National Health and Nutrition Examination Survey 2003-2004

Documentation, Codebook, and Frequencies

MEC Laboratory Component: Plasma Glucose, Serum C-peptide, and Insulin

Survey Years:
2003 to 2004

SAS Export File:
L10am_C.XPT

First Published: January 2006
Last Revised: March 2007

NHANES 2003–2004 Data Documentation

Laboratory Assessment: Lab 10AM – Glucose, C-Peptide, and Insulin

Years of Coverage: 2003–2004 **First Published:** January 2006 **Last Revised:** March 2007

Component Description

See important notes for insulin and fasting weights under the **Analytic Notes** section below.

Diabetes mellitus was assessed by measures of plasma glucose and serum c-peptide in participants aged 12 years and older in the morning (AM) examination session only. Glycohemoglobin measures were available for a full sample for participants 12 years and older. Diabetes is a leading cause of disease and death in the United States. Eight million Americans are known to have diabetes, and an equal number have undiagnosed diabetes. In 1993, nearly 18 percent of all deaths for persons over the age of 25 had diabetes. The prevalence of diabetes and overweight (one of the major risk factors for diabetes) continues to increase. Substantial new efforts to prevent or control diabetes have begun, including the Diabetes Prevention Trial and the National Diabetes Education Program.

Information on the prevalence of diabetes disease, especially in its early stages, and associated risk factors will be used to help develop early intervention and prevention programs for the disabling consequences of this condition. Specifically, the diabetes disease examination will provide population data to: 1) determine a national estimate of diabetes disease prevalence (diagnosed and undiagnosed), including those at high risk for the late complications of the disease (i.e., ulceration and amputation); 2) identify the risk factors of diabetes disease; 3) permit a national cohort to be established for follow-up studies of this condition; and 4) provide critical information to clinicians and public health officials for the development of preventive care and community-based interventions.

Eligible Sample

Participants aged 12 years and older who were examined in the morning session were tested.

Description of Laboratory Methodology

Glucose

The enzyme hexokinase (HK) catalyzes the reaction between glucose and adenosine triphosphate (ATP) to form glucose-6-phosphate (G-6-P)

and adenosine diphosphate (ADP). In the presence of nicotinamide adenine dinucleotide (NAD), G-6-P is oxidized by the enzyme glucose-6-phosphate dehydrogenase (G-6-PD) to 6-phosphogluconate and reduced nicotinamide adenine dinucleotide (NADH). The increase in NADH concentration is directly proportional to the glucose concentration and can be measured spectrophotometrically at 340 nm.

C-Peptide

C-peptide radioimmunoassay (RIA) is a competitive assay where 125I-labeled C-peptide competes with C-peptide in the specimen for antibody sites. Bound and free C-peptide is separated by adding a second PEG-accelerated double antibody. The antibody-bound fraction is precipitated and counted. The radioactivity is inversely proportional to the quantity of C-peptide in the specimen.

Insulin

Human insulin is a polypeptide hormone originating in the ßeta-cells of the pancreas and serving as a principal regulator for the storage and production of carbohydrates. Its secretion is normally stimulated by increases in the amount of glucose in the circulation.

The Tosoh AIA-PACK IRI is a two-site immunoenzymometric assay which is performed entirely in the AIA-PACK. 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 IRI concentration in the test sample. A standard curve is constructed, and unknown sample concentrations are calculated using this curve. The amount of sample required for Tosoh insulin analysis is 25uL.

There were changes to the equipment and lab method from the previous 2 years.

Laboratory Quality Control and Monitoring

The NHANES quality assurance and quality control (QA/QC) protocols meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed QA/QC instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed QA/QC protocols.

A detailed description of the quality assurance and quality control procedures can be found on the NHANES website.

Data Processing and Editing

Blood specimens were processed, stored and shipped to University of Missouri-Columbia, Columbia, Missouri for analysis. Detailed specimen collection and processing instructions are discussed in the NHANES LPM. Read the LABDOC file for detailed data processing and editing protocols. The analytical methods are described in the Description of the Laboratory Methodology section.

There was no top coding or derived variables in this file.

Detailed instructions on specimen collection and processing can be found on the NHANES website.

Analytic Notes

1. Comparison of NHANES 2003-2004 to NHANES 1999-2002
Insulin Values:
The serum insulin method changed for NHANES in 2003. A Pharmacia method (see above) was used for NHANES 1999-2002 and a Tosoh method (see above) was used for NHANES 2003-2004. The mean value for the Tosoh method was about 11% lower than the Pharmacia method mean value. Two crossover studies were performed comparing the Pharmacia to the Tosoh values on split specimens. The following linear regression was obtained for LBXIN (uU/mL):

Y (Tosoh) = (1.0027 * Pharmacia) - 2.2934
n=245
r=0.981
We recommend using this linear regression to adjust the NHANES 1999-2002 Pharmacia values when comparing them to NHANES 2003-2004 insulin values.

2. Conversion factor for insulin units
The conversion factor for insulin is 1uU/mL=6.00 pmol/L. This unit conversion is based on the WHO standard adopted in 1987 based on a human insulin with a potency of 26000 U/g (1,2).

3. Survey design and basic demographic variables
The analysis of NHANES 2003–2004 laboratory data must be

conducted with the key survey design and basic demographic variables. The NHANES 2003–2004 Household Questionnaire Data Files contain demographic data, health indicators, and other related information collected during household interviews. They also contain all survey design variables for these age groups. The phlebotomy file includes auxiliary information such as the conditions precluding venipuncture. The household questionnaire and phlebotomy files may be linked to the laboratory data file using the unique survey participant identifier SEQN.

4. Plasma glucose and serum c-peptide
LBXGLU and LBXGLUSI: Plasma glucose
LBXCPSI: C-peptide
Plasma glucose and serum c-peptide were measured by the Diabetes Diagnostic Laboratory at the University of Missouri-Columbia on participants aged 12 years and older in the morning examination session only.

5. LBXGLU vs. LBXSGL
The lab 10 data file contains laboratory test results for glucose measured using the reference analytic method. However, the lab 40 biochemistry profiles also included measurements of this analyte. The serum glucose values (LBXSGL) reported in the lab 40 release should not be used to determine undiagnosed diabetes or pre-diabetes. Instead, plasma glucose values (LBXGLU) from lab10 should be used based on the reference analytic method of this analyte.

6. Sampling Weights
WTSFA2YR (2-year fasting weights for participants 12+ years):
One-half of the participants were sampled to attend the morning session. Those participants ages 12 and older appointed to attend the morning session were instructed to fast at least 9 hours prior to their appointment time.

Subsample weights were required for analysis since the analysis of interest involves only those sampled persons ages 12 and older examined in the morning. Because fasting is a key characteristic of this subsample, this data item is called “fasting” weight. Non-zero fasting weights were generated for sample persons 12 years and older who fasted 8 to 24 hours and had plasma glucose values and diabetics who fasted but had missing plasma glucose values. Diabetics who did not fast have zero weights.

The 2-year fasting weights (WTSFA2YR) should be used when analyzing NHANES 2003-2004. The use of the full sample MEC examined weights (WTMEC2YR) should not be used to analyze the data if the outcome of interest is only measured on the morning fasting sample.

See the Analytic Guidelines regarding applying weights for analysis of data.

References

1. Volund A. Conversion of Insulin units to SI units. Am J Clin Nutr 1993; 58: 714-5.

2. Robbins, DC, et al. Report of the American Diabetes Association's task force on standardization of the insulin assay. Diabetes; 1996; 45(2): 242-56.

Locator Fields

Title: Glucose, C-Peptide, and Insulin
Contact Number: 1-866-441-NCHS
Years of Content: 2003–2004
First Published: January 2006
Revised: March 2007
Access Constraints: None
Use Constraints: None
Geographic Coverage: National
Subject: Glucose, C-Peptide and Insulin
Record Source: NHANES 2003–2004
Survey Methodology: NHANES 2003–2004 is a stratified multistage probability sample of the civilian non-institutionalized population of the U.S.
Medium: NHANES Web site; SAS transport files

National Health and Nutrition Examination Survey
Codebook for Data Production (2003-2004)

Plasma Glucose, Serum C-peptide, and Insulin (L10AM_C)
Person Level Data

First Published January 2006
Last Revised March 2007

SEQN	Target
	B(12 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Respondent sequence number
English Text: Respondent sequence number.	
English Instructions:	

WTSFA2YR	Target
	B(12 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Fasting Subsample 2 Year Mec Weight
English Text: Fasting Subsample 2 Year Mec Weight	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
0 to 355659.48	Range of Values	3356	3356	
.	Missing	0	3356	

LBXGLU	Target
	B(12 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Glucose, plasma (mg/dL)
English Text: Glucose, plasma (mg/dL)	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
45.7 to 547.6	Range of Values	3169	3169	
.	Missing	187	3356	

LBDGLUSI	Target
	B(12 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Plasma glucose: SI(mmol/L)
English Text: Plasma glucose: SI(mmol/L)	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
2.537 to 30.397	Range of Values	3169	3169	
.	Missing	187	3356	

LBXCPSI	Target
	B(12 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	C-peptide: SI(nmol/L)
English Text: C-peptide (nmol/L) in SI units	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
0.068 to 5.112	Range of Values	3131	3131	
0.021	Below Limit of Detection	6	3137	
.	Missing	219	3356	

LBXIN	Target
	B(12 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Insulin (uU/mL)
English Text: Insulin (uU/mL)	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
1 to 205.69	Range of Values	3120	3120	
0.71	Below Limit of Detection	16	3136	
.	Missing	220	3356	

LBDINSI	Target
	B(12 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Insulin: SI(pmol/L)
English Text: Insulin: SI(pmol/L)	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
6 to 1234.14	Range of Values	3120	3120	
4.26	Below Limit of Detection	16	3136	
.	Missing	220	3356	