PhenX Toolkit

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

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

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

2 [ ] No

7 [ ] Refused

9 [ ] Don’t Know

If the SP answers "Yes," the SP is excluded from the blood draw. If the SP answers "No" or "Don’t Know," blood is drawn from the SP.

2. Have you received cancer chemotherapy in the past 4 weeks or do you anticipate such therapy in the next 4 weeks?

1 [ ] Yes

2 [ ] No

7 [ ] Refused

9 [ ] Don’t Know

If the SP answers "Yes," the SP is excluded from the blood draw. If the SP answers "No" or "Don’t Know," blood is drawn from the SP.

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

Protocol source: https://www.phenxtoolkit.org/protocols/view/140901