

## 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.

### 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 made because it will depend 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

#### Collection Container/Tube:

**Preferred:** Red top

**Acceptable:** Serum gel

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 0.5 mL

#### Specimen Minimum Volume

0.25 mL

### Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	28 days	

Specimen Type	Temperature	Time	Special Container
	Ambient	7 days	
	Refrigerated	7 days	

## Clinical and 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

Reference values have not been established for patients who are <18 years of age.

Adult male: 22-87 mcg/L

Adult female premenopausal: 19-83 mcg/L

Adult female postmenopausal: 16-96 mcg/L

### Interpretation

This test should be performed before beginning osteoporosis treatment (ie, prior to the start of therapy) to establish a baseline procollagen type I intact N-terminal propeptide (PINP) level. Three to 6 months after initiation of therapy, a change of 21% or more (least significant change) from baseline PINP levels indicates an adequate therapeutic response. This assay is specific for the intact trimeric form of PINP.

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 bisphosphonates 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 of >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.

PINP is metabolized in the liver. In individuals with severe liver disease, clearance from the circulation might be

affected resulting in elevated PINP levels.

Some patients that have been exposed to mouse antigens, whether in the environment or as part of treatment or imaging procedures, may have circulating antimouse antibodies. These antibodies may interfere with the assay reagents to produce unreliable PINP assay results.

### Clinical Reference

1. Liberman UA, Weiss SR, Broll J, et al: Effect of oral alendronate on bone mineral density and the incidence of fractures in postmenopausal osteoporosis. The Alendronate Phase III Osteoporosis Treatment Study Group. N Engl J Med. 1995;333(22):1437-1443
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 Aug 8-22;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. Vasikaran S, Eastell R, Bruyere O, et al: IOF-IFCC Bone Marker Standards Working Group. Markers of bone turnover for the prediction of fracture risk and monitoring of osteoporosis treatment: a need for international reference standards. Osteoporos Int. 2011;22(2):391-420

### 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

1 to 5 days

### Specimen Retention Time

14 days

### Performing Laboratory Location

Rochester

### Fees and Codes

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**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 Regional Manager. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been cleared, approved or is exempt by the U.S. 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	In Process

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