Comparison between the Nichols and Scantibodies IRMA PTH Assays of 1999 and 2003 for Stored Samples

Tom Cantor[1], Patty Glowacki[1], Pierre D'Amour[2]
[1]Scantibodies Laboratory, Inc, Santee, CA, USA
[2]Centre De Recherche Du CHUM, Montreal, Quebec, Canada

The stability of a PTH assay is an important requirement when monitoring the long term course of renal bone disease and secondary hyperparathyroidism. There is an overall assumption that a PTH assay from one manufacturer will be stable over time. Changes in antibodies, critical components or standardization could result in a change in test performance such that patient values shift which could result in a misdiagnosis. Therefore, we investigated the differences in PTH values for samples tested with the same Nichols IRMA and Scantibodies IRMA intact PTH assays for 20 samples tested in 1999, stored at -20 degrees C and then retested in 2003. It is reasonable to assume that some degradation of PTH may have occurred during the four year frozen storage. The data is shown below. Both the Nichols and the Scantibodies IRMA intact assays reveal stability from 1999 to 2003. Scientific publications for more than 15 years have been based on both the Nichols and Scantibodies IRMA intact PTH assays. If these assays are used in routine ESRD patient care, one may have confidence to apply the conclusions reached in those publications to routine patient care.

	ALP (U/l)	I-PTH (NID 1999, IRMA, pg/mL)	I-PTH (NID 2003, IRMA, pg/mL)	T-PTH (SLI 1999, pg/mL)	T-PTH (SLI 2003, pg/mL)	Whole PTH (SLI 1999, pg/mL)	Whole PTH (SLI 2003, pg/mL)
	259	81	77.8	70	58.6	57	53.4
	49	36	37.3	37	42.4	29	33.5
	435	125	119.7	110	102.8	69	78.3
	115	266	264.7	254	266.8	178	216.7
	98	452	335.8	372	332.6	270	263.3
		25	31.9	27		23	27.9
		310	320.6	272	258.8	170	197.1
		370	367.9	322	252.2	169	165.6
		88	91.2	83	80	67	68.6
	82	97	74.2	59	67.3		50.5
	55	71	65.3	69	62.2	47	44.8
	61	78	83	76	76.1	54	54.1
	78	100	111.5	101	108.5	61	82.2
	132	127	152.2	149	153.5	107	115.6
	47	60	63.1	60	62.2	38	51.4
	145	23	26.5	28	33.1	23	31.5
	72	244	253.6	247	239.2	177	177.6
	66	97	103.5	97	93.7	56	72.1
	48	214	206	205	207.1	150	151.9
	84	194	213.2	186	177.8	102	128.5
mean:	**114.1**	**152.9**	**150.0**	**141.2**	**140.8**	**97.2**	**103.2**
S.D.:	**100.7**	**120.4**	**108.1**	**104.0**	**92.2**	**69.1**	**69.8**

Cantor T, Glowacki P, D'Amour P. "Comparison between the Nichols and Scantibodies IRMA PTH Assays of 1999 and 2003 for Stored Samples". *J Amer Soc Nephrol 2003(Nov); 14:590.*