

## Data Collection Worksheet

**Please Note:** The Data Collection Worksheet (DCW) is a tool to aid investigators to integrate the collection of PhenX measures in your study. The PhenX measures that you selected and added to your Cart are presented in the DCW in alphabetical order. The DCW includes worksheets for data collection. Variables derived from the collected data are shown in the Data Dictionary (DD) with variable names and unique PhenX variable identifiers. The collection of DCWs produced by the Toolkit is not designed as a data collection instrument. Each investigator will decide how to integrate PhenX measures into data collection for their study.

The following is a summary version of the full National Health and Nutrition Examination Survey 2007-2008 protocol.

The full National Health and Nutrition Examination Survey 2007-2008 Glycohemoglobin (HbA1C) test is part of the Laboratory Procedures Manual which can be found here: [2007-2008 NHANES Lab Manual](#).

The National Health and Nutrition Examination Survey protocol lists the following specifications for the Glycohemoglobin (HbA1C) test on page 8-3 of the Laboratory Manual:

Sample (mL): 0.4

Sample type: Whole Blood

Collection type: 4 mL EDTA

Vessel type: 2 mL

Remarks: Refrigerate

### Venipuncture

Venipuncture should generally be performed using the median cubital, cephalic, or basilic veins in the left arm unless this arm is unsuitable. If the veins in the left arm are unsuitable, look for suitable veins on the right arm. If the veins in the antecubital space on both arms are not suitable, then look for veins in the forearm or dorsal side of the hand on the left arm/hand and then the right arm/hand.

*Editor's Note: Please review chapter 4 of the Laboratory Procedures Manual from the National Health and Nutrition Examination Survey for a full description of Phlebotomy procedures. [2007-2008 NHANES Lab Manual](#).*

### Recording the Results of the Venipuncture Procedure

Immediately after completing the venipuncture, record the results of the blood draw, the reasons for a tube not being drawn according to the protocol, and any comments about the venipuncture.

### Process the Sample for the Glycosylated Hemoglobin Assay

**Note:** If the EDTA tube is clotted, do not process the HbA1C vessel.

- Invert the appropriate EDTA tube several times to remix contents thoroughly.
- Use trace-metal-free pipette tips and the 50-1,000 µL Eppendorf pipette to aliquot 0.4 mL whole blood for vessel 4 (Glycohem) on primary SPs aged 12+ into a 2 mL vessel.
- Securely close all vessels to prevent leakage and evaporation.
- Store specimen in a refrigerator at 4°C until the sample is tested.

### Laboratory Assay for Glycosylated Hemoglobin

There are now many laboratory assays that have been certified by the National Glycohemoglobin Standardization Program (NGSP). The Diabetes Working Group (WG) recommends that Toolkit users review the National Glycohemoglobin Standardization Program (NGSP) website to select an appropriate assay that is standardized to the Diabetes Control and Complications Trial (DCCT). Once an assay is chosen for a particular study, the WG recommends that no changes in the protocol be made over the course of the study.

### Reference Ranges

Glycosylated hemoglobin ranges between 4.4% and 6.0% normally

### Exclusion Criteria

Persons will be **excluded** from this component if they:

- Report that they have hemophilia; or
- Report that they have received cancer chemotherapy in the last 4 weeks

SP= Sample Person.

1. Do you have hemophilia?

1  Yes ->Exclude (Reason: Hemophilia)

2  No -> Continue

7  Refused -> Continue

9  Don't Know -> Continue

2. Have you received cancer chemotherapy in the past four weeks or do you anticipate such therapy in the next four weeks?

1  Yes ->Exclude (Reason: Hemophilia)

2  No -> Continue

7  Refused -> Continue

9  Don't Know -> Continue

3. Please mark reason for exclusion

Hemophilia

Received cancer chemotherapy in the last 4 weeks

None - proceed with Blood draw.

4. Was blood drawn?

Yes

No - Record reason below

4.1 Was full amount obtained

Yes

No - Record reason below

4.2 Record any comments about the blood draw, including any reasons for the tube not being drawn according to the protocol.

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5. Record any comments about the blood during processing, such as whether or not the sample was clotted:

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6. Record the type of assay used to perform the determination of glycosylated hemoglobin:

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7. Make and manufacturer of the equipment used to perform the determination of glycosylated hemoglobin:

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8. Repeatability of the assay: \_\_\_\_\_

9. Coefficient of variation for the assay: \_\_\_\_\_

10. Percent Glycosylated Hemoglobin: \_\_\_\_\_ (%)

Protocol source: <https://www.phenxtoolkit.org/protocols/view/140901#Source>