N-telopeptides (NTX) in Urine

Method:	Enzyme linked immunosorbent assays (ELISA)
Kit Manufacturer:	Wampole Laboratories, Princeton, NJ
Description:	The Osteomark NTx assays are competitive inhibition ELISA that use microwells in strips as the solid phase onto which NTx has been absorbed. NTx in the patient sample competes with the NTx absorbed on the solid phase for binding sites on a horseradish peroxide labelled monoclonal antibody. The amount of antibody bound is inversely proportional to the amount of NTx in the sample. The NTx concentration in the patient sample is determined spectrophotometrically and calculated from a standard calibration curve. In urine, ELISA results are expressed in nM of bone collagen equivalents (nM BCE) per mM of creatinine. In serum, ELISA results are expressed in nM BCE, i.e. no correction for creatinine is necessary.

Collection and Performance Characteristics

Specimen type:	Spot or 24 hour urine with no preservative (second void morning urine)
Minimum Volume:	1 mL
Lowest Reportable Value:	20 nM BCE
Dynamic Range:	20-3000 nM BCE
Precision:	The intra-assay variation is 4.2-5.2% The inter-assay variation is 4.6-7.4%
Reference Range:	Premenopausal Women: 5 – 65 nM BCE/mM Creatinine Men:3 – 63 nM BCE/mM Creatinine

Note: The formula for correction of NTX/creatinine is as follows
Assay Value of NTX reported by HCCL = X nMBCE (nanomole Bone Collagen Equivalent)
Urinary Creatine mg/dL / 11.3 = Y mM creatinine*
Corrected result for NTX = X nMBCE / Y mM creatinine = Z nMBCE/mM creatinine (Final NTX result)

** Conversion factor used to convert mg creatinine per dL to millimole creatinine per liter.*