





Certificate of Analysis

SALSA® MLPA® Probemix P438 Celiac Disease

Catalogue #	P438-025R, P438-050R, P438-100R	
Product name	Probemix P438 Celiac Disease	
 LOT	D3-0921	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: September 2026, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Purpose	This probemix has been developed to determine specific HLA-DQ variants, 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	<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 reference 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 P438-D3 Celiac Disease sample picture

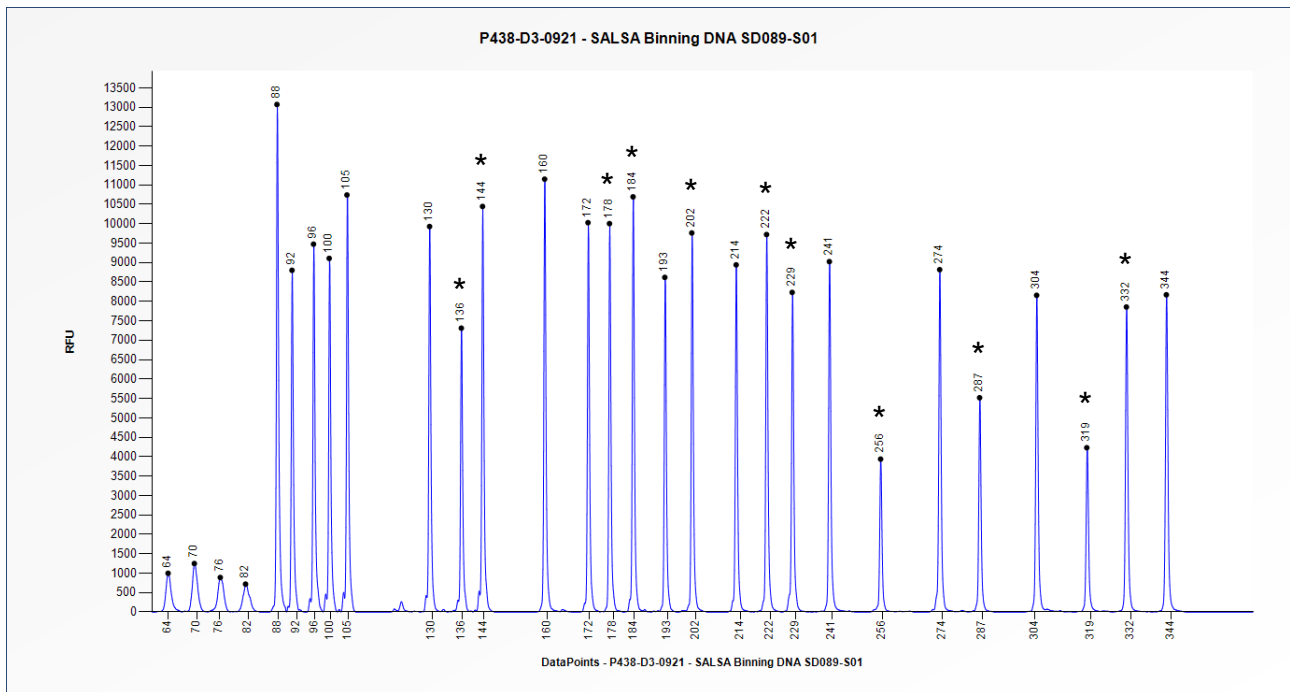


Figure 1. Capillary electrophoresis pattern from SALSA Binning DNA SD089-S01 (approximately 50 ng) analysed with SALSA MLPA Probemix P438 Celiac Disease (D3-0921). The location of the probes specific for HLA-DQ2.2, HLA-DQ2.5 and HLA-DQ8 are indicated.

This lot was certified by MRC Holland on 04 October 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.

Implemented changes in the COA

Version 02 – 19 February 2025 (6)

- Reference to Product Description tables removed from section Purpose.
- SALSA Binning DNA SD089 removed from section Purpose.

Version 01 – 18 October 2022 (6)

- Not applicable, new document.