



**Longitudinal Urinary NTx data
from Baseline through Visit 08**

CODEBOOK

ARCHIVED DATASET 2018

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GENERAL DOCUMENTATION FOR THE LONGITUDINAL URINARY NTx DATASET

This codebook documents the release of the SWAN Urinary NTx data from Baseline through Visit 08 done by Unipath, Ltd, a subsidiary of Inverness Medical Innovations Inc. (IMI), a company that specializes in development and marketing of rapid diagnostics in areas of women's health. Unipath, located in Bedford, England, is the primary R&D site for the women's health program of the parent company, IMI.

Through acquisition of Ostex by the parent company IMI, Unipath secured the bone turnover marker NTx (N-telopeptide) and marketing interest in the urine and serum ELISAs point of care NTx assays.

Who is included in the frozen dataset: This dataset contains data from 2407 women for whom urine specimens were received by Unipath.

Brief description of the data: Urinary N-telopeptide of type 1 collagen (NTx) was measured in singlicate using an automated immunoassay (Vitros ECi; Ortho Clinical., Rochester, NT, USA). The assay is based on competition between urinary peptide and synthetic NTx peptide coating the wells, for binding by an anti-NTx monoclonal antibody conjugated to horse radish peroxidase. The bound conjugate is measured by chemiluminescence. NTx is expressed as nanomoles of bone collagen equivalents per litre per millimole creatinine per liter (nM BCE/mM creatinine). The lower limit of detection was 10nM BCE and intra and inter assay coefficients of variation were 2.75% and 4.8% respectively, over the assay range. Samples >3000nM BCE were diluted 1/20 prior to measurement.

Creatinine was measured on the Cobas Mira (Horiba ABX, Montpellier, France) based on the Jaffé reaction. The lower limit of detection was 0.014mM and the intra and inter assay coefficients of variation were 0.62% and 4.12% respectively, across the assay range.

Missing NTX records:

There are 631 urine samples (554 IDs) which have urine collection records but do not have NTX results. The repository in Michigan was queried and below is the summary table with the status of urine availability from the repository for the 631 samples.

The status of urine availability for 631 missing NTX samples

Visit	# of missing samples	Sent to Unipath	No Urine	Last Vial	Urine Available
V00	35	1	26	3	5
V01	43	0	40	2	1
V02	19	1	10	0	8
V03	17	2	1	13	1
V04	73	1	4	65	3
V05	142	1	4	29	108
V06	49	2	1	43	3
V07	72	1	5	52	14
V08	181	2	12	61	106
Total	631	11	103	268	249

Listing of all variables in the dataset:

Variable Name	Variable Label	Data Source
ARCHID		
VISIT	SWAN visit number	
RACE	Race/ethnicity	1 = Black 2 = Chinese/Chinese American 3 = Japanese/Japanese American 4 = White Non-Hispanic 5 = Hispanic
SITE	Study Site	11 = Detroit, MI 12 = Boston, MA 13 = Chicago, IL 14 = Oakland, CA 15 = Los Angeles, CA 16 = Newark, NJ 17 = Pittsburgh, PA
URINDAY	Urine specimen collection day	
URINTIME	Urine specimen collection time in military	
FLG_URTM	Flag for missing urine collection date/time	1 = Flagged
NTX_UNADJ	Unadjusted NTx value (nMBCE)	Unipath generated
CREAT	Creatinine value (mmol/L)	Unipath generated
NTXCR	CORRECTED NTx (nMBCE) / Creatinine (mmol/L)	Unipath generated
FLG_NTX	NTx value flag*	Unipath generated 1 = Flagged

*Note: FLG_NTX is set to "1" under following criteria:

FLG_NTX = 1 if the unadjusted NTx value and creatinine value are both available and those values are > 0, but the NTXCR is either 0 or 0.1 (very low NTx/cr ratio). These will be cases where the creatinine value is quite high, and/or the NTx (unadj) is very small. (i.e. FLG_NTX = 1 if NTXCR in (0, 0.1) and NTX_UNADJ not in (., 0) and creatinine not in (., 0)

Please note the following Analysis Advisory: Bone turnover markers, including NTX, exhibit large diurnal variation [Gertz et al., Greenspan et al.]. Therefore, it is advised that when analyzing NTX data, you account for the time of specimen collection.

Citation:

1. Gertz BJ, Clemens JD, Holland SD, Yuan W, Greenspan S Application of a New Serum Assay for Type I Collagen Cross-Linked N-Telopeptides: Assessment of Diurnal Changes in Bone Turnover With and Without Alendronate Treatment. *Calcif Tissue Int* (1998) 63:102-106
2. Greenspan S, Dresner-Pollak R, Parker RA, London D, Ferguson L (1997) Diurnal Variation of Bone Mineral Turnover in Elderly Man and Women. *Calcif Tissue Int* (1997) 60:419-423