

Certificate of Analysis

SALSA® MLPA® Probemix P163 GJB-WFS1-POU3F4

Catalogue #	P163-025R, P163-050R, P163-100R	
Product name	Probemix P163 GJB-WFS1-POU3F4	
 LOT	E1-0921	
	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 product has been developed to determine the DNA copy number of the human <i>GJB2</i> , <i>GJB6</i> , <i>WFS1</i> , <i>POU3F4</i> genes, genomic microdeletions upstream of <i>POU3F4</i> , and the presence of six specific mutations in the <i>GJB2</i> gene, 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 from the same sex, 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 peaks below the 25% threshold with lengths of approximately 259 and 364 nt in a No-DNA control.	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 P163-E1 GJB-WFS1-POU3F4 sample pictures

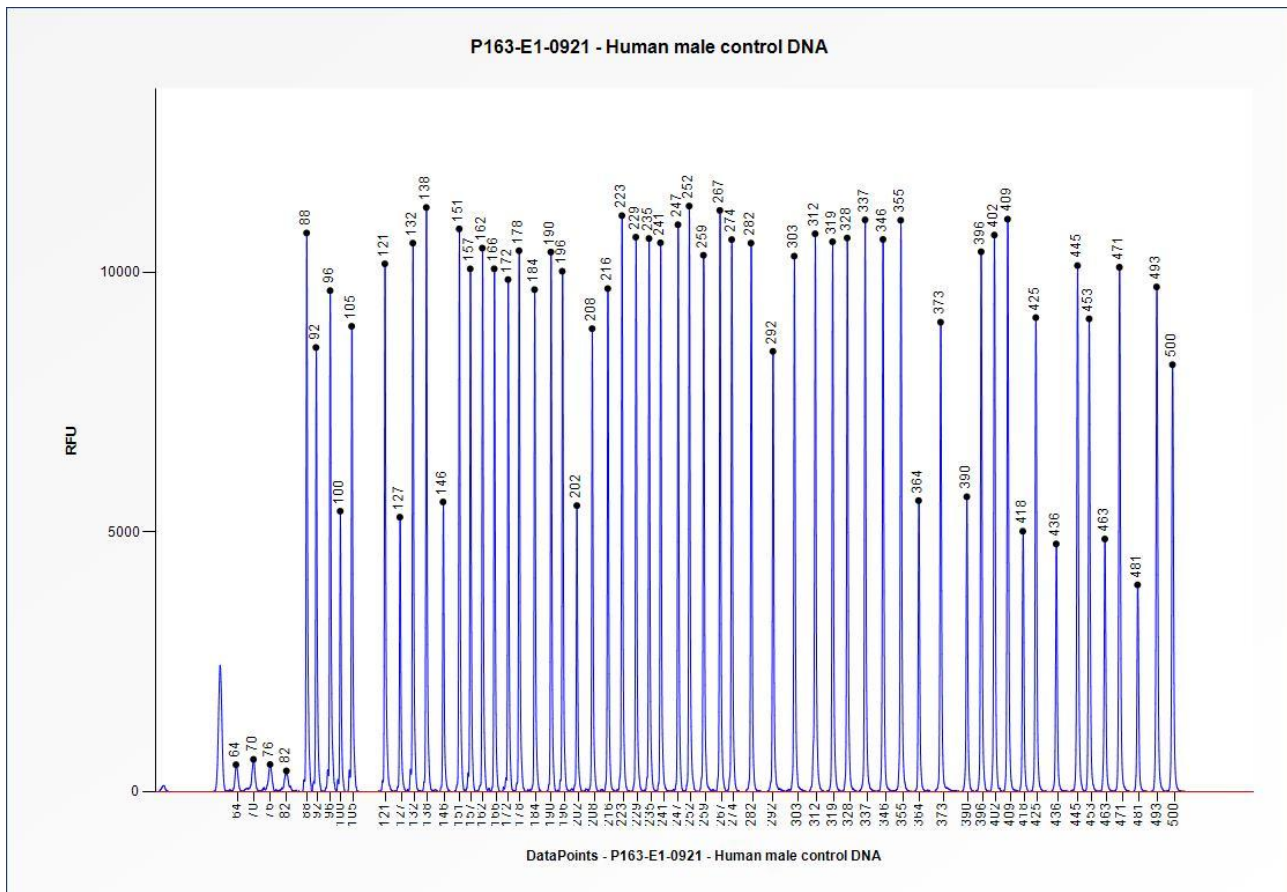


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P163 GJB-WFS1-POU3F4 (E1-0921).

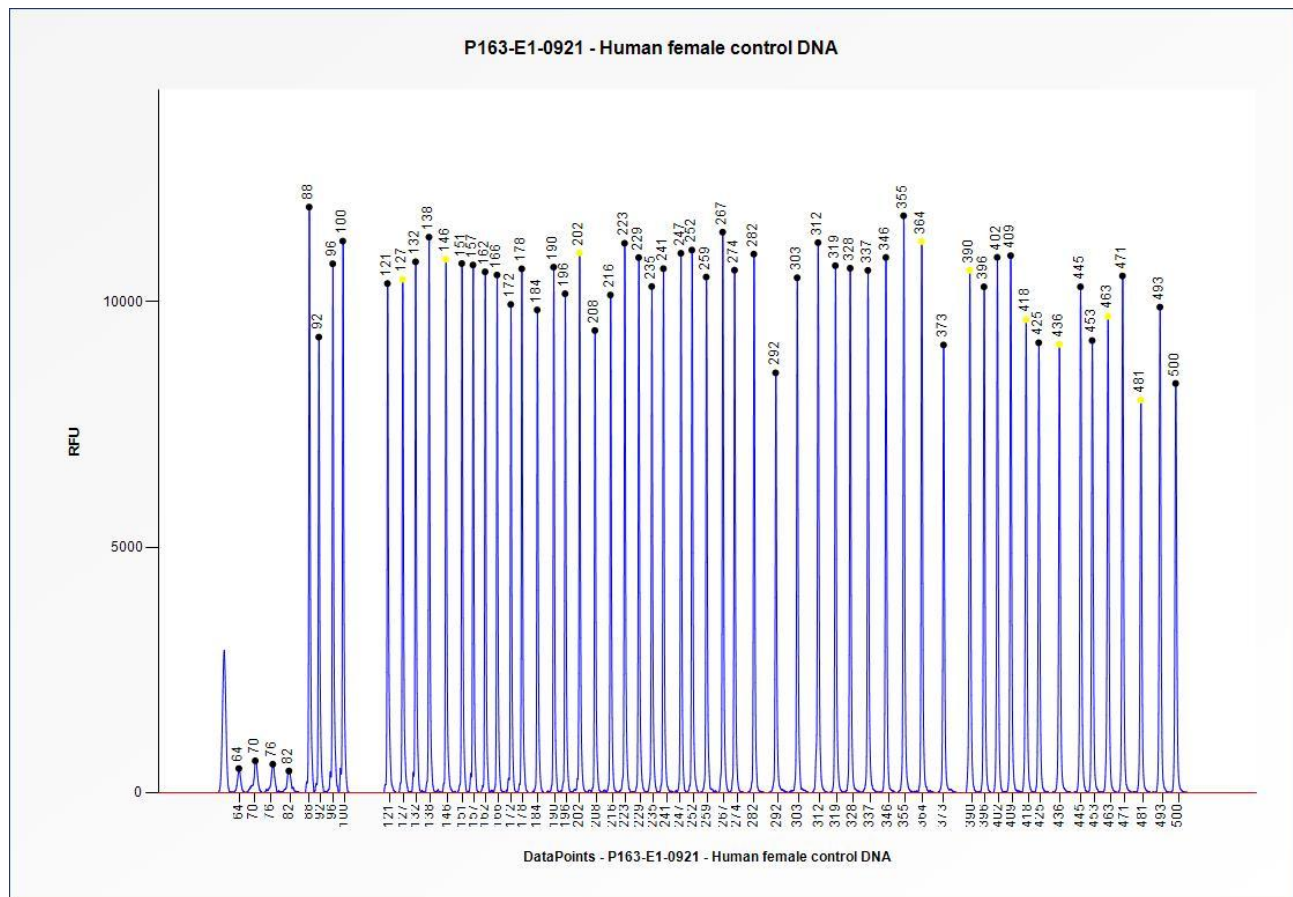


Figure 2 Capillary electrophoresis pattern from a sample of approximately 50 ng human female control DNA analysed with SALSA MLPA Probemix P163 GJB-WFS1-POU3F4 (E1-0921).

This lot was certified by MRC Holland on 25 January 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 – 9 January 2026 (6)

- *GJB3* gene removed from the purpose section.
- Reference to Table 1 and 2 of the product description removed from the purpose section.
- Note added to quality control specifications section that two peaks below the 25% threshold have been observed in a No-DNA control

Version 01 – 01 February 2022 (6)

- Not applicable, new document.