

## Product Description SALSA® Binning DNA SD067-S01

### Version S01.

**Catalogue number: SD067:** SALSA® Binning DNA, 6 reactions

To be used with the following SALSA MLPA probemixes: P045-C1/D1 BRCA2/CHEK2, P051-D2/P052-D2 Parkinson, P056-D1 TP53 and P102-D1 HBB, in combination with a SALSA® MLPA® reagent kit, available for various number of reactions. MLPA reagent kits are either provided with FAM or Cy5.0 dye-labelled PCR primer, suitable for Applied Biosystems and Beckman capillary sequencers, respectively (see [www.mlpa.com](http://www.mlpa.com)).

**Certificate of Analysis:** Information regarding storage conditions, quality tests, and a sample electropherogram from the current sales lot is available at [www.mlpa.com](http://www.mlpa.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 or the MS-MLPA General Protocol before use: [www.mlpa.com](http://www.mlpa.com).

**Intended use:** 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-C1/D1, P051-D2, P052-D2, P056-D1, P102-D1, 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, *HBB* c.20A>T.

Please note that this Binning DNA is a mixture of female genomic DNA from healthy individuals and artificial DNA fragments of 50-80 nt length not covering the whole exon.

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 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 must 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 patient samples. Coffalyser.Net software is available free of charge on [www.mlpa.com](http://www.mlpa.com).

**Warning: 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).** It is strongly advised to use sample and reference DNA extracted with the same method and derived from the same source of tissue.

**Binning DNA content:** MRC-Holland is unable to provide mutation positive human DNA samples. As an alternative, we have prepared a mixture of female genomic DNA from healthy individuals and a titrated amount of plasmid DNA that contains the target sequences recognised by the mutation-specific probes present in the MLPA probemix versions as specified above and in Table 1.

The plasmid included in the SD067 DNA contains partial sequences of the *CHEK2*, *LRRK2*, *SNCA* and *HBB* genes. These sequences include four different point mutations which will be detected by MLPA probes that

are present in the aforementioned probemix versions (for details, see Table 1) and will generate a mutation-specific signal for these probes.

Please note that the plasmid contains the target sequences detected by the above mentioned probes and the sequence of the 105 nt chromosome Y specific control fragment. The amount of plasmid in this Binning DNA (relative to the genomic DNA) results in a relative probe signal for the 105 nt probe in this female DNA which is similar to the relative probe signal obtained in male DNA samples. As a result, the 100 and 105 nt control fragments indicate the presence of two copies chromosome X and one copy chromosome Y.


**Storage and stability:** Upon arrival, Binning DNA must be stored between -25 °C and -15 °C, in the original packaging. When stored under the recommended conditions, a shelf life of at least 1 year is guaranteed, also after opening. The expiry date is mentioned on the label of the vial.

**Table 1. Mutation-specific probe targets in SD067-S01 Binning DNA**

Probemix	Gene/Exon	Probe length	Probe ID	Present in probemix version	Details
P045	<i>CHEK2</i> exon 11	490 nt	01772-L01336	D1, C1	1100delC
P051	<i>SNCA</i> exon 2	154 nt	02166-L27543	D2	c.88G>C; p.A30P
	<i>LRRK2</i> exon 41	196 nt	04575-L27549	D2	c.6055G>A; p.G2019S
P052	<i>LRRK2</i> exon 41	172 nt	04574-L27601	D2	c.6055G>A; p.G2019S
P056	<i>CHEK2</i> exon 11	208 nt	18318-L26751	D1	1100delC
P102	<i>HBB</i> exon 1	214 nt	21234-L29609	D1	c.20A>T; p.Glu7Val

**Note:** Mutation nomenclature and exon numbering used here may differ from literature! Please notify us of any mistakes: [info@mlpa.com](mailto:info@mlpa.com). Please consult the respective probemix product description to find corresponding gene transcripts.

**More information: [www.mlpa.com](http://www.mlpa.com); [www.mlpa.eu](http://www.mlpa.eu)**

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	EUROPE*  ISRAEL
	ALL OTHER COUNTRIES

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

**Implemented Changes – compared to the previous SD067 product description versions**

*Version S01-06 – 20 October 2020 (02)*

- Intended use was updated.
- Minor textual adjustments.

*Version S01-05 – 28 May 2019 (02)*

- New template version.
- Information added on P045-D1 to be used with SD067 on page 1 and Table 1.

*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.

*Version S01-01 – 12 December 2016 (01)*

- Not applicable, new document.