

Ref: VIG-12-2015-01

Lisses, on 17 December 2015

To the attention of: Directors of Health Establishments
Persons in charge of Laboratories
Local Correspondents of Vigilance

**RE: INFORMATION / RECOMMENDATION
CAPILLARYS 3 TERA (PN 1246)
with software releases up to 1.04**

Dear Sir / Madam,

Some users of the CAPILLARYS 3 TERA have been confronted to a problem of tube identification. Our investigations revealed that this defect for identification of the sample tubes, concerns only CAPILLARYS 3 TERA and barcodes 2/5 interleaved.

Because of its design, the reliability of this type of barcode is problematic and, in very rare cases, can occur, due to a complex combination such as:

- difficulties of reading causing a decoding by the reader at the very end of the reading window,
- and a delayed transmission of the barcode read to the electronic board managing the barcode reader (checksum error during the first attempts of transmission).

to an assignment of the identifier of the previous sample to the next sample.

In this case, there is a sample "n" non identified, followed by sample "n+1" with "n" as identifier. If the reading of the barcodes of the sample "n+2" is correct the sample is identified and the problem is circumscribed to the previous sample. On the contrary, if sample "n+2" is not identified, the sample "n+3" can be identified with "n+2" identifier and so on.

This shift is solely limited to the tube following the problem of reading and transmission of information, the system being resynchronized once the correct reading is done.

The problem could not be reproduced in a direct manner during tests with instruments voluntarily disturbed and with barcodes, 2/5 interleaved. The problem can be reproduced only by a software simulation. This means that an outside factor, such as a problem of connection and/or an environmental disturbance, generates the problems of transmission.

CAPILLARYS 3 TERA reads continuously the barcodes of the sample tubes. Until the release 1.04 the indexing of every tube was achieved only one time when the barcode was allocated to the tube, this explains why the combined delays of reading and transmission could cause a shift. This has been corrected in the release 1.04A and the barcode read is validated and affected to the tube only if the indexing of the tube is identical between the beginning of the reading of the barcode and the end of its transmission to the board managing the barcode reader.

The version 1.04A correcting this defect, has been generated on 14 December. This release has been validated and it will be installed as soon as we receive your agreement. After its installation, please return the enclosed receipt back to SEBIA.

The French Health Products Safety Agency (ANSM) has been informed about this communication.

Please do not hesitate to call your local SEBIA contact for further information.

We apologize for any inconvenience caused and we thank you for your confidence in Sebia.

Yours sincerely,



P. Blangarin
Quality and Coordinator Director

INFORMATION / RECOMMENDATION RECEIPT
CAPILLARYS 3 TERA (PN 1246)
with software releases up to 1.04

Please fill out this document and return it to us upon reception

Laboratory Stamp (mandatory)

We certify, Madam, Mister.....

To have taken knowledge of the mail « VIG-12-2015-01 ».

Release: _____ has been installed on _____

(Place) _____, (Date) _____

Signature:

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