Test Definition: P1NP

Intact Procollagen I N-Terminal, Serum

Overview

Useful For

Aiding in monitoring antiresorptive and anabolic therapy in patients with osteoporosis

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

Method Name

Chemiluminescence

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation: For 12 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).
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: 0.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Ambient	7 days	
	Frozen	90 days	

Clinical & Interpretive

Clinical Information

Procollagen type I propeptides are derived from collagen type I, the most common collagen in mineralized bone. In bone, collagen is synthesized by osteoblasts in the form of procollagen, a precursor that 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 circulate in blood, and their concentrations reflect the rate of collagen type I synthesis. Although collagen type I propeptides may also originate from other tissues, including 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 is particularly useful for monitoring bone formation and antiresorptive therapies. Testing is recommended at baseline before osteoporosis therapy begins and again 3 to 6 months later.

Reference Values

Adult male: 26-108 ng/mL
Adult female premenopausal: 22-103 ng/mL
Adult female postmenopausal: 18-119 ng/mL

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, the reference change value (RCV) has been estimated to be ?-19.9% for decreases and?+24.8% for increases 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

Intact procollagen type I N-terminal propeptide (PINP) is metabolized in the liver. In individuals with severe liver disease,

clearance from the circulation might be affected resulting in elevated PINP levels.

The use of biotin-containing supplements may lead to inaccurately reduced PINP measurements.

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. Osteoporosis 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
5. Bhattoa HP, Vasikaran S, Trifonidi I, et al. Update on the role of bone turnover markers in the diagnosis and management of osteoporosis: a consensus paper from The European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO), International Osteoporosis Foundation (IOF), and International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Osteoporos Int. 2025;36(4):579-608. doi:10.1007/s00198-025-07422-3
6. Morovat A, Catchpole A, Meurisse A, et al. IDS iSYS automated intact procollagen-1-N-terminus pro-peptide assay: method evaluation and reference intervals in adults and children. Clin Chem Lab Med. 2013;51(10):2009-2018. doi:10.1515/cclm-2012-0531

Performance

Method Description

The assay is based on chemiluminescence technology. Twenty microliters of patient sample or calibrator are added to a diluent, and a portion incubated with a biotinylated anti-procollagen type I N-terminal propeptide (PINP) monoclonal antibody, an acridinium labelled monoclonal antibody, streptavidin labelled magnetic particles and an assay buffer. The magnetic particles are captured using a magnet, and a wash step is performed to remove any unbound analyte. Trigger reagents are added; the resulting light emitted by the acridinium label is directly proportional to the concentration of intact PINP in the original sample.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 3 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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

83520

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
P1NP	Intact Procollagen I N-Terminal, S	77370-5

Result ID	Test Result Name	Result LOINC® Value
P1NP	Intact Procollagen I N-Terminal, S	77370-5