



Segrate, 23<sup>rd</sup> March 2012

Inpeco ref. 001-2012

**Subject: Potential Risk on Aliquotter Module – First update of Field Safety Notice**

To Whom It May Concern,

This letter is to give you the first update about the potential risk associated with the functionality of the Aliquotter Module (List Number F3.6-012-00). The risk is associated with the dispensing functionality of the pipetting unit, version Setup\_InpecoSXD1-2-1.exe.

Internal testing has identified that under certain conditions secondary samples have been diluted with a small percentage of Deionized (DI) Water.

The internal testing involved aliquotting 240 secondary samples, 2 of which were estimated to be diluted with up to 20µL of DI water.

This information is being provided so that clinicians can take appropriate action according to their lab's operating procedures. Follow your internal laboratory procedures to determine if a review of samples processed by the aliquotter is needed.

As a precautionary measure, we confirm our suggestion to temporarily suspend the use of the Aliquotter Module for processes which may be impacted by the identified risk.

Inpeco is working to provide a solution as quickly as possible. You will receive an update when additional information is available.

We regret any inconvenience this matter may have caused. We sincerely appreciate your cooperation and thank you for your assistance.

If you have any questions concerning his matter, you may contact me at +39 (02) 3668 13 [REDACTED] ([REDACTED]@Inpeco.com).

Best Regards

[REDACTED]

*Quality Assurance and Regulatory Manager*

Segrate, 12<sup>th</sup> April 2012

## ALIQOTER MODULE DILUTION - FINAL REPORT

Subject: Solution to the Potential Risk on Aliquoter Module connected to FlexLab 3.6

**Dear Valued Customer,**

This letter is to inform you that we have identified the solution to the potential risk associated to the functionality of the Aliquoter Module connected to FlexLab 3.6 Automation System. The potential risk was notified by Inpeco letter dated March, 20<sup>th</sup> 2012.

A software version named **Setup\_InpecoSXD 1a2a1c.exe** that solves the dilution potential risk has been developed, tested and released.

You will be contacted by a Customer Support Representative to plan the installation of the new software version at your Laboratory.

We regret any inconvenience this matter may have caused.

Should you need any further information, please contact [REDACTED]

e-mail: [REDACTED]@inpeco.com

Phone number: +39 02 3668 [REDACTED]

Best Regards, [REDACTED]

*Quality Assurance and Regulatory Manager*