

COA Version 03; Issued 06 November 2018

Certificate of Analysis SALSA® Binning DNA SD022

Catalogue #	SD022	
Product name	SALSA [®] Binning DNA SD022	
LOT	S01-0717	
Σ	6 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25 °C and -15 °C.	
	Expiration date: July 2022, when stored at recommended conditions.	
Use	To be used with SALSA MLPA P043-E1 probemix (APC), SALSA MLPA P072-D1 probemix (MSH6-MUTYH) or SALSA MLPA P378-D1 probemix (MUTYH); and SALSA MLPA reagent kits as described in the MLPA General Protocol and the corresponding probemix product descriptions.	
Quality Test 1	The mutation-specific probes, as described in the product description, produce a signal at the designed length.	PASS
Quality Test 2	The signal of the mutation-specific probes when tested with wild-type genomic DNA is <5% of the peak height generated when tested with SD022 SALSA Binning DNA.	PASS
Quality Test 3	The signal of the mutation-specific probes when tested with SD022 SALSA Binning DNA is at least 15% in peak height of the average probe signal of the 10 neighbouring probes	PASS
Quality Test 4	The 105 nt chromosome Y specific control probe should generate a signal on SD022 SALSA Binning DNA which is similar (+/-20%) to the signal obtained on wild-type male genomic DNA.	PASS
Quality Test 5	All SALSA MLPA probemix P043 (APC), P072 (MSH6-MUTYH) or P378 (MUTYH) probes, other than the mutation-specific probes, show normal signals, similar to the peak pattern obtained on wild-type genomic DNA.	PASS

EUROPE*: FOR IN VITRO DIAGNOSTIC (IVD) USE. THIS PRODUCT IS CE MARKED. OUTSIDE EUROPE: FOR RESEARCH USE ONLY (RUO).

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		
~	MRC-Holland bv; Willem Schoutenstraat 1 1057 DL, Amsterdam, The Netherlands	
E-mail	info@mlpa.com (information & technical questions); order@mlpa.com (orders)	
Phone	+31 888 657 200	

^{*}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.



Certificate of Analysis SALSA® Binning DNA SD022 sample pictures

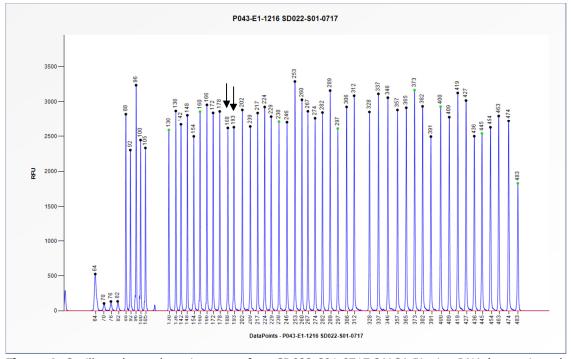


Figure 1. Capillary electrophoresis pattern from SD022-S01-0717 SALSA Binning DNA (approximately 50 ng) analysed with SALSA MLPA probemix P043 APC (E1-1216). The locations of the *MUTYH* c.536A>G (p.Tyr179Cys) mutation-specific probe at 188 nt and the *MUTYH* c.1187G>A (p.Gly396Asp) mutation-specific probe at 193 nt are indicated. Probe peak heights may vary between probemix version E1 lots.

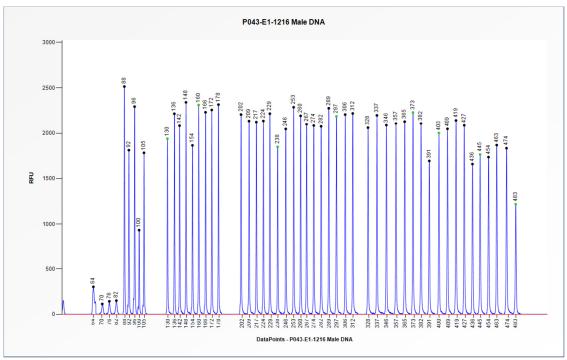


Figure 2. Capillary electrophoresis pattern from a sample of approximately 50 ng human male wild-type genomic DNA analysed with SALSA MLPA probemix P043 APC (E1-1216). Probe peak heights may vary between probemix version E1 lots.



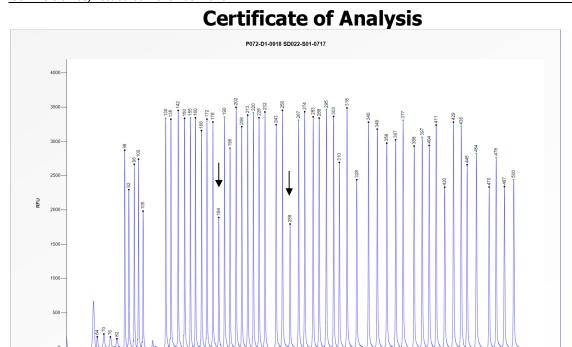


Figure 3. Capillary electrophoresis pattern from SD022-S01-0717 SALSA Binning DNA (approximately 50 ng) analysed with SALSA MLPA probemix P072 MSH6-MUTYH (D1-0918). The locations of the *MUTYH* c.536A>G (p.Tyr179Cys) mutation-specific probe at 184 nt and the *MUTYH* c.1187G>A (p.Gly396Asp) mutation-specific probe at 258 nt are indicated. Probe peak heights may vary between probemix version D1 lots.

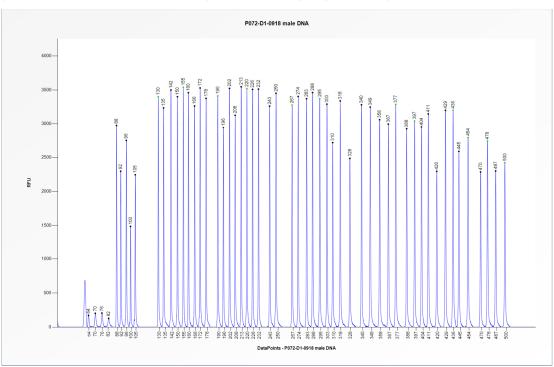


Figure 4. Capillary electrophoresis pattern from a sample of approximately 50 ng human male wild-type genomic DNA analysed with SALSA MLPA probemix P072 MSH6-MUTYH (D1-0918). Probe peak heights may vary between probemix version D1 lots.



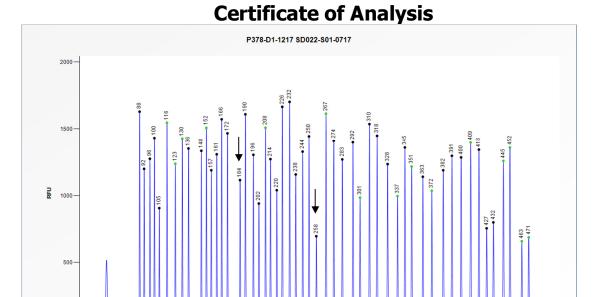


Figure 5. Capillary electrophoresis pattern from SD022-S01-0717 SALSA Binning DNA (approximately 50 ng) analysed with SALSA MLPA probemix P378 MUTYH (D1-1217). The locations of the *MUTYH* c.536A>G (p.Tyr179Cys) mutation-specific probe at 184 nt and the *MUTYH* c.1187G>A (p.Gly396Asp) mutation-specific probe at 258 nt are indicated. Probe peak heights may vary between probemix version D1 lots.

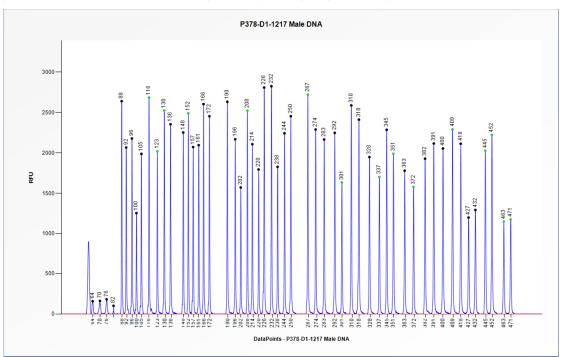


Figure 6. Capillary electrophoresis pattern from a sample of approximately 50 ng human male wild-type genomic DNA analysed with SALSA MLPA probemix P378 MUTYH (D1-1217). Probe peak heights may vary between probemix version D1 lots.



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Certificate of Analysis

This lot was certified by MRC-Holland on 11 August 2017.

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 03 – 06 November 2018 (03)

- Information about probemix P072-D1 added.

Version 02 – 21 February 2018 (03)

- Information about probemix P378-D1 added.

Version 01 – 15 August 2017 (03)

- Not applicable, new document.