

**ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
INITIAL VISIT FORM - PART B**

Form Completion Instructions:

The units for reporting each laboratory measurement are indicated on the form. If the value is reported to the Clinical Center in units other than those listed, the Clinical Center must convert the value to the correct units and record that value on the form. **DO NOT** cross off the pre-printed unit of measure to write in another.

<u>QUESTION #</u>	<u>ITEM</u>	<u>INSTRUCTIONS</u>
6-9	Bloodwork	Record the results of each of the specified tests that were done with the \pm 3 month time window. If, for instance, blood gases are not done or not available, record "00/00/00" for the date and skip each of the items listed below it or write in "NOT DONE" over the entire section. If a series of tests are done, but the test tube breaks or becomes contaminated and results cannot be determined, enter a "9" in each of the dashes. Identify whether the arterial blood gases were drawn pre- or post-bronchodilator.
10-11	Chest X-Ray	Results from a chest x-ray within the past year should be recorded at the time of the initial visit to the Clinical Center. Results of CT scans can be written in the comment section following the x-ray questions.
12	Urinalysis	Routine lab report results should be entered here. Enter 9's if unknown. Be as complete as possible.

ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
Initial Visit Form - Part B

This form should be completed at the patient's first Registry visit. Non-physician personnel can complete this form.

1. Date form completed: F2BQ01-fzd (fuzzed) ___/___/___
month day year
2. Patient Registry ID: Newid (scrambled)
3. Patient name code: namecode (censored)
4. Clinical Center code number: clinic (censored)
5. Date of visit: F2BQ05-fzd (fuzzed) ___/___/___
month day year
visit number vsno

LABORATORY RESULTS

It is preferred that laboratory tests be done at the Clinical Centers, however, data from outside laboratories will be accepted.

Complete Blood Count

6. a. Date Blood Drawn: F2BQ06A-fzd (fuzzed) ___/___/___
month day year
- b. Location of test: F2BQ06B (1) Registry Clinical Center (code: F2BQ06B2 (censored))
____ (2) Local Physician's office
____ (3) Other (Specify): never entered
____ (9) Unknown
- c. White Blood Count ($\times 10^3$ mm³): F2BQ06C
- d. Hemoglobin (g/dl): F2BQ06D
- e. Hematocrit (%): F2BQ06E

Serum Chemistries/Enzymes

7. a. Date Blood Drawn: F2BQ07A-fzd (fuzzed) ___/___/___
month day year
- b. Location of test: F2BQ07B (1) Registry Clinical Center (code: F2BQ07B2 (censored))
____ (2) Local Physician's office
____ (3) Other (Specify): never entered
____ (9) Unknown
- c. Creatinine (mg/dl): F2BQ07C

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

PWO 1863

Patient Registry ID: _____
Date of Visit: _____/_____/_____
month day year

Hemoglobin Oxygen Saturation (SaO₂)

9. a. Date of SaO₂ measurement..... F2BQ09A-fzd (fuzzed) / ____ / ____
month day year
- b. Location of SaO₂ test: F2BQ09B..... F2BQ09B2
 (1) Registry Clinical Center (code: censored)
 (2) Local Physician's office
 (3) Other (Specify): never entered
 (9) Unknown
- c. How was SaO₂ measured: F2BQ09C..... (1) by blood gas analysis
 (2) by pulse oximeter
 (3) calculated
- d. SaO₂ (%)..... F2BQ09D..... _____

CHEST X-RAY

10. a. Date of chest x-ray: F2BQ10A-fzd (fuzzed) ____ / ____ / ____
month day year
- b. Location of test: F2BQ10B..... F2BQ10B2
 (1) Registry Clinical Center (code: censored)
 (2) Local Physician's office
 (3) Other (Specify): Never entered
 (9) Unknown
11. a. Results of chest x-ray: F2BQ11A..... (0) Normal (1) Abnormal
 If Abnormal,
 b. Evidence of Hyperinflation: F2BQ11B..... (1) Yes (2) No
 c. Bullae: F2BQ11C..... (1) Yes (2) No
 d. Cancer: F2BQ11D..... (1) Yes (2) No
 e. Interstitial Lung Disease: F2BQ11E..... (1) Yes (2) No
 f. Cardiomegaly: F2BQ11F..... (1) Yes (2) No
 g. Pneumothorax: F2BQ11G..... (1) Yes (2) No

Patient Registry ID: _____
Date of Visit: _____/_____/_____
month day year

Chest X-Ray, continued:

h. Other Abnormal Findings (Specify in comments section): F2BQ11H (1) Yes _____(2) No

i. Evidence of hyperlucency:..... F2BQ11I (1) Yes _____(2) No

If YES,

- 1. Location of hyperlucency: F2BQ11I
 - ___(1) Diffuse (Upper and lower lung zones only)
 - ___(2) Lower lung zones only (one or both sides)
 - ___(3) Upper lung zones only (one or both sides)

Comments regarding chest x-ray: never entered

j. Other radiological evidence of emphysema (1) yes (2) No F2BQ11J

Urinalysis

12. a. Date of urinalysis:..... F2BQ12A.. Fzd (fuzzed)/.../...
month day year

b. Location of test:..... F2BQ12B (1) Registry Clinical Center (code: ^{F2BQ12B2} ~~censored~~)
 ___(2) Local Physician's office
 ___(3) Other (Specify): never entered
 ___(9) Unknown

c. Glucose: ... F2BQ12C ___(0) Neg/Normal ___(3) 3+(1000mg/dl)
 ___(5) Trace (100mg/dl) ___(4) 4+(>2000mg/dl)
 ___(1) 1+(250mg/dl) ___(9) Unknown
 ___(2) 2+(500mg/dl)

d. Bilirubin: ... F2BQ12D ___(0) Neg/Normal ___(3) 3+(large)
 ___(1) 1+(small) ___(9) Unknown
 ___(2) 2+(moderate)

e. Ketones: ... F2BQ12E ___(0) Neg/Normal ___(3) 80
 ___(5) Trace (5) ___(4) >160
 ___(1) Small (15) ___(9) Unknown
 ___(2) Moderate (40)

f. Specific gravity: ... F2BQ12F

g. Blood, occult: F2BQ12G (1) Yes ___(2) No ___(9) Unknown
 White/Yellow: Clinical Coordinating Center, Pink: Clinical Center

Patient Registry ID: _____
Date of Visit: ____/____/____
 month day year

Urinalysis, continued:

h. pH: F2BQ12H

- i. Protein:..... F2BQ12I.....
- | | |
|------------------------|---------------------------|
| _____ (0) Neg/Normal | _____ (3) 3+(300mg/dl) |
| _____ (5) Trace | _____ (4) 4+(>2000mg/dl) |
| _____ (1) 1+(30mg/dl) | _____ (9) Unknown |
| _____ (2) 2+(100mg/dl) | |

j. Casts: F2BQ12J /LPF
If casts = "000," skip to end of form.

If casts >0, identify type of casts:

- | | | | |
|----------------------------------|---------------|--------------|-------------------|
| 1. RBC: F2BQ12J1..... | _____ (1) Yes | _____ (2) No | _____ (9) Unknown |
| 2. WBC: F2BQ12J2..... | _____ (1) Yes | _____ (2) No | _____ (9) Unknown |
| 3. Hyaline: F2BQ12J3..... | _____ (1) Yes | _____ (2) No | _____ (9) Unknown |
| 4. Granular: F2BQ12J4..... | _____ (1) Yes | _____ (2) No | _____ (9) Unknown |
| 5. Other: F2BQ12J5..... | _____ (1) Yes | _____ (2) No | _____ (9) Unknown |

Specify: never entered

For WBC, RBC, Epithelial Cells, and Bacteria use the following scale:

0=0-5/HPF, negative, trace, rare, occasional, few
1=6-20/HPF, 1+, 2+, some, moderate
2=>20/HPF, 3+, 4+, great, many, too numerous to count
9=Unknown

k. WBC: F2BQ12K

l. RBC: F2BQ12L

m. Epithelial Cells: F2BQ12M

n. Bacteria: F2BQ12N

Form Completed By (Name): never entered

Notes on Coding:

Additional variables coded by the CCC:

Question 11j. Other radiological evidence of emphysema: ___(1)Yes ___(2)No

Coded by CCC personnel based on comments provided in question 11.

Variable name: F2BQ11J