National Health and Nutrition Examination Survey 2003-2004

Documentation, Codebook, and Frequencies

MEC Laboratory Component: Glycohemoglobin

Survey Years:
2003 to 2004

SAS Export File:
L10_C.XPT

January 2006

NHANES 2003–2004 Data Documentation

Laboratory Assessment: Lab 10 – Glycohemoglobin

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

Component Description

Diabetes mellitus will be assessed by measures of blood glycohemoglobin, plasma glucose, serum insulin, and serum c-peptide in participants aged 12 years and over.

Glycohemoglobin measures are available for a full sample. Measures of blood glycohemoglobin, plasma glucose, serum insulin, and serum c-peptide in the morning examination session only can be found in the Lab10AM data file.

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 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.

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 were tested.

Description of Laboratory Methodology

Glycohemoglobin

Glycated proteins differ from non-glycated proteins by the attachment of a sugar moiety(s) at various binding sites by means of a ketoamine bond. Glycohemoglobin (GHb) thus contains 1,2-cis-diol groups not found in non-glycated proteins. These diol groups provide the basis for separation of glycated and non-glycated components by boronate affinity chromatography 11a,11b,11c. In this analytical technique, a boronate such as phenylboronic acid is bonded to the surface of the column support. When a solution of proteins (e.g. hemolysate) is passed through the column, the glycated component is retained by the complexing of its diol groups with the boronate. After the unretained non-glycated component elutes from the column, the glycated component is eluted from the column with a reagent that displaces it from the boronate.

The Primus instrument is a fully automated glycohemoglobin analyzer, which utilizes the principle of boronate affinity high performance liquid chromatography (HPLC)P 11dP. The analytical column contains aminophenylboronic acid bonded to a porous polymer support (gel). The low- and high-pressure pumps transfer reagents through the analytical column, with reagent selection executed by a switching valve. Hemolyzed samples are automatically injected onto the column during the flow of A-Elution Reagent #1. The glycated component binds to the boronate, while the non-glycated component passes through the column to the spectrophotometric detector, where it is detected at wavelength of 413-±2 nm. After the elution of non-glycated component, the Primus instrument pumps B-Elution Reagent #2, which displaces the glycated component from the column. The glycated component then passes through the detector. In the final stage of each sample cycle, the column is re-equilibrated with Elution A-Reagent #1. All reagent selection occurs in a timed sequence designed to allow complete elution of non-glycated and glycated components.

Microprocessors (Model CLC330) or the PC computer (Model CLC385) control all functions in the liquid chromatograph and computing integrator. The signal from the spectrophotometric detector is processed and the concentration of glycohemoglobin is calculated as a percentage of the total detected. Integration is by peak area in millivolt-seconds. The chromatogram is plotted first as the signal is received by the detector. The raw % glycohemoglobin is calculated when glycated hemoglobin peak area is divided by the total hemoglobin peak area.

Primus HPLC uses two point calibrators with HbA1c assigned values to obtain a final standardized glycohemoglobin. The Schiff base does not interfere with boronate affinity method. The report is then printed with the sample information, raw Glycohemoglobin and standardized Glycohemoglobin results.

A detailed description of the laboratory method used can be found at NHANES web page.

Laboratory Quality Control and Monitoring

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

There were no changes to the equipment, lab method, or lab site from the previous 2 years.

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 UNHANES Laboratory/Medical Technologists Procedures Manual (LPM)U. 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 were 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

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 and sample weights 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.

LBXGH: Glycohemoglobin

Glycohemoglobin measurements for NHANES 2003-2004 were performed by the Diabetes Diagnostic Laboratory at the University of Missouri-Columbia using Primus CLC330 and Primus CLC 385 (Primus Corporation, Kansas City, MO). The Boronate Affinity High Performance Liquid Chromatography (HPLC) system determines total glycohemoglobin by measuring 1,2-cis diol group found in glycated hemoglobin. The system has been standardized to the reference method used for the Diabetes Control and Complications Trial (DCCT). The affinity chromatographic method has demonstrated excellent, long-term precision (interassay CV's <3.0%) and is not affected by the presence of hemoglobin variants S, C, D and elevated HbF. The method is also less sensitive to hemoglobin degradation due to improper sample handling.

References

1. Fluckiger R, et al. Quantitation of Glycohemoglobin by boronate affinity chromatography. Diabetes 1984;33:73-6.

2. Gould BJ, et al. A sensitive method for the measurement of glycosylated plasma proteins using affinity chromatography. Ann Clin Biochem 1984;21:16-21.

3. Mallia AK, et al. Preparation and use of a boronic acid affinity support for separation and quantitation of glycosylated hemoglobins. Anal Lett 1981;14:649-61.

4. Primus Corporation Glycated Hemoglobin and Plasma Protein Analyzer Operator's Manual for the Diabetes Care Test Package of the CLC330TM and CLC385TM (Primus Corporation, Kansas City, MO 64110).

Locator Fields

Title: Glycohemoglobin

Contact Number: 1-866-441-NCHS

Years of Content: 2003–2004

First Published: January 2006

Revised: April 2006

Access Constraints: None

Use Constraints: None

Geographic Coverage: National

Subject: Glycohemoglobin, Diabetes

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)

Glycohemoglobin (L10_C)
Person Level Data

April 2006

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

LBXGH	Target
	B(12 Yrs. to 150 Yrs.)
Hard Edits	**SAS Label**
	Glycohemoglobin (%)
English Text: Glycohemoglobin (%)	
English Instructions:	

Code or Value	Description	Count	Cumulative	Skip to Item
3.3 to 18	Range of Values	6601	6601	
.	Missing	389	6990	