




## Certificate of Analysis

### SALSA® MC002 SMA Newborn Screen

<b>Catalogue #</b>	<b>MC002-100R, MC002-1000R</b>	
<b>Product name</b>	<b>SALSA MC002 SMA Newborn Screen</b>	
<b>Version</b>	<b>Version A</b>	
	100 or 1000 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25°C and -15°C.	
	Expiration date: see Appendix I, when stored at recommended conditions. This product should not be frozen/thawed more than 10 times.	
Purpose	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-A Instructions for Use.	
<b>Quality control specifications</b>		<b>Test result</b>
SALSA MC002 probemix	<ul style="list-style-type: none"> <li>- Sufficient distance between peaks, absence of extra or shoulder peaks, correct signal strength and correct peak pattern when testing a standard set of control and positive DNA samples, ensuring correct identification of positive samples.</li> <li>- Results obtained on crude extracts of dried blood spots, prepared according to the MC002-A Instructions for Use, meeting reaction-specific criteria with regard to T<sub>m</sub> and peak pattern.</li> <li>- Melting curves obtained on a single DNA sample under various experimental conditions, meet reaction-specific criteria with regard to T<sub>m</sub> and peak pattern, minimising inter lot variation. Conditions tested include: pipetting errors, evaporation and presence of impurities in the DNA sample.</li> <li>- No-DNA controls resulted in only 1 major peak, being derived from the Q-fragment.</li> <li>- Relative SMN1, SMN2 and Q-fragment derived peak heights within specified borders when testing various amounts of input DNA, , ranging from 0.25 to 20 ng.</li> </ul>	PASS
SALSA MC Polymerase	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
SD074 and SD075	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.

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. For lot details see Appendix I, which is available at [www.mrcholland.com](http://www.mrcholland.com).

<b>More information:</b> <a href="http://www.mrcholland.com">www.mrcholland.com</a> ; <a href="http://www.mrcholland.eu">www.mrcholland.eu</a>	
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<b>Implemented changes in the COA</b>	
Version 03 – 14 June 2023 (03) <ul style="list-style-type: none"><li>- Clarifications added to Quality control specifications.</li><li>- Quality control specifications rewritten to be more uniform, concise and reflective of quality control.</li><li>- Minor textual changes.</li></ul> Version 02 – 29 June 2021 (02) <ul style="list-style-type: none"><li>- 2000 reactions volume removed as this volume is discontinued.</li></ul> Version 01 – 05 May 2021 (02) <ul style="list-style-type: none"><li>- Not applicable, new document.</li></ul>	