

Confirmation of the Upward Shift in the Commonly Used Nichols Advantage Intact PTH Assay Use Compared to the Publication Based Nichols IRMA Intact PTH Assay

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K/DOQI is based on the Nichols IRMA iPTH assay. Until 1992 this same Nichols IRMA intact PTH assay was used clinically as a guide for treatment decisions of ESRD patients. However, in 1992 a more rapid (37 minutes versus 18 hrs), non-radioactive (chemiluminescent versus 125-Iodine) and automated iPTH assay was launched by Nichols called the Advantage iPTH assay. This assay became the most widely used iPTH assay for nephrologists. At first the two assays gave the same values (aligned) for the same specimens, but, sometime before 2001 the Advantage iPTH assay began to generate significantly higher PTH values compared to the Nichols IRMA iPTH assay. For this reason we requested Dr. Laurence Demers of the M.S. Hershey Medical Center at Pennsylvania State University to conduct his own independent studies of this non alignment. Dr. Demers is the distinguished Professor of Pathology and Medicine, Director of Clinical Chemistry and the Automated Testing Laboratory and is a well-known expert in immunoassays. Dr. Demers collected his own specimens which included the following ESRD specimens and reported the following comparison between the Nichols IRMA iPTH assay and the Nichols Advantage iPTH assay. These data shows overall approximate 40% higher values with the Nichols Advantage versus IRMA iPTH assay. Moreover, the lack of a consistent factor for differences in values between the 2 assays makes it difficult to correlate Advantage assay values to IRMA assay equivalents. The difference between the commonly used Advantage iPTH assay and the research based Nichols IRMA iPTH assay (upon which K/DOQI guidelines are based) should be taken into consideration.

ACCESSION # SAMPLE	SAMPLE DATE	CEL NID ISOTOPIC IRMA INTACT PTH (PG/ML)	GEISINGER NID ADVANTAGE INTACT PTH (PG/ML)	ADVANTAGE TO IRMA RATIO (%)
F31737	9/5/2003	183	248	136%
H42988	9/11/2003	229	275	120%
H43706	9/11/2003	283	379	134%
F33382	9/12/2003	209	170	81%
M50064	9/15/2003	420	418	100%
W47166	9/17/2003	528	698	132%
W47164	9/17/2003	997	>1800	181%
F35423	9/19/2003	317	391	123%
M51628	9/22/2003	97	105	108%
M51312	9/22/2003	208	205	99%
H47131	9/25/2003	192	241	126%
H48428	9/25/2003	177	201	114%
F39805	10/3/2003	317	391	123%
F39663	10/3/2003	99	109	110%
W54260	10/8/2003	114	156	137%
W53075	10/8/2003	322	419	130%
W53067	10/8/2003	406	715	176%
W53072	10/8/2003	543	868	160%
W54114	10/8/2003	446	715	160%
W53069	10/8/2003	740	1147	155%
W53068	10/8/2003	587	848	144%
H51346	10/9/2003	898	1148	128%
H52054	10/9/2003	66	1261	1911%
F41580	10/10/2003	102	246	241%
M57576	10/13/2003	198	156	79%

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