ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
QUALITY CONTROL OF PFT DATA

Form Completion Instructions:

Forms 17A and 17B will only be used by Clinical Coordinating Center personnel. There may be multiple Form 17A's submitted for each PFT session, since the results may be reviewed by more than one reviewer.

Note that Form 17B (Pulmonary Physician Review) is completed only when the reviewers obtain different reproducibility scores for the same PFT session.

See Section 4.9 of the Manual of Operations for a detailed explanation of quality control procedures. See also Appendix 9.5.

ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
Quality Control of PFT Data Form

This form is completed by the Clinical Coordinating Center for each PFT form submitted by Clinical Centers.

1. Date form completed:..... ___ ___/ ___ ___/
   month day

1a. Reviewer Code Number: .....

2. Patient Registry ID: .....

3. Patient name code:..... ___ ___

4. Clinical Center code number:..... .....___ ___

5. Date of pulmonary function tests:..... ___ ___/ ___ ___/ ___ ___
   month day year

6. Three liter calibration attached: .....___

6a. Three liter calibration a .....___

7. Weekly contr .. (1=Yes, 2=No) .....___

8. Quer , 2=No): .....___

9 ..... ___ ___/ ___ ___/ ___ ___
   month day year

received:..... ___ ___/ ___ ___/ ___ ___
   month day year

RY PRE-BRONCHODILATOR

	TEST 1	TEST 2	TEST 3
11. Cough before 1st second? (1=Yes, 2=No)	___	___	___
12. FEF 50% (L/sec):	___.___ ___	___.___ ___	___.___ ___
13. PEF (L/sec) (BTPS):	___ ___.___	___ ___.___	___ ___.___
14. EV (L) (BTPS):	___.___	___.___	___.___
15. EV/FVC (%):	___ ___.___ ___	___ ___.___ ___	___ ___.___ ___
16. Exp. Test Time (secs):	___ ___.___	___ ___.___	___ ___.___
17. Start of test criteria met? (1=Yes, 2=No)	___	___	___
18. End of test criteria met? (1=Yes, 2=No)	___	___	___

White/Yellow: Clinical Coordinating Center, Pink: Clinical Center

PWO 1882

No SAS Dataset Made For This Form

Patient Registry ID: ___ ___ ___ ___ ___
Date of Tests: ___ ___/ ___ ___/ ___ ___
month day year

	TEST 1	TEST 2	TEST 3
19. Acceptability Rating: (2 points each for each acceptable curve)	___	___	___
20. Reproducibility Rating (FEV_1): (2 points for each FEV_1 within 5% or 100 ml of largest, largest = 2 points, unless no other reproducible FEV_1s, then all = 0 points)	___	___	___
21. Patient Reproducibility Factor for Session:			___ ___
22. Ratable? (1=Yes, 2=No):	___	___	___

For questions 23-24: Rate reproducibility of FVC and FEV_1, regardless of Acceptability Rating.

23. FVC Reproducibility (2 points each for each acceptable curve)	___	___	___
24. FEV_1 Reproducibility: (2 points for each FEV_1 within 5% or 100 ml of largest, largest = 2 points, unless no other reproducible FEV_1s, then all = 0 points)	___	___	___

Comments: _____

_____

_____

_____

SPIROMETRY POST-BRONCHODILATOR

	TEST 1	TEST 2	TEST 3
25. Cough before 1st second? (1=Yes, 2=No)	___	___	___
26. FEF 50% (L/sec):	___.___ ___	___.___ ___	___.___ ___
27. PEF (L/sec) (BTPS):	___ ___.___	___ ___.___	___ ___.___
28. EV (L) (BTPS):	___.___	___.___	___.___
29. EV/FVC (%):	___ ___.___ ___	___ ___.___ ___	___ ___.___ ___
30. Exp. Test Time (secs):	___ ___.___	___ ___.___	___ ___.___
31. Start of test criteria met? (1=Yes, 2=No)	___	___	___
32. End of test criteria met? (1=Yes, 2=No)	___	___	___

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Patient Registry ID: ___ ___ ___ ___ ___
Date of Tests: ___ ___/ ___ ___/ ___ ___
month day year

	TEST 1	TEST 2	TEST 3
33. Acceptability Rating: ..... (2 points each for each acceptable curve)	___	___	___
34. Reproducibility Rating (FEV_1):..... (2 points for each FEV_1 within 5% or 100 ml of largest, largest = 2 points, unless no other reproducible FEV_1s, then all = 0 points)	___	___	___
35. Patient Reproducibility Factor for Session:	___	___	
36. Ratable? (1=Yes, 2=No):	___	___	___

For questions 37-38: Rate reproducibility of FVC and FEV_1, regardless of Acceptability Rating.

37. FVC Reproducibility..... (2 points each for each acceptable curve)	___	___	___
38. FEV_1 Reproducibility:..... (2 points for each FEV_1 within 5% or 100 ml of largest, largest = 2 points, unless no other reproducible FEV_1s, then all = 0 points)	___	___	___

Comments: _____

_____

_____

_____

Reviewer Signature: _____

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PWO 1882

Notes on Coding:

This form underwent five revisions during the study. Question numbers on earlier hard copy versions of the form do not always match this form.

The most recent version (Rev 5 8/95) prior to this version included only questions 1-10, 11, 16, 17, 18, 22, 25, 30, 31, 32, and 36.

Questions 11-20, 22-38 each have three variables in the data base, named with suffixes A, B, C to identify tests A, B, C respectively.

ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
Quality Control of PFT Data Form
Pulmonary Physician Review

This form is completed by the Pulmonary Physician for each PFT data form submitted.

1. Date form completed:..... ___ ___/ ___ ___/ ___ ___ (month / day / year)

1a. Pulmonary Physician Reviewer Code Number: ..... ___

2. Patient Registry ID: ..... ___ ___ ___ ___ ___

3. Patient name code:..... ___ ___ ___ ___

4. Clinical Center code number:..... ___ ___

5. Date of pulmonary function tests:..... ___ ___/ ___ ___/ ___ ___ (month / day / year)

5a. Visit type:..... ___(1)Initial ___(2)Follow-Up

		REVIEW A Rev. Code #:___ PFT Rev. Date: ___ ___/___ ___/___ ___	REVIEW B Rev. Code #:___ PFT Rev. Date: ___ ___/___ ___/___ ___	MD REVIEW
*6.	Pre-BD Pt. Repro. Score:.....	___ ___	___ ___	___ ___
*7.	Post-BD Pt. Repro. Score:	___ ___	___ ___	___ ___
8.	Pre-BD FVC Repro. Score:.....	___ ___	___ ___	___ ___
9.	Pre-BD FEV_1 Repro. Score:.....	___ ___	___ ___	___ ___
10.	Post-BD FVC Repro. Score:.....	___ ___	___ ___	___ ___
11.	Post-BD FEV_1 Repro. Score:....	___ ___	___ ___	___ ___

Physician Reviewer Signature: _____

Comments: _____

_____

*Patient Reproducibility Score first assesses acceptability of the test in strict accordance with ATS criteria. Each acceptable effort is awarded 2 points. Each acceptable curve is then assessed for reproducibility of the FEV1. Each FEV1 is awarded 2 points if it is within 5% or 100 ml of the largest FEV1, whichever is larger. Unacceptable efforts automatically receive 0 (zero) points for reproducibility. A minimum score for a testing session that meets ATS criteria for acceptability and reproducibility (three acceptable curves at 2 points each plus the two largest FEV1 values within 5% or 100 ml of each other) at 2 points each = 6 + 4 = 10 points/session.
**Reproducibility-Only Assessment awards 2 points for each reproducible FVC or FEV1 reported on Form #03 regardless of the acceptability of the curve they were reported from.

White/Yellow: Clinical Coordinating Center, Pink: Clinical Center

Notes on Coding:

Questions 6-11:

Only the MD Review Scores were entered into the database:

F17BQ06 = Pre-BD Pt. Repro. Score, MD Review

⋮

F17BQ11 = Post-BD FEV1 Repro. Score, MD Review

A later revision (Rev 2, 11/89) dropped questions 8, 9, 10, and 11.