




Certificate of Analysis

SALSA® MC002 SMA Newborn Screen

Catalogue #	MC002-100R	
Product name	MC002 SMA Newborn Screen	
LOT	21-7MCA.002	
	100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: 12-2022, when stored at recommended conditions. This product should not be frozen/thawed more than 10 times.	
Use	Detection of the presence or absence of SMN1 copies in DNA samples in order to identify Spinal Muscular Atrophy patients. This product is designed to be used only with DNA samples that have been prepared as described in the MC002 Instructions for Use.	
		Test result
Quality control specifications MC002 probemix	<ul style="list-style-type: none"> - Sufficient distance between peaks, absence of extra or shoulder peaks, correct signal strength and correct relative peak heights when testing a standard set of control and positive DNA samples. - Results obtained on crude extracts of dried blood spots, prepared according to the MC002 Instructions for Use, meeting reaction-specific criteria with regard to T_m, peak height and peak pattern. - Melting curves obtained on a single DNA sample under various experimental conditions, meeting reaction-specific criteria with regard to T_m, peak height and peak pattern. Conditions tested include: pipetting errors; evaporation; deviating thermocycler temperatures; presence of salts (affecting DNA sample denaturation) or presence of impurities in the DNA sample. - No-DNA controls resulted in only 1 major peak, being derived from the Q-fragment. - Relative SMN1, SMN2 and Q-fragment derived peak heights within specified borders when testing various amounts of Coriell sample HG01701, ranging from 0.25 to 20 ng. 	PASS
Quality control specification MC polymerase	<ul style="list-style-type: none"> - Remains within specified borders when tested in different concentrations, in combination with a range of DNA concentrations, and after being subjected to suboptimal storage conditions. 	PASS
Quality control specification SDs	<ul style="list-style-type: none"> - Displayed correct peak patterns under normal testing conditions. 	PASS

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 (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.

More information: www.mrcholland.com ; www.mrcholland.eu	
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Certificate of Analysis

This lot was certified by MRC-Holland on 20 January 2021.

This certificate is a declaration of analysis at the time of the manufacturing process. All assays were run in compliance with manufacturer's instructions for use.

Implemented changes in the COA
<i>Version 01 – 12 March 2021 (01)</i> - Not applicable, new document.