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 (NHANES) 2007–2008 protocol.

Urine Collection

Editors Note: Please review chapter 5 of the Laboratory Procedures Manual from the NHANES 2007-2008 for a full description of urine collection and processing procedures: [alink[NHANES_Lab_Manual.pdf|2007-2008 NHANES Lab Manual]].

The coordinator explains the following instructions to the subject before urine collection:

- Wash hands with soap and water.
- It is important that the cup and cap not touch or come into contact with any parts of the body, clothing, or external surfaces.
- Close container to minimize exposure to air.

Refrigerate all insufficient urine samples. When additional urine is obtained, pool the urine, mix, and process.

Record the Results of Urine Specimen Collection

Note whether or not urine was collected, whether the volume of urine was sufficient or required a second specimen.

Note whether blood is present/visible in the specimen.

Laboratory Procedure for Chlamydia/Gonorrhea

The Infectious Diseases and Immunity Working Group (WG) recommends that *Chlamydia trachomatis* and *Neisseria gonorrhoeae* be determined according to the Strand Displacement Amplification (SDA) Assay developed by the National Center for Infectious Diseases, the Center for Disease Control and Prevention, for use in the NHANES: [alink[NHANES_chlamydia_2007.pdf|*Chlamydia trachomatis* and *Neisseria gonorrhoeae*]]

To aid comparability, the Infectious Diseases and Immunity WG recommends that the investigator record the make and manufacturer of equipment used and the repeatability and coefficients of variation for the assay.

Reference Ranges

Chlamydia trachomatis* and *Neisseria gonorrhoeae Result Interpretation With the Amplification Control (AC)

CT or GC MOTA Score	AC MOTA Score	Report	Interpretation	Result
≥10,000	Any	*C. trachomatis* plasmid and/or *N. gonorrhoeae* DNA detected by SDA	Positive for *C. trachomatis* and/or *N.gonorrhoeae*. *C. trachomatis* and/or *N.gonorrhoeae* organism viability and/or infectivity cannot be inferred because target DNA may persist in the absence of viable organisms.	Positive
2,000–9,999	Any	*C. trachomatis* plasmid and/or *N. gonorrhoeae* DNA detected by SDA	*C. trachomatis* and/or *N.gonorrhoeae* likely. Repeat testing may be useful for verifying presence of *C. trachomatis* and/or *N.gonorrhoeae*.	Low Positive
<2000	≥1000	*C. trachomatis* plasmid and/or *N. gonorrhoeae* DNA NOT detected by SDA	Presumed negative for *C. trachomatis* and/or *N.gonorrhoeae*. A negative result does not preclude *C. trachomatis* and/or *N.gonorrhoeae* infection because results are dependent on adequate specimen collection, absence of	Negative

			inhibitors, and sufficient DNA to be detected.	
<2000	<1000	Amplification Control inhibited. Repeat test.	Repeatedly inhabited specimen. *C. trachomatis* and/or *N.gonorrhoeae*, if present, would not be detectable using SDA. Submit another specimen for testing.	Indeterminate

Chlamydia trachomatis* and *Neisseria gonorrhoeae Result Interpretation Without the AC

CT or GC MOTA Score	Report	Interpretation	Result
≥10,000	*C. trachomatis* plasmid and/or *N. gonorrhoeae* DNA detected by SDA	Positive for *C. trachomatis* and/or *N.gonorrhoeae*. *C. trachomatis* and/or *N.gonorrhoeae* organism viability and/or infectivity cannot be inferred because target DNA may persist in the absence of viable organisms.	Positive
2,000-9,999	*C. trachomatis* plasmid and/or *N. gonorrhoeae* DNA detected by SDA	*C. trachomatis* and/or *N.gonorrhoeae* likely. Repeat testing may be useful for verifying presence of *C. trachomatis* and/or *N.gonorrhoeae*.	Low Positive
< 2000	*C. trachomatis* plasmid and/or *N. gonorrhoeae* DNA NOT detected by	Presumed negative for *C. trachomatis* and/or *N.gonorrhoeae*. A negative result does not preclude *C. trachomatis* and/or *N.gonorrhoeae* infection because results are dependent on adequate specimen collection,	Negative

	SDA	absence of inhibitors, and sufficient DNA to be detected.	

Protocol source: https://www.phenxtoolkit.org/protocols/view/160101