

**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](mailto: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

# DECLARATION OF DESTRUCTION

## SALSA MLPA probemix P060 B2-1116

29 March 2018



EMAIL TO [QA-RA@mlpa.com](mailto:QA-RA@mlpa.com) OR FAX TO +3188 8657201. attn. Eman Aanzi, QA Manager Rep.

---

### Customer Details

MRC-Holland customer number: 120  
Institute / Department: xxxxx  
Contact person name: xxxxx  
Contact person email address: xxxxx

### 1. Declaration

I hereby confirm that we have read the Field Safety Notice on P060 lot B2-1116 and completed all sections of the current form.

As declared by (name): [Click here to enter text.](#)  
Function: [Click here to enter text.](#)

Signature and date:

*Please sign this form by pen and return the completed document (by FAX or as a scanned PDF) to the address provided above within two weeks. Upon receipt of this form, we will provide you with an ordering code to include in your replacement order. No shipping costs will be charged. For questions, please contact [QA-RA@mlpa.com](mailto:QA-RA@mlpa.com).*

### 2. Replacement conditions:

- MRC-Holland will replace any destroyed vials of P060 lot B2-1116 (*option A below*) by the newly produced lot of P060 SMA.
- If retesting of patients will be performed (*option B below*), MRC-Holland will provide the required amount P060 SMA probemix + MLPA reagents.

### 3. Declarations

#### A. Declaration of Destruction:

As stated in the letter "Field Safety Notice regarding MLPA probemix P060 lot B2-1116" any remaining vials of lot P060 B2-1116 should be destroyed.

- No vials were left to destroy
- The following remaining vials of P060 lot B2-1116 (full or partially used) have been destroyed:
  - Number of 25 reaction vials that have been destroyed: [Click here to enter text.](#)
  - Number of 50 reaction vials that have been destroyed: [Click here to enter text.](#)
  - Number of 100 reaction vials that have been destroyed: [Click here to enter text.](#)

**DECLARATION OF DESTRUCTION**  
**SALSA MLPA probemix P060 B2-1116**

29 March 2018



**B. Retesting:**

- No reagents are needed to retest patient samples and/or no patients will be retested.
- We will retest the following:
  - Number of patient samples that will be retested for SMN2 exon 7 copy number changes:  
[Click here to enter text.](#)