Analytical Performance of a Bone Specific ALP Automated Immunoassay

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Background

Serum bone–specific alkaline phosphatase (bone ALP), a marker of bone turnover, has been proposed as an alternative biochemical target for clinical management of CKD-MBD patients. We assessed the analytical performance of the IDS-iSYS Ostase BAP (IDS, UK) automated assay and compared this method to the manual Ostase BAP Immunoenzymetric assay [EIA] (IDS, UK). The observed ranges for apparently healthy children and reference intervals for pre-menopausal, post-menopausal women and men were established.

Materials and Methods

- Accuracy profile: determined with serum pools.
- Linearity: verified with 2 sets of high/low serum.
- Method comparison: 116 samples [6.1-75.7µg/L].
- Reference intervals: males, pre-menopausal and post-menopausal.
- Paediatric observed ranges: healthy <20 yrs. old.

Results

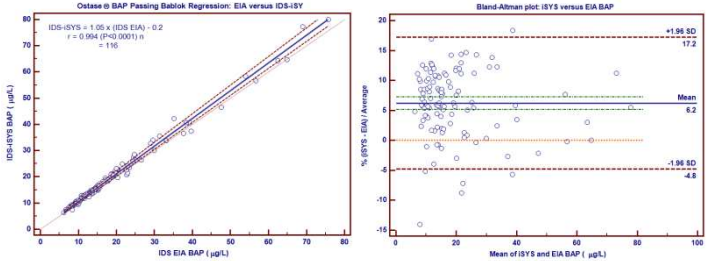
Precision profile

Total imprecision %CV between ranged from 4.0 to 6.3% in 4 pool levels with concentration between 10..2 - 62.7 µg/L.

Linearity

Observed = 1.05 x (Expected) – 1.89; R^2 = 0.997.

Method Comparison



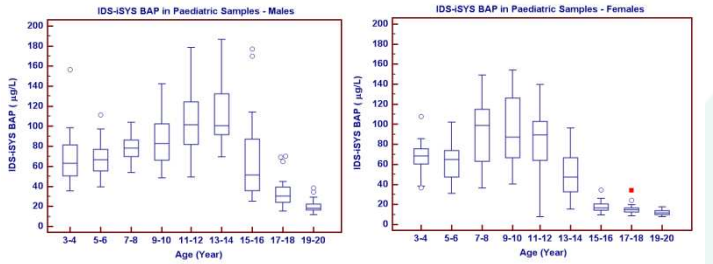
iSYS = 1.05 x (EIA) + 0.25
Pearson r = 0.994.

Good correlation between the method with Mean difference of 6.2%

Reference Intervals

- Males: 5.7 – 32.9 µg/L (n = 120).
- Pre-menopausal: 4.7 – 27.0 µg/L (n=54)
- Post-menopausal:5.5 – 27.1 µg/L (n=79)

Paediatric Observed Ranges



Males

Age (year)	N	Mean (µg/L)	SD (µg/L)	Median (µg/L)	Minimum (µg/L)	Maximum (µg/L)	5 - 95 Percentile Obs. Range
3-4	20	68.6	27.6	62.9	35.2	156.8	37.2 - 127.7
5-6	20	69.2	19.3	66.7	39.2	111.4	42.0 - 104.2
7-8	20	79.4	12.9	78.4	53.8	103.7	59.0 - 101.3
9-10	20	84.4	25.2	82.8	48.2	142.1	50.4 - 133.0
11-12	20	101.2	30.3	101.4	49.4	178.6	53.3 - 156.8
13-14	20	112.5	29.6	100.5	69.5	186.8	77.5 - 169.8
15-16	20	67.6	44.8	51.4	25.1	177	26.8 - 173.4
17-18	20	34.6	16.5	30.3	15.1	70.3	15.4 - 69.8
19-20	20	20.2	7.0	18.2	11.6	38.5	12.2 - 36.6

Females

Age (year)	N	Mean (µg/L)	SD (µg/L)	Median (µg/L)	Minimum (µg/L)	Maximum (µg/L)	5 - 95 Percentile Obs. Range
3-4	20	67.4	16.4	68.5	36.6	108	37.4 - 96.8
5-6	20	63.6	21.1	64.8	30.7	102.1	31.4 - 100.8
7-8	20	90.8	30.8	98.9	36.3	149.2	44.0 - 135.8
9-10	20	94.8	34.3	87.2	40.4	154	47.9 - 150.8
11-12	20	84.2	31.0	89.7	7.5	139.8	24.2 - 133.3
13-14	20	50.6	23.0	47.3	15.2	96.4	19.8 - 92.7
15-16	20	17.9	5.6	16.8	9.6	34.5	11.2 - 30.2
17-18	20	15.5	5.6	14.8	8.6	33.8	8.8 - 29.0
19-20	20	11.8	2.7	11.8	7.4	17.5	7.7 - 16.8

Conclusion

- The IDS-iSYS Ostase BAP assay performed well; it showed suitable characteristics to achieve acceptable precision and accuracy.
- The method comparison between the IDS-iSYS and the EIA showed an excellent relationship.
- The IDS-iSYS Ostase BAP is a suitable tool in clinical laboratories.

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