


Certificate of Analysis

SALSA® MC002 SMA Newborn Screen

Catalogue #	MC002-100R	
Product name	SALSA MC002 SMA Newborn Screen	
Version	A	
Lot	26.0011	
	Expiration date: October 2027.	
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 lot was certified by MRC Holland on 14 April 2026.

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.

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Implemented changes in the COA
Version 01 – 17 April 2026 (03) - Not applicable, new document.