

# Large Differences Between Commercial Intact PTH Assays

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Circulating fragments of PTH meant that 1st generation competitive PTH assays could not measure “intact” PTH. When the dual antibody sandwich assay technology was applied to PTH, a number of manual and automated “intact” PTH assays became commercially available. It has been assumed that all of these “intact” PTH assays will generate the same patient values. We investigated this assumption, using EDTA plasma from 46 dialysis patients which were divided and measured with the most common manual and automated intact PTH assays. Surprisingly, we found on average as much as a 3-fold difference in intact PTH values.

	DiaSorin IRMA Intact PTH	DPC IRMA Intact PTH	Scantibodies IRMA Total Intact PTH	Nichols IRMA Intact PTH	Roche ElecSys Intact PTH	Nichols Advantage Intact PTH	DSL IRMA Intact PTH
Mean PTH (pg/mL)	122	196	227	226	218	294	328
% Difference When Compared to Nichols IRMA Intact PTH Assay	-39.9%	-6.61%	-1.25%	————	2.92%	35.75%	47.37%

Intact PTH assays and their reported values are not the same. As new treatment guidelines (e.g., K/DOQI) make reference to intact PTH assay values, it is essential that the exact intact PTH assay upon which guidelines are based be identified. Moreover, if a manufacturer changes their PTH assay (e.g., change in standardization or antibodies) there is no guarantee that the new assay will perform as previously. Therefore, there is a need for a PTH reference material, made up of native dialysis patient plasma, to which all intact PTH assays calibrate. Scientific publications have relied on the Nichols manual IRMA intact PTH assay (including bone biopsy studies upon which K/DOQI have been based), yet dialysis patient lab values are from the Nichols automated Advantage intact PTH assay which generates 30% higher values than their IRMA. Many US dialysis patients are diagnosed/monitored with the DiaSorin intact PTH assay which measures nearly 3 times lower than the Nichols Advantage intact PTH assay. In conclusion, all intact PTH assays should be calibrated to a single reference material and diagnostic/treatment guidelines should be developed and validated with bone biopsies for each PTH assay.

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