Multiple gas analyzers are used in the various pulmonary function tests (PFTs). One of the first steps in ensuring validity of test results is dependent upon following the current recommendations for calibration and quality control (QC). Calibration and QC are discussed in the National Committee for Clinical Laboratory Standards (NCCLS) guideline, “A Model for a Quality System for Healthcare,” as an equipment quality system essential (QSE) and in the pre-analytical phase of the path of workflow.

Recommendations, standards, and guidelines have been published in several of the AARC clinical practice guidelines (CPGs), the American Thoracic Society (ATS) “Pulmonary Function Laboratory Management and Procedure Manual,” and the ATS “Single-Breath Carbon Monoxide Diffusing Capacity (Transfer Factor); Recommendations for a Standard Technique—1995 Update.”

Performance, evaluation, and documentation of calibration and QC procedures should be included in all training and competence assessment programs.

Diffusing capacity

According to the ATS recommendations, gas analyzers must be able to provide a linear output; and the linearity must be within 1 percent of the full scale. It is reasonable to expect the manufacturer to display the gas concentrations measured so linearity can be verified. Linearity should also be verified by the user on a quarterly basis.

Methods to assess gas-analyzer linearity have been previously described by the European Respiratory Society and Okubo and Lenfant. Gas analyzer performance may be impacted by carbon dioxide (CO₂) and/or H₂O. The system should provide a mechanism to remove interfering substances prior to analyzing the test gas concentrations.

Methods to verify equipment function include the performance of physiologic controls on a regular schedule. This is the practice of testing standard subjects or known healthy non-smokers. It has also been used to assess intra- and inter-laboratory variance between testing systems. The ATS recommends the variance in carbon monoxide diffusing capacity (DLCO) in a standard subject should not exceed 10 percent of the known previous...
value. The AARC CPG “Single-Breath Carbon Monoxide Diffusing Capacity–1999 Update” recommends performing physiologic controls (tests) on a quarterly basis or more frequently based on the tendency of the equipment to vary. In addition, the CPG suggests that it may be advantageous to perform the controls at weekly or semi-monthly intervals.

**Cardiopulmonary exercise**

Oxygen and carbon dioxide analyzers are used to assess oxygen uptake and carbon dioxide production during cardiopulmonary exercise testing. A two-point minimum calibration should be performed prior to all testing. The calibration gas concentrations should reflect the measuring range of the analyzers.

Primary standard-grade tank values are required, and the measured results should fall within 1 percent of the certified tank values. Many of the exercise systems also require knowing the time delay between the gas analyzer and pneumotach signals. Each laboratory may calculate a standard deviation (SD) and mean for the time delay.

Testing of physiologic controls is also recommended by the ATS. Depending on the variance of the equipment and the volume of testing, controls should be performed weekly or at least monthly. In some testing environments, the controls may be performed daily. According to the ATS, clinicians should perform a maximal oxygen consumption study on the healthy control subjects. Once the maximal results are documented, use 40 to 50 percent of the maximum workload for a steady-state level to be performed at the laboratory's designated frequency. It is a good practice to use more than one healthy control subject. For example, if the control results fall outside the recommended 95 percent confidence interval, the next step is to test an alternative subject.

In 1990, Wasserman and colleagues described a mechanical simulator for verifying equipment function. The advantage of a simulator is the ability to test equipment performance at multiple metabolic rates. As with all methods of mechanical QC, there are also limi-
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references


A QC plan should include a combination of daily calibration, physiologic, and mechanical controls. For each method, a mean and SD will need to be established similar to an arterial blood gas QC system.

Summary

Applying the mindset used in clinical laboratory testing for
gas analyzers (oxygen and carbon dioxide) to the pulmonary function laboratory is considered good laboratory practice. Time standards for QC are also discussed in the AARC “Diagnostic Uniform Reporting Manual,” which will become available in November 1999.

QC records should be documented and maintained in the same manner as in the arterial blood gas laboratory. The use of Levey Jennings charts is helpful to identify trends and out-of-control results. The responsibility for ensuring accurate and reliable test results resides with the individual performing the tests. Respiratory therapists must continue to improve their ability to understand statistical control to ensure clinically meaningful results in all testing areas. Do you know the variance in QC parameters and physiologic controls in your laboratory?

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