

Chapter 50. Pulmonary Function Testing Overview

50.1 General Overview

Pulmonary Function Testing (PFT) testing is one of several tests required for the PVDOMICS Study. This Manual of Operations (MOP) chapter provides an overview to additional PFT chapters which constitute a ‘complete set’ of PFTs and include the following components:

- Spirometry: MOP Chapter 51
- Lung Volumes by Body Plethysmography: MOP Chapter 52
- Single-Breath Carbon Monoxide Diffusing Capacity (DLCO): MOP Chapter 53

PFTs performed for the purposes of the PVDOMICS study are ideal. However, there are exceptions including when PFTs are performed for clinical care and/or historical data are available. Specific data items needed are discussed in the corresponding chapters for each of the PFT components identified above.

50.2 Logistics

The PFT Core is a subsection of the Lung Physiology Core which is under the direction of Dr. Mitchell Olman and is part of the PVDOMICS Study Data Coordinating Center at the Cleveland Clinic, Cleveland, Ohio. Kevin McCarthy, RPPT, former manager of the Cleveland Clinic Pulmonary Function Lab and PVDOMICS Study consultant, provides technical direction and quality review of pulmonary function data submitted by the clinical centers. Additional contact information can be found in the PVDOMICS Address Directory.

All PFT tracings and study files will be transmitted to the DCC Core for assessment of quality. Parameters for assessing quality of PFTs review procedures are provided in MOP Chapter 55.

50.3 General Philosophy on Standardization

1. Equipment, procedures, and personnel qualifications are based on the commendations of the American Thoracic Society (ATS)
2. Spirometry procedures and systems at all sites must meet or exceed ATS-ERS standards.

50.4 System and Personnel Requirements

50.4.1 Local Center provides:

- o Dedicated testing room
- o PFT Equipment – type of machine is not dictated by PVDOMICS Study but PFT Core should be notified if equipment changes
- o Names and contact information of PVDOMICS PFT personnel who are considered primary contacts at clinical center PFT Labs
- o PVDOMICS data collection form(s), pens
- o PVDOMICS Study ID and Alphacode (provided by the Study Coordinator)

50.4.2 PFT Core Provides:

- o Instructions for standardized participant testing
- o Webinar and individual training for:
 - PFT testing guidelines for PFTs completed for PVDOMICS Study
 - Instructions for transferring tracings to DCC/PFT Core

50.4.3 Clinical Center Personnel Requirements

All technicians should be certified pulmonary function technologists (National Board of Respiratory Care) or meet the recommendations for personnel qualifications issued by the ATS.

The PFT Core will provide training for PFT Lab, techs and coordinators as follows:

- o Review of completed PFT Lab Exam form
- o Initial PVDOMICS Study central training
- o Webinar
- o Data transfer
- o Review of data and provide feedback to local center on transfer of first 5 cases per PFT tech and QC review
- o Individual guidance by PFT Core personnel

50.5 Participant Exclusion from Pulmonary Function Testing

50.5.1 As previously stated, PFTs completed for clinical care will be accepted and must be within 1 year from date of PVDOMICS Form 100-Initial Enrollment.

50.5.2 Excluded from PFT Testing for PVDOMICS Study
Clinical Center PI or other Physician should determine whether undergoing a PFT for the purposes of the PVDOMICS Study will be harmful to the participant and should not be completed.

50.6 Participant Preparation

Participant preparation is described in detail for each component of the measurements. See Chapter 51 for spirometry, Chapter 52 for lung volumes, 53 for DLCO.

50.7 Equipment Quality Control

Table 1. ATS-ERS Recommended Spirometer Quality Control Procedures

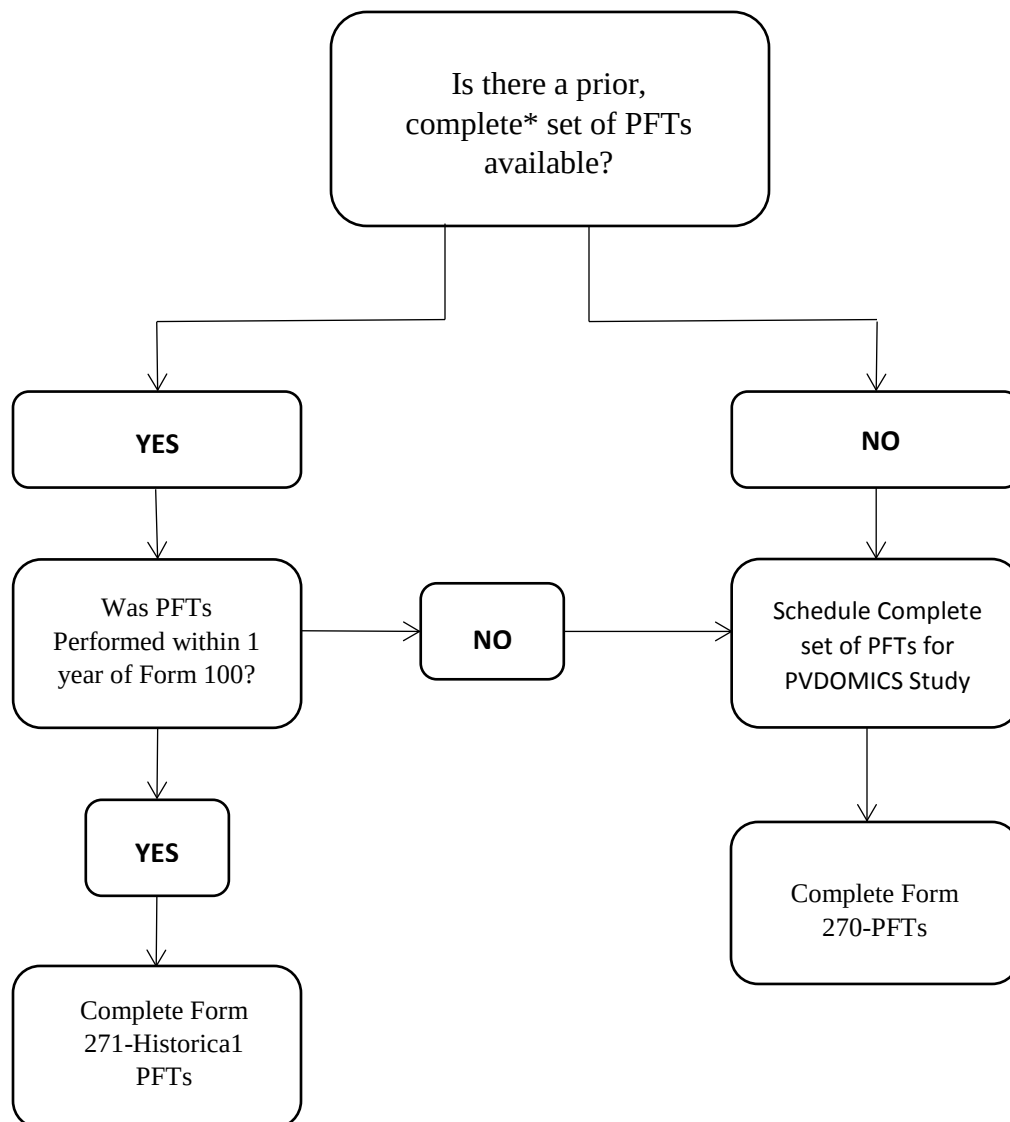
Test	Minimum Interval	Action
Volume	Daily	Calibration check with a 3-liter syringe
Software	2x/month	Perform test using “known biological control” subject, send to DCC

50.8 Data Submission

Specific data submission requirements for each test are documented in the three individual chapters (Chapters 51-53).

It is important for the technician to provide comments summarizing the technical acceptability of the testing session including any problems encountered.

Clinical Care/Historical PFTs



*Complete set of PFT's includes:
Spirometry, Lung Volumes, DLCO