

COOPERATIVE STUDY OF SICKLE CELL DISEASE

LAB

LABORATORY TEST RESULTS

ANONID

LABID2

1. Person completing form (Name): _____ (Initials):

LABFG

2. CSSCD code number of person completing form:

LABCODE

3. Date form completed (Month, Day, Year): _____ / _____ / _____

LAB_DFC

4. Has the patient received any transfusions within the past 4 months? 1. NO 2. YES
IF YES, COMPLETE TRANSFUSION FORM FOR EACH TRANSFUSION

LABTRANS

5. CBC: (RECORD THE VALUES FOR ALL TESTS COMPLETED)

5.1 Date of CBC Sample (Month, Day, Year): _____ / _____ / _____

LAB_DTE

5.2 CBC RESULTS

5.2.A. White cell count (x 10⁹/l uncorrected): LABCBCWB .

5.2.B. Red cell count (x 10¹²/l): LABCBCRB .

5.2.C. Hemoglobin (g/dl): LABCBCHB .

5.2.D. Hematocrit (%): LABCBCHC .

5.2.E. Mean Cell Volume (fl): LABCBCMV

5.2.F. Mean Cell Hemoglobin (pg): LABCBCMH .

5.2.G. MCHC (g/dl): LABCBCMC .

6. PLATELETS (x 10⁹/l): LABPLATE

7. FETAL HEMOGLOBIN

7.1 Date of Fetal Hemoglobin Sample (Month, Day, Year): _____ / _____ / _____

LABF_DTE

7.2 HbF (%) LABHBF .

7.3 Method: 1. Alkaline Denaturation 2. Other → 7.3.1 Specify: _____

LABFMTH

LABFSPF

LABVERS

8. SERUM CHEMISTRIES

8.1 Date of Serum Chemistry Sample (Month, Day, Year): _____/_____/_____

LAB_DTE2

8.2 CHEMISTRY RESULTS

8.2.A. Serum Creatinine (mg/dl): **LABCRTN** .

THE FOLLOWING TESTS ARE NOT REQUIRED; HOWEVER, IF ANY OF 8.2.B - H WERE PERFORMED AT THIS VISIT, PLEASE RECORD RESULTS BELOW:

8.2.B. BUN (mg/dl): **LABBUN**

8.2.C. Alkaline Phosphatase (units/l): **LABALKPH**

8.2.D. AST (SGOT) (units/l): **LABSGOT**

8.2.E. ALT (SGPT) (units/l): **LABSGPT**

8.2.F. Total Bilirubin (mg/dl): **LABBLRBN** .

8.2.G. Direct Bilirubin (mg/dl): **LABDBILI** .

8.2.H. Uric Acid (mg/dl): **LABURA** .

9. URINALYSIS

9.1 Date of Urine Sample (Month, Day, Year): _____/_____/_____

LAB_DTE3

9.2 URINALYSIS RESULTS:	Negative	Trace	1+	2+	3+	4+	
9.2.A Urine Protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	LABURPRO
9.2.B Urine Hemoglobin	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	LABURHB

**** ATTACH INSTITUTIONAL REPORTS FOR ALL TESTS PERFORMED ****

Signature of Data Coordinator: _____

Date: _____/_____/_____

QUESTION-BY-QUESTION SPECIFICATIONS FOR LABORATORY TEST RESULTS FORM

CSSCD Phases 2 and 3
1.4: Laboratory Test Results – Form LAB

Question 1. Person completing form: The person completing the lab form should enter his/her name on the line and initials in the three boxes to the right of the line.

Question 2. CSSCD code number of person completing form: The code number of the person completing the tab form is to be assigned by the Data Coordinator at each clinic.

Question 3. Date form completed: The date the laboratory form was completed should be entered in the MM/DD/YY date format (e.g., October 24, 1994, would be entered 10/24/94).

Question 4. Has the patient received any transfusions within the past 4 months?: Review the patient's chart to see whether the patient received any transfusions within the four months preceding this visit. ALSO, ask the patient/parent of the patient if the patient received any transfusions within the four months preceding this visit. If either chart review or parent response indicates that the patient was transfused during this time period, place a check mark in the YES box. If both chart review and patient/ parent of patient response indicate the patient was not transfused within the preceding four months, place a check mark in the NO box.

CBC, platelet count, and fetal hemoglobin are NOT REQUIRED IF the transfusion response is YES (i.e., the form will not be edited for missing results for these tests). Results for tests done but not required may be reported.

A sample for the CSSCD Serum Repository SHOULD NOT BE COLLECTED IF the patient has been transfused within the preceding four months.

If the YES box is checked, (i.e., the patient was transfused within the past four months), a Transfusion Form should be completed for each transfusion given at a CSSCD center within the four month period preceding the visit.

Question 5. CBC:

Question 5.1. Date of CBC Sample: Enter the date that the CBC sample was DRAWN. This date should be the same as the date of the physical exam for this study visit. The date of the CBC sample should be entered in the MM/DD/YY date format (e.g., October 24, 1994, would be entered 10/24/94).

Question 5.2. CBC Results: Blood for the CBC sample will be drawn from an arm vein with

CSSCD Phases 2 and 3
1.4: Laboratory Test Results – Form LAB

minimal stasis, into a lavender top (EDTA) vacutainer. CBC counts will be performed by automatic dilution of the blood in a standard automated hematology instrument which counts RBC, WBC, measures hemoglobin, and calculates RBC indices in triplicate; the machine used should be in a department participating in one of the National Quality Control Programs and should be

NOTE: THE WBC REPORTED ON THE LAB FORM MUST BE UNCORRECTED FOR NUCLEATED RBC'S

standardized at least once daily.

Question 6. Platelets: Either the Brecher method using phase contrast microscopy OR an electronic particle counting method may be used to obtain a platelet count.

Question 7. Fetal Hemoglobin:

Question 7.1 Date of Fetal Hemoglobin Sample: Enter the date that the sample for quantitation of fetal hemoglobin was DRAWN. This date should be the same as the date of the physical exam for this study visit. The date of the fetal hemoglobin sample should be entered in the MM/DD/YY date format (e.g., October 24, 1994, would be entered 10/24/94).

Question 7.2 HbF%: Enter the results of the Hemoglobin F quantitation. The percentage of HbF should be recorded up to 1 place after the decimal.

Question 7.3 HbF Method: Place a check mark in the appropriate box indicating which method was used to measure the percentage of HbF. If a method other than alkaline denaturation was used, place a check mark in the "Other" box and specify the alternate method used (Q. 7.3.1).

Question 8. Serum Chemistries:

Question 8.1 Date of Serum Chemistry Sample: Enter the date that the serum chemistry sample was DRAWN. This date should be the same as the date of the physical exam for this study visit. The date of the chemistry sample should be entered in the MM/DD/YY date format (e.g., October 24, 1994, would be entered 10/24/94).

Question 8.2.A Serum Creatinine: Serum creatinine is the only required serum chemistry test. Blood for the serum creatinine sample should be drawn at the same time as the CBC sample. The blood for the creatinine sample should be drawn into a red-top vacutainer. The creatinine testing

CSSCD Phases 2 and 3
1.4: Laboratory Test Results – Form LAB

will be performed on a routine automated chemistry analyzer; the machine used should be in a department participating in one of the National Quality Control Programs and should be standardized at least once daily. Results should be recorded in the boxes to the right of this question. Results should be recorded up to 1 place after the decimal.

Questions 8.2. B-H: The following chemistry tests are not required: BUN, Alkaline Phosphatase, AST (SGOT), ALT (SGPT), Total Bilirubin, Direct Bilirubin, and Uric Acid. However, if they were performed at this visit, please record them in the appropriate boxes on the Laboratory Test Results form.

Question 9. Urinalysis: Question 9.1 Date of Urine Sample: Enter the date that the urine sample was COLLECTED. This date should be the same as the date of the entry physical exam. The date of the urine sample should be entered in the MM/DD/YY date format (e.g., October 24, 1994, would be entered 10/24/94).

Question 9.2.A Urine Protein: Standard dip stick method will be used to measure urine protein. Results of urine protein testing should be recorded on the laboratory form by placing a check mark in the appropriate box for each test. Results are recorded as Negative, Trace, 1+, 2+,3+, or4+.

Question 9.2.B Urine Hemoglobin: Standard dip stick method will be used to measure urine hemoglobin. Results of urine hemoglobin testing should be recorded on the laboratory form by placing a check mark in the appropriate box for each test. Results are recorded as Negative, Trace, 1+, 2+, 3+, or 4+.

CONTENTS OF SAS DATASET: LAB_PUB.SD2
DATA FROM CSSCD FORM LAB - LABORATORY TEST RESULTS
VARIABLES ARE LISTED IN ALPHABETICAL ORDER AND IN ORDER OF THEIR POSITION
IN THE SAS DATASET AND ON FORM LAB

CODEBOOK FOR CSSCD FORM LAB
LABORATORY TEST RESULTS
 CSSCD INFANT COHORT PATIENTS

DATE VARIABLES HAVE BEEN REMOVED & CSSCD ID #S REPLACED W/ ANONYMIZED ID #

The SAS System

11:20 Tuesday, February 17, 2004 1

The CONTENTS Procedure

Data Set Name:	IN.LAB_PUBN	Observations:	3020
Member Type:	DATA	Variables:	41
Engine:	V6	Indexes:	0
Created:	11:24 Tuesday, February 17, 2004	Observation Length:	383
Last Modified:	11:24 Tuesday, February 17, 2004	Deleted Observations:	0
Protection:		Compressed:	NO
Data Set Type:		Sorted:	NO
Label:			

-----Engine/Host Dependent Information-----

Data Set Page Size:	16384
Number of Data Set Pages:	73
First Data Page:	1
Max Obs per Page:	42
Obs in First Data Page:	28
Number of Data Set Repairs:	0
File Name:	lab_pun.sd2
Release Created:	6.08.00
Host Created:	WIN

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos	Format	Informat	Label
1	ANONID	Char	8	0			ANONYMIZED ID #
35	LABA2MTH	Num	8	276	2.	2.	TESTING METHOD FOR HEMOGLOBIN A2 (PH2)
36	LABA2SPF	Char	25	284			OTHER TEST METHOD FOR HBA2 (PH2)
37	LABA2UL	Num	8	309	4.1	4.1	%HBA2 LAB UPPER LIMIT OF NORMAL (PH2)
19	LABALKPH	Num	8	154	4.	4.	82C ALKALINE PHOSPHATASE
22	LABBLRBN	Num	8	178	4.1	4.1	82F TOTAL BILIRUBIN
4	LABBNO	Num	8	17	3.	3.	DATA ENTRY BATCH NUMBER
18	LABBUN	Num	8	146	3.	3.	82B BLOOD UREA NITROGEN
8	LABCBCHB	Num	8	49	4.1	4.1	52C CBC - HEMOGLOBIN
9	LABCBCHC	Num	8	57	4.1	4.1	52D CBC - HEMATOCRIT
12	LABCBCMC	Num	8	81	4.1	4.1	52G CBC - MCHC
11	LABCBCMH	Num	8	73	4.1	4.1	52F CBC - MEAN CELL HEMOGLOBIN
10	LABCBCMV	Num	8	65	3.	3.	52E CBC - MEAN CELL VOLUME
7	LABCBCRB	Num	8	41	5.2	5.2	52B CBC - RED BLOOD CELL COUNT
6	LABCBCWB	Num	8	33	4.1	4.1	52A CBC - WHITE BLOOD CELL COUNT
17	LABCRTN	Num	8	138	4.1	4.1	82A SERUM CREATININE
23	LABDBILI	Num	8	186	4.1	4.1	82G DIRECT BILIRUBIN
38	LABDIAG	Num	8	317	2.	2.	DIAGNOSIS (PH2)
39	LABDIAGS	Char	25	325			SPECIFY OTHER DIAGNOSIS (PH2)
15	LABFMTH	Num	8	105	2.	2.	73 TESTING METHOD FOR HEMOGLOBIN F
16	LABFSPF	Char	25	113			731 SPECIFY OTHER METHOD HBF TEST
33	LABFUL	Num	8	260	4.1	4.1	%HBF LAB UPPER LIMIT OF NORMAL (PH2)
32	LABHBA	Num	8	252	4.1	4.1	HEMOGLOBIN ELECTROPHORESIS %A (PH2)
34	LABHBA2	Num	8	268	4.1	4.1	HEMOGLOBIN ELECTROPHORESIS %A2 (PH2)
31	LABHBC	Num	8	244	4.1	4.1	HEMOGLOBIN ELECTROPHORESIS %C (PH2)
14	LABHBF	Num	8	97	4.1	4.1	72 HEMOGLOBIN F PERCENT
30	LABHBS	Num	8	236	4.1	4.1	HEMOGLOBIN ELECTROPHORESIS %S (PH2)
2	LABID2	Num	8	8	3.	3.	FOLLOW-UP IDENTIFIER
27	LABIRPT	Num	8	218	2.	2.	LAB INSTITUTIONAL REPORTS RECEIVED

CODEBOOK FOR CSSCD FORM LAB
LABORATORY TEST RESULTS
 CSSCD INFANT COHORT PATIENTS

2004 2

The SAS System

11:20 Tuesday, February 17,

The CONTENTS Procedure

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos	Format	Informat	Label
40	LABOMTH	Num	8	350	2.	2.	METH OTHER THAN ELECTROPHORESIS (PH2)
41	LABOSPF	Char	25	358			SPECIFY OTHER METHOD USED (PH2)
29	LABOVERS	Char	2	234			VERSION DATA TRANSCRIBED FROM
13	LABPLATE	Num	8	89	4.	4.	6 PLATELET COUNT
20	LABSGOT	Num	8	162	4.	4.	82D AST(SGOT)
21	LABSGPT	Num	8	170	4.	4.	82E ALT(SGPT)
5	LABTRANS	Num	8	25	2.	2.	4 PT TRANSFUSED W/IN PAST 4 MONTHS
28	LABTRNSC	Num	8	226	2.	2.	DATA TRANSCRIBED FROM OLDER VERSION
24	LABURA	Num	8	194	4.1	4.1	82H URIC ACID
26	LABURHB	Num	8	210	2.	2.	92B URINE HEMOGLOBIN
25	LABURPRO	Num	8	202	2.	2.	92A URINE PROTEIN
3	LABVERS	Char	1	16			FORM VERSION

CODEBOOK FOR CSSCD FORM LAB
LABORATORY TEST RESULTS
CSSCD INFANT COHORT PATIENTS

```
*****
* LABN.FMT contains value labels for numerical codes assigned to categorical*
* variables in the SAS dataset LAB_PUN.SD2
*****;
```

PROC FORMAT;

VALUE ID2F 1='1-PH2 ENTRY VIS'
 3='3-PH2 ANN 1 VIS'
 5='5-PH2 ANN 2 VIS'
 7='7-PH2 ANN 3 VIS'
 9='9-PH2 ANN 4 VIS'
 11='11-PH3 ENTRY VIS'
 13='13-PH3 ANN 1 VIS'
 15='15-PH3 ANN 2 VIS'
 17='17-PH3 ANN 3 VIS'
 19='19-PH3 ANN 4 VIS';

VALUE LABTRANS 1='NO'
 2='YES';

VALUE LABFMTH 1='ALKALINE DENATURATION'
 2='OTHER METHOD';

* Format DIPSTICK is defined for variables LABURPRO LABURHB;

VALUE DIPSTICK 1='NEGATIVE'
 2='TRACE'
 3='1+'
 4='2+'
 5='3+'
 6='4+';

VALUE LABIRPT 1='NO'
 2='YES';

VALUE LABA2MTH 1='COLUMN CHROMATOGRAPHY'
 2='OTHER';

VALUE LABDIAG 1='SS'
 2='SC'
 3='SB+THAL'
 4='SBOTHAL'
 5='SS ALPHA THAL'
 6='OTHER';

VALUE LABOMTH 1='NO'
 2='YES';

format LABID2 ID2F.
LABTRANS LABTRANS.LABFMTH LABFMTH.LABURPRO LABURHB DIPSTICK.
LABIRPT LABIRPT. LABA2MTH LABA2MTH. LABDIAG LABDIAG.LABOMTH LABOMTH..;

run;
quit;

CODEBOOK FOR CSSCD FORM LAB
LABORATORY TEST RESULTS - PAGE 1
 CSSCD INFANT COHORT PATIENTS

LABID2 ----- FOLLOW-UP IDENTIFIER

type: numeric (float)
 label: LABID2

range: [1,19] units: 1
 unique values: 12 coded missing: 0 / 3020

tabulation:	Freq.	Numeric	Label
	464	1	1-PH2 ENTRY VIS
	416	3	3-PH2 ANN 1 VIS
	385	5	5-PH2 ANN 2 VIS
	362	7	7-PH2 ANN 3 VIS
	139	9	9-PH2 ANN 4 VIS
	359	11	11-PH3 ENTRY VIS
	1	12	
	303	13	13-PH3 ANN 1 VIS
	2	14	
	281	15	15-PH3 ANN 2 VIS
	292	17	17-PH3 ANN 3 VIS
	16	19	19-PH3 ANN 4 VIS

LABVERS ----- FORM VERSION

type: string (str1)

unique values: 6 coded missing: 0 / 3020

tabulation:	Freq.	Value
	794	"?"
	1	"A"
	83	"B"
	875	"E"
	12	"G"
	1255	"H"

LABTRANS ----- 4 PT TRANSFUSED W/IN PAST 4 MONTHS

type: numeric (float)
 label: LABTRANS

range: [1,2] units: 1
 unique values: 2 coded missing: 12 / 3020

tabulation:	Freq.	Numeric	Label
	2703	1	NO
	305	2	YES

CODEBOOK FOR CSSCD FORM LAB
 LABORATORY TEST RESULTS - PAGE 1
 CSSCD INFANT COHORT PATIENTS

range: [1,2] units: 1
 unique values: 2 coded missing: 1629 / 3020

tabulation:	Freq.	Numeric	Label
	1144	1	ALKALINE DENATURATION
	247	2	OTHER METHOD

LABFSPF ----- 731 SPECIFY OTHER METHOD HBF TEST

type: string (str25)

unique values: 14 coded missing: 0 / 3020

tabulation:	Freq.	Value
	3	"."
	1	"B"
	2773	"C"
	1	"ACID CITRATE"
	5	"AGAR"
	2	"CELLULOSE ACETATE"
	72	"COLUMN"
	28	"DENSITOMETRY"
	24	"HELENA LAB"
	52	"HPLC"
	1	"IMMUNOFLOURESCENCE"
	2	"ISOELECTRIC FOCUSING"
	1	"PART OF EP"
	55	"RADIAL IMMUNODIFFUSION"

LABFSPF:

1. Required only if LABFMTH=2.

CODEBOOK FOR CSSCD FORM LAB
LABORATORY TEST RESULTS - PAGE 2
CSSCD INFANT COHORT PATIENTS

LABCRTN ----- 82A SERUM CREATININE

type: numeric (float)

range: [.1,10.1] units: .1
unique values: 15 coded missing: 1878 / 3020

mean: .550438
std. dev: .33354

percentiles:	10%	25%	50%	75%	90%
	.4	.4	.5	.6	.8

LABCRTN:
1. Required only if LABVERS='H'.

LABBUN ----- 82B BLOOD UREA NITROGEN

type: numeric (float)

range: [1,101] units: 1
unique values: 22 coded missing: 2145 / 3020

mean: 7.55657
std. dev: 4.35705

percentiles:	10%	25%	50%	75%	90%
	4	6	7	9	11

LABBUN:
1. Optional if LABVERS='H'.

LABALKPH ----- 82C ALKALINE PHOSPHATASE

type: numeric (float)

range: [38,404] units: 1
unique values: 248 coded missing: 2320 / 3020

mean: 174.346
std. dev: 64.1031

percentiles:	10%	25%	50%	75%	90%
	95	129	166	214	261

LABALKPH:
1. Optional if LABVERS='H'.

LABSGOT ----- 82D AST(SGOT)

CODEBOOK FOR CSSCD FORM LAB
LABORATORY TEST RESULTS - PAGE 2
CSSCD INFANT COHORT PATIENTS

range: [1,6] units: 1
unique values: 6 coded missing: 1919 / 3020

tabulation:	Freq.	Numeric	Label
	917	1	NEGATIVE
	110	2	TRACE
	37	3	1+
	14	4	2+
	10	5	3+
	13	6	4+

LABURHB:

1. Required only if LABVERS='H'.

LABIRPT ----- LAB INSTITUTIONAL REPORTS RECEIVED

type: numeric (float)
label: LABIRPT

range: [1,2] units: 1
unique values: 2 coded missing: 71 / 3020

tabulation:	Freq.	Numeric	Label
	110	1	NO
	2839	2	YES

