# Product Description
# SALSA® Binning DNA SD032-S02

**Version S02**
As compared to version S01, a new plasmid was used. The probe targets remained the same.

**Catalogue number**
- **SD032:** 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 SD032 is an in vitro diagnostic (IVD)[1] or research use only (RUO) reagent to be used in combination with SALSA MLPA Probemix P256-C1 FLCN, 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. SD032 contains the targets of all probes included in the above-listed probemix, including the two mutation-specific probe targets *FLCN* c.1285delC and c.1285dupC.

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).

[1]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 SD032 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 SD032 in the *bin smpl* –column. By selecting the SD032 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**
SD032 consists of a mixture of female genomic DNA from healthy individuals and a titrated amount of plasmid DNA that contains partial sequences of the *FLCN* gene. These partial sequences include two 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 SD032.

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 SD032-S02

| Probemix | Gene/Exon | Probe length (nt) | Probe ID | Probemix version | Details |
|---|---|---|---|---|---|
| P256 | *FLCN* exon 11 | 188 | 08598-L31913 | C1 | c.1285delC |
| | *FLCN* exon 11 | 195 | 08598-L31789* | C1 | c.1285dupC |

*Warning: In the majority of the samples without the c.1285dupC mutation, this probe will generate a background signal of 5-10% of the median peak height of all reference probes, which indicates absence of the mutation.

**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* CE |
| 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**

*Version S02-01 - 18 March 2022 (03)*
- Product description adapted to a new version of SD032.
- Product description adapted to a new template.

*Version S01-07 – 17 August 2021 (02)*
- The intended use is adapted to a new template.
- UK added to the list of countries in Europe that accept the CE-mark.
- Various minor textual changes.

*Version S01-06 - 06 December 2019 (02)*
- Product is now registered for IVD use in Europe.
- Probemix P256-B versions have been removed; the product description was rewritten for P256-C1.

*Version S01-05 – 23 October 2018 (15)*
- Information about P256-B4 probemix added in text on page 1 and table 1.
- Various minor textual changes.

*Version S01-04 – 31 January 2018 (15)*
- Information about P256-B1 and P256-B2 probemix removed.
- Product description adjusted to a new product description template (Precautions and warnings and information about experimental set-up added to page 1; Various textual and layout changes).

*Version 03 – 03 August 2016 (14)*
- Information on where to find corresponding gene transcripts added to Table 1.
- Various minor textual and layout changes.