



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 description is a summary. See Clinical and Laboratory Standards Institute (CLSI) document C34-A2 for the full protocol. The test should be performed at a CFF accredited laboratory. In addition, the CFF has also provided testing guidelines (LeGrys et al., 2007) that should be followed.

- Pilocarpine is applied to gauze or filter paper.
- Electrodes are attached to the gauze or filter paper.
- The electrodes are attached to the newborn's lower arm or upper leg for about 5 minutes. Sweat collection should not occur longer than 30 minutes.
- Collect a minimum of 75 mg of sweat.
- Quantitatively analyze the sweat for chloride concentration by coulometric titration using a chloridometer, or using the Schales and Schales mercuric nitrate procedure or an automated analyzer that has been validated against the other methods.
- It is recommended but not required that the test be repeated on the newborn.

Reference values

Sweat chloride concentrations < 40 mmol/L are negative; 40 to 60 mmol/L are borderline/intermediate; > 60 mmol/L are positive.

Protocol source: <https://www.phenxtoolkit.org/protocols/view/221701>