Public Use Dataset
Annotated eCRF

Application of Transcriptional Signatures for Diagnosis of Febrile Infants within

the Pediatric Emergency Care Applied Research Network

PECARN Protocol Number 022

_____

Primary Investigators:

Octavio Ramilo, M.D.

Prashant Mahajan, M.D.

Nathan Kuppermann, M.D.

Protocol Version 2.3

Version Date: September 24, 2012

PUD Annotated eCRF Version 1.0

Version Date: January 12, 2017

Table of Contents:

Annotations key:

Table name

Column name followed by: # or N
\# = numeric
N = character N = length

Format (name)
Code list

Calculated / Derived variable

Value not provided

Table name_Child table name

Variable in question group

Notes:

StudySubjectID is the original infant identifier. A new masked identifier named PId has been created; this variable is present in all datasets to facilitate merging. A dataset linking StudySubjectID to PId will be retained for internal records. StudySubjectID has been removed from all datasets.

Each public use dataset is sorted by PId to ensure the final order of the records does not correspond to order defined by StudySubjectID.

All out of range and other questionable data has been included in the public use datasets.

Sensitive and/or identifying information entered in free text fields has been removed from the public use datasets.

All date variables have been recoded to be number of days since screen date. The associated formats have been dropped and the names and labels have been changed as well. For example, the portion of the name that shows the variable to be a date (either "Date" or "Dat") has uniformly been changed to "Day," so that ExampleDate and ExampleDat1 would be renamed ExampleDay and ExampleDay1 respectively, and the label has been changed from "Date of [Example]" to "Day of [Example] relative to screen date". No actual dates have been included.

Many of the datasets include only one record per subject (unique identifier *PId*). Other datasets are relational, that is, may have more than one record per patient. These records are uniquely identified by *PId* and *ItemGroupRepeatKey*.

The datasets are primarily based on raw datasets (i.e., as captured in study database with minimal modifications). Selected derived data elements will also be included.
- PreviouslyEnrolled will be included to flag infants that were enrolled after an initial enrollment.
- ANC (calculated absolute neutrophil count) will be included.

Demographics

Subject...(0/6) -- Select to Jump --

Title: Subject Demographics

Date of Birth

BirthDay, #   DD-MMM-YYYY   ☐ Date of Birth not available per parental refusal

BirthdateNA, $4

NA
98=Date of Birth not available per parental refusal

Gender

Gender, #   *

Gender
1=Male
2=Female

Race

Race, #   ▼ *   Other (specify)   Value not provided

Ethnicity

Ethnicity, #   *

Race
1=American Indian or Alaska Native
2=Asian
3=Black or African American
4=Native Hawaiian or Other Pacific Islander
5=White
92=Stated as Unknown
90=Other

Ethnic
1=Hispanic or Latino
2=Not Hispanic or Latino
92=Unknown

Screening and Enrollment

| Inclusi...(0/4) | Exclusi...(0/10) | Permiss...(0/3) | ► | -- Select to Jump -- ▼ |

Title: Inclusion Criteria

Screening Date

Screening Date [ ] 📅 * DD-MMM-YYYY   ScreenDay, #

Inclusion Criteria: If any inclusion criteria are 'NO', this patient is ineligible.

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

    ○ Yes ○ No *   Inclusion1, #

2. Did the patient have a documented rectal temperature ≥ 38 ℃ in the ED OR have a history of fever (temperature measured by any route, of ≥ 38 ℃ at home / outside clinic) within 24 hours of ED presentation?

    ○ Yes ○ No *   Inclusion2, #

3. Is the patient being evaluated for serious bacterial infections with screening tests, as standard procedure for the site, including but not limited to blood culture?

    ○ Yes ○ No *   Inclusion3, #

DV6032G
1=Yes
0=No

| Inclusi...(0/4) | Exclusi...(0/10) | Permiss...(0/3) | ► | -- Select to Jump -- ▼ |

Title: Exclusion Criteria

Exclusion Criteria: If any exclusion criteria are 'YES', this patient is ineligible.

4. Premature birth (< 37 weeks gestational age)

    ○ Yes ○ No *   Exclusion4, #

5. Administration of antibiotics within 4 days of ED presentation

    ○ Yes ○ No *   Exclusion5, #

6. Overwhelming clinical sepsis (i.e. requiring emergent interventions such as endotracheal intubation, use of vasoactive medications or cardiopulmonary resuscitation)

    ○ Yes ○ No *   Exclusion6, #

7. Presence of a major congenital abnormality

    ○ Yes ○ No *   Exclusion7, #

8. Presence of inborn errors of metabolism

    ○ Yes ○ No *   Exclusion8, #

9. Presence of a congenital heart disease

    ○ Yes ○ No *   Exclusion9, #

10. Presence of chronic lung disease

    ○ Yes ○ No *   Exclusion10, #

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

    ○ Yes ○ No *   Exclusion11, #

12. Presence of indwelling catheters or shunts

    ○ Yes ○ No *   Exclusion12, #

13. Evidence of focal infections such as abscesses, cellulitis, or other focal infections

    ○ Yes ○ No *   Exclusion13, #

Screening and Enrollment

| Inclusi...(0/4) | Exclusi...(0/10) | **Permiss...(0/3)** | ▶ | -- Select to Jump -- ▼ |

Title: Permission/Consent

Permission/Consent

Was consent obtained?

⬤ Yes ⬤ No *   Consent, # ————— DV6032G
1=Yes
0=No

Date parent/guardian signed consent

ConsentDay, #   ▦ DD-MMM-YYYY

Time parent/guardian signed consent

ConsentTime, $5   HHMM

PreviouslyEnrolled, # ————— DV6032G
1=Yes
0=No

Clinical Data

Clinica....(0/13) | Yale Ob...(0/7) | ► | -- Select to Jump -- ▼

Title: Clinical Data

Temperature

Date of qualifying elevated temperature

TempDay, #   * DD-MMM-YYYY

Location where qualifying elevated temperature was taken

TempLoc, #

DV7021G
1=PECARN site ED
2=Non-PECARN site ED
3=PCP office or other facility

Qualifying elevated temperature

Temperature, #

Duration of fever (prior to ED visit)?

DurationFever, #

Duration
1=Less than 12 hours
2=12-24 hours
3=Greater than 24 hours
4=Unable to estimate
5=Enrolled during year 2

DV7126G
1=1.0 ml was collected and stored for shipment
2=0.5 ml to less than 1.0 ml was collected and stored for shipment
3=Less than 0.5 ml OR no blood was collected (no sample stored)
4=From 3/30/09 to 5/20/09 only: sample was QNS (amount of blood unknown) and sample stored for shipment
5=More than 1 ml was collected

Blood Collection

How much blood was collected in the baby tempus tube? (Biosignatures sample)

BloodColl, #

Was blood collected in the red top tube? (Procalcitonin sample)

ProcalcitoninYN, #   If yes, how much blood was collected?   ProcalcAmt, #

Was a blood culture done?

BloodCultYN, #   Stop here if **NO**. No further data collection in this form or any other forms is required.

Were antibiotics given in the ED prior to obtaining the study blood sample and blood culture?

BloodAnt, #   Stop here if **YES**. No further data collection in this form or any other forms is required.

ED Discharge

Patient's status after ED visit

EDStatus, #   Other (specify)   Value not provided

REMINDER: If patient was discharged home and a CSF culture was NOT done, then the Follow-up form must be completed.

Date of ED discharge   EDDischDay, #   DD-MMM-YYYY

Time of ED discharge   EDDischTime, $5   HHMM

DV6032G
1=Yes
0=No

DV7039G
1=Discharged home
2=Admitted to hospital
3=Died
4=Transferred to another hospital
90=Other

Clinical Data

DV7024G
1=Cries briefly then stops OR Content and not crying
3=Cries off and on
5=Continual cry OR Hardly responds

DV7023G
1=Strong with normal tone OR Content and not crying
3=Whimpering or Sobbing
5=Weak OR Moaning OR High pitched

DV7025G
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

| ◄ | Clinica...(0/13) | **Yale Ob...(0/7)** | ► | -- Select to Jump -- | ▼ |

Title: Yale Observation Scale

Yale Observation Scale

Quality of cry	YOSCry, #
Reaction to parents	YOSReaction, # ▼
State variation	YOSState, #
Color	YOSColor, # ▼
Hydration	YOSHydration, #
Response (talk, smile) to social overtures	YOSResponse, #

Risk for Serious Bacterial Infection (SBI)

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

SBI, #

DV7028G
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.)

DV7047G
1=Less than 1 %
2=1-5 %
3=6-10 %
4=11-50 %
5=Greater than 50 %

DV7027G
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

DV7026G
1=Pink
3=Pale extremities OR Acrocyanosis
5=Pale OR Cyanotic OR Mottled OR Ashen

Laboratory Results

| CBC, Di...(0/35) | Urinaly...(0/11) | Chest X...(0/3) | ▶ | -- Select to Jump -- ▼ |

Title: CBC, Differential and Other Blood Studies

Instructions: All laboratory tests collected during the ED visit are to be recorded. If the patient is admitted to the hospital directly from the ED, all cultures (i.e. blood, urine, CSF), CSF tests and viral studies obtained during the first 48 hours of hospital admission are also to be recorded. If the patient is hospitalized, CBC with platelet counts, other blood studies and urinalysis tests will not be collected during the first 48 hours of hospital admission.

CBC with Platelet Count

Was a CBC with platelet count obtained?

CBCPlatelet, #   *

DV6032G
1=Yes
0=No

*Upload de-identified lab report for CBC with platelet count and differential tests obtained

Value not provided | Click to upload file |

NOTE: For the following platelet and WBC differential tests, the unit of measurement x 10^3/uL can also be represented as x 10^9/L, /nl, THOU/uL, K/cumm, K/MM^3 or K/mcL. Contact the CDMCC project manager if your site laboratory uses a different unit of measurement. Do not attempt to convert any lab values prior to notifying the CDMCC.

Hemoglobin (gm/dl)	Platelets (x 10^3/µL)	White Blood Count (x 10^3/µL)
Hgb, #	Platelet, #	WBC, #

Was a WBC differential count obtained?

WBCDiff, #

DV6032G
1=Yes
0=No

Was the test manual, automated or both?

DiffAutoMan, # ▼

WBCTest
1=Manual
2=Automated
3=Combination (Manual and Automated)

ANC, #

Neutrophils

Manual Abs Count	Manual %	Automated Abs Count	Automated %
NeutroMan, #	NeutrManPerc, #	NeutroAut, #	NeutrAutPerc, #

Lymphocytes

Manual Abs Count	Manual %	Automated Abs Count	Automated %
LymphMan, #	LymphManPerc, #	LymphAut, #	LymphAutPerc, #

Monocytes

Manual Abs Count	Manual %	Automated Abs Count	Automated %
MonoMan, #	MonoManPerc, #	MonoAut, #	MonoAutPerc, #

Laboratory Results

Eosinophils

| Manual Abs Count | EosinMan, # | Manual % | EosinManPerc, # | Automated Abs Count | EosinAut, # | Automated % | EosinAutPerc, # |

Basophils

| Manual Abs Count | BasoMan, # | Manual % | BasoManPerc, # | Automated Abs Count | BasoAut, # | Automated % | BasoAutPerc, # |

Bands

| Manual Abs Count | BandsMan, # | Manual % | BandsManPerc, # | Automated Abs Count | BandsAut, # | Automated % | BandsAutPerc, # |

Other Blood Studies

Were other blood studies obtained? (C-reactive protein, Procalcitonin, Interleukins, ESR)

OtherBlood, # *

DV6032G
1=Yes
0=No

*Upload de-identified lab report for other blood studies

Value not provided   Click to upload file

Which blood study was obtained?	Result	
BloodTest, #	BloodResult, #	X

LabResults_OtherBlood

ADD

DV7032G
1=C-reactive protein (mg/L)
2=Procalcitonin (ng/ml)
3=Interleukins (pg/L)
4=ESR (mm/hour)

Laboratory Results

CBC, Di...(0/35)	**Urinaly...(0/11)**	Chest X...(0/3)	►	-- Select to Jump --

Title: Urinalysis

Urinalysis

Was a urinalysis obtained?

UrinalysisYN, #

DV6032G
1=Yes
0=No

*Upload de-identified lab report for urinalysis tests obtained

Value not provided | Click to upload file

Urine collection site

UrineSite, #

DV6807G
1=Catherization
2=Suprapubic
3=Bag Sample
94=Not Documented

Urine nitrite

Is a test result available? NitriteYN, #   Result NitriteRes, #

DV2100G
1=Positive
0=Negative

Urine Leukocyte Esterase

Is a test result available? UrineLECYN, #   Result UrineLEC, #

DV6032G
1=Yes
0=No

DV7033G
1=1+ (or 'small')
2=2+ (or 'moderate')
3=3+ or more (or 'large')
4=Negative

Urinalysis WBC

Is a test result available? UrinalWBCYN, #   Result UrinalWBC, #

DV7034G
1=Positive (6/hpf or greater)
2=Negative (5/hpf or less)

Urine bacteria

Is a test result available? UrinalBactYN, #   Result UrinalBact, #

DV7035G
1=Present
2=Absent

Urinaly...(0/11)	**Chest X...(0/3)**	Culture...(0/47)	►	-- Select to Jump --

Title: Chest X-ray

Chest X-ray

Was a chest x-ray performed?

CXRYN, #   *

DV6032G
1=Yes
0=No

What was the result of the chest x-ray?

CXRResult, #

DV6815G
1=Positive for pneumonia
2=Negative for pneumonia
3=Unknown or inconclusive result

*Upload de-identified chest x-ray report if the result was positive

Value not provided | Click to upload file

Laboratory Results

Title: Cultures, CSF Test and Viral Studies Obtained at ED Visit and During First 48 Hours of Direct Hospital Admission

Blood Culture

LabResults_BloodCulture

Date blood culture was obtained (DD-MMM-YYYY)	Time blood culture was obtained (HHMM)
BlCultDay, #	BlCultTime, $6

ADD

Blood Culture Result	*Upload de-identified blood culture report if the result was positive or unknown/inconclusive	
BloodCulture, #	Value not provided	X

DV6813G
1=Positive
2=Negative
3=Unknown or inconclusive result

Urine Culture

Was a urine culture obtained? (select one)   UrineCultYN, #

DV6032G
1=Yes
0=No

LabResults_UrineCulture

Date urine culture was obtained (DD-MMM-YYYY)	Time urine culture was obtained (HHMM)	Urine collection site	Result	*Upload de-identified urine culture report if the result was positive or unknown/inconclusive	
UrineCultDay, #	UrineCultTim, $5	UrineSite2, #	UrineCultRes, #	Value not provided	X

ADD

DV6807G
1=Catherization
2=Suprapubic
3=Bag Sample
94=Not Documented

DV6813G
1=Positive
2=Negative
3=Unknown or inconclusive result

CSF Tests and Cultures

Was a lumbar puncture performed?

LPYN, #

DV6032G
1=Yes
0=No

When was the lumbar puncture performed?

LPLocation, #

Were antibiotics given prior to the lumbar puncture?

LPAntibiotYN, #

If yes, when were antibiotics given?   LPAntibioLoc, #

DV7048G
1=During ED Visit
2=During Hospital Admission
3=Both

DV6032G
1=Yes
0=No

Laboratory Results

CSF Tests (cell count, glucose, protein, bacteria)

NOTE: The unit of measurement for CSF RBC and CSF WBC is /hpf, but can also be represented as /mm^3, CUMM, /uL or /mcL. Contact the CDMCC project manager if your site laboratory uses a different unit of measurement.

Were CSF tests obtained? CSFTestYN, #

DV6032G
1=Yes   0=No

DV7035G
1=Present   2=Absent

LabResults_CSFTest

Date CSF test was obtained (DD-MMM-YYYY)	Time CSF test was obtained (HHMM)	Type of CSF test	Result	Bacteria result	*Upload de-identified lab report for each set of CSF tests obtained	
CSFTestDay, #	CSFTestTime, $5	CSFTestType, #	CSFTestRes, #	CSFBactRes, #	Value not provided [upload file]	X

ADD

DV7049G
1=CSF red blood cell count (/hpf)
2=CSF white blood cell count (/hpf)
3=CSF glucose (mg/dl)
4=CSF protein (mg/dl)
5=CSF bacteria

CSF Culture

REMINDER: If patient was discharged home from the ED and a CSF culture was NOT obtained, the Follow-up form must be completed.

Was a CSF culture obtained? CSFCultDone, #

DV6032G
1=Yes   0=No

LabResults_CSFCulture

Date CSF culture obtained (DD-MMM-YYYY)	Time CSF culture obtained (HHMM)	CSF culture result	*Upload de-identified report if the CSF culture was positive or unknown/inconclusive	
CSFCultDay, #	CSFCultTime, $5	CSFCultRes, #	Value not provided [click to upload file]	X

ADD

DV6813G
1=Positive
2=Negative
3=Unknown or inconclusive result

Bacterial Cultures
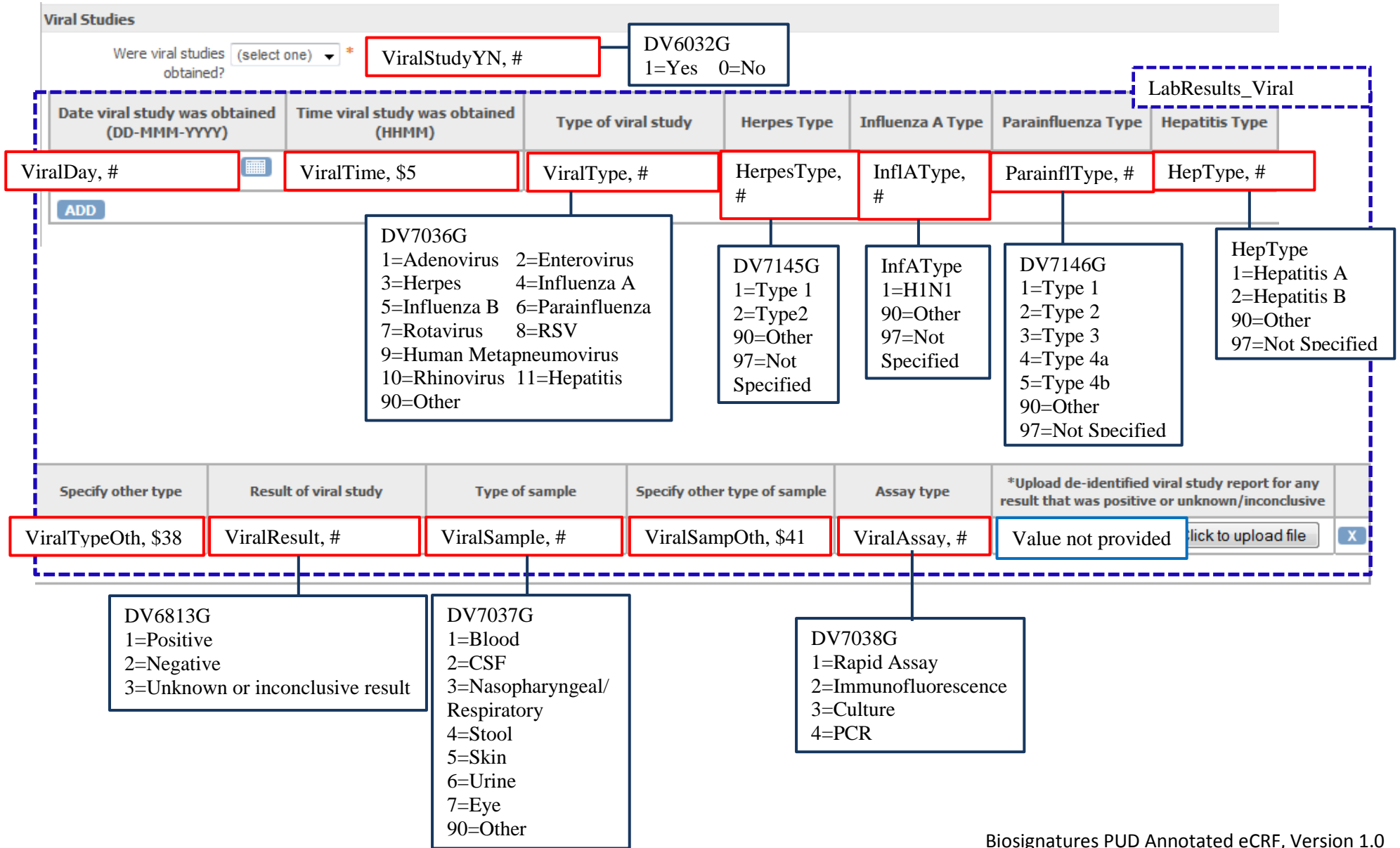
Were other bacterial cultures obtained? (select one) * BactCult, #

DV6032G
1=Yes   0=No

LabResults_BacterialCulture

Date culture was obtained (DD-MMM-YYYY)	Time culture was obtained (HHMM)	Type of sample cultured	Specify other type	Result	*Upload de-identified bacterial culture report for any result that was positive or unknown/inconclusive	
DayBactCult, #	TimeBactCult, $5	BactCultType, #	Value not provided	BactCultResult, #	Value not provided [Click to upload file]	X

ADD

BactType
1=Stool
2=Eye
3=Ear
90=Other

Laboratory Results

Viral Studies

Were viral studies obtained? (select one) ▼ *

ViralStudyYN, #

DV6032G
1=Yes   0=No

LabResults_Viral

Date viral study was obtained (DD-MMM-YYYY)	Time viral study was obtained (HHMM)	Type of viral study	Herpes Type	Influenza A Type	Parainfluenza Type	Hepatitis Type
ViralDay, #	ViralTime, $5	ViralType, #	HerpesType, #	InflAType, #	ParainflType, #	HepType, #

ADD

DV7036G
1=Adenovirus   2=Enterovirus
3=Herpes   4=Influenza A
5=Influenza B   6=Parainfluenza
7=Rotavirus   8=RSV
9=Human Metapneumovirus
10=Rhinovirus   11=Hepatitis
90=Other

DV7145G
1=Type 1
2=Type2
90=Other
97=Not Specified

InfAType
1=H1N1
90=Other
97=Not Specified

DV7146G
1=Type 1
2=Type 2
3=Type 3
4=Type 4a
5=Type 4b
90=Other
97=Not Specified

HepType
1=Hepatitis A
2=Hepatitis B
90=Other
97=Not Specified

Specify other type	Result of viral study	Type of sample	Specify other type of sample	Assay type	*Upload de-identified viral study report for any result that was positive or unknown/inconclusive
ViralTypeOth, $38	ViralResult, #	ViralSample, #	ViralSampOth, $41	ViralAssay, #	Value not provided

click to upload file X

DV6813G
1=Positive
2=Negative
3=Unknown or inconclusive result

DV7037G
1=Blood
2=CSF
3=Nasopharyngeal/ Respiratory
4=Stool
5=Skin
6=Urine
7=Eye
90=Other

DV7038G
1=Rapid Assay
2=Immunofluorescence
3=Culture
4=PCR

Follow-up

| Follow-...(0/4) | Medical...(0/4) | CSF Tes...(0/24) | ► | -- Select to Jump -- ▼ |

Title: Follow-up

Phone Follow-up

Did patient return to a doctor's office, clinic or ED after initial ED discharge?

DV7040G
1=Yes 0=No
98=Unable to Contact

PhoneFU, #

* Stop here if **NO**. No further data collection is required.
If **Unable To Contact**, complete the Medical Chart Review section.

Which medical setting did patient go to?

DV7041G
1=Initial ED or hospital
2=Primary care physician
3=Other facility

PlaceFU, #

If the patient returned to the primary care physician or other facility, were they subsequently admitted to the hospital?

DV6032G
1=Yes 0=No

FUHospAdmit, #

Stop here if **NO**. No further data collection is required.

Were medical records collected from the primary care physician or other facility?

MedicalRec, #

Stop here if **NO**. No further data collection is required.

| Follow-...(0/4) | Medical...(0/4) | CSF Tes...(0/24) | ► | -- Select to Jump -- ▼ |

Title: Medical Record Review

Medical Record Review

Did patient return to the ED, primary care physician or other facility which resulted in being admitted to the hospital within 7 days following discharge?

PtReturn, #

Stop here if **NO**. No further data collection is required.

Date of admission

AdmitDay, #

DD-MMM-YYYY

Was a lumbar puncture performed?

LPFU, #

Stop here if a lumbar puncture was not performed (CSF testing not done).

Were antibiotics given prior to the lumbar puncture?

LPAntibiotFU, #

Follow-up

Follow-...(0/4)   Medical...(0/4)   **CSF Tes...(0/24)**   ▶   -- Select to Jump --

Title: CSF Testing

CSF Tests (cell count, glucose, protein, bacteria)

Were CSF tests obtained?   CSFTestsFU, #

DV6032G
1=Yes   0=No

FollowUp_CSFTest

Date CSF test was obtained (DD-MMM-YYYY)	Time CSF test was obtained (HHMM)	Type of CSF test	Result	Bacteria result	*Upload de-identified lab report for each set of CSF tests obtained	
CSFTestDayFU, #	CSFTestTimFU, $5	CSFTestTypFU, #	CSFTestResFU, #	CSFBactFU, #	Value not provided upload file	X

ADD

DV7049G
1=CSF red blood cell count (/hpf)
2=CSF white blood cell count (/hpf)
3=CSF glucose (mg/dl)
4=CSF protein (mg/dl)
5=CSF bacteria

DV7035G
1=Present
2=Absent

CSF Culture

Was a CSF culture obtained?

CSFCultFU, #

DV6032G
1=Yes   0=No

Date CSF culture was obtained

CSFCultDayFU, #   DD-MMM-YYYY

Time CSF culture was obtained

CSFCultTimFU, $5   HHMM

DV6813G
1=Positive
2=Negative
3=Unknown or inconclusive result

CSF culture result

CSFCultResFU, #

*Upload de-identified lab report if the CSF culture was positive or unknown/inconclusive

Value not provided   Click to upload file

Follow-up

Viral Studies on CSF

Were viral studies obtained from the CSF sample? | ViralCSFYN, #

DV6032G
1=Yes   0=No

Followup_CSFViral

Date viral study was obtained (DD-MMM-YYYY)	Time viral study was obtained (HHMM)	Type of viral study	Herpes Type	Influenza A Type	Parainfluenza Type
ViralDayFU, #	ViralTimeFU, $5	ViralTypeFU, #	FUHerpes, #	FUInfluA, #	FUParaInflu, #

ADD

DV7036G
1=Adenovirus   2=Enterovirus
3=Herpes   4=Influenza A
5=Influenza B 6=Parainfluenza
7=Rotavirus   8=RSV
9=Human metapneumovirus
10=Rhinovirus 11=Hepatitis
90=Other

DV7145G
1=Type 1
2=Type 2
90=Other
97=Not Specified

InfAType
1=H1N1
90=Other
97=Not Specified

DV7146G
1=Type 1
2=Type 2
3=Type 3
4=Type 4a
5=Type 4b
90=Other
97=Not Specified

Hepatitis Type	Specify other type	Result of viral study	Assay type	*Upload de-identified viral study report for any result that was positive or unknown/inconclusive	
FUHepType, #	ViralOthFU, $14	ViralResFU, #	ViralAssayFU, #	Value not provided	Click to upload file X

HepType
1=Hepatitis A
2=Hepatitis B
90=Other
97=Not Specified

DV6813G
1=Positive
2=Negative
3=Unknown or inconclusive result

DV7038G
1=Rapid assay
2=Immunofluorescence
3=Culture
4=PCR

Sample Destruction

Sample ...(0/8) | -- Select to Jump -- ▼

Title: Sample Destruction

Sample Destruction

Which sample was destroyed?

DestroyedSample, # *

DV7187G
1=Biosignatures sample
2=PCT sample
3=Both

Biosignatures Sample

Baby Tempus Tube Barcode #

Value not provided

Date sample was destroyed

DestroyedDay, #   📅 DD-MMM-YYYY

DV7178G
1=Patient later found to be ineligible
2=Patient received antibiotics after consent but prior to obtaining the study blood sample and blood culture
3=Consent issues
90=Other

Reason sample was destroyed

DestroyedReason, #   Other (specify)   Value not provided

Procalcitonin Sample

Date sample was destroyed

PCTDestroyDay, #   📅 DD-MMM-YYYY

Reason sample was destroyed

PCTDestroyReas, #   Other (specify)   Value not provided

DV7188G
1=Patient later found to be ineligible
2=Patient received antibiotics after consent but prior to obtaining the study blood sample and blood culture
3=Sample processing errors (blood not separated, contamination, no serum, etc.)
4=Consent issues
90=Other

Culture Review

Culture...(0/56)

Title: Culture Review

Blood Culture

Date of Culture (DD-MMM-YYYY):	Time of Culture (HHMM):	Organism 1:	Other specify:
BloodDay, #	BloodTime, $5	BloodOrg1, #	BloodOrg1Other, $45

Add

Organism 2:	Other specify:	Organism 3:	
BloodOrg2, #	BloodOrg2Other, $48	BloodOrg3, #	BloodOrg3Other, $26

DCC Assessment:	PI review needed?	PI Assessment:	
BloodDCCAssess, #	BloodPINeeded, #	BloodPIAssess, #	X

PNIntUn
1=Positive
2=Negative
3=Intermediate
93=Unable to determine

DV6032G
1=Yes
0=No

PNInt
1=Positive
2=Negative
3=Intermediate

Organism
1=Alpha-hemolytic streptococcus   2=Bacillus species
3=Campylobacter   4=Citrobacter
5=Cocci   6=Corynebacteria
7=E. coli   8=Enterobacter cloacae
9=Enterococcus   10=Enterococcus faecalis
11=Flavobacterium   12=Gamma streptococcus
13=Gram negative rods   14=Gram positive cocci
15=Group B streptococcus (GBS)   16=Klebsiella
17=Klebsiella oxytoca   18=Klebsiella pneumonia
19=Lactobacilli   20=Micrococcus
21=Mixed/multiple flora/organisms 22=Neisseria meningitides
23=Normal flora   24=Nonhemolytic streptococcus
25=Peptostreptococcus   26=Propionibacteria
27=Proteus mirabilis   28=Pseudomonas
29=Salmonella   30=Salmonella group B
31=Shigella   32=Staph.
33=Staph. aureus   34=Staph. coagulase negative
35=Staph. diphtheroids   36=Staph. epi
37=Staph. hominis   38=Staph. non-aureus
39=Staph. warneri   40=Strep. mitis
41=Strep. viridans   42=Yersinia
97=Not specified   90=Other

Culture Review

Urine Culture

CultureReview_Urine

DV6807G
1=Catherization
2=Suprapubic
3=Bag Sample
94=Not Documented

DV6032G
1=Yes
0=No

Date of Culture (DD-MMM-YYYY):	Time of Culture (HHMM):	Urine Colle...		Other specify:	CFU available?	Low:	High:
UrineDay, #	UrineTime, $5	UrineSite, #	UrineOrg1, #	UrineOrg1Other, $101	UrineOrg1CFU, #	UrineOrg1Low, #	UrineOrg1High, #

Add

Organism 2:	Other specify:	CFU available?	Low:	High:	Organism 3:	Other specify:	CFU available?	Low:	High:
UrineOrg2, #	UrineOrg2Other, $48	UrineOrg2CFU, #	UrineOrg2Low, #	UrineOrg2High, #	UrineOrg3, #	UrineOrg3Other, $41	UrineOrg3CFU, #	UrineOrg3Low, #	UrineOrg3High, #

Urinalysis available?	Urinalysis Result:	DCC Assessment:	PI review needed?	PI Assessment:
Urinalysis, #	UrinalysisResult, #	UrineDCCAssess, #	UrinePINeeded, #	UrinePIAssess, #

DV6032G
1=Yes
0=No

PNInc
1=Positive
2=Negative
3=Inconclusive

PNIntUn
1=Positive
2=Negative
3=Intermediate
93=Unable to determine

DV6032G
1=Yes
0=No

PNInt
1=Positive
2=Negative
3=Intermediate

Organism
1=Alpha-hemolytic streptococcus   2=Bacillus species
3=Campylobacter   4=Citrobacter
5=Cocci   6=Corynebacteria
7=E. coli   8=Enterobacter cloacae
9=Enterococcus   10=Enterococcus faecalis
11=Flavobacterium   12=Gamma streptococcus
13=Gram negative rods   14=Gram positive cocci
15=Group B streptococcus (GBS)   16=Klebsiella
17=Klebsiella oxytoca   18=Klebsiella pneumonia
19=Lactobacilli   20=Micrococcus
21=Mixed/multiple flora/organisms   22=Neisseria meningitides
23=Normal flora   24=Nonhemolytic streptococcus
25=Peptostreptococcus   26=Propionibacteria
27=Proteus mirabilis   28=Pseudomonas
29=Salmonella   30=Salmonella group B
31=Shigella   32=Staph.
33=Staph. aureus   34=Staph. coagulase negative
35=Staph. diphtheroids   36=Staph. epi
37=Staph. hominis   38=Staph. non-aureus
39=Staph. warneri   40=Strep. mitis
41=Strep. viridans   42=Yersinia
97=Not specified   90=Other

Culture Review

CSF Culture

CultureReview_CSF

Date of Culture (DD-MMM-YYYY):	Time of Culture (HHMM):	Organism 1:	Other specify:
CSFDay, #	CSFTime, $5	CSFOrg1, #	CSFOrg1Other, $45

Add

Organism 2:	Other specify:	Organism 3:	
CSFOrg2, #	CSFOrg2Other, $31	CSFOrg3, #	CSFOrg3Other, $61

DCC Assessment:	PI review needed?	PI Assessment:	
CSFDCCAssess, #	CSFPINeeded, #	CSFPIAssess, #	X

PNIntUn
1=Positive
2=Negative
3=Intermediate
93=Unable to determine

DV6032G
1=Yes
0=No

PNInt
1=Positive
2=Negative
3=Intermediate

Organism
1=Alpha-hemolytic streptococcus   2=Bacillus species
3=Campylobacter   4=Citrobacter
5=Cocci   6=Corynebacteria
7=E. coli   8=Enterobacter cloacae
9=Enterococcus   10=Enterococcus faecalis
11=Flavobacterium   12=Gamma streptococcus
13=Gram negative rods   14=Gram positive cocci
15=Group B streptococcus (GBS)   16=Klebsiella
17=Klebsiella oxytoca   18=Klebsiella pneumonia
19=Lactobacilli   20=Micrococcus
21=Mixed/multiple flora/organisms 22=Neisseria meningitides
23=Normal flora   24=Nonhemolytic streptococcus
25=Peptostreptococcus   26=Propionibacteria
27=Proteus mirabilis   28=Pseudomonas
29=Salmonella   30=Salmonella group B
31=Shigella   32=Staph.
33=Staph. aureus   34=Staph. coagulase negative
35=Staph. diphtheroids   36=Staph. epi
37=Staph. hominis   38=Staph. non-aureus
39=Staph. warneri   40=Strep. mitis
41=Strep. viridans   42=Yersinia
97=Not specified   90=Other

Culture Review

Stool Culture

CultureReview_Stool

Date of Culture (DD-MMM-YYYY):	Time of Culture (HHMM):	Organism 1:	Other specify:
StoolDay, #	StoolTime, $5	StoolOrg1, #	StoolOrg1Other, $65

Add

Organism 2:	Other specify:	Organism 3:	
StoolOrg2, #	StoolOrg2Other, $201	StoolOrg3, #	StoolOrg3Other, $15

DCC Assessment:	PI review needed?	PI Assessment:	
StoolDCCAssess, #	StoolPINeeded, #	StoolPIAssess, #	X

PNIntUn
1=Positive
2=Negative
3=Intermediate
93=Unable to determine

DV6032G
1=Yes
0=No

PNInt
1=Positive
2=Negative
3=Intermediate

Organism
1=Alpha-hemolytic streptococcus   2=Bacillus species
3=Campylobacter   4=Citrobacter
5=Cocci   6=Corynebacteria
7=E. coli   8=Enterobacter cloacae
9=Enterococcus   10=Enterococcus faecalis
11=Flavobacterium   12=Gamma streptococcus
13=Gram negative rods   14=Gram positive cocci
15=Group B streptococcus (GBS)   16=Klebsiella
17=Klebsiella oxytoca   18=Klebsiella pneumonia
19=Lactobacilli   20=Micrococcus
21=Mixed/multiple flora/organisms 22=Neisseria meningitides
23=Normal flora   24=Nonhemolytic streptococcus
25=Peptostreptococcus   26=Propionibacteria
27=Proteus mirabilis   28=Pseudomonas
29=Salmonella   30=Salmonella group B
31=Shigella   32=Staph.
33=Staph. aureus   34=Staph. coagulase negative
35=Staph. diphtheroids   36=Staph. epi
37=Staph. hominis   38=Staph. non-aureus
39=Staph. warneri   40=Strep. mitis
41=Strep. viridans   42=Yersinia
97=Not specified   90=Other

Unknown / Inconclusive Viral Studies

DV7146G
1=Type 1
2=Type 2
3=Type 3
4=Type 4a
5=Type 4b
90=Other
97=Not Specified

UnknownViral

Unknown...(0/13)

Title: Unknown / Inconclusive Viral Studies

Viral Studies

Viral Study	Herpes Type	Influenza A Type	Parainfluenza Type	Hepatitis Type	Specify Other Type	Date of viral study (DD-MMM-YYYY)	Time of viral study (HHMM)
(select one)	HerpesType, #	InflATypeRev, #	ParainflType, #	HepType, #	ViralOther1, $17	ViralDay1, #	ViralTime1, $5

DV7036G
1=Adenovirus   2=Enterovirus
3=Herpes   4=Influenza A
5=Influenza B   6=Parainfluenza
7=Rotavirus   8=RSV
9=Human metapneumovirus
10=Rhinovirus   11=Hepatitis
90=Other

DV7145G
1=Type 1
2=Type 2
90=Other
97=Not Specified

InfAType
1=H1N1
90=Other
97=Not Specified

HepType
1=Hepatitis A
2=Hepatits B
90=Other
97=Not Specified

Type of Sample	Other Sample Type	Assay Type	Reviewer's Assessment	Notes
ViralSample, #	ViralSampOth, $24	ViralAssay, #	ViralAssess1, #	ViralNotes1, $14

DV7037G
1=Blood   2=CSF
3=Nasopharyngeal/Respiratory
4=Stool   5=Skin
6=Urine   7=Eye
90=Other

DV7038G
1=Rapid Assay
2=Immunofluorescence
3=Culture
4=PCR

DV6813G
1=Positive
2=Negative
3=Unknown or inconclusive result

PCT Data

Variable	Format	Type	Label	Algorithm / Notes
PCTBloodDay		#	PCTBloodDay relative to screen date	
PCTShipDay		#	PCTShipDay relative to screen date	
PCTDayReceived		#	PCTDayReceived relative to screen date	
PCTResult		$50	PCTResult	