


Certificate of Analysis

SALSA® MC002 SMA Newborn Screen

Catalogue #	MC002-100R, MC002-1000R	
Product name	SALSA MC002 SMA Newborn Screen	
Version	A	
Lot	For details see Appendix I, which is available at www.mrcholland.com .	
	For expiration date see Appendix I.	
Quality control specifications		Test result
SALSA MC002 probemix	<ul style="list-style-type: none"> - 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. - 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_m and peak pattern. - Melting curves obtained on a single DNA sample under various experimental conditions, meet reaction-specific criteria with regard to T_m and peak pattern, minimising inter lot variation. Conditions tested include: pipetting errors, evaporation and 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 input DNA, ranging from 0.25 to 20 ng. 	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
SALSA SD074 and SD075	Displayed correct peak patterns under normal testing conditions.	PASS

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.

More information: www.mrcholland.com ; www.mrcholland.eu	
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Implemented changes in the COA
<p>Version 04 – 24 December 2024 (04)</p> <ul style="list-style-type: none"> - Removed 'number of reactions', 'shipping conditions', 'storage conditions' and 'purpose' sections (information moved to IFU SALSA® MC002-A SMA Newborn Screen IFU v10). - Removed text on Safety Data Sheet (information moved to IFU SALSA® MC002-A SMA Newborn Screen IFU v10). - Moved lot information to top of the document. - Adjusted 'expiration date' section.

Version 03 – 14 June 2023 (03)

- Clarifications added to Quality control specifications.
- Quality control specifications rewritten to be more uniform, concise and reflective of quality control.
- Minor textual changes.

Version 02 – 29 June 2021 (02)

- 2000 reactions volume removed as this volume is discontinued.

Version 01 – 05 May 2021 (02)

- Not applicable, new document.