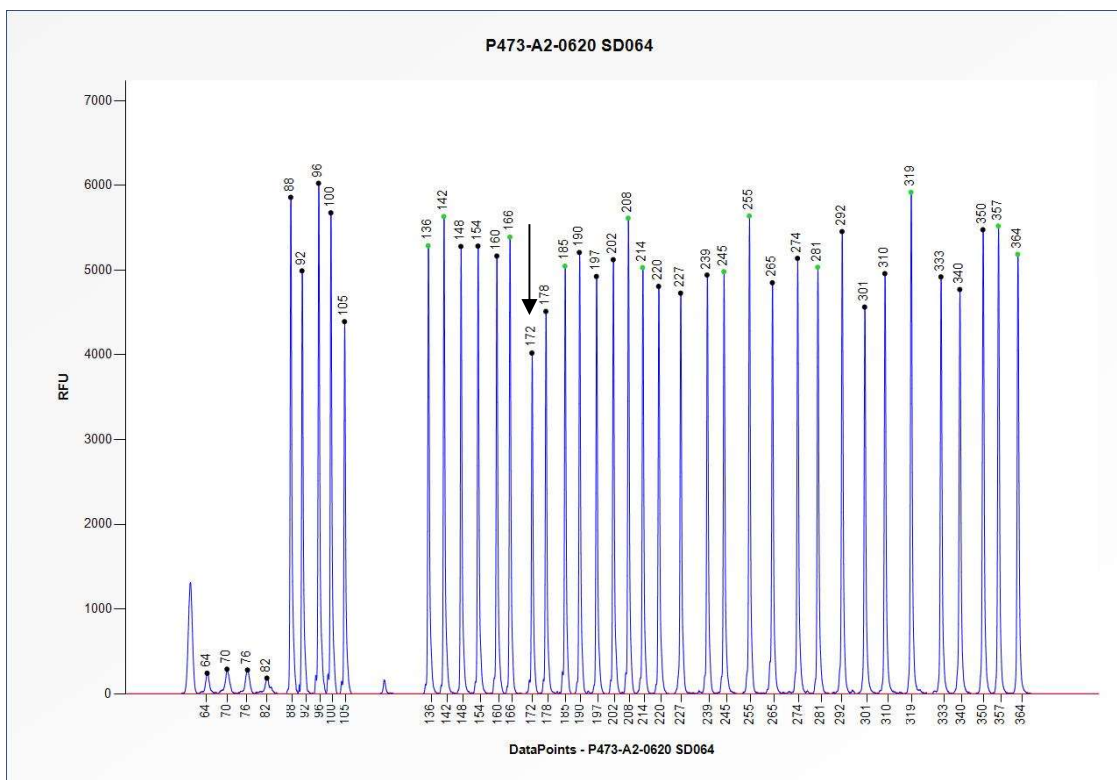


Figure 2. Capillary electrophoresis pattern from SALSA Binning DNA SD064-S01 (approximately 50 ng) analysed with SALSA MLPA Probemix P473 CTNS (A2-0620). The location of the *CTNS* c.414G>A mutation specific probe at 172 nt is indicated.

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This lot was certified by MRC-Holland on 23 September 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
<i>Version 01 – 23 September 2020 (04)</i> - Not applicable, new document.