



# Technical Bulletin

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## FastPack<sup>®</sup> Vitamin D

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January 21, 2014

An important issue affecting all manufacturers of vitamin D testing is the lack of an internationally recognized vitamin D standard. As a result, vitamin D measurements performed by different methods may not agree. In fact, the differences between methods can be dramatic. While lack of standardization plays a major role in the differences observed, variation can also be attributed to each manufacturer's internal standards, calibrators and other components used in the assay. Consequently, vitamin D test results obtained using different methods are not interchangeable with one another.

In an effort to address this issue, the National Institute of Standards and Technology (NIST) have introduced a vitamin D standard. NIST is internationally recognized and provides standards for many different assays, and manufacturers have now begun to adopt the NIST vitamin D standard. After thorough analysis, Qualigen will now use this standard for the FastPack<sup>®</sup> IP Vitamin D Immunoassay to provide customers with the most accurate vitamin D test available. However, due to the fact that not all manufacturers are using this standard and to the other factors listed above, some variation between vitamin D test methodologies will still remain. There are informative resources that discuss variation in Vitamin D results at length.<sup>1</sup>

To further our effort in providing customers with the highest quality vitamin D immunoassay, all FastPack<sup>®</sup> IP Vitamin D Immunoassay Kits will now include matching calibrators, controls and other components together in one convenient kit box.

Qualigen continues to discover methods of enhancing our product line of FastPack<sup>®</sup> IP Immunoassay kits and we welcome comments that arise through the experience of our customers.

If you have questions, please contact Qualigen System Support at [systemsupport@qualigeninc.com](mailto:systemsupport@qualigeninc.com), 877-770-6127 (USA only) or 760-579-6900. You may also visit our website at [www.qualigeninc.com](http://www.qualigeninc.com) for information on other Qualigen products.

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<sup>1</sup> [Analytical variability among methods for the measurement of 25-hydroxyvitamin D: still adding to the noise. Holmes EW, Garbincius J, McKenna KM. PUB DATE. October 2013. SOURCE. Am J Clin Pathol. 140\(4\):550-60](#)