Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

April xx, 2012

URGENT FIELD SAFETY NOTICE

Software Anomaly Using VITROS® 5600 Integrated System Software Version 1.6 & Below

Dear Customer,

As part of a Field Safety Corrective Action, the purpose of this communication is to inform you that Ortho Clinical Diagnostics (OCD) has identified an anomaly with VITROS® 5600 Integrated System Software Version 1.6 and below. Internal testing determined that under very *specific* conditions (listed below), a surfactant addition (i.e., VITROS® Chemistry Products FS Diluent Pack 4) may inadvertently be added to a CuveTip or an empty CuveTip position for which it was not intended.

Investigation Summary & Resolution

Our internal investigation determined that while performing Drugs of Abuse Tests (DATs) on the VITROS® 5600 System, all VITROS® MicroTip assays could potentially be affected by the anomaly. In addition, samples that are scheduled for on-board dilutions for VITROS® MicroSlides could also be affected.

For the anomaly to occur on a VITROS® 5600 System, all of the following must occur in order:

1. Surfactant from Diluent Pack 4 for a DAT assay is not added to the CuveTip within the maximal allowable time limit, the test is cancelled (i.e., *No Result*) and the CuveTip is discarded. A condition code (i.e., PEW-026) is generated. **Note:** The rate of this occurring is infrequent; however, the system responds as intended.
2. Due to the software anomaly, the pending surfactant addition is not cancelled as expected.
3. The next available CuveTip Ring position is the same one that was previously cancelled. The system places a new CuveTip from a different sample into the same CuveTip position as the cancelled position.
4. Surfactant is then inadvertently added to the new (unintended) CuveTip.

This anomaly was identified during internal testing. Subsequently, we reviewed the last four months of e-Connectivity™ data and found two occurences out of 1.2 million DATs processed. **Refer to the enclosure that contains the list of potentially affected assays and the average biases that could be seen if this anomaly occurs on your VITROS® 5600 System.**

The resolution to this anomaly is contained in Software Version 2.0 that is scheduled to be released within a few weeks. Until Software Version 2.0 is installed on your VITROS® 5600 System, we recommend that you group all DAT assays into a single run as described below.

Actions Required

To help reduce the potential of the anomaly from occurring, OCD recommends:

- Allow all testing to complete prior to processing DAT assays.
- Process DAT assays in groups of no more than 8 patient samples per run.
  NOTE: Do not load additional reagents or slides while DAT assays are processing.
- Allow the testing to complete prior to starting the next run of DAT assays.
- Once DAT processing is complete, it is acceptable to process other types of assays.
- Complete and return the Confirmation of Receipt form no later than **May x, 2012**.
- **Refer to the enclosure to determine the potential affect of this anomaly on your test results.**
- Post this notification by each VITROS® System in your facility or with the user documentation.

We apologize for the inconvenience this may cause your laboratory. We have anticipated some questions you may have in the following Questions and Answers section. If you have any additional questions, please contact Customer Technical Services at *insert appropriate number*.

Sincerely,

insert appropriate name
insert appropriate title

Enclosure:
Potential Impact to Results on VITROS® 5600 Systems

Questions and Answers

1. How often did this anomaly occur?

This anomaly was identified during internal testing. As a result, we reviewed the last four months of customer data using e-Connectivity™. We found two occurrences out of 1.2 million DATs processed whereby a surfactant addition was inadvertently added to a CuveTip.

We are proactively monitoring systems that are e-connected. OCD will notify your laboratory if surfactant is inadvertently added to an unintended CuveTip on your e-connected VITROS® 5600 System.

2. What VITROS® Systems are affected by this anomaly?

This anomaly only affects VITROS® 5600 Systems with Software Version 1.6 & below that are used to process Drugs of Abuse Tests (DATs). VITROS® 5,1 FS Systems and VITROS® 4600 Systems are not affected.

3. What are the Drugs of Abuse Tests (DATs)?

The following DATs are the only assays that require surfactant from VITROS® FS Diluent Pack 4:

Product Code	Product Name
6801988	VITROS® BARBITUATES Reagent
6801989	VITROS® BENZODIAZEPINES Reagent
6801991	VITROS® AMPHETAMINES Reagent
6801994	VITROS® THC Reagent
6801995	VITROS® COCAINE METABOLITE Reagent
6801996	VITROS® METHADONE Reagent
6801997	VITROS® OPIATES Reagent
6801998	VITROS® PHENCYCLIDINE Reagent

4. What are the assays that could potentially be affected?

Our internal investigation determined that while processing DATs, all VITROS® MicroTip assays including User Defined Assays (UDAs) and Manufacturer Validated Applications (MVAs) could potentially be affected by this anomaly. In addition, samples that require on-board dilutions (out of range or standard dilutions) for VITROS® MicroSlides could also be affected. **Refer to enclosure that contains list of potentially affected assays and the average biases that could be seen if this anomaly occurs on your VITROS® 5600 System.**

VITROS® MicroWell assays are not affected.

5. Should I take any action on previously reported patient results using my VITROS® 5600 System?

We recommend that you discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action. Results should be reviewed and interpreted in the context of the overall clinical picture.

6. If this anomaly occurs, how will my test results be affected?

An erroneous result could potentially be generated by the VITROS® 5600 System under a very specific set of circumstances (defined on page one).

7. How can I determine if this anomaly has occurred on my VITROS® 5600 System?

If your VITROS® 5600 System is e-connected, OCD is monitoring your system. We have reviewed the last 4 months of data and we would have contacted you if surfactant was inadvertently added to a CuveTip. We will continue to do so until Software Version 2.0 is installed.

For systems that are not e-connected, upon request, OCD can perform a review of your electronic Datalogger files to understand the impact to your laboratory. Please indicate your preference for assistance on your Confirmation of Receipt form. A follow up notification will be sent to you with detailed information.

NOTE: To help reduce the potential of the anomaly from occurring, we recommend that you group all DAT assays into a single run as described on page one until Software Version 2.0 is installed on your VITROS® 5600 System.

8. What actions are required if my VITROS® 5600 System is configured with an enGen™ Laboratory Automation System?

For VITROS® 5600 System configured with an enGen™ Laboratory Automation System:

- Do not use the enGen™ Laboratory Automation System to process samples for DAT assays.
- Prior to performing DATs, stop both Bypass Modules for the VITROS® 5600 System you wish to use.
- Load samples for DAT assays at the front of the VITROS® 5600 System, group all DAT assays as described on page one.

9. When will this anomaly be resolved?

This anomaly is resolved in Software Version 2.0 that is scheduled to be released within a few weeks.

Confirmation of Receipt – Response Required

URGENT FIELD SAFETY NOTICE

Software Anomaly Using
VITROS® 5600 Integrated System Software Version 1.6 & Below

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

FAX TO: *insert appropriate name*
FAX: *insert appropriate number*

Section I – Acknowledgement & Product Assessment

I received the Urgent Field Safety Notice (Ref. CL12-133_EU) regarding an anomaly using VITROS® 5600 Integrated System Software Version 1.6 and below. I understand that until Software Version 2.0 is installed on my system, OCD recommends that I group all Drugs of Abuse (DATs) tests into a single run as described on page one.

For VITROS® 5600 Systems that are e-connected, OCD is proactivley monitoring your system.

For systems that are NOT e-connected, OCD can perform a review of your data upon request.
Please choose one of the following options:

☐ I would like OCD to review my electronic Datalogger files. I understand that I will be contacted by OCD to initiate the process of data retrieval.

or

☐ I do NOT wish to have OCD perform a review of my electronic Datalogger files.

Section II– Confirmation

Your Name: _____ Name of Facility: _____

*Your Signature/Date: _____ Telephone: _____

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

Verify your name and mailing address or add it to Section III if none is present:

Section III – Please Complete If Your Contact Information Has Changed

Customer Number: _____

Customer Name: _____

Address: _____

Address: _____

City: _____

State/Province/Postal: _____

Potential Impact to results if Anomaly Occurs Using VITROS® 5600 Integrated System Software Version 1.6 & Below

VITROS® MicroSlide Assays Out-of-Range (OOR) on-board dilutions using ADD Default Dilution factors values				
Assay	**Body Fluid Type**	**Test Concentration**	**Units**	**%Bias Observed**
ACET	Serum/plasma	167	µg/mL	-16
ALC	Serum/plasma	221	mg/dL	-17
ALKP	Serum/plasma	489	U/L	-23
ALT	Serum/plasma	207	U/L	-12
AMON	Plasma	168	µmol/L	-28
AMYL	Urine	105	U/L	-69
	Serum/plasma	424	U/L	-25
AST	Serum/plasma	189	U/L	-24
Bc	Serum/plasma	4.8	mg/dL	-22
Bu	Serum/plasma	9.8	mg/dL	-22
BUN/UREA	Serum/plasma	51	mg/dL (urea N)	-20
Ca	Urine	10.5	mg/dL	-26
	Serum/plasma	10.8	mg/dL	-24
CHE	Serum/plasma	8.77	U/mL	-19
CHOL	Serum/plasma	248	mg/dL	-18
CK	Serum/plasma	1043	U/L	-24
CKMB	Serum	47	U/L	-20
CREA	Serum/plasma	5.30	mg/dL	-23
CRP	Serum/plasma	87	mg/L	-34
DGXN	Serum/plasma	2.4	ng/mL	+5
dHDL	Serum/plasma	61.3	mg/dL	-16
ECO2	Serum/plasma	29	mmol/L	-38
Fe	Serum/plasma	228	µg/dL	-32
GGT	Serum/plasma	471	U/L	-16
GLU	Serum/plasma	281	mg/dL	-25
	Urine	301	mg/dL	-22
LAC	Plasma	3.2	mmol/L	-26
LDH	Serum/plasma	1804	U/L	-17
Li	Serum/plasma	2.4	mmol/L	-18
LIPA	Serum/plasma	637	U/L	-28
Mg	Serum/plasma	4.4	mg/dL	-22
PHBR	Serum/plasma	52.3	µg/mL	-21
PHOS	Serum/plasma	6.9	mg/dL	-18
PHYT	Serum/plasma	26.9	µg/mL	-28
PROT	Cerebrospinal Fluid	167	mg/dL	-19
SALI	Serum/plasma	30	mg/dL	-23
TBIL	Serum/plasma	13.4	mg/dL	-25

Potential Impact to results if Anomaly Occurs Using VITROS® 5600 Integrated System Software Version 1.6 & Below

VITROS® MicroSlide Assays (Continued) Out-of-Range (OOR) On-Board Dilutions using ADD Default Dilution Factors Values				
Assay Name	**Body Fluid Type**	**Test Concentration**	**Units**	**%Bias Observed**
THEO	Serum/plasma	23.9	µg/mL	-13
TP	Serum/plasma	7.1	g/dL	-17
TRIG	Serum/plasma	255	mg/dL	-24
UPRO	Urine	126	mg/dL	-12
URIC	Serum/plasma	10.6	mg/dL	-25

VITROS® MicroSlide Assays Standard On-Board Dilutions using ADD Default Dilution Factors Values				
Assay Name	**Body Fluid Type**	**Test Concentration**	**Units**	**%Bias Observed**
CREA	Urine	129	mg/dL	-28
BUN/UREA	Urine	712	mg/dL urea N	-30
K+	Urine	9.8	mmol/L	-25
		50.4	mmol/L	-28
Mg	Urine	12.1	mg/dL	-29
Na+	Urine	29	mmol/L	-1
		52	mmol/L	+1
PHOS	Urine	52.9	mg/dL	-30
URIC	Urine	23.3	mg/dL	-34

VITROS® MicroTip Standard Processing - NO Dilutions				
Assay Name	**Body Fluid Type**	**Test Concentration**	**Units**	**%Bias Observed**
AAT	Serum	274	mg/dL	-27
AMPH	Urine	369	ng/mL	-9
		613	ng/mL	-11
ApoA1	Serum/Plasma	114	mg/dL	-29
ApoB	Serum/Plasma	121	mg/dL	-32
ASO	Serum/Plasma	282	IU/mL	-61
BARB	Urine	145	ng/mL	-10
		259	ng/mL	-10
BENZ	Urine	130	ng/mL	+1
		288	ng/mL	-9
C3	Serum/Plasma	264	mg/dL	-22
C4	Serum/Plasma	46	mg/dL	-26
CAFFN	Serum/Plasma	20	µg/mL	-16

Potential Impact to results if Anomaly Occurs Using VITROS® 5600 Integrated System Software Version 1.6 & Below

VITROS® MicroTip (Continued) Standard Processing - NO Dilutions				
Assay Name	**Body Fluid Type**	**Test Concentration**	**Units**	**%Bias Observed**
COCM	Urine	93	ng/mL	-14
		169	ng/mL	-6
d%A1c	Whole Blood	11.5	%A1c NGSP Units	-2
dHA1c	Whole Blood	1.5	g/dL	-19
dHb	Whole Blood	14.2	g/dL	-17
dLDL	Serum/Plasma	158	mg/dL	-35
dTIBC	Serum	335	µg/dL	-27
GENT	Serum/Plasma	7.13	µg/mL	-22
HCY	Serum/Plasma	38.5	µmol/L	-32
HPT	Serum/Plasma	225.27	mg/dL	-31
hsCRP	Serum/Plasma	10.8	mg/L	-26
IgA	Serum/Plasma	379	mg/dL	-32
IgG	Serum/Plasma	1731	mg/dL	-18
IgM	Serum/Plasma	208	mg/dL	-29
METD	Urine	103	ng/mL	-6
		182	ng/mL	-12
OP-HI	Urine	1537	ng/mL	-10
		2527	ng/mL	-5
OP-LO	Urine	260	ng/mL	-9
		400	ng/mL	-10
PALB	Serum/Plasma	23.7	mg/dL	-28
PCP	Urine	17.4	ng/mL	-6
		28.8	ng/mL	-7
RF	Serum/Plasma	29	IU/mL	-22
THC	Urine	15.9	ng/mL	-8
		28.1	ng/mL	-12
TOBRA	Serum/Plasma	7.62	µg/mL	-31
TRFRN	Serum/Plasma	530	mg/dL	-18
VALP	Serum/Plasma	125.9	µg/mL	-26
VANC	Serum/Plasma	35.34	µg/mL	-27