Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Fax Transmission

TO: Medical device section
The Danish Medicines Agency
Axel Heides Gade 1
DK - 2300 –Kobenhavn
Denmark
Tel: +45 44 88 95 95
Fax: +45 44 88 95 99

FROM:
Nicholas Gould
Safety Risk Management & Surveillance

LOCATION/FAX NUMBER: Fax: +45 44 88 95 99

NUMBER OF PAGES: 4

DATE: 25 June 2012

FAX NUMBER: +33 388654741
TEL.: +33 388654752

Dear Sir/Madam,

Software Anomaly Using
VITROS® 5,1 FS System Software Version 2.6.1 & Below
VITROS® 4600 Chemistry System Software Version 2.0 & Below
VITROS® 5600 Integrated System Software Version 2.0 & Below

Please find attached the Addendum Field Safety Notice CL12-173 relating to the subject shown above.

Regards

Nicholas Gould on behalf of Marta Carnielli
Safety Risk Management & Surveillance Manager

Ortho Clinical Diagnostics

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June xx, 2012

UPDATED URGENT FIELD SAFETY NOTICE

Software Anomaly Using VITROS® 5,1 FS System Software Version 2.6.1 & Below VITROS® 4600 Chemistry System Software Version 2.0 & Below VITROS® 5600 Integrated System Software Version 2.0 & Below

Dear Customer,

This is an addendum to a Field Safety Corrective Action (Ref. CL12-154_EU) that was previously issued in May 2012. The purpose of this communication is to provide clarification to information regarding quality control results.

Summary of Anomaly

Ortho Clinical Diagnostics (OCD) identified an anomaly using the VITROS® System Software listed above. Our investigation determined that following the successful calibration of the *new* GENs of VITROS® VANC Reagent (*GEN 21 & above*) or VITROS® VALP Reagent (*GEN 16 & above*) the system unexpectedly switched and used the *previous* lot on board the system to process post calibration quality control samples. If the operator does not notice the lot switch condition code (i.e., PV2-097) that was posted, the new calibration may not be verified by the proper quality control assessment.

If the anomaly occurs and is undetected by the operator, biased results could potentially occur from a calibration that is suboptimal. While the VITROS® VALP and VANC Reagents are performing to specifications, to prevent this issue from occurring, OCD has discontinued supporting VITROS® VALP GENs 14 & 15 and VITROS® VANC GENs 19 & 20. This anomaly will be resolved in a future version of software.

Required Actions

1. All customers are required to complete and return the enclosed Confirmation of Receipt form no later than **June xx, 2012**.
2. Ensure that you only have VITROS® VANC Reagent (*GEN 21 & above*) or VITROS® VALP Reagent (*GEN 16 & above*) in the reagent supply on your system.
3. Process quality control samples on the GENs of VITROS® VANC Reagent (*GEN 21 & above*) or VITROS® VALP Reagent (*GEN 16 & above*) in the reagent supply. If your quality control results are outside acceptable limits, we recommend that you review all patient results reported since VITROS® VANC Reagent (*GEN 21 & above*) or VITROS® VALP Reagent (*GEN 16 & above*) were first calibrated with your Laboratory Medical Director to determine the appropriate course of action (Go to section 5).

   If the quality control results for these GENs are within acceptable limits, the calibration curve is verified and you can report patient results in the normal way (Go to section 4).

Required Actions (Continued)

4. Review your previous quality control results b*eginning on th*e date that you first calib*rated VITROS®* VANC Reagent *(GEN 21 & above)* or VITROS® VALP Reagent *(GEN 16 & above)* to verify that all QC results were within acceptable ranges:
   - ✓ If quality control results obtained since these GENs were first calibrated are within acceptable ranges, NO patient results obtained during that time are impacted by the unexpected lot switch on your system.
   - ✓ If any quality control results were outside of the expected range, review all results for that assay in the timeframe between the previous acceptable quality control results and the next acceptable set of quality control results obtained since the quality control results that were outside of the expected range were obtained. We recommend that you discuss any concerns you may have regarding patient results reported during this period with your Laboratory Medical Director to determine the appropriate course of action.
5. Post this notification by each VITROS® System in your facility that utilizes the VITROS® VALP Reagent or VITROS® VANC Reagent or with your user documentation.
6. Forward the information in this notification, if you have distributed these products outside of your facility.

We apologize for any inconvenience this may cause your laboratory. If you have any additional questions, please call Customer Technical Services at *insert appropriate number*.

Sincerely,

insert appropriate name
insert appropriate title

Confirmation of Receipt - Important Response Required

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So that we can complete our records, please return this form to us no later than June xx, 2012.

FAX TO: *Insert appropriate name*
FAX: *Insert appropriate number*

Section I: Confirmation

I received and understand the Updated Urgent Field Safety Notice (Ref. CL12-173_EU) and I understand and have implemented the instructions provided in this notification.

**Your signature provides confirmation that you have received and understood this notification.*

Your Name: _____ Job Title (optional): _____

Signed*: _____ Date: _____

Fax Number: _____ Telephone Number: _____

J Number: _____ Institution: _____

Your comments are always welcome:

_____

Section II – Verification of your Name and Address

Verify your name and mailing address:

Please complete this section if your name and/or mailing address have changed:

Institution / Contact Name: _____

Address: _____

City: _____ State/Province: _____ Zip/Postal Code: _____

Telephone: _____ FAX: _____