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.

Specimen Requirements and Storage Instructions

The thyroid-stimulating hormone assay is performed on serum. 0.3 to 0.8 milliliters of serum should be collected in a red-top or gel-barrier tube. The sample is stable for 14 days at room temperature, refrigerated or frozen.

Summary of the Thyroid-Stimulating Hormone Assay

The sample is incubated with biotinylated and ruthenium labeled monoclonal TSH-specific antibodies to form a sandwich complex. Voltage is applied to the sample to induce a chemiluminescence which is measured by a photomultiplier. Results are measured against a calibration curve.

Thyroid-Stimulating Hormone Assay Reference Ranges

Age	Range (micro-International Units per milliliter – ulU/mL)
0 to 6 d	0.700–15.200
7 d to 3 m	0.720–11.000
3 m 1 d to 12 m	0.730–8.350
1 to 5 y	0.700–5.970
6 to 10 y	0.600–4.840

>10 y	0.450–4.500

The Sickle Cell Disease Curative Therapies Working Group notes that there are a number of different assays and instruments that are appropriate to measure thyroid stimulating hormone. 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 comparability, the Working Group recommends that the investigator record the name of the assay, the make and manufacturer of equipment used and the repeatability and coefficients of variation for the assay.

Protocol source: https://www.phenxtoolkit.org/protocols/view/851101