

Product Description

SALSA® Reference Selection DNA SD072-S01

Version S01

Catalogue number

- **SD072:** SALSA Reference Selection DNA, 20 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.

SALSA Reference Selection DNA SD072 is no longer intended for use in combination with SALSA MLPA Probemix P008 PMS2. SALSA Reference Selection DNA SD082 is now available as an aid to select suitable reference samples for use with the P008 PMS2 probemix, and is included in every order of the probemix.

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

SALSA Reference Selection DNA SD072 is an in vitro diagnostic (IVD)¹ or research use only (RUO) reagent to be used in combination with SALSA MLPA Probemix P236-B1 CFH Region, 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 SD072 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. When testing DNA samples from healthy Caucasian individuals, approximately 50% of all DNA samples tested are suitable as reference samples for use with SALSA MLPA Probemix P236-B1 CFH Region.

¹Please note that this Reference Selection 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 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 SD072 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 SD072 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

SD072 consists of human genomic DNA purified from a selected cell line. This cell line has two copies of the *CFH*, *CFHR1*, *CFHR2*, *CFHR3*, *CFHR4* and *CFHR5* genes. Probes for these six genes are included in SALSA MLPA Probemix P236-B1 CFH Region (for details, see Table 1).

Table 1. P236 CFH Region probe targets in Reference Selection DNA SD072-S01

Probe length (nt)	Gene/Exon	Probe ID	Probemix version	Copy number
130	Reference	00797-L00463	B1	2
135	<i>CFHR3</i> upstream	22996-L32432	B1	2
139	<i>CFH</i> downstream	22043-L08618	B1	2
142	<i>CFH</i> exon 2	07821-L07575	B1	2
148	<i>CFHR4</i> exon 10	22111-L31098	B1	2
154	<i>CFHR3</i> exon 4	22069-L31040	B1	2
157	Reference	02731-L01824	B1	2
164	<i>CFHR3</i> exon 1	07832-L07588	B1	2
168	<i>CFHR3</i> exon 6	08218-L09921	B1	2
172	<i>CFH</i> exon 15	22071-L31042	B1	2
179	<i>CFH</i> exon 3	07822-L07576	B1	2
184	<i>CFHR2</i> exon 4	07844-L07600	B1	2
190	Reference	03915-L03370	B1	2
196	<i>CFHR1</i> exon 4	22072-L31043	B1	2
202	<i>CFH</i> exon 1	07820-L07574	B1	2
208	<i>CFH</i> exon 18	22073-L31044	B1	2
214	<i>CFH</i> exon 14	22074-L31045	B1	2
220	Reference	08879-L08935	B1	2
226	<i>CFHR2</i> exon 3	21368-L31327	B1	2
232	<i>CFHR5</i> exon 3	07847-L07603	B1	2
238	<i>CFHR3</i> upstream	22997-L32433	B1	2
244	<i>CFHR1</i> exon 5	22076-L31047	B1	2
253	<i>CFHR5</i> exon 8	22077-L31048	B1	2
258	Reference	16472-L26940	B1	2
265	<i>CFHR2</i> exon 2	07842-L07598	B1	2
274	<i>CFHR3</i> exon 2	07833-L07589	B1	2
283	<i>CFHR1</i> intron 1	22112-L31100	B1	2
292	<i>CFH</i> intron 9	22079-L31050	B1	2
301	Reference	02767-L02196	B1	2
310	<i>CFH</i> exon 12	07828-L07583	B1	2
317	<i>CFHR4</i> exon 5	22994-L32539	B1	2
324	<i>CFH</i> exon 22	22044-L31698	B1	2
330	<i>CFHR5</i> exon 1	07845-L30998	B1	2
337	<i>CFH</i> exon 6	07824-L07578	B1	2
346	<i>CFHR1</i> intron 3	07839-L07595	B1	2
355	Reference	05991-L05416	B1	2
364	<i>CFHR3</i> intron 4	07835-L07591	B1	2
373	<i>CFH</i> intron 11	07827-L07582	B1	2
382	<i>CFH</i> exon 17	07830-L07586	B1	2
392	<i>CFHR3</i> exon 3	07834-L07590	B1	2
400	<i>CFHR4</i> exon 6	22558-L31052	B1	2
406	<i>CFHR2</i> intron 1	22113-L31101	B1	2
414	Reference	12787-L20671	B1	2
419	<i>CFH</i> exon 4	07823-L16758	B1	2
427	<i>CFHR5</i> exon 2	07846-L16757	B1	2
436	<i>CFH</i> exon 21	22082-L31053	B1	2
445	<i>CFHR4</i> exon 1	22084-L31055	B1	2

Probe length (nt)	Gene/Exon	Probe ID	Probemix version	Copy number
454 ◊	CFHR1 exon 6	22995-L32431	B1	2
463	Reference	12460-L13461	B1	2
472	CFH exon 19	22559-L31056	B1	2
481	CFHR5 exon 10	22086-L31057	B1	2
494	CFHR1 exon 2	22087-L31058	B1	2
500	Reference	09682-L22509	B1	2

◊ Probe can give a background signal in case of heterozygous or homozygous deletion of *CFHR1*.

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

More information: www.mrcholland.com ; www.mrcholland.eu	
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IVD	EUROPE* (until lot 0720)  ISRAEL
RUO	EUROPE* (as of lot 0724) 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><i>Version S01-06 – 14 August 2024 (03)</i></p> <ul style="list-style-type: none"> - Regulatory status has changed: SD072 is no longer CE marked from lot 0724 onwards. - A warning for the 454 nt CFHR1 exon 6 probe, which may give a residual signal in some patients with a deletion, is added to Table 1. <p><i>Version S01-05 – 04 November 2021 (03)</i></p> <ul style="list-style-type: none"> - Product description rewritten and adapted to a new template. - Intended purpose updated. - Information about P008-C1 PMS2 probemix removed. - Information about <i>PMS2</i> and <i>PMS2CL</i> genes removed. - Note added to precautions and warnings section about availability of SALSA Reference Selection DNA SD082 for use in combination with the P008 PMS2 probemix. <p><i>Version S01-04 – 12 May 2021 (02)</i></p> <ul style="list-style-type: none"> - Intended use updated. - Product can now be used with P236-B1. - UK has been added to the list of countries in Europe that accept the CE mark. <p><i>Version S01-03 – 15 January 2021 (02)</i></p> <ul style="list-style-type: none"> - Intended use updated. - Product description rewritten and adapted to a new template. - More details on the selection of suitable reference DNA samples added to the experimental set-up and data analysis sections. - Minor textual changes in Table 1. <p><i>Version S01-02 – 11 May 2020 (01)</i></p> <ul style="list-style-type: none"> - Product is now registered for IVD use in Israel.