Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

March xx, 2014

URGENT FIELD SAFETY NOTICE

VITROS® Chemistry Products Specialty Diluent, Lot F3168 (Product Code 8559825)

Dear Customer,

As part of a Field Safety Corrective Action, this is to inform you of an urgent field safety notice for the VITROS® Chemistry Product listed below:

Product Name	Product Code	Affected Lot Number	Expiry Date
VITROS® Chemistry Products Specialty Diluent	8559825	F3168	30-SEPTEMBER-2014

This field safety notice has been initiated due to the potential for lower than expected C- Reactive Protein (CRP) results from samples diluted with VITROS® Specialty Diluent. Our records indicate that you were shipped the affected lot listed above.

The VITROS® Chemistry Products CRP Slides Instructions for Use states that if a C-reactive protein concentration exceeds the system's measuring (reportable or dynamic) range:

1. Dilute the sample with VITROS® Specialty Diluent or a patient sample containing a low concentration of CRP. An initial threefold dilution is recommended.
2. Reanalyze.
3. Multiply the results by the dilution factor to obtain an estimate of the original sample's C-reactive protein concentration.

Investigation Summary

Ortho Clinical Diagnostics, Inc. (OCD) confirmed reports of lower than expected CRP results when using the affected lot of VITROS® Specialty Diluent to dilute samples tested on VITROS® CRP Slides. Refer to the Question & Answer section on page three for an example.

Impact to CRP Results

When using the affected lot of diluent, our internal testing determined that results using VITROS® CRP Slides may be negatively biased by approximately 51% using a 3X dilution factor. As a result, you must immediately discontinue using and discard your remaining inventory of VITROS® Specialty Diluent, Lot F3168. We have an adequate supply of alternate lots available for replacement.

Required Actions

- Immediately discontinue using and discard all remaining inventory of VITROS® Specialty Diluent, Lot F3168.
- Review previously reported results using the affected lots. Discuss any concerns regarding previously reported results with your Laboratory Medical Director or with the requesting physician.
- Complete the attached Confirmation of Receipt form no later than **April xx, 2014**. OCD will replace your product or credit your account for your remaining inventory of the affected lots.
- Forward this notification if you have distributed this product outside of your facility.

Intended Use for Affected Products

VITROS® Chemistry Products Specialty Diluent is used to dilute samples when assay values exceed the measuring (reportable or dynamic) range using VITROS® 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS® 5600 Integrated System.

VITROS® Specialty Diluent is recommended as a diluent for VITROS® Chemistry Products CRP, AMYL, PHBR and ACET Slides. Diluted sample results using VITROS® AMYL Slides or VITROS® ACET Slides are not affected. As a reminder, VITROS® PHBR Slides are not supported at this time.

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

Sincerely,

insert appropriate name
insert appropriate title

Enclosure:
Confirmation of Receipt Form

Questions and Answers

1. How does this scenario occur?

The following is an example of how this scenario may occur when processing a CRP sample:

1. Sample is processed neat (undiluted), CRP result exceeds the measuring range.
2. Sample is diluted **3X**, final CRP result is well within the measuring range as shown below:

Initial CRP Result (Neat/Undiluted)	Diluted CRP Result	3 X Dilution Factor	Calculated CRP Result	Interpretation
> 9.0 mg/dL	2.0 mg/dL	Sample result is multiplied by 3	6.0 mg/dL	Calculated result should have predicted greater than the upper measuring range of 9.0 mg/dL (> 90 mg/L) (> 9000 µg/dL)
> 90 mg/L	20 mg/L		60 mg/L	
> 9000 µg/dL	2000 µg/dL		6000 µg/dL	

2. What is the bias observed if this issue occurs while performing a dilution for a CRP result?

When using the affected lot of diluent, our internal testing determined that results using VITROS® CRP Slides may be negatively biased by approximately 51% when using a 3x dilution factor.

3. Should I take any action on previously reported diluted CRP results using VITROS® CRP Slides and VITROS® Specialty Diluent?

We recommend that you discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director or with the requesting physician. The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.

4. Are any other lots affected?

No, this issue only affects VITROS® Specialty Diluent, Lot F3168.

5. Are diluted results for assays other than CRP affected by this issue?

Specialty Diluent is recommended as a diluent for VITROS® Chemistry Products CRP, AMYL, PHBR and ACET Slides. Diluted sample results using VITROS® AMYL Slides or VITROS® ACET Slides are not affected.

NOTE: As a reminder, VITROS® PHBR slides are not supported at this time.

6. What action is required for my current inventory of VITROS® Specialty Diluent, Lot F3168?

You are advised to discontinue using all remaining inventory of the affected lot. OCD will replace your product for your remaining inventory. It is acceptable to use the VITROS® Specialty Diluent from the affected lot to perform dilutions for samples intended to measure AMYL and ACET concentrations only until your replacement order arrives.

7. Is there an alternate diluent that I may use for out-of-range CRP samples until I have received my replacement lot of VITROS® Specialty Diluent?

Yes. As stated in the VITROS® Chemistry Products CRP Slides Instructions for Use, it is acceptable to manually dilute CRP samples using a patient sample containing a low concentration of CRP. Refer to the operating instructions for your system for more information on programming a manually diluted sample.