IMMUNOLOGY AND VIROLOGY FORMS

HIV WESTERN BLOT

FORM # 21

INSTRUCTIONS

Complete this form for Group IIb patients (controls and those randomized off study) at month 18, if the 18 month ELISA test is POSITIVE. If the 18 month ELISA test is negative, this form is not required.

ITEM # INSTRUCTIONS/NOTES 1a The "date of the specimen" is the date the serum sample is taken. 2a - 2i Complete if response to 1c is "1" (positive) or "3" (equivocal). Respond to each item listed. Positive Western Blot = 1. positive p24, p31 and p41, or 2. positive p120, or

3. positive pl60

HIV WESTERN BLOT

GROUPS I, II (0-23 MONTHS) AND IIa (24-52 MONTHS) PATIENTS

Patie	nt's	ID #: J D NO	Form #: 2 1	DT- FORM
Comple	eted	by:(print name)	Date Completed:	_///
Visit	: M	onth VISMTH		
1.	Wes	tern Blot:		DT-WB
	a.	Date of specimen (mm/dd/yy)		_// WBS NO
	b.	Specimen number	······	
	c.	Result 0 = negative 1 = positive 3 = equivocal		<u>w v</u>
		result is positive or equivocal, c		
2.	Wes	tern Blot banding patterns (responding of the control of the contr	d to each):	
	_	17		<u>WB</u> 17
	a. b.	24		WB24 WB31
	c.	31	• • • • • • • • • • • • • • • • • • • •	
	đ.	41		<u>WB41</u> WB51
	e.	51	• • • • • • • • • • • • • •	
	f.	55	• • • • • • • • • • • • • • • • • • • •	<u>WB5</u> 5
	g.	66		WB66
	h.	120		WBIZO
	i.	160		<u>WB160</u>
Enter	ed b	y: <u>CER7-NO</u> (cert. #)	Date entered:	DT_F/YENT _(mm/dd/yy)

HIV ELISA

FORM # 22

INSTRUCTIONS

Complete this form for Group IIb patients (controls and those randomized off study) at month 18.

ITEM # INSTRUCTIONS/NOTES

1a The "date of the specimen" is the date the serum sample is taken.

P²C² HIV HIV ELISA

GROUPS II, (0-23 MONTHS) AND IIb (24-52 MONTHS) PATIENTS

Patie Compl	leted	ID #:	Form #: 2 2 Date Completed:	DT- FORM // (mm/dd/yy)
1.	ELI a. b.	Date of specimen (mm/dd/yy)		DT-ELISA J-J- ELISASNO ELISA
Ente	red b	oy: (CERT-NO) (Cert. #)	Date entered:	DT- FMENT // (mm/dd/yy)

Form # 22.02 Rev. 08/01/91

HIV CULTURE

FORM # 23

INSTRUCTIONS

Routine Schedule:

Group II - Complete this form at baseline (not cord blood) and at months 3 and 6. (NOTE: If the baseline and month 3 HIV culture test are both <u>positive</u>, it is not necessary to repeat the test at month 6).

ITEM # INSTRUCTIONS/NOTES

The "date of the specimen" is the date the culture sample is taken.

HIV CULTURE

GROUP II PATIENTS

Patient's		Form #: 2 3 Date Completed:	DT-FORM
Completed b	y:(print name)	<u> </u>	$\frac{1}{mm/dd/yy}$
Visit: Mor	oth <u>VJSM</u> TH		
2. Date	of specimen (mm/dd/yy) placed in culture (mm/dd/yy) imen number	····· <u> </u>	DT-HIVS DT-HIVP HIVSNO
	consensus protocol method 1 = quantitative 2 = qualitative		AC <u>TG</u> PRO
5. Fina	<pre>1 Reading</pre>		HIV
Entered by	: <u>CERT-NO</u> (cert. #)	Date entered:	DT- FMENT _//_ (mm/dd/yy)

CMV SEROLOGY (PATIENT)

FORM # 24

INSTRUCTIONS

Schedule:

Group I - When clinically warranted.

Group II - Complete this form at month 6, 12, 18, 24, 30, 36, 42 and 48, 54, 60, 66, 72, 78. Testing will be discontinued once test is positive.

Indicate the reason for testing. Testing may be routine or due to illness (unscheduled inpatient or outpatient). Choose the appropriate response. 2a The "date of the specimen" is the date the serology sample is taken. 2c Two methods can be used for serology testing, antibody titer and ELISA. In the first column, under "Test Done", indicate if the specific test was performed by entering a "O"(no) or "1" (yes). If the response in the first column is "1", enter the test result in the second and third column under IgG and IgM.

CMV SEROLOGY (PATIENT)

GROUPS I AND II PATIENTS

Patient's	ID #:		Form #:	2 4 DT-F	ORM
Completed	by:(print	name)	Date Complet	ted:/(mm/d	_/
Visit: Mo	onth VJSM7H				
1. Indi	cation for CMV te 1 = routine 2 = unscheduled 3 = unscheduled	outpatient		· · ·	<u>ND</u> SERO
2. Cyto	megalovirus:			7.	T-SCHV
	-			·/	<i></i>
ъ.	Specimen number .		• • • • • • • • • • • • • • • •	••	
	by entering "0"(n	o) or "1"(yes	of test performed) in the first co nt the test resul	lumn.	
		<u>Test Done</u>	IgG		<u>M</u>
	Antibody titer	SCHVAT	1: _SCHVTIT		MVTITZ - — —
		0041517	(titer)		ter) 4VOD2
	ELISA	SCHVELI	SCMVOD	(optical or in	density
d.	Final result 0 = negative 1 = positive, No 2 = positive, p.	os 4 -	positive, active unsatisfactory equivocal	••	SEHV
If a	n ELISA was done,	complete 2e:			
e.	Method of testing 1 - Sigma Diagn 2 - Becton Dick 3 - Diamedix Co	ostics 4 = inson 9 =		 CHVSPEC	<u>(HV</u> ME TH)
Entered by	:		Date enter	red:	- FMENT Tyy)

CMV CULTURE (PATIENT)

FORM # 25

INSTRUCTIONS

Schedule:

Group I - When clinically warranted.

Group II - Complete this form at birth and at months 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

INSTRUCTIONS/NOTES ITEM # Indicate the reason for testing. Testing may be routine or due to 1 illness (unscheduled inpatient or outpatient). Choose the appropriate response. The "date of the specimen" is the date the urine sample is taken. 2 Indicate if specimen is for culture or storge. (NOTE: Once the 3 child is CMV positive [See protocol section 5.1.4], specimens will be stored rather than cultured.) Tubes will be read every two - three days and will be discarded 4c after four weeks. The date of the final reading will be entered.

CMV CULTURE (PATIENT)

GROUPS I AND II PATIENTS

Patie	ID #:	Form #: 2 5	DT-FORM
Comp?	eted by:(print name) :: Month VISMTH	Date Completed:	(mm/dd/yy)
1.	Indication for collection of urine space of a collection of urine space of a collection of urine space of a collection of urine space of specimen (mm/dd/yy)		INBCHV DT_CHVS _//
3.	Urine specimen taken		U <u>RI</u> NE SF
4.	Urine Culture a. Specimen number b. Date placed in culture (mm/dd/yy) c. Date of final reading (mm/dd/yy) d. Final reading 0 = negative 1 = positive 2 = unsatisfactory		CHVSNO DT-CHVP JBT-CHV CHV
Ente	red by: (cert. #)	Date entered:	17-FMENT (mm/dd/yy)

Form # 25.03 Rev. 10/01/92

EBV CULTURE (PATIENT)

FORM # 26

INSTRUCTIONS

Schedule:

- Group I When clinically warranted.
- Group II Complete this form at birth and at months 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

(NOTE: The data collection form will be completed at the University of Texas Health Science Center in San Antonio, Texas and returned to the Clinical Center for data entry.)

ITEM # INSTRUCTIONS/NOTES Indicate the reason for testing. Testing may be routine or due to illness (unscheduled inpatient or outpatient). Choose the appropriate response. The "date of the specimen" is the date the saliva specimen is taken. Enter the specimen number as identified by the laboratory department. Cultures are held for eight weeks; cells are checked weekly. Enter the date of the final reading.

Enter the titer if the final reading is positive.

6b

EBV CULTURE (PATIENT)

GROUPS I AND II PATIENTS

Comp1	nt's ID #:	Form #: 2 6 Date Completed:	DT-FORM // (mm/dd/yy)
1. 2. 3. 4. 5.	Throat washing (some state of the state of t	······································	INDEBV DT-EBVS DT-EBCP EBVSNO LBV
	1 - positive 2 - unsatisfactory If positive, complete 6b: b. Titer of positive specimen (TD ₅	₀ /ml) (Log ₁₀)	EBVTITER ———
Enter	red by: CFRT_NO (cert. #)	Date entered:	NT-FMENT (mm/dd/yy)

Form # 26.03 Rev. 08/01/91

LABORATORY

FORM # 27

INSTRUCTIONS

Routine Schedule:

- Group I Complete this form at the initial visit and at months 12, 24, 36 48, 60 and 72.
- Group II Complete this form at birth and at months 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

Schedule during Intercurrent Illness:

Groups I and II - Complete this form when the respiratory symptom evaluation is indicated.

ITEM #	INSTRUCTIONS/NOTES
1	Testing may be routine or due to illness (unscheduled inpatient or outpatient). Choose the appropriate response.
2	The "date" refers to the date the blood sample was taken.
6	Enter the white blood count as 10^3 per millimeters cubed. If the total count is given, move the decimal three spaces to the left.
	Example: WBC 10,000 is entered as $\underline{1} \underline{0} \underline{0}$.
7a — 7g	Counts are recorded in percent. Round to whole numbers.
	Example: 20.5% is entered as $2 1$.
8	Enter the platelet count as 10^3 per millimeter cubed. If the total count is given, move the decimal three spaces to the left.
	Example: Platelet count of 350,000 is entered as $3 5 0$.
9	Erythrocyte sedimentation rate will not be performed at birth; enter "F6" as not applicable.
10	The "date" refers to the date the chemistry sample was taken.
11	Enter the lactate dehydrogenase level in international units per

mEq/L - milli-equivalents per liter

Rev. 06/01/93

12 - 14

liter.

P²C² HIV LABORATORY

GROUPS I AND II PATIENTS

Comple	IDNO Form #: 2	7
1.	<pre>Indications for lab testing</pre>	I N∆∠AB
	<u>Hematology</u>	DT-HEMA
2.	Date (mm/dd/yy)	·//
3.	Hemoglobin (g/dl)	
4.	Hematocrit (%)	
5.	MCV (μ^3)	<u>MC V</u>
6.	WBC (10 ³ /mm ³)	··· WBCLAB
7.	Differential	
	a. Neutrophils (%)	NEUTRO
	b. Bands (%)	BANDS
	c. Lymphocytes (%)	NoulandTE
	d. Monocytes (%)	FOST NO
	e. Eosinophils (%)	PASO
	f. Basophils (%)	
	g. Atypical Lymphocytes (%)	DI ATE I AT
8.9.	Platelets (10 ³ /mm ³) Erythrocyte sedimentation rate (mm/hr) (This test is not performed at birth; enter F6.)	FSR

Form # 27.03 Rev. 08/01/91

_			
Patient	#•	-	
Lacrence	"		

P^2C^2 HIV LABORATORY

	Chemistry	DT-CHEM
10.	Date (mm/dd/yy)	/
11.	LDH (iU/L)	LDH
12.	Sodium (mEq/L)	SODTUM
13.	Chloride (mEq/L)	<u>CHLORI</u> DE
14.	Potassium (mEq/L)	<u>PotAs</u> s
15.	BUN (mg/dl)	<u> Ви м</u> _
16.	Creatinine (mg/dl)	<u> </u>
17.	Total protein (g/dl)	TOTPROT
18.	Albumin (g/dl)	<u>ALBU</u> HIN

DT_FMEN

Form # 27.03 Rev. 08/01/91

IMMUNOLOGIC STUDIES (PATIENT)

FORM # 28

INSTRUCTIONS

Routine Schedule:

- Group I Complete this form at the initial visit, and at months 12, 24, 36, 48, 60 and 72.
- Group II Complete this form at the time of birth, and at months 3, 9, 15, 21, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

Schedule during Intercurrent Illness:

Group I and II - Complete this form when the respiratory symptom evaluation is indicated (unless tests were performed within the previous two months).

ITEM # INSTRUCTIONS/NOTES

- Indicate the reason for testing. Testing may be routine or due to illness (unscheduled inpatient or outpatient). Choose the appropriate response.
- The "date of the test" is the date the blood sample is taken.
- Enter the white blood count as 10^3 per millimeters cubed. If the total count is given, move the decimal three spaces to the left and enter the number.

Example: WBC count of 10,000 is entered as $\frac{1}{0} \cdot \frac{0}{0}$

- 5 Lymphocyte % = Total lymphocyte count
 Total white blood count
- 6 10 Lymphocyte subset % = <u>Total subset count</u>
 Total lymphocyte count

IMMUNOLOGIC STUDIES (PATIENT)

GROUPS I AND II PATIENTS

Patie	ent's ID #:	Form #: 2 8	DT-FORM	
Completed by:(print name)		Date Completed:	- · · · · · · · · · · · · · · · · · · ·	
Visit	: Month VISHTH			
1.	Indication for immunologic studies 1 = routine 2 = unscheduled outpatient		JNDIHM	
	<pre>3 = unscheduled inpatient</pre>		DT_IMM	
2.	Date of test (mm/dd/yy)			
3.	Specimen number	· · · · · · · · · · · · · · · · · · ·	TWW2N0	
4.	WBC (x 10 ³ /mm ³)		WBC	
5.	Lymphocytes (%)		LYHPH	
6.	CD3 (T-cells) (%)		<u>CD3</u>	
7.	CD4 (T-Helper cells) (%)	• • • • • • • • • • • • • • • • • • • •	<u>CD4</u>	
8.	CD8 (T-Suppressor cells) (%)		<u>CD8</u>	
9.	CD19 (B-cells) (%)		<u>CD19</u>	
10.	CD20 (B-cells) (%)		<u>Cb20</u>	

Entered by:	(cert. #)	Date entered:	DT_FMENT

Form # 28.02 Rev. 08/01/91

QUANTITATIVE IMMUNOGLOBULIN LEVELS

FORM # 29

INSTRUCTIONS

Routine Schedule:

Group I -	Complete thi	s form at	the	initial	visit	and	at	months
•	12, 24, 36,	48, 60, 7	2.					

Group II - Complete this form at the time of birth and at months 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

Schedule during Intercurrent Illness:

Groups I and II - Complete this form when the respiratory symptom evaluation is indicated (unless test had been performed with the previous two months).

QUANTITATIVE IMMUNOGLOBULIN LEVELS

Patient's ID #:	
1 = routine 2 = unscheduled outpatient 3 = unscheduled inpatient 2. Date of specimen (mm/dd/yy) 3. Specimen number 4. Results: a. IgG (mg/dl) b. IgM (mg/dl) c. IgA (mg/dl) TIGA TIGA	
2. Date of specimen (mm/dd/yy)	I
a. IgG (mg/d1)	
11/16	T ./
5. a. Is the patient receiving IVIG injections? 0 = no 1 = yes If yes, complete item 5b: b. Indicate the date of the last injection	
Entered by: CERT-NO Date entered:	7

Form # 29.03 Rev. 10/01/92

DELAYED HYPERSENSITIVITY SKIN TEST

FORM # 30

INSTRUCTIONS

Results of this test are to be read by <u>medical personnel</u>. If a medical reading cannot be obtained, the test is to be entered as missing. (NOTE: The computer will now require a date of antigen placement to be entered for all "missing" DHST records. If the antigens were placed, enter the appropriate date in the field provided. If the antigens were NOT PLACED, enter "F8" [01/01/00] in the date field.)

The DHST "sub-study" will require additional reporting. At the time of antigen placement, the parent/guardian will be instructed in performing DHST readings. An instruction sheet will be provided to the participant. The parent/guardian will be asked to perform two readings the day of the return visit. One reading will be performed in the HOME; and one in the presence of the Nurse Coordinator, while in the CLINIC. NOTE: The participant who performs the reading at home and at the clinic, must be the individual who received the verbal instructions from the Nurse Coordinator at the time of the antigen placement. The yellow "Parent Instruction" sheet will be used by the parent/guardian to record the results read at home. The results from the sheet will be transcribed onto Form 30 (see item 5). At the return visit, the parent/guardian will perform a second reading. The results will be recorded directly onto Form 30 by the nurse (see item 6).

Once verbal and written instructions are given, the DHST Reader Questionnaire (See Form 35) must also be completed.

Routine Schedule:

- Groups I Complete this form at enrollment (only if the child is 1 year of age or older) and at months 12, 24, 36, 48, 60 and 72.
- Group II Complete this form at months 12, 24, 36, 48, 60 and 72.

Schedule during Intercurrent Illness:

Groups I and II - Testing is performed at the time of Respiratory Symptom
Evaluation (unless test had been performed within the
previous two months).

ITEM # INSTRUCTIONS/NOTES

- Testing may be routine or unscheduled. Choose the appropriate response.
- 4b 4d If no reaction is seen, record observations as _____0.

DELAYED HYPERSENSITIVITY SKIN TEST

FORM # 30

ITEM #	INSTRUCTIONS/NOTES
5a	Enter "0" if the parent/guardian is instructed, but does not perform the reading.
	Enter "1" if the parent/guardian performs the reading at HOME on the same day as the medical reading.
	If the parent/guardian was not instructed to perform the reading, record "F7" (note done) for this item.
5b - 5d	Enter the results of the parent/guardian readings.
6a	Enter "0" if the parent/guardian is instructed, but does not return to the Clinical Center to perform the reading.
	Enter "1" if the parent/guardian performs the reading at the CLINIC on the same day as the medical reading.
	If the parent/guardian was not instructed to perform the reading, record "F7" (note done) for this item.
6b - 6d	Enter the results of the parent/guardian readings.

P²C² STUDY

DELAYED HYPERSENSITIVITY SKIN TEST

GROUPS I AND II PATIENTS

Patie	ent's	ID #: _	IDM	<u> </u>	Form #	: 3 0	DT- FOR	o N
Comp1	Leted	by:			Date Co	ompleted: _	/_	
_			(print	name)			(mm/dd/y	<i>(</i>)
Visit	:: M	onth	V <u>IS</u> MTH					
Code	miss	ing data	items as	follows:				
		F!	5 = Unknowr	1	F7 - Not Done	,		
1.	Ind	ication	for DHST				I	ND DHST
			cheduled outpa				0	,
		3 = uns	cheduled inpat	ient			DT_AN	71
2.				, , , , , , , ,	• • • • • • • • • • • • • • • • • • • •		//_ TxAN	7 <u> </u>
3.	Tim	e antige	ns placed	(00:00 - 23:5	9)	• • • • • • •	:	
4.	a.		•				K,	EADDHST ——
			idy personnel lical non-study	personnel				
				Antigen	Time of	Final Rea	ding (mm)	
				<u>Placed</u> 0 = no 1 = yes	<u>Reading</u> 1 = 48 hours 2 = 72 hours	Redness	Swelling	
		b .	Candida	CANPLACE	CANTIME	CANBED	CANSWEL	•
		c.	PPD	PPDPLACE	PPDTIHE	PPARED	PPDSWE	<u>L</u>
		d.	Tetanus	TETPLALE	T <u>ETT</u> IHE	TETRED	TETSWE	<u>'</u>
5.	a.		read by p	articipant a	t home: (same	day as medical	reading) R	<u>RPA</u> RTH
		0 = no 1 = yes	•	Redness	Swelling			
		ъ.	Candida	CANREDZ	CANSWELZ			
		c.	PPD	PPDREDZ	PPDSWELZ			
		d.	Tetanus	TET BEDZ	TETSWEL:	2		
6.	a.	Results	read by pa	articipant at	: Clinical Cer	iter: (same d	ay as above)	RRPARTC
		1 = yes	•	<u>Redness</u>	Swelling			
		ъ.	Candida	<u>CANR</u> ED3	CANSWEL	3		
		c.	PPD	PPDRED3	PPDSWEL:	3		
		d.	Tetanus	TETRE03	<u>TET</u> SWEL	3		
Enter	ced b	y:	t. #)		Date	entered: _		-

SERUM STORAGE

FORM # 31

INSTRUCTIONS

Routine Schedule:

Group I - Complete this form at the initial visit and at months

12, 24, 36, 48, 60 and 72.

Group II - Complete this form at birth and at months 6, 12, 18, 24,

30, 36, 42, 48, 54, 60, 66, 72 and 78.

ITEM # INSTRUCTIONS/NOTES

(No special instructions for this form.)

P²C² STUDY SERUM STORAGE

GROUPS I AND II	PATIENTS	
Patient's ID #: Completed by: (print name) Visit: MonthVISHTH	Form #: 3 1 Date Completed:	DT-FORM _// (mm/dd/yy)
 Date serum taken for storage (mm/dd/2. Specimen number	 L)	DT-SS SSNBR SSMLS SSNTBS

		¥ = 11/1= //=
Entered by:	CERT- NO	
Encered by:	(cert. #)	(mm/dd/yy)

Form # 31.03 Rev. 10/25/93

SERUM STORAGE

FORM 31

VARIABLE NAME	OUESTION #	REQUIRED	RANGE
DT_FORM	-	Y	≥ 5/22/90 AND ≤ DATE()
DT_SS	1	Y	≥ 2/22/90 AND ≤ DT_FORM
SSNBR	2	И	
SSMLS	3	N	<u>></u> 0
SSNTBS	4	N	<u>></u> 0

Added on 1/2/97 to record amount shipped to McKesson (data as per Center):

Date shipped DT_SHPD Amount shipped (mls) **AMTSHPD** Number of tubes shipped NUMSHPD Reason not shipped. NOTSHPD

Form # 31

Added 5/12/97 to record amount received by McKesson (data per McKesson):

Number of tubes received by McKesson (mls received could not be determined NUMRCVD at this time since specimens were frozen)

Added 12/15/97 to record samples sent for Triponin and RNA:

Indicates if sample shipped for Triponin (0=not sent, 1=sent, -2=NA) TRIPONIN Indicates if sample shipped for RNA (0=not sent, 1=sent, -2=NA RNA

Added 04/98 to record inventory following shipping for Triponin and RNA:

Inventory date provided by McKesson DT 0498

Indicates the inventory in mls following shipping of samples for Triponin and INV_0498

RNA.

NOTE: Exact inventory from Central Lab is not available for specimans not yet pulled (unfrozen) for studies.

Rev. 07/05/00

EBV SEROLOGY (PATIENT)

FORM # 32

INSTRUCTIONS

Schedule:

Group I - When clinically warranted.

Group II - Complete this form at month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

(NOTE: The data collection form will be completed at the University of Texas Health Science Center in San Antonio, Texas and returned to the Clinical Center for data entry.)

ITEM # INSTRUCTIONS/NOTES Indicate the reason for testing. Testing may be routine or due to illness (unscheduled inpatient or outpatient). Choose the appropriate response. The "date of the specimen" is the date the sample is taken. Enter the specimen number as identified by the laboratory department.

EBV SEROLOGY (PATIENT)

GROUPS I AND II PATIENTS

Patient	's ID #:	Form #:	3 2	DT-FORM
Complet	(print name)	Date Comple	ted:/	nm/dd/yy)
Visit:	Month VISHTH			
1. I	<pre>Indication for EBV testing 1 = routine 2 = unscheduled outpatient 3 = unscheduled inpatient</pre>		7	<u>EBV</u> INI)T_SEBV
2. D	Date of specimen (mm/dd/yy)		/	/
	pecimen number			CBVSNO
4. V	CA-IgG titer			EBVIGG JEBVIGM
	CA-IgM titer		<u>1</u> :	
	BNA titer			EAIGG_
	If response is "O", skip to item 8.			
	Directed to			<u>Ebv</u> DIR
8. I	Final result			SEBV
	11 = positive, NOS, maternal of 12 = positive, past 13 = positive, acute, primary 14 = positive, recent or convents = positive, reactivation of 16 = unsatisfactory	alescent		
Entered	i by: (cert. #)	Date ente	ered:	T-FHENT m/dd/yy)

Form # 32.04 Rev. 08/01/92

EBV SEROLOGY FOR PATIENTS

FORM 32

VARIABLE NAME	OUESTION	REQUIRED	RANGE
DT_FORM	-	Y	≥ 5/22/90 AND ≤ DATE()
EBVIND	1	Y	
DT_SEBV	2	Y	≥ 2/22/90 AND ≤ DT_FORM
SEBVSNO	3	N	
SEBVIGG	4	N	≥ 0
SEBVIGM	5	N	≥ 0
SEBNA	6	N	≥ 0
EAIGG	7a	N	≥ 0
EBVDIR	7ь	N	
SEBV	8	Y	

Added 12/2/96 per request of Mark/Scott:

NEG6MOS This variable is used to code patients who were EBV negative at 6 months [0 =

negative]. Records coded per list from Scott.

Added 10/5/98. Data per McKesson:

MCKESSO This variable indicates the number of specimens received by McKesson, matched on ID#

and date (NOTE: If one record listed, then "1" entered; if two records listed then "2" entered. No amounts were provided. Also note that a large number of records could not

be matched because no date was provided from McKesson.)

Added 10/5/98. Data per San Antonio:

INACTIV This variable indicates the estimated amount that San Antonio sent to McKesson that was

heat inactivated.

NOTINAC This variable indicates the estimated amount that San Antonio sent to McKesson

that was not heat inactivated.

IVIG AND ANTI-RETROVIRAL MEDICATION FORM FORM # 34

INSTRUCTIONS

The medication form will be completed and updated for all Group I and IIa patients according to the routine schedule provided below. The form will be a complete history of pertinent medication data. Data concerning blinded treatment protocols should not be entered on this form. Once a treatment protocol is unblinded, the specific treatment will be entered. Only one form will be completed per patient. Updates to the database will be made on the original data collection form and entered into the database in the EDIT mode.

If the patient <u>is not on IVIG or an anti-retroviral drug</u>, an update will still be required. In these instances, the appropriate visit month and date of the update should be entered. Item #1 should be completed with a "0" (no) and the remainder of the form should be left blank.

Routine Schedule:

Groups I and IIa - Complete this form at month 06, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

Initial Completion of the Form:

Enter the date the form is first completed in the "Initial Date" field and enter the Visit Month. Enter <u>all</u> data related to IVIG or anti-retroviral medications from the time of birth to the present.

<u>Updates:</u>

The form will be <u>updated</u> according to the routine schedule shown above. Enter the visit month and the date of the update. Enter all medication data pertinent to the period between the last update and the present.

IVIG AND ANTI-RETROVIRAL MEDICATION FORM

FORM # 34

<u>Item</u> <u>Instructions</u>

Medication Codes - Codes for IVIG, AZT, DDI, DDC, T3C, Interferon, Nevirapine and D4T have been provided on the form.

 $\underline{\text{Codes }(91-94)}$ - If the patient is receiving an antiretroviral medication not listed, use codes 91-94 to list the specific medication.

Start Date - Enter the date the patient began receiving the medication. For IVIG it is assumed that infusions are given at regular intervals. Enter the day the patient

received his/her first infusion.

Stop Date - Enter the date the patient discontinued the medication. If the patient is receiving the medication during the period in which the form is being completed, enter "F8" (01/01/00) in the date field. At the time of the subsequent update, if the treatment is discontinued,

"F8" should be replaced with the appropriate date.

In the case of IVIG, enter the date of the last infusion if the patient is no longer receiving the treatment. Do not enter the date of the last infusion if the patient is due to return for treatment. If the patient's treatment included only a <u>single</u> infusion of IVIG, the start date and stop date will be the date of the

Dosage/Frequency -

Specify the dosage and frequency of medication. If there are changes in dosage, this should be described in

the comments field.

infusion.

Comments - The comments field should be used when there are pertinent data in addition to what was already described and documented in items 2 through 15.

Comments: Item #2: 11/15/93 180mg/m² qid: 01/05/94 90mg/m²/qid: 03/15/94
60mg/m²/qid: 09/06/94 90mg/m²/qid:

(NOTE: At the time of data entry - Once all necessary lines of data are completed, "F6" should be entered in the first field immediately following the last entry in order to bypass the remaining unused fields.

Rev. 07/06/95

P²C² STUDY

IVIG AND ANTI-RETROVIRAL MEDICATION FORM

GROUPS I and IIa

Patient's ID #:	(print name)	Form #:	3 4 Date://
Visit: Month VI	SMTH (When first completed)		
Updates: (Month and	Date of Update)		
Month a) MTH 1 c) MTH2 e) MTH3 b) MTH4	Date DT_MTHI ————————————————————————————————————	Month b) MTH5 d) MTH6 f) MTH7 h) MTH8	Date DTMTH 5 DTMTH 4 DTMTH 7 DTMTH 8

Code missing data items as follows:

F6 = not applicable

F8 = date unknown

1. Has the patient received treatment with IVIG or an antiretroviral; or is the patient enrolled on a blinded study involving IVIG or anti-retroviral treatment

MEDTREAT

0 = no1 = yes

If no, STOP here.

CODES AND INSTRUCTIONS

Medication Codes

1 = IVIG *	5 = 3TC	91 =	MED91
2 – AZT	6 = Interferon	92 =	MED 92
3 - DDI	7 = Nevirapine	93 =	MED93
4 = DDC	8 = D4T	94 =	MED94

Codes 91 through 94 should be used if the patient is on a medication other than 1 - 8 listed above.

⁽It is assumed IVIG will be administered at regular intervals with START date as first infusion and STOP date as last infusion. If IVIG was a single infusion, START and STOP dates should be the same.)

$\overline{P^2}C^2$ STUDY

IVIG AND ANTI-RETROVIRAL MEDICATION FORM

IVIG AND ANTI-RETROVIRAL MEDICATION DATA

<u>Medication</u> (Code)	Start Date	Stop Date	<u>Dosage</u> (Amount including units and frequency)
2. HEDCDEI	_ DT-STRI_		MEODSE1
3. MEDCDE2	STR2		MEDDSEZ
4. MEDIDE 3			MEDDSE 3
5. MEDCOEY	AT-STR4	DT_STP4	MEDDS E4
6. HEDCDES	DT-STR5	DT-STP5	MEDOSE 5
7. MEDCDEG	DT-STR4	DT- 5,TP6	MEDDS EG
8. MEDCDET		DT-SJP7	MEDDSE 7
9. HEDCDE8		DT- STP8	HED DS E8
10. HEDCDE9	- DT-STR9 -	- JT- STP9	MEDDSE 9
	- DT-STR10	- DT- STP10	MEDDS E 10
11. MED CDE/D	STRII	- DT-STP, II	MEDDSEII
12. <u>MEDCDE</u> 11	DT_STR12	// DT- STP12	
13. <u>MEDCDE</u> 12	//	//	<u>HEDOSEIZ</u>
14. <u>MEDCDE</u> 13	DT STR13	DT-STP13	MEDDSE 13
15. <u>MEDCDE</u> 14	DT_STR14 //		MEDDSE 14

Comments:	 	 	

Entered by: <u>CER_T_NO</u> (cert.#)

$P^2C^2 \; STUDY \\$ IVIG AND ANTI-RETROVIRAL MEDICATION FORM

<u>Medicat</u> (Code)	tion	Start Date	Stop Date	Dosage (Amount including units	
16. MEDCE 17. MEDCE 18. MEDCE 19. MEDCE 20. MEDCE 21. MEDCE	ΕΙΦ _ ΔΕΙ7 _ ΔΕΙ8 _ ΔΕΙ9 _	DT-STR15 DT-STR17 DT-STR18 DT-STR19 DT-STR20 DT-STR21	DT-STP15 - J-STP16 - DT-STP17 - DT-STP18 - DT-STP19 - DT-STP20 - DT-STP20	MEDDJE 15 MEDDSE 14 MEDDSE 17 MEDDSE 18 MEDDSE 19 MEDDSE 20	
22. <u>NEACL</u> 23. <u>HEMD</u>				MEDDSE 21 MEDDSE22	
Comments co	ontinued	:M&I	SCO HM		

DHST READER QUESTIONNAIRE

FORM # 35

INSTRUCTIONS

This form is to be completed for the DHST comparison reading sub-study. The form provides demographics on the individual who was instructed by the Nurse Coordinator to perform the additional readings. The Nurse Coordinator should complete this form immediately following giving the verbal and written instructions to the parent/guardian.

ITEM #

INSTRUCTIONS/NOTES

(No item specific instructions provided at this time)

P^2C^2 STUDY

DHST READER QUESTIONNAIRE

GROUPS I AND II PATIENTS

Patient's ID #:	Form #: 3 5] , , ,	
Completed by:(print name)	Date Completed:	/	- FOR M _/_ ld/yy)
Code missing data items as follows:			
F5 - Unknown			
1. Date antigens placed (mm/dd/yy)		<u>}</u>	DHSTR
THE FOLLOWING QUESTIONS PERTAIN TO THE DHST READING (Item 5a & 6a on	O THE INDIVIDUAL INST Form 30).	RUCTED TO	_
2. Participant's age (in years)			PARTAGE ———
3. Participant's sex			PARTSEX
2 = female 4. Participant's race			PART RAC
<pre>2 = Black Non-Hispanic 3 = Hispanic 4 = Asian/Pacific Islander 5 = American Indian/Alaskan 9 = other (Specify:</pre>	Native PARTRACS)	000
5. Participant's education level 1 = < 12 years high school 2 = high school graduate 3 = some college 4 = college graduate			PARTESU
6. Participant's primary language			PARTLAN
<pre>1 = English 2 = Spanish 9 = other (Specify:</pre>	PARTLANS)	
7. Relationship to patient 1 = child's biologic mother 2 = child's biologic father			<u>PAR</u> T REL
9 = other (Specify:	PARTRELS)	
Comments:	HSTCOM		
Entered by: (CERT-NO)	Date entered	:	- FMENT