

Product Description SALSA® Binning DNA SD031-S01

Version S01.

Catalogue number: SD031: SALSA® Binning DNA, 6 reactions

To be used with the following SALSA MLPA probemix: P140-C1 HBA, 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).

Certificate of Analysis: Information regarding storage conditions, quality tests, and a sample electropherogram from the current sales lot is available at 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.

Intended use: The SALSA Binning DNA SD031 is an in vitro diagnostic (IVD)¹ or research use only (RUO) reagent to be used in combination with SALSA MLPA Probemix P140-C1 HBA, 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. SD031 contains the targets of all probes included in the above-listed probemix, including the mutation specific probe target *HBA2* c.427T>C.

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.

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 SD031 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 SD031 in the *bin smpl*-column. By selecting the SD031 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.

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, as for this purpose true mutation-positive patient samples or cell lines should be used. 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 sequence recognised by the mutation-specific probe present in the MLPA probemix version as specified above and in Table 1.

The plasmid DNA included in the SD031 DNA contains a partial sequence of the *HBA2* gene. This sequence includes one mutation which will be detected by the MLPA probe that is present in the aforementioned probemix version (for details, see Table 1) and will generate a mutation-specific signal for this probe. Please note that the plasmid DNA contains the target sequence detected by the above mentioned probe 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 on this female DNA

which is similar to the relative probe signal obtained on 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 target in SD031-S01 Binning DNA

Probemix	Gene/Exon	Probe length	Probe ID	Present in probemix version	Details
P140	HBA2 exon 3	136 nt	S0585-SP0043-L09493	C1	c.427T>C; p.*143Glnext*31 (Hb Constant Spring mutation)

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

More information: www.mlpa.com; www.mlpa.eu

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IVD	EUROPE*  COLOMBIA ISRAEL
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 – compared to the previous SD031 product description versions

Version S01-08 – 06 May 2021 (02)

- Intended use adjusted.
- UK has been added to the list of countries in Europe that accept the CE mark.

Version S01-07 – 05 February 2019 (02)

- Product description adapted to a new template.
- Product is now registered for IVD use in Colombia and Israel.

Version S01-06 – 9 June 2017 (01)

- Product description adapted to a new template.
- Information about P247, P280 and P347 probemixes has been removed and can be found in the product description of SD071 Binning DNA from now on.

Version 05 – 27 June 2016 (14)

- Exon number and mutation names are adjusted for P247 mutation-specific probes for CX3CR1 and CCR2 genes in Table 1.
- Lot number removed throughout document.
- Statement on use for IVD purposes added.
- Contact details adjusted.
- Various minor textual and layout changes.