

Product Description

SALSA® Binning DNA SD079-S01

Version S01

Catalogue number

- **SD079:** 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 SD079 is an in vitro diagnostic (IVD)¹ or research use only (RUO) reagent to be used in combination with SALSA MLPA Probemix P088-D1 Oligodendroglioma 1p-19q, 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. SD079 contains the targets of all probes included in the above-listed probemix, including the targets of the IDH1 p.R132H, IDH1 p.R132C, IDH2 p.R172K and IDH2 p.R172M mutation-specific probes.

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 SD079 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 SD079 in the *bin smpl* –column. By selecting the SD079 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

SD079 consists of a mixture of female genomic DNA from healthy individuals and a titrated amount of synthetic DNA that contains partial sequences of the *IDH1* and *IDH2* genes. These partial sequences include four different mutations that will be detected by the mutation-specific probes present in the above-listed probemix. See Table 1 and the corresponding probemix product description for more details on mutation-specific probe targets present. The indicated mutation-specific probes will generate a signal on SD079.

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 SD079-S01

Probemix	Gene/Exon	Probe length (nt)	Probe ID	Probemix version	Details
P088	IDH1 exon 6	227	14787-L23353	D1	c.394C>T; p.R132C
	IDH1 exon 6	202	19529-L16492	D1	c.395G>A; p.R132H
	IDH2 exon 5	238	20963-L29002	D1	c.515G>A; p.R172K
	IDH2 exon 5	244	20963-L29001	D1	c.515G>T; p.R172M

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* 
RUO	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 S01-03 – 23 February 2023 (03)</i></p> <ul style="list-style-type: none"> - Product description rewritten and adapted to a new template. - Intended purpose updated; protein nomenclature instead of DNA nomenclature is used to indicate mutation-specific probe targets, and sentence about the content of the Binning DNA was removed as this information is covered elsewhere in the product description. - Small change of probe lengths in Table 1 in order to better reflect the true length of the amplification products. - UK has been added to the list of countries in Europe that accept the CE mark. <p><i>Version S01-02 – 14 December 2020 (02)</i></p> <ul style="list-style-type: none"> - Intended use/purpose updated to new template. <p><i>Version S01-01 – 27 April 2020 (02)</i></p> <ul style="list-style-type: none"> - Not applicable, new document.