

Ortho Clinical Diagnostics	IMPORTANT NOTIFICATION Shift in Performance using VITROS® Chemistry Products CRP Slides, New Generations (GENs) 30 through 90 Product Codes 1926740 & 8097990
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Topic Ortho Clinical Diagnostics (Ortho) has validated a new lot of European Reference Material (ERM) for use with the reference method for VITROS® Chemistry Products CRP Slides. This notification is to inform customers about a shift in results that may be observed when using new GENs 30 through 90 of VITROS® CRP Slides, when compared with previous GENs.

The VITROS® CRP Slide method is performed using the VITROS® CRP Slides and the VITROS® Chemistry Products Calibrator Kit 7 on VITROS® 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS® 5600 Integrated System.

Traceability of Calibration Values assigned to the VITROS® Chemistry Products Calibrator Kit 7 for C-Reactive Protein (CRP) are traceable to the ERM® DA470 reference material. Our calibration laboratory has crossed over from ERM472/IFCC to ERM® DA474/IFCC (traceable to ERM® DA470) to calibrate a nephelometric method for CRP to support value assignment for VITROS® Calibrator Kit 7.

Impact to Results The shift in CRP results that may be observed when using VITROS® CRP Slides, GENs 30 through 90, when compared to previous GENs is approximately -4 to -5 mg/L (-0.4 to -0.5 mg/dL) across the measuring range as shown on page two. These are average results; your results may vary slightly depending upon your current system performance, slide lot, and calibrator kit lot.

For additional information, refer to the Method Comparison section in the revised Instructions for Use.


Revised Instructions for Use The Instructions for Use listed below have been revised and are available on our website at <http://www.orthoclinical.com/>. Please use these revised documents when using VITROS® CRP Slides, GENs 30 through 90:

- VITROS® CRP Slides Instructions for Use (**Pub. No. J56062, Version 1.0**)
- VITROS® Calibrator Kit 7 Instructions for Use (**Pub No. J11385, Version 10.0**)

Technical changes in each IFU are highlighted by a change bar (|) to the left of the edited text.

Product Availability We will deplete our inventory of current VITROS® CRP Slides GENs and anticipate that GENs 30 through 90 will begin shipping at the middle to end of February, 2016.

Contact Information If you have any questions, contact our Technical Solutions Center at 1-800-421-3311.


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Comparison of Results using current VITROS CRP Slide GENs (ERM472) vs. GENs 30-90 (ERM474)

