

# Product Description

## SALSA® Binning DNA SD067-S01

### Version S01

#### Catalogue number

- **SD067:** 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](http://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](http://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 SD067 is an in vitro diagnostic (IVD)<sup>1</sup> or research use only (RUO) reagent to be used in combination with SALSA MLPA Probemixes P045-D1 BRCA2/CHEK2, P051-D2 Parkinson mix 1, P052-D2 Parkinson mix 2, P056-D1 TP53, P102-D1 HBB, 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. SD067 contains the targets of all probes included in the above-listed probemixes, including the mutation-specific probe targets *CHEK2* c.1100delC, *SNCA* c.88G>C, *LRRK2* c.6055G>A and *HBB* c.20A>T.

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).

<sup>1</sup>Please 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 SD067 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 SD067 in the *bin smpl* –column. By selecting the SD067 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](http://www.mrcholland.com).

#### Binning DNA content

SD067 consists of a mixture of female genomic DNA from healthy individuals and a titrated amount of plasmid DNA that contains partial sequences of the *CHEK2*, *SNCA*, *LRRK2* and *HBB* genes. These partial sequences include four 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 SD067.

Please note that the plasmid 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 SD067-S01**

Probemix	Gene/Exon	Probe length (nt)	Probe ID	Probemix version	Details
P045	CHEK2 exon 11	490	01772-L01336	D1	1100delC
P051	SNCA exon 2	154	02166-L27543	D2	c.88G>C; p.A30P
	LRRK2 exon 41	196	04575-L27549	D2	c.6055G>A; p.G2019S
P052	LRRK2 exon 41	172	04574-L27601	D2	c.6055G>A; p.G2019S
P056	CHEK2 exon 11	208	18318-L26751	D1	1100delC
P102	HBB exon 1	214	21234-L29609	D1	c.20A>T; p.Glu7Val

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

<b>More information:</b> <a href="http://www.mrcholland.com">www.mrcholland.com</a> ; <a href="http://www.mrcholland.eu">www.mrcholland.eu</a>	
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<b>IVD</b>	EUROPE*  ISRAEL
<b>RUO</b>	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.

<b>Implemented changes in the product description</b>
<p><i>Version S01-07 – 22 July 2022 (03)</i></p> <ul style="list-style-type: none"> <li>- Product description adapted to a new template.</li> <li>- Intended purpose updated: P045-C1 removed and sentence covering the components removed as this is covered elsewhere in the product description.</li> <li>- Information about P045-C1 probemix removed.</li> <li>- UK has been added to the list of countries in Europe that accept the CE mark.</li> </ul> <p><i>Version S01-06 – 20 October 2020 (02)</i></p> <ul style="list-style-type: none"> <li>- Intended use was updated.</li> <li>- Minor textual adjustments.</li> </ul> <p><i>Version S01-05 – 28 May 2019 (02)</i></p> <ul style="list-style-type: none"> <li>- New template version.</li> <li>- Information added on P045-D1 to be used with SD067 on page 1 and Table 1.</li> </ul>

*Version S01-04 – 04 February 2019 (01)*

- Product is now registered for IVD use in Israel.

*Version S01-03 – 28 August 2018 (01)*

- Information added on P051-D2/P052-D2 and P102-D1 to be used with SD067.
- Table 1 modified to include details about the additional targets on SD067.
- Minor textual adjustments.

*Version S01-02 – 04 July 2018 (01)*

- Information added on P056-D1 to be used with SD067.
- Table 1 modified to include details about the additional target on SD067.
- Minor textual adjustments.