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.
Table of Contents:
Annotations key: .................................................................................................................................................. 3
Notes: .................................................................................................................................................................. 4
Demographics .................................................................................................................................................... 5
Screening and Enrollment ............................................................................................................................... 6
Clinical Data .................................................................................................................................................... 8
Laboratory Results ........................................................................................................................................... 10
Follow-up ....................................................................................................................................................... 16
Sample Destruction ....................................................................................................................................... 19
Culture Review ............................................................................................................................................... 20
Unknown / Inconclusive Viral Studies .......................................................................................................... 24
PCT Data ......................................................................................................................................................... 25
<table>
<thead>
<tr>
<th>Table name</th>
<th>Column name followed by: # or $N</th>
<th>Format (name)</th>
<th>Code list</th>
<th>Calculated / Derived variable</th>
<th>Value not provided</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># = numeric</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$N = character $N = length</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BirthDay</td>
<td>DD-MMM-YYYY</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>[Date not available per parental refusal]</td>
</tr>
<tr>
<td>Gender</td>
<td>[Value not provided]</td>
</tr>
<tr>
<td>Race</td>
<td>[Value not provided]</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>[Value not provided]</td>
</tr>
<tr>
<td>Ethnic</td>
<td>[Value not provided]</td>
</tr>
</tbody>
</table>

- **Gender**: 1 = Male, 2 = Female
- **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
- **BirthdateNA**: $4
- **NA**: 98 = Date of Birth not available per parental refusal
### Screening and Enrollment

#### Inclusion Criteria

1. **Inclusion1**: Is the patient 60 years of age or younger? 
   - Yes
   - No
2. **Inclusion2**: Did the patient have a documented rectal temperature ≥ 38 °C in the ED or have a history of fever (temperature measured by any route, of ≥ 38 °C at home/ outside clinic) within 24 hours of ED presentation? 
   - Yes
   - No
3. **Inclusion3**: Is the patient being evaluated for serious bacterial infection with screening tests, as standard procedure for the site, including but not limited to blood culture? 
   - Yes
   - No

#### Exclusion Criteria

1. **Exclusion1**: Premature birth (< 37 weeks gestational age) 
   - Yes
   - No
2. **Exclusion2**: Administration of antibiotics within 4 days of ED presentation 
   - Yes
   - No
3. **Exclusion3**: Overwhelming clinical sepsis (i.e., requiring emergent interventions such as endotracheal intubation, use of vasoactive medications or cardiopulmonary resuscitation) 
   - Yes
   - No
4. **Exclusion4**: Presence of a major congenital abnormality 
   - Yes
   - No
5. **Exclusion5**: Presence of inborn errors of metabolism 
   - Yes
   - No
6. **Exclusion6**: Presence of a congenital heart disease 
   - Yes
   - No
7. **Exclusion7**: Presence of chronic lung disease 
   - Yes
   - No
8. **Exclusion8**: Presence of indwelling catheters or shunts 
   - Yes
   - No
9. **Exclusion9**: Evidence of focal infections such as abscesses, cellulitis, or other focal infections 
   - Yes
   - No

#### DV6032G

- **1=Yes**
- **0=No**

---

Biosignatures PUD Annotated eCRF, Version 1.0
Screening and Enrollment

Consent, #

ConsentDay, #

ConsentTime, $5

PreviouslyEnrolled, #

DV6032G
1=Yes
0=No

DV6032G
1=Yes
0=No
### Clinical Data

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>TempDay</td>
<td>Date of qualifying elevated temperature</td>
<td>DD-MM-YYYY</td>
</tr>
<tr>
<td>TempLoc</td>
<td>Location where qualifying elevated temperature was taken</td>
<td></td>
</tr>
<tr>
<td>Temperature</td>
<td>Qualifying elevated temperature</td>
<td></td>
</tr>
<tr>
<td>DurationFever</td>
<td>Duration of fever (prior to ED visit)</td>
<td>1 = Less than 12 hours, 2 = 12-24 hours, 3 = Greater than 24 hours, 4 = Unable to estimate, 5 = Enrolled during year 2</td>
</tr>
<tr>
<td>BloodColl</td>
<td>How much blood was collected in the baby tempus tube? (biosignatures sample)</td>
<td></td>
</tr>
<tr>
<td>ProcalcYN</td>
<td>If yes, how much blood was collected?</td>
<td></td>
</tr>
<tr>
<td>ProcalcYN</td>
<td>Were antibiotics given in the ED prior to obtaining the study blood sample and blood culture?</td>
<td></td>
</tr>
<tr>
<td>BloodAnt</td>
<td>Blood culture done?</td>
<td></td>
</tr>
<tr>
<td>EDStatus</td>
<td>Patient’s status after ED visit</td>
<td></td>
</tr>
<tr>
<td>EDDischDay</td>
<td>Date of ED discharge</td>
<td>DD-MM-YYYY</td>
</tr>
<tr>
<td>EDDischTime</td>
<td>Time of ED discharge</td>
<td>HH:MM</td>
</tr>
</tbody>
</table>

### Data Validation Codes

- **DV7021G**: 1 = PECARN site ED, 2 = Non-PECARN site ED, 3 = PCP office or other facility
- **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
- **DV7039G**: 1 = Discharged home, 2 = Admitted to hospital, 3 = Died, 4 = Transferred to another hospital, 90 = Other
- **DV6032G**: 1 = Yes, 0 = No
### Laboratory Results

**CBC with Platelet Count**

- **Was a CBC with platelet count obtained?**
  - DV6032G
    - 1=Yes
    - 0=No

**Was a WBC differential count obtained?**

- **WBCDiff, #**

**Was the test manual, automated or both?**

- **DiffAutoMan, #**

**Hgb, #**  
**Platelet, #**  
**WBC, #**

**ANC, #**

**Value not provided**

### Hemoglobin (g/dL)

- **Hgb, #**

### Platelets (× 10^3/µL)

- **Platelet, #**

### White Blood Count (× 10^3/µL)

- **WBC, #**

**WBCTest**

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

**ANC, #**

### Neutrophils

- **NeutroMan, #**
- **NeutrManPerc, #**
- **NeutroAut, #**
- **NeutrAutPerc, #**

### Lymphocytes

- **LymphMan, #**
- **LymphManPerc, #**
- **LymphAut, #**
- **LymphAutPerc, #**

### Monocytes

- **MonoMan, #**
- **MonoManPerc, #**
- **MonoAut, #**
- **MonoAutPerc, #**
## Laboratory Results

<table>
<thead>
<tr>
<th>Laboratory Results</th>
<th>Value not provided</th>
</tr>
</thead>
</table>

### Eosinophils
- **EosinMan, #**
- **EosinManPerc, #**
- **EosinAut, #**
- **EosinAutPerc, #**

### Basophils
- **BasoMan, #**
- **BasoManPerc, #**
- **BasoAut, #**
- **BasoAutPerc, #**

### Bands
- **BandsMan, #**
- **BandsManPerc, #**
- **BandsAut, #**
- **BandsAutPerc, #**

### Other Blood Studies
- **OtherBlood, #**

### DV6032G
- 1 = Yes
- 0 = No

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

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

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSFTestYN</td>
<td>CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestDay</td>
<td>Date of CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestTime</td>
<td>Time of CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestRes</td>
<td>Type of CSF test</td>
<td></td>
</tr>
<tr>
<td>CSFTestRes</td>
<td>CSF test result</td>
<td></td>
</tr>
<tr>
<td>CSFTestType</td>
<td>CSF test type</td>
<td></td>
</tr>
<tr>
<td>CSFTestDone</td>
<td>CSF test done</td>
<td></td>
</tr>
<tr>
<td>CSFTestDay</td>
<td>Date of CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestTime</td>
<td>Time of CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestRes</td>
<td>CSF test result</td>
<td></td>
</tr>
<tr>
<td>CSFTestType</td>
<td>CSF test type</td>
<td></td>
</tr>
<tr>
<td>CSFTestDone</td>
<td>CSF test done</td>
<td></td>
</tr>
<tr>
<td>CSFTestYN</td>
<td>CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestDay</td>
<td>Date of CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestTime</td>
<td>Time of CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestRes</td>
<td>Type of CSF test</td>
<td></td>
</tr>
<tr>
<td>CSFTestRes</td>
<td>CSF test result</td>
<td></td>
</tr>
<tr>
<td>CSFTestType</td>
<td>CSF test type</td>
<td></td>
</tr>
<tr>
<td>CSFTestDone</td>
<td>CSF test done</td>
<td></td>
</tr>
<tr>
<td>CSFTestYN</td>
<td>CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestDay</td>
<td>Date of CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestTime</td>
<td>Time of CSF test obtained</td>
<td></td>
</tr>
<tr>
<td>CSFTestRes</td>
<td>Type of CSF test</td>
<td></td>
</tr>
<tr>
<td>CSFTestRes</td>
<td>CSF test result</td>
<td></td>
</tr>
<tr>
<td>CSFTestType</td>
<td>CSF test type</td>
<td></td>
</tr>
<tr>
<td>CSFTestDone</td>
<td>CSF test done</td>
<td></td>
</tr>
</tbody>
</table>

#### CSF Culture

- **DV6032G**: 1=Yes 0=No
  - **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
- **DV6813G**: 1=Positive 2=Negative 3=Unknown or inconclusive result

#### Bacterial Cultures

- **BactCult**, #: 1=Yes 0=No
- **BactCultRes**, #: Value not provided
- **BactCultDone**, #: Value not provided
- **BactCultType**, #: 1=Stool 2=Eye 3=Ear 90=Other
- **BactCultResult**, #: Value not provided

---

Biosignatures PUD Annotated eCRF, Version 1.0
## Laboratory Results

### Viral Studies

<table>
<thead>
<tr>
<th>Field</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date viral study</td>
<td>Viral Study YN, #</td>
</tr>
<tr>
<td>obtained (DD-MM-YYYY)</td>
<td>1=Yes 0=No</td>
</tr>
<tr>
<td>Time viral study</td>
<td>Viral Time, $S5</td>
</tr>
<tr>
<td>obtained (HHMM)</td>
<td></td>
</tr>
<tr>
<td>Type of viral study</td>
<td>Viral Type, #</td>
</tr>
<tr>
<td>Herpes Type</td>
<td>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</td>
</tr>
<tr>
<td>Influenza A Type</td>
<td>DV7145G 1=Type 1 2=Type 2 90=Other 97=Not Specified</td>
</tr>
<tr>
<td>Parainfluenza Type</td>
<td>DV7146G 1=Type 1 2=Type 2 3=Type 3 4=Type 4a 5=Type 4b 90=Other 97=Not Specified</td>
</tr>
<tr>
<td>Hepatitis Type</td>
<td>DV7038G 1=Rapid Assay 2=Immunofluorescence 3=Culture 4=PCR</td>
</tr>
<tr>
<td>Specify other type</td>
<td>Viral Type Other, $S38</td>
</tr>
<tr>
<td>Result of viral study</td>
<td>Viral Result, #</td>
</tr>
<tr>
<td>Type of sample</td>
<td>Viral Sample, #</td>
</tr>
<tr>
<td>Specify other type of</td>
<td>Viral Sample Other, $S41</td>
</tr>
<tr>
<td>sample</td>
<td></td>
</tr>
<tr>
<td>Assay type</td>
<td>Viral Assay, #</td>
</tr>
<tr>
<td>Result of viral study</td>
<td>Value not provided</td>
</tr>
</tbody>
</table>
Follow-up

Phone Follow-up

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

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

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

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

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

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, #

MedicalRec, #

DV5031G
1=Yes 0=No

Follow-up (1 of 3)
Follow-up

**Follow-up (2 of 3)**

---

**Title: CSF Testing**

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

- **CSFTestsFU, #**
- **DV6032G**
  - 1=Yes
  - 0=No
- **DV6813G**
  - 1=Positive
  - 2=Negative
  - 3=Unknown or inconclusive result
- **DV7035G**
  - 1=Present
  - 2=Absent
- **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**

- **CSFCultFU, #**
- **CSFCultDayFU, #**
- **CSFCultTimFU, $#**
- **DV6032G**
  - 1=Yes
  - 0=No
- **CSFCultResFU, #**
- **DV6813G**
  - 1=Positive
  - 2=Negative
  - 3=Unknown or inconclusive result

---

FollowUp_CSFTest

FollowUp (2 of 3)
### Follow-up

#### Viral Studies on CSF

<table>
<thead>
<tr>
<th>Date viral study was obtained (DD-MM-YYYY)</th>
<th>Time viral study was obtained (HHMM)</th>
<th>Type of viral study</th>
<th>Herpes Type</th>
<th>Influenza A Type</th>
<th>Parainfluenza Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>ViralDayFU, #</td>
<td>ViralTimeFU, $5</td>
<td>ViralTypeFU, #</td>
<td>FUHerpes, #</td>
<td>FUInfluA, #</td>
<td>FUParaInflu, #</td>
</tr>
</tbody>
</table>

**ADD**

- **DV6032G**
  - 1=Yes
  - 0=No

- **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

- **DV7146G**
  - 1=Type 1
  - 2=Type 2
  - 3=Type 3
  - 4=Type 4a
  - 5=Type 4b
  - 90=Other

- **InfAType**
  - 1=H1N1
  - 90=Other

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

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

- **ViralCSFYN, #**

- **Followup_CSFViral**

- **Value not provided**

---

**Hepatitis Type**
- 1=Hepatitis A
- 2=Hepatitis B
- 90=Other
- 97=Not Specified

**DV6813G**
- 1=Positive
- 2=Negative
- 3=Unknown or inconclusive result
## Sample Destruction

<table>
<thead>
<tr>
<th>Sample Destruction</th>
<th>DestroyedSample, #</th>
<th>PV47187G</th>
<th>DestroyedDay, #</th>
<th>DestroyedReason, #</th>
<th>PV47188G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which sample was destroyed?</td>
<td></td>
<td>1=Biosignatures sample</td>
<td>1=Patient later found to be ineligible</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2=PCT sample</td>
<td>2=Patient received antibiotics after consent but prior to obtaining the study blood sample and blood culture</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3=Both</td>
<td>3=Consent issues</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>90=Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biosignatures Sample</td>
<td>Baby Tempus Tube Barcode #</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Value not provided</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date sample was destroyed</td>
<td></td>
<td>DestroyedDay, #</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Value not provided</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reason sample was destroyed</td>
<td></td>
<td>DestroyedReason, #</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Value not provided</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procalcitonin Sample</td>
<td>Date sample was destroyed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PCTDestroyDay, #</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Value not provided</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reason sample was destroyed</td>
<td></td>
<td>PCTDestroyReas, #</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Value not provided</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PV47187G: 1=Biosignatures sample, 2=PCT sample, 3=Both

PV47188G: 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

Value not provided
## Culture Review

<table>
<thead>
<tr>
<th>Date of Culture (DD-MM-YYYY)</th>
<th>Time of Culture (HHMM):</th>
<th>Organism 1:</th>
<th>Other specify:</th>
</tr>
</thead>
<tbody>
<tr>
<td>BloodDay, #</td>
<td>BloodTime, $5</td>
<td>BloodOrg1, #</td>
<td>BloodOrg1Other, $45</td>
</tr>
<tr>
<td>Add</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>BloodOrg2, #</td>
<td>BloodOrg2Other, $48</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BloodOrg3, #</td>
<td>BloodOrg3Other, $26</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organism 2:</th>
<th>Other specify:</th>
<th>Organism 3:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DCC Assessment</th>
<th>PI review needed?</th>
<th>PI Assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>BloodDCCAssess, #</td>
<td>BloodPINeeded, #</td>
<td>BloodPIAssess, #</td>
</tr>
</tbody>
</table>

- **Organisms**
  - 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

- **PNInt**
  - 1=Positive
  - 2=Negative
  - 3=Intermediate
  - 9=Unable to determine

- **DV6032G**
  - 1=Yes
  - 0=No
Culture Review

<table>
<thead>
<tr>
<th>Organism</th>
<th>Other specify</th>
<th>CFU available?</th>
<th>Low:</th>
<th>High:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-hemolytic streptococcus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacillus species</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Campylobacter</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citrobacter</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cocci</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corynebacteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E. coli</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterobacter cloacae</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterococcus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterococcus faecalis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flavobacterium</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gamma streptococcus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group B streptococcus (GBS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Klebsiella</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Klebsiella oxytoca</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Klebsiella pneumonia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactobacilli</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactobacillus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Micrococcus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixed/multiple flora/organisms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neisseria meningitides</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal flora</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonhemolytic streptococcus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propionibacteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proteus mirabilis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pseudomonas</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salmonella</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salmonella group B</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shigella</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staph. aureus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staph. coagulase negative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staph. diphtheroids</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staph. epi</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staph. hominis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staph. non-aureus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staph. warneri</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strep. mitis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strep. viridans</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yersinia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not specified</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Urine Culture

- **Date of Culture (DD-MM-YYYY):**
- **Time of Culture (HHMM):**
- **Urine Culture:**
- **Other specify:**
- **CFU available:**
- **Low:**
- **High:**

#### Organism Details

- **UrineOrg1:**
- **UrineOrg1Other:**
- **UrineOrg1CFU:**
- **UrineOrg1Low:**
- **UrineOrg1High:**

- **UrineOrg2:**
- **UrineOrg2Other:**
- **UrineOrg2CFU:**
- **UrineOrg2Low:**
- **UrineOrg2High:**

- **UrineOrg3:**
- **UrineOrg3Other:**
- **UrineOrg3CFU:**
- **UrineOrg3Low:**
- **UrineOrg3High:**

#### Urinalysis Details

- **Urinalysis available:**
- **Urinalysis Result:**
- **DCC Assessment:**
- **PT review needed:**
- **PT Assessment:**

#### Additional Fields

- **UrineDay:**
- **UrineTime:**
- **UrineSite:**
- **UrineOrg1:**
- **UrineOrg1Other:**
- **UrineOrg2:**
- **UrineOrg2Other:**
- **UrineOrg3:**
- **UrineOrg3Other:**
- **Urinalysis:**
- **UrinalysisResult:**
- **UrineDCCAssess:**
- **UrinePINeeded:**
- **UrinePIAssess:**
- **PNIntUn:**
- **PNInt:**
- **DV6032G:**
- **DV6807G:**

#### Additional Notes

- **DV6032G:**
  - 1=Yes
  - 0=No
- **DV6807G:**
  - 1=Catherization
  - 2=Suprapubic
  - 3=Bag Sample
  - 94=Not Documented
- **PNIntUn:**
  - 1=Positive
  - 2=Negative
  - 3=Intermediate
  - 93=Unable to determine
- **PNInt:**
  - 1=Positive
  - 2=Negative
  - 3=Intermediate
  - 93=Unable to determine

#### Relevant Organisms

- 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

<table>
<thead>
<tr>
<th>Date of Culture (DD-MM-YYYY)</th>
<th>Time of Culture (HH:MM)</th>
<th>Organism 1:</th>
<th>Other specify:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSFDay, #</td>
<td>CSFTime, $5</td>
<td>CSFOrg1, #</td>
<td>CSFOrg1Other, $45</td>
</tr>
</tbody>
</table>

**Add**

<table>
<thead>
<tr>
<th>Organism 2:</th>
<th>Other specify:</th>
<th>Organism 3:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSFOrg2, #</td>
<td>CSFOrg2Other, $31</td>
<td>CSFOrg3, #</td>
</tr>
</tbody>
</table>

**Organism**

1. Alpha-hemolytic streptococcus
2. Bacillus species
3. Campylobacter
4. Citrobacter
5. Coci
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

#### DCC Assessment

<table>
<thead>
<tr>
<th>PI review needed?</th>
<th>PI Assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSFPINeeded, #</td>
<td>CSFPIAssess, #</td>
</tr>
</tbody>
</table>

**PNIntUn**

1. Positive
2. Negative
3. Intermediate
93. Unable to determine

**DV6032G**

1. Yes
0. No

**PNInt**

1. Positive
2. Negative
3. Intermediate
### Culture Review

<table>
<thead>
<tr>
<th>Date of Culture (DD-MM-YYYY):</th>
<th>Time of Culture (HHMM):</th>
<th>Organism 1:</th>
<th>Other specify:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>StoolDay, #</strong></td>
<td><strong>StoolTime, $5</strong></td>
<td><strong>StoolOrg1, #</strong></td>
<td><strong>StoolOrg1Other, $65</strong></td>
</tr>
<tr>
<td><strong>Add</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organism 2:</th>
<th>Other specify:</th>
<th>Organism 3:</th>
<th>Other specify:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>StoolOrg2, #</strong></td>
<td><strong>StoolOrg2Other, $201</strong></td>
<td><strong>StoolOrg3, #</strong></td>
<td><strong>StoolOrg3Other, $15</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Organisms

- 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

#### PNIntUn

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

#### DV6032G

- 1=Yes
- 0=No

#### PIInt

- 1=Positive
- 2=Negative
- 3=Intermediate

#### DCC Assessment

- **StoolDCCAssess, #**

#### PI review needed?

- **StoolPINeeded, #**

#### PI Assessment

- **StoolPIAssess, #**

---

Biosignatures PUD Annotated eCRF, Version 1.0

23
### Unknown / Inconclusive Viral Studies

<table>
<thead>
<tr>
<th>Viral Study</th>
<th>Herpes Type</th>
<th>InflA Type</th>
<th>Parainfl Type</th>
<th>HepType</th>
<th>Specify Other Type</th>
<th>Date of viral study (DD-MM-YYYY)</th>
<th>Time of viral study (HHMM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(select one)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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
- 3 = Type 3
- 4 = Type 4a
- 5 = Type 4b
- 90 = Other
- 97 = Not Specified

**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

**DV7039G**
- 1 = Blood
- 2 = CSF
- 3 = Nasopharyngeal/Respiratory
- 4 = Stool
- 5 = Skin
- 6 = Urine
- 7 = Eye
- 90 = Other

**DV7146G**
- 1 = Type 1
- 2 = Type 2
- 3 = Type 3
- 4 = Type 4a
- 5 = Type 4b
- 90 = Other
- 97 = Not Specified
## PCT Data

<table>
<thead>
<tr>
<th>Variable</th>
<th>Format</th>
<th>Type</th>
<th>Label</th>
<th>Algorithm / Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCTBloodDay</td>
<td>#</td>
<td></td>
<td>PCTBloodDay relative to screen date</td>
<td></td>
</tr>
<tr>
<td>PCTShipDay</td>
<td>#</td>
<td></td>
<td>PCTShipDay relative to screen date</td>
<td></td>
</tr>
<tr>
<td>PCTDayReceived</td>
<td>#</td>
<td></td>
<td>PCTDayReceived relative to screen date</td>
<td></td>
</tr>
<tr>
<td>PCTResult</td>
<td>$50</td>
<td></td>
<td>PCTResult</td>
<td></td>
</tr>
</tbody>
</table>