

Certificate of Analysis

SALSA® MLPA® Probemix P091 CFTR

Catalogue #	P091-025R, P091-050R, P091-100R	
Product name	Probemix P091 CFTR	
 LOT	D2-0324	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: March 2029, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Purpose	This product has been developed to detect deletions or duplications in the human <i>CFTR</i> gene and the wild type allele of the <i>CFTR</i> p.Phe508del and p.Ile507del mutations, as described in the product description. This probemix is designed for use only in combination with SALSA MLPA reagent kits and Coffalyser.Net analysis software 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 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.	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 P091-D2 CFTR sample picture

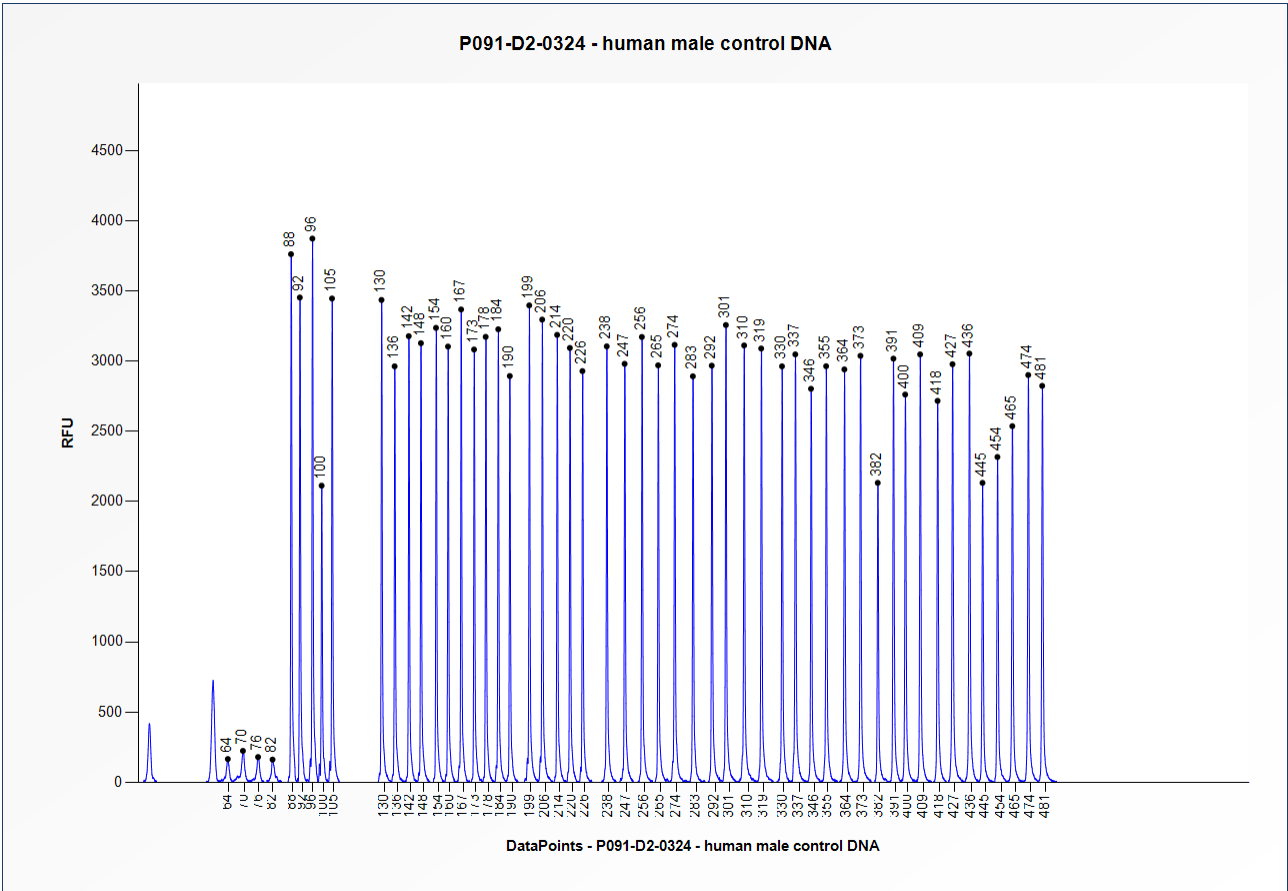


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P091 CFTR (D2-0324).

This lot was certified by MRC Holland on 08 April 2024.

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 02 – 19 June 2025 (6) - Reference to product description in Purpose section updated.
Version 01– 08 April 2024 (6) - Not applicable, new document.