ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
FOLLOW-UP 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.

QUESTION #	ITEM	INSTRUCTIONS
6-10	Bloodwork	Record the results of each of the specified tests that were analyzed at your Clinical Center's laboratory. If, for instance, blood gases were not done, record "00/00/00" for the date and skip each of the items listed below it or indicate "NOT DONE" in large print over the entire section of tests not performed. If a series of tests were done, but the test tube breaks or becomes contaminated and results can be determined, enter a "9" in each of the dashes.
8	Serum Level	An Alpha 1-antitrypsin serum level may be obtained at each follow-up visit. If the patient is receiving augmentation therapy, the alpha 1-antitrypsin level should be obtained immediately prior to infusion of the therapy or within one day prior to infusion. Record results in micromolar units. To convert: mg/dl x .1923 = lab value in μM. See Section 4.11.
11-12	Chest X-Ray	Results from a chest x-ray within the past six months can be recorded at the time of each follow-up visit to the Clinical Center. CT scan results can be recorded in the comment section.
13	Urinalysis	Routine lab report results should be entered here. Enter 9's if unknown.

ALPHA 1-ANTITRYPSIN DEFICIENCY REGISTRY
Follow-Up Visit Form - Part B

This form should be completed for every follow-up visit. Except for medical history, a non-physician should complete this form.

1. Date form completed: F5BQØ1_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: F5BQØ5_fzd (fuzzed) ___ ___/ ___ ___/ ___ ___ (month / day / year)
   Visit number vsno

LABORATORY RESULTS

Complete Blood Count

6. a. Date Blood Drawn: F5BQØ6A_fzd (fuzzed) ___ ___/ ___ ___/ ___ ___ (month / day / year)

   b. Location of test: F5BQØ6B
   ___(1)Registry Clinical Center (code: F5BQØ6B2 censored)
   ___(2)Local Physician's office
   ___(3)Other (Specify): never entered
   ___(9)Unknown

   c. White Blood Count ($x10^3$ mm^3): F5BQØ6C ___ ___ ___.___

   d. Hemoglobin (g/dl): F5BQØ6D ___ ___.___

   e. Hematocrit (%): F5BQØ6E ___ ___.___

Serum Chemistries/Enzymes

7. a. Date blood drawn: F5BQØ7A_fzd (fuzzed) ___ ___/ ___ ___/ ___ ___ (month / day / year)

   b. Location of test: F5BQØ7B
   ___(1)Registry Clinical Center (code: F5BQØ7B2 censored)
   ___(2)Local Physician's office
   ___(3)Other (Specify): never entered
   ___(9)Unknown

   c. Creatinine (mg/dl): F5BQØ7C ___ ___.___

   d. Blood Urea Nitrogen (mg/dl): F5BQØ7D ___ ___ ___

   e. SGPT (IU/L): F5BQØ7E ___ ___ ___ ___

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

Serum Chemistries/Enzymes, continued:

f. SGOT (AST) (IU/L): F5BQØ7F ___ ___ ___ ___

g. Alkaline Phosphatase (IU/L): F5BQØ7G ___ ___ ___ ___

h. Total Bilirubin (mg/dl): F5BQØ7H ___ ___.___

i. Serum Bicarbonate (measured) (mEq/L) HCO_3: F5BQØ7I ___ ___.___

Alpha 1-Antitrypsin Serum Level

8. a. Date Blood Drawn: F5BQØ8A_fzd (fuzzed) ___ ___/ ___ ___/ ___ ___
month day year

b. Location of test: F5BQØ8B ___(1)Registry Clinical Center (code: F5BQØ8B2 censored)

___(2)Local Physician's office

___(3)Other (Specify): never entered

___(9)Unknown

c. Alpha 1-antitrypsin serum level (micromolar): F5BQØ8C ___ ___.___ ___

c. 1. Is this an adjusted value? (See Forms Instructions) F5BQØ8C1 ___(1)Yes ___(2)No

d. If female, is patient pregnant? F5BQØ8D ___(1)Yes ___(2)No

e. If YES, how many months pregnant? F5BQØ8E ___.___

Arterial Blood Gases

9. a. Date Blood Drawn: F5BQØ9A_fzd (fuzzed) ___ ___/ ___ ___/ ___ ___
month day year

b. Location of test: F5BQØ9B ___(1)Registry Clinical Center (code: F5BQØ9B2 censored)

___(2)Local Physician's office

___(3)Other (Specify): never entered

___(9)Unknown

1. ABGs taken in relationship to PFT bronchodilator: F5BQØ9B1 ___(1)Pre-BD ___(2)Post-BD

c. Position: F5BQØ9C ___(1)Sitting ___(2)Recumbent ___(3)Semi-recumbent

d. Is patient on supplemental oxygen? F5BQØ9D ___(1)Yes ___(2)No

If YES, complete Questions 9e - f. If NO, skip to Question 9g.

e. Duration of time off oxygen before sample taken: F5BQØ9E1 ___ hour F5BQØ9E2 ___ min

f. Usual Liter Flow (L/minute): F5BQØ9F ___ ___ ___

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

Arterial Blood Gases, continued:

g. PaO_2 (mmHg): F5BQ09G ___ ___ ___

h. $PaCO_2$ (mmHg): F5BQ09H ___ ___ . ___

i. pH: F5BQ09I ___.___ ___

j. Serum Bicarbonate (calculated) (mEq/L) HCO_3: F5BQ09J ___ ___.___

k. Carboxyhemoglobin (%): F5BQ09K ___ ___.___

Hemoglobin Oxygen Saturation ($Sa0_2$)

10. a. Date of SaO_2 measurement: F5BQ10A-Fzd (fuzzed) ___ ___/ ___ ___/ ___ ___
month day year

b. Location of SaO_2 test: F5BQ10B ___(1)Registry Clinical Center (code: F5BQ10B2 censored)
___(2)Local Physician's office
___(3)Other (Specify): never entered
___(9)Unknown

c. How was SaO_2 measured: F5BQ10C ___(1)by blood gas analysis
___(2)by pulse oximeter
___(3)calculated

d. SaO_2 (%): F5BQ10D ___ ___ ___ . ___

CHEST X-RAY

11. a. Date of chest x-ray: F5BQ11A-Fzd (fuzzed) ___ ___/ ___ ___/ ___ ___
month day year

b. Location of test: F5BQ11B ___(1)Registry Clinical Center (code: F5BQ11B2 censored)
___(2)Local Physician's office
___(3)Other (Specify): never entered
___(9)Unknown

12. a. Results of chest x-ray: F5BQ12A ___(0)Normal ___(1)Abnormal

If Abnormal,

b. Evidence of Hyperinflation: F5BQ12B ___(1)Yes ___(2)No

c. Bullae: F5BQ12C ___(1)Yes ___(2)No

d. Cancer: F5BQ12D ___(1)Yes ___(2)No

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

Chest X-Ray Findings, continued:

e. Interstitial Lung Disease: F5BQ12E ___(1)Yes ___(2)No

f. Cardiomegaly: F5BQ12F ___(1)Yes ___(2)No

g. Pneumothorax: F5BQ12G ___(1)Yes ___(2)No

h. Other Abnomal Findings (Specify in comments section): F5BQ12H ___(1)Yes ___(2)No

i. Evidence of hyperlucency: F5BQ12I ___(1)Yes ___(2)No
If YES,
1. Location of hyperlucency: F5BQ12I1
___(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

Urinalysis

13. a. Date of urinalysis: F5BQ13A-fzd (fuzzed) ___ ___/ ___ ___/ ___ ___
month day year

b. Location of test: F5BQ13B ___(1)Registry Clinical Center (code: F5BQ13B2 censored)
___(2)Local Physician's office
___(3)Other (Specify): never entered
___(9)Unknown

c. Glucose: F5BQ13C ___(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: F5BQ13D ___(0)Neg/Normal ___(3)3+(large)
___(1)1+(small) ___(9)Unknown
___(2)2+(moderate)

e. Ketones: F5BQ13E ___(0)Neg/Normal ___(3)80
___(5)Trace (5) ___(4)>160
___(1)Small (15) ___(9)Unknown
___(2)Moderate (40)

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

Urinalysis, continued:

f. Specific gravity: F5BQ13F ___.___ ___ ___

g. Blood, occult: F5BQ13G ___(1)Yes ___(2)No ___(9)Unknown

h. pH: F5BQ13H ___.___

i. Protein: F5BQ13I ___(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: F5BQ13J ___ ___ ___/LPF
If casts = "000," skip to end of form.

If casts >0, identify type of casts:

1. RBC: F5BQ13J1 ___(1)Yes ___(2)No ___(9)Unknown
2. WBC: F5BQ13J2 ___(1)Yes ___(2)No ___(9)Unknown
3. Hyaline: F5BQ13J3 ___(1)Yes ___(2)No ___(9)Unknown
4. Granular: F5BQ13J4 ___(1)Yes ___(2)No ___(9)Unknown
5. Other: F5BQ13J5 ___(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: F5BQ13K ___

l. RBC: F5BQ13L ___

m. Epithelial Cells: F5BQ13M ___

n. Bacteria: F5BQ13N ___

Form Completed By (Name): never entered

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