

National Health and Nutrition Examination Survey

August 2021-August 2023 Data Documentation, Codebook, and Frequencies

Insulin (INS_L)

Data File: INS_L.xpt

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Last Revised: NA

Component Description

Insulin is the primary hormone responsible for controlling glucose metabolism, and its secretion is determined by plasma glucose concentration. The insulin molecule is synthesized in the pancreas as pro-insulin and is later cleaved to form C-peptide and insulin. The principal function of insulin is to control the uptake and utilization of glucose in the peripheral tissues. Insulin concentrations are severely reduced in insulin-dependent diabetes mellitus (IDDM) and some other conditions, while insulin concentrations are raised in non-insulin-dependent diabetes mellitus (NIDDM), obesity, and some endocrine disorders.

Eligible Sample

All examined participants 12 years and older, in the NHANES August 2021 – August 2023 sample, were eligible.

Description of Laboratory Methodology

Insulin

The AIA-PACK IRI is a two-site immunoenzymometric assay, which is performed on a Tosoh AIA System analyzer. This assay is designed for the quantitative measurement of Insulin (IRI) in human serum. Insulin present in the test sample is bound with monoclonal antibody immobilized on a magnetic solid phase and enzyme-labeled monoclonal antibody in the AIA-PACK. The magnetic beads are washed to remove unbound enzyme-labeled monoclonal antibody and are then incubated with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled monoclonal antibody that binds to the beads is directly proportional to the insulin concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve.

Refer to the Laboratory Method Files section for a detailed description of the laboratory methods used.

Laboratory Method Files

[Insulin](#) (September 2024)

Laboratory Quality Assurance and Monitoring

Serum specimens were processed, stored, and shipped to the University of Missouri-Columbia, Columbia, MO for analysis.

Detailed instructions on specimen collection and processing are discussed in the [NHANES Laboratory Procedure Manual \(LPM\)](#). Vials are stored under appropriate frozen (-30°C) conditions until they are shipped to University of Missouri-Columbia for testing.

The NHANES quality assurance and quality control (QA/QC) protocols meet the 1988 Clinical Laboratory Improvement Amendments mandates. Detailed QA/QC instructions are discussed in the [NHANES LPMs](#).

Mobile Examination Centers (MECs)

Laboratory team performance is monitored using several techniques. NCHS and contract consultants use a structured competency assessment evaluation during visits to evaluate both the quality of the laboratory work and the QC procedures. Each laboratory staff member is observed for equipment operation, specimen collection and preparation; testing procedures and constructive feedback are given to each staff member. Formal retraining sessions are conducted annually to ensure that required skill levels were maintained.

Analytical Laboratories

NHANES uses several methods to monitor the quality of the analyses performed by the contract laboratories. In the MEC, these methods include performing blind split samples collected on "dry run" sessions. In addition, contract laboratories randomly perform repeat testing on 2% of all specimens.

NCHS developed and distributed a QC protocol for all CDC and contract laboratories, which outlined the use of Westgard rules (Westgard et. al., 1981) when testing NHANES specimens. Progress reports containing any problems encountered during shipping or receipt of specimens, summary statistics for each control pool, QC graphs, instrument calibration, reagents, and any special considerations are submitted to NCHS quarterly. The reports are reviewed for trends or shifts in the data. The laboratories are required to explain any identified areas of concern.

Data Processing and Editing

The data were reviewed. Incomplete data or improbable values were sent to the performing laboratory for confirmation.

One variable was created in this data file. The variable LBDINSI was created using the following formula:

LBDINSI: The insulin value in $\mu\text{U}/\text{mL}$ (LBXIN) was converted to pmol/L (LBDINSI) by multiplying by 6.0 (rounded to 2 decimals).

Analytic Notes

There are over 800 laboratory tests performed on NHANES participants. However, not all participants provided biospecimens or enough volume for all the tests to be performed. The specimen availability can also vary by age or other population characteristics. Analysts should evaluate the extent of missing data in the dataset related to the outcome of interest as well as any predictor variables used in the analyses to determine whether additional re-weighting for item non-response is necessary.

Please refer to the NHANES [Analytic Guidelines](#) and the on-line [NHANES Tutorial](#) for further details on the use of sample weights and other analytic issues.

Subsample Weights

Insulin was measured in a fasting subsample of participants 12 years and older. Specific sample weights (WTSAF2YR) for this subsample are included in this data file and should be used when analyzing these data.

Participants included in the fasting subsample but did not provide a blood specimen (n=324) have an assigned sample weight value of "0" in their records. In addition, participants who provided blood specimen but did not meet the 8 to less than 24 hour fasting criteria (n=311) have the sample weight value assigned as "0" (WTSAF2YR =0) as well. Twenty-one out of these 311 participants did not provide enough volume to have their insulin tested. Insulin measurements for the other 290 participants are included in the dataset. However, to include these data in the analysis, a reweighting is required. There are another 168 participants in the fasting subsample that did not provide enough blood; therefore, they did not have insulin measured. However, these participants have data in at least one other fasting subsample tests (e.g., plasma fasting glucose). Therefore, they have a sample weight larger than "0," regardless of missing their insulin test results.

Demographic and Other Related Variables

The analysis of NHANES laboratory data must be conducted using the appropriate survey design and demographic variables. The [NHANES August 2021 - August 2023 Demographics File](#) contains demographic data, health indicators, and other related information collected during household interviews as well as the sample design variables. The recommended procedure for variance estimation requires use of stratum and PSU variables (SDMVSTRA and SDMVPSU, respectively) in the demographic data file.

The [Fasting Questionnaire File](#) includes auxiliary information, such as fasting status, length of fast and the time of venipuncture.

This laboratory data file can be linked to the other NHANES data files using the unique survey participant identifier (i.e., SEQN).

Detection Limits

The detection limits were constant for all of the analytes in the data set. Two variables are provided for each of these analytes. The variable name ending "LC" (ex., LBDINLC) indicates whether the result was below the limit of detection: the value "0" means that the result was at or above the limit of detection, "1" indicates that the result was below the limit of detection. The other variable prefixed LBX (ex., LBXIN) provides the analytic result for that analyte. For analytes with analytic results below the lower limit of detection (ex., LBDINLC=1), an imputed fill value was placed in the analyte results field. This value is the lower limit of detection divided by the square root of 2 (LLOD/sqrt[2]).

The lower limit of detection (LLOD, in $\mu\text{U}/\text{mL}$) for insulin is:

Variable Name	Analyte Description	LLOD
LBXIN	Insulin	0.5

References

- Westgard J.O., Barry P.L., Hunt M.R., Groth T. A multi-rule Shewhart chart for quality control in clinical chemistry. *Clin Chem* (1981) 27:493-501.

Codebook and Frequencies

SEQN - Respondent sequence number

Variable Name: SEQN
SAS Label: Respondent sequence number
English Text: Respondent sequence number.
Target: Both males and females 12 YEARS - 150 YEARS

WTSAF2YR - Fasting Subsample 2 Year MEC Weight

Variable Name: WTSAF2YR
SAS Label: Fasting Subsample 2 Year MEC Weight
English Text: Fasting Subsample 2 Year MEC Weight
Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
11459.183689 to 561922.42956	Range of Values	3361	3361	
0	No Lab Result or Not Fasting for 8 to <24 hours	635	3996	
.	Missing	0	3996	

LBXIN - Insulin (uU/mL)

Variable Name: LBXIN
SAS Label: Insulin (uU/mL)
English Text: Insulin (uU/mL)
Target: Both males and females 12 YEARS - 150 YEARS
Hard Edits: 0 to 9999.99

Code or Value	Value Description	Count	Cumulative	Skip to Item
0.35 to 699.9	Range of Values	3510	3510	
.	Missing	486	3996	

LBDINSI - Insulin (pmol/L)

Variable Name: LBDINSI

SAS Label: Insulin (pmol/L)

English Text: Insulin (pmol/L)

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
2.1 to 4199.4	Range of Values	3510	3510	
.	Missing	486	3996	

LBDINLC - Insulin Comment Code

Variable Name: LBDINLC
SAS Label: Insulin Comment Code
English Text: Insulin Comment Code
Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0	Detectable result	3509	3509	
1	Below detectable limit	1	3510	
.	Missing	486	3996	

