

Date January 2017**Affected Products** Ortho Clinical Diagnostics determined that calibrator values (data/calibration mathematics) for VITROS FS Calibrator 1, Lot 9146 are not available for selection on the Assay Data Diskettes (ADDs) listed below. Our records indicate that you were shipped Lot 9146.

Product (Unique Device No.)	Affected Data Release Versions (DRV)	Affected Product	Lot 9146 Expiry Date
Assay Data Diskette (ADD) Product Code: 6801876 (10758750001576)	5904 through 5910	VITROS FS Calibrator 1 Lot 9146	2018-09-19

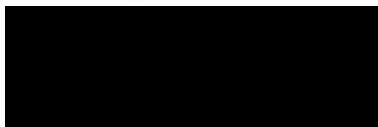
VITROS FS Calibrator 1 is used on VITROS Systems to calibrate the following assays: VITROS AMPH, ASO, BARB, BENZ, COCM, d%A1c, dLDL, hsCRP, PCP, RF and THC Reagents.

Resolution Although the calibrator values are contained on these ADDs, they are not available for selection by the operator. Assay Data Diskette DRV 5911 and above contains the resolution that allows operators to select "9146" when using this lot of VITROS FS Calibrator 1.**Impact to Results** If ADD DRV 5911 or above is not installed on your VITROS System, operators are unable to calibrate any of the assays (listed above) when using VITROS FS Calibrator, Lot 9146.

- Required Actions**
- Ensure that ADD DRV 5911 or above is installed on your VITROS System prior to using VITROS FS Calibrator 1, Lot 9146.
NOTE for e-Connected systems: Automatic download of DRV 5911 was available beginning on December 11, 2016.
 - Post this notification by your VITROS System or with your user documentation.
 - Complete the Confirmation of Receipt form and return by **January 20, 2017**.

Contact Information We apologize for the inconvenience this may cause your laboratory. If you have additional questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646 766.

Sincerely,



Jon Wong, 9 January 2017
QA Manager