

Chapter 51. Spirometry

51.1 Introduction

Spirometry will be used to determine pulmonary functional impairment for PVDOMICS study. Results will be used to aid in classification of participants with pulmonary arterial hypertension.

51.2 Participant Preparation

1. Participant must be seated during test.
2. Nose clip must be worn during testing.
3. Participant should loosen any restrictive clothing.
4. If participant has dentures that are tight fitting they should remain in place. If dentures are loose they should be removed and the technician should ensure that the participant can form a tight seal around the mouthpiece.
5. In the event the participant is unable for any reason (i.e., scleroderma) to develop a tight seal around the mouthpiece, then an alternative mouthpiece can be used and, if necessary, held in place. If so, document non-standard mouthpiece on Form # 270 and document quality of seal on PFT report form.

51.3 Forced Vital Capacity (FVC)

1. Instruct participant, including a demonstration. Emphasize the necessity for a deep, full inspiration, a hard and forceful “blast,” and a complete expiration for at least 6 seconds.
2. Perform at least three acceptable and reproducible FVC maneuvers as described below.

51.4 PVDOMICS Acceptability and Repeatability Criteria

Within Maneuver Criteria (“acceptability”):

1. Maneuver is free from artifacts
 - a) cough during the first second of exhalation
 - b) glottis closure that influences the measurement
 - c) early termination or cutoff
 - d) effort that is not maximal throughout the first second
 - e) leak
 - f) obstructed mouthpiece
2. Maneuver has good start
 - a) back-extrapolated volume less than 5% of FVC or 0.15 L, whichever is greater
 - b) time to peak expiratory flow is less than or equal to 0.12s
3. Maneuver has satisfactory end of test.
 - a) duration of at least six seconds and a plateau ($\geq 1s$) on the volume-time curve unless the participant cannot or should not continue to exhale for medical reasons (e.g., syncope)

51.5 Between Maneuver Criteria (“repeatability”)

1. After three acceptable spiroms have been obtained, apply the following tests:
 - a) the two largest FVCs must be within 0.150 L of each other
 - b) the two largest FEV₁s must be within 0.150 L of each other
2. If both of these criteria are met, the test session may be concluded.
3. If both of these criteria are not met, continue testing until:
 - a) both of the criteria are met with analysis of additional acceptable spiroms

OR

 - b) a total of eight tests have been performed (optional)

OR

 - c) the participant/participant cannot or should not continue
4. Save, as a minimum, three reproducible maneuvers.

51.6 Post-bronchodilator Testing

After the initial measurements of forced expiratory maneuvers, the test is repeated after an inhaled bronchodilator. Albuterol is the bronchodilator selected for use in the PVDOMICS study. Post-bronchodilator testing allows the investigators to determine how much the participant’s lung function can be quickly reversed or returned toward normal.

Administer two puffs of albuterol using an aerosol spacer:

1. Shake the metered-dose inhaler (MDI) several times. Prime the MDI per the instructions on the package insert and attach it to an aerosol spacer.. Hand the MDI to the participant. The technician should observe the inhalation for proper administration and technique. The technician may administer the albuterol if this is lab policy.
2. The participant should exhale.
3. The spacer mouthpiece should be inserted fully into the mouth with the participant’s lips closed around it—the MDI should be in its upright position in the spacer.
4. As the participant begins to inhale very slowly, the MDI should be triggered.
5. The participant should continue to inhale slowly and deeply to maximal inhalation (total lung capacity or TLC).
6. The breath should be held for at least 5 seconds at the end of a full inspiration.
7. Instruct the participant to shake the MDI and repeat steps 2–6 for a total of 4 puffs.

Although there may be a small benefit to waiting 5 minutes between inhalations of a bronchodilator, it is more practical and satisfactory to administer the second inhalation (1puff) about 30–60 seconds after the first. After administration of albuterol, maximum bronchodilation may take 30 minutes, but sufficient bronchodilation occurs within 15 minutes. Wait 15 minutes before performing post-bronchodilator spirometry.

51.7 Spirometry Data Submission Requirements:

1. Volume-time tracing for each effort.
2. Flow-volume curve for each effort.
3. Data table showing FVC, FEV1, FEV1/FVC ratio, FET (forced expiratory time), Vbe (back-extrapolated volume in liters, Vbe% (back-extrapolated volume, as % of FVC), TPEF (time to peak expiratory flow rate), PEF, PIFR, FEF50, FIF50 for each effort.

A screen shot after completion of each effort is the most expedient method for obtaining all of the above.