

**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 >
7. Weekly control (1=Yes, 2=No)
8. Question (1=Yes, 2=No):
9. Received:..... month / day / year

No SAS Dataset Made For This Form

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

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 ₁ s, 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 FEV₁, 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 ₁ s, 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)	---	---	---

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

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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 ₁ s, 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 FEV₁, 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 ₁ s, 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	REVIEW B	MD REVIEW
Rev. Code #:____	Rev. Code #:____	
PFT Rev. Date: ____/____/____	PFT Rev. Date: ____/____/____	

- | | | |
|---|-------|-------|
| *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.

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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.