## National Health and Nutrition Examination Survey

2015-2016 Data Documentation, Codebook, and Frequencies

Plasma Fasting Glucose (GLU\_I)

Data File: GLU\_I.xpt

First Published: June 2018

Last Revised: February 2019

Note: See Analytic Note describing the change in method in the 2015-2016 survey cycle.

## **Component Description**

Diabetes is a leading cause of disease and death in the United States. More than 29 million Americans are living with diabetes, and 86 million are living with prediabetes, a serious health condition that increases a person's risk of type 2 diabetes and other chronic diseases. In 2014, nearly 9 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.

There are several exclusion criteria, including hemophilia and chemotherapy safety exclusions, fasting less than nine hours and refusing phlebotomy.

## Eligible Sample

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

### Description of Laboratory Methodology

#### Glucose

In this enzymatic method glucose is converted to glucose-6-phosphate (G-6-P) by hexokinase in the presence of ATP, a phosphate donor. Glucose-6-phosphate dehydrogenase then converts the G-6-P to gluconate-6-P in the presence of NADP+. As the NADP+ is reduced to NADPH during this reaction, the resulting increase in absorbance at 340 nm (secondary wavelength = 700 nm) is measured. This is an endpoint reaction that is specific for glucose.

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

There were no changes to the lab site or lab method for this component in the NHANES

2015-2016 cycle. There were changes to the lab equipment. In 2015, the laboratory instrumentation changed from the Roche C501 to the Roche C311 instrument.

### Laboratory Method Files

Plasma Fasting Glucose (June 2018)

### Laboratory Quality Assurance and Monitoring

Plasma samples are 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 Procedures 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 Act mandates. Detailed QA/QC instructions are discussed in the NHANES LPM.

#### 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 quality control 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 quality control protocol for all CDC and contract laboratories, which outlined the use of Westgard rules (Westgard et al, 1981) when running 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 was created using the following formulas:

#### 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).

### **Analytic Notes**

Refer to the 2015 - 2016 Laboratory Data Overview for general information on NHANES laboratory data.

### **Subsample Weights**

Glucose were measured in a fasting subsample of participants 12 years and older. Special sample weights are required to analyze these data properly. Specific sample weights for this subsample are included in this data file and should be used when analyzing these data.

#### **Demographic and Other Related Variables**

The analysis of NHANES laboratory data must be conducted using the appropriate survey design and demographic variables. The NHANES 2015-2016 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.

Starting in the 2015-2016 NHANES cycle, the variables PHAFSTHR (total length of "food fast", hours) and PHAFSTMN (Total length of "food fast", minutes) will not be reported in this file. PHAFSTHR and PHAFSTMN can be found in the Fasting Questionnaire File (FASTQX\_I). The fasting questionnaire data file also includes additional auxiliary information such as fasting status, 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., LBDGLULC) 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. For analytes with analytic results below the lower limit of detection (ex., LBDGLULC=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 other variable prefixed LBX (ex., LBXGLU) provides the analytic result for that analyte.

The lower limit of detection (LLOD, in mg/dL) for fasting glucose:

Variable Name	SAS LABEL	LLOD
LBXGLU	Fasting glucose	2.0

#### Glucose regression equations to compare 2015-16 and 2013-14 data:

A method validation (bridging) study was performed to compare results from an instrument change in 2015-2016 cycle with earlier data. The Cobas C311 analyzer was used for most of 2015-2016 and the Cobas C501 analyzer was used in 2013-2014. Randomly selected plasma samples (n=165) from NHANES 2015-2016 participants were measured using both instruments and the results were used to conduct the analysis. On average, glucose values measured from the Cobas C311 analyzer were 2% higher than values from the Cobas C501 (p<.0001). Based on manufacture information, the two analyzers have the same variation (Roche Diagnostics, 2009), and data from the bridging study indicated the correlation coefficient (r) between the measurements was 0.999. Regression analyses were performed using Analyse-it, v4.30.4. Given that the data showed proportional differences in variability, a weighted Deming regression was chosen to adjust the plasma glucose results (mg/dL). The forward and backward equations are below:

```
Forward: Y (C311) = 1.023 (95%CI: 1.014 – 1.032) * X (C501) - 0.5108 (95%CI: -1.441 – 0.4197)

Backward: Y (C501) = 0.9776 (95%CI: 0.9692 - 0.9860) * X (C311) + 0.4994 (95%CI: -0.4064 - 1.405)
```

These regression equations should be used when examining trends of plasma glucose data across 2015-2016 and 2007-2014 cycles, or combining 2015-2016 data with these previous cycles. For analysis involving 2015-2016 data and data collected prior to 2007-2008 cycle, please refer to the documentation accompanying the 2007-2008 (GLU\_E) and 2005-2006 (GLU\_D) fasting glucose data for additional adjustments.

As mentioned above, most of the 2015-2016 samples were measured using the Cobas C311. Results in this 2015-2016 dataset from specimens analyzed using the Cobas C501 were adjusted using the above forward regression equation.

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.

### References

- Roche Diagnostics Technical Publications Department (December 2009). Cobas C 501 Analyzer and Cobas C 311 Analyzer Within Run Imprecision Guidelines, Volume 6. https://www.rochediagnostics.fr/Htdocs/media/pdf/actualites/2g\_Specif\_Repeta\_c501.pdf
- 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 I tem
13612.331812 to 521632.18583	Range of Values	2743	2743	
0	No Lab Result	448	3191	
	Missing	0	3191	

# LBXGLU - Fasting Glucose (mg/dL)

Variable Name: LBXGLU

**SAS Label:** Fasting Glucose (mg/dL)

**English Text:** Fasting Glucose (mg/dL)

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to I tem
21 to 479	Range of Values	2972	2972	
	Missing	219	3191	

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# LBDGLUSI - Fasting Glucose (mmol/L)

Variable Name: LBDGLUSI

SAS Label: Fasting Glucose (mmol/L)

English Text: Fasting Glucose (mmol/L)

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cu	mulative	Skip to I tem
1.17 to 26.6	Range of Values	2972	2972		
	Missing	219	3191		

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