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 Biochemistry\(^7\) 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
ADVIA Centaur Intact PTH Assay Specifications

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

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

Ordering Information

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Contents</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>10699154</td>
<td>1 ReadyPack® plus 1 Calibrator Set</td>
<td>100 tests</td>
</tr>
<tr>
<td>10699155</td>
<td>5 ReadyPacks plus 2 Calibrator Sets</td>
<td>500 tests</td>
</tr>
<tr>
<td>10699156</td>
<td>2 Sets of Quality Control Material (3 levels)</td>
<td>2 x 1.0 mL (Levels 1, 2, and 3)</td>
</tr>
<tr>
<td>10492364</td>
<td>Multi-Diluent 13 (2 ReadyPack Ancillary Packs)</td>
<td>2 x 10 mL</td>
</tr>
<tr>
<td>10698597</td>
<td>1 Set of Master Curve Material (5 levels)</td>
<td>1 x 12.0 mL (Levels 1–5)</td>
</tr>
</tbody>
</table>

References:

ADVIA Centaur, ReadyPack, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc., or its affiliates. All other trademarks and brands are the property of their respective owners.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Local Contact Information

Siemens Healthcare Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Phone: +1 914-631-8000
siemens.com/healthcare

Siemens Healthcare Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens.com/healthcare