MRC-Holland MLPA®

COA Version 02; Issued 05 October 2018

Certificate of Analysis
SALSA® MLPA® Probemix P045 BRCA2/CHEK2

Catalogue #	**P045-025R, P045-050R, P045-100R**
Product name	**Probemix P045 BRCA2/CHEK2**
LOT	**C1-0416**

Σ	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25 °C and -15 °C.	
	Expiration date: April 2021, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Use	Detection of deletions or duplications in the human *BRCA2* gene, and the presence of the c.156_157insAlu mutation, in order to determine predisposition to hereditary breast and ovarian cancer (HBOC), as well as for the detection of the 1100delC mutation and deletions or duplications of exon 1 and 9 in *CHEK2* as a risk factor for breast cancer. 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 121 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 121 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 (50-250 ng) sample DNA is used.	PASS

EUROPE*, COLOMBIA, MOROCCO AND ISRAEL: FOR IN VITRO DIAGNOSTIC (IVD) USE. THIS PRODUCT IS CE MARKED.
ALL OTHER COUNTRIES: 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.

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More information: www.mlpa.com; www.mlpa.eu	
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SALSA® MLPA® probemix P045-C1 BRCA2/CHEK2 sample picture

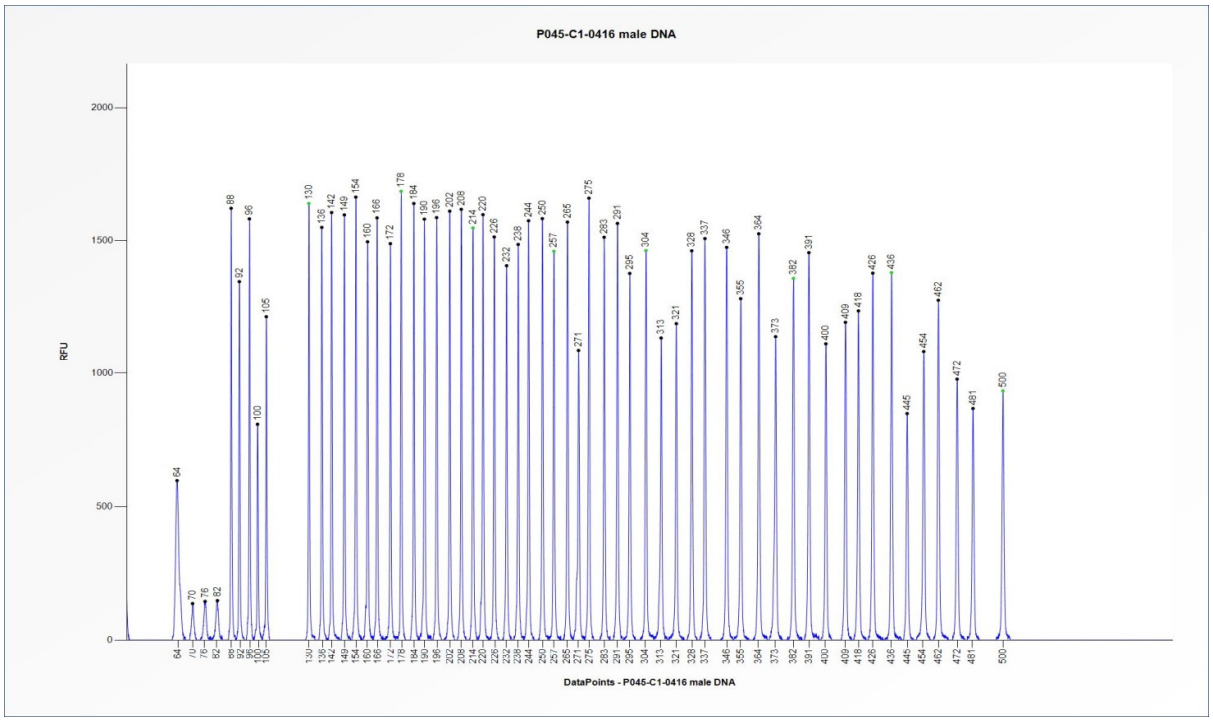

Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA probemix P045 BRCA2/CHEK2 (C1-0416).

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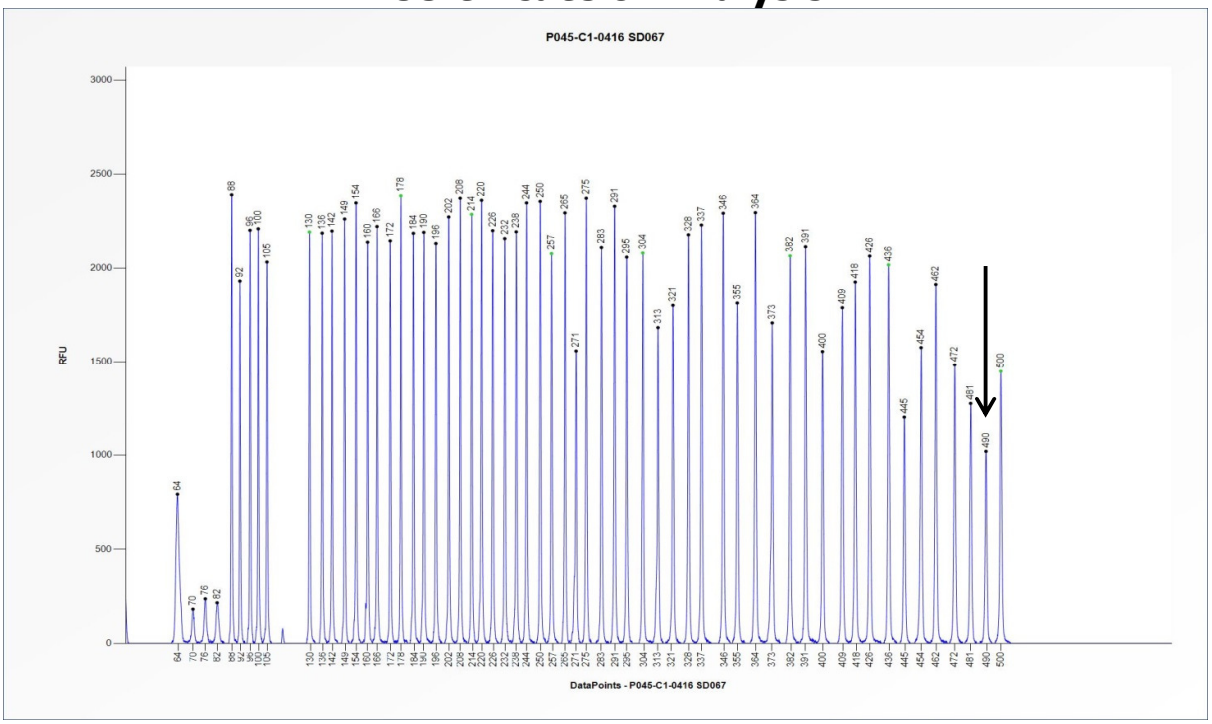

Figure 2. Capillary electrophoresis pattern of SALSA Binning DNA SD067 (approximately 50 ng) analysed with SALSA MLPA probemix P045 BRCA2/CHEK2 (C1-0416). The location of the *CHEK2* 1100delC mutation specific probe at 490 nt is indicated.

This lot was certified by MRC-Holland on 20 July 2016.
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- 05 October 2018 (03) - COA restructured and adapted to a new template. - Use was adjusted to better reflect the intended use of the product. - Countries where product has IVD status was updated. *Version 01 – 06 December 2016 (02)* - Not applicable, new document.