# Documentation, Codebook, and Frequencies

Plasma Fasting Glucose and Insulin

Laboratory

**Survey Years: 2005 to 2006** 

SAS Transport File: GLU\_D.XPT



First Published: April 2008 Last Revised: July 2008

#### NHANES 2005–2006 Data Documentation

Laboratory Assessment: Plasma Fasting Glucose and Insulin (GLU\_D)

First Published: April 2008 Last Revised: July 2008

Note: An additional regression equation was added to compare 2003-2004 glucose data to 2005-2006 glucose data. See **Analytical Notes**.

## **Component Description**

Diabetes mellitus was assessed by measures of fasting plasma glucose, two-hour glucose (OGTT) and serum insulin in participants aged 12 years and over in the morning (AM) examination session only. Glycohemoglobin measures are also available for a full sample.

Diabetes is a leading cause of disease and death in the United States. Eight million Americans are known to have diabetes, and an approximately equal number have undiagnosed diabetes. In 1993, nearly 18 percent of all deaths for persons over the age of 25 were among people with diabetes. The prevalence of diabetes and overweight (one of the major risk factors for diabetes) continue to increase. Substantial new efforts to prevent or control diabetes have begun, including the Diabetes Prevention Trial and the National Diabetes Education Program.

Diabetes testing provides population data to: 1) determine a national estimate of diabetes disease prevalence (diagnosed and undiagnosed), 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

Glucose concentration was determined by a hexokinase method. It is an endpoint enzymatic method with a sample blank correction.

#### Insulin

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.

The Merocodia Insulin ELISA is a two-site enzyme immunoassay utilizing the direct sandwich technique with two monoclonal antibodies directed against separate antigenic determinants of the insulin molecule. Specimen, control, or standard is pipetted into the sample well, and then followed by the addition of peroxidase-conjugated anti-insulin antibodies. Insulin present in the sample will bind to anti-insulin antibodies bound to the sample well, while the peroxidase-conjugated anti-insulin antibodies will also bind to the insulin at the same time. After washing to remove unbound enzyme-labelled antibodies, a labelled substrate is added and binds to the conjugated antibodies. Acid is added to the sample well to stop the reaction, and the colorimetric endpoint is read on a microplate spectrophotometer set to the appropriate light wavelength.

There were changes to the equipment and laboratory from NHANES 2003-2004. For NHANES 2005-2006, glucose and insulin measurements were performed by the Fairview Medical Center Laboratory at the University of Minnesota and for NHANES 2003-2004 glucose and insulin measurements were performed by the Diabetes Diagnostic Laboratory at the University of Missouri-Columbia.

The following is a listing of instruments and methods used for glucose and insulin for NHANES 2003-2006:

Year	Analyte	Instrument	Method
2005-	Glucose	Roche/Hitachi	Hexokinase
2006		911	
2003-	Glucose	Roche Cobas	Hexokinase
2004		Mira	
2005-	Insulin	Merocodia	ELISA
2006		Insulin	
2003-	Insulin	Tosoh AIA-	immunoenzymometric
2004		PACK IRI	-

Beginning in 2005, an oral glucose tolerance test (OGTT) was added to the laboratory protocol. A fasting glucose blood test was performed on all participants 12 years and older who were examined in the morning session after a 9 hour fast. After the initial venipuncture, participants were asked to drink a calibrated dose (generally 75 grams of glucose) of Trutol<sup>TM</sup> and had a second venipuncture 2 hours (plus or minus 15

minutes) after drinking the Trutol<sup>TM</sup>.

There are seven exclusion criteria including hemophilia and chemotherapy safety exclusions, fasting < 9 hours, taking insulin or oral medications for diabetes, refusing phlebotomy, and not drinking all the entire Trutol solution within the allotted time.

A detailed description of the laboratory methods for glucose, OGTT and insulin can be found in the Laboratory Procedures Manual.

#### Laboratory Quality Control and Monitoring

The NHANES quality assurance and quality control (QA/QC) protocols meet the 1988 Clinical Laboratory Improvement Act (CLIA) 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.

#### Data Processing and Editing

Blood specimens were processed, stored and shipped to Fairview Medical Center Laboratory at the University of Minnesota, Minneapolis Minnesota 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.

Two derived variables were created in this data file. The formula for their derivation is as follows:

#### LBXGLU and LBDGLUSI:

The fasting glucose value in mg/dL (LBXGLU) was converted to mmol/L (LBDGLUSI) by multiplying by 0.05551 (rounded to 3 decimals).

#### LBXIN and LBDINSI:

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

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

## Analytic Notes

Glucose regression equation to compare 2005-2006 and 2003-2004 data:

A crossover study was performed to compare the 2005-2006

Roche/Hitachi 911 glucose method to the 2003-2004 Roche Cobas Mira glucose method. A linear regression analysis was done and the following regressions were obtained for glucose (mg/dL):

Y (Cobas Mira) = 0.9835\*X (Hitachi 911), n=92, r=0.9993, intercept not significant.

Y (Hitachi 911) = 0.9815\*X (Cobas Mira) + 3.5707, n=92, r=0.9919

These regression equations may be used to trend the glucose data.

## Insulin regression equation to compare 2005-2006 data to 2003-2004 data:

A crossover study was performed to compare the 2005-2006 Mercodia insulin method to the 2003-2004 Tosoh insulin method. A Deming regression analysis was done and the following regression was obtained for insulin (uU/mL):

Y(Tosoh) = 1.0526 \*X(Mercodia) - 1.5674, n=189, r=0.9870

This regression may be used to trend the insulin data.

#### NHANES 2005-2006 Survey Design:

The analysis of NHANES 2005–2006 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES 2005–2006 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.

The Minnesota Laboratory Data File (GLU\_D) (which contains laboratory test results for glucose - LBXGLU) was measured using the reference analytic method. However, the lowa laboratory (BIOPRO\_D), that measures biochemistry profiles, also included measurements of serum glucose. The serum glucose values (LBXSGL) reported in the lowa lab should not be used to determine undiagnosed diabetes or prediabetes. Instead, plasma glucose values from the Minnesota Lab (LBXGLU) should be for data analysis.

#### **Sampling Weights**

The analyst is strongly encouraged to use the fasting sampling weights in this file to analyze 2005–2006 glucose and insulin levels.

There will be two weight files associated with diabetes data. Use the fasting sample weights (WTSAF2YR) when analyzing the fasting glucose and insulin levels only. Use the OGTT sample weights (WTSOG2YR) when analyzing the insulin, fasting AND OGTT glucose levels or when analyzing ONLY OGTT glucose levels. NOTE: the OGTT weights and data are in a separate file (OGTT\_d).

References

None

#### **NCHS Locator Fields**

Title: Fasting glucose and Insulin

Contact Number: 1-866-441-NCHS

Years of Content: 2005–2006 First Published: April 2008 Last Revised: July 2008 Access Constraints: None

Use Constraints: None

Geographic Coverage: National
Subject: Fasting glucose and Insulin
Record Source: NHANES 2005–2006

Survey Methodology: NHANES 2005–2006 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 (2005-2006)

Plasma Fasting Glucose and Insulin (GLU\_D)

April 2008



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

WTSFA2YR		Target				
VV 10171211X		B(12 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
	I I	Fasting Subsample 2 Year MEC Weight				
English Text: Fasting Su	sting Subsample 2 Year MEC Weight					
English Instructions:						
Code or Value	Code or Value Description Count Cumulative					
0 to 327394.027	Range of Values	3352	3352			
	Missing	0	3352			

LBXGLU		Target				
B(12 Yrs. to 150 Yrs.)  Hard Edits  SAS Label						
Haru Euro						
		Fasting Glucose (mg/dL)				
English Text: Fasting						
<b>English Instructions:</b>						
Code or Value	Description	Count	Cumulative	Skip to Item		
45 to 418	Range of Values	3128	3128			

Missing

LBDGLUSI		Target				
		B(12 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Fasting Glucose (mmol/L)				
English Text: Fasting	Glucose (m	e (mmol/L)				
<b>English Instructions:</b>						
Code or Value	I	Description Count Cumulative Skip to Item				
2.498 to 23.203	Rai	nge of Values	3128	3128		

Missing

Missing

LBXIN		Target					
<b>LDXII</b>		B(12 Yrs. to 150 Yrs.)					
Hard Edits		SAS Label					
		Insulin (uU/mL )					
English Text: Insulin	(uU/mL)	)					
<b>English Instructions:</b>							
Code or Value	Description	Count	Cumulative	Skip to Item			
1 to 293.58	Range of Values	3080	3080				

LBDINSI		Target					
		B(12 Yrs. to 150 Yrs.)					
Hard Edits		SAS Label					
		Insulin (pmol/L)					
English Text: Insulin (	pmol/L)						
<b>English Instructions:</b>							
Code or Value	Γ	Description	Count	Cumulative	Skip to Item		
6 to 1761.48	Rai	nge of Values	3080	3080			
		Missing	272	3352			

PHAFSTHR		Target				
		B(12 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Total length of 'food fast', hours				
English Text: Total leng	gth of 'food	fast', hours				
English Instructions:						
Code or Value Description Count Cumulative Skip to Ite						
0 to 64	Rang	e of Values	3251	3251		
	N	Missing	101	3352		

PHAFSTMN		Target				
		B(12 Yrs. to 150 Yrs.)				
Hard Edits	5	SAS Label				
		Total length of 'food fast', minutes				
English Text: Total le	ength of 'foc	food fast', minutes				
<b>English Instructions:</b>						
Code or Value	I	Description	Count	Cumulative	Skip to Item	
0		CIII	2251	2251		

Code or Value	Description	Count	Cumulative	Skip to Item
0 to 59	Range of Values	3251	3251	
	Missing	101	3352	