

Chapter 53: Clinical Center Single-Breath Carbon Monoxide Diffusing Capacity (DLCO) MOP

53.1 Introduction

The DLCO will determine the degree of pulmonary impairment in participants enrolled in the PVDOMICS Study. The purpose of this chapter is to ensure that the DLCO test is performed using standardized procedures and techniques in order to provide accurate test results and a safe testing environment for the participants enrolled in the PVDOMICS Study.

The diffusing capacity of the lung for carbon monoxide (DLCO) is used to evaluate the transfer of gas from the distal air spaces into the pulmonary capillaries. It can be measured when known and very low concentrations of carbon monoxide (CO) are inspired. The rate of CO disappearance is calculated from the ratio of the CO concentrations of the estimated alveolar and expired gas and then expressed as a function of the driving pressure (mLCO/min/mmHg).

53.2 Participant Preparation (Pre-Test Instructions):

- The participant should refrain from smoking or other CO exposures on the day of the test. The time of the last cigarette smoked should be recorded and noted in interpretation. Measure participant's height in centimeters (cm) to nearest cm, or in inches (in) to nearest ½ in, while he/she is standing erect, without shoes.
- The participant's weight should be measured using an accurate scale: weight is not required for reference values for DLCO, but may be useful for interpretive purposes.
- The participant's age should be recorded as age on their last birthday.
- The DLCO test should be done in the sitting position, with the participant sitting quietly for at least 5 minutes before testing and remaining seated throughout the procedure.
- The participant should refrain from exercise for at least 1 hour before the test and a large meal for at least 2 hours before the test.
- The participant should refrain from drinking alcohol for at least 4 hours before testing.
- If clinically acceptable, supplemental O₂ should be discontinued for 10 minutes before beginning the test. If this is done, monitor SpO₂ and resume oxygen therapy if the SpO₂ falls below 80%. Note the time off of supplemental oxygen and the SpO₂.
- If the participant cannot be off supplemental oxygen for a full 10 minutes plus 2 minutes for the DLCO test without the SpO₂ falling below 80%, the interval of time off O₂ should be adjusted appropriately and recorded so that the results can be interpreted accordingly.

53.3 Assessment of Participants:

- Assess each participant for physical and developmental status to determine ability to perform the diagnostic test and if special arrangements are required. If there is a language barrier, an interpreter will be used.
- Participants should be asked if they have complied with the preparation criteria including:
 - If they have recently smoked, and if so, what was the time?
 - If they have consumed alcohol within 4 hours of test starting time.

- If they have eaten within 2 hours of test starting time.
- If they have exercised within an hour of test starting time.
- Postponement may be necessary if the participant has not complied with the preparation criteria.

The ordering physician is to be contacted to determine if rescheduling is necessary.

In order to properly interpret the test results, relevant clinical information should be provided in writing by the ordering physician (i.e., diagnosis and type of treatment).). Additionally, a measurement of hemoglobin concentration within two (2) weeks of the PFT needs to be obtained in order for accurate interpretation of DLCO.

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53.4 Special Safety Precautions

The following may pose a relative danger to the participant and/or affect the validity of the test:

- More than five maneuvers will likely increase the COHb level by approximately 3.5%, which in turn will likely decrease the DLCO value by approximately 3-3.5%, and is not recommended.
- A large meal or vigorous exercise immediately before the test
- Mental confusion or poor muscular coordination that prevents the participant from adequately performing the maneuver or the inability to adequately seal their lips on the instrument mouthpiece.

53.5 Equipment Preparation

- Ensure CO₂ and H₂O absorbers (if applicable) are replaced at a frequency recommended by the manufacturer, when saturated (as indicated by color change), or sooner. Additionally, they should be placed in the proper order (i.e., the CO₂ absorber should precede H₂O absorber). If selectively permeable tubing is used, ensure it has been replaced at appropriate intervals as recommended by the manufacturer.
- Turn on the equipment to ensure adequate warm-up time, usually at least 30 minutes.
- Ensure the system is leak-free each day of use.
- Check inspiratory flow from the demand valve (if applicable, the maximal inspiratory pressure required for a 6 L/s inspiratory flow should be less than 10 cmH₂O).
- Ensure gas chromatograph columns, or elements of the gas measuring system with limited life span are replaced at the frequency recommended by the manufacturer.

53.6 Calibration Check (Verification)

- Volume calibration check (verification) with a validated known-volume syringe (e.g., 3.00 L) should be performed each day the test is performed. The accuracy validation limit for recovered volume is $\pm 3.5\%$. For large surveys or high participant loads the volume calibration check should be done more frequently.
- Two-point (zero and full scale) calibration of the gas analyzer(s) should be done each day. The gas used to calibrate the DLCO tracer gas and carbon monoxide analyzers should be certified to the hundredth of a percent for the tracer gas (helium or methane) and the nearest thousandth of a percent for carbon monoxide with an analytical accuracy of two percent.

53.7 DLCO Testing Procedures

Pre-Test Procedure	
Check participant identification	Identify the participant using an institutionally approved process.
Orders	Check for a complete physician's order.
Demographics	Collect and record demographic information.
Test explanation and participant training	Explain and demonstrate test maneuver, including a tight mouth seal.
	A complete deep breath with rapid inspiration is required after a complete slow exhalation.
	The breath hold should not consist of expiratory effort against the closed airway (Valsalva maneuver), and/or no inspiratory effort against a closed airway (Mueller maneuver).

Test Procedure	
Procedure	Instruct the participant to put mouthpiece in mouth and nose clip on nose and breathe quietly.
	Begin by measuring tidal breathing.
	After at least three breaths, instruct participant to exhale slowly to residual volume (RV).
	When at or near RV, activate the valves and instruct participant to inhale to total lung capacity (TLC) so that VI is inspired in less than 4 seconds. The inspired volume to test gas (VI should be at least 85% of the largest vital capacity measured that day.
	Coach the participant to hold his/her breath with the lungs held full for approximately 10 seconds.
	Instruct the participant to exhale at a moderate speed.
	After an appropriate washout volume (0.75-1.0L may be reduced to 0.5L if the VC is less than 2.0L) has been expired, collect a gas sample (alveolar sample) of 0.5 – 1.0L should be collected or measure the mean exhaled gas concentration over a comparable volume change
	Instruct the participant to come off the mouthpiece, but remain seated.
	Perform at least two acceptable maneuvers that agree within the largest of 10% of the mean value, or within 3 traditional DLCO units (1 SI unit) of each other. At least 4 minutes should be allowed between each test trial.

53.8 Review of Test Results:

- Individual test maneuvers are acceptable if:
 - Properly quality controlled instrumentation was used.
 - Inspire volume of test gas was at least 85% of largest VC in less than 3 seconds.
- A stable calculated breath-hold time of 10 ± 2 seconds (8 to 12 seconds).
 - No evidence of leaks or Valsalva or Mueller maneuvers during the breath hold.
 - Expiration after breath hold in less than 4 seconds with appropriate clearance of dead space before sampling the alveolar gas. Note: tests outside these limits may still have clinical utility, but deviations from the standard acceptability criteria should be

noted and possible impact considered.

- Assure that the washout volume of anatomical and mechanical dead space before the alveolar sample is collected is 0.75 to 1.0 L. If a participant's VC is less than 2.0 L, the washout volume may need to be reduced to 0.5 L.
- Using a rapid gas analyzer with visual display, these washout and sample volumes can be adjusted in participants with low vital capacities to assure an appropriate sample for analysis. Settings should remain as indicated above (#2) for participant's whose vital capacity allows those volumes to be met easily.
- Assure that there were at least 4 minutes between maneuvers.
- Assure that at least two acceptable maneuvers have been performed that agree within the larger of 5% of the mean value, or 3 traditional DLCO units (1 SI unit) of each other.

Assure that the Jones-Mead method of calculating breath hold time was used. See Figure 1

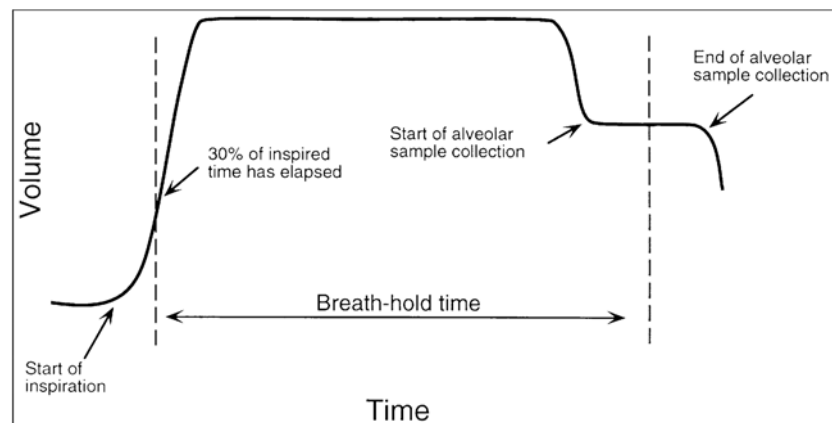


Figure 1: Graphic illustration of the Jones-Meade method for calculating the breath-hold time during the DLCO maneuver. The breath-hold time starts after 30% of the time it takes to inspire the test gas has elapsed, and ends halfway into the alveolar sample collection. The beginning of inspiration is determined using the back extrapolation technique, although it has been recently reported that there are no significant differences between the visual and extrapolation approaches.

- Assure between maneuver repeatability criteria has been met.

53.9 Reporting of Test Results:

- The average of at least two acceptable maneuvers that meet the repeatability requirement should be reported (i.e., outliers need to be excluded).
- The report should always include:
 - Measured uncorrected DLCO
 - DLCO/VA, also known as KCO (VA is reported as BTPS)
- Any adjustments (e.g., Hb, COHb, PO₂) should also be reported separately along with the data used to make the adjustment.
- The average VA (BTPS) should be reported along with the predicted VA (the predicted TLC minus predicted dead space) and % predicted VA.
- The average VI at BTPS should be reported.

53.10 Data Submission requirements

- Screen shot showing volume-time tracing with mouth pressure for each effort.
- Screen shot showing gas analysis curve for each effort.
- Data table showing uncorrected DLCO, DL/VA, VA, Vin (IVC), VCmax, discard volume, sample volume, Tin (inspiratory time), Tex (expiratory time), BHT, FIHe(or FICH3), FAHe(or FACH3), FICO, FACO, Hb (if available), COHb (if available) for each effort and altitude (Pbar)

53.11 Procedure Notes:

- Various miscellaneous factors may affect this test.
 - A diurnal variation (1.2% fall/h from 9:30 AM to 5:30 PM) has been reported. However, this fall can be explained by increasing COHb and decreasing Hb concentrations.
 - A 13% change during menstrual cycle has been reported. The highest DLCO value was observed just before the menses and the lowest DLCO value on the third day of menses.
 - A 15% reduction 90 minutes after ingesting ethanol has been reported.
 - Cigarette smoking or other causes of elevated COHb
 - Increased altitude. This will be adjusted for by the DCC.
- When test specifications are not met, such data should be reported with the warning that the data are suboptimal by providing technician comments detailing the procedural shortcoming.
- Small increases in COHb (about 0.7% per inhalation of test gas) occur when CO is inspired during the DLCO test.
- An adjustment for Hb concentration will be performed by the DCC. Measurements of Hb are acceptable within 2 weeks (in clinically stable participants without a suspicion for blood loss) of the DLCO measurement; the date and source of the Hb should be documented in the COMMENTS section of the report.

53.12 Equipment and Supplies:

- System description (e.g., manufacturer, model, type, accessories, additional features, and software version). The system should meet or exceed recommendations made in the latest ATS standardization document on DLCO.
- Cylinder of test gas appropriate for the testing system.
- Mouthpiece, nose clip, carbon dioxide (CO₂) and water absorbers, and other miscellaneous supplies needed (e.g., tissues, chart paper).
- Infection control supplies: disposable in-line filters (if used), gloves, gowns, masks, and protective eye wear (if applicable).
- Computer/recorder supplies.