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## Revised Reference Interval for VITROS Immunodiagnostic Products Intact PTH Assay

Dear Customer,

As a resolution to a Field Safety Notice issued in 2016, the following Instructions for Use (IFU) is revised.

Revised Instructions for Use	Product Code	Pub No.	Version No.
VITROS <sup>®</sup> Immunodiagnostic Products Intact PTH Reagent Pack	6802892	GEM1040_xUS	Version 9.0
VITROS <sup>®</sup> Immunodiagnostic Products Intact PTH Calibrators	6802893		

### Background Information

In 2016, we issued a customer letter (Ref. CL2016-220) regarding VITROS iPTH Reagent Packs stating:

- **An interim Reference Interval of 10.8-79.4 pg/mL (1.1 -8.4 pmol/L) was suggested by additional testing.**
- Consider verifying or re-establishing the reference interval for your laboratory.
- An update to the reference interval in the Instructions for Use may be required.

In May 2018, we issued a Technical Bulletin containing the same information included in the customer letter.

### Revised Instructions for Use

We have completed our investigation and the reference interval in the VITROS Intact PTH Reagent Pack and Calibrators Instructions for Use (IFU) is revised:

Current Reference Interval (IFU: Version 8)	Interim Reference Interval (Technical Bulletin: Pub. No.: J65495_xUS)	Revised Reference Interval (IFU: Version 9)
Units = pg/mL (pmol/L)	Units = pg/mL (pmol/L)	Units = pg/mL (pmol/L)
7.5–53.5 (0.8–5.7)	<b>10.8-79.4 (1.1 -8.4)</b>	<b>13.6 – 85.8 (1.4 – 9.1)</b>
Mean: 24.1 (2.6)	Mean: 46.1 (4.9)	Mean: 43.9 (4.6)
Sample size and criteria used for the reference population, along with other factors such as pre-analytical handling of the samples, statistical analysis, etc., contribute to variability in reference interval values. It is recommended that each laboratory establish its own expected values for the population it serves.		

### Obtaining Instructions for Use (IFU)

The VITROS iPTH Reagent Pack and Calibrators IFU (Version 9.0) can be obtained from our website at <http://www.orthoclinical.com>. IFUs on the website are the official source of information for all VITROS Products.

Refer to the Revision History section included at the end of the IFU for a comprehensive list of changes. Technical changes in each IFU are marked by a change bar (|) to the left of the edited text.

### **Obsolete Technical Bulletin**

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The Technical Bulletin: *Positively Biased Results using VITROS Immunodiagnostic Products Intact PTH Reagent Packs* (Pub No.: J65495\_xUS, 2018-02-28) is now obsolete.

### **Contact Information**

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If you have questions, please contact our Ortho Care™ Technical Solutions Center at **insert number**.  
**Insert signatory if appropriate.**