

Urgent Field Safety Notice
SALSA MLPA P060-B2-1116 SMA
29 March 2018



29 March 2018, Amsterdam

Attention: Field Safety Notice regarding SALSA MLPA probemix P060 SMA lot B2-1116 affecting SMN2 (not SMN1) quantification

Dear customer,

Your institute purchased SALSA MLPA probemix P060 SMA, lot B2-1116:

PO number	Item number	Lot no.	Unit	Shipping date (day/month/year)

Please pass this notice on to all those who need to be aware within your organisation or to any organisation to which the potentially affected device has been transferred.

We regret to inform you that we have established that a problem occurred in the production of MLPA probemix P060 SMA lot B2-1116, which was sold between 07 July 2017 and 28 March 2018. It has been established that the following probe may show more variable results:

Length (nt)	Gene detected	SALSA MLPA probe
282	SMN2 exon 7	14921-L17083

Consequences

This may cause a deviation in copy number detected for the SMN2 exon 7 probe by this lot in certain samples. Please note: this problem does NOT affect the identification of carriers, nor the identification of patients. Both these aspects are determined on the basis of the SMN1 copy number, the quantification of which can be correctly done with this lot. However, for those labs who use SMN2 copy number for prognosis or treatment, this may have consequences.

The consequence of the variability of the SMN2 exon 7 probe may be that a SMA patient sample tested in your lab with probemix P060 lot B2-1116 could have a wrong result for the above mentioned SMN2 exon 7 probe. This could have an impact on the decision to treat SMA and pre-symptomatic patients with the newly available therapy Nusinersen/Spinraza.

The problem detected is only present in P060 lot B2-1116 due to a production error related to the relative concentration of two oligonucleotides in this lot.

Measures taken

We have taken immediate action to prevent such an error from happening in the future. A new lot is currently in preparation. The version of this lot is identical (version B2), meaning probe lengths and sequences have remained unchanged.

MRC-Holland requests you to destroy any vials that are still in your possession, and offers their free replacement. In addition, if retesting of SMA patient samples is needed, MRC-Holland will supply reagents and probemix.

With this communication, we supply the Declaration Document P060 lot B2-1116. Please return the completed document within 2 weeks.

Disposal of vials

Urgent Field Safety Notice
SALSA MLPA P060-B2-1116 SMA
29 March 2018



Any remaining vials of lot P060 lot B2-1116 should not be used. If you have any remaining vials, please dispose all of these vials and sign and return the attached document to us no later than two weeks after the date of issue of this letter.

Retesting

We will offer replacement probemix and reagents to retest SMA patient samples previously tested with P060 lot B2-1116. Please provide details about retesting in the attached Declaration Document.

For any remaining questions, please contact MRC-Holland at info@mlpa.com.

The undersigned confirms that the appropriate Regulatory Agency has been notified.

We sincerely apologize for our mistake. We will do our utmost best to regain your confidence in our technology and our products.

Sincerely,
Jan Schouten
CEO, MRC-Holland