

# Comparison between the Nichols Manual IRMA Intact PTH Assay and the Nichols Automated Advantage Intact PTH Assay

Tom Cantor<sup>1</sup>, Pierre D'Amour<sup>2</sup>

<sup>1</sup>Scantibodies Laboratory, Inc., Santee, CA, USA; <sup>2</sup>Centre De Recherche Du CHUM, Montreal, Quebec, Canada

Since the introduction of the Nichols manual IRMA intact PTH assay in the 1980's, a number of published studies with bone biopsies have been based on the use of this assay and practical clinical conclusions have been drawn from this literature. Indeed, treatment protocols—including the draft K/DOQI clinical practice guidelines on Bone Metabolism and Disease in Chronic Kidney Disease—have been based on reference to studies that used the Nichols manual IRMA intact PTH assay. Since the 1990's, however, the majority of ESRD patients' routine PTH values have been determined using the Nichols automated Advantage Intact PTH assay. To ensure proper interpretation of the literature and patients' routine test results, it is essential that the Nichols automated Advantage Intact PTH assay give the same results as (or be aligned with) the Nichols manual IRMA intact PTH assay. This study investigated the differences between the Nichols automated Advantage intact PTH assay and the Nichols manual IRMA Intact PTH assay. We found a significant nonalignment between these two assays. The following data reveals differences ranging from -1.9% to 74.7% between the two PTH assays with an overall difference such that the Nichols Advantage Intact PTH assay read 27.5% higher than the Nichols IRMA Intact PTH assay.

When treatment guidelines are based on one PTH assay, it is important to have alignment with the assay generating patient values.

Patient	Group	Age	Sex	Ca ++ (mmol/L)	Creat (umol/L)	Total Ca (mmol/L)	Phos (mmol/L)	Alb (g/L)	ALP (U/L)	I-PTH (NID 2003, IRMA, pgm/mL)	I-PTH (NID 2003, Advantage, pg/mL)	IRMA -2003 vs. Advantage-2003
1	PHP	32	F		77	1.72	0.76	23	259	77.8	92.2	18.5
2	OTHER	65	M	1.25	86	2.23	0.96	27	49	37.3	57.5	54.1
3	CRF	35	M	1.02	517	1.89	1.8	25	435	119.7	131.2	9.6
4	CRF	48	F	1.09	827	2.15	1.54	30	115	264.7	357.2	34.9
5	CRF	66	F	1.05	434	2.06	1.29	29	98	335.8	586.7	74.7
6	CRF	74	M	1.14	641	2.28	1.56	31		31.9	44.3	38.8
7	CRF	50	M	1.13	118	2.15	1.34	28		320.6	327.6	2.2
8	CRF	74	M	1.23	672	2.42	1.99	30		367.9	360.9	-1.9
9	PHP	57	F							91.2	114.2	25.2
10	OTHER	31	F		88	2.47	0.63	40	82	74.2	101.9	37.3
11	CRF	74	M	1.18	412	2.25	1	35	55	65.3	78.3	19.9
12	CRF	76	M	1.15	573	2.03	1.54	25	61	83	104.1	25.5
13	CRF	64	M	1.12	158	2.14	0.85	37	78	111.5	117.0	5.0
14	CRF	67	M	0.83	474	1.65	1.8	25	132	152.2	186.4	22.5
15	CRF	56	M	1.1	292	1.98	0.94	21	47	63.1	92.3	46.2
16	CRF	59	M	1.15	138	2.17	1.19	27	145	26.5	42.3	59.5
17	CRF	31	F	1.16	523	2.25	1.31	40	72	253.6	292.1	15.2
18	CRF	66	F	1.13	459	2.2	1.21	34	66	103.5	129.4	25.0
19	CRF	33	M	1	487	2.05	2.45	29	48	206	261.1	26.8
20	CRF	78	F	1.13	360	2.21	1.69	32	84	213.2	236.2	10.8
Mean										150.0	185.6	27.5

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