

Product Description

SALSA® Binning DNA SD022-S01

Version S01

Catalogue number

- **SD022:** SALSA Binning DNA, 6 reactions

Certificate of Analysis

Information regarding storage conditions, quality tests, and a sample electropherogram from the current sales lot is available at www.mrcholland.com.

Precautions and warnings

For professional use only. Always consult the most recent product description AND the corresponding probemix product description AND the MLPA General Protocol before use: www.mrcholland.com. Binning DNA is not known to contain any harmful agents.

Safety data sheet

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.

Intended purpose

The SALSA Binning DNA SD022 is an in vitro diagnostic (IVD)¹ or research use only (RUO) reagent to be used in combination with SALSA MLPA Probemixes P043-E1 APC, P072-D1 MSH6-MUTYH or P378-D1 MUTYH, a SALSA MLPA Reagent Kit, and Coffalyser.Net analysis software for the processes of linking all probe signals to their identity by use of the probe lengths. SD022 contains the targets of all probes included in the above-listed probemixes, including the two mutation specific probe targets *MUTYH* c.536A>G (p.Tyr179Cys) and c.1187G>A (p.Gly396Asp).

Binning DNA should never be used as a reference sample in the MLPA data analysis. Neither should it be used in quantification of mutation signal(s).

¹Please note that this Binning DNA is for in vitro diagnostic (IVD) use in the countries specified at the end of this product description. In all other countries, the product is for research use only (RUO).

Experimental set up

MLPA reactions for binning purposes should be performed with 5 µl of Binning DNA. Inclusion of one reaction with SALSA Binning DNA SD022 in the initial MLPA experiment is essential as it can aid in data binning of the peak pattern when using Coffalyser.Net software. Furthermore, Binning DNA should be included in the experiment whenever changes have been applied to the set-up of the capillary electrophoresis device (e.g. when a different polymer type is used).

Data analysis

Coffalyser.Net software should be used for analysis of MLPA experiments. When performing the fragment analysis step in Coffalyser.Net, select SD022 in the *bin smpl* –column. By selecting the SD022 sample as your binning sample, probes will be correctly identified in the peak pattern across all samples. Coffalyser.Net software is freely downloadable at www.mrcholland.com.

Binning DNA content

SD022 consists of a mixture of female genomic DNA from healthy individuals and a titrated amount of synthetic DNA that contains partial sequences of the *MUTYH* gene. These partial sequences include two different mutations that will be detected by the mutation-specific probes present in the above-listed probemixes. See Table 1 and the corresponding probemix product descriptions for more details on mutation-specific probe targets present. The indicated mutation-specific probes will generate a signal on SD022.


Please note that the synthetic DNA also contains the target sequence of the 105 nt chromosome Y specific control fragment. As a result, the 100 and 105 nt control fragments indicate the presence of two copies chromosome X and one copy chromosome Y.

Table 1. Mutation-specific probe targets in Binning DNA SD022-S01

Probemix	Gene/Exon	Probe length (nt)	Probe ID	Probemix version	Details
P043	<i>MUTYH</i> exon 7	188	18416-SP0654-L29811	E1	c.536A>G (p.Tyr179Cys)
	<i>MUTYH</i> exon 13	193	21267-SP0655-L23442	E1	c.1187G>A (p.Gly396Asp)
P072	<i>MUTYH</i> exon 7	184	18416-SP0654-L23441	D1	c.536A>G (p.Tyr179Cys)
	<i>MUTYH</i> exon 13	258	18417-SP0655-L23442	D1	c.1187G>A (p.Gly396Asp)
P378	<i>MUTYH</i> exon 7	184	18416-SP0654-L23441	D1	c.536A>G (p.Tyr179Cys)
	<i>MUTYH</i> exon 13	258	18417-SP0655-L23442	D1	c.1187G>A (p.Gly396Asp)

Note: Please consult the corresponding probemix product description for more information about exon numbering, mutation nomenclature and gene transcripts used.

More information: www.mrcholland.com ; www.mrcholland.eu	
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IVD	EUROPE* (until lot 0421)  ISRAEL
RUO	EUROPE* (as of lot 1124) ALL OTHER COUNTRIES

*comprising EU (candidate) member states and members of the European Free Trade Association (EFTA), and the UK. The product is for RUO in all other European countries.

Implemented changes in the product description
<p><i>Version S01-10 – 10 December 2024 (03)</i></p> <ul style="list-style-type: none"> - Regulatory status has changed: SD022 is no longer CE marked from lot 1124 onwards. <p><i>Version S01-10 – 13 October 2022 (03)</i></p> <ul style="list-style-type: none"> - Product description rewritten and adapted to a new template. <p><i>Version S01-09 – 23 July 2021 (02)</i></p> <ul style="list-style-type: none"> - Product description rewritten and adapted to a new template. - Intended use was rewritten using new template text. - Warning related to quantification of mutation signals was adjusted to match the statements in the product descriptions of P043, P072 and P378. - UK has been added to the list of countries in Europe that accept the CE mark. <p><i>Version S01-08 – 16 June 2020 (01)</i></p> <ul style="list-style-type: none"> - Product is now registered for IVD use in Israel.