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Intervariability among serum intact parathyroid hormone assays: a need for standardization

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Dear Editors,

The measurement of parathyroid hormone (PTH) is both common and important in the field of osteoporosis for research and clinical diagnoses. Variations in the estimation of PTH have been reported [1,2] but have *not* focused on the more commonly used intact PTH (1–84) assays. Because we recently found marked variability between two PTH immunoradiometric assays (IRMA) in the lab, we evaluated PTH by a variety of methods using commercially available intact PTH (1–84) assay kits. This report highlights variability in PTH assay methods obtained by using various kits and assays from different companies. The goal was to define the inconsistencies between PTH assays when values range from normal to slightly high levels.

To examine serum intact PTH (1–84), we compared 42 serum samples between different assays and methods. The three methods used included the following: (a) enzyme-linked immunosorbent assay (ELISA); (b) IRMA and (c) chemiluminescence. We assessed six commercially available second generation assays. The ELISA kits were provided by ALPCO (ELISA-A), MD Biosciences (ELISA-B) and Immunodiagnostic Systems Inc., (IDS; ELISA-I) and IRMA kit by Scantibodies (IRMA-A) and Diagnostic System Laboratories (DSL; IRMA-B). In addition, a subset of samples at the high and low end of our range (n=4) were examined using electrochemiluminescence (Roche, Automated Random Analyzer), which is used by most clinical and hospital labs. It should be noted that a very common commercial method used previously (Nichols PTH assays) is no longer available, and therefore was not tested in this analysis. Samples were performed in duplicate for each assay. We examined healthy women (aged 59 ± 4.8 years; BMI 33 ± 5.5 kg/m²) with a relatively wide range of PTH.

The mean values and ranges for the six commercially available PTH assay kits are shown in Table 1. There was a good and better correlation between the ELISA A and B ($R^2=0.97$), compared to ELISA on ice ($R^2=0.71$). For the IRMA, assays A and B, there was also a good correlation ($R^2=0.93$), although absolute values differed markedly. The range of values in our samples and confidence interval in the IRMA-B assay is larger compared to other methods.

Lack of standardization of PTH assays is a concern and may be partially due to the synthetic 1–84 PTH molecules that are made from different species and may alter absolute values in the different assays [3]. There continues to be substantial methodological variation in the intact PTH assay, and therefore a single absolute level of serum PTH should not be used to define hyperparathyroid disease. It is suggested that when examining PTH values between labs or when switching assay companies (even if it is the same methodology), that a conversion factor is determined to address the expected differences between assays. Since higher values of PTH determine treatment of hyperparathyroidism, clinicians must be aware of quantitative differences between available intact PTH assays.

Reference

1. Ljungdahl N, Haarhaus M, Linder C, Magnusson P. Comparison of 3 third-generation assays for bio-intact parathyroid hormone. *Clin Chem* 2006;52(5):903–904. [PubMed: 16638963]
2. Torres PU. The need for reliable serum parathyroid hormone measurements. *Kidney Int* 2006;70(2): 240–243. [PubMed: 16838038]
3. Souberbielle JC, Boutten A, Carlier MC, Chevenne D, Coumaros G, Lawson-Body E, Massart C, Monge M, Myara J, Parent X, Plouvier E, Houillier P. Inter-method variability in PTH measurement: implication for the care of CKD patients. *Kidney Int* 2006;70(2):345–350. [PubMed: 16788691]

Table 1

Variability in PTH assays for 42 samples

Methodology	Abbrev.	Diagnostic kit		Sample required (ul)	Normal range (pg/mL)	Results		
		Company				Range (pg/mL)	95% CI (pg/mL)	Mean $\pm$ SD (pg/mL)
Immunoradiometric assay	IRMA-A	Scantibodies, CA, USA		200	9–77	19–98	34–50	42 $\pm$ 23
	IRMA-B	Diagnostic Systems Laboratory (DSL), TX, USA		200	9–55	21–228	83–115	99 $\pm$ 54
Enzyme-linked immunosorbent assay	ELISA-A	Alpco Diagnostics, NH, USA		25	9–77	33–150	63–83	73 $\pm$ 32
	ELISA-B	MD Biosciences, MN, USA		25	9–77	38–144	63–83	73 $\pm$ 34
	ELISA-I*	Immunodiagnostic Systems (IDS), AZ, USA		200	8–37	17–79	30–38	34 $\pm$ 14
Chemiluminescence	Chemi **	Roche, Basel, Switzerland		100	15–65	22–83	—	—

* ELISA-I (done at 0°C on ice (I) compared to others done at 37°C);

** includes only two highest and lowest samples