

What's the Quality Score in Your PF Lab?

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Why does it matter?

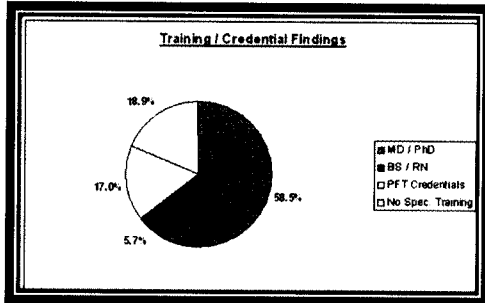
- Prevention
- Healthcare costs
- Misclassification of disease process
 - Therapeutic intervention
- Clinical research
- Global requirements

Results from a survey of 73 PFT labs in the USA

- 3 page prequalification questionnaire
- 50% with RPFT credentialed tech
- 76% with CPFT credentialed tech
- 100% with daily spirometer cal checks
- 28% ever checked spirometer linearity
- 50% checked DLCO bio QC monthly
- 31% checked DLCO with 3L syringe
- 26% ever checked body box (isothermal)

Enright, Blonshine, Harris 2007 ATS abstract

Discussion



Bloshine SB, Harris R, Cangiamilla S, Enright P 2007 ERS Abstract

Comparative Survey Results

	US	Non-US
CREDENTIALS	RRT, CRT, CPFT, RPFT, Other	MD, PhD, BS, RN, Other
DAILY CALIBRATIONS	100%	88%
SYRINGE LOOPS	28%	33%
SYRINGE DLCO	31%	31%
BIOLOGIC QC	50%	56%

Bloshine SB, Harris R, Cangiamilla S, Enright P 2007 ERS Abstract

Results

Intensity of Training-Mean Values

Syringe QC	BioQC	Spirometry	DLCO	Lung Volumes
2.31	2.13	1.15	1.46	2.28

46 percent of the DLCO Simulation studies were **Unacceptable**

Bloshine SB, Harris R, Cangiamilla S, 2007 ERS Abstract

Comparative Results

	US	Non-US
Syringe QC	2.04	2.31
BioQC	2.04	2.13
Spirometry	1.10	1.15
DLCO	1.24	1.46
Lung Volumes	2.14	2.28
DLCO Simulation failure rate	26%	46%

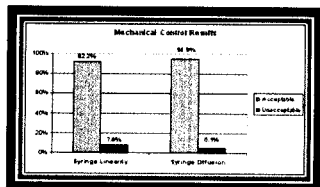
Blosshine SB, Harris R, Cangiamilla S, 2007 ERS Abstract

Conclusion

- Educational needs exist globally
- Developing an understanding of the learning needs and existing gaps provides a foundation for improvement
 - University-based
 - Continuing education
 - Accreditation programs

Blosshine SB, Harris R, Cangiamilla S, 2007 ERS Abstract

Mechanical QC



Blosshine SB, Harris R, Snow, M 2007 ERS Abstract

Introduction

- Biologic control standards are recommended by the 2005 ATS and ERS guidelines as a method of quality control
- Limited studies are available
 - None with 2005 guidelines

Blonahne SB, Harris R, Snow, M 2007 ERS Abstract

Aim

- To evaluate within visit and between visit variation for biologic controls performed in a large multi-center clinical trial for inhaled insulin

Blonahne SB, Harris R, Snow, M 2007 ERS Abstract

Methods

- Two healthy individuals at each site completed Spirometry, DLCO, and lung volumes by plethysmography
 - 20 consecutive days initially
 - Weekly
- Means and SD calculated for expected range

Blonahne SB, Harris R, Snow, M 2007 ERS Abstract

Methods

- Data transmitted to a central site for evaluation
- All tests were reviewed for adherence to 2005 guidelines by an independent third party
- Feedback and coaching provided to the pulmonary laboratory staff

Blonshine SB, Harris R, Snow, M 2007 ERS Abstract

Methods

- Evaluated data from 81 PFLs and 186 subjects
– 6174 BioQC tests

Blonshine SB, Harris R, Snow, M 2007 ERS Abstract

Results

Within Visit Variation		
Within Visit	CoVar%	Acceptability%
FEV1	2.85%	96.8%
FRC	3.35%	97.6%
DLCO	3.67%	85.6%

Blonshine SB, Harris R, Snow, M 2007 ERS Abstract

Results

Between Visit Variation		
DLCO CoVar	FEV1 CoVar	FRC _{PL} CoVar
6.60%	3.36%	7.46%

Bionhine SB, Harris R, Snow, M 2007 ERS Abstract

Conclusions

- Within visit exceeds current expectations from ATS and ERS guidelines
- DLCO between visit variation less than reported to date
- Education, comprehensive QC programs, monitoring and technical support may lead to improved reliability of PE results

Bionhine SB, Harris R, Snow, M 2007 ERS Abstract

Discussion and Next Steps

- Re-analyze data with 20 more sites and addition of Jaeger equipment
- Evaluate absolute change in DLCO
- Evaluate additional parameters
- Evaluate trends
- Correlate with mechanical QC methods

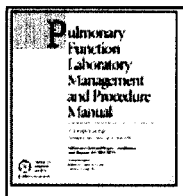
Bionhine SB, Harris R, Snow, M 2007 ERS Abstract

American Thoracic Society Recommendations

- Equipment
 - System design requirements
 - Quality control
 - Infection control
- Standardization Issues
 - Technique factors
 - Calculations
 - Interpretation of results

Standards and Guidelines

- American Thoracic Society
 - ATS Pulmonary Function Laboratory Management and Procedure Manual
 - Updated 2005
 - www.thoracic.org
 - Education
 - Education Products



2005 ATS/ERS Standards General Considerations

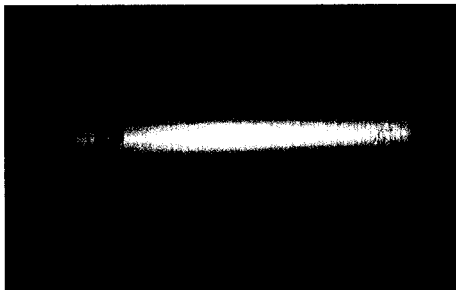
- Technologist's role in quality control
 - Manual of procedures containing: calibration procedures, test performance procedures, calculations, criteria, reference values source
 - Defined actions to be taken when "panic" values are observed.
 - Logbook
 - Daily calibration, corrective action, system hardware or software upgrades

2005 ATS/ERS Standards General Considerations

- Technologist feedback
 - Information concerning the nature and extent of unacceptable maneuvers and non-reproducible tests
 - Corrective action the technologist can take to improve the quality and number of acceptable maneuvers
 - Positive feedback to technologists for good performance
 - Comments regarding system set-up and reporting results

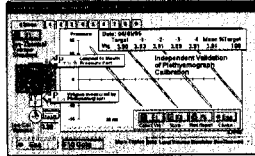
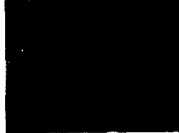
Mechanical QC

- Syringe
 - 3 Liter
 - 7 Liter
- DLCO Simulation Device
- Metabolic Simulation Device
- Isothermal bottle



2005 ATS/ERS Standards Plethysmography

- Validation using a known volume should be performed periodically
- Model lung with thermal mass to simulate isothermal conditions of the lung.
- Accuracy 50 ml or 3%



Biologic QC

- Biologic controls
 - Spirometry
 - Lung Volumes
 - DLco
- Mean and coefficient of variation

Diffusing Capacity - QA

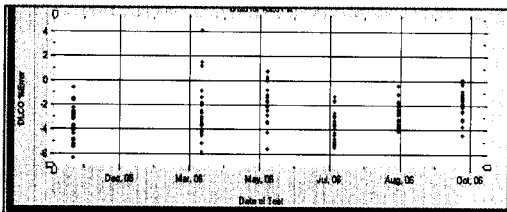
- Biologic QC – 2 reference subjects
- At least weekly
- Or whenever errors are suspect
- Or whenever a calibration tank is replaced

RDM Relational Database Manager
Biological Standard Data Log

Biological Standard - BC-Standard: 01/04/95 - 01/04/95

Date	Name	Pier	FVC	FEV1	FEF	FEF100%	FRC	IC	TLC	DLCO	VA	Technician
			PRE	PRE	PRE	PRE	PRE	PRE	PRE	PRE	PRE	
			LITER	LITER	LITER	LITER	LITER	LITER	LITER	LITER	LITER	
01/04/95	BC-Standard	760	8.00	5.00	16.2	10.2	3.20	4.00	7.20	38.8	7.10	DS
01/05/95	BC-Standard	766	6.10	5.04	16.8	11.2	3.24	4.08	7.32	39.4	7.12	DS
01/06/95	BC-Standard	755	6.05	5.05	16.4	10.8	3.25	4.10	7.25	39.9	7.22	DS
01/07/95	BC-Standard	763	6.04	5.10	16.4	11.2	3.18	4.02	7.20	39.5	7.18	DS
01/08/95	BC-Standard	785	5.98	5.03	15.8	10.2	3.20	4.00	7.20	38.8	7.10	DS
01/09/95	BC-Standard	762	6.00	5.00	16.2	10.2	3.20	4.00	7.20	38.8	7.10	DS

EasyLab QC



What have we learned?

- Expired CO
- Medical gas source
- Gas conditioning
- Analyzers
- Volume measuring device
- Temperature

Test Performance Monitors

- Spirometry
- DLco
- LungVolumes

2005 ATS/ERS Standards

General Considerations

- **Repeatability:** closeness of agreement between the results of successive measurements
- **Reproducibility:** 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.

2005 ATS/ERS Standards

General Considerations

- **Position**
 - Sitting is preferable for safety reasons in order to avoid falling due to syncope.
 - Chair should have arms and without wheels
 - Obese patients with mid-section distribution will frequently be able to take a deeper breath if tested standing
 - If test is performed standing a chair without wheels should be placed behind them.
 - Report should include the position tested

ATS/ERS Standards

General Considerations

- **Height and weight**
 - Measured in indoor clothes without shoes
 - Patients with deformities of the thoracic cage should have their arm span measured
 - $Ht = \text{arm span}/1.06$



2005 ATS/ERS Standards
General Considerations

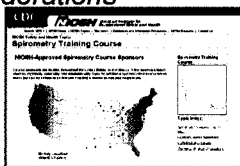
- Subject preparation
- Activities that should preferably be avoided prior to lung function testing.
 - Smoking within 4 hours of testing
 - Consuming alcohol within 4 hours of testing
 - Performing vigorous exercise within 30 minutes of testing
 - Wearing clothing that substantially restricts full chest and abdominal expansion
 - Eating a large meal within 2 hours of testing

2005 ATS/ERS Standards
General Considerations

- “Laboratory Details”
 - Ambient temperature, barometric pressure and time of day must be recorded
 - *Ideally* a return patient should be tested on the same equipment by the same operator at the same time of day (within 2 hours)
 - Testing sequence

ATS/ERS Standards
General Considerations

- Personnel qualifications
 - Completion of secondary education and at least two years of college education
 - Formal classroom instruction does not establish competency
 - Minimum requirements include sufficient education and training to assure that the technician is competent
 - NIOSH training
 - Every 3-5 years



2005 ATS/ERS Standards
General Considerations

- **Technologist feedback**
 - Information concerning the nature and extent of unacceptable maneuvers and non-reproducible tests
 - Corrective action the technician can take to improve the quality and number of acceptable maneuvers
 - Positive feedback to technicians for good performance
 - Comments regarding system set-up and reporting results

2005 ATS/ERS Standards
Standardization of Spirometry

Summary of Acceptable Blow Criteria

1. Without an unsatisfactory start of expiration,
2. Without coughing in the 1st second
3. Without early termination
4. Without a Valsalva maneuver (glottis closure)
5. Without a leak
6. Without an obstructed mouthpiece
7. Without evidence of an extra breath

2005 ATS/ERS Standards
Standardization of Spirometry

- *Note: a Useable curve must only meet conditions 1 and 2*
- *while an Acceptable curve must meet all of the above seven conditions.*

**2005 ATS/ERS Standards
Standardization of Spirometry**

Between Maneuver Evaluation

- Minimum of 3 maneuvers
- Acceptable *repeatability* is achieved when the difference between the largest and the next largest FVC is 0.150 L or less **AND** the difference between the largest and next largest FEV₁ is 0.150 L or less.
- For those with an FVC of 1.0 L or less both these values are 0.100 L.

**2005 ATS/ERS Standards
Standardization of Spirometry**

Between Maneuver Evaluation

- If these criteria are not met in three maneuvers, additional trials should be attempted, up to but usually no more than 8 maneuvers.
- Enright PL, Beck KC, Sherrill DL. Repeatability of spirometry in 18,000 adult patients [see comment]. (Journal Article) *American Journal of Respiratory & Critical Care Medicine*. 169(2):235-8, 2004 Jan 15.

**2005 ATS/ERS Standards
Standardization of Spirometry**

Test Result Selection

- FVC and FEV₁ selected from a minimum of 3 expiratory maneuvers
- Largest FVC and the largest FEV₁ (BTPS) should be recorded, after examining the data from all of the useable curves, even if they do not come from the same curve.

2005 ATS/ERS Standards Standardization of Spirometry

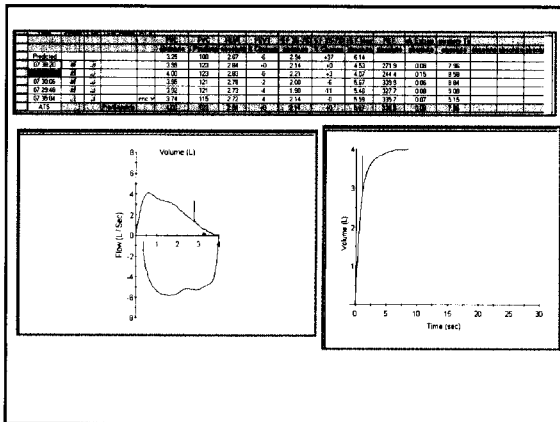
Reversibility Testing

- Pre-test instructions
 - Withholding bronchodilators
 - 4 hours for short-acting β agonists (e.g. albuterol)
 - 12 hours for long-acting β agonists (e.g. salmeterol) and systemic bronchodilators

2005 ATS/ERS Standards Standardization of Spirometry

Reversibility Testing

- Minimum of 3 acceptable maneuvers
- Administer drug
 - Example: albuterol 100 μg
 - MDI: Use spacer, inhale slowly to TLC and hold breath for 5-10 sec.
 - 4 doses (400 μg), 30 seconds apart
 - ipratropium bromide the total dose is 160 μg (4 \times 40 μg)



2005 ATS/ERS Standards
Standardization of Diffusing Capacity

Inspired vital capacity

- IVC should be at least 85% of patient's previous best VC.
 - Because it appears that VI reductions as much as 15% of the known VC will reduce the DLCO less than 5% (18), a VI target of 85% of the largest known VC seems both reasonable and attainable.

2005 ATS/ERS Standards
Standardization of Diffusing Capacity

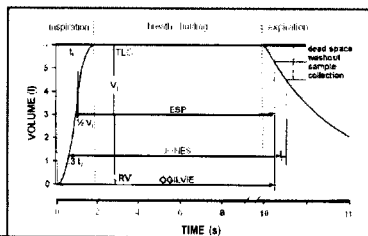
Breath hold time

- 10 ± 2 seconds
- Avoid valsalva (expiratory efforts against a closed airway) and Muller maneuvers (inspiratory efforts against a closed airway) during the breath-hold, by decreasing and increasing thoracic blood volume respectively, will decrease and increase DLCO respectively

2005 ATS/ERS Standards
Standardization of Diffusing Capacity

Calculating breath-hold time

- Jones and Meade method is recommended



2005 ATS/ERS Standards
Standardization of Diffusing Capacity

Washout and sample collection volume

- Pre-sample washout volume should be 0.75 to 1.0 liter, 0.5 liter in patients with IVC < 2.0 liter.
- A gas sample taken before anatomic dead space has cleared will be contaminated by inspired gas (not pure alveolar).
- In patients with maldistribution of ventilation (COPD) timing of gas collection may be more important.

2005 ATS/ERS Standards
Standardization of Diffusing Capacity

Washout and sample collection volume

- Sample volume of 0.50 to 1.00 L should be collected for analysis
- In patients with VC < 1 L, smaller sample volumes below 0.50L may be used if it can be assured that VD has been cleared
- Allow 4 minutes in between tests

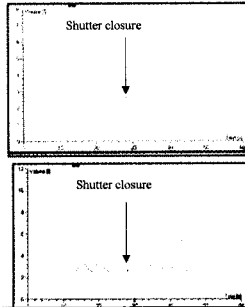
2005 ATS/ERS Standards
Standardization of Diffusing Capacity

Miscellaneous factors

- Diurnal variation
 - One study showed DLCO fell 1.2-2.2% per hour throughout the day.
- Menstrual cycle
 - 13% fall during cycle
- Alcohol use
- Bronchodilators (effect on VA)

ATS/ERS Standards
Standardization of Lung Volumes

- Alternative method
 - Patient then performs an IC followed by a slow exp. VC



2005 ATS/ERS Standards
Standardization of Lung Volumes

Reporting (Preferred method)

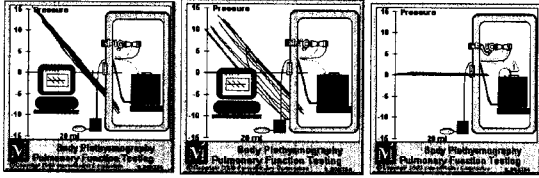
- Reported FRC is the mean of the technically satisfactory measurements linked to the technically satisfactory ERV and IVC maneuvers used for calculating RV and TLC.
- Reported TLC is the reported value for RV plus the largest of the technically acceptable IVC's
- Repeatability- Highest-Lowest/Mean

2005 ATS/ERS Standards
Standardization of Lung Volumes

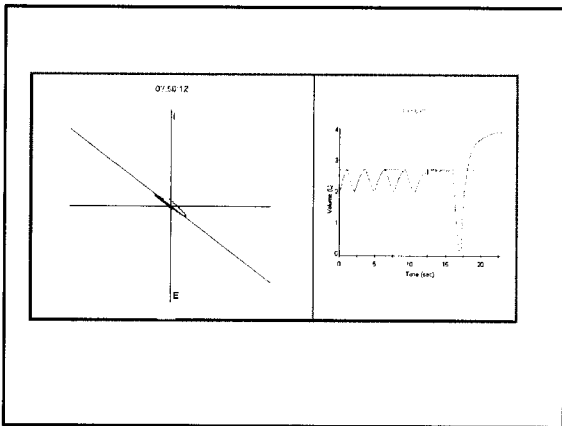
Reporting – Alternative Method

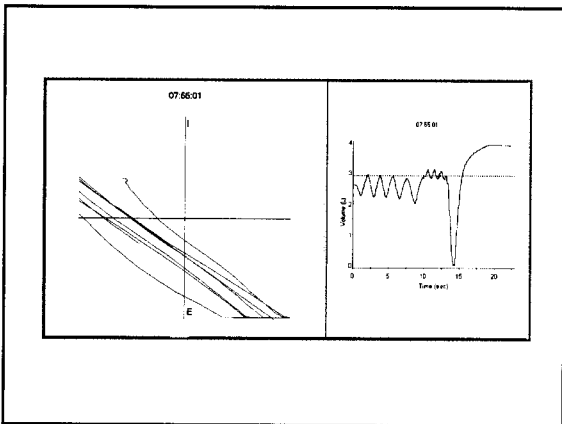
- Reported FRC is the mean of technically acceptable measurements used for the calculation of TLC
- Reported TLC mean of the 3 largest sums of technically acceptable FRC and linked IC maneuvers

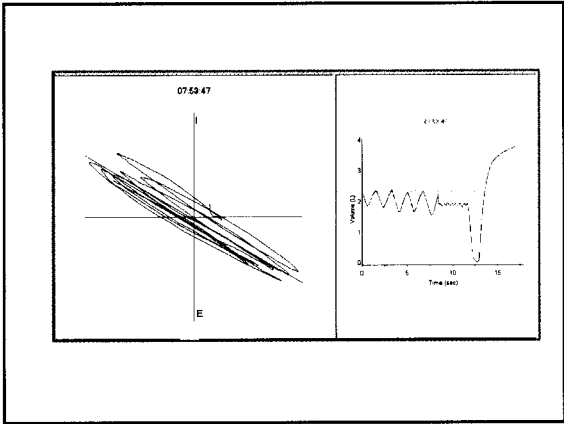
Vtg Lung Volume Standard

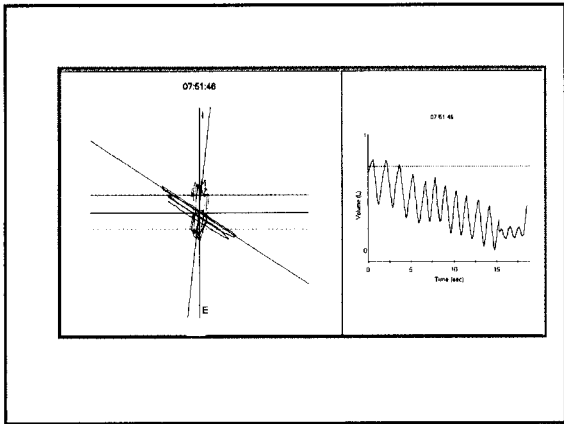


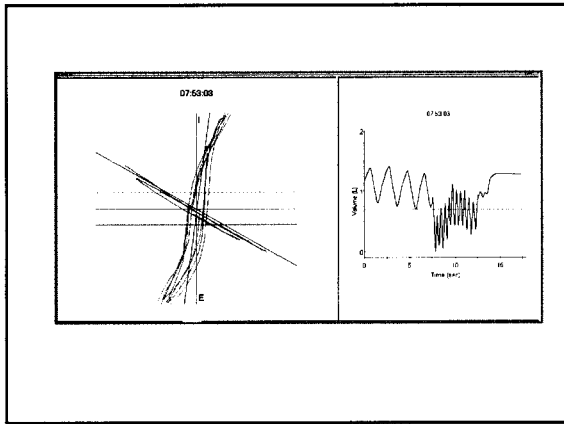
Acceptable Tracing Excessive Signal Drift No Pressure Signal

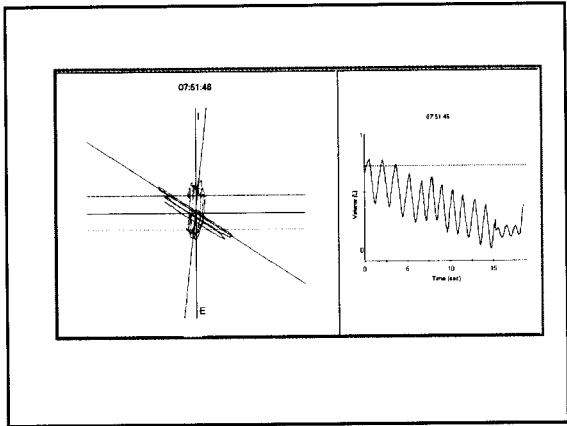






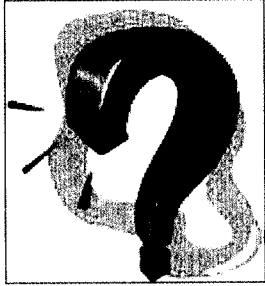






- Accuracy is Clinically Important**
- Differential diagnosis
 - Obstruction
 - Restriction
 - IPF lung transplant listing
 - COPD LVRS indication
 - <40% predicted DLCO
 - Treatment response
 - Side-effects of medications

Doing it Right!



Thank-you!

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