

Certificate of Analysis SALSA[®] digitalMLPA Probemix D001 Hereditary Cancer Panel 1

Catalogue #	D001-025R, D001-050R, D001-100R	
Product name	Probemix D001 Hereditary Cancer Panel 1	
LOT	C1-1221	
Σ	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
X	Store upon arrival between -25°C and -15°C.	
	Expiration date: December 2026, when stored at recommended product should not be frozen/thawed more than 25 times.	conditions. This
Purpose	This product has been developed for the detection of exon deletions or duplications in the human genes mentioned in Table 2 of the product description. This probemix is designed for use only in combination with a digitalMLPA reagent kit, SALSA barcode solution plate and Coffalyser digitalMLPA as described in the digitalMLPA General Protocol and D001-C1 product description.	
Quality control specifications	- Absence of non-specific interactions and completeness of hybridisation of each individual probe, as tested on MiSeq and	Test result
	 MiniSeq Illumina sequencers. Standard deviation of ≤0.10 for all probes with the exception of SNP- and mutation-specific probes, when tested on 48 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. 	PASS
	- Each individual probe is compatible (absence of non-specific interactions) with all available digitalMLPA barcode solutions.	
	- Each individual probe shows the expected final ratio when tested on positive samples with verified genomic aberrations.	

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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Certificate of Analysis

This lot was certified by MRC Holland on 21 February 2022.

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 – 06 September 2023 (01D)

- A reference to the D001-C1 product description was added to the purpose section.

Version 01 – 21 February 2022 (01D)

- Not applicable, new document.