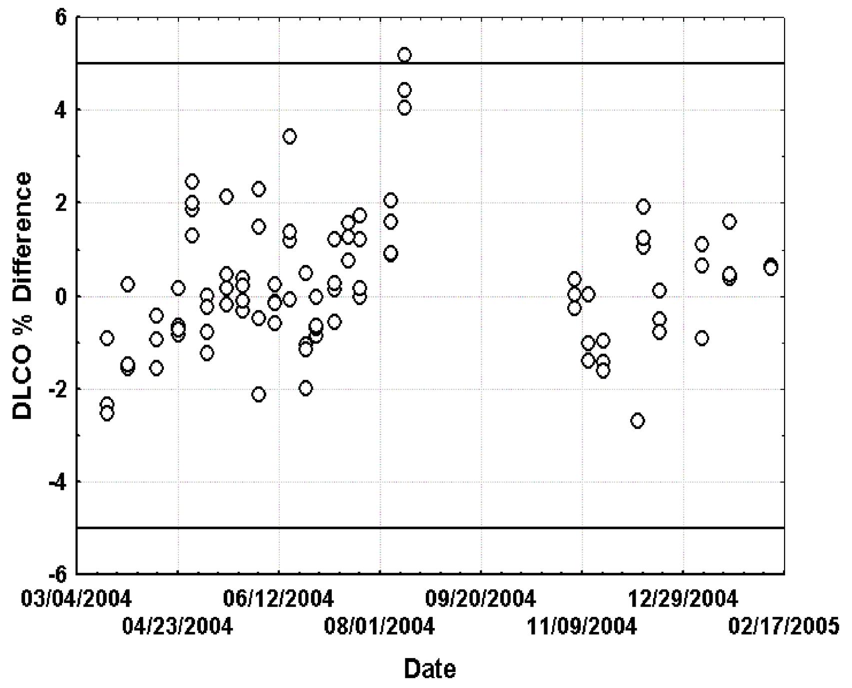
Laboratory Quality Control Using A DL_{CO} Simulator

RL Jensen, RO Crapo, HM Howell

LDS Hospital and University of Utah, Salt Lake City, Utah USA

ABSTRACT

Introduction. Until recently there has not been a simulator to test the performance of DLCO instruments. With a simulator, known volumes and concentrations of gas can be injected and removed from a DLCO instrument, simulating patient tests with a precisely known target value. The accuracy and precision of each individual device can be measured and tracked to ensure proper instrument performance.
Methods. DLCO simulations using high precision test gases (± 1%) were performed weekly on three instrument models for one year. The inspired volume was 4.5 L. At each test session eight trials were done on each device, four each with mid level and low level simulated alveolar gas samples. The first trial of each test set was discarded as a system flush. The remaining three trials were analyzed. Changes from target of ±2 DLCO units or 5% were set as thresholds to initiate an investigation. In addition, we watched for trends in both variability and deviation from the target DLCO.
Results. The graph below represents data for one device. In an instrument presumed to be working, a >5% deviation from simulator target resulted in the discovery of a small leak in a rolling seal. Once fixed, instrument performance returned to normal.
Conclusions. Regular use of a DLCO simulator enabled us to find instrument failures that were not otherwise obvious with routine quality control and calibrations.



METHODS

Background

Quality control in pulmonary laboratories has mainly been performed using a certified calibrated 3.0 liter syringe. Other quality control measures include testing body plethysmographs with oscillating pumps, using a 3.0 liter syringe to test carbon monoxide diffusing capacity (DL_{CO}) instruments by producing a zero DL_{CO} and using human biological controls. However, devices and methods have not been available to test the accuracy and precision of DL_{CO} instruments in clinical laboratories. Three primary measurements along with barometric pressure (BP), ambient temperature and breath hold time (BHT) are necessary to calculate DL_{CO}. Testing DL_{CO} instruments involves evaluating the accuracy of the three primary measurements: 1) inspired volumes, 2) carbon monoxide (CO) gas concentrations and 3) the tracer gas (He, Ne or CH4) concentrations.

A testing instrument was recently developed that can introduce a known value for the carbon monoxide diffusing capacity into commercial devices (Hans Rudolph, Inc. Kansas City, MO, USA). The device uses a combination of highly accurate, settable syringes and precision mixtures of gases that contain concentrations of carbon dioxide, carbon monoxide, tracer (He, Ne, CH4), oxygen and nitrogen that would be similar to those observed in a subject's alveolar gas during a DL_{CO} test. The DL_{CO} simulator has been used in several clinical drug studies to quality control laboratory DL_{CO} instruments throughout the studies and to test for DL_{CO} measurement accuracy in a random sample of laboratories in the United States. The accuracy of the DL_{CO} simulator varies with the gas mixture and the simulated inspiratory volumes employed during the testing procedure, but is not thought to exceed 1.0 mm CO/min/mmHg in most test conditions.

Study Design

DL_{CO} simulations were performed on three DL_{CO} instrument models in the pulmonary function laboratory at LDS Hospital in Salt Lake City, Utah, USA.

Device Table

Device	Age	Tracer Gas
Sensormedics Vmax Spectra 229	3 years	Methane
Collins CPL	4 years	Methane
Sensormedic Vmax Spectra 22D	3 years	Methane

Each instrument was calibrated daily with a standard 3.0 liter syringe. All gases used for patient testing were ordered to be gravimetrically mixed and made to "Primary" standards with accuracies of +/- 1.0% of the concentrations reported on the analysis certificate. DL_{CO} simulator test gases were individually gravimetrically mixed into small ED cylinders by Puritan Bennett for Hans Rudolph, Inc.

ANALYSIS

Measurements recorded from each DL_{CO} instrument:

DL_{CO} (ml CO/min/mmHg)
Alveolar volume (VA) liters
Breath-Hold-Time (BHT)
Inspiratory Vital Capacity (IVC)
CO concentration (%)
CH4 concentration (%)
Barometric Pressure (mmHg)
Temperature (Degrees C)

Protocol

- The inspired volume on the large syringe was set to 4.5 L
- The small-standardized gas syringe was filled to 2.5 L with a known high precision gas (±1%)
- After filling the small gas syringe the pressure was purged via a one-way valve
- Each testing session was comprised of eight trials on each device, four trials with a mid level simulated alveolar gas and four trials with a low level simulated alveolar gas
- The first trial of each test set was discarded as a system flush
- Each device was calibrated prior to each test
- Changes from simulator target of ±2 DL_{CO} units or ±5% were set as thresholds to discontinue a device for patient use and initiate an investigation

DL_{CO} Simulations

For each simulation, the DL_{CO} instrument was calibrated prior to beginning a DL_{CO} maneuver. The large inspiratory volume syringe is used to perform tidal breathing (simulating a patient). At the end of an exhalation the DL_{CO} maneuver is initiated. Again using the large syringe, 4.5 L of test gas was "inhaled" and held for ten seconds. As the end of the ten second breath hold time (BHT) approached the two-way valve was turned to allow "exhalation" using the simulated alveolar gases in the small gas syringe. The reported DL_{CO}, inspired volume, breath-hold time, and the simulated gas concentrations were entered into the simulator's software (EasyLab QC). The EasyLab QC software calculates a simulator target value for each trial based on device specifications, daily barometric pressure, daily temperature, the simulator inspired volume, and the breath hold time. These target values were compared to the DLCO value reported by the DL_{CO} instrument. measurements.

Data were collected over an eighteen-month period with simulations performed weekly on each device on the same day of the week throughout the study.

RESULTS/CONCLUSIONS

Results

The following are graphs of the differences between the simulation DLco, Gas concentrations for CO and CH4 and the inspiratory volumes and tested instruments.

Figure 1

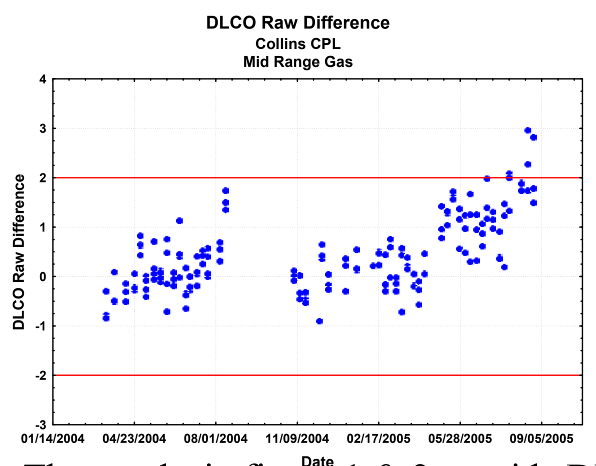
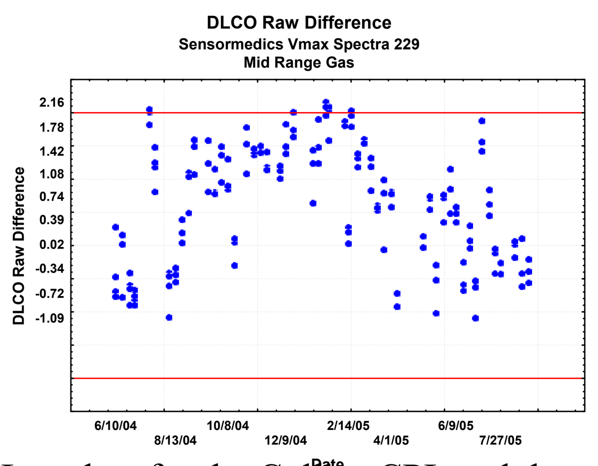


Figure 2



The graphs in figure 1 & 2 provide DL_{CO} data for the Collins CPL and the Sensormedics Vmax Spectra 229 instruments. The Collins data shows two periods of drift in DL_{CO} measurements. The upward trend was used to identify problems with the equipment (i.e., a leak in the rolling seal). The drift seen with the Collins instrument correlated with changes in measured inspired volume (figure 5).
The Sensormedics data shows a slow trend upward which went back down. These trends correlated with changes in measured [CO] and were found to be caused by problems with the Sensormedics instrument's test gas which was produced by a local company.

Figure 3

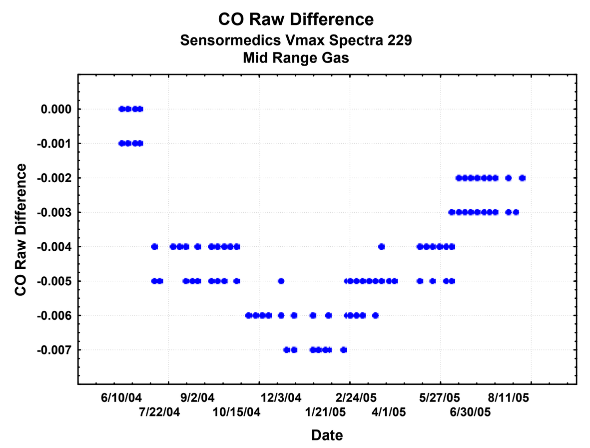
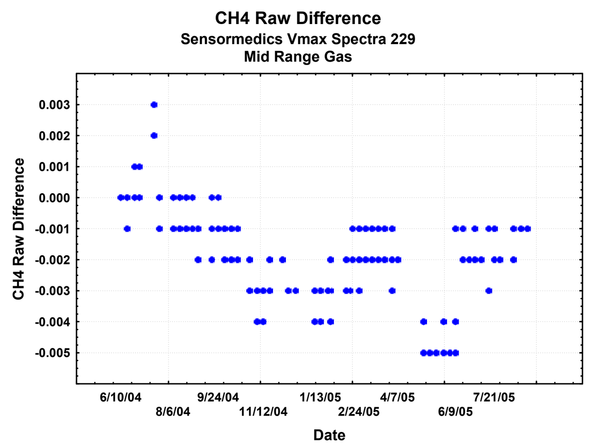


Figure 4

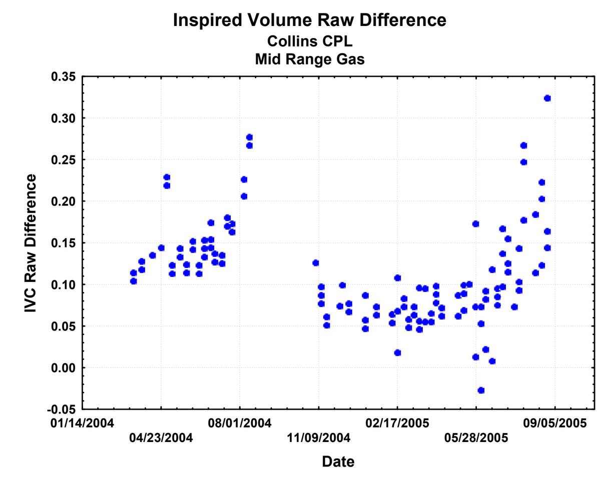


Graphs of measured gas concentrations (CO & Tracer) for one device, figures 3 & 4 show shifts in measurements when instrument test gas tank is changed.

Device	# Failures Detected	Type of Failure
Sensormedics Vmax Spectra 229	9	CO
Collins CPL	4	Volume/Flow

Accurate inspiratory volume measurements are critical to the DLco measurements. The graph below shows how our Collins instrument deviated from simulated target IVC values until it reached failure conditions. A broken seal was identified in the first failure and the second is being evaluated.

Figure 5



Graph represents difference in inspired volume between the simulator and the Collins CPL.

CONCLUSIONS

1. Regular use of a DLCO simulator identified instrument failures that were not identified with our routine quality control and calibration procedures.
2. Regular use of a simulator increases our confidence in the accuracy of our patient data which is used for diagnosis and treatment.