




Certificate of Analysis

SALSA® MLPA® Probemix P040 CLL

Catalogue #	P040-025R, P040-050R, P040-100R	
Product name	Probemix P040 CLL	
LOT	B2-0622	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: June 2027, 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 following genomic regions and/or genes; the <i>TP53</i> gene (17p13), the <i>RB1/DLEU/MIR15A-16</i> -region (13q14), the <i>ATM</i> gene (11q22), and chromosome 12, 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 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, 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.

More information: www.mrcholland.com ; www.mrcholland.eu	
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SALSA MLPA Probemix P040-B2 CLL sample picture

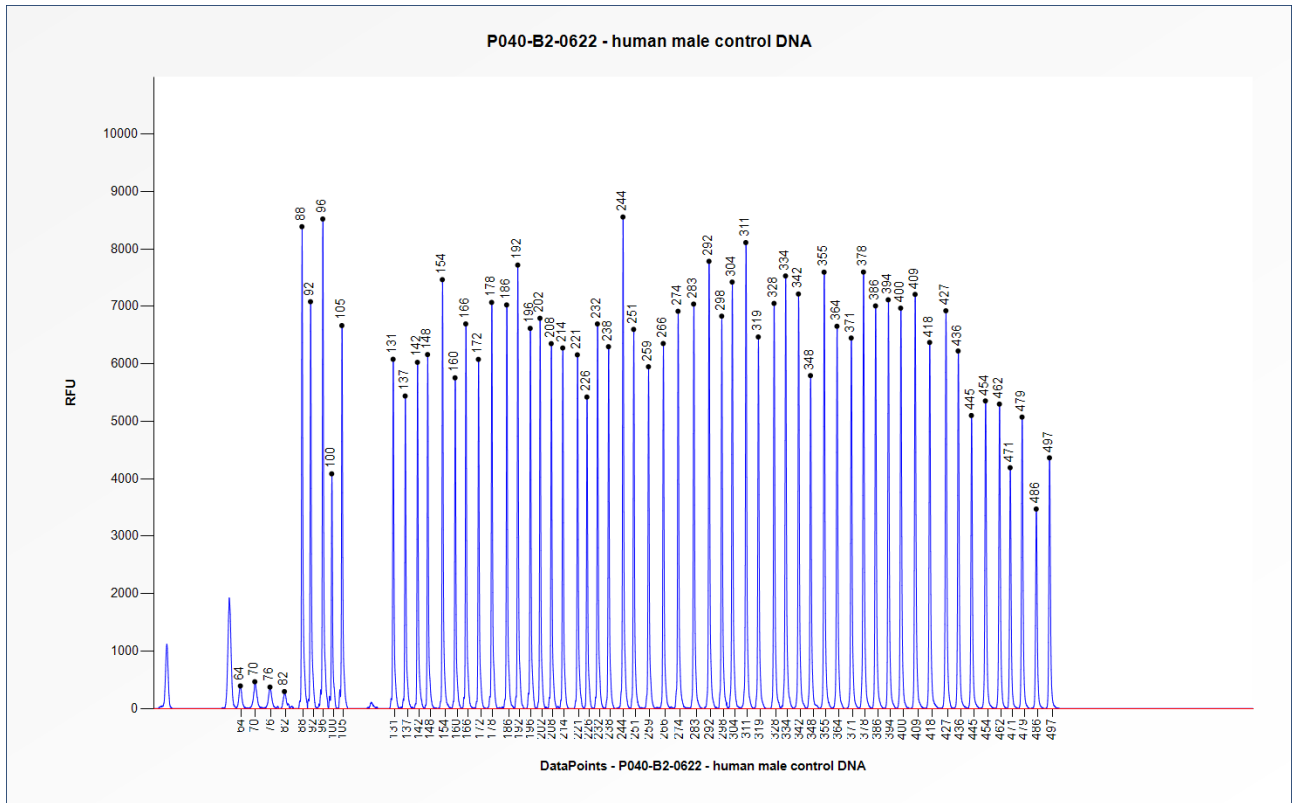


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA Probemix P040 CLL (B2-0622).

This lot was certified by MRC Holland on 25 May 2023

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 01 – 25 May 2023 (6) - Not applicable, new document.

Implemented changes of this TEMPLATE compared to the previous TEMPLATE(s)
Version 6 – 5 November 2020

- Changed default font type to Roboto as it has been decided to be the font type of body texts in IFUs.

Version 5 – 16 June 2020

- Updated company name, logo, web URL, email addresses.
- Document adapted to new company style: font changed to Montserrat, applied technique-specific title colour.
- QC specifications 1st remark: removed “3130” because ABI 3500 is used as well.
- Added comment to insert SD number in Purpose if an SD is used.
- Added “analysis software” after Coffalyser.Net.
- Changed length of the primer peak from 19 nt to the range of 0-40 nt to reflect that it depends on CE device.
- Added instructive comment to the implemented changes box for the case of template change: check previous COA version for notes/warnings.
- Minor textual changes.

Version 4 – 01 November 2018

- Use: Additional comment added: Do **NOT** include the disease/condition for which the probemix can be used to diagnosis (as the regulatory status of the probemix is now removed).
- Table listing separate Quality Tests has changed to remarks under Quality control specifications.
 - 1st remark: SCIEX added to Beckman.
 - 2nd remark: <0.10 changed to ≤0.10.
 - 3rd remark: Entire text has changed.
 - 4th remark: Word in first sentence “resulted” changed to “result”. Reorganized last sentences (starting at Non-specific peaks...) to include a standard sentence at the end regarding the observation of nonspecific peaks.
- Statement regarding IVD or RUO status removed.
- Added hyperlink to the www.mlpa.eu text in the more information box.
- Figure title: removed ® symbols.
- Figure legends: changed “pattern OF a sample” to “pattern FROM a sample.”
- Added SD version number to figure legend.

Version 03 – 13 December 2017

- Separate COA template made for ME probemixes.
- Header: COA template version number removed as it is also found in the implemented changes in the COA box.
- Expiration date: comment added regarding date.
- Quality Test 4: range of sufficient DNA changed from 50-200 ng to 50-250 ng.
- Figures: additional figure legends added if relevant to the probemix.

Version 02 – 12 February 2016

- Use section: information regarding the EK1 and EK5 SALSA MLPA reagents kits has been removed.
- New text regarding the Hazard Communication Standard has been added.
- www.mlpa.eu added to more information box.

Version 01 – 11 June 2015

- Not applicable, new document.