

Overview

Useful For

Aiding in monitoring antiresorptive and anabolic therapy in patients with osteoporosis

An adjunct in the assessment of conditions associated with increased bone turnover, such as Paget disease

This test **should not be used** as a screening test for osteoporosis in the general population.

Method Name

Radioimmunoassay (RIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

This test should not be requested in patients who have recently received radioisotopes, therapeutically or diagnostically, because of potential assay interference. A recommended time period before collection cannot be provided, as it depends on the isotope administered, the dose given, and the clearance rate in the individual patient. Specimens will be screened for radioactivity prior to analysis. Radioactive specimens received in the laboratory will be held and assayed after the radioactivity has sufficiently decayed. This will result in a test delay.

Specimen Required

Supplies: Sarstedt Aliquot Tube 5 mL (T914)

Collection Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL serum

Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

Serum: 0.25 mL

Reject Due To

| | |
|-------|--------|
| Gross | Reject |
|-------|--------|

| | |
|---------------|--------|
| hemolysis | |
| Gross lipemia | Reject |
| Gross icterus | Reject |

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---------------|--------------------|----------|-------------------|
| Serum | Frozen (preferred) | 180 days | |
| | Ambient | 7 days | |
| | Refrigerated | 7 days | |

Clinical & Interpretive

Clinical Information

Procollagen type I propeptides are derived from collagen type I, which is the most common collagen type found in mineralized bone. In bone, collagen is synthesized by osteoblasts in the form of procollagen. This precursor contains a short signal sequence and terminal extension peptides: amino-terminal propeptide (PINP) and carboxy-terminal propeptide. These propeptide extensions are removed by specific proteinases before the collagen molecules form. Both propeptides can be found in the circulation and their concentration reflects the synthesis rate of collagen type I. Although collagen type I propeptides may also arise from other tissues (such as the skin, vessels, fibrocartilage, and tendons), most nonskeletal tissues exhibit a slower turnover than bone and contribute very little to the circulating pool of PINP. PINP is considered the most sensitive marker of bone formation, and it is particularly useful for monitoring bone formation therapies and antiresorptive therapies; it is recommended that the test be performed at baseline before starting osteoporosis therapy and performed again 3 to 6 months later.

Reference Values

Adult male: 22-87 mcg/L

Adult female premenopausal: 19-83 mcg/L

Adult female postmenopausal: 16-96 mcg/L

Reference values have not been established for patients who are younger than 18 years.

Interpretation

This assay is specific for the intact trimeric form of procollagen type I N-terminal propeptide (PINP). When monitoring response to osteoporosis treatment, a change of greater or equal to 21% (least significant change) from baseline PINP levels (ie, prior to the start of therapy), 3 to 6 months after initiation of therapy indicates an adequate therapeutic response.

The direction of the change in PINP levels (decrease or increase) will depend on the type of osteoporosis treatment. In patients taking bisphosphonates, PINP levels have been shown to decrease up to 70% from baseline after 6 months of therapy. Treatment with hormone replacement therapy also shows a decrease in PINP levels but to a lesser degree than bisphosphonate therapy.

In patients treated with teriparatide (recombinant human parathyroid hormone 1-34), PINP levels increase from baseline, reflecting the stimulatory effect of teriparatide on osteoblasts and bone formation. PINP levels have been

shown to significantly increase as early as 1 month after teriparatide treatment, peaking at 6 months following treatment. Increases greater than 10 mcg/L have been reported in 77% to 79% of teriparatide-treated patients after 3 months of therapy and are considered a successful response.

Cautions

There is diurnal variation of procollagen I intact N-terminal propeptide (PINP) levels, with the values being higher at night. When serial measurements of PINP are performed, specimens should be collected at the same time of the day.

Procollagen I intact N-terminal propeptide is metabolized in the liver. In individuals with severe liver disease, clearance from the circulation might be affected resulting in elevated PINP levels.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1. Naylor KE, Jacques RM, Paggiosi M, et al. Response of bone turnover markers to three oral bisphosphonate therapies in postmenopausal osteoporosis: the TRIO study. *Osteoporos Int.* 2016;27(1):21-31. doi:10.1007/s00198-015-3145-7
2. McClung MR, San Martin J, Miller PD, et al. Opposite bone remodeling effects of teriparatide and alendronate in increasing bone mass. *Arch Intern Med.* 2005;165(15):1762-1768
3. Eastell R, Krege JH, Chen P, et al. Development of an algorithm for using PINP to monitor treatment of patients with teriparatide. *Curr Med Res Opin.* 2006;22(1):61-66
4. Brown JP, Don-Wauchope A, Douville P, Albert C, Vasikaran SD. Current use of bone turnover markers in the management of osteoporosis. *Clin Biochem.* 2022;109-110:1-10. doi:10.1016/j.clinbiochem.2022.09.002

Performance**Method Description**

The procollagen I intact N-terminal (PINP) kit is based on the competitive radioimmunoassay technique. A known amount of labeled PINP and an unknown amount of unlabeled PINP in the sample compete for a limited number of high-affinity binding sites of the polyclonal rabbit anti-PINP antibody. A second antibody, directed against rabbit IgG and coated Kaolin particles, is used to separate the antibody-bound PINP from free PINP. The radioactivity of the bound tracer antigen is measured on a gamma counter. The amount of labeled PINP in the sample tube is inversely proportional to the amount of PINP in the sample. The concentrations in unknown samples are obtained from a calibration curve, which is based on the concurrent testing of PINP calibrators. (Package insert: UniQ PINP RIA, Intact N-terminal propeptide of type I procollagen. Orion Diagnostica; 03/2016)

PDF Report

No

Day(s) Performed

Tuesday, Thursday

Report Available

2 to 6 days

Specimen Retention Time

2 weeks

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes**Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

83519

LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---------|------------------------------------|--------------------|
| PINP | Procollagen I Intact N-Terminal, S | 47255-5 |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|------------------------------------|---------------------|
| 61695 | Procollagen I Intact N-Terminal, S | 47255-5 |