

Differences in Correlations Between Nichols Bio-Intact PTH Assay to the Nichols IRMA Intact PTH Equivalent Assay vs Nichols Advantage Intact PTH Assay

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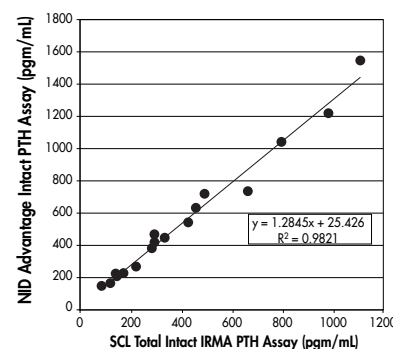
Recently, Nichols Institute Diagnostics introduced the Bio-Intact PTH assay (BI-PTH) and this assay is being used for dialysis patients in place of the Nichols Advantage intact PTH assay. In order to interpret BI-PTH test values correlation studies have been performed using ESRD patient samples measured by both the BI-PTH assay and the Nichols automated Advantage Intact PTH assay. BI-PTH has been reported to be 52% of intact PTH. These correlation studies have used the Nichols automated Advantage Intact PTH assay, however, scientific publications including those with bone histology have been based on the use of the Nichols manual IRMA Intact PTH assay. We undertook this study to see if there was a difference in the correlation using the Nichols manual IRMA intact PTH assay. Therefore, we studied and compared the correlation between the BI-PTH assay with the Nichols automated Advantage Intact PTH assay and the correlation between the BI-PTH assay with an assay equivalent to the Nichols manual IRMA Intact PTH assay. We assayed 18 dialysis patient samples and found that the BI-PTH was 51% of the Nichols automated Advantage intact PTH assay. But we also found that the BI-PTH assay value was 65% of the value from the Nichols manual IRMA intact PTH equivalent assay value. This difference of 51% vs 65% in correlations arises from the differences between the Nichols manual IRMA intact PTH equivalent assay and the Nichols automated Advantage intact PTH assay and raises the question of how to interpret the Nichols Bio-Intact PTH assay with regards to the Nichols Intact PTH assay products (i.e., 52% vs. 65%).

Patient Data

Patient	2 nd Generation Intact PTH pgm/mL		3 rd Generation 1-84 PTH pgm/mL
	Scantibodies Total Intact (equivalent to NID IRMA intact)	Nichols Advantage Intact PTH	Nichols Bio-Intact
1	423	540	250
2	288	464	217
3	331	446	185
4	141	205	93
5	661	736	347
6	1101	1546	815
7	136	224	103
8	453	628	288
9	794	1042	531
10	79	141	67
11	216	268	150
12	277	379	155
13	290	413	183
14	164	232	114
15	112	158	73
16	164	221	95
17	978	1216	557
18	489	715	371

Total iPTH vs. BI PTH factor = 0.65r = 0.979 b = -2.2	Advantage iPTH vs. BI PTH factor = 0.52r = 0.994 b = -17.0
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NID Advantage Intact PTH vs. SCL Total Intact IRMA PTH



Cantor T, Scheibe S, Glowacki P. "Differences in Correlations Between Nichols Bio-Intact PTH Assay to the Nichols IRMA Intact PTH Equivalent Assay vs Nichols Advantage Intact PTH Assay". *J Amer Soc Nephrol* 2003(Nov); 14:584.