





Certificate of Analysis

SALSA® MLPA® Probemix P380 Wilms' tumour

Catalogue #	P380-025R, P380-050R, P380-100R	
Product name	Probemix P380 Wilms' tumour	
LOT	B1-0220	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: February 2025, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Use	This product has been developed to detect DNA copy number alterations on chromosomes 1 and 16 and in the human <i>MYCN</i> , <i>FBXW7</i> , <i>WT1</i> , <i>TP53</i> , and <i>AMER1</i> genes, as described in Table 1 and 2a 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 of 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 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 P380-B1 Wilms' tumour sample picture

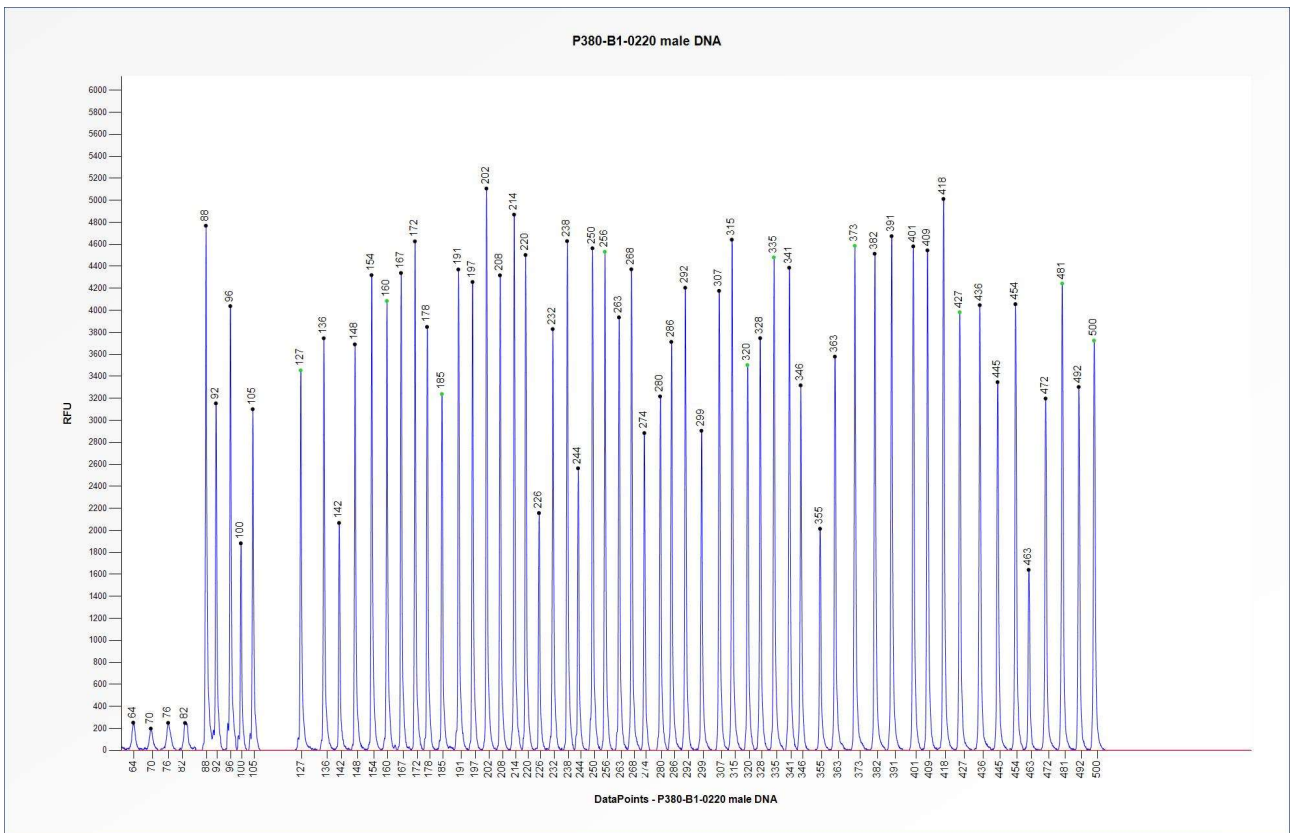


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P380-B1 Wilms' tumour (B1-0220).

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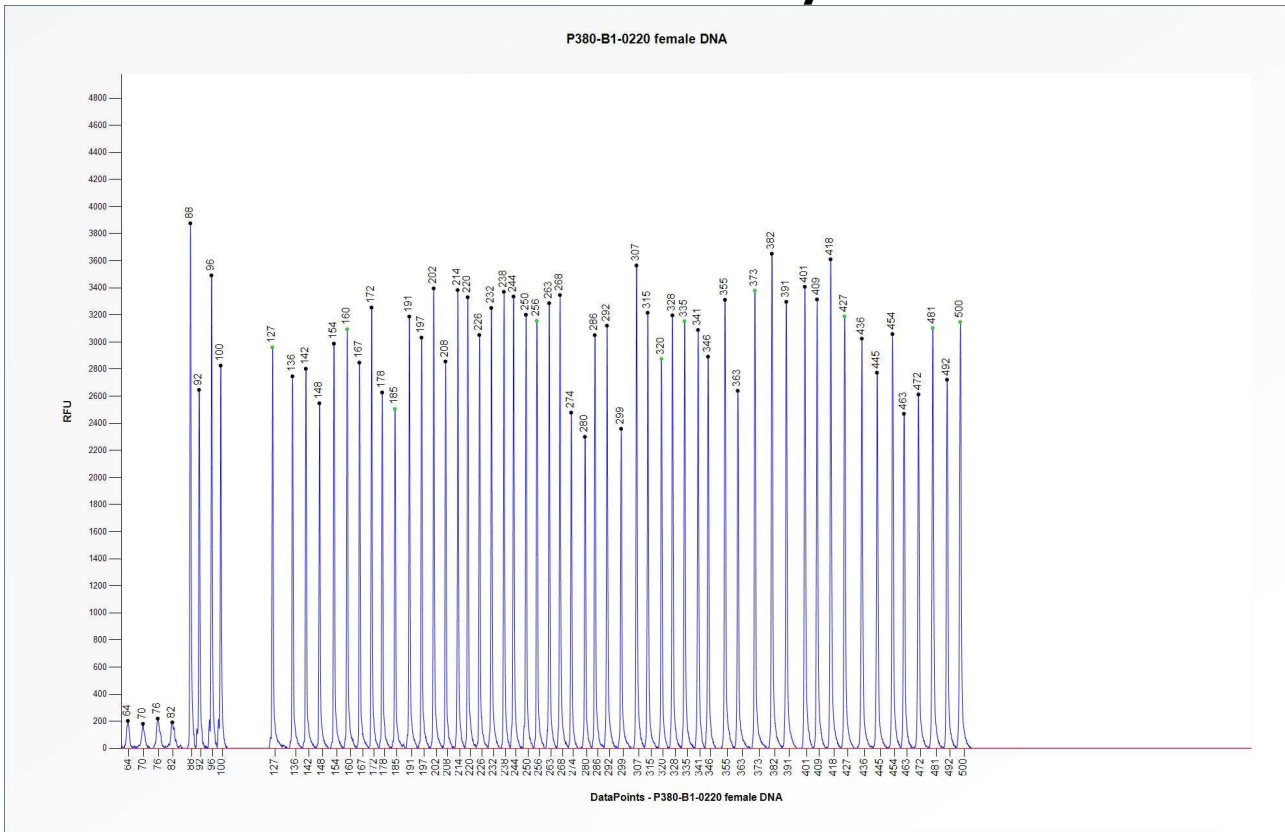


Figure 2. Capillary electrophoresis pattern from a sample of approximately 50 ng human female control DNA analysed with SALSA MLPA Probemix P380-B1 Wilms' tumour (B1-0220).

This lot was certified by MRC-Holland on 12 November 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

Version 02 – 02 December 2020 (04)

- Sentence about reaction-specific criteria was added to Quality control specifications.

Version 01 – 12 November 2020 (04)

- Not applicable, new document.