

PRODUCT RECALL     MARKET WITHDRAWAL     FIELD CORRECTIVE ACTION     NOTIFICATION

**TO:** All users of the Thermo Scientific Indiko, Indiko Plus, Gallery, Gallery Plus and Gallery Plus BeerMaster analyzers

**FROM:** Thermo Fisher Scientific Oy, Clinical Diagnostics Finland

**DATE:** August 23, 2013

**SUBJECT:** The Report-to-File feature **MUST NOT** be used

**IMPORTANT NOTIFICATION**

**for all users of the Thermo Scientific Indiko, Indiko Plus, Gallery, Gallery Plus and Gallery Plus BeerMaster analyzers**

-----**The Report-to-File feature MUST NOT be used**-----

**Description:** potential risk of mis-match of sample ID and test results when using Report-to-File feature

**Root cause:** Bug in the off-the-shelf reporting software connected to Thermo Scientific Indiko, Indiko Plus, Gallery, Gallery Plus and Gallery Plus BeerMaster instruments.

**Immediate actions:** Inform customers immediately to stop using Report-to-File feature in Reports window and in Archive window .

**Corrective action:** Bug fix and launch of sw 5.0.1, expected to be released after testing on Sept 9<sup>nd</sup>, 2013. Mandatory update of software.

We are sorry for the inconvenience caused. For any questions, please feel free to contact us at [info.cdx.fi@thermofisher.com](mailto:info.cdx.fi@thermofisher.com).

Sincerely,

Päivi Sormunen  
Director of Quality, Regulatory and Compliance  
CDD Finland  
Thermo Fisher Scientific Oy