Product Description SALSA® Binning DNA SD022-S01

Version S01.

Catalogue number: SD022: SALSA® Binning DNA, 6 reactions

To be used with the following SALSA probemixes: P043-E1 APC, P072-D1 MSH6-MUTYH and P378-D1 MUTYH, 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 before use: www.mlpa.com. It is the responsibility of the user to be aware of the latest scientific knowledge of the application before drawing any conclusions from findings generated with this product.

Intended use: This SD022 DNA is a Binning DNA sample for the MLPA probemix versions as specified above and in Table 1. See Table 1 and the corresponding probemix product description for more details on mutation-specific probe targets present. Binning and filtering are the processes of linking a signal to its probe identity by use of the probe length.
Please note that this Binning DNA is a mixture of female genomic DNA from healthy individuals and artificial DNA of 50-80 nt length not covering the whole exon.

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 SD022 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 SD022 in the *bin smpl* –column. By selecting the SD022 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 signals, 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 synthetic 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 synthetic DNA included in the SD022 DNA contains partial sequences of the MUTYH gene. These sequences include two different mutations which will be detected by MLPA probes that are present in the aforementioned probemix versions (for details, see Table 1) and will generate mutation-specific signals for these probes.
Please note that the synthetic DNA 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 synthetic DNA 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 targets in SD022-S01 Binning DNA

Probemix	Gene/Exon	Probe length	Probe ID	Present in probemix version	Details
P043	MUTYH exon 7	188 nt	18416-SP0654-L29811	E1	c.536A>G, p.Tyr179Cys (Y179C)
	MUTYH exon 13	193 nt	21267-SP0655-L23442	E1	c.1187G>A, p.Gly396Asp (G396D)
P072	MUTYH exon 7	184 nt	18416-SP0654-L23441	D1	c.536A>G, p.Tyr179Cys (Y179C)
	MUTYH exon 13	258 nt	18417-SP0655-L23442	D1	c.1187G>A, p.Gly396Asp (G396D)
P378	MUTYH exon 7	184 nt	18416-SP0654-L23441	D1	c.536A>G, p.Tyr179Cys (Y179C)
	MUTYH exon 13	258 nt	18417-SP0655-L23442	D1	c.1187G>A, p.Gly396Asp (G396D)

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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***EUROPE:** CE * comprising EU member states, EU member state candidates and members of the European Free Trade Association (EFTA).

OUTSIDE EUROPE: RUO **The product is for RUO in all other countries within Europe**

Implemented Changes – compared to the previous SD022 product description versions

Version S01-07 – 24 October 2018 (01)
- Information about P072-D1 probemix added in text on page 1 and table 1.

Version S01-06 – 30 January 2018 (01)
- Adjusted version for P378 probemix in text on page 1 and table 1.
- Adjusted document to IVD template.

Version S01-05 – 04 August 2017 (15b)
- Statement on use for IVD purposes added.

Version S01-04 – 22 February 2017 (15)
- Lot removed throughout document.
- Information about P043-E1 probemix added in text on page 1 and table 1.
- Precautions and warnings added on page 1.
- Various textual and layout changes.

Version 03 (08)
- Product description adapted to a new lot.

Version 02 (07)
- Product description adapted to a new lot.
- Information about P378-C probemix added in text on page 1 and in table 1.
- Exon numbering of the MUTYH gene has been updated in Table 1 due to changing to the new NG exon numbering (NG_008189.1).

Version 01 (01) - Not applicable, new document.