



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.

National Health and Nutrition Examination Survey (NHANES) 2011-2012 Total Testosterone

The following is a summary version of information from the National Health and Nutrition Examination Survey (NHANES) 2011-2012 Laboratory Procedure Manual.

Utilize a trained and experienced phlebotomist for venipuncture.

Equipment and supplies needed

Standard venipuncture supplies

6 to 10 mL red top tube

2 mL cryovial with external screw caps

Personal protective equipment

Centrifuge

-70° C Freezer

A morning fasting blood sample is recommended to minimize variability. During the National Health and Nutrition Examination Survey (NHANES), participants fasted for a minimum of 9 hours.

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.

Processing

If blood left at ambient temperature, serum should be centrifuged within 6 hours of venipuncture. Aliquot the supernatant to a 2 mL cryovial with external screw caps. A minimum of 0.5 mL of serum is required for the total testosterone assay.

Storage

If testosterone assay is not possible for several days, store serum sample in freezer box in a -70°C freezer. Serum samples could be stored up to 3 days in a refrigerator if analysis is possible in that timeframe.

Analyses

The Sickle Cell Disease Genitourinary Working Group notes that there are a number of different assays and instruments that are appropriate to measure the concentration of testosterone levels. Once an assay is chosen for a particular study, the Working Group recommends that no changes in the protocol be made over the course of the study. To aid in comparability, the Working Group recommends that the investigator record the make and manufacturer of equipment used and the repeatability and coefficients of variation for the assay.

If results are being provided back to participants, a CLIA certified laboratory must be used. Commercial laboratories perform total testosterone assays on a routine basis.

Reference Ranges (Bhasin et al., 2006)

The minimum value for the range of total testosterone in healthy young men is 300 ng/dL.

Protocol source: <https://www.phenxtoolkit.org/protocols/view/880201>