

Intact PTH Assay Specifications

Intact PTH Assay on the ADVIA Centaur CP, XP, and XPT Systems

Clinical Value of Intact PTH Measurements

Parathyroid hormone (PTH), also known as parathormone or parathyrin, is secreted by parathyroid glands as a polypeptide that contains 84 amino acids. PTH is the most important endocrine regulator of circulating calcium and phosphorus concentrations. Its contribution to calcium homeostasis is accomplished through its effects on bone, kidney, and intestine.¹⁻⁴

Quantification of circulating intact PTH assists in the differential diagnosis of hypercalcemia and hypocalcemia. In conjunction with the measurement of ionized calcium, intact PTH evaluations can be used to distinguish between patients with hyperparathyroidism, hypoparathyroidism, or hypercalcemia of malignancy. The diagnosis of primary hyperparathyroidism, a common cause of hypercalcemia, is confirmed by elevated ionized calcium concentrations and normal or elevated PTH concentrations.

Intact PTH levels are also used to assess and manage other metabolic bone disorders, including osteoporosis and renal osteodystrophy.^{5,6} Additionally, intra-operative PTH measurement can be used, in conjunction with improved pre-operative localization methods (ultrasound and Sesta-MIBI scan), to control the success of parathyroidectomy for both primary and renal hyperparathyroidism.

The National Academy of Clinical Biochemistry⁷ recommends the use of intra-operative parathyroid hormone testing for:

- Patients undergoing initial surgery for primary hyperparathyroidism
- Patients undergoing re-operative surgery for hyperparathyroidism
- During pre-operative localization in patients with primary hyperparathyroidism.

According to the National Kidney Foundation, chronic kidney disease affects 26 million Americans with another 20 million at risk. Chronic kidney disease (CKD) will affect approximately 5–10% of the world's population. When kidney disease progresses, normal concentrations of calcium and phosphorous are disrupted, which leads to elevated levels of PTH and decreased levels of Vitamin D.

Consequently, this leads to abnormalities in the bone turnover process. Patients with CKD stages 3–5 often experience secondary hyperparathyroidism and bone abnormalities. Measuring PTH is of increased importance when a patient progresses from CKD stage 3 through to End Stage Renal Disease.

Clinical Benefits

- Reduce lot-to-lot variability with a monoclonal antibody format and kitted calibrators
- Consolidate testing on a fully-automated, high-throughput immunoassay system with a rapid time to first result (18 minutes)
- Have confidence in patient results with a design that is not affected by biotin interference up to 1000 ng/mL, has excellent precision for monitoring patients, and reference ranges for both serum and plasma
- Utilize assay for both calcium homeostasis management and intraoperative use

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The assay utilizes a new, high-quantum-yield molecule, the Zwitterionic Acridinium Ester (ZAE), to reduce non-specific binding; has improved sensitivity and precision, requires smaller sample volume, and provides better onboard stability and longer shelf life for reagents.

ADVIA Centaur Intact PTH Performance Summary

ADVIA Centaur XP/CP/XPT*	
Sample Type	Serum, Plasma (lithium heparin, sodium heparin, EDTA)
Sample Volume	50 µL
Assay Range	4.6–2,200 pg/mL (0.488–233 pmol/L)
Time to First Result	XP: 18 minutes CP: 15 minutes XPT: 18 minutes
On-board Stability	28 days
Calibration Interval	14 days
Dilution	1:5
Limit of Detection	3.2 pg/mL (0.339 pmol/L)
EDTA Plasma Reference Range	18.4–80.1 pg/mL (1.95–8.49 pmol/L)
Serum Reference Range	18.5–88.0 pg/mL (1.96–9.33 pmol/L)

Ordering Information		
Catalog No.	Contents	Quantity
10699154	1 ReadyPack* plus 1 Calibrator Set	100 tests
10699155	5 ReadyPacks plus 2 Calibrator Sets	500 tests
10699156	2 Sets of Quality Control Material (3 levels)	2 x 1.0 mL (Levels 1, 2, and 3)
10492364	Multi-Diluent 13 (2 ReadyPack Ancillary Packs)	2 x 10 mL
10698597	1 Set of Master Curve Material (5 levels)	1 x 12.0 mL (Levels 1–5)

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