Certificate of Analysis
SALSA® MLPA® probemix P043 APC

Catalogue #	**P043-25R, P043-50R, P043-100R**
Product name	**Probemix P043 APC**
LOT	**E1-1216**

Σ	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25 °C and -15 °C.	
	Expiration date: December 2021, 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 exons of the human *APC* and *MUTYH* genes, and the region upstream of the *GREM1* gene, 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 as described in the MLPA General Protocol.	
Quality Test 1	Sufficient distance between peaks, absence of extra or shoulder peaks, completeness of hybridisation of each individual probe, as tested on Applied Biosystems 3130 and Beckman GeXP sequencers.	PASS
Quality Test 2	Standard deviation of each individual probe is <0.10, when tested on 23 different DNA samples of healthy individuals, extracted by various methods.	PASS
Quality Test 3	Standard deviation of each individual probe, tested on a single DNA sample under various experimental conditions, meeting reaction-specific criteria. Conditions tested include: pipetting errors; evaporation; deviating thermocycler temperatures; presence of salts (affecting DNA sample denaturation) or presence of impurities in the DNA sample.	PASS
Quality Test 4	No DNA controls resulted in only 5 major peaks shorter than 120 nucleotides (nt): 4 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 120 nt AND with a height >25% of the median of the 4 Q fragments were not observed. Note: peaks below this 25% threshold are not expected to affect MLPA reactions when sufficient (50-200 ng) sample DNA is used.	PASS

EUROPE*: **FOR IN VITRO DIAGNOSTIC (IVD) USE. THIS PRODUCT IS CE MARKED.**
OUTSIDE EUROPE: **FOR RESEARCH USE ONLY (RUO).**

*comprising EU member states, EU member states candidates, and members of the European Free Trade Association (EFTA). The product is for RUO in all other countries within Europe.

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	
	MRC-Holland bv; Willem Schoutenstraat 1 1057 DL, Amsterdam, The Netherlands
E-mail	info@mlpa.com (information & technical questions); order@mlpa.com (orders)
Phone	+31 888 657 200

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SALSA® MLPA® probemix P043-E1 APC sample pictures

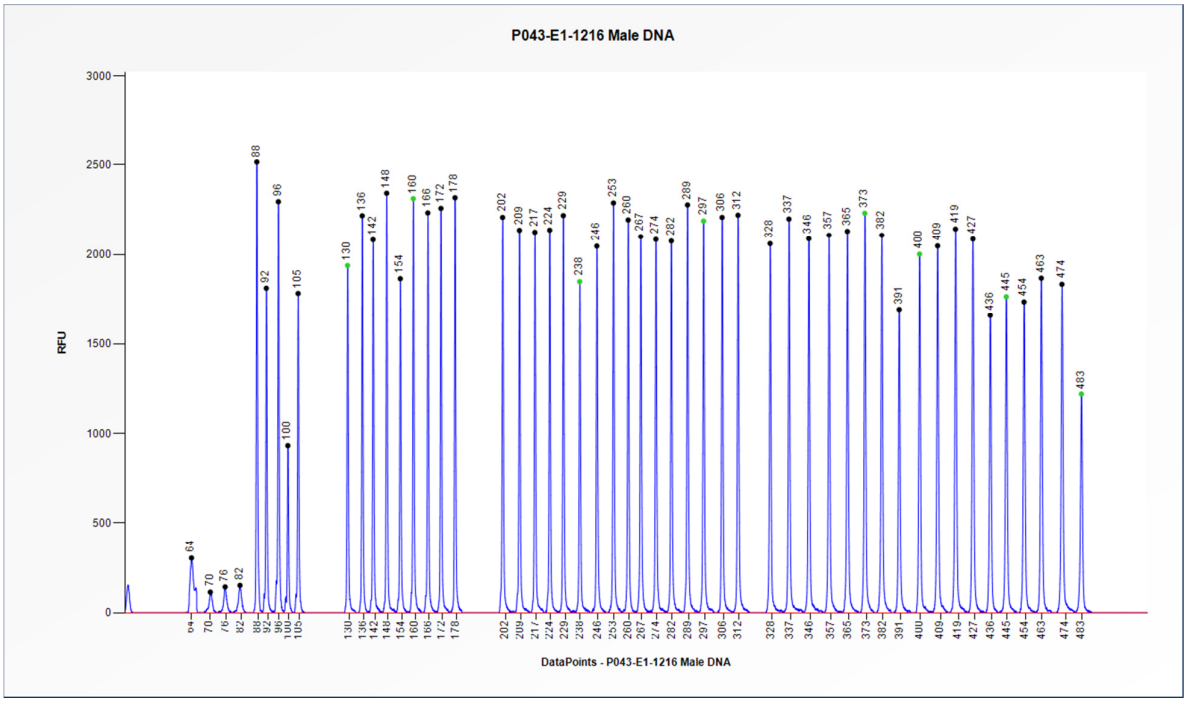

Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA probemix P043 APC (E1-1216).

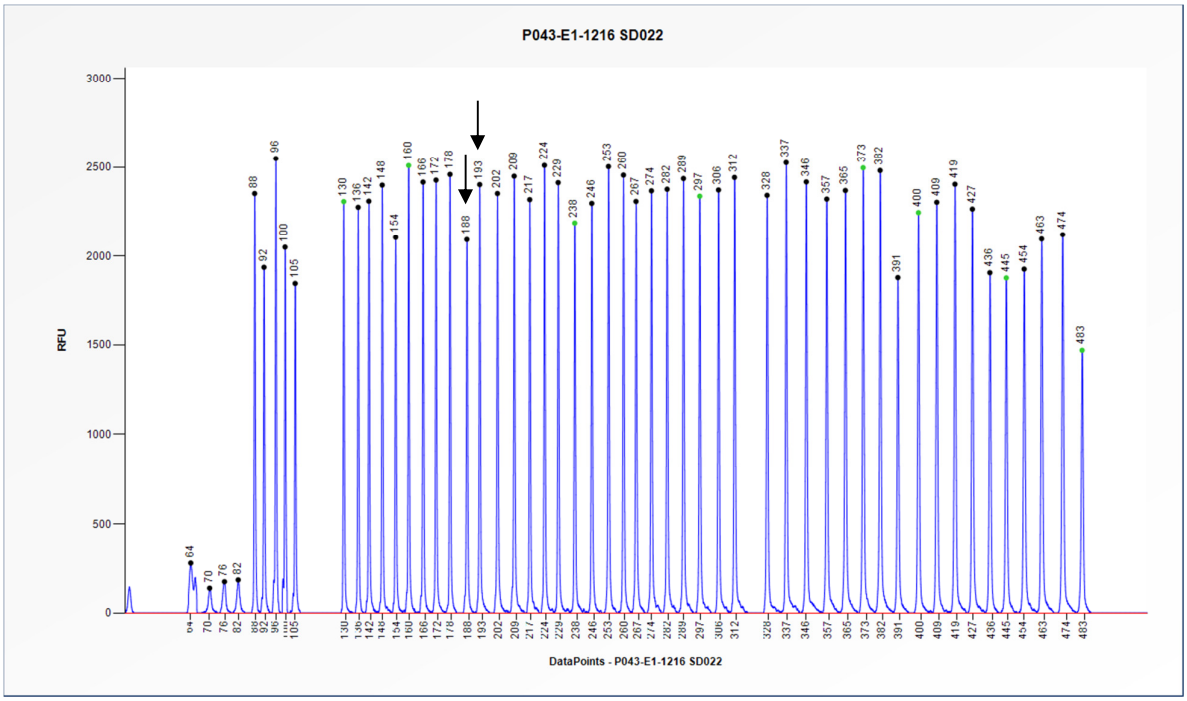

Figure 2. Capillary electrophoresis pattern of SD022 sample DNA (approximately 50 ng) analysed with SALSA MLPA probemix P043-E1 APC (lot E1-1216). The location of the c.536A>G (p.Tyr179Cys) and c.1187G>A (p.Gly396Asp) mutation-specific probes at 188 nt and 193 nt, respectively, are indicated.

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This lot was certified by MRC-Holland on 25 July 2017.
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 – 25 July 2017 (02) - Statement on use for in vitro diagnostic (IVD) purpose added. *Version 01 – 03 March 2017 (02)* - Not applicable, new document.