

Product Description

SALSA® Reference Selection DNA SD039-S02

Version S02

Catalogue number

- **SD039:** SALSA Reference Selection 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. Reference Selection 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 Reference Selection DNA SD039 is an in vitro diagnostic (IVD)* or research use only (RUO) reagent to be used in combination with SALSA MLPA Probemix P050 CAH, a SALSA MLPA Reagent Kit and Coffalyser.Net analysis software for the selection of suitable reference samples.

We recommend the use of this Reference Selection DNA SD039 only for initial experiments on DNA samples from healthy individuals with the intention to select suitable reference samples. Reference Selection DNA should never be used as a reference sample in the MLPA data analysis.

Reference samples for use in MLPA experiments should preferably be derived from the same type of tissue, and be purified by the same method, as the DNA samples to be tested. It is expected that approximately 1 in 5 (~20%) DNA samples from the general population are suitable as reference samples for use with SALSA MLPA Probemix P050 CAH.

*Please note that this Reference Selection DNA is for in vitro diagnostic (IVD) use in combination with SALSA MLPA Probemix P050-D1 CAH in the countries specified at the end of this product description. In all other countries, and/or when used in combination with SALSA MLPA Probemix P050-C1 CAH, the product is for research use only (RUO).

Experimental set up

MLPA reactions for reference selection purposes should be performed with 5 µl of Reference Selection DNA. Initial experiments for the selection of suitable reference samples should include three reactions with SALSA Reference Selection DNA SD039 as well as reactions on a number of independent DNA samples from healthy individuals. Patient samples should not be included in the experiment.

Data analysis

Coffalyser.Net software should be used for analysis of MLPA experiments. Coffalyser.Net software is freely available at www.mrcholland.com. When the SD039 reactions are set as reference samples in the data analysis, suitable reference samples will be those samples from healthy individuals that have a final probe ratio between 0.80 and 1.20 for all probes included in the probemix. Suitable reference samples selected as described can subsequently be used as reference samples in experiments with patient samples.

Reference Selection DNA content

SD039 consists of human genomic DNA purified from a selected cell line. This cell line has one copy/cell for the two *CYP21A2* alleles at the I2G locus and one copy/cell for the sequences detected by the chromosome Y specific MLPA probes in SALSA MLPA Probemix P050 CAH. Furthermore, it contains two copies/cell of each sequence detected by the other MLPA probes in this probemix, including six *CYP21A2* and four *CYP21A1P* pseudogene specific MLPA probes (for details, see Table 1 and Table 2).

General note

Reference Selection DNA SD039 is only an IVD reagent when used with the **D1** version of SALSA MLPA Probemix P050 CAH (IVD; Table 1) and not when used with the **C1** version of SALSA MLPA Probemix P050 CAH (RUO; Table 2).

Table 1. P050-D1 CAH probe targets in Reference Selection DNA SD039-S02

Probe length (nt)	Gene/Exon	Probe ID	Probemix version	Copy number	Remarks
130	Reference	00797-L13645	D1	2	
135	Reference	16316-L21434	D1	2	
148	TNXB Exon 35	19037-L14637	D1	2	
157	CYP21A2 Exon 4	22959-L32396	D1	2	I173N location
166	Reference	05721-L31493	D1	2	
175	CYP21A1P Exon 4	22961-L32398	D1	2	I173N location
184	CYP21A1P Exon 3	15221-L20262	D1	2	del8bp location
190	CYP21A2 Exon 3	15221-L20261	D1	2	del8bp location
202	TNXB Exon 20	22962-L32399	D1	2	
208	Reference	13384-L25019	D1	2	
214	CYP21A2 Exon 7	17261-L21169	D1	2	F308+T location
220	CYP21A1P Exon 7	17261-L21170	D1	2	F308+T location
226	Reference	14471-L16191	D1	2	
232	CYP21A2 Exon 6	17270-L16990	D1	2	V238E location
238	CYP21A2 Exon 6	17271-L16989	D1	2	M240K location
244	Reference	16307-L19696	D1	2	
253	CYP21A2 Exon 3	21552-L32321	D1	1	I2G location, C-allele
258	CYP21A2 Exon 3	21552-L20299	D1	1	I2G location, A-allele
267	Reference	14758-L32312	D1	2	
279	Reference	04988-L20303	D1	2	
292	CYP21A1P Exon 1	22963-L32401	D1	2	Exon 1, -113 SNP
307	CYP21A2 Exon 1	22964-L32402	D1	2	Exon 1, -113 SNP
318	TNXB Exon 35	15230-L14636	D1	2	
326	TNXB Exon 29	22965-L32568	D1	2	
336	Reference	09027-L09281	D1	2	
346	ATF6B Exon 1B	01979-L20800	D1	2	
355	TNXB Exon 31	15232-L01515	D1	2	
364	TNXB Exon 19	15235-L04400	D1	2	
373	Reference	05953-L30687	D1	2	
382	Reference	13329-L14755	D1	2	

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

Table 2. P050-C1 CAH probe targets in Reference Selection DNA SD039-S02

Probe length (nt)	Gene/Exon	Probe ID	Probemix version	Copy number	Remarks
130	Reference	00797-L13645	C1	2	
135	Reference	16316-L21434	C1	2	
148	TNXB Exon 35	19037-L14637	C1	2	
166	Reference	10729-L11311	C1	2	
184	CYP21A1P Exon 3	15221-L20262	C1	2	del8bp location
190	CYP21A2 Exon 3	15221-L20261	C1	2	del8bp location
214	CYP21A2 Exon 7	17261-L21169	C1	2	F308+T location
220	CYP21A1P Exon 7	17261-L21170	C1	2	F308+T location
226	Reference	14471-L16191	C1	2	
232	CYP21A2 Exon 6	17270-L16990	C1	2	V238E location
238	CYP21A2 Exon 6	17271-L16989	C1	2	M240K location
244	Reference	16307-L19696	C1	2	
254	CYP21A2 Exon 3	16645-L20231	C1	1	I2G location, C-allele
259	CYP21A2 Exon 3	16645-L20299	C1	1	I2G location, A-allele
265	CYP21A2 Exon 4	15220-L20667	C1	2	I173N location
272	CYP21A1P Exon 4	15220-L20668	C1	2	I173N location
279	Reference	04988-L20303	C1	2	
292	CYP21A1P Exon 1	15945-L18079	C1	2	Exon 1, -113 SNP
309	CYP21A2 Exon 1	15944-L18351	C1	2	Exon 1, -113 SNP
318	TNXB Exon 35	15230-L14636	C1	2	
326	TNXB Exon 23	19038-L17756	C1	2	
336	Reference	09027-L09281	C1	2	
346	ATF6B Exon 1B	01979-L20800	C1	2	
355	TNXB Exon 31	15232-L01515	C1	2	
364	TNXB Exon 19	15235-L04400	C1	2	
373	TNXB Exon 26	15233-L15002	C1	2	
382	Reference	13329-L14755	C1	2	

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* 
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 S02-10 – 03 May 2022 (03)

- Product is now CE marked in combination with P050-D1.
- Information about P050-D1 probemix added to intended purpose and Table 1; information about P050-C1 moved to Table 2.
- Mutation nomenclature is updated to current clinical guidelines.
- Various minor textual changes.

Version S02-09 – 20 September 2021 (03)

- Product description rewritten and adapted to a new template.

Version 08 – 28 January 2019 (12)

- Reference DNA was renamed to Reference Selection DNA.
- The position of the ATF6B probe was updated to exon 1B.
- Number of reactions is adjusted on page 1.

Version 07 – 9 May 2017 (12)

- SD lot removed on page 1.
- Information about experimental set up added on page 1.
- Contact details adjusted on page 1.
- Various minor textual and layout changes.