MRC-Holland MLPA®

*COA Version 01; Issued 27 June 2018*

# Certificate of Analysis
# SALSA® MLPA® Probemix P055 PAH

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|---|---|
| **Catalogue #** | **P055-25R, P055-50R, P055-100R** |
| **Product PAH** | **Probemix P055 PAH** |
| LOT | **D1-0418** |

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| 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 2023, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times. | |
| Use | This product is designed to determine the DNA copy number of the exons of the human PAH 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 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*, MOROCCO: 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.


| **More information: www.mlpa.com; www.mlpa.eu** | |
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| | MRC-Holland bv; Willem Schoutenstraat 1<br>1057 DL, Amsterdam, The Netherlands |
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| Phone | +31 888 657 200 |

# Certificate of Analysis

## SALSA® MLPA® probemix P055-D1 PAH sample picture

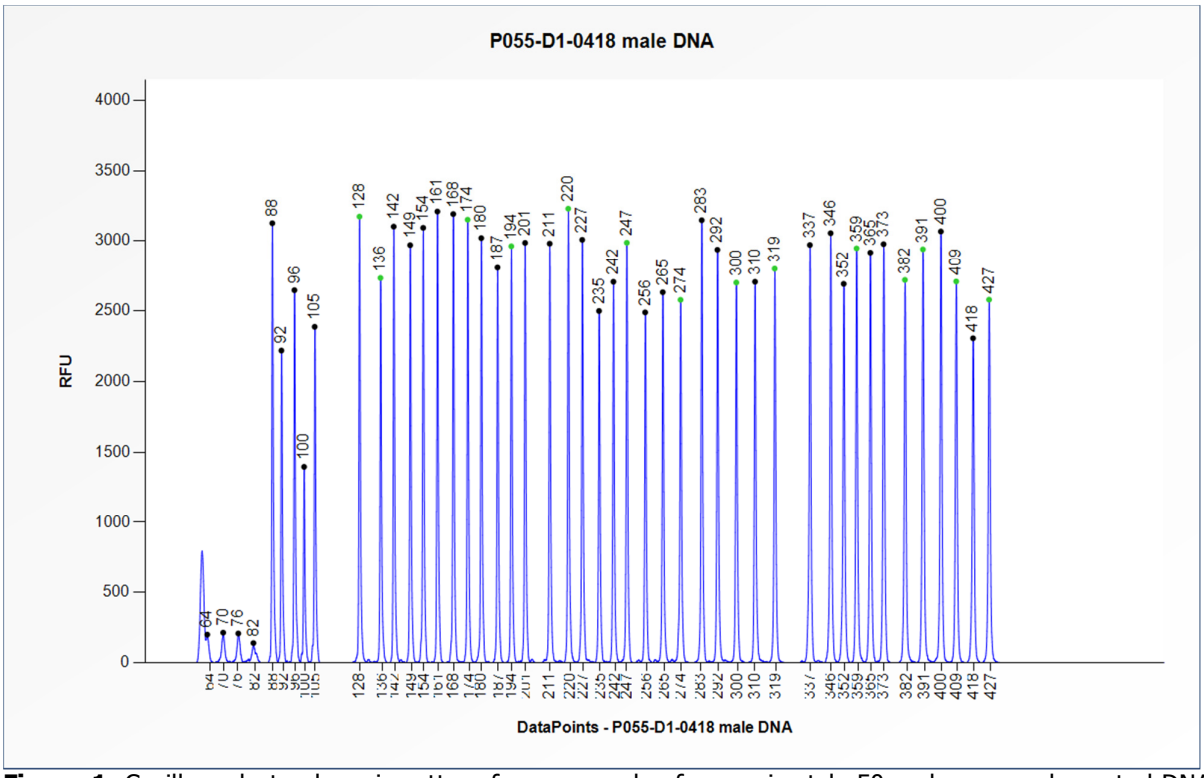


**Figure 1**. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA probemix P055 PAH (D1-0418).

**This lot was certified by MRC-Holland on 27 June 2018.**
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** |
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| *Version 01 – 27 June 2018 (03)*<br>- Not applicable, new document. |