

Detection of Intact Parathyroid Hormone in Human Serum with Roche e801

Test Name: Immunoassay for the in vitro quantitative determination of intact parathyroid hormone (PTH) in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. This assay can be used intraoperatively.

Method Name: The Elecsys assay for determining intact PTH employs a sandwich test principle in which a biotinylated monoclonal antibody reacts with the N terminal fragment (1-37) and a monoclonal antibody labeled with a ruthenium complex reacts with the C terminal fragment (38-84). The antibodies used in this assay are reactive with epitopes in the amino acid regions 26-32 and 37-42.

Results: Technical Range: 1.2-5000 pg/mL
Reportable Range: 1.45-3267 pg/mL

Reference Ranges: <39.6 pg/mL

Clinical Significance: Parathyroid hormone (PTH) is a single-chain 84 amino-acid peptide produced by the parathyroid glands in response to decreased extracellular concentrations of ionized calcium. Its main role is to increase serum calcium levels by stimulating the release of calcium from bone and its renal re-absorption in the distal tubule. In the proximal tubule, PTH stimulates the synthesis of calcitriol which in turn increases intestinal absorption of calcium and exerts an endocrine feed-back on the secretion of PTH at the parathyroid level. PTH also decreases the renal re-absorption of phosphate in the proximal tubule, thereby decreasing serum phosphate.

Parathyroid gland disorders lead to elevated or depressed blood calcium levels (hypercalcemia or hypocalcemia) brought about by a change in the secretion of PTH.

Detection of subfunctioning parathyroid glands (hypoparathyroidism) requires the use of a highly sensitive test in order to be able to measure PTH levels well below normal. Hyperfunctioning of the parathyroid glands results in an increased secretion of PTH (hyperparathyroidism). Primary causes are adenomas of the parathyroid glands. In secondary hyperparathyroidism the blood calcium level is low as a result of other pathological states (e.g. vitamin D deficiency).

The determination of PTH intraoperatively during adenoma resection in the parathyroid glands has been reported for primary hyperparathyroidism, secondary hyperparathyroidism relating to renal failure, and tertiary hyperparathyroidism post renal transplant surgery. Because PTH has a reported half life of 3-5 minutes, a significant drop in PTH levels after resection of the abnormal gland or glands enables the surgeon to assess whether all hyperfunctioning parathyroid tissue has been removed from the patient.

The National Academy of Clinical Biochemistry recommends routine use of intraoperative PTH testing for patients undergoing surgery for primary hyperparathyroidism, both in initial surgeries and in reoperative procedures.

Submission Criteria: For specimen collection and preparation, only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum

Plasma: Li-heparin and K₂-EDTA plasma

Do not use fluoride plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, therefore not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Storage and Stability: **Serum**

6 months at -20°C

2 days at 2-8°C

Plasma

6 months at -20°C

3 days at 2-8°C

2 days at 15-25 °C

Rejection Criteria: Rejection criteria include but are not limited to:

1. Specimens containing fibrin or clots.
2. Excessive platelet clumping
3. Leaking specimens
4. Substandard mixing or collection
5. Expired or improperly stored collection tubes.
6. Improperly filled tubes based on collection tube manufacturer's guidelines.
7. Contaminated specimens (IV fluid, foreign particles, etc.)
8. Specimens not analyzed within the appropriate time frame.
9. Samples not shipped at appropriate temperature.
10. Samples without 2 proper identifiers or samples having identifiers that do not match the electronic or paper lab requisition.

Authorization: Diagnostic testing can only be performed with approval from an authorized provider/agency.

Turn Around Time: 1 day.

Instructions for Serum Specimen Submission

General Information

The detection of intact parathyroid hormone in human serum and plasma is performed using a Roche cobas i58 analyzer. However, serum specimens are preferred.

Serum specimens must be collected and stored at 2-8°C if to be analyzed within 2 days and stored at -20°C if to be analyzed within 6 months. Please be aware that storing specimens at $\leq -70^{\circ}\text{C}$ ($\leq -94^{\circ}\text{F}$) is not permissible.

Specimens MUST be received at Reditus Laboratories within 2 days of collection.

Collection Instructions for Serum Specimen

1. Do not use expired collection tubes. Store collection tubes as per manufacturers recommendations. Use standard venipuncture practices for collecting samples. Filled gold top serum tubes are preferred.
2. Ensure that the patient's name, date-of-birth, and time/date of collection are recorded on the specimen tube along with the name or initials of the individual collecting the sample.
3. Complete all the demographic information on a sample requisition form through the approved electronic submission process
4. Refrigerate the specimen between 2-8°C (36-46°F) and ship or courier the specimen(s) within 48 hours.
5. The specimen(s) *must* be received at the laboratory **no later than** 48 hours *from the time of collection*.
 - a. **Avoid shipping specimens over weekends or holidays** as they may not be received at the laboratory and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.
 - b. Ensure that specimens shipped by commercial carrier are shipped with **overnight delivery**. If shipping on a Friday for Saturday delivery, ***you must include Saturday Delivery*** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result in specimens being rejected from testing.
6. For any questions pertaining to sample collection, storage, or shipping, please contact the Reditus Laboratories using the below contact information.

Instructions for Specimen Transport

1. **Messenger/Courier by ground transport.** Place specimen(s) into a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed biohazard bag and test requisition(s) inside the shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. The shipping container must be rigid, such as a Styrofoam cooler, and labeled with the UN 3373 Biological Substance Category B marking. Close securely.
2. **Commercial carrier by ground/air transport.** Place the specimen(s) inside a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed bag and completed test requisitions(s) inside the outer shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. Label the outer shipping container with Reditus Laboratories address listed below. Complete the return address section to include the name of the person shipping the package, business name and address, and a business phone number. The shipping container must include the UN3373 Biological Substance Category B marking.
3. *Ship specimens by overnight delivery* to the attention of Clinical Chemistry at Reditus Laboratories. This can be accomplished by use of local courier, shipping corporations or U.S. Postal Service.
 - a. **If specimens are shipped on a Friday for Saturday delivery, you must include/indicate Saturday delivery** during shipment, or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result

- in specimens being rejected from testing.
4. The specimen(s) must be received at the laboratory **no later than** 48 hours *from the time of collection* and 24 hours from the time of shipment. Do not ship specimens over weekends or holidays as they will not be received, and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.

NOTE: Testing may be delayed, or specimens may be considered UNSATISFACTORY if the above instructions are not followed or the requisition form is not filled out completely. If there are any questions about specimen collection, handling, or shipping please contact the Reditus Laboratories to speak with laboratory personnel.

Ship specimens by a local courier or overnight by commercial carrier to the designated laboratories indicated below.

Send to: Reditus Laboratories
200 Enterprise Drive
Pekin, IL 61554

Phone: (469) 498-0222

Website: <https://www.redituslabs.com/>