

# Product Description

## SALSA® Binning DNA SD086-S01

### Version S01

#### Catalogue number

- **SD086:** 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 MS-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 SD086 is an in vitro diagnostic (IVD)<sup>1</sup> or research use only (RUO) reagent to be used in combination with SALSA MS-MLPA Probemix ME011-D1 Mismatch Repair Genes, a SALSA MLPA Reagent Kit, SALSA Hhal and Coffalyser.Net analysis software for the processes of linking all probe signals to their identity by use of the probe lengths. SD086 contains the targets of all probes included in the above-listed probemix, including the mutation-specific probe target *BRAF* p.V600E and SNP-specific probe target *MLH1* rs104894994 (C>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/SNP signals.

<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 SD086 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 SD086 in the *bin smpl* –column. By selecting the SD086 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

SD086 consists of a mixture of female genomic DNA from healthy individuals and a titrated amount of synthetic DNA that contains partial sequences of the *BRAF* and *MLH1* genes. These partial sequences include one mutation and one SNP that will be detected by the mutation/SNP-specific probes present in the above-listed probemix. See Table 1 and the corresponding probemix product description for more details on

mutation- and SNP-specific probe targets present. The indicated mutation- and SNP-specific probes will generate a signal on SD086.

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- and SNP-specific probe targets in Binning DNA SD086-S01**

Probemix	Gene/Exon	Probe length (nt)	Probe ID	Probemix version	Details
ME011	<i>BRAF</i> exon 15	226	08780-SP0039-L08904	D1	c.1799T>A; p.Val600Glu
	<i>MLH1</i> exon 1 <sup>i) ii)</sup>	289	22572-L31773	D1	SNP rs104894994 (C>T)

<sup>i)</sup> The rs104894994 SNP detected by the 289 nt SNP-specific probe (22572-L31773) is located at the HhaI enzyme recognition site of the 172 nt *MLH1* methylation-specific probe (01686-L28585), and therefore, in the *digested MS-MLPA reaction* 33% residual signal is expected on SD086.

<sup>ii)</sup> The target sequence of the 289 nt rs104894994 SNP-specific probe (22572-L31773) largely overlaps with the target sequence of the 172 nt methylation-specific probe (01686-L28585), resulting in increased signal (one additional copy) of the 172 nt probe on SD086 (ratio 1.3-1.65 expected) in the *undigested MS-MLPA reaction*.

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

More information: <a href="http://www.mrcholland.com">www.mrcholland.com</a> ; <a href="http://www.mrcholland.eu">www.mrcholland.eu</a>	
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	EUROPE* 
	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>Version S01-02 – 01 July 2022 (03)</p> <ul style="list-style-type: none"> <li>- Product description rewritten and adapted to a new template.</li> <li>- The intended purpose has been rephrased for clarity. There are no extensions or major changes to the intended purpose.</li> <li>- UK has been added to the list of countries in Europe that accept the CE mark.</li> </ul> <p>Version S01-01 – 22 April 2020 (2)</p> <ul style="list-style-type: none"> <li>- Not applicable, new document.</li> </ul>