General considerations for lung function testing


CONTENTS

Background ............................................................... 154
Definitions ................................................................ 154
Patient considerations ....................................................... 154
  Contraindications .......................................................... 154
  Position .................................................................. 154
Patient details ............................................................. 154
  Age, height and weight .................................................. 154
  Therapy .................................................................. 154
  Subject preparation ..................................................... 154
Laboratory details .......................................................... 155
Hygiene and infection control ............................................. 155
  Transmission by direct contact ....................................... 155
  Transmission by indirect contact .................................... 155
  Prevention ................................................................. 155
    Transmission to technicians ......................................... 155
    Cross-contamination .................................................. 156
    Volume-based spirometers .......................................... 156
    Tuberculosis ................................................................ 156
    Haemoptysis and oral lesions ...................................... 156
    Other known transmissible infectious diseases ............... 156
    Disposable in-line filters ........................................... 156
    Equipment design ...................................................... 157
    Level of infection risk ................................................ 157
Personnel qualifications and technician’s role in quality control .................................................. 157
  Personnel qualifications ................................................ 157
  Technician’s role in quality control ................................. 158
Reference values ........................................................... 158
Interpretation strategies ..................................................... 158
Abbreviations ............................................................... 159

KEYWORDS: Diffusing capacity, infections, lung function measurements, lung volume measurements, reference values, spirometry standardisation

For editorial comments see page 1.
BACKGROUND
In preparing the joint statements on lung function testing for the American Thoracic Society (ATS) and the European Respiratory Society (ERS), it was agreed by the working party that the format of the statements should be modified so that they were easier to use by both technical and clinical staff. This statement contains details about procedures that are common for many methods of lung function testing and, hence, are presented on their own. A list of abbreviations used in all the documents is also included as part of this statement.

DEFINITIONS
All terms and abbreviations used here are based on a report of the American College of Chest Physicians/ATS Joint Committee on Pulmonary Nomenclature [1]. The metrology definitions agreed by the International Standards Organization (ISO) are recommended [2] and some important terms are defined as follows.

Accuracy is the closeness of agreement between the result of a measurement and the conventional true value.

Repeatability is the closeness of agreement between the results of successive measurements of the same item carried out, subject to all of the following conditions: same method, same observer, same instrument, same location, same condition of use, and repeated over a short space of time. In previous documents, the term reproducibility was used in this context, and this represents a change towards bringing this document in line with the ISO.

Reproducibility is the closeness of agreement of the results of successive measurements of the same item where the individual measurements are carried out with changed conditions, such as: method of measurement, observer, instrument, location, conditions of use, and time. Thus, if a technician tests a subject several times, this is looking at the repeatability of the test. If the subject is then given a bronchodilator drug and tested again after 30 min, one needs to know the reproducibility of the test in order to make a decision on this comparison.

The measurement range for a recording device is the range over which the manufacturer indicates the device complies with the recommendations below.

Equipment resolution is the smallest detectable change in measurement.

PATIENT CONSIDERATIONS
Contraindications
Performing lung function tests can be physically demanding for a minority of patients. It is recommended that patients should not be tested within 1 month of a myocardial infarction. Patients with any of the conditions listed in table 1 are unlikely to achieve optimal or repeatable results.

Position
Testing may be performed either in the sitting or standing position, and the position should be recorded on the report [3, 4]. Sitting is preferable for safety reasons in order to avoid falling due to syncope. The chair should have arms and be without wheels. If a wheelchair is used, the wheels should be locked. If the standing position is used, a chair can be placed behind the patient/subject, so that they can be quickly and easily moved into a sitting position if they become light-headed during the maneuver. Obese subjects, or those with excessive weight at the mid-section, will frequently obtain a deeper inspiration when tested in the standing position. Consequently, forced expiratory volumes and flows may improve with the standing position in these individuals. Normal-weight subjects typically have equivalent values when tested sitting or standing, but, for longitudinal studies, the same test position should be used each time.

Contraindications

<table>
<thead>
<tr>
<th>Conditions where suboptimal lung function results are likely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest or abdominal pain of any cause</td>
</tr>
<tr>
<td>Oral or facial pain exacerbated by a mouthpiece</td>
</tr>
<tr>
<td>Stress incontinence</td>
</tr>
<tr>
<td>Dementia or confusional state</td>
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</tbody>
</table>

TABLE 1

PATIENT DETAILS
Age, height and weight
The patient’s age, height and weight (wearing indoor clothes without shoes) are recorded for use in the calculation of reference values. The age should be expressed in years. Height and weight should be expressed with the units in use in the country, corresponding to the ones of the selected reference equation. Body mass index should be calculated as kg·m⁻². The height should be measured without shoes, with the feet together, standing as tall as possible with the eyes level and looking straight ahead, and using an accurate measuring device. For patients with a deformity of the thoracic cage, such as kyphoscoliosis, the arm span from fingertip to fingertip can be used as an estimate of height. Arm span should be measured with the subject standing against a wall with the arms stretched to attain the maximal distance between the tips of the middle fingers. A regression equation using arm span, race, sex and age has been found to account for 87% of the variance in standing height [5], with the standard error of the estimate for height ranging from 3.0 to 3.7 cm. Using fixed arm-span ratios (e.g. height=arm span/1.06) estimated the standing height reasonably well, except at the extremes, but was always inferior to the regression equation. Estimating height in this way introduces a further level of uncertainty with regard to the predicted value of the lung function index, and the use of fixed ratios has been shown to lead to misclassification of disease [6]. The use of knee height to predict height can also be used for handicapped people where arm span may be difficult to measure [7, 8].

Therapy
The operator should record the type and dosage of any (inhaled or oral) medication that may alter lung function and when the drugs were last administered.

Subject preparation
Subjects should avoid the activities listed in table 2, and these requirements should be given to the patient at the time of making the appointment. On arrival, all of these points should be checked, and any deviations from them recorded.
Subjects should be as relaxed as possible before and during the tests. The decision to avoid long- and short-acting bronchodilators is a clinical one, dependent on the question being asked. If the study is performed to diagnose an underlying lung condition, then avoiding bronchodilators is useful. If the study is carried out to determine a response to an existing therapeutic regimen, then one may choose not to withhold bronchodilator medications.

Patients should be asked to loosen tight-fitting clothing. Dentures should normally be left in place; if they are loose, they may interfere with performance and are, therefore, best removed.

LABORATORY DETAILS
Ambient temperature, barometric pressure and time of day must be recorded. Temperature is an important variable in most pulmonary function tests and is often measured directly by the instrument. The way in which it is measured and used may vary from instrument to instrument. For example, it may be measured with a simple thermometer or an internal thermistor. Regardless of the method used, it is the responsibility of the laboratory to confirm the accuracy of temperature measurements, and it is the responsibility of the manufacturer to describe or provide a clear mechanism for checking the accuracy of instrument temperature measurements. They should also provide instructions on how to respond when acceptable temperature performance cannot be confirmed.

Ideally, when patients return for repeat testing (e.g. at a clinic), the equipment and the operator should be the same, and the time of day should be within 2 h of previous test times.

The order for performing lung function tests should take into account the optimum work flow in the laboratory, potential influences of one test on another and the ability of the subject to undertake the test. One possible order is shown in table 3.

There should be appropriate delays between tests, as indicated in the subsequent sections of this series of documents. Other orders of testing are acceptable (e.g. static lung volumes, diffusing capacity, dynamic studies, inhalation of bronchodilator agent and then repeat dynamic studies, as taken from table 3), but the order should be kept constant to avoid introducing unanticipated variability to test results. The choice of order of testing should consider the potential effect of one test on the subsequent test. For example, the measurement of carbon monoxide diffusing capacity of the lung (DL,CO) immediately after a nitrogen washout measurement of the total lung capacity (TLC) will be affected by the increased oxygen content in the lungs, unless enough time has passed to allow the oxygen concentration to return to normal. Also, tidal breathing manoeuvres may be disturbed by a recently performed maximal forced expiratory manoeuvre. Bronchodilator administration may affect static lung volumes, reducing hyperinflation by up to 0.5 L [9]. While bronchodilators do not seem to affect diffusing capacity when measured by the Jones–Meade method, they may allow ~10% of patients to obtain a measurement of diffusing capacity that was not possible pre-bronchodilator [10].

HYGIENE AND INFECTION CONTROL
The goal of infection control is to prevent the transmission of infection to patients/subjects and staff during pulmonary function testing. The number of documented cases of infection transmission is very small, but the potential is real (see Level of infection risk section). This set of recommendations focuses on equipment used to measure spirometry, diffusing capacity and lung volumes. Organisms may also be transmitted via pulse oximeter probes and nebulisers used to administer bronchodilators [11, 12]. Although infection risks increase with exposure to blood, this document does not deal with the risks of arterial blood gases. Pulmonary laboratories performing blood gas analysis should follow the same infection-control procedures used by their clinical laboratory.

Infection can be transmitted by direct contact or by indirect means, which is discussed as follows.

Transmission by direct contact
There is potential for transmission of upper respiratory diseases, enteric infections and blood-borne infections through direct contact. Although hepatitis and HIV contagion are unlikely via saliva, transmission becomes a possibility with open sores on the oral mucosa or bleeding gums. The most likely surfaces for contact are mouthpieces and the immediate proximal surfaces of valves or tubing.

Transmission by indirect contact
There is potential for transmission of tuberculosis (TB), various viral infections, opportunistic infections and nosocomial pneumonia through aerosol droplets. The most likely surfaces for possible contamination by this route are mouthpieces, proximal valves and tubing.

Prevention
Transmission to technicians
Prevention of infection transmission to technicians exposed to contaminated spirometer surfaces can be accomplished through proper hand washing and use of barrier devices, such as suitable gloves. To avoid technician exposure and cross-contamination, hands should be washed immediately.

TABLE 2 Activities that should preferably be avoided prior to lung function testing

<table>
<thead>
<tr>
<th>Activity</th>
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<tbody>
<tr>
<td>Smoking within at least 1 h of testing</td>
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<tr>
<td>Consuming alcohol within 4 h of testing</td>
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<tr>
<td>Performing vigorous exercise within 30 min of testing</td>
</tr>
<tr>
<td>Wearing clothing that substantially restricts full chest and abdominal expansion</td>
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<tr>
<td>Eating a large meal within 2 h of testing</td>
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</table>

TABLE 3 Possible order for undertaking lung function tests in a laboratory

<table>
<thead>
<tr>
<th>Test Order</th>
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<tbody>
<tr>
<td>Dynamic studies: spirometry, flow–volume loops, PEF</td>
</tr>
<tr>
<td>Static lung volumes</td>
</tr>
<tr>
<td>Inhalation of bronchodilator agent (if used)</td>
</tr>
<tr>
<td>Diffusing capacity</td>
</tr>
<tr>
<td>Repeat dynamic studies (if a bronchodilator was given)</td>
</tr>
</tbody>
</table>

PEF: peak expiratory flow.
after direct handling of mouthpieces, tubing, breathing valves or interior spirometer surfaces. Gloves should be worn when handling potentially contaminated equipment if the technician has any open cuts or sores on his/her hands. Hands should always be washed between patients. Indications and techniques for hand washing during pulmonary function testing have previously been reviewed [13].

Cross-contamination

To avoid cross-contamination, reusable mouthpieces, breathing tubes, valves and manifolds should be disinfected or sterilised regularly. Mouthpieces, nose clips and any other equipment that comes into direct contact with mucosal surfaces should be disinfected, sterilised or, if disposable, discarded after each use. The optimal frequency for disinfection or sterilisation of tubing, valves or manifolds has not been established. However, any equipment surface showing visible condensation from expired air should be disinfected or sterilised before reuse.

Since the use of cold sterilising agents is not without risk, laboratory staff should take care to follow the manufacturer’s recommendations concerning proper handling of these products. Some respiratory equipment may be damaged by some methods of sterilisation. For example, heat sterilisation or cold sterilisation chemicals could damage some flow sensors, tubing or seals. Manufacturers should explicitly describe acceptable methods of cleaning and disinfecting their equipment, including recommended chemicals and concentrations, as well as safety precautions for the technicians. Manufacturers’ recommendations should be followed; however, a hospital infection-control department’s requirements will probably supersede both manufacturers’ recommendations and those in this document. If hospital infection-control recommendations have the potential to harm instruments, compromises may have to be negotiated.

Volume-based spirometers

Volume-based spirometers used with a closed-circuit technique should be flushed between subjects with room air at least five times over the entire volume range of the spirometer to enhance clearance of droplet nuclei. The breathing tube and mouthpiece should be decontaminated or changed between patients.

When the open-circuit technique is used and the patient/subject only exhales into the spirometer, only the portion of the circuit through which rebreathing occurs must be decontaminated between patients. For example, when a pneumotachometer system is used, either avoid having the patient inspire through the device, or decontaminate or replace the resistive element and tubing between subjects. Alternatively, a disposable sensor may be used. Disposable sensors, when appropriately used, avoid the need for decontamination of sensors and mouthpieces (see Disposable in-line filters section).

When an open-circuit technique (either volume or flow spirometers) is used without inspiration from the measuring system, only the mouthpiece would need to be changed or decontaminated between subjects. However, it is difficult, if not impossible, to assure that patients do not inhale through the device. A low-resistance one-way valve may be used to prevent inhalation, and, if used, must be demonstrated not to alter the spirometric measurements. Not having patients inspire through the device may make it difficult to assess test quality because of the absence of an inspiratory tracing. Hence, this technique should be used with caution. Disassembling, cleaning and/or sensor replacement will usually require recalibration of the spirometer.

Tuberculosis

In settings where TB or other diseases that are spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering controls, such as ventilation, air filtration or ultraviolet decontamination of air, should be used to prevent disease transmission.

Haemoptysis and oral lesions

Special precautions should be taken when testing patients with haemoptysis, open sores on the oral mucosa or bleeding gums. Tubing and breathing valves should be decontaminated before reuse, and internal spirometer surfaces should be decontaminated with accepted disinfectants for blood-transmissible agents.

Other known transmissible infectious diseases

Extra precautions should be taken for patients with known transmissible infectious diseases. Possible precautions include the following: 1) reserving equipment for the sole purpose of testing infected patients; 2) testing such patients at the end of the day to allow time for spirometer disassembly and disinfection; and 3) testing patients in their own rooms with adequate ventilation and appropriate protection for the technician.

Disposable in-line filters

These may be an effective and less expensive method of preventing equipment contamination. The influence of commercially available in-line filters on forced expiratory measures, such as forced vital capacity (FVC) and forced expiratory volume in one second (FEV1) has not been well characterised. A low-impedance barrier device was found not to have a significant effect on FVC and FEV1 [14], whereas a barrier filter has been shown to cause small but significant reductions in FEV1 (-44 mL) and peak expiratory flow (PEF; -0.47 L s⁻¹), but did not appear to affect DLCO, alveolar volume or TLC [15]. Although significant differences between measurements with and without filters have been demonstrated for FVC, FEV1, airway resistance and specific airway conductance (sGaw) [16], these differences were unrelated to the average values of the measurements (except for sGaw), and the limits of agreement were within the range of intra-individual short-term repeatability for almost all of the function indices. Thus, the effect of a filter with optimal characteristics is not considered to be clinically significant, and no appreciable classification error was found in diagnostic tests.

If in-line filters are used, the measuring system should meet the minimum recommendations for accuracy, precision (reproducibility), flow resistance and back pressure with the filter installed. Airflow resistance must be measured with in-line filters in place if that is how patients are tested. Manufacturers of in-line filters should provide evidence that
increasing the prevalence of contaminated lung function equipment may be implicated in TB [24]. Likewise, there is circumstantial evidence that spirometry previously used to test a patient with documented report of a TB skin-test conversion following exposure to a flows generated during spirometric manoeuvres may be high surfaces of tubing through which subjects breathe [19, 23]. The have been recovered from mouthpieces and the proximal testing. Organisms from the respiratory tract of test subjects evidence of infection transmission during pulmonary function testing. Although there is indirect evidence that pneumotachometer-based systems are less susceptible to bacterial contamination than water-sealed spirometers [26]. In addition, it is well documented that community water supplies can be contaminated with Mycobacteria spp. and Pseudomonas aeruginosa organisms [27–29]. Thus, there is a potential for both patients/subjects and healthcare workers to deposit microorganisms onto spirometer surfaces (including mouthpieces, nose clips, tubing and any internal or external machine surface), which could subsequently come into direct or indirect contact with other patients or healthcare workers.

This does not pose an appreciable threat to patients/subjects/ workers with competent immune systems. It has been argued that immunocompromised patients may require only a relatively small infective dose of either opportunistic organisms or common pathogens for infection to occur. However, there is no direct evidence that routine pulmonary function testing poses an increased risk of infection to immunocompromised patients.

Concerns for the protection of immunocompromised patients, along with increased public and provider awareness of hospital infection-control issues since the 1990s, has led many laboratory directors to routinely use in-line filters to reassure patients and laboratory personnel that their protection has been considered.

PERSONNEL QUALIFICATIONS AND TECHNICIAN’S ROLE IN QUALITY CONTROL

Personnel qualifications

Previously, the ATS has published recommendations for laboratory personnel conducting pulmonary function tests [30]. Minimum requirements include sufficient education and training to assure that the technician understands the fundamentals of the tests, the common signs of pulmonary diseases and the management of the acquired pulmonary function data. The ATS also recommended that medical directors should have appropriate training and be responsible for all pulmonary function testing [31]. Since these initial recommendations, pulmonary function testing equipment and procedures have become considerably more complex. The use of computers has reduced the need for routine manual measurement; however, new and more complex training issues have evolved. Many providers of pulmonary function training programmes have expanded the scope and length of training to accommodate these new needs.

The current guidelines suggest that completion of secondary education and at least 2 yrs of college education would be required to understand and fulfil the complete range of tasks undertaken by a pulmonary function technician.

For pulmonary function testing, an emphasis on health-related sciences (nursing, medical assistant, respiratory therapy, etc.) is desirable. Formal classroom-style training alone does not, however, establish competency in pulmonary function testing. Technicians who conduct pulmonary function testing need to be familiar with the theory and practical aspects of all commonly applied techniques, measurements, calibrations, hygiene, quality control and other aspects of testing, as well as having a basic background knowledge in lung physiology and pathology. In the USA, the National Institute for Occupational
Safety and Health (NIOSH) has developed a model program, and reviews and approves spirometry training courses. These 2- and 3-day courses include the fundamentals of spirometry standards and hands-on training. The workshop experience provides hands-on instruction in a small group setting with an experienced instructor. Students are expected to demonstrate their ability to properly prepare and administer a spirometric test, and demonstrate competency in other areas, such as calibration, recognition of unacceptable manoeuvres, etc.

This standard recommends training similar to the NIOSH-approved spirometry programme. Competency is demonstrated by passing a written and practical examination in the presence of an experienced instructor (i.e. hands-on testing and calibration). In Europe, training is being carried out differently in various countries. The ERS, through a specific Assembly (Assembly 9 for Allied Respiratory Professionals), regularly delivers relevant postgraduate course training at their annual Congress.

Spirometry refresher training is also recommended. Refresher training helps to ensure that testing technicians are informed of changes in spirometry standards and learn new skills. It also provides a mechanism for technicians to obtain answers to questions not foreseen during initial training. The need for refresher training has been recognised by several organisations, including the Lung Health Study [32], the National Health and Nutrition Examination Survey [33, 34] and the American College of Occupational and Environmental Medicine [35]. The frequency of refresher training is dependent on many factors that differ among individuals. A recommended frequency of every 3–5 yrs is recommended, or shortly after changes to lung function standards are published. While in-house training may achieve the desired goals, laboratory directors should strongly consider the benefits of formal training programmes from outside providers.

**Technician’s role in quality control**

Quality control is important to ensure that the laboratory is consistently meeting appropriate standards. In any quality-control programme, an important element is a manual of procedures that contains the following: calibration procedures, test-performance procedures, calculations, criteria, reference values source, and action to be taken when “panic” values are observed. A notebook or an equivalent method of recording and later producing these results should be maintained, which documents the daily instrument calibration, as well as any problems encountered with the system, corrective action required, and system hardware and software upgrades. Records of anomalous events involving either patients/subjects or the technician should be documented with the results of subsequent evaluation and responses to the event. The technician should also maintain records of continuing education and the results of evaluation and feedback provided by the medical director. The ATS has produced a complete procedure manual (Pulmonary Function Laboratory Management and Procedure Manual), which is available in paper and electronic format (www.thoracic.org/education/labmanual.asp), so as to be modifiable by laboratories to meet their individual needs.

In Europe, technical information on lung function tests is contained in a series of publications in the European Respiratory Journal [36–42].

Perhaps the most important component in successful pulmonary function testing is a well-motivated, enthusiastic technician. The importance of a quality-control programme with feedback to technicians in obtaining adequate spirometry results has been documented [32]. A quality-control programme that continuously monitors technician performance is critical to the collection of high-quality data. Feedback to the technicians concerning their performance should be provided on a routine basis, which should include, at a minimum: 1) information concerning the nature and extent of unacceptable manoeuvres and nonreproducible tests; 2) corrective action that the technician can take to improve the quality and number of acceptable manoeuvres; 3) positive feedback to technicians for good performance; and 4) comments regarding system setup and reporting results.

Manufacturers are encouraged to include quality-control aids in their software packages. However, technicians should be trained not to rely exclusively on these quality-control prompts, since technical errors may occur that are not among those recognised by the software. An example of a quality-control aid is a calibration-logging program, which stores the date, time, technician name and the results of routine daily calibration checks. Additionally, the program could issue a warning if an acceptable daily calibration check has not been performed.

**REFERENCE VALUES**

Detailed statements on the selection of reference values and interpretation of lung function tests have been published [39, 41–43] and new recommendations have just been created [44]. In selecting appropriate reference values, it is important to choose a source that used similar equipment and had a test population that included the age range, sex and ethnic group of individuals to be tested. Also, all spirometric indices should use the same source for reference values (i.e. FVC and FEV₁ should not be taken from a different reference value source than the FEV₁/FVC %).

**INTERPRETATION STRATEGIES**

For a full account of interpretive strategies, the ATS and ERS have now revised [44] their previous statements [39, 41–43].

The interpretation of lung function tests involves two tasks: 1) the classification of the derived values with respect to a reference population and assessment of the reliability of the data; and 2) the integration of the obtained values into the diagnosis, therapy and prognosis for an individual patient.

The first task is ordinarily the responsibility of the laboratory director or his/her designee, and not only serves to communicate information to referring healthcare providers, but is also an important aspect of laboratory quality control. The second task is usually the responsibility of the physician requesting the studies and is performed within the context of patient care.
TABLE 4 (Continued)

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>RT</td>
<td>Rise time from 10% to 90% of PEF</td>
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<tr>
<td>RV</td>
<td>Residual volume</td>
</tr>
<tr>
<td>s</td>
<td>Seconds</td>
</tr>
<tr>
<td>STPD</td>
<td>Standard temperature (273 K, 0°C), pressure (101.3 kPa, 760 mmHg) and dry</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>TGV (or Vtg)</td>
<td>Thoracic gas volume</td>
</tr>
<tr>
<td>ti</td>
<td>Time taken for inspiration</td>
</tr>
<tr>
<td>TLC</td>
<td>Total lung capacity</td>
</tr>
<tr>
<td>Tr</td>
<td>Tracer gas</td>
</tr>
<tr>
<td>tot</td>
<td>Total time of respiratory cycle</td>
</tr>
<tr>
<td>VA</td>
<td>Alveolar volume</td>
</tr>
<tr>
<td>VAeff</td>
<td>Effective alveolar volume</td>
</tr>
<tr>
<td>VC</td>
<td>Vital capacity</td>
</tr>
<tr>
<td>Vc</td>
<td>Pulmonary capillary blood volume</td>
</tr>
<tr>
<td>Vd</td>
<td>Dead space volume</td>
</tr>
<tr>
<td>Vi</td>
<td>Inspired volume</td>
</tr>
<tr>
<td>Vs</td>
<td>Volume of the expired sample gas</td>
</tr>
<tr>
<td>μg</td>
<td>Micrograms</td>
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</table>

It is the responsibility of the laboratory director to develop explicit procedures for the interpretation of lung function tests and to select appropriate reference values. The procedures for interpretation and choosing reference values may legitimately vary from laboratory to laboratory, depending upon geographical location and the characteristics of the population being tested. The interpretative strategy should be consistent and take into consideration the consequences of false-positive and false-negative errors. In this way, referring physicians will not infer a change in the condition of the patient from a change in interpretation when it is, in fact, the result of a change in the approach of the interpreting physician.

ABBREVIATIONS

Table 4 contains a list of abbreviations and their meanings, which will be used in this series of Task Force reports.

ACKNOWLEDGEMENTS

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