



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.

Timing

An immunoassay or pregnancy test kit can be used within a few days of the woman's missed menstrual period.

Exclusion Criteria

None.

Sample Collection Procedures

Follow standard urine collection procedures. Ask the woman to self-collect a urine sample, preferably a first morning void sample in a sterile 120 ml urine collection container with a screw-on lid. Label the urine sample. Since only a small amount of urine is needed for the pregnancy test, the remainder of the sample may be used for additional analyses. The detailed sample collection procedures from the National Children's Study are available [here](#).

Record the Results of the Urine Collection Procedure

Record the date and time that the urine sample was collected. If the woman was unable to collect a urine sample or refused, record this information.

Pregnancy Test Procedures

There are multiple ways to perform a pregnancy test with a urine sample. Two of the most common methods, which are both accurate, and quantify human chorionic gonadotropin (hCG), are an immunoassay test kit and a digital pregnancy test device. Never use an expired immunoassay kit or device.

NHANES utilizes an immunoassay test kit which can be performed on either a urine or a serum sample. The immunoassay test includes quality control procedures which would need to be completed by a trained technician. See Chapter 5 of the NHANES Lab Procedures Manual [[alink\[2013_MEC_Laboratory_Procedures_Manual.pdf|here\]](#)] for the entire testing

protocol.

Women may self-administer a digital pregnancy test device. If this method is chosen, utilize the most accurate FDA approved device available.

Record the Test Results

Record the results as positive, negative or invalid.

If the immunoassay or device quantifies the hCG concentrations, record the results in mIU/mL.

The NHANES immunoassay quantifies hCG in a urine or serum sample at the sensitivity of 25 mIU/mL. Other glycoproteins do not affect the results of this immunoassay.

NOTE: If a woman has just missed her period by 1-2 days, the test should be repeated in 7-10 days.

Reference Values

NHANES immunoassay results of 25 mIU/mL hCG or more are indicative of a positive pregnancy test. Digital devices may have lower or higher thresholds for a positive test.

Protocol source: <https://www.phenxtoolkit.org/protocols/view/240601>