

Certificate of Analysis

SALSA[®] MLPA[®] Probemix P128 CYP450

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| Catalogue # | P128-025R, P128-050R, P128-100R |
| Product name | Probemix P128 CYP450 |
| LOT | D2-0625 |

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|  | 25, 50, or 100 reactions. | |
| Shipping conditions | Dry ice or cooling elements. | |
|  | Store upon arrival between -25°C and -15°C. | |
|  | Expiration date: June 2030, 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>GSTM1</i> , <i>CYP1B1</i> , <i>CYP3A4</i> , <i>CYP3A5</i> , <i>CYP2C19</i> , <i>CYP2C9</i> , <i>CYP2E1</i> , <i>GSTP1</i> , <i>CYP1A2</i> , <i>CYP1A1</i> , <i>CYP2A6</i> , <i>CYP2B6</i> , <i>GSTT1</i> and <i>CYP2D6</i> genes, 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 | <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 reference probe ≤ 0.10, when tested on 23 different DNA samples of healthy individuals, 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. | 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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| More information: www.mrcholland.com ; www.mrcholland.eu | |
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SALSA MLPA Probemix P128-D2 CYP450 sample picture

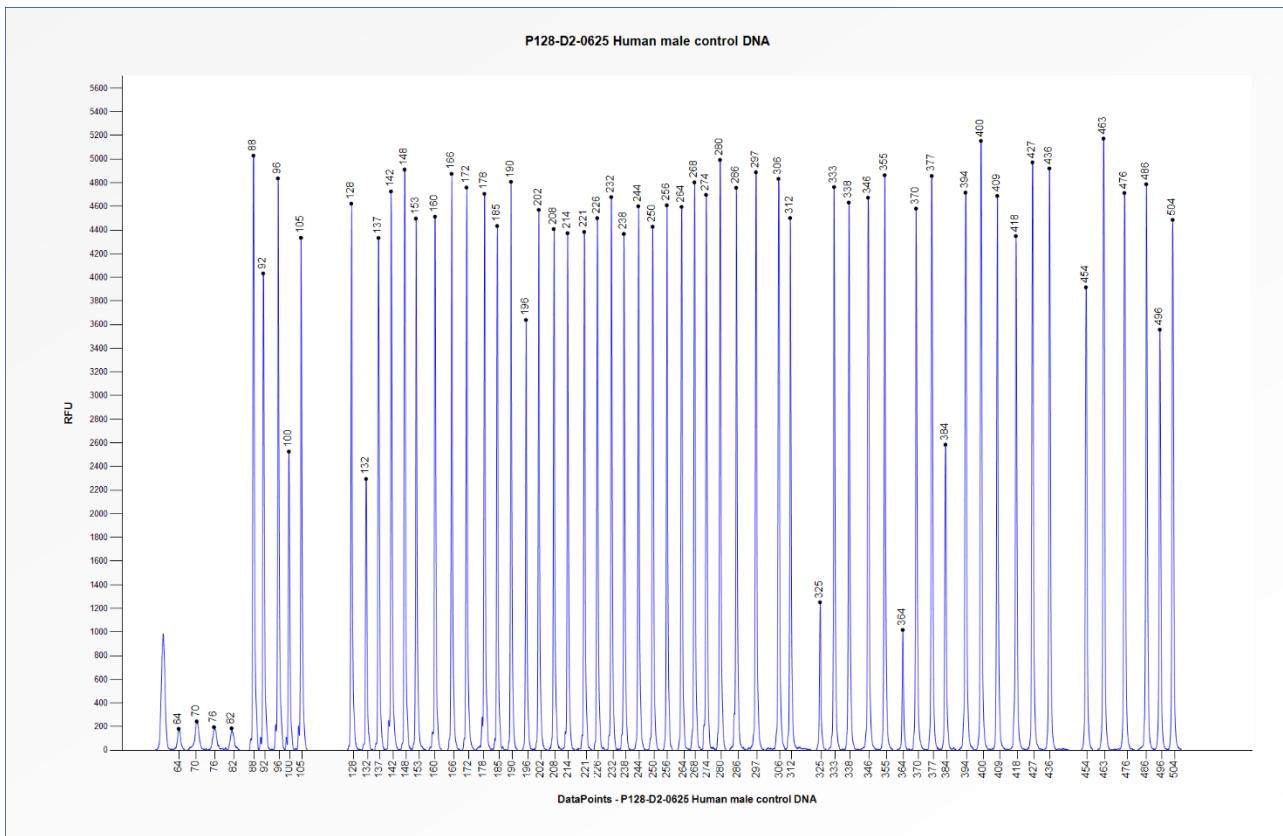


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P128 CYP450 (D2-0625). Be aware that CYP and GST genes are highly variable (in copy number) among healthy persons. The human male control DNA used here is a mixture of several male DNA's, therefore Figure 1 will not resemble the pattern obtained when testing a single sample.

This lot was certified by MRC Holland on 27 August 2025.

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 August 2025 (6) |
| - Not applicable, new document. |