

# Product Description

## SALSA® MLPA® Reagent Kit

To be used with the (MS-)MLPA General Protocol.

### Catalogue numbers

- **EK1-FAM:** SALSA® MLPA® Reagent Kit, 100 reactions – FAM
- **EK1-CY5:** SALSA® MLPA® Reagent Kit, 100 reactions – Cy5
- **EK5-FAM:** SALSA® MLPA® Reagent Kit, 500 reactions – FAM
- **EK5-CY5:** SALSA® MLPA® Reagent Kit, 500 reactions – Cy5
- **EK20-FAM:** SALSA® MLPA® Reagent Kit, 2000 reactions – FAM

The SALSA® MLPA® Reagent Kit (hereafter: MLPA Reagent Kit) is either provided with FAM dye-labelled PCR primer which is suitable for Applied Biosystems or with Cy5 dye-labelled PCR primer which is suitable for Beckman/SCIEX capillary sequencers.

### Certificate of Analysis

Information regarding quality tests from the current sales lots is available at [www.mrcholland.com](http://www.mrcholland.com).

### Intended purpose

SALSA® MLPA® Reagent Kit is an in vitro diagnostic (IVD)<sup>1</sup> or research use only (RUO) reagent to be used in combination with a SALSA® MLPA® probemix<sup>2</sup> as described in the (MS-)MLPA General Protocol.

<sup>1</sup> SALSA® MLPA® Reagent Kit is registered for in vitro diagnostic (IVD) use in countries specified at the end of this product description. In all other countries, SALSA® MLPA® Reagent Kit is for research use only (RUO).

<sup>2</sup> To be used in combination with Coffalyser.Net™ analysis software, SALSA® Hhal, and SD0XX as specified in the product description of the application-specific probemix.

**Table 1. MLPA Reagent Kit components**

Reagent kit component	Volumes			Ingredients
	EK1-FAM EK1-CY5	EK5-FAM EK5-CY5	EK20-FAM	
SALSA® MLPA® Buffer (yellow cap)	180 µl	5×180 µl	5×700 µl	KCl, Tris-HCl, EDTA, PEG-6000, DTT, oligonucleotides
SALSA® Ligase-65 (green cap)	115 µl	5×115 µl	5×460 µl	Glycerol, EDTA, DTT, KCl, Tris-HCl, non-ionic detergent, Ligase-65 enzyme (bacterial origin)
SALSA® Ligase Buffer A (transparent cap)	360 µl	5×360 µl	5×1420 µl	Coenzyme NAD (bacterial origin)
SALSA® Ligase Buffer B (white cap)	360 µl	5×360 µl	5×1420 µl	Tris-HCl, MgCl <sub>2</sub> , non-ionic detergent
SALSA® PCR Primer Mix (brown cap)	240 µl	5×240 µl	5×940 µl	Synthetic oligonucleotides with fluorescent dye (6-FAM or Cy5), dNTPs, Tris-HCl, KCl, EDTA, non-ionic detergent
SALSA® Polymerase (orange cap)	65 µl	5×65 µl	5×240 µl	Glycerol, non-ionic detergents, EDTA, DTT, KCl, Tris-HCl, Polymerase enzyme (bacterial origin)

None of the ingredients are derived from humans, animals, or pathogenic bacteria. 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 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.

### Instructions for use

See (MS-)MLPA General Protocol, available at [www.mrcholland.com](http://www.mrcholland.com).

### Precautions and warnings

For professional use only. Always consult the most recent probemix product description AND the (MS-)MLPA General Protocol before use: [www.mrcholland.com](http://www.mrcholland.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. Always vortex thawed buffers, followed by brief centrifugation, never vortex the enzymes and pipette enzymes and buffers when at room temperature. Additionally, pipette Ligase Buffer B with care to prevent the formation of bubbles. Do not use the product if the packaging is damaged or opened. Leave chemicals in original containers. Waste material must be disposed of in accordance with the national and local regulations.

### Storage and shelf life

All components of the MLPA Reagent Kit must be stored at -15°C to -25°C shielded from light and in the original packaging directly upon arrival. The reagent kits should not be aliquoted.

A shelf life of until the expiry date is guaranteed, when stored in the original packaging under recommended conditions. For the exact expiry date, see the label on the vial. Reagents should not be exposed to more than 25 freeze-thaw cycles.

MLPA Buffer is typically frozen at -20°C, but may remain liquid due to its high salt concentration. If precipitate is observed, it can be heated under warm water (65-70°C) for a few minutes, cooled down to room temperature, and vortexed until precipitate disappears before use.






### Summary of Safety and Performance

The Summary of Safety and Performance will be available in the European database on medical devices (Eudamed), <https://ec.europa.eu/tools/eudamed>.

Basic UDI-DI: 872021148ReagentKitHP

Serious incidents that have occurred in relation to the device shall be reported to MRC Holland and the competent authority of the Member State in which the user and/or the patient is established.

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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EK1-FAM EK1-CY5 EK5-FAM EK5-CY5		EUROPE*  COLOMBIA ISRAEL
EK20-FAM		EUROPE*  ISRAEL
EK1-FAM EK1-CY5 EK5-FAM EK5-CY5 EK20-FAM		ALL OTHER COUNTRIES

\*comprising EU (candidate) member states, members of the European Free Trade Association (EFTA), and the UK. The product is for RUO in all other European countries.

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#### Implemented changes in the product description

##### *Version 08 – 12 January 2024*

- Product is no longer registered for IVD use in Morocco.
- Added reference to the Certificate of Analysis.
- Added a note on dye compatibility.
- Specified that the FAM fluorescent dye is 6-FAM in Table 1.
- Added a note saying that SALSA MLPA buffer might remain liquid at -20°C.
- Summary of safety and performance section with location of the summary of safety and performance and instructions on how to proceed in case of a serious incident added.
- Minor textual and layout changes.

##### *Version 07 – 22 March 2022*

- Version for internal use only.

##### *Version 06 – 28 May 2021*

- Product description had been previously discontinued as all pertinent information can also be found in the (MS-)MLPA General Protocol.
- EK20 information added.
- Intended purpose updated.
- Warning added to storage and shelf life that SALSA MLPA Reagent Kits should not be aliquoted.
- Instructions added in case a precipitate is observed in SALSA MLPA buffer.
- Sections on materials required but not provided and MLPA technique removed as this information can be found in the (MS-)MLPA General Protocol and probemix-specific product description.