March 25, 2016

URGENT: MEDICAL DEVICE CORRECTION

4500MD LC/MS/MS System

Dear Valued SCIEX Customer,

SCIEX is initiating a field action for the product listed above. This letter contains important information that needs your immediate attention.

These products are mass spectrometers for clinical use. They are intended to identify inorganic or organic compounds in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and magnetic field according to their mass. They are intended for *in vitro* diagnostic use.

Reasons for the voluntary field correction

An issue has been identified with a small number of 4500MD LC/MS/MS Systems where under certain conditions, there is the possibility that a user will be presented with incorrect quantitative results.

The issue can occur if the system is exposed to electromagnetic interference which generates false ion counts on the detector, leading to incorrect quantitative results.

It may be possible to identify an erroneous result caused by this issue, by review of the result or by review of the raw data:

- An erroneous result may be outside of the expected concentration range of normal results, thereby rendering the result unbelievable
- The raw data may display irregularities in signal intensity or signal stability

Risk to Health:

If the aforementioned conditions are met, the software will display the incorrect quantitative results without indication to the user, which could result in incorrect reporting of patient results.

How to recognize if the issue has occurred:

It may be difficult to identify if incorrect data has been reported. SCIEX recommends that the below actions are taken to eliminate the potential for erroneous results and to review initial files and verify the results.

Actions to be taken by the Customer/User:

In order to eliminate the potential for erroneous results, do not use the affected systems to generate results until the issue has been addressed by this field corrective action to be carried out by a Sciex Field Service Employee (FSE).

Product information

Provided below are the details of the affected products at your site:

Instrument Model Name	Instrument Part Number (REF)	Serial Numbers
Triple Quad ™ 4500MD LC/MS/MS System	5031231	BX21081601 BX21101601

There are a limited number of affected products in the field. No other affected units have been distributed to customers.

Type of action by the Company

A Sciex Field Service Employee (FSE) will be sent to customer sites to perform the field corrective action on the affected systems. The approximate date of the corrective field action at your site is March 28th, 2016.

Other information

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact SCIEX at +1 289 982 2531.

We sincerely apologize for the inconvenience that this causes you. SCIEX aims to provide you with products of the highest quality.

Sincerely,

2016/03/24

X Michael Jarvis

Michael Jarvis
IVD Systems Product Manager
Signed by: Michael.Jarvis

Michael Jarvis
IVD Systems Product Manager
2016/03/25

Enclosure: Response Form

RESPONSE FORM

Device Name (check appropriate boxes):	Part Number
☐ Triple Quad™4500MD LC/MS/MS System	5031257
Serial Numbers: BX21081601, BX21101601	

Check the appropriate box below:

☐ I have read and understood the information within the accompanying SCIEX Notification dated March 25, 2016. All relevant personnel have been informed of its contents, any necessary actions taken and records retained as part of our Laboratory Quality System documentation.

or:

☐ We do not have this product.

Have there been adverse events associated with the affected product at your site?
Yes ☐ No ☐

If yes, please explain:

_____

_____

_____

Have these events already been reported to SCIEX?
Yes ☐ No ☐

Please sign the section below, indicating your acknowledgement of this communication.

_____
Contact Person Name and Title (Please Print)

_____
Company Name

_____

SCIEX

Company Address (Street)

Company Address (City) Company Address (Country, Zip Code)

Signature Date

Telephone Email

Please complete and return this form to:

AB Sciex
Attention: Regulatory Affairs Department

Email: regulatoryaffairs@sciex.com

OR

Fax: 905-660-2629