



PAML Introduces Third-Generation, Bio-Intact PTH Testing

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Parathyroid hormone (PTH) is made up of 84 amino acids, but it is quickly cleaved *in vivo* to smaller fragments. Measuring intact, physiologically active PTH in the presence of a wide range of fragments has presented a formidable analytical challenge since the first PTH methods were introduced in the early 1980s. Over the years, diagnostics companies have steadily improved their methods by developing increasingly specific PTH assays.

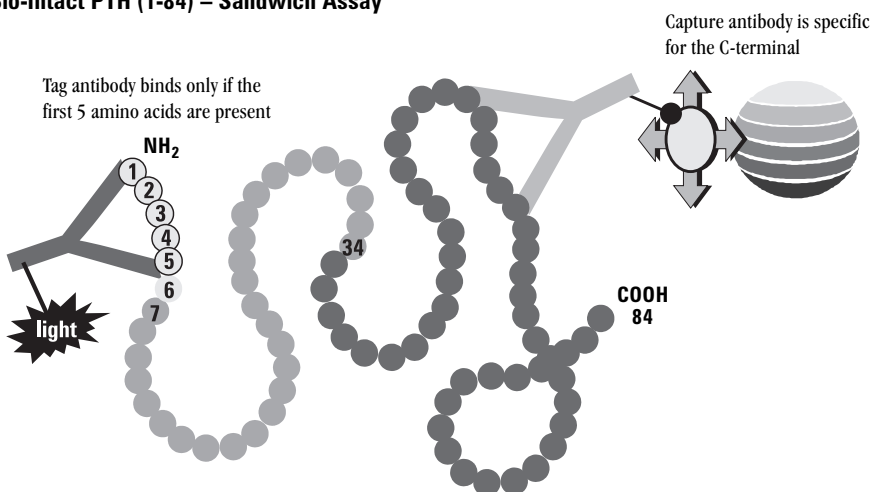
For some time now, the “Gold Standard” for PTH assays has been the Nichols Institute Diagnostics Intact PTH test. This is the test that PAML currently offers. This test has supplanted all other assays by providing the best estimate of intact PTH in the differential diagnosis and monitoring of hypo- and hypercalcemic disorders.

Recent studies have shown, however, that all current Intact PTH assays show some cross-reactivity with the largest fragment, which is composed of amino acids 7-84. In response to these findings, Nichols Institute has introduced a 3rd Generation, Bio-Intact PTH assay that recognizes only the entire PTH molecule (see method diagram). Bio-Intact PTH shows no reactivity with the 7-84 fragment or any other fragments. Bio-Intact PTH should replace conventional assays, since it can provide more valid clinical information for diagnosis and monitoring. This is particularly important in renal failure patients, who build up large amounts of the 7-84 fragment, due to their inability to clear it from the blood.

Bio-intact PTH results are substantially lower than results obtained with the current Intact PTH assay. Correlation studies between the two methods (see correlation graph) show a slope of about 0.6, meaning that the results with the new method are about 60% of those from the old method. Some patients will vary from this percentage, due to the fact that they may have varying amounts of fragments relative to the amount of Bio-Intact PTH.

PAML will continue to offer the conventional Intact PTH method for physicians who prefer to monitor their patients with this assay.

Bio-Intact PTH (1-84) – Sandwich Assay



Features

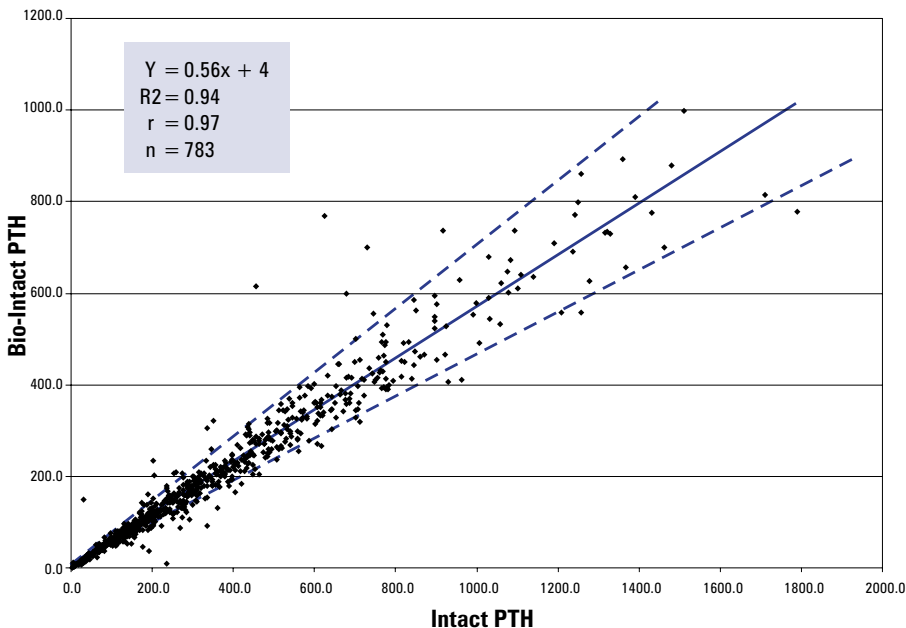
- ▶ **Bio-Intact PTH measures only the complete, biologically-active PTH molecule.**
- ▶ **Bio-Intact PTH results will be about 60% of the results from the conventional Intact PTH assay, but individual patients may vary from this difference.**
- ▶ **Bio-Intact PTH is particularly useful in renal failure patients who have large amounts of the 7-84 fragment and other fragments in their blood.**

For more information, please contact Client Services or see us on the Web at

www.paml.com

Bio-Intact PTH (1-84)

Correlation with Conventional Intact PTH Method



References

Cohn DV and MacGregor RR. The biosynthesis, intracellular processing and secretion of parathormone. *Endocr Rev* 1981;2:1-26.

Ratcliffe WA, et al. Performance and diagnostic application of a two-site immunoradiometric assay for parathyrin in serum. *Clin Chem* 1989;35:1957-67.

Markus RJ, et al. A novel immunoradiometric assay detects full-length human PTH but not amino-terminally truncated fragments: Implications for PTH measurements in renal failure. *J Clin Endocr Metab* 1999;84:4287-90.

Brossard JH, et al. Influence of glomerular filtration rate on non-(1-84) parathyroid hormone detected by intact PTH assays. *Clin Chem* 2000;46:697-703.

Test Information

DESCRIPTION **BIO-INTACT PARATHYROID HORMONE**

METHOD Chemiluminescence

ORDER CODE BPTHNC

CPT CODE 83970

SPECIMEN 1 mL frozen EDTA plasma (lavender-top tube). Separate plasma from cells, put in separate plastic tube, and freeze. A refrigerated centrifuge is preferred for this process. Fasting specimen is preferred. Store and transport frozen.

COMMENTS *Minimum amount:* 0.5 mL

Other acceptable specimens: Serum. If calcium is requested and sample is serum, order BPTH.

Unacceptable conditions: Heparin plasma, gross hemolysis, gross lipemia.

Stability: 3 months frozen.

SCHEDULE Monday, Wednesday, Friday nights

TURNAROUND 2-4 days

RANGES **Bio-Intact Parathyroid Hormone** 6-40 pg/mL

DESCRIPTION **BIO-INTACT PARATHYROID HORMONE / CALCIUM**

METHOD Chemiluminescence

ORDER CODE BPTH

CPT CODE 83970, 82310

SPECIMEN 1 mL frozen serum (red-top tube). Separate serum from cells, put in separate plastic tube, and freeze. A refrigerated centrifuge is preferred for this process. Fasting specimen is preferred. Store and transport frozen.

COMMENTS *Minimum amount:* 0.5 mL

Unacceptable conditions: EDTA or heparin plasma, gross hemolysis, gross lipemia.

Stability: 3 months frozen.

SCHEDULE Monday, Wednesday, Friday nights

TURNAROUND 2-4 days

RANGES **Bio-Intact Parathyroid Hormone** 6-40 pg/mL
Calcium 8.5-10.5 mg/dL

Provided for the clients of

PATHOLOGY ASSOCIATES MEDICAL LABORATORIES
PACLAB NETWORK LABORATORIES
TRI-CITIES LABORATORY
TREASURE VALLEY LABORATORY
ALPHA MEDICAL LABORATORY

*For more information, please contact
your local representative.*