

Background

Serum osteocalcin, also known as bone Gla protein, is a marker of bone turnover with short half-life and is hydrolyzed in the kidney and liver. Osteocalcin is a 49-residue (5.8 kDa) polypeptide; the C-terminal fragment is easily cleaved and the N-terminal mid-fragment shows greater stability. Immunoassays detecting only intact osteocalcin will be particularly sensitive to samples degradation; assays detecting fragments may, depending on the fragments recognized, overestimate the concentrations of intact osteocalcin. The intact molecule and the N-terminal fragment are the most abundant immunoreactive forms in healthy and osteoporotic patients. We reported the analytical performance of the automated IDS-iSYS N-Mid Osteocalcin assay.

Materials and Methods

The precision profile was determined with 11 serum pool levels (0.5 - 177.5 ng/mL). The linearity was verified with two sets of high/low serum samples. Over 200 serum samples were used for the method comparison between three N-Mid Osteocalcin assays: IDS-iSYS versus the IDS ELISA (n = 263, 1.9 – 176.2 ng/mL) and the IDS-iSYS versus Roche Elecsys (n = 208, 3.0 – 142.2 ng/mL).

Results

Precision profile

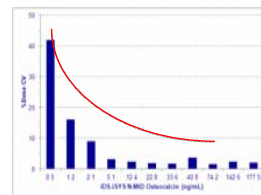


Fig.1: IDS-iSYS N-MID Osteocalcin precision profile.

The precision profile of 11 serum pools (0.5 - 177.5 ng/mL) ranged from 1.6 to 42%. The assay's LoQ was confirmed as 1.5 ng/mL.

Linearity profile

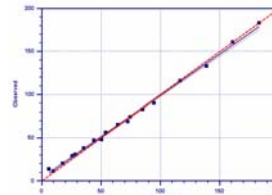


Fig.2: IDS-iSYS N-MID Osteocalcin linearity profile.

The linear regression of high/low serum samples dilutions (n=18) was: Observed = 0.96 x (Expected) + 3.4; R² = 0.997

IDS ELISA versus IDS-iSYS

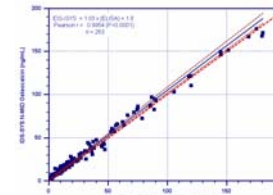


Fig. 3: Method comparison Passing Bablok regression plot between IDS ELISA and IDS-iSYS (n = 263).

We observed excellent correlation regression slope (95% CI) was 1.03(1.00 to 1.07) with correlation (r) of 0.995 (0.994 to 0.996).

Elecsys versus IDS-iSYS

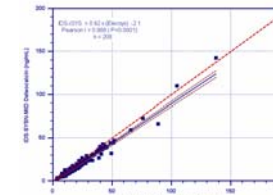


Fig. 4: Method comparison Passing Bablok regression plot between Roche Elecsys and IDS-iSYS (n = 208).

Good correlation obtain when measuring 208 serum samples in two fully automated N-MID Osteocalcin kits, Elecsys and IDS-iSYS. correlation regression slope (95% CI) was 0.92 (0.89 to 0.94) with correlation (r) of 0.988 (0.981 to 0.989).

Conclusion

- Our data shows that the fully automated IDS-iSYS N-MID Osteocalcin method offers a reliable alternative method for osteocalcin blood test.
- We verified the manufacturer's claims of Limit of Quantitation (LoQ), precision, linearity and assay measurable range.
- The IDS-iSYS N-Mid Osteocalcin gave similar results to two other FDA 510(k) cleared N-Mid Osteocalcin immunoassays.
- This automated assay demonstrated suitable characteristics as a high throughput bone turnover assay for clinical laboratories