Nonalignment of The Nichols IRMA Intact PTH Assay with the Nichols Advantage Intact PTH Assay: Implications for K/DOQI Diagnosis & Treatment

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The Nichols manual IRMA intact PTH assay has been used extensively in clinical studies including those with bone histology which have been referenced as supporting documentation for the evidence reported in the K/DOQI guidelines. Today the Nichols automated Advantage intact PTH assay is used to generate routine patient values. In order for there to be a reliable application of Nichols IRMA intact PTH assay evidence based treatment guidelines with routine Nichols Advantage intact PTH patient values both the Nichols IRMA and Advantage intact PTH assays must be aligned. That is, both must generate the same values for the same specimens. Disturbances in mineral and bone metabolism are common ESRD clinical pathologies. For diagnostic purposes 3 essential bone conditions are important to predict: adynamic low bone turnover, normal bone turnover and high bone turnover. We compared assay results of plasma specimens from 51 dialysis patients measured with both the Nichols IRMA intact PTH assay and the Nichols Advantage intact PTH assay. The average Nichols IRMA intact PTH assay value was 226 pgm/ml and the average Nichols Advantage intact PTH assay was 294 pgm/ml. Considering the average per cent difference between the paired samples the Nichols Advantage intact PTH assay measured 35.75% higher than the Nichols IRMA intact PTH assay. Guideline 13A in the K/DOQI draft guideline states that high bone turnover is indicated in the dialysis patient by an intact PTH assay value of >300 pgm/ml, this would correspond to Nichols Advantage intact PTH assay value of >408 pgm/ml. K/DOQI draft guideline 13C states adynamic low bone turnover is indicated by intact PTH <100 pgm/ml, this would correspond to a Nichols Advantage intact PTH assay this guideline of <136 pgm/ml. K/DOQI draft guideline 14 recommends parathyroidectomy when intact PTH is >800 pgm/ml with hypercalcemia and/or hyperphosphatemia this would correspond to a Nichols Advantage intact PTH assay of >1088 pgm/ml. It is important to recognize that the routinely used Nichols Advantage intact PTH assay reads 36% higher than the publication based Nichols IRMA intact PTH assay to avoid over treatment.

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