Public Use Dataset
Annotated eCRF

RNA Biosignatures: A Paradigm Change for the Management of Young Febrile Infants (Biosig II)
PECARN Protocol Number 035

Pediatric Emergency Care Applied Research Network
National Institute for Child Health and Human Development (NICHD)

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Annotated eCRF Version v1.0
Version Date: June 3, 2020

Table of Contents:

Notes:

- The datasets are primarily based on raw datasets (i.e., as captured in study database with minimal modifications). Selected derived data elements were also included.
- **StudySubjectID** is the original identifier for the datasets from OpenClinica. We have created a new masked identifier **PUDID**; this variable is present in all datasets to facilitate merging. We will retain a dataset that links the original **StudySubjectID and RecordID** to the **PUDID** for internal records. **StudySubjectID and RecordID** have been removed from all public use datasets.
- After the new masked identifier is created and used to replace the original, each public use dataset is sorted by PUDID, Occurrence, and ItemGroupRepeatKey. This ensures that the final sorting of records does not correspond to the ordering of the original identifier
- Open text fields and other variables have been reviewed for sensitive or identifying information and modified as needed.
- All out of range and other questionable data has been included in the public use datasets.
- Many of the datasets include only one record per subject (unique identifier **PUDID**). Other datasets are relational, that is, may have more than one record per patient. These records are uniquely identified by **PUDID** and *ItemGroupRepeatKey* and *Occurrence*.
- All date variables are recoded to be number of days since ScreenDate. Variable names and labels are changed as well. For example, the variable TempDate will be called TempDay and the label will change from “Date qualifying temperature taken” to “Day qualifying temperature taken (relative to screening date)”. No actual dates are included.
- If labels were deemed insufficiently descriptive, text was added to clarify, e.g. “Type 1” label for HerpesType1 variable was changed to “Herpes Type 1”.

Table name: Demographics

Biosig II Demographics v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Demogra...(0/5)

Title: Demographics

Date of Birth: Birthday # DD-MMM-YYYY

BirthdateNA #
NA
Date of birth not available =98

Sex: Sex # *
MFr
Male =1
Female =2

Ethnicity: Ethnicity # *
Ethnic
Hispanic or Latino =1
Not Hispanic or Latino =2
Unknown or Not Reported =92

Race: *
(select all that apply)
American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
White
Unknown or Not Reported

Derived variables included in the Demographics dataset:

Variable	Format	Type	Label	Algorithm / Notes
Race1	Yes = 1, No = 0	#	American Indian or Alaska Native	
Race2	Yes = 1, No = 0	#	Asian	
Race3	Yes = 1, No = 0	#	Black or African American	
Race4	Yes = 1, No = 0	#	Native Hawaiian or Other pacific Islander	
Race5	Yes = 1, No = 0	#	White	
Race92	Yes = 1, No = 0	#	Unknown or Not Reported	

Table name: Eligibility

Biosig II Screening and Enrollment v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Screeni...(0/15) | Permiss...(0/13) | -- Select to Jump --

Title: Screening

Instructions: Enter subjects who meet all inclusion criteria, regardless of meeting an exclusion criteria.

All inclusion criteria must be "Yes" and all exclusion must be "No" in order to meet study eligibility.

Screening

Screening Date: ScreenDay # * DD-MMM-YYYY

Inclusion Criteria

1. Is the subject 60 days of age or younger?

Inclusion1 # *
YNr
Yes =1
No =0

2. Is the subject febrile with a documented rectal temperature = 38 °C in the ED OR a history of fever measured by any route at home or outside clinic within 24 hours of ED presentation?

Inclusion2 # *
YNr
Yes =1
No =0

3. Is the subject being evaluated for serious bacterial infections (SBI) with blood screening tests including, but not limited to, blood culture?

Inclusion3 # *
YNr
Yes =1
No =0

Exclusion Criteria

1. Premature birth (< 37 weeks gestational age)

Exclusion1 # *
YNr
Yes =1
No =0

2. Administration of antibiotics within 4 days of ED presentation

Exclusion2 # *
YNr
Yes =1
No =0

3. Overwhelming clinical sepsis requiring emergent interventions such as intubation and/or vasopressors

Exclusion3 # *
YNr
Yes =1
No =0

4. Presence of a major congenital anomaly

Exclusion4 # *
YNr
Yes =1
No =0

5. Presence of inborn errors of metabolism

Exclusion5 # *
YNr
Yes =1
No =0

6. Presence of a congenital heart disease

Exclusion6 # *
YNr

Yes =1
No =0

7. Presence of chronic lung disease

Exclusion7 # *
YNr
Yes =1
No =0

8. Presence of a disease or medication that would affect the immune system

Exclusion8 # *
YNr
Yes =1
No =0

9. Presence of indwelling catheters or shunts

Exclusion9 # *
YNr
Yes =1
No =0

10. Evidence of focal infections such as abscess or cellulitis (otitis media is not an exclusion criterion)

Exclusion10 # *
YNr
Yes =1
No =0

11. Previously enrolled in this study

Exclusion11 # *
YNr
Yes =1
No =0

Table name: Eligibility

Biosig II Screening and Enrollment v1

CRF Header Info

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Exit

Screeni...(0/15) | Permiss...(0/13) | -- Select to Jump --

Title: Permission

Eligibility

Is subject eligible?

Eligible # *
YNr
Yes =1
No =0

Qualifying Temperature

Qualifying temperature

Temp # °C or °F

Date qualifying temperature taken

TempDay # DD-MMM-YYYY

Location where qualifying temperature was taken

(Select one) TempLoc #
temploc
1=Enrolling ED
2=Outside/referring hospital
3=Doctor's office, clinic or other facility (i.e. urgent care)
4=Home

Consent (Parental Permission)

If eligible, was the parent/guardian approached for consent?

(Select one) Approached #
YN
1=Yes
0=No

If not approached, please provide the primary reason: (Select one) NotApproached #
noappr
1=Research staff not available for enrollment
2=Not possible within clinical window (prior to blood draw)
3=Language/custody barrier
4=Physician discretion
90=Other (specify)

If "Other" reason, specify: NotApproachedSpecify $

If parent/guardian was approached, was consent given?

(Select one) Consent #
YN
1=Yes
0=No

Most applicable reason for refusal: (Select one) RefusalReason #
refreas
1=Concerned about risks, survey content and/or procedures (Not interested in study)
2=Unable to wait/want to discuss with others
3=Distrust research
4=Too overwhelmed
5=Too much pain involved
6=No reason given/unknown
90=Other (specify)

If "Other" reason, specify: RefusalReasonSpecify $

Date and Time Consent was Signed

Date: ConsentDay # DD-MMM-YYYY Time: ConsentTime $ HHMM

Sequential Sample

Was consent given for the sequential sample?

(Select one) SequentialConsent #

YN
1=Yes
0=No

Table name: ClinicalLab

Biosig II Clinical and Laboratory Data v3

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Disposi...(0/7) | ED Visit (0/38) | Medicat...(0/9) | Urinaly...(0/9) | CSF (0/13) | Viral S...(0/24) | Cultures (0/4) | -- Select to Jump --

Title: Initial ED Disposition

Instructions: This form is required on consented and "missed eligible" subjects. If subject is a "missed eligible", only the first lab results of each test is required.

Initial ED Disposition

Subject's Status after ED Visit

(Select one) SubjectStatus # *

EDStatus
1=Discharged
2=Admitted
3=Transferred
4=Left Against Medical Advice
5=Died

Date of ED Discharge: EDDischDay # (DD-MMM-YYYY)

Date of Hospital Admission: HospitalAdmitDay # (DD-MMM-YYYY)

Date Transferred: TransferDay # (DD-MMM-YYYY)

Were antibiotics prescribed at discharge?

(Select one) AntibioticsDisch #

YN
1=Yes
0=No

If "Yes", specify antibiotic: (Select one) AntibioticsDischName #

antibio
1=Amoxicillin
2=Ampicillin
6=Cefepime
3=Cefotaxime
7=Ceftazidime
4=Ceftriaxone
8=Cephalexin
5=Gentamicin
9=Vancomycin
90=Other (specify)

Specify "Other" antibiotic: AntibioticsDischSpec $

Table name: ClinicalLab

Biosig II Clinical and Laboratory Data v3

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Disposi...(0/7) | **ED Visit** (0/38) | Medicat...(0/9) | Urinaly...(0/9) | CSF (0/13) | Viral S...(0/24) | Cultures (0/4) | -- Select to Jump --

Title: Initial ED Clinical Assessments, CBC with Differential, Blood Studies and Chest X-Rays

Instructions: Enter vital signs, blood testing and chest x-ray results collected during the ED visit.

Initial Clinical Assessment

Were vitals (temp/HR/RR) collected within the first hour of triage at the enrolling PECARN ED?

EDVitals, #
YNr
- Yes =1
- No =0

Initial ED Temp (°C or °F) _____ EDTemp #

TempND #
TempND
- Temp Not Done =95

Heart Rate (HR) (beats/min.) _____ EDHeartRate #

HeartRateND #
HRND
- HR Not Done =95

Respiratory Rate (RR) (breaths/min.) _____ EDRespRate #

RespRateND #
RRND
- RR Not Done =95

Was oxygen saturation measured in the enrolling PECARN ED?

EDOxSat #
YNr
- Yes =1
- No =0

Was oxygen saturation measured at room air or while on supplemental oxygen?

(Select one) OxSatRoomAir #
OxSat
1=Room air
2=Supplemental Oxygen

O_2 Saturation (%) _____ OxSatResult #

Does the subject have any evidence of increased work of breathing (WOB)/respiratory distress during the ED clinician's physical assessment?

EDRespDistress #
YNr
- Yes =1
- No =0

Specify the signs of increased WOB or respiratory distress: (Check all that apply)
- Retractions (subcostal/intercostal/suprasternal)
- Nasal flaring
- Grunting
- Tachypnea

CBC with Differential

Were CBC tests obtained during the ED visit?

CBCObtained # *
YNr
- Yes =1
- No =0

Date collected: _____ CBCDay # (DD-MMM-YYYY) Time collected: _____ CBCTime $ (HHMM)

Hemoglobin _____ Hgb # Platelets _____ Platelets # White Blood Count _____ CBCWBC #

(g/dL) (x 10³/µL) (x 10³/µL)

Upload a de-identified CBC report (with Differential, if applicable): Click to upload file Value not provided

Were differential tests obtained with the CBC?

(Select one) CBCDiff #
YN
1=Yes
0=No

If "Yes", what type of test was used? (Select one) CBCDiffType #
ManAuto
1=Manual
2=Automated

Type of result: (Select one) AbsolutePercent #
AbsPerc
1=Absolute count
2=Percent

Neutrophils Neutrophils # Lymphocytes Lymphocytes # Monocytes Monocytes #

Eosinophils Eosinophils # Basophils Basophils # Bands Bands # BandsND #
BandsND
Bands Not Done =95

Other Blood Studies: C-Reactive Protein (CRP) and Procalcitonin (PCT)

Were other blood studies obtained during the ED visit?

EDBloodStudies, # *
YNr
Yes =1
No =0

Date collected: EDBloodDay # (DD-MMM-YYYY) Time collected: EDBloodTime $ (HHMM)

CRP (mg/L) CRP # PCT (ng/mL) PCT #

Upload a de-identified blood studies report: Click to upload file Value not provided

Chest X-Ray

Was a chest x-ray performed during the ED visit?

ChestXray # *
YNr
Yes =1
No =0

Chest x-ray result: (Select one) ChestXrayResult #
cxr
1=Positive for pneumonia
2=Unknown or inconclusive result
0=Negative for pneumonia

Upload a de-identified report for **positive** x-ray: Click to upload file Value not provided

Derived variables included in the CLINICALLAB dataset:

Variable	Format	Type	Label	Algorithm / Notes
RespDistressSpec1	Yes = 1, No = 0	#	Retractions (subcostal/intercostalsuprasternal)	
RespDistressSpec2	Yes = 1, No = 0	#	Nasal flaring	
RespDistressSpec3	Yes = 1, No = 0	#	Grunting	
RespDistressSpec4	Yes = 1, No = 0	#	Tachypnea	

Table name: ClinicalLab

Biosig II Clinical and Laboratory Data v3

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Disposi...(0/7) | ED Visit (0/38) | Medicat...(0/9) | Urinaly...(0/9) | CSF (0/13) | Viral S...(0/24) | Cultures (0/4) | [redacted]

Title: Antibiotics, Antivirals and Antipyretic Medications

Instructions: Enter all antibiotics, antivirals and antipyretic medications administered during the ED visit and, if applicable, throughout hospitalization.

Were antibiotics, antivirals or antipyretics administered during ED stay or throughout hospitalization?

Meds # *
YNr
Yes =1
No =0

If 'Yes", enter all antibiotics, antivirals and antipyretics medications administered during the ED visit and through hospitalization (if applicable):

Table name: ClinicalLab_Meds1

Start Date (DD-MMM-YYYY)	Start Time (HHMM)	Name of Antibiotic	If "Other" antibiotic, specify:	Name of Antiviral	If "Other" antiviral, specify:	Name of Antipyretic	If "Other" antipyretic, specify:	

[redacted] AntiStartDay #	[redacted] AntiStartTime $	[redacted] AntibioticsName # antibio
		1=Amoxicillin
		2=Ampicillin
		6=Cefepime
		3=Cefotaxime
		7=Ceftazidime
		4=Ceftriaxone
		8=Cephalexin
		5=Gentamicin
		9=Vancomycin
		90=Other (specify)
			[redacted] AntibioticsSpec $	[redacted] AntiviralName # antivir
				1=Oseltamivir (Tamiflu)
				2=Acyclovir (Zovirax)
				90=Other (specify)
					[redacted] AntiviralSpecify $	[redacted] AntipyreticName # antipyr
						1=Ibuprofen (Motrin/Advil)
						2=Acetaminophen (Tylenol)
						90=Other (specify)
							[redacted] AntipyreticSpec $	X

Add

Table name: ClinicalLab

Biosig II Clinical and Laboratory Data v3

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Disposi...(0/7) | ED Visit (0/38) | Medicat...(0/9) | Urinaly...(0/9) | CSF (0/13) | Viral S...(0/24) | Cultures (0/4) | [redacted]

Title: Urinalysis

Instructions: Enter all urinalysis testing done during the ED visit and, if applicable, throughout hospitalization.

Urinalysis Testing

Was a urinalysis obtained during ED stay or throughout hospitalization?

Urinalysis # *
YNr
Yes =1
No =0

If 'Yes", enter all urinalyses obtained during the ED visit and through hospitalization (if applicable).

Table name: ClinicalLab_Urinalysis1

Date Collected (DD-MMM-YYYY)	Time Collected (HHMM)	Collection Site	Nitrite	Leukocyte Esterase	WBC	Bacteria	Upload a de-identified urinalysis report	
[redacted] UrinalysisDay #	[redacted] UrinalysisTime $	[redacted] UrinalysisSite # CollSite 1=Catheterization 2=Suprapubic 3=Bag sample 94=Not documented	[redacted] Nitrite # Nitrite 1=Positive 0=Negative 95=Not done	[redacted] Leukocyte # Leuko 1=1+ (small) 2=2+ (moderate) 3=3 or more (large) 0=Negative 95=Not done	[redacted] UrineWBC # WBC 1=Positive (or >= 6) 0=Negative (or <= 5) 95=Not done	[redacted] UrineBacteria # Bacteria 1=Present 0=Absent 95=Not done	[redacted] Value not provided	X

Add

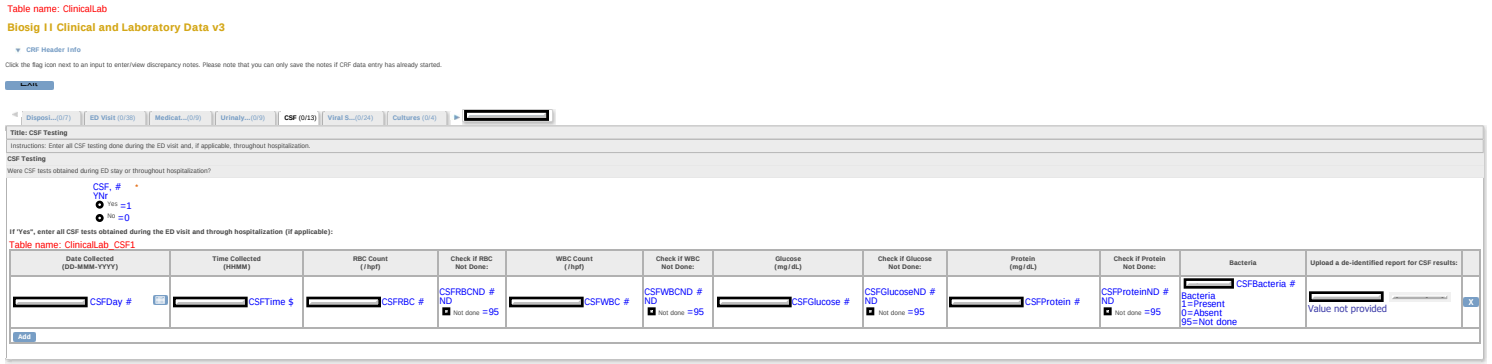


Table name: ClinicalLab

Biosig I I Clinical and Laboratory Data v3

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Dispos...(0/7) | ED Visit (0/38) | Medicat...(0/9) | Urinaly...(0/9) | CSF (0/13) | Viral S...(0/24) | Cultures (0/4) | [redacted]

Title: CSF Testing

Instructions: Enter all CSF testing done during the ED visit and, if applicable, throughout hospitalization.

CSF Testing

Were CSF tests obtained during ED stay or throughout hospitalization?

CSF, # *
YNr
Yes =1
No =0

If 'Yes", enter all CSF tests obtained during the ED visit and through hospitalization (if applicable):

Table name: ClinicalLab_CSF1

Date Collected (DD-MMM-YYYY)	Time Collected (HHMM)	RBC Count (/ hpf)	Check if RBC Not Done:	WBC Count (/ hpf)	Check if WBC Not Done:	Glucose (mg / dL)	Check if Glucose Not Done:	Protein (mg / dL)	Check if Protein Not Done:	Bacteria	Upload a de-identified report for CSF results:	
[redacted] CSFDay #	[redacted] CSFTime $	[redacted] CSFRBC #	CSFRBCND # ND Not done =95	[redacted] CSFWBC #	CSFWBCND # ND Not done =95	[redacted] CSFGlucose #	CSFGlucoseND # ND Not done =95	[redacted] CSFProtein #	CSFProteinND # ND Not done =95	[redacted] CSFBacteria # Bacteria 1=Present 0=Absent 95=Not done	[redacted] Value not provided	X

Add

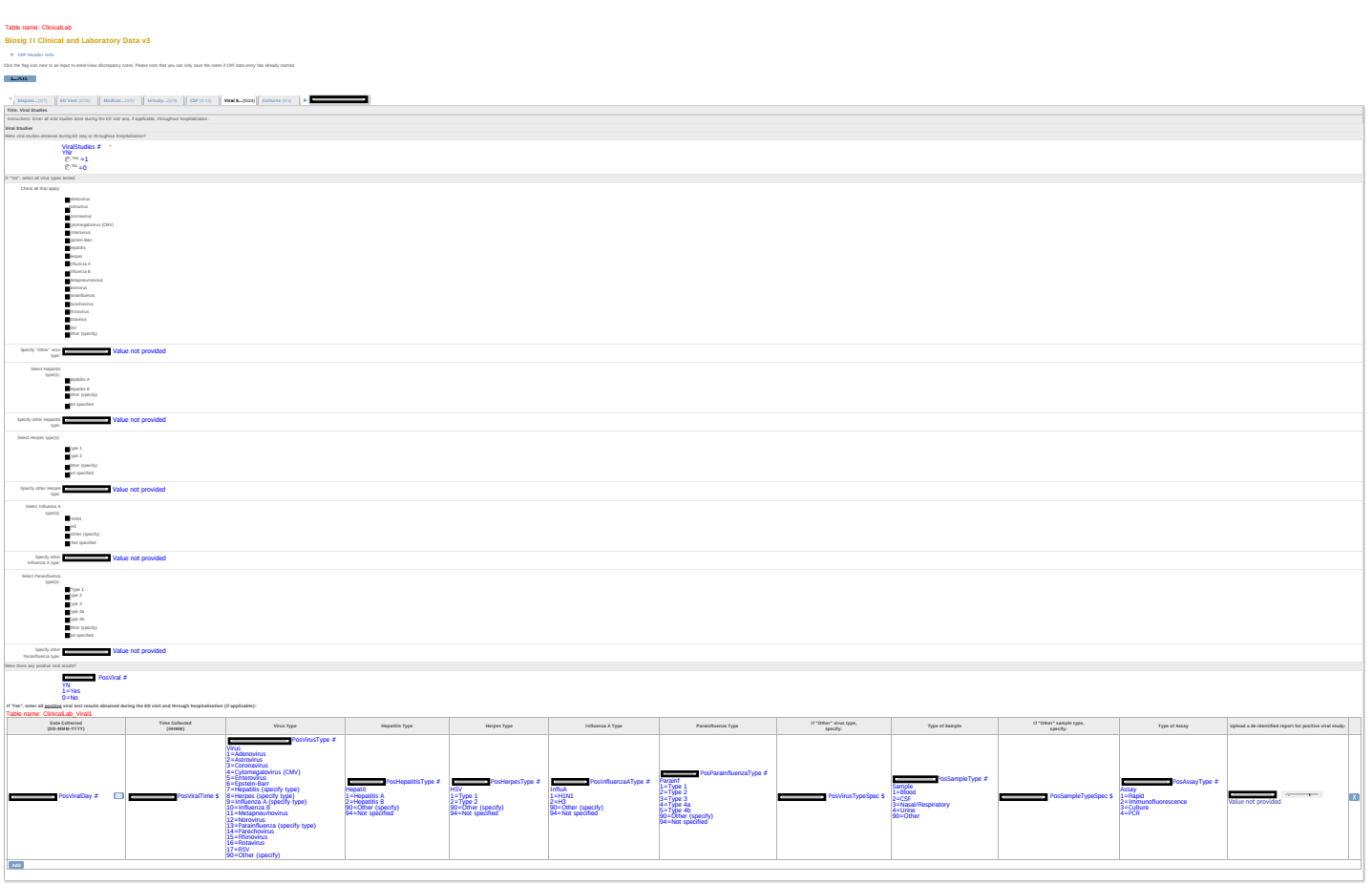


Table name: ClinicalLab

Biosig II Clinical and Laboratory Data v3

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

EXIT

Dispos...(577) | ED Visit (6108) | Medicat...(974) | Urinaly...(978) | CSF (6132) | **Viral S...(6152)** | Cultures (616) | [redacted]

Title: Viral Studies

Instructions: Enter all viral studies done during the ED visit and, if applicable, throughout hospitalization.

Viral Studies

Were viral studies obtained during ED stay or throughout hospitalization?

ViralStudies # *
YNI
Yes =1
No =0

If "Yes", select all virus types tested:

Check all that apply

- adenovirus
- astrovirus
- coronavirus
- cytomegalovirus (CMV)
- enterovirus
- epstein-Barr
- hepatitis
- herpes
- influenza A
- influenza B
- metapneumovirus
- parainfluenza
- parechovirus
- rhinovirus
- rotavirus
- RSV
- other (specify)

Specify "Other" virus type: [redacted] Value not provided

Select Hepatitis type(s):

- hepatitis A
- hepatitis B
- other (specify)
- not specified

Specify other Hepatitis type: [redacted] Value not provided

Select Herpes type(s):

- type 1
- type 2
- other (specify)
- not specified

Specify other Herpes type: [redacted] Value not provided

Select Influenza A type(s):

- H1N1
- H3
- Other (specify)
- Not specified

Specify other Influenza A type: [redacted] Value not provided

Select Parainfluenza type(s):

- Type 1
- type 2
- type 3
- type 4a
- type 4b
- other (specify)
- not specified

Specify other Parainfluenza type: [redacted] Value not provided

Were there any positive viral results?

[redacted] PosViral #
YN
1=Yes
0=No

If "Yes", enter all positive viral test results obtained during the ED visit and through hospitalization (if applicable):

Table name: ClinicalLab_Viral1

Date Collected (DD-MMM-YYYY)	Time Collected (HHMM)	Virus Type	Hepatitis Type	Herpes Type	Influenza A Type	Parainfluenza Type	If "Other" virus type, specify:	Type of Sample	If "Other" sample type, specify:	Type of Assay	Upload a de-identified report for positive viral study:
[redacted] PosViralDay #	[redacted] PosViralTime $	[redacted] PosVirusType # Virus 1=Adenovirus 2=Astrovirus 3=Coronavirus 4=Cytomegalovirus (CMV) 5=Enterovirus 6=Epstein-Barr 7=Hepatitis (specify type) 8=Herpes (specify type) 9=Influenza A (specify type) 10=Influenza B 11=Metapneumovirus 12=Norovirus 13=Parainfluenza (specify type) 14=Parechovirus 15=Rhinovirus 16=Rotavirus 17=RSV 90=Other (specify)	[redacted] PosHepatitisType # Hepatiti 1=Hepatitis A 2=Hepatitis B 90=Other (specify) 94=Not specified	[redacted] PosHerpesType # HSV 1=Type 1 2=Type 2 90=Other (specify) 94=Not specified	[redacted] PosInfluenzaAType # Influa 1=H1N1 2=H3 90=Other (specify) 94=Not specified	[redacted] PosParainfluenzaType # Parain 1=Type 1 2=Type 2 3=Type 3 4=Type 4a 5=Type 4b 90=Other (specify) 94=Not specified	[redacted] PosVirusTypeSpec $	[redacted] PosSampleType # Sample 1=Blood 2=CSF 3=Nasal/Respiratory 4=Urine 90=Other	[redacted] PosSampleTypeSpec $	[redacted] PosAssayType # Assay 1=Rapid 2=Immunofluorescence 3=Culture 4=PCR	[redacted] Value not provided

Add

Table name: ClinicalLab

Biosig II Clinical and Laboratory Data v3

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Disposi...(0/7) | ED Visit (0/38) | Medicat...(0/9) | Urinaly...(0/9) | CSF (0/13) | Viral S...(0/24) | **Cultures** (0/4) | -- Select to Jump --

Title: Cultures

Instructions: If "Yes" to any of the questions below, complete the respective section(s) in the Culture Log.

Were any blood cultures obtained during ED stay or through hospitalization?

BloodCulture # YNr * If "Yes", enter blood culture(s) in the Cultures Log

- Yes =1
- No =0

Were any CSF cultures obtained during ED stay or through hospitalization?

CSFCulture # YNr * If "Yes", enter CSF culture(s) in the Cultures Log

- Yes =1
- No =0

Were any stool cultures obtained during ED stay or through hospitalization?

StoolCulture # YNr * If "Yes", enter stool culture(s) in the Cultures Log

- Yes =1
- No =0

Were any urine cultures obtained during ED stay or through hospitalization?

UrineCulture # YNr * If "Yes", enter urine culture(s) in the Cultures Log

- Yes =1
- No =0

Table name: YOS

Biosig II Yale Observation Scale v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

YOS (0/7)

Title: Yale Observation Scale

Instructions: This form is required on all consented subjects.

Yale Observation Scale

Quality of cry

(Select one) YOSCry # *

yoscry
1=Strong with normal tone OR content and not crying
3=Whimpering or sobbing
5=Weak OR moaning OR high pitched
99=Not assessed

Reaction to parents

(Select one) YOSReaction # *

yosreact
1=Cries briefly then stops OR content and not crying
3=Cries off and on
5=Continual cry OR hardly responds
99=Not assessed

State variation

(Select one) YOSState # *

yosstate
1=If awake, stays awake OR if asleep and stimulated, wakes up quickly
3=Eyes close briefly, awake OR awakes with prolonged stimulation
5=Falls to sleep OR will not rouse
99=Not assessed

Color

(Select one) YOSColor # *

yoscolor
1=Pink
3=Pale extremities OR acrocyanosis
5=Pale OR cyanotic OR mottled OR ashen
99=Not assessed

Hydration

(Select one) YOSHydration # *

yoshydr
1=Skin normal, eyes normal AND mucous membranes moist
3=Skin, eyes-normal AND mouth slightly dry
5=Skin doughy OR tented AND dry mucous membranes AND/OR sunken eyes
99=Not assessed

Response (talk, smile) to social overtures

(Select one) YOSResponse # *

yosresp
1=Smiles OR alert (<= 2 mo)
3=Brief smile OR alerts briefly (<= 2 mo)
5=No smile OR face anxious dull expressionless OR no alerting (<= 2 mo)
99=Not assessed

Risk for Serious Bacterial Infection (SBI)

After your physical exam (but before laboratory testing), what is your assessment of risk of serious bacterial infection?

(Select one) SBI # *

sbi
1=< 1% (minimal)
2=1 - 5% (slight)
3=6 - 10% (somewhat)
4=11 - 50% (likely)
5=>50% (very likely)
99=Not assessed

Table name: ParentInterview

Biosig II Parent/Guardian Interview v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Intervi...(0/10)

Title: Parent/Guardian Interview

Instructions: This form is to be completed by study personnel with the parent/guardian in an interview.

Prior to coming to the Emergency Department, how long did your baby have a fever (give your best estimate)?

(Select one) FeverDuration #

Duration
1=Less than 12 hours
2=12-24 hours
3=Greater than 24 hours
92=Unknown/unable to estimate

Before coming to the Emergency Department, was your baby given Acetaminophen or Ibuprofen (for any reason)?

(Select one) GivenMeds #

YN
1=Yes
0=No

If "Yes", how long before coming to the Emergency Department did they receive the most recent dose?

(Select one) GivenMedsYes #

Duration
1=Less than 12 hours
2=12-24 hours
3=Greater than 24 hours
92=Unknown/unable to estimate

From your perspective, have you noticed any of the following?

My baby's **cry** is different than normal

(Select one) Cry #

YN
1=Yes
0=No

My baby is not able to be **comforted** when crying

(Select one) Comforted #

YN
1=Yes
0=No

My baby is **more sleepy** than usual

(Select one) Sleepy #

YN
1=Yes
0=No

The color or quality of my baby's **skin** is concerning

(Select one) Skin #

YN
1=Yes
0=No

My baby is not **eating/drinking** well

(Select one) Eating #

YN
1=Yes
0=No

My baby seems less **alert** than usual

(Select one) Alert #

YN
1=Yes
0=No

From your perspective, what is the chance that your child's fever is due to a serious infection? (select the category that fits best)

(Select one) FeverInfection #

Chance
1=< 1% chance (minimal)
2=1-5% chance (slight)
3=6-10% chance (somewhat)
4=11-50% chance (likely)
5=> 50% chance (very likely)

Table name: SampleAccountability

Biosig II Sample Accountability v2

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Sample (0/22)

Title: Sample Accountability

Initial Biosignature Sample (0.5mL -1.0 mL)

Was a viable biosignature sample obtained and placed in freezer?

BiosigSample # *
YNr
- Yes =1
- No =0

If "Yes", was the sample drawn from an existing IV line? (Select one) BiosigSampleIV #
YNU
1=Yes
0=No
92=Unknown

Was more than 1 mL of blood wasted prior to study sample collection? (Select one) BiosigSampleIVWasted #
YNU
1=Yes
0=No
92=Unknown

If "No", select primary reason: (Select one) BiosigNotObtained #
nosample
1=Unsuccessful blood draw attempt
2=Clinical staff neglected or refused to draw
3=Sample destroyed prior to freezing
90=Other (specify)

Specify other reason: BiosigNotObtainedSpec $

Primary reason sample destroyed: (Select one) BiosigDestroyed #
destroy
1=Patient later found to be ineligible
2=QNS or processing issues
3=Consent issue
90=Other (specify)

Specify other reason: BiosigDestroyedSpec $

Viral PCR Sample (1.0 mL)

Was a viable PCR sample obtained and placed in freezer?

PCRSample # *
YNr
- Yes =1
- No =0

If "No", select primary reason: (Select one) PCRNotObtained #
nosample
1=Unsuccessful blood draw attempt
2=Clinical staff neglected or refused to draw
3=Sample destroyed prior to freezing
90=Other (specify)

Specify other reason: PCRNotObtainedSpec $

Primary reason sample destroyed: (Select one) PCRDestroyed #
destroy
1=Patient later found to be ineligible
2=QNS or processing issues
3=Consent issue
90=Other (specify)

Specify other reason: PCRDestroyedSpec $

Procalcitonin Sample (> 0.3 mL of serum)

Was a viable procalcitonin sample obtained and placed in freezer?

PCTSample # *
YNr
Yes =1
No =0

If "No", select primary reason: (Select one) PCTNotObtained #
nosample
1=Unsuccessful blood draw attempt
2=Clinical staff neglected or refused to draw
3=Sample destroyed prior to freezing
90=Other (specify)

Specify other reason: PCTNotObtainedSpec $

Primary reason sample destroyed: (Select one) PCTDestroyed #
destroy
1=Patient later found to be ineligible
2=QNS or processing issues
3=Consent issue
90=Other (specify)

Specify other reason: PCTDestroyedSpec $

Nasopharyngeal (NP) Swab

Was an NP sample obtained and placed in freezer?

NPSwab # *
YNr
Yes =1
No =0

If "No", select primary reason: (Select one) NPSwabNotObtained #
noswab
1=Unsuccessful NP collection
2=Clinical staff neglected or refused to collect swab
3=Sample destroyed prior to freezing
90=Other (specify)

Specify other reason: NPSwabNotObtainedSpec $

Primary reason NP swab destroyed: (Select one) NPSwabDestroyed #
destroy
1=Patient later found to be ineligible
2=QNS or processing issues
3=Consent issue
90=Other (specify)

Specify other reason: NPSwabDestroyedSpec $

Table name: SequentialSample

Biosig II Sequential Sample v2

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Sequent...(0/33)

Title: Sequential Sample

Instructions: Complete this form if permission for sequential sampling was obtained at the time of consent. The sequential sample window is defined as **24-72 hours** (+/- 8 hours) from initial Biosignature sample.

Cohort Assignment

Select main cohort group assignment:

(Select one) CohortAssignment #

cohort
1=Bacterial
2=Viral
3=Co-Infection
4=Negative
93=Unable to classify (no viral testing)

If Bacterial, specify type(s):

(select all that apply)

- ☐ Bacteremia
- ☐ Urinary Tract Infection (UTI)
- ☐ Bacterial Meningitis

Was cohort assignment made within sequential sample window?

(Select one) SampleWindow #

YN
1=Yes
0=No

If "No", select primary reason: (Select one) NoAssignment #

nocohort
1=Research staff unavailable
2=PI unable to classify
90=Other (specify)

Specify other reason: NoAssignmentSpec $

Subject Location

Was the subject in the ED or hospitalized during the sequential sample window?

(Select one) SubjectLocation # If subject returned to the ED, complete the Medical Record Review form.

YN
1=Yes
0=No

Attempt

Was an **attempt** made to collect sample within the sequential sample window?

(Select one) SeqSampleAttempt #

YN
1=Yes
0=No

If "No", select primary reason: (Select one) NoSeqSampleAttempt #

attempt
1=Clinical staff unavailable/unwilling
2=Research staff unavailable
3=Parent refused
4=Cohort closed
90=Other (specify)

Specify other reason: NoSeqSampleAttemptSpec $

Accountability

Was a viable sample obtained and placed in freezer?

(Select one) SeqSampleObtained #

YN
1=Yes
0=No

If "Yes", was the sample drawn from an existing IV line? (Select one) SeqSampleIV #
YNU
1=Yes
0=No
92=Unknown

Was more than 1 mL of blood wasted prior to study sample collection? (Select one) SeqSampleIVWasted #
YNU
1=Yes
0=No
92=Unknown

If "No", select primary reason: (Select one) NoSeqSampleObtained #
noseqsam
1=Unsuccessful blood draw attempt
2=Clinical staff neglected or refused to draw
3=Sample destroyed prior to freezing
90=Other (specify)

Specify other reason: NoSeqSampleObtainedSpec $

Primary reason sample was destroyed: (Select one) SeqSampleDestroyed #
destroy
1=Patient later found to be ineligible
2=QNS or processing issues
3=Consent issue
90=Other (specify)

Specify other reason: SeqSampleDestroyedSpec $

CBC with Differential

Was a CBC obtained within 12 hours of the sequential sample?

(Select one) CBCObtained #
YN
1=Yes
0=No

Date collected: CBCDay # (DD-MMM-YYYY) Time collected: CBCTime $ (HHMM)

Hemoglobin (g/dL) Hgb # Platelets (x 10^3/µL) Platelets # White Blood Count (x 10^3/µL) CBCWBC #

Upload a de-identified CBC report (with Differential, if applicable): Click to upload file...
Value not provided

Were differential tests obtained with the CBC?

(Select one) CBCDiff #
YN
1=Yes
0=No

If "Yes", what type of test was used? (Select one) CBCDiffType #
ManAuto
1=Manual
2=Automated

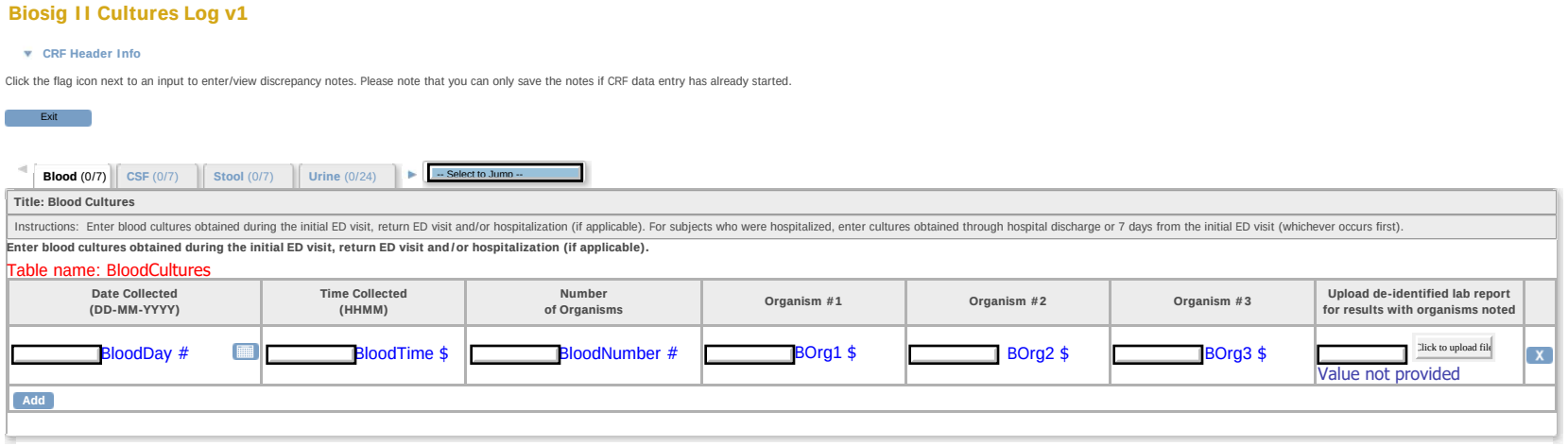
Type of result: (Select one) AbsolutePercent #
AbsPerc
1=Absolute count
2=Percent

Neutrophils Neutrophils # Lymphocytes Lymphocytes # Monocytes Monocytes #

Eosinophils Eosinophils # Basophils Basophils # Bands Bands # BandsND #
BandsND
Bands Not Done =95

Derived variables included in the SEQUENTIALSAMPLE dataset:

Variable	Format	Type	Label	Algorithm / Notes
BacterialType1	Yes = 1, No = 0	#	Bacteremia	
BacterialType2	Yes = 1, No = 0	#	Urinary Tract Infection (UTI)	
BacterialType3	Yes = 1, No = 0	#	Bacterial Meningitis	



Variable	Format	Type	Label	Algorithm / Notes
nOrg		#	Number of blood culture organisms listed	
bOrg1Type	OrgClass. Contaminant = 1 Inconclusive = 2 Pathogen = 3	#	Organism 1 blood culture type	
bOrg2Type	OrgClass. Contaminant = 1 Inconclusive = 2 Pathogen = 3	#	Organism 2 blood culture type	
bOrg3Type	OrgClass. Contaminant = 1 Inconclusive = 2 Pathogen = 3	#	Organism 3 blood culture type	

Biosig II Cultures Log v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Blood (0/7) | CSF (0/7) | Stool (0/7) | Urine (0/24) | -- Select to Jump --

Title: CSF Cultures

Instructions: Enter CSF cultures obtained during the initial ED visit, return ED visit and/or hospitalization (if applicable). For subjects who were hospitalized, enter cultures obtained through hospital discharge or 7 days from the initial ED visit (whichever occurs first).

Enter CSF cultures obtained during the initial ED visit, return ED visit and/or hospitalization (if applicable).

Table name: CSFCultures

Date Collected (DD-MM-YYYY)	Time Collected (HHMM)	Number of Organisms	Organism #1	Organism #2	Organism #3	Upload de-identified lab report for results with organisms noted	
CSFDay #	CSFTime $	CSFNumber #	CSFOrg1 $	CSFOrg2 $	CSFOrg3 $	Click to upload file Value not provided	X

Add

Variable	Format	Type	Label	Algorithm / Notes
nOrg		#	Number of CSF culture organisms listed	
csfOrg1Type	OrgClass. Contaminant = 1 Inconclusive = 2 Pathogen = 3	#	Organism 1 CSF culture type	
csfOrg2Type	OrgClass. Contaminant = 1 Inconclusive = 2 Pathogen = 3	#	Organism 2 CSF culture type	
csfOrg3Type	OrgClass. Contaminant = 1 Inconclusive = 2 Pathogen = 3	#	Organism 3 CSF culture type	

Variable	Format	Type	Label	Algorithm / Notes
UrineUAAbsDiff		#	Difference (in hours) between UA and urine culture	Only the first UA closest to the date and time of urine culture is included. Additionally, If the time between a culture and UA is > 2 hours, then the UA is not found in this table.
UAResult	UA. Positive = 1 Negative/Absent = 0 No Urine Culture = .m No Urine Culture associated with UA = .u	#	Urinalysis result	Only the first UA closest to the date and time of urine culture is included. Additionally, If the time between a culture and UA is > 2 hours, then the UA is not found in this table.
nOrg		#	Number of urine culture organisms listed	
uCultureReturn	YNR. No = 0 Yes = 1	#	Urine culture obtained on return visit	
uOrg1Type	OrgClass. Contaminant = 1 Inconclusive = 2 Pathogen = 3	#	Organism 1 urine culture type	
uOrg2Type	OrgClass. Contaminant = 1 Inconclusive = 2 Pathogen = 3	#	Organism 2 urine culture type	
uOrg3Type	OrgClass. Contaminant = 1 Inconclusive = 2 Pathogen = 3	#	Organism 3 urine culture type	
uOrg1		$	Organism 1 urine culture	
uOrg2		$	Organism 2 urine culture	
uOrg3		$	Organism 3 urine culture	

Table name: FollowUp

Biosig II Follow-Up v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

FollowUp (0/7)

Title: Follow-Up

Instructions: This form is required on subjects who were discharged at the initial ED visit.

Completion

Were follow-up questions completed with parent/guardian?

(Select one) SurveyCompleted # *

YN
1=Yes
0=No

If "Yes", specify parent: (Select one) ParentCompleted #

parent
1=Same parent who was present during enrollment
2=Parent/guardian other than the one who was present during enrollment

Date completed: FollowUpDay # DD-MM-YYYY

If "No", does subject's medical record reveal documentation of return ED visit or hospital admission within 7 days of initial ED discharge?

(Select one) RecordEDReturn # If "Yes", complete the Medical Record Review.

YN
1=Yes
0=No

Parent Questions

Since the ED visit, has your baby's condition _____?

(Select one) BabyCondition #

cond
1=Improved
2=Remained the same
3=Worsened

Did you seek additional medical attention for your baby's illness?

(Select one) MedAttention # If subject returned to ED or was admitted to a hospital, complete the Medical Record Review.

medatt
0=No
1=Yes, primary care doctor, clinic, or other facility
2=Yes, returned to the Emergency Department
3=Yes, admitted to a hospital

Date of admission: AdmissionDay #

Table name: MedicalRecord

Biosig II Medical Record Review v2

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

ED Retu...(0/18) | Urinaly...(0/9) | CSF (0/13) | Viral S...(0/24) | Cultures (0/4) | [redacted]

Title: Return ED Visit

Instructions: This form is to be completed if the subject was discharged from the initial ED visit following enrollment and returned for a subsequent ED visit and/or hospitalization.

Return to ED

Did subject **return to the ED** within 7 days following initial ED discharge?

ReturnED #
YNr
Yes =1
No =0
* If "No", save this section and proceed to the next tab.

Primary reason for returning to ED:

[redacted] ReturnReason #
return
1=Called back (positive test/culture result)
2=Worsening symptoms
3=Not improving
4=Referred back (by physician or other)
90=Other (specify)

Specify other reason for return: [redacted] ReturnReasonSpec $

Date of return ED visit: [redacted] ReturnEDDay # (DD-MMM-YYYY)

Temperature at triage: [redacted] ReturnTemperature # °C or °F

ED Disposition

Subject's Status after return ED visit

[redacted] ReturnSubjectStatus #
EDStatus
1=Discharged
2=Admitted
3=Transferred
4=Left Against Medical Advice
5=Died

Date of return ED discharge: [redacted] ReturnEDDischDay # (DD-MMM-YYYY)

Date of hospital admission: [redacted] HospitalAdmitDay # (DD-MMM-YYYY)

Date transferred: [redacted] TransferDay # (DD-MMM-YYYY)

Antibiotics/Antivirals/Antipyretics

Were antibiotics, antivirals or antipyretics administered during the return ED visit or within 24 hours prior to this return ED visit (at home or outside clinic)?

[redacted] ReturnAntiMeds #
YNU
1=Yes
0=No
92=Unknown

If "Yes", enter all antibiotics, antivirals and antipyretics administered within 24 hours prior to and during the ED return visit (at home or outside clinic):

Table name: MedicalRecord_Meds2

Start Date (DD-MMM-YYYY)	Start Time (HHMM)	Name of Antibiotic	If "Other" antibiotic, specify:	Name of Antiviral	If "Other" antiviral, specify:	Name of Antipyretic	If "Other" antipyretic, specify:	
[redacted] AntiStartDay #	[redacted] AntiStartTime $	[redacted] AntibioticsName # antibio 1=Amoxicillin 2=Ampicillin 6=Cefepime 3=Cefotaxime 7=Ceftazidime 4=Ceftriaxone 8=Cephalexin 5=Gentamicin 9=Vancomycin 90=Other (specify)	[redacted] AntibioticsSpec $	[redacted] AntiviralName # antivir 1=Oseltamivir (Tamiflu) 2=Acyclovir (Zovirax) 90=Other (specify)	[redacted] AntiviralSpecify $	[redacted] AntipyreticName # antipyr 1=Ibuprofen (Motrin/Advil) 2=Acetaminophen (Tylenol) 90=Other (specify)	[redacted] AntipyreticSpec $	X

Add

Table name: MedicalRecord

Biosig II Medical Record Review v2

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

ED Retu...(0/18) | Urinaly...(0/9) | CSF (0/13) | Viral S...(0/24) | Cultures (0/4) | [redacted]

Title: Urinalysis

Instructions: Enter all urinalysis testing obtained during hospitalization or return ED visit.

Were urinalyses obtained during hospitalization or return ED visit?

UrinalysisHospital #
YNr
Yes =1
No =0

If 'Yes", enter all urinalyses obtained during the return ED visit or hospitalization (if applicable):

Table name: MedicalRecord_Urinalysis2

Date Collected (DD-MMM-YYYY)	Time Collected (HHMM)	Collection Site	Nitrite	Leukocyte Esterase	WBC	Bacteria	Upload a de-identified urinalysis report	
[redacted] UrinalysisDay #	[redacted] UrinalysisTime $	[redacted] UrinalysisSite # CollSite 1=Catheterization 2=Suprapubic 3=Bag sample 94=Not documented	[redacted] Nitrite # Nitrite 1=Positive 0=Negative 95=Not done	[redacted] Leukocyte # Leuko 1=1+ (small) 2=2+ (moderate) 3=3 or more (large) 0=Negative 95=Not done	[redacted] UrineWBC # WBC 1=Positive (or >= 6) 0=Negative (or <= 5) 95=Not done	[redacted] UrineBacteria # Bacteria 1=Present 0=Absent 95=Not done	[redacted] Value not provided	X

Add

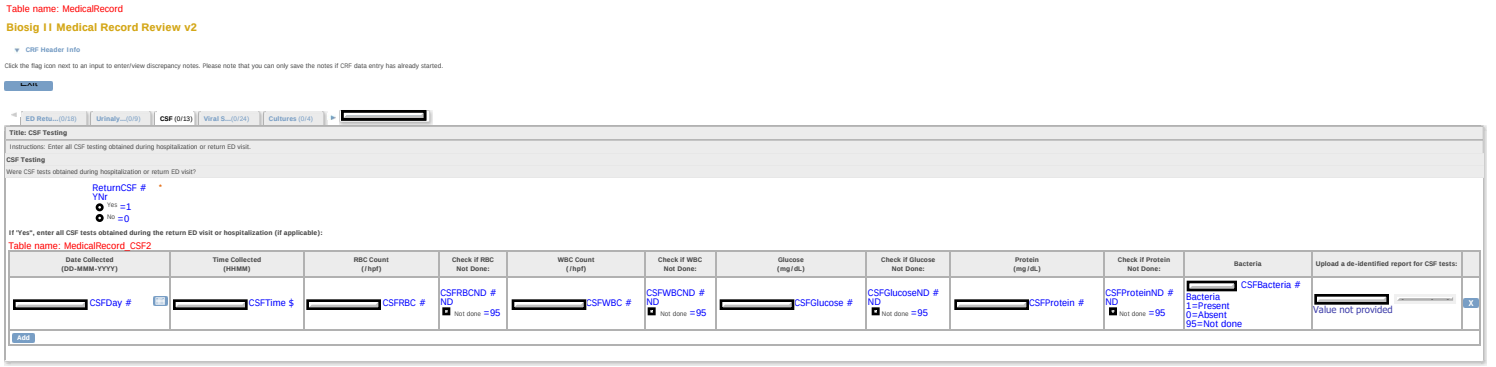


Table name: MedicalRecord

Biosig I I Medical Record Review v2

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

ED Retu...(0/18) | Urinaly...(0/9) | CSF (0/13) | Viral S...(0/24) | Cultures (0/4) | [redacted]

Title: CSF Testing

Instructions: Enter all CSF testing obtained during hospitalization or return ED visit.

CSF Testing

Were CSF tests obtained during hospitalization or return ED visit?

ReturnCSF # *
YNr
Yes =1
No =0

If "Yes", enter all CSF tests obtained during the return ED visit or hospitalization (if applicable):

Table name: MedicalRecord_CSF2

Date Collected (DD-MMM-YYYY)	Time Collected (HHMM)	RBC Count (/hpf)	Check if RBC Not Done:	WBC Count (/hpf)	Check if WBC Not Done:	Glucose (mg/dL)	Check if Glucose Not Done:	Protein (mg/dL)	Check if Protein Not Done:	Bacteria	Upload a de-identified report for CSF tests:	
[redacted] CSFDay #	[redacted] CSFTime $	[redacted] CSFRBC #	CSFRBCND # ND Not done =95	[redacted] CSFWBC #	CSFWBCND # ND Not done =95	[redacted] CSFGlucose #	CSFGlucoseND # ND Not done =95	[redacted] CSFProtein #	CSFProteinND # ND Not done =95	[redacted] CSFBacteria # Bacteria 1=Present 0=Absent 95=Not done	[redacted] Value not provided	X

Add

Table name: MedicalRecord

Biosig II Medical Record Review v2

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

EXIT

[redacted] | ED Reta...(0/18) | Urinaly...(0/9) | CSF (0/13) | **Viral S...(0/16)** | Cultures (0/6) | [redacted]

Title: Viral Studies

Instructions: Enter all viral studies obtained during hospitalization or return ED visit.

Viral Studies

Were viral studies obtained during hospitalization or return ED visit?

ReturnViralStudies # *
Y/N
Yes =1
No =0

If "Yes", select all viral types tested:

Check all that apply:

- Adenovirus
- Astrovirus
- Coronavirus
- Cytomegalovirus (CMV)
- Enterovirus
- Epstein-Barr
- Hepatitis
- Herpes
- Influenza A
- Influenza B
- Metapneumovirus
- Norovirus
- Parainfluenza
- Parechovirus
- Rhinovirus
- Rotavirus
- RSV
- Other (specify)

Specify "Other" virus type: [redacted] Value not provided

Select Hepatitis type(s):

- Hepatitis A
- Hepatitis B
- Other (specify)
- Not specified

Specify other Hepatitis type: [redacted] Value not provided

Select Herpes type(s):

- Type 1
- Type 2
- Other (specify)
- Not specified

Specify other Herpes type: [redacted] Value not provided

Select Influenza A type(s):

- H1N1
- H3
- Other (specify)
- Not specified

Specify other Influenza A type: [redacted] Value not provided

Select Parainfluenza type(s):

- Type 1
- Type 2
- Type 3
- Type 4a
- Type 4b
- Other (specify)
- Not specified

Specify other Parainfluenza type: [redacted] Value not provided

Were there any positive viral results?

[redacted] PosViral #
Y/N
1=Yes
0=No

If "Yes", enter all positive viral test results obtained during the return ED visit or hospitalization (if applicable):

Table name: MedicalRecord_Viral2

Date Collected (DD-MMM-YYYY)	Time Collected (HHMM)	Virus Type	Hepatitis Type	Herpes Type	Influenza A Type	Parainfluenza Type	If "Other" virus type, specify:	Type of Sample	If "Other" sample type, specify:	Type of Assay	Upload a de-identified report for positive viral study:	
[redacted] PosViralDay #	[redacted] PosViralTime $	[redacted] PosVirusType # Virus 1=Adenovirus 2=Astrovirus 3=Coronavirus 4=Cytomegalovirus (CMV) 5=Enterovirus 6=Epstein-Barr 7=Hepatitis (specify type) 8=Herpes (specify type) 9=Influenza A (specify type) 10=Influenza B 11=Metapneumovirus 12=Norovirus 13=Parainfluenza (specify type) 14=Parechovirus 15=Rhinovirus 16=Rotavirus 17=RSV 90=Other (specify)	[redacted] PosHepatitisType # Hepatiti 1=Hepatitis A 2=Hepatitis B 90=Other (specify) 94=Not specified	[redacted] PosHerpesType # HSV 1=Type 1 2=Type 2 90=Other (specify) 94=Not specified	[redacted] PosInfluenzaAType # Influa 1=H1N1 2=H3 90=Other (specify) 94=Not specified	[redacted] PosParainfluenzaType # Parain 1=Type 1 2=Type 2 3=Type 3 4=Type 4a 5=Type 4b 90=Other (specify) 94=Not specified	[redacted] PosVirusTypeSpec $	[redacted] PosSampleType # Sample 1=Blood 2=CSF 3=Nasal/Respiratory 4=Urine 90=Other	[redacted] PosSampleTypeSpec $	[redacted] PosAssayType # Assay 1=Rapid 2=Immunofluorescence 3=Culture 4=PCR	[redacted] Value not provided	

Add

Table name: MedicalRecord

Biosig II Medical Record Review v2

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

ED Retu...(0/18) | Urinaly...(0/9) | CSF (0/13) | Viral S...(0/24) | **Cultures** (0/4) | -- Select to Jump --

Title: Cultures

Instructions: If "Yes" to any of the questions below, enter the details of the respective culture(s) in the Culture Log.

Were any blood cultures obtained during hospitalization or return ED visit?

BloodCulture # * If "Yes", enter blood culture(s) in the Cultures Log
YNr
Yes =1
No =0

Were any CSF cultures obtained during hospitalization or return ED visit?

CSFCulture # * If "Yes", enter CSF culture(s) in the Cultures Log
YNr
Yes =1
No =0

Were any stool cultures obtained during hospitalization or return ED visit?

StoolCulture # * If "Yes", enter stool culture(s) in the Cultures Log
YNr
Yes =1
No =0

Were any urine cultures obtained during hospitalization or return ED visit?

UrineCulture # * If "Yes", enter urine culture(s) in the Cultures Log
YNr
Yes =1
No =0

Table name: Withdrawal

Biosig II Withdrawal of Consent v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Withdra...(0/4)

Title: Withdrawal of Consent

Instructions: This form should be completed if parent/guardian withdraws subject from the study.

Date and Time Consent was Withdrawn

Date: WithdrawnDay # * (DD-MMM-YYYY)

Time: WithdrawnTime $ (HHMM)

Please identify the time point when consent was withdrawn

(select one) TimePoint # *

TimeWD
1=Prior to initial sample collection
2=Prior to sequential sample collection
3=Prior to follow-up data collection

Please specify the reason the parent/guardian withdrew, if offered:

ReasonWithdrew $

Table name: HealthyEligibility

Biosig II Healthy Controls Eligibility v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Screeni...(0/14) | Permiss...(0/12) | -- Select to Jump --

Title: Screening

Instructions: Enter subjects who meet all inclusion criteria, regardless of meeting an exclusion criteria.

All inclusion criteria must be "Yes" and all exclusion must be "No" in order to meet study eligibility.

Screening

Screening Date: ScreenDay,# * DD-MMM-YYYY

Inclusion Criteria

1. Is the subject 60 days of age or younger?

Inclusion1,# *
YNr
Yes =1
No =0

2. Is the subject documented to be afebrile (< 38 °C) within 24 hours of presentation?

Inclusion2,# *
YNr
Yes =1
No =0

3. Is the subject being evaluated for care unrelated to a serious bacterial infection and has had no antibiotics in the past two weeks?

Inclusion3,# *
YNr
Yes =1
No =0

Exclusion Criteria

1. Premature birth (< 37 weeks gestational age)

Exclusion1,# *
YNr
Yes =1
No =0

2. Administration of antibiotics within 4 days of presentation at well-baby clinic, day surgery unit, ED, or other clinic

Exclusion2,# *
YNr
Yes =1
No =0

3. Presence of a major congenital anomaly

Exclusion3,# *
YNr
Yes =1
No =0

4. Presence of inborn errors of metabolism

Exclusion4,# *
YNr
Yes =1
No =0

5. Presence of a congenital heart disease

Exclusion5,# *
YNr
Yes =1
No =0

6. Presence of chronic lung disease

Exclusion6,# *
YNr

Yes =1
No =0

7. Presence of a disease or medication that would affect the immune system

Exclusion7,# *
YNr
Yes =1
No =0

8. Presence of indwelling catheters or shunts

Exclusion8,# *
YNr
Yes =1
No =0

9. Evidence of focal infections such as abscess or cellulitis (otitis media is not an exclusion criterion)

Exclusion9,# *
YNr
Yes =1
No =0

10. Previously enrolled in this study

Exclusion10,# *
YNr
Yes =1
No =0

Table name: HealthyEligibility

Biosig II Healthy Controls Eligibility v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Screeni...(0/14) | Permiss...(0/12) | -- Select to Jump --

Title: Permission

Eligibility

Is the subject eligible?

Eligible,# *
YNr
- Yes =1
- No =0

Qualifying Temperature

Temperature

Temp,# °C or °F

Date temperature taken

TempDay,# DD-MMM-YYYY

Location where temperature was taken

(Select one) TempLoc,#
temploca
1=Well-baby clinic
2=Day surgery unit
3=ED visit
4=Other clinic or facility (i.e. urgent care)

Consent (Parental Permission)

If eligible, was the parent/guardian approached for consent?

(Select one) Approached,#
YN
1=Yes
0=No

If not approached, please provide the primary reason: (Select one) NotApproached,#
notappr
1=Research staff not available for enrollment
2=Parent/guardian not available for consent
3=Not possible within clinical window (prior to blood draw)
4=Language/custody barrier
5=Physician discretion
90=Other (specify)

Specify other reason: NotApproachedSpecify,$

If parent/guardian was approached, was consent given?

(Select one) Consent,#
YN
1=Yes
0=No

Most applicable reason for refusal: (Select one) RefusalReason,#
refusal
1=Concerned about risks and/or procedures (including blood draw)
2=Unable to wait/want to discuss with others
3=Distrust research
4=Too overwhelmed
5=Too much pain involved
6=No reason given/unknown
90=Other (specify)

Specify other reason: RefusalReasonSpecify,$

Date and Time Consent was Signed

Date: ConsentDay,# DD-MMM-YYYY Time: ConsentTime,$ HHMM

Table name: HealthySamples

Biosig II Healthy Controls Sample Accountability v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Sample (0/17) | CBC (0/17) | -- Select to Jump --

Title: Sample Accountability

Initial Biosignature Sample (0.5mL -1.0 mL)

Was a viable biosignature sample obtained and placed in freezer?

BiosigSample,# *
YNr
Yes =1
No =0

If "Yes", was the sample drawn from an existing IV line? (Select one) BiosigSampleIV,#
YNU
1=Yes
0=No
92=Unknown

Was more than 1 mL of blood wasted prior to study sample collection? (Select one) BiosigSampleIVWasted,#
YNU
1=Yes
0=No
92=Unknown

If "No", select primary reason: (Select one) BiosigNotObtained,#
nosample
1=Unsuccessful blood draw attempt
2=Clinical staff neglected or refused to draw
3=Sample destroyed prior to freezing
90=Other (specify)

Specify other reason: BiosigNotObtainedSpec,$

Primary reason sample destroyed: (Select one) BiosigDestroyed,#
destroy
1=Patient later found to be ineligible
2=QNS or processing issues
3=Consent issue
90=Other (specify)

Specify other reason: BiosigDestroyedSpec,$

Viral PCR Sample (1.0 mL)

Was a viable PCR sample obtained and placed in freezer?

PCRSample,# *
YNr
Yes =1
No =0

If "No", select primary reason: (Select one) PCRNotObtained,#
nosample
1=Unsuccessful blood draw attempt
2=Clinical staff neglected or refused to draw
3=Sample destroyed prior to freezing
90=Other (specify)

Specify other reason: PCRNotObtainedSpec,$

Primary reason sample destroyed: (Select one) PCRDestroyed,#
destroy
1=Patient later found to be ineligible
2=QNS or processing issues
3=Consent issue
90=Other (specify)

Specify other reason: PCRDestroyedSpec,$

Nasopharyngeal (NP) Swab

Was an NP sample obtained and placed in freezer?

NPSwab,# *
YNr
- Yes =1
- No =0

If "No", select primary reason: (Select one) NPSwabNotObtained,#
noswab
1=Unsuccessful NP collection
2=Clinical staff neglected or refused to collect swab
3=Sample destroyed prior to freezing
90=Other (specify)

Specify other reason: NPSwabNotObtainedSpec,$

Primary reason NP swab destroyed: (Select one) NPSwabDestroyed,#
destroy
1=Patient later found to be ineligible
2=QNS or processing issues
3=Consent issue
90=Other (specify)

Specify other reason: NPSwabDestroyedSpec,$

Table name: HealthySamples

Biosig II Healthy Controls Sample Accountability v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Sample (0/17) | CBC (0/17) | -- Select to Jump --

Title: CBC and Differential Testing

CBC with Differential

Were CBC tests obtained during the visit?

CBCObtained,# *
YNr
Yes =1
No =0

Date collected: CBCDay,# (DD-MMM-YYYY) Time collected: CBCTime,$ (HHMM)

Hemoglobin (g/dL): Hgb,# Platelets (x 10^3/µL): Platelets,# White Blood Count (x 10^3/µL): CBCWBC,#

Upload a de-identified CBC report (with Differential, if applicable): Click to upload file
Value not provided

Were differential tests obtained with the CBC?

(Select one) CBCDiff,#
YN
1=Yes
0=No

If "Yes", what type of test was used? (Select one) CBCDiffType,#
ManAuto
1=Manual
2=Automated

Type of result: (Select one) AbsolutePercent,#
AbsPerc
1=Absolute count
2=Percent

Neutrophils: Neutrophils,# Lymphocytes: Lymphocytes,# Monocytes: Monocytes,#

Eosinophils: Eosinophils,# Basophils: Basophils,# Bands: Bands,#

BandsND,$
BandsND
Bands Not Done =95

Table name: PCTRESULTS

Variable	Format	Type	Label	Algorithm / Notes
DayReceived		#	Day Received	
SpecimenNumber		$	Specimen Number	
SpecimenStatus		$	Specimen Status	
PCTResult		$	PCT Result	

Table name: VIRALTESTS (1 of 2)

Variable	Format	Type	Label	Algorithm / Notes
PUDID		#	PUD ID	
StudyEvent		$	Study event	
PosViralDay		#	Positive viral day (relative to screening date)	
ViralType	Virus. Adenovirus = 1 Astrovirus = 2 Coronavirus = 3 Cytomegalovirus (CMV) = 4 Enterovirus = 5 Epstein-Barr = 6 Hepatitis (specify type) = 7 Herpes (specify type) = 8 Influenza A (specify type) = 9 Influenza B = 10 Metapneumovirus = 11 Norovirus = 12 Parainfluenza (specify type) = 13 Parechovirus = 14 Rhinovirus = 15 Rotavirus = 16 RSV = 17 Other (specify) = 90	#	Positive virus type	
ViralHepatitisType	HEPATIT. Hepatitis A = 1 Hepatitis B = 2 Other (specify) = 90 Not specified = 94	#	Hepatitis type	
ViralHerpesType	HSV. Type 1 = 1 Type 2 = 1 Other (specify) = 90 Not specified = 94	#	Positive herpes type	
ViralFluAType	INFLUA. H1N1 = 1 H3 = 2 Other (specify) = 90 Not specified = 94	#	Positive influenza A type	
ViralParafluType	PARAINF. Type 1 = 1 Type 2 = 2 Type 3 = 3 Type 4a = 4 Type 4b = 5 Other (specify) = 90 Not specified = 94	#	Positive parainfluenza type	

Table name: VIRALTESTS (2 of 2)

Variable	Format	Type	Label	Algorithm / Notes
ViralTest		$	All virus types that were tested by the clinical site	
ViralTestPositive		$	Positive viral tests by the clinical site	
ViralTestPositiveInd	YN. No = 0 Yes = 1	#	Positive viral test YN	
PosAssayTypeRapidYN	YN. No = 0 Yes = 1	#	Positive rapid assay	
PosAssayTypeImmunofluorescenceYN	YN. No = 0 Yes = 1	#	Positive immunofluorescence	
PosAssayTypeCultureYN	YN. No = 0 Yes = 1	#	Positive culture assay	
PosAssayTypePCRYN	YN. No = 0 Yes = 1	#	Positive PCR assay	
PosSampleTypeBloodYN	YN. No = 0 Yes = 1	#	Positive blood sample	
PosSampleTypeCSFYN	YN. No = 0 Yes = 1	#	Positive CSF sample	
PosSampleTypeNasalYN	YN. No = 0 Yes = 1	#	Positive nasal/respiratory sample	
PosSampleTypeUrineYN	YN. No = 0 Yes = 1	#	Positive urine sample	
PosSampleTypeOtherYN	YN. No = 0 Yes = 1	#	Positive 'other' sample	

Table name: MAIN

Variable	Format	Type	Label	Algorithm / Notes
PUDID		#	PUD ID	
Meningitis	Infect. Positive = 1 Negative = 0 Unable to classify = .c Unknown or needs PI review = .k	#	Bacterial meningitis	
UTI	Infect. Positive = 1 Negative = 0 Unable to classify = .c Unknown or needs PI review = .k	#	Urinary tract infection (UTI)	
BacterialInfection	Infect. Positive = 1 Negative = 0 Unable to classify = .c Unknown or needs PI review = .k	#	Bacterial Infection	

Table name: BIOFIRERESPIRATORY (1 of 2)

Variable Name	Label / Description	Format / Values
NoViralDataSpecify	No viral data specify	Character
Adv	Adv: Adenovirus	YN. 0 = No 1 = Yes
AH109	AH109: Influenza A H1N1 2009	YN. 0 = No 1 = Yes
AH3	AH3: Influenza A H3N2	YN. 0 = No 1 = Yes
BPP	BPP: Bordetella parapertussis	YN. 0 = No 1 = Yes
BPT	BPT: Bordetella pertussis	YN. 0 = No 1 = Yes
CPN	CPN: Chlamydophila pneumoniae	YN. 0 = No 1 = Yes
CV229E	CV229E: Coronavirus 229E	YN. 0 = No 1 = Yes
CVHKU1	CVHKU1: Coronavirus HKU1	YN. 0 = No 1 = Yes
CVNL63	CVNL63: Coronavirus NL63	YN. 0 = No 1 = Yes
CVOC43	CV0C43: Coronavirus 0C43	YN. 0 = No 1 = Yes
FLUB	Flu B: Influenza B	YN. 0 = No 1 = Yes
hMPV	hMPV: Human metapneumovirus	YN. 0 = No 1 = Yes
MPN	MPN: Mycoplasma pneumoniae	YN. 0 = No 1 = Yes

Table name: BIOFIRERESPIRATORY (2 of 2)

Variable Name	Label / Description	Format / Values
PIV1	PIV1: Parainfluenza virus 1	YN. 0 = No 1 = Yes
PIV2	PIV2: Parainfluenza virus 2	YN. 0 = No 1 = Yes
PIV3	PIV3: Parainfluenza virus 3	YN. 0 = No 1 = Yes
PIV4	PIV4: Parainfluenza virus 4	YN. 0 = No 1 = Yes
RSV	RSV: Respiratory syncytial virus	YN. 0 = No 1 = Yes
RVEV	RVEV: Rhinovirus/Enterovirus	YN. 0 = No 1 = Yes
HealthyControlSubj	Health control subject	YN. 0 = No 1 = Yes

Table name: STOOLANCILLARY (1 of 2)

Variable Name	Label / Description	Format / Values
HealthySubject	Enrolled at well baby clinic	YN. 0 = No 1 = Yes
StudyEvent	StudyEvent	Char
FecalSwab	Was a fecal swab obtained and placed in the freezer?	YN. 0 = No 1 = Yes
FecalSwabNo	If fecal swab not obtained, select the primary reason why not	NOFECAL. 1 = Unsuccessful attempt 2 = Clinical staff neglected or refused 3 = Parent/guardian refused 90 = Other (specify)
FecalSwabNoSpec	Specify other primary reason fecal swab was not obtained	Char
BulkStool	Was a bulk stool sample obtained and placed in the freezer?	YN. 0 = No 1 = Yes
BulkStoolNo	If bulk stool sample not obtained, select the primary reason why not	NOBULK. 1 = Bulk stool sample not available (no bowel movement) 2 = Unsuccessful attempt 3 = Clinical staff neglected or refused 4 = Parent/guardian refused 90 = Other (specify)
BulkStoolNoSpec	Specify other primary reason bulk stool sample was not obtained	Char
Isolate	Was a culture isolate(s) obtained and placed in the freezer?	YN. 0 = No 1 = Yes

Table name: STOOLANCILLARY (2 of 2)

Variable Name	Label / Description	Format / Values
IsolateNo	If culture isolate not obtained, select the primary reason why not	NOISOLAT. 1 = Subject did not demonstrate an IBI 2 = Culture isolates not available 3 = Clinical staff neglected or refused 4 = Parent/guardian refused 90 = Other (specify)
IsolateNoSpec	Specify other primary reason culture isolate was not obtained	Char
BloodCultureCollected	Blood culture collected	YN. 0 = No 1 = Yes
CSFCultureCollected	CSF culture collected	YN. 0 = No 1 = Yes
UrineCultureCollected	Urine culture collected	YN. 0 = No 1 = Yes
BiosigCohorts	Biosignature cohorts	Cohorts. 1 = Bacterial infection 2 = Viral infection 3 = Coinfection 4 = Negative .c = Unable to classify