Serum Osteocalcin Assay by the Elecsys 2010 is Robust and Suitable for Monitoring Bone Turnover

Abstract
Serum osteocalcin (OC) has demonstrated clinical utility as a biomarker of bone formation. However, OC is commonly believed to be unstable and to require several serial freeze-thaw cycles before analysis. The objective of this study was to evaluate the long-term performance of the N-MID Osteocalcin assay on the automated Elecsys 2010 analyzer (Roche Diagnostics) and the stability of different sample types under a variety of conditions. The Elecsys OC is specific for intact OC (amino acids 1-49) and the main N-terminal fragment (amino acids 1-43) resulting from proteolytic cleavage after blood collection. OC assay precision was evaluated by commercial and in-house quality control samples. To evaluate the stability of OC by Elecsys, matched serum, K3 EDTA plasma (EDTA) and Heparin plasma (Heparin) were collected from volunteers. Sample stability was evaluated at room temperature, at 4 °C for 7 days and at -70 °C for 2 yr. To measure OC in a specimen matrix likely to accumulate fragment, matched serum, EDTA and Heparin samples were collected from 4 subjects on kidney hemodialysis. OC was analyzed within one month of collection and again after 4 yr of storage at -70 °C. The within-run precision of OC was 1.4-3.6% CV at 72-7.9 ng/mL. Among-run precision was 2.7-0.9% CV at 21.3-110 ng/mL. OC concentrations in serum, EDTA and Heparin did not offer significantly different values. EDTA was a more stable matrix at room temperature than after serum or Heparin. After 24 months storage at -70 °C, change in OC at 24 mo at -70 °C was less than 10% for all three sample types, with no trend. Analysis of samples from subjets on renal dialysis with greatly elevated values (7-1135 ng/mL, SD = 330 ng/mL) recovered well in dialysis controls. OC values agreed after 4 yr of storage in serum, EDTA, and Heparin and restored well with the initial results (r = 0.98 slopes were not significantly different from 1) but the absolute values were slightly lower. Short-term and long-term consistency of the N-MID OC assay was observed in serum pools during multiple time periods. The N-MID OC assay exhibited a mean decrease of 20.2% from baseline (baseline mean = 32.2 ng/mL) compared to –7.2 % (baseline mean = 30.4 ng/mL) measured in samples following 3 yr of storage. Among-run precision was 2.7-3% CV at 72-7.9 ng/mL. Among-run precision was 2.7-0.9% CV at 21.3-110 ng/mL. OC concentrations in serum, EDTA and Heparin did not offer significantly different values. EDTA was a more stable matrix at room temperature than after serum or Heparin. After 24 months storage at -70 °C, change in OC at 24 mo at -70 °C was less than 10% for all three sample types, with no trend. Analysis of samples from subjets on renal dialysis with greatly elevated values (7-1135 ng/mL, SD = 330 ng/mL) recovered well in dialysis controls. OC values agreed after 4 yr of storage in serum, EDTA, and Heparin and restored well with the initial results (r = 0.98 slopes were not significantly different from 1) but the absolute values were slightly lower. Short-term and long-term consistency of the N-MID OC assay was observed in serum pools during multiple time periods. The N-MID OC assay exhibited a mean decrease of 20.2% from baseline (baseline mean = 32.2 ng/mL) compared to –7.2 % (baseline mean = 30.4 ng/mL) measured in samples following 3 yr of storage. Among-run precision was 2.7-3% CV at 72-7.9 ng/mL. Among-run precision was 2.7-0.9% CV at 21.3-110 ng/mL. OC concentrations in serum, EDTA and Heparin did not offer significantly different values. EDTA was a more stable matrix at room temperature than after serum or Heparin. After 24 months storage at -70 °C, change in OC at 24 mo at -70 °C was less than 10% for all three sample types, with no trend. Analysis of samples from subjets on renal dialysis with greatly elevated values (7-1135 ng/mL, SD = 330 ng/mL) recovered well in dialysis controls. OC values agreed after 4 yr of storage in serum, EDTA, and Heparin and restored well with the initial results (r = 0.98 slopes were not significantly different from 1) but the absolute values were slightly lower. Short-term and long-term consistency of the N-MID OC assay was observed in serum pools during multiple time periods. The N-MID OC assay exhibited a mean decrease of 20.2% from baseline (baseline mean = 32.2 ng/mL) compared to –7.2 % (baseline mean = 30.4 ng/mL) measured in samples following 3 yr of storage.