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ORIGINAL ARTICLE

The Development of Novel N-Terminal Pro-Peptide of Type I Chemiluminescence Assay

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SUMMARY

Background: **P1NP can be used for monitoring patients treated with both bisphosphonates and teriparatide as bone formation markers. P1NP assays include two types, intact trimeric form of P1NP assay and total P1NP assay. In this study we provided another type of P1NP assay.**
Methods: **The α-1 chain was constructed as recombined P1NP protein in the Corynebacterium glutamicum gene expression system. Native proteins were purified from Hydrothorax. Antibody clones were screened using mice immune to the α-1 chain peptide. The screened antibody was used for assay development. Assay performance was verified and afterwards the method comparison was analyzed between the self-developed assay and Roche P1NP assay.**
Results: **α-1 chain and native P1NP proteins were purified and used for antibody selection and making the calibrator. Three clones of antibody were screened and 2 of them were used in the assay development. The assay performance was characterized, including the linearity, precision, and sensitivity. Method comparison was also performed between our assay and Roche P1NP assay showing a 0.98 slope.**
Conclusions: **A new P1NP assay was provided that recognizes only the α-1 chain and, thus, may provide more insight for disease monitoring when the P1NP assay is applied in clinic in the future.**
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Supplementary Table 1. Value assignment of purified P1NP proteins.

Sample ID	Value assigned by Roche	
	1/20 dilution	1/200 dilution
Faction 1	< 5	< 5
Faction 2	< 5	< 5
Faction 3	< 5	< 5
Faction 4	< 5	< 5
Faction 5	< 5	< 5
Faction 6	749.3	57.32
Faction 7	> 1,200	224.8
Faction 8	1,064	> 1,200
Faction 9	1,094	> 1,200
Faction 10	> 1,200	807
Faction 11	933.7	87.95
Faction 12	238.3	27.39
Faction 13	114.9	11.27
Faction 14	55.64	6.72
Faction 15	28.8	< 5
Faction 16	12.88	< 5
Faction 17	7.28	< 5