

Chapter 31. Clinical Center Local Labs

31.1 Overview

Clinical Centers will be asked to provide one-time local lab values that have been analyzed locally and enter results into the PVDOMICS Study database. All labs must have been analyzed by a CLIA certified laboratory. In some instances, historical data may be used (see section 31.4 below).

31.2 Blood Collection and Supplies

If blood is collected for the PVDOMICS Study, each clinical center will need to follow their own local laboratory guidelines for collecting blood.

It is important to note that blood collection tubes for blood analyzed locally are **NOT** provided by the PVDOMICS Study. The Biorepository provides blood kits for collecting Clinical Chemistry Blood (tubes are labeled as PRL) and OMICS bloods only. Please keep these tubes separate from what is used locally.

31.3 Clinical Center Local Labs drawn for PVDOMICS Study

The table below identifies specific local labs must be done on or after PVDOMICS Form 100- Initial Enrollment date at the clinical center's local laboratory. No historical values will be accepted for these labs.

Form #	Form Name	Data Timing
205	Clinical Center Prothrombin Time (PT) Results	Lab draw <u>must be on or after the Form 100 date</u>
206	Clinical Center Pregnancy Test Results	Urine (or blood) for pregnancy test <u>must be on or after the Form 100 date</u>
207	Clinical Center Arterial Blood Gases (ABG) Results (not required but if collected, results requested)	Lab draw <u>must be on or after the Form 100 date</u>

31.4 Historical Labs

Historical lab work can be used in certain circumstances for the PVDOMICS study. Acceptable results for use in the PVDOMICS Study must have been analyzed by a CLIA certified laboratory and should be done at clinical center.

Form #	Form Name	Historical Data Timing
200	Clinical Center CBC w Diff Results	<u>no more than 1 month before the Form 100 date</u>
201	Clinical Center Complete Metabolic Panel (CMP) Results	<u>must be no more than one month before the Form 100 date.</u>
202	Clinical Center Antinuclear Antibody (ANA) Results	Lab draw must be no more than 45 days before the Form 100 date
203	Clinical Center HIV Antigen/Antibody Screen Result	Within past year from 100 date
204	Clinical Center Hepatitis Screen Result	Within past year from 100 date