PULMONARY AIDS CLINICAL STUDY FORM V - SPECIMEN EVALUATION FORM

Introduction

There are a number of procedures that will be performed throughout the study. These procedures will result in specimens for analysis. When a procedure is performed, two forms must be filled out: one describing the procedure itself (Sputum Collection Form--M, Bronchoscopy Form--B, or Other Diagnostic Procedures--O) and the other describing the specimen taken and the results of the analysis of the specimen (Specimen Evaluation Form--V). For a given procedure each specimen requires a separate specimen evaluation form. Thus, if bronchoscopy is performed and both bronchoalveolar lavage and a biopsy are taken, then a separate specimen form must be filled out for each of these specimens.

Version Date: The version date of the form, located in the upper right corner of the form, should be checked by the interviewer to insure that the correct version of the form is being used.

- Patient ID: The patient's ID label should be affixed here. If a label is not available, the ID should be printed neatly in the space provided.
- 2. Clinic: Enter the two digit clinic-specific ID number in the boxes provided. For all clinics that are composed of only one primary center, a '01' should be entered. If there is more than one clinic at a particular center, the investigator at the center should assign each clinic a different clinic ID number beginning with '01' and going in sequence. A list of the assigned clinic numbers should then be sent to the Coordinating Center.
- 3. a. **Current Date**: Enter the date the form was completed. This date must be recorded as a complete date.
 - b. **Time of Procedure**: Record military time procedure was performed or 00:00.

- 4. Type of Specimen: This section links the form to the one of the three procedure forms (Sputum Collection, Bronchoscopy, Other Diagnostic Procedures). Check only one box and use only one form for each specimen. Write in the site the specimen was taken from. Be as specific as possible, e.g., for endobronchial biopsy the answer could be *R Mainstem bronchus*.
- 5. Results: Each specimen may have many different tests performed on it. Check the box corresponding to whether the particular test listed was completed on the specimen. If so, give the positive diagnosis code corresponding to the diagnosis found. Example: 32 herpes simplex and 31 cytomegalovirus may grow out of viral cultures, so both codes would be entered. The diagnosis (page V-4) are divided by type. Some ARE quite specific and self-explanatory such as 43, S. Pneumoniae, others are nonspecific such as 46G+ cocci (gram positive cocci). The latter descriptive would result from a stain. The former from a culture. Do not make assumptions about a specific diagnosis. If the lab result says *G+ cocci* do not assume it is *S. penumoniae*.
- 6. Visit Type: Indicate the visit type by checking the appropriate box. If **Baseline** or **Scheduled Follow-up** visit, skip to Question 8.
- 7. **Qualify as Scheduled Visit**: Indicate Yes or No if the symptom generated or one month follow-up visit qualifies by protocol definition as a scheduled visit. If the visit does not qualify as a scheduled visit, skip to Question 9.
- 8. Scheduled Follow-up Month: If baseline visit, enter 00 in the boxes provided. Otherwise, indicate which scheduled follow-up visit the form is being completed for. For routine patients, these should be the 06, 12, 18, 24, 30, 36, 42 and 48 month visits. For intense patients, these should be the 03, 06, 09, 12, 15, 18, etc. month visits.
- 9. Date of Associated Intake, Interval, or Hospital Form: Indicate the date of the Intake, Interval, or Hospital form that was completed at the visit in which this form is also being completed. If no Interval, Intake or Hospital form is associated with this form, the date should be left blank and keyed as a -1 in the Day boxes.

Form Reviewer/Date: The individual, other than the interviewer, that reviews the form for completeness and correctness should print their name and the date the form was reviewed in a legible manner in the space provided.

Form Keyer/Date: The individual that keys the form using the RTIDE screen entry package should print their name and the date the form was keyed in a legible manner in the space provided.

89 0 1 NOV

FORM V

PULMONARY COMPLICATIONS OF HIV INFECTION SPECIMEN EVALUATION FORM

1.	Pat	ient ID						
2.	Cli	nic			Day	 Month		ear
3.	Date	e of Collection						
	Time	e of Day (Military Tim	e)				•	
4.		E OF SPECIMEN (check o	nly one):	Site	:		1000-10-00-00-00-00-00-00-00-00-00-00-00	
	Α.	Sputum (spontaneous)	₀₁					
	Β.	Sputum (induced)	02		9 <u></u>			
	C.	Bronchoalveolar Lavage	03					
	D.	Protected Specimen Brush	04					
	E.	Transbronchial Needle Aspirate	05			~		
	F.	Transbronchial Bx	06		<u></u>			
	G.	Endobronchial Bx	07				1997-749-88 A. O. C. C. M. BORL & Margin &	
	H.	Pleural Fluid					an de campital	gan yin da da angingi man na man
	Ι.	Pleural Bx	09					
	J.	Open Lung Bx						
	K.	Lymph Node Bx						
	L.	Other						
	Spe	cify:	an a					

FORM	FORM V		Version:	0 1 N 0 V 8 9
5. F	Results:		Completed	
ļ	A. St	ains:	Yes No	Positive Diagnosis
	1.	Giemsa	y n	
	2.	Silver	y n	
	3.	Toluidine Blue	y n	
	4.	PAS	y n	
	5.	H & E	y n	
	б.	PAP	y n	
	7.	AFB	y n	
	8.	Gram	y n	
	9.	Dieterle		
	10	Other	y n	
Ē	3. M	AB	y n	
(C. D	NA Probe	y n	
[). D	Specify: FASpecify:	y n	

V-2

FORM V		Version:	0 1 N 0 V 8 9
E.	Path	y n	
F.	Fungal Culture		
G.	Bacterial Culture	y n	
Η.	Viral Culture		
Ι.	Mycobacterial Culture	y n	

 $= \frac{1}{2} + s \frac{1}{2} \left(s + \frac{1}{2} \right) + \frac{1}{2} \left(s +$

FORM V		Version:	0 1 N 0 V 8 9
DIAGNOSIS CODE	S FOR SPECIMENS:		
Parasites	101 Pneumocystis Carinii 102 Toxoplasmosis 103 Cryptosporidium 199 Other Parasites (specify)		
Mycobacterium	201 M. Tuberculosis 202 M. Avium-Intracellularae 203 M. Kansasii 204 M. Gordonnae 205 M. Xenopi 206 AFB 298 Culture Pending 299 Other Mycobacteria (specify)		
Fungal	<pre>301 Cryptococcosis 302 Histoplasmosis 303 Coccidioidomycosis 304 Candidiasis 305 Blastomycosis 306 Aspergillosis 399 Other Fungus (specify)</pre>		
Virus	401 Cytomegalovirus 402 Herpes Simplex 403 Varicella-zoster 404 Inclusion Bodies 499 Other Virus (specify)		
Bacteria	501 Legionella 502 Mycoplasma 503 S. Pneumoniae 504 H. Influenzae 505 S. Aureus 506 G+ Cocci 507 G+ Rods 508 G- Cocci 509 G- Rods 599 Other (specify)		
Neoplasm	601 Kaposi's Sarcoma 602 Lymphoma 603 Squamous Cell Carcinoma 604 Adenocarcinoma 605 Large Cell Carcinoma 606 Small Cell Carcinoma 607 Malignant Cells 699 Other (specify)		
Other Path	901 LIP 902 Nonspecific Interstitial Pneu 903 Lymph Node Hyperplasia 904 Granulomatous Inflammation 999 Other (specify)		

FORM V Version: 01 N0V 89
6. Visit Type: Baseline Scheduled Follow-up Symptom Generated
One Month Follow-up Hospital
* If Baseline or Scheduled Follow-up, skip to 8. Yes No
7. Does this visit qualify as a scheduled visit?
If No, skip to 9.
8. For which scheduled follow-up visit does this qualify? month (00=Baseline; 03 month, 06 month, 09 month, etc.)
9. Date of Intake, Interval, or Hospital Form associated with this form:
Day Month Year
Form Reviewed By: Date Date
Form Keyed By: Date: