

IMMUNOLOGY AND VIROLOGY FORMS

P²C² HIV
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 p160

P²C² HIV
HIV ELISA
FORM # 22

INSTRUCTIONS

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

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1a	The "date of the specimen" is the date the serum sample is taken.

P²C² HIV
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 positive, it is not necessary to repeat the test at month 6).

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1	The "date of the specimen" is the date the culture sample is taken.

P²C² HIV HIV CULTURE

GROUP II PATIENTS

Patient's ID #: J B NO

Form #: 2 3

Completed by: _____
(print name)

Date Completed: DT-FORM
(mm/dd/yy)

Visit: Month VISMTH

- 1. Date of specimen (mm/dd/yy) DT-HIVS
- 2. Date placed in culture (mm/dd/yy) DT-HIVP
- 3. Specimen number HIVSNO
- 4. ACTG consensus protocol method ACTG PRO
 1 - quantitative
 2 - qualitative
- 5. Final Reading HIV
 0 - negative
 1 - positive
 2 - unsatisfactory
 3 - indeterminate (only one well positive in quantitative culture)

Entered by: CERT-NO
(cert. #)

Date entered: DT-FMENT
(mm/dd/yy)

P²C² HIV
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.

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1	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 "0"(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.

P²C² HIV
CMV SEROLOGY (PATIENT)

GROUPS I AND II PATIENTS

Patient's ID #: JDNO - - - -

Form #: 24

DT-FORM

Completed by: _____
(print name)

Date Completed: ___/___/___
(mm/dd/yy)

Visit: Month VJSMTH

1. Indication for CMV testing
- 1 - routine
 - 2 - unscheduled outpatient
 - 3 - unscheduled inpatient

NBSERO

2. Cytomegalovirus:

a. Date of specimen (mm/dd/yy) ___/___/___

DT-SCMV

b. Specimen number - - - - -

SCMVSNO

c. Test Done - Indicate the type of test performed
by entering "0"(no) or "1"(yes) in the first column.
If the response is yes, document the test results.

	<u>Test Done</u>	<u>IgG</u>	<u>IgM</u>
Antibody titer	<u>SCMVAT</u>	<u>1</u> : <u>SCMVTIT</u> (titer)	<u>1</u> : <u>SCMVTIT2</u> (titer)
ELISA	<u>SCMVELI</u>	<u>SCMVOB</u> (optical density or index)	<u>SCMVOB2</u> (optical density or index)

- d. Final result
- 0 - negative
 - 1 - positive, NOS
 - 2 - positive, past
 - 3 - positive, active
 - 4 - unsatisfactory
 - 5 - equivocal

SCMV

If an ELISA was done, complete 2e:

- e. Method of testing
- 1 - Sigma Diagnostics
 - 2 - Becton Dickinson
 - 3 - Diamedix Corp.
 - 4 - Wittaker Labs
 - 9 - Other
- (Specify: CMVSPER)

CMVMETH

Entered by: CERT-NO
(cert. #)

Date entered: ___/___/___
(mm/dd/yy) DT-FMENT

P²C² HIV
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.

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

P²C² HIV
CMV CULTURE (PATIENT)

GROUPS I AND II PATIENTS

Patient's ID #: JDNO - - - -

Form #: 2 5

Completed by: _____
(print name)

Date Completed: DT-FORM
____/____/____
(mm/dd/yy)

Visit: Month VISMTH

1. Indication for collection of urine specimen
 - 1 - routine
 - 2 - unscheduled outpatient
 - 3 - unscheduled inpatient

INDCMV

2. Date of specimen (mm/dd/yy)

DT-CMVS

3. Urine specimen taken
 - 1 - for culture
 - 2 - for storage

URINE SP

If response is "1", complete item 4,
If response is "2", STOP HERE.

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-CMVP

DT-CMV

CMV

Entered by: CERT-NO
(cert. #)

Date entered: DT-FMENT
____/____/____
(mm/dd/yy)

P²C² HIV
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.)

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1	Indicate the reason for testing. Testing may be routine or due to illness (unscheduled inpatient or outpatient). Choose the appropriate response.
2	The "date of the specimen" is the date the saliva specimen is taken.
4	Enter the specimen number as identified by the laboratory department.
5	Cultures are held for eight weeks; cells are checked weekly. Enter the date of the final reading.
6b	Enter the titer if the final reading is positive.

P²C² HIV
LABORATORY

GROUPS I AND II PATIENTS

Patient's ID #: JDNO - - - -

Form #: 27

Completed by: _____
(print name)

Date Completed: DT-FORM ___/___/___
(mm/dd/yy)

Visit: Month VJSMTH

1. Indications for lab testing INDLAB
- 1 - routine
 - 2 - unscheduled outpatient
 - 3 - unscheduled inpatient

Hematology

2. Date (mm/dd/yy) DT-HEMA ___/___/___
3. Hemoglobin (g/dl) HB _____
4. Hematocrit (%) HCT _____
5. MCV (μ^3) MCV _____
6. WBC ($10^3/mm^3$) WBCELLAB _____
7. Differential
- a. Neutrophils (%) NEUTRO _____
 - b. Bands (%) BANDS _____
 - c. Lymphocytes (%) LYMPHLAB _____
 - d. Monocytes (%) MONOCYTE _____
 - e. Eosinophils (%) EOSINO _____
 - f. Basophils (%) BASO _____
 - g. Atypical Lymphocytes (%) ATYPLYM _____
8. Platelets ($10^3/mm^3$) PLATELAT _____
9. Erythrocyte sedimentation rate (mm/hr) ESR _____
(This test is not performed at birth; enter F6.)

Patient #: ___-___-___-___

**P²C² HIV
LABORATORY**

Chemistry

- | | | | |
|-----|----------------------------|-------------|----------|
| 10. | Date (mm/dd/yy) | ___/___/___ | DT-CHEM |
| 11. | LDH (iU/L) | ___ | LDH |
| 12. | Sodium (mEq/L) | ___ | SODIUM |
| 13. | Chloride (mEq/L) | ___ | CHLORIDE |
| 14. | Potassium (mEq/L) | ___ | POTASS |
| 15. | BUN (mg/dl) | ___ | BUN |
| 16. | Creatinine (mg/dl) | ___ | CRT |
| 17. | Total protein (g/dl) | ___ | TOT PROT |
| 18. | Albumin (g/dl) | ___ | ALBUMIN |

Entered by: CERT-NO
(cert. #)

Date entered: DT-FMENT
(mm/dd/yy)

P²C² HIV
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).

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1	Indicate the reason for testing. Testing may be routine or due to illness (unscheduled inpatient or outpatient). Choose the appropriate response.
2	The "date of the test" is the date the blood sample is taken.
4	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 <div style="margin-left: 100px;"> <u> </u> <u> 1 </u> <u> 0 </u> <u> 0 </u> </div>
5	Lymphocyte % = $\frac{\text{Total lymphocyte count}}{\text{Total white blood count}}$
6 - 10	Lymphocyte subset % = $\frac{\text{Total subset count}}{\text{Total lymphocyte count}}$

P²C² HIV
IMMUNOLOGIC STUDIES (PATIENT)

GROUPS I AND II PATIENTS

Patient's ID #: INDNO

Form #: 28

Completed by: _____
(print name)

Date Completed: DT-FORM
____/____/____
(mm/dd/yy)

Visit: Month VISMTH

- 1. Indication for immunologic studies INDIMM
 1 - routine
 2 - unscheduled outpatient
 3 - unscheduled inpatient
- 2. Date of test (mm/dd/yy) DT-IMM
 ____/____/____
- 3. Specimen number IMMSNO

- 4. WBC (x 10³/mm³)..... WBC

- 5. Lymphocytes (%) LYMPH
- 6. CD3 (T-cells) (%) CD3
- 7. CD4 (T-Helper cells) (%) CD4
- 8. CD8 (T-Suppressor cells) (%) CD8
- 9. CD19 (B-cells) (%) CD19
- 10. CD20 (B-cells) (%) CD20

Entered by: CERT-NO
(cert. #)

Date entered: DT-FMENT
____/____/____
(mm/dd/yy)

P²C² HIV
QUANTITATIVE IMMUNOGLOBULIN LEVELS
FORM # 29

INSTRUCTIONS

Routine Schedule:

- Group I - Complete this form at the initial visit and at months 12, 24, 36, 48, 60, 72.
- 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).

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1	Indicate the reason for testing. Testing may be routine or due to illness (unscheduled inpatient or outpatient). Choose the appropriate response.
2	The "date of the specimen" is the date the blood sample is taken.
4a - 4c	Results are recorded in milligrams per deciliter.
5a - 5b	Indicate if the patient is receiving IVIG injections and enter the date of the last injection.

P²C² HIV
QUANTITATIVE IMMUNOGLOBULIN LEVELS

GROUPS I AND II PATIENTS

Patient's ID #: IDNO

Form #: 29

Completed by: _____
(print name)

Date Completed: DT-FORM
(mm/dd/yy)

Visit: Month VISMTH

- 1. Indication for immunoglobulin testing INDQI
 - 1 - routine
 - 2 - unscheduled outpatient
 - 3 - unscheduled inpatient
 - 2. Date of specimen (mm/dd/yy) DT-QI
 - 3. Specimen number QISNO
 - 4. Results:
 - a. IgG (mg/dl) IGG
 - b. IgM (mg/dl) IGM
 - c. IgA (mg/dl) IGA
 - 5. a. Is the patient receiving IVIG injections? IVIGINJ
 - 0 - no
 - 1 - yes
- If yes, complete item 5b:
- b. Indicate the date of the last injection DT-IVIGI

Entered by: CERT-NO
(cert. #)

Date entered: DT-FMENT
(mm/dd/yy)

P²C² HIV**DELAYED HYPERSENSITIVITY SKIN TEST****FORM # 30****INSTRUCTIONS**

Results of this test are to be read by medical personnel. 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).

<u>ITEM #</u>	<u>INSTRUCTIONS/NOTES</u>
1	Testing may be routine or unscheduled. Choose the appropriate response.
4b - 4d	If no reaction is seen, record observations as <u> 0 </u> .

P²C² HIV

DELAYED HYPERSENSITIVITY SKIN TEST

FORM # 30

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

P²C² HIV
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 #:
IDNO

Form #: 31

DT-FORM

Completed by: _____
(print name)

Date Completed:
(mm/dd/yy)

Visit: Month
VISMTH

1. Date serum taken for storage (mm/dd/yy)
DT-SS

2. Specimen number
SSNBR

3. Amount of serum taken for storage (ml)
SSMLS

4. Number of storage tubes
SSNTBS

Entered by:
CERT-NO
(cert. #)

Date entered:
DT-MENT
(mm/dd/yy)

SERUM STORAGE

FORM 31

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

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

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

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

NUMRCVD	Number of tubes received by McKesson (mls received could not be determined at this time since specimens were frozen)
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Added 12/15/97 to record samples sent for Triponin and RNA:

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

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

DT_0498	Inventory date provided by McKesson
INV_0498	Indicates the inventory in mls following shipping of samples for Triponin and RNA.

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

P²C² HIV
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.)

- | <u>ITEM #</u> | <u>INSTRUCTIONS/NOTES</u> |
|----------------------|---|
| 1 | Indicate the reason for testing. Testing may be routine or due to illness (unscheduled inpatient or outpatient). Choose the appropriate response. |
| 2 | The "date of the specimen" is the date the sample is taken. |
| 3 | Enter the specimen number as identified by the laboratory department. |

EBV SEROLOGY FOR PATIENTS

FORM 32

<u>VARIABLE NAME</u>	<u>QUESTION</u>	<u>REQUIRED</u>	<u>RANGE</u>
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	7b	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.

P²C² HIV
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 is not on IVIG or an anti-retroviral drug, 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 all data related to IVIG or anti-retroviral medications from the time of birth to the present.

Updates:

The form will be updated 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.

P²C² STUDY

IVIG AND ANTI-RETROVIRAL MEDICATION FORM

GROUPS I and IIa

Patient's ID #: I DND

Form #: 3 4

Completed by: _____
(print name)

Initial Date: / / ^{DT-FORM}
(mm/dd/yy)

Visit: Month VIS MTH (When first completed)

Updates: (Month and Date of Update)

<u>Month</u>	<u>Date</u>	<u>Month</u>	<u>Date</u>
a) <u>MTH1</u>	<u> DT-MTH1 </u>	b) <u>MTH5</u>	<u> DT-MTH5 </u>
c) <u>MTH2</u>	<u> DT-MTH2 </u>	d) <u>MTH6</u>	<u> DT-MTH6 </u>
e) <u>MTH3</u>	<u> DT-MTH3 </u>	f) <u>MTH7</u>	<u> DT-MTH7 </u>
g) <u>MTH4</u>	<u> DT-MTH4 </u>	h) <u>MTH8</u>	<u> DT-MTH8 </u>

Code missing data items as follows:

F6 = not applicable F8 = date unknown

1. Has the patient received treatment with IVIG or an anti-retroviral; or is the patient enrolled on a blinded study involving IVIG or anti-retroviral treatment
- 0 = no
1 = yes

MEDTREAT

If no, STOP here.

CODES AND INSTRUCTIONS

Medication Codes

1 = IVIG *	5 = 3TC	91 = <u> MED91 </u>
2 = AZT	6 = Interferon	92 = <u> MED92 </u>
3 = DDI	7 = Nevirapine	93 = <u> MED93 </u>
4 = DDC	8 = D4T	94 = <u> MED94 </u>

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.)

P²C² STUDY

IVIG AND ANTI-RETROVIRAL MEDICATION FORM

IVIG AND ANTI-RETROVIRAL MEDICATION DATA

<u>Medication</u> (Code)	<u>Start Date</u>	<u>Stop Date</u>	<u>Dosage</u> (Amount including units and frequency)
2. <u>MEDCDE1</u>	<u>DT-STR1</u>	<u>DT-STP1</u>	<u>MEDDSE1</u>
3. <u>MEDCDE2</u>	<u>DT-STR2</u>	<u>DT-STP2</u>	<u>MEDDSE2</u>
4. <u>MEDCDE3</u>	<u>DT-STR3</u>	<u>DT-STP3</u>	<u>MEDDSE3</u>
5. <u>MEDCDE4</u>	<u>DT-STR4</u>	<u>DT-STP4</u>	<u>MEDDSE4</u>
6. <u>MEDCDE5</u>	<u>DT-STR5</u>	<u>DT-STP5</u>	<u>MEDDSE5</u>
7. <u>MEDCDE6</u>	<u>DT-STR6</u>	<u>DT-STP6</u>	<u>MEDDSE6</u>
8. <u>MEDCDE7</u>	<u>DT-STR7</u>	<u>DT-STP7</u>	<u>MEDDSE7</u>
9. <u>MEDCDE8</u>	<u>DT-STR8</u>	<u>DT-STP8</u>	<u>MEDDSE8</u>
10. <u>MEDCDE9</u>	<u>DT-STR9</u>	<u>DT-STP9</u>	<u>MEDDSE9</u>
11. <u>MEDCDE10</u>	<u>DT-STR10</u>	<u>DT-STP10</u>	<u>MEDDSE10</u>
12. <u>MEDCDE11</u>	<u>DT-STR11</u>	<u>DT-STP11</u>	<u>MEDDSE11</u>
13. <u>MEDCDE12</u>	<u>DT-STR12</u>	<u>DT-STP12</u>	<u>MEDDSE12</u>
14. <u>MEDCDE13</u>	<u>DT-STR13</u>	<u>DT-STP13</u>	<u>MEDDSE13</u>
15. <u>MEDCDE14</u>	<u>DT-STR14</u>	<u>DT-STP14</u>	<u>MEDDSE14</u>

Comments: _____

Entered by: CERT-NO
(cert.#)

Date entered: DJ-FMENT
(mm/dd/yy)

P²C² STUDY

IVIG AND ANTI-RETROVIRAL MEDICATION FORM

<u>Medication</u> (Code)	<u>Start Date</u>	<u>Stop Date</u>	<u>Dosage</u> (Amount including units and frequency)
16. <u>MEDCDE15</u>	<u>DT-STR15</u>	<u>DT-STP15</u>	<u>MEDDSE15</u>
17. <u>MEDCDE16</u>	<u>DT-STR16</u>	<u>DT-STP16</u>	<u>MEDDSE16</u>
18. <u>MEDCDE17</u>	<u>DT-STR17</u>	<u>DT-STP17</u>	<u>MEDDSE17</u>
19. <u>MEDCDE18</u>	<u>DT-STR18</u>	<u>DT-STP18</u>	<u>MEDDSE18</u>
20. <u>MEDCDE19</u>	<u>DT-STR19</u>	<u>DT-STP19</u>	<u>MEDDSE19</u>
21. <u>MEDCDE20</u>	<u>DT-STR20</u>	<u>DT-STP20</u>	<u>MEDDSE20</u>
22. <u>MEDCDE21</u>	<u>DT-STR21</u>	<u>DT-STP21</u>	<u>MEDDSE21</u>
23. <u>MEDCDE22</u>	<u>DT-STR22</u>	<u>DT-STP22</u>	<u>MEDDSE22</u>

Comments continued : MEDCOMM

P²C² HIV
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)

P²C² STUDY

DHST READER QUESTIONNAIRE

GROUPS I AND II PATIENTS

Patient's ID #: IDNO - - - -

Form #: 35

Completed by: _____
(print name)

Date Completed: DT-FORM
(mm/dd/yy)

Code missing data items as follows:

F5 - Unknown

1. Date antigens placed (mm/dd/yy) DT-DHSTR

THE FOLLOWING QUESTIONS PERTAIN TO THE INDIVIDUAL INSTRUCTED TO PERFORM THE DHST READING (Item 5a & 6a on Form 30).

2. Participant's age (in years) PARTAGE

3. Participant's sex PARTSEX
1 - male
2 - female

4. Participant's race PARTRAC
1 - White Non-Hispanic
2 - Black Non-Hispanic
3 - Hispanic
4 - Asian/Pacific Islander
5 - American Indian/Alaskan Native
9 - other (Specify: PARTRACS)

5. Participant's education level PARTEDU
1 - < 12 years high school
2 - high school graduate
3 - some college
4 - college graduate

6. Participant's primary language PARTLAN
1 - English
2 - Spanish
9 - other (Specify: PARTLANS)

7. Relationship to patient PARTREL
1 - child's biologic mother
2 - child's biologic father
9 - other (Specify: PARTRELS)

Comments: DHSTCOM

Entered by: CERT-NO
(cert. #)

Date entered: DT-FMENT
(mm/dd/yy)