

Nonalignment of The Nichols IRMA Intact PTH Assay with the Nichols Advantage Intact PTH Assay: Implications for K/DOQI Dosing for Vitamin D Sterols Guidelines

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In 1987 Nichols introduced their manual IRMA intact PTH assay. This assay has been used extensively in clinical studies including those with bone histology. Many of these publications have been referenced as supporting documentation for the evidence reported in the K/DOQI guidelines. Later Nichols introduced the automated Advantage intact PTH (iPTH) assay which is used to generate routine patient values. In order for there to be a reliable application of Nichols IRMA iPTH assay evidence-based treatment guidelines with routine Nichols Advantage iPTH patient values, both the Nichols IRMA and Advantage iPTH assays must be aligned. That is, the two tests must generate the same values for the same specimens. Disturbances in mineral and bone metabolism are common clinical pathologies in ESRD patients. We compared the assay results of plasma specimens from 51 dialysis patients measured with both the Nichols IRMA iPTH assay and the Nichols Advantage iPTH assay. The average of the Nichols IRMA iPTH assay values was 226 pgm/mL and the average of the Nichols Advantage iPTH assay was 294 pgm/mL. Considering the average per cent difference between the paired samples the Nichols Advantage iPTH assay measured 35.75% higher than the Nichols IRMA iPTH assay. Guideline 8B, Table 28 in the K/DOQI draft guideline provides dosing indications for calcitriol, paricalcitol and Doxercalciferol. The first level for dosing is for iPTH assay values of 300-600 pgm/mL. Considering that routine patient values are from the Nichols Advantage iPTH assay this guideline would be 408-816 pgm/mL. The second level for dosing is for iPTH values of 600-1000 pgm/mL. For the Nichols Advantage iPTH assay this level would be 816-1360 pgm/mL. The third level for dosing is for iPTH values that are >1000 pgm/mL. For the Nichols Advantage iPTH assay this level would be >1360 pgm/mL. It is important to recognize that the routinely used Nichols Advantage iPTH assay reads 36% higher than the publication-based Nichols IRMA iPTH assay to avoid over suppression with vitamin D sterols when applying publication-evidence based guidelines such as K/DOQI.

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