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 prothrombin time assay can be performed on whole blood or plasma. 4.5 milliliters of sample should be collected in a blue-top tube with 3.2% buffered sodium citrate. Specimens should be discarded if the tube is less than 90% full. The sample should be inverted six or more times to ensure mixing of the blood with the anticoagulant. The sample is stable for 24 hours at room temperature. For longer storage, specimens can be centrifuged and then frozen.

Summary of the Prothrombin Time Assay

The prothrombin time assay measures the extrinsic or tissue factor pathway of the coagulation system. The prothrombin time assay is performed on platelet-poor plasma to which 3.2% sodium citrate has been added to chelate calcium and prevent coagulation. Thromboplastin (tissue factor plus phospholipid) and calcium chloride are added to the sample to begin the assay. The time (in seconds) for a fibrin clot to form is measured by optical or mechanical methods. Normal prothrombin test values range from 10 to 13 seconds.

Prothrombin Time Reference Ranges	
Age	Range
0 to 30 days	9.8–13.2 seconds
1 to 6 months	9.8–12.6 seconds

7 months to 1 year	9.8–12.2 seconds
2 to 17 years	9.9–12.1 seconds
≥18 years	9.1–12.0 seconds

The Sickle Cell Disease Curative Therapies Working Group notes that there are several different assays and instruments that are appropriate to measure the prothrombin time. 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/850101