PERCH Annotated eCRFs

Purpose: Contains all forms and question text with corresponding field names. Variables in **red** text represent calculated variables located in the analytic datasets.

The PERCH Core Team recommends using the calculated variables when they are available, in place of the raw variables, to ensure standardization across analyses.

For additional information on variables, including definitions and programming, see the Clinical and Laboratory Definitions Documents (insert filename). If it is necessary to create new calculated variables, please review the annotated eCRFs and Data Dictionary (insert filename) to identify the appropriate variables.

For questions regarding the PERCH datasets or derived variables, please contact the PERCH Core Team (cprospe1@jhu.edu and mhigdon@jhu.edu).

Date of last update: 30Jan2015

CRF 01: Case Screening (ELS)

Segment *(PROTSEG)*:

Instructions: If at any point during the completion of this CRF, the child is determined to be not eligible, end the form. Save the form with all available data and then confirm Q23 (eligibility question on page 3 of CRF 01) is answered No.

Check one: *(ELSRESCR)* ☐ 1 - Initial Screening   ☐ 2 - Re-screening

If Re-screening, initial PERCH ID: *(ELSRESID)* ☐

Section A: Screening

Date of screening: *(ELSSCRDT)* ☐ *(ddMMMyyyy)*

1. Time of Screening: *(ELSTM)* ☐ *(hh:mm)* *(24 hour clock)*

2. Optional local site Participant ID number(s):   *(ELSPIDA)* a. ☐

    (ELSPIDB) b. ☐

    (ELSPIDC) c. ☐

_SEX
1=Female
0=Male

3. Sex of the child: *(ELSGEN)* ☐ 0 - Male   ☐ 1 - Female

_LT1M
1=Yes
0=No

4. Age of the child:

   Is the child less than 1 month old?   *(ELSLT1M)* ☐ 1 - Yes   ☐ 0 - No

_AGEM
(months)

   a. If Yes: *(ELSAGED)* ☐ *(xx)* days

   b. If No: *(ELSAGEM)* ☐ *(xx)* months

_AGECAT
1=0-5 m
2=6-11 m
3=12-23 m
4=24-59 m

5. Where was the child evaluated?

```
01-01 - ER
02-02 - Main ICU
03-03 - High care area
04-04 - Ward
05-05 - Outpatient department
*Additional Options Listed Below
```

See additional options listed on the last page of CRF 01 (page 4).

(ELSEVAL)

Other, specify:*(ELSEVASP)* ☐   Code:*(ELSEVACO)* ☐

Inclusion Criteria

To be eligible for PERCH, answers to **ALL** of the following must be **Yes**.

6. Age 28 days to 59 months inclusive?   *(ELSAGE)* ☐ 1 - Yes   ☐ 0 - No

7. Ill with cough or difficulty breathing?   *(ELSILL)* ☐ 1 - Yes   ☐ 0 - No

8. Lives in catchment area?   *(ELSCATCH)* ☐ 1 - Yes   ☐ 0 - No

   a. If Yes, where does the child live? *(ELSGEO)* ☐ *(enter coded geographic area)*

   b. Was the child born in Bara?   *(ELSBARA)* ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

Exclusion Criteria

To be eligible for PERCH, answers to **BOTH** questions 9 and 10 must be **No**.

9. Has the child been hospitalized overnight in the past 14 days (other than hospitalization at a referring hospital for this pneumonia episode <24 hours before screening)?   *(ELSHOSPT)* ☐ 1 - Yes   ☐ 0 - No

   a. Was this child admitted overnight at a referral hospital **in the previous 24 hours** for this pneumonia episode?   *(ELSHOREF)* ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

10. Has the child been discharged from the hospital in the past 30 days having been enrolled as a PERCH case?   *(ELSDISCH)* ☐ 1 - Yes   ☐ 0 - No

11. Section A Comments:

(ELSCOMMA)

Section A Staff Code: *(ELSSTAFF)*

Initial QC by: *(ELSINQC)*

Additional Selection Options for ELS

Where child evaluated
06-06 - Clinic (Dhaka and Gambia only)
99-99 - Other

Additional options corresponding to the question 'Where child evaluated' (Q5 on CRF 01).

For remainder of the document, refer to this section at the end of each CRF for any codelist with '*Additional Options Listed Below'

CRF 01: Case Screening Clinical Exam (ELC)

Segment *(PROTSEG)*:

Section B: Clinical Exam

12. Was a clinical exam performed on this child by a PERCH trained examiner? *(ELCEXAM)* ☐ 1 - Yes ☐ 0 - No

> 01-01 - Died
> 02-02 - Refused
> 03-03 - Not referred for hospital admission
> 04-04 - No trained examiner
> 99-99 - Other

    a. If No, why not?*(ELCNOEX)*

Other, specify:*(ELCNEXSP)* [_____]   Code:*(ELCNEXCO)* [____]

13. Where was the clinical exam conducted?

> 01-01 - ER
> 02-02 - Main ICU
> 03-03 - High care area
> 04-04 - Ward
> 05-05 - Outpatient department
> *Additional Options Listed Below

(ELCEXLOC)

Other, specify:*(ELCEXLSP)* [_____]   Code:*(ELCEXLCO)* [____]

Inclusion Criteria

To be eligible for PERCH, answer to **Q14h** must be **Yes**.

14. Assess the following symptoms of severe and very severe pneumonia:

    a. Lower chest wall indrawing: *(ELCLCWI)* ☐ 1 - Yes ☐ 0 - No

    b. Head nodding: *(ELCHEAD)* ☐ 1 - Yes ☐ 0 - No

    c. Central cyanosis: *(ELCCENTR)* ☐ 1 - Yes ☐ 0 - No

    d. Unable to feed *(must be observed by examiner)*: *(ELCFEED)* ☐ 1 - Yes ☐ 0 - No

    e. Vomiting everything *(must be observed by examiner)*: *(ELCVOM)* ☐ 1 - Yes ☐ 0 - No

_VS_SYNDROME
1=Head nodding only
2=Central cyanosis only
3=Unable to feed only
4=Vomiting everything only
5=Lethargic only
6=Convulsions only
7=Two symptoms
8=Three or more symptoms

_LETHARGIC
1=Yes
0=No

    f. Lethargy or impaired consciousness:

> 0-0 - A: Alert and awake
> 1-1 - V: Responds to voice
> 2-2 - P: Responds to pain
> 3-3 - U: Unresponsive
> 9-9 - Pharmacologically sedated

(ELCLETH)

    Note: Wait for > 30 minutes after any convulsion before carrying out assessment of consciousness.

_MPCONVUL
1=Yes
0=No

    g. Did child have convulsions? *(ELCCONV)* ☐ 1 - Yes ☐ 0 - No

      i. If Yes, what kind *(check all that apply)*?

    (ELCMCONV) ☐ Multiple (≥2 episodes) *(ELCPCONV)* ☐ Prolonged (≥15 minutes) *(ELCSCONV)* ☐ Single brief (<15 minutes)

    h. Does the child have severe or very severe pneumonia? *(ELCPNEUM)* ☐ 1 - Yes ☐ 0 - No

    Answer is pre-populated based on responses to Q14a-f and Q14g.i. indicating multiple or prolonged convulsions.
    Severe or very severe pneumonia is defined as having ONE or MORE responses in 14a-f checked Yes or multiple or prolonged convulsions in 14g.i.

15. Did a PERCH study physician verify the signs/symptoms of severe/very severe pneumonia? *(ELCVERIF)* ☐ 1 - Yes ☐ 0 - No

Oxygen Saturation and Respiratory Rate

_ONO2
1=Yes
0=No
8=Unk
9=NR

16. Is the child on O$_2$? *(Assess only if >30 min after seizure)*

> 1-1 - Yes
> 0-0 - No
> 8-8 - UNK
> 9-9 - NR

(ELCOXA)

    a. If Yes, record route of administration *(select one)*: *(ELCRTA)*

_O2SAT (%)

1-1 - Nasal prongs
2-2 - Nasal catheter
3-3 - Mechanical ventilation
4-4 - Face mask without reservoir
5-5 - Non-rebreathing mask with reservoir
*Additional Options Listed Below

_HYPOX
1=Yes
0=No

b. If Yes, oxygen delivery flow rate: (ELCFLOA) [ ] (xx.x) L/min   (ELCFLOAU) ☐ 8 - UNK ☐ 9 - NR

17. Oxygen saturation by pulse oximetry (*on room air whenever possible*):   (ELCSATA) [ ] (xxx) %   (ELCSATAU) ☐ 8 - UNK ☐ 9 - NR

_O2MEASON
1=Oxygen
2=Room air
8=Unk
9=NR

a. Measured when child was on:

1-1 - Oxygen
2-2 - Room air
8-8 - UNK
9-9 - NR

(ELCOMSA)

b. If oxygen saturation measured when child was on oxygen (Q17a ="1- Oxygen"),   (ELCSATT) [ ] (xxx) %   (ELCSATTU) ☐ 8 - UNK ☐ 9 - N/A
record oxygen saturation measurement on room air *(if available from chart)*:

_RR_ADM
_TACHYPNEA
1=Yes
0=No

18. Respiratory rate (# of breaths counted in 60 seconds):   (ELCRRA) [ ] (xxx) per minute   (ELCRRAUN) ☐ 8 - UNK ☐ 9 - NR ☐
(Only if not on assisted ventilation)   7 - N/A

Oxygen Saturation and Respiratory Rate

_ONO2
1=Yes
0=No
8=Unk
9=NR

16. Is child on O$_2$? (*Assess only if >30 min after seizure*)

1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR

(ELCOXB)

a. If Yes, record route of administration (*select one*):   (ELCRTB)

1-1 - Nasal prongs
2-2 - Nasal catheter
3-3 - Mechanical ventilation
4-4 - Face mask without reservoir
5-5 - Non-rebreathing mask with reservoir
*Additional Options Listed Below

_O2SAT (%)

_HYPOX
1=Yes
0=No

b. If Yes, oxygen delivery flow rate: (ELCFLOB) [ ] (xx.x) L/min   (ELCFLOBU) ☐ 8 - UNK ☐ 9 - NR

17. Oxygen saturation by pulse oximetry (*on room air whenever possible*):   (ELCSATB) [ ] (xxx) %   (ELCSATBU) ☐ 8 - UNK ☐ 9 - NR

_O2MEASON
1=Oxygen
2=Room air
8=Unk
9=NR

a. Measured when child was on:

1-1 - Oxygen
2-2 - Room air
8-8 - UNK
9-9 - NR

(ELCOMSB)

b. If oxygen saturation measured when child was on oxygen (Q17a ="1- Oxygen"),   (ELCSATS) [ ] (xxx) %   (ELCSATSU) ☐ 8 - UNK ☐ 9 - N/A
record oxygen saturation measurement on room air *(if available from chart)*:

_RR_ADM
_TACHYPNEA
1=Yes
0=No

18. Respiratory rate (# of breaths counted in 60 seconds):   (ELCRRB) [ ] (xxx) per minute   (ELCRRBUN) ☐ 8 - UNK ☐ 9 - NR ☐
(Only if not on assisted ventilation)   7 - N/A

If Q14h is checked Yes, please continue. If Q14h is checked No, skip to Q23.

19. Does this child have <u>very</u> severe pneumonia?
Answer is pre-populated based on responses to Q14b-f and Q14g.i. indicating multiple or prolonged convulsions.
If Yes, skip to Q22.
If No, answer Q20 (i.e. child has lower chest wall indrawing but no 'very severe' signs).

1-1 - Yes
0-0 - No

(ELCVSPN)

BRONCHODILATOR CHALLENGE

Inclusion criteria:
To be eligible, Q21c must be **Yes** *if the child has <u>severe</u> pneumonia.*
If the child has very severe pneumonia (i.e., any of Q14b-g is Yes), skip to Q22.

20. Does the child have lower chest wall indrawing and <u>auscultatory wheeze</u>?   (ELCWHZ) ☐ 1 - Yes ☐ 0 - No

21. Were all required doses of bronchodilators administered before consent?
If Yes, complete Q21a-c below.
If No, select 'Pending' and complete Q21a-c when information is available.

1-1 - Yes
8-8 - N/A (e.g. met quota or not during the hours of enrollment)
9-9 - No, pending

(ELCREQBD)

a. Number of bronchodilators given: (ELCNUMBD) [ ] (x) doses

b. Does child have wheeze on auscultation after bronchodilator challenge? *(ELCWHZBD)* ☐ 1 - Yes ☐ 0 - No

c. Is the lower chest wall indrawing still present after bronchodilator challenge? *(ELCLCWBD)* ☐ 1 - Yes ☐ 0 - No

Initial QC by: *(ELCINQC)*

Additional Selection Options for ELC

Clinical exam location
06-06 - Clinic (Dhaka and Gambia only)
99-99 - Other

Route of oxygen adm in A
6-6 - Head box
8-8 - UNK
9-9 - NR

CRF 01: Case Admission and Consent (ELE)

Segment *(PROTSEG)*:

Section B: Clinical Exam continued

Admission Eligibility: To be eligible for PERCH, the answer to Q22b below must be **Yes.**

22 a. What is the hospital admission status of this child? *(only one must be checked)*

(ELEADM) ☐ Admitted to study hospital

        Date:*(ELEADMDT)* ☐☐☐☐☐☐ *(ddMMMyyyy)*   Time:*(ELEADMTM)* ☐☐☐☐☐ *(hh:mm) (24 hour clock)*

(ELEREC) ☐ Recommended for admission to study hospital, but not admitted

      i. Will the child be available to study staff for sufficient time to   *(ELEAVAIL)* ☐ 1 - Yes ☐ 0 - No

         complete all study procedures?

      ii. Specify reason not admitted:

> 01-01 - Parent refused admission
> 02-02 - Died
> 99-99 - Other

(ELERNA)

Other, specify:*(ELERNASP)* ☐   Code:*(ELERNACO)* ☐

(ELEREF) ☐ Not referred for admission to study hospital

      iii. Specify reason:

> 01-01 - Physician deemed not severe enough
> 02-02 - Parent refused admission
> 03-03 - Referred to another facility
> 04-04 - Died
> 99-99 - Other

(ELEREFR)

Other, specify:*(ELEREFSP)* ☐   Code:*(ELEREFCO)* ☐

22 b. Does the child meet hospital admission criteria?   *(ELEADCR)* ☐ 1 - Yes ☐ 0 - No
    Answer is pre-populated based on responses to Q22a and 22a.i.

Eligibility for PERCH

ELIG
1=Yes
0=No

23. Is this child eligible for PERCH?   *(ELEELIG)* ☐ 1 - Yes ☐ 0 - No

    Answer is populated after the form is saved based on responses to inclusion and exclusion criteria.
    I.e. If Q6-8, Q14h, Q22b, Q25 are Yes, Q21 is Yes or No, pending (as applicable), answers to Q9-10 are No, and Q25b is not blank, then child is eligible for PERCH.

    For Q 23 to be Yes (child is eligible) after saving the form, ensure Section C is completed. If child is not eligible, answer N/A to Q 25.

24. Section B Comments:

(ELEBCOMM)

Clinical Exam /Eligibility Status Staff Code: *(ELEBSTAF)* ☐

Section C: Consent and Enrollment for PERCH

25. Has consent been obtained?*(ELECONNA)* ☐ 9 - N/A   *(ELECONS)* ☐ 1 - Yes ☐ 0 - No

    Must be Yes to continue enrollment.
    If No, skip to Q25c below.

a. If Yes, child's date of birth: *(When date of birth is uncertain,*
   always estimate the date and check 'Date uncertain' box)

Date of birth: *(ELEDOB)* [＿＿＿＿] *(ddMMMyyyy)*   *(ELEDOBUN)* ☐ 8 - Date uncertain

b. If Yes, date and time of enrollment:

Date of enrollment: *(ELEENRDT)* [＿＿＿＿] *(ddMMMyyyy)*   Time of enrollment: *(ELEENRTM)* [＿＿＿＿] *(hh:mm) (24 hour clock)*

c. If Q25 is No, indicate reason why consent was not obtained:

```
01-01 - Refused consent
02-02 - Died
03-03 - N/A (e.g. met quota or not during the hours of enrollment)
99-99 - Other
```
(ELENOC)

Other, specify: *(ELENOCSP)* [＿＿＿＿]   Code: *(ELENOCCO)* [＿＿＿]

26. Section C Comments:

[   ]
(ELECCOMM)

Section C Staff Code: *(ELECSTAF)* [＿＿＿]

Initial QC by: *(ELEINQC)* [＿＿＿＿]

Supervisor Staff Code: *(ELESUPER)* [＿＿＿]

Supervisor Verification Date: *(ELEVERDT)* [＿＿＿] *(ddMMMyyyy)*

CRF 01A: Control Screening and Eligibility (ELN)

Web Version: 1.0; 3.02; 16APR13

Segment *(PROTSEG)*:

Instructions: If at any point during the completion of this CRF, the child is determined to be not eligible, end the form. Save the form with all available data and then confirm Q13 (eligibility) is answered No.

Section A: Screening

Date of screening: *(ELNSCRDT)* [   ]   *(ddMMMyyyy)*

1. Time of screening: *(ELNTM)* [   ]   *(hh:mm)*   *(24 hour clock)*

2. Optional local site Participant ID number(s):

    a. *(ELNPIDA)* [   ]

    b. *(ELNPIDB)* [   ]

    c. *(ELNPIDC)* [   ]

_SEX
1=Female
0=Male

3. Sex of the child: *(ELNGEN)* ☐ 0 - Male ☐ 1 - Female

4. Age of the child:

_LT1M
1=Yes
0=No

_AGEM
(months)

    Is the child less than 1 month old?   *(ELNLT1M)* ☐ 1 - Yes ☐ 0 - No

    a. *(ELNAGED)* If Yes: [   ] *(xx)* days

_AGECAT
1=0-5 m
2=6-11 m
3=12-23 m
4=24-59 m

    b. *(ELNAGEM)* If No: [   ] *(xx)* months

5. Where was the child evaluated?

> 01-01 - Home
> 02-02 - Study facility
> 03-03 - Health center/clinic
> 99-99 - Other

(ELNEVAL)

    Other, specify:*(ELNEVASP)* [   ]   Code:*(ELNEVACO)* [   ]

Inclusion Criteria

To be eligible, **BOTH** of the following must be **Yes**.

6. Age 28 days to 59 months inclusive?   *(ELNAGE)* ☐ 1 - Yes ☐ 0 - No

7. Lives in catchment area?   *(ELNCATCH)* ☐ 1 - Yes ☐ 0 - No

    a. If Yes, where does the child live?   *(ELNGEO)* [   ]   *(enter coded geographic area)*

    b. Was the child born in Bara?   *(ELNBARA)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

Exclusion Criteria

To be eligible, **BOTH** of the following must be **No**.

8. Has the child been hospitalized in the past 14 days?   *(ELNHOSPT)* ☐ 1 - Yes ☐ 0 - No

9. Has the child been discharged from the hospital in the past 30 days having been enrolled as a PERCH case?   *(ELNDISCH)* ☐ 1 - Yes ☐ 0 - No

Section A Staff Code: *(ELNASTAF)* [   ]

Section B: Clinical Exam

10. Was child examined by a trained examiner for completion of this Section?   *(ELNEXAM)* ☐ 1 - Yes ☐ 0 - No

> 01-01 - Refused
> 02-02 - No trained examiner
> 03-03 - Unable to contact after initial screen
> 99-99 - Other

    a. If No, why not?*(ELNNOEX)*

    Other, specify:*(ELNNEXSP)* [   ]   Code:*(ELNNEXCO)* [   ]

Exclusion Criteria

To be eligible for PERCH, Q11 and Q12i below must be '**No**'.

11. Does this child appear very sick requiring urgent medical attention?   *(ELNURG)* ☐ 1 - Yes ☐ 0 - No

    If Yes, child is ineligible; prompt evaluation and treatment should be sought.

12. Assess the following symptoms of severe and very severe pneumonia:

a. Is child ill with cough or difficulty breathing? *(ELNILL)* ☐ 1 - Yes ☐ 0 - No

b. Lower chest wall indrawing: *(ELNLCWI)* ☐ 1 - Yes ☐ 0 - No

c. Head nodding: *(ELNHEAD)* ☐ 1 - Yes ☐ 0 - No

d. Central cyanosis: *(ELNCENTR)* ☐ 1 - Yes ☐ 0 - No

e. Unable to feed *(must be observed by examiner)*: *(ELNFEED)* ☐ 1 - Yes ☐ 0 - No

f. Vomiting everything *(must be observed by examiner)*: *(ELNVOM)* ☐ 1 - Yes ☐ 0 - No

g. Lethargy or impaired consciousness:

| 0-0 - A: Alert and awake |
| 1-1 - V: Responds to voice |
| 2-2 - P: Responds to pain |
| 3-3 - U: Unresponsive |
| 9-9 - Pharmacologically sedated |

(ELNLETH) ▮

Note: Wait for > 30 minutes after any convulsion before carrying out assessment of consciousness.

h. Did child have convulsions? *(ELNCONV)* ☐ 1 - Yes ☐ 0 - No

   i. If Yes, what kind *(check all that apply)*?

   (ELNMCONV) ☐ Multiple *(≥2 episodes)*   *(ELNPCONV)* ☐ Prolonged *(≥15 minutes)*   *(ELNSCONV)* ☐ Single brief *(<15 minutes)*

i. Does the child have <u>severe</u> or <u>very severe</u> pneumonia? *(ELNPNEUM)* ☐ 1 - Yes ☐ 0 - No

  Answer is pre-populated based on responses to Q12a-g and Q12h.i. indicating multiple or prolonged convulsions.
  *Severe or very severe pneumonia is defined as having **cough or difficulty breathing** (i.e. 12a is Yes) **AND ONE or MORE** responses in 12b-g checked Yes or multiple or prolonged convulsions in 12h.i.*

Eligibility for PERCH

ELIG
1=Yes
0=No

13. Is this child eligible for PERCH? *(ELNELIG)* ☐ 1 - Yes ☐ 0 - No

  Answer is populated after the form is saved based on responses to inclusion and exclusion criteria.
  If answers to Q6-7 and Q15 are Yes and Q8-9, Q11, and Q12i are No, and Q15b is not blank, then child is eligible for PERCH.

For Q13 to be Yes (child is eligible) after saving the form, ensure Section C is completed. If child is not eligible, answer N/A to Q15.

14. Section B Comments:

(ELNBCOMM) [   ]

Section B Staff Code: *(ELNBSTAF)* [   ]

Section C:
Consent and Enrollment for PERCH

15. **Has consent been obtained?** *(ELNCONNA)* ☐ 9 - N/A   *(ELNCONS)* ☐ 1 - Yes ☐ 0 - No

  Must be Yes to continue enrollment.
  If No, mark the reason why not in Q15c below.

  a. If Yes, child's date of birth: *(When date of birth is uncertain, <u>always</u> estimate the date and check Date uncertain box)*

_DOB

Date of birth: *(ELNDOB)* [   ] *(ddMMMyyyy)*   *(ELNDOBUN)* ☐ 8 - Date uncertain

  b. If Yes, date and time of enrollment:

ENRLDATE

ENRL
1=Yes
0=No

Date of enrollment: *(ELNENRDT)* [   ] *(ddMMMyyyy)*   Time of enrollment: *(ELNENRTM)* [   ] *(hh:mm) (24 hour clock)*

| 01-01 - Refused consent |
| 99-99 - Other |

  c. If No, reason why not: *(ELNNOC)* ▮

Other, specify: *(ELNNOCSP)* [   ]   Code: *(ELNNOCCO)* [   ]

16. Section C Comments:

(ELNCCOMM)

Section C Staff Code: (ELNCSTAF)

Initial QC by: (ELNINQC)

Supervisor Staff Code: (ELNSUPER)

Supervisor Verification Date: (ELNVERDT) (ddMMMyyyy)

CRF 01B: HIV+ Control Screening and Eligibility (ELH)

Segment *(PROTSEG)*:

Instructions: If at any point during the completion of this CRF, the child is determined to be not eligible, end the form. Save the form with all available data and then confirm Q17 (eligibility) is answered No.

Section A: Screening

Date of screening: *(ELHSCRDT)* _____ *(ddMMMyyyy)*

1. Time of screening: *(ELHTM)* _____ *(hh:mm)* *(24 hour clock)*

2. Optional local site Participant ID number(s):

   a. *(ELHPIDA)* _____

   b. *(ELHPIDB)* _____

   c. *(ELHPIDC)* _____

_SEX
1=Female
0=Male

3. Sex of the child: *(ELHGEN)* ☐ 0 - Male ☐ 1 - Female

_LT1M
1=Yes
0=No

4. Age of the child:

   Is the child less than 1 month old? *(ELHLT1M)* ☐ 1 - Yes ☐ 0 - No

   _AGECAT
   1=0-5 m
   2=6-11 m

   a. If Yes: *(ELHAGED)* _____ *(xx)* days

   3=12-23 m

   b. If No: *(ELHAGEM)* _____ *(xx)* months

_AGEM
(months)

   4=24-59 m

5. Where was the child recruited from? *(ELHRECR)* HIV Clinic number: _____ *(xx)*

6. Where was the child evaluated?

   01-01 - Home
   02-02 - Study facility
   03-03 - Health center/clinic
   99-99 - Other
   (ELHEVAL) ▇▇▇▇▇▇▇▇▇

   Other, specify:*(ELHEVASP)* _____ Code:*(ELHEVACO)* _____

Inclusion Criteria

To be eligible for PERCH, ALL of **Q7-9** must be **Yes** and Q9b must **NOT be UNK**.

7. Age 28 days to 59 months inclusive? *(ELHAGE)* ☐ 1 - Yes ☐ 0 - No

8. Lives in catchment area? *(ELHCATCH)* ☐ 1 - Yes ☐ 0 - No

   a. If Yes, where does the child live? *(ELHGEO)* _____ *(enter coded geographic area)*

   b. Was the child born in Bara? *(ELHBARA)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

9. Is the child confirmed as HIV positive? *(ELHHIVP)* ☐ 1 - Yes ☐ 0 - No

   a. If Yes, source of confirmation of HIV status:

   01-01 - Hospital outpatient folder
   02-02 - HIV clinic folder
   03-03 - Laboratory database
   99-99 - Other
   (ELHSRC) ▇▇▇▇▇▇▇▇▇

   Other, specify:*(ELHSRCSP)* _____ Code:*(ELHSRCCO)* _____

   b. If Yes, has the child had <3 months of ART treatment?

   1-1 - Yes
   0-0 - No
   8-8 - UNK
   (ELHART) ▇▇▇▇▇▇▇▇▇

Exclusion Criteria

To be eligible for PERCH, **ALL** of the following must be **No.**

10. Has the child been hospitalized in the past 14 days? *(ELHHOSPT)* ☐ 1 - Yes ☐ 0 - No

11. Has the child been discharged from the hospital in the past 30 days having been enrolled as a PERCH case? *(ELHDISCH)* ☐ 1 - Yes ☐ 0 - No

12. Has the child been admitted to the hospital in the past 30 days for an acute illness? *(ELHACUTE)* ☐ 1 - Yes ☐ 0 - No

13. Section A Comments:

(ELHACOMM)

Section A Staff Code: *(ELHASTAF)*

Section B: Clinical Exam

14. Was child examined by a trained examiner for completion of this Section?   *(ELHEXAM)* ☐ 1 - Yes   ☐ 0 - No

           01-01 - Refused
           02-02 - Administrative error
           99-99 - Other

     a. If No, why not?*(ELHNOEX)*

     Other, specify:*(ELHNEXSP)*   Code:*(ELHNEXCO)*

Exclusion Criteria

To be eligible for PERCH, Q15 and Q16i below must be '**No**'.

15. Does this child appear very sick requiring urgent medical attention?   *(ELHURG)* ☐ 1 - Yes   ☐ 0 - No

     If Yes, child is ineligible; prompt evaluation and treatment should be sought.

16. Assess the following symptoms of severe and very severe pneumonia:

     a. Is child ill with cough or difficulty breathing?   *(ELHILL)* ☐ 1 - Yes   ☐ 0 - No

     b. Lower chest wall indrawing: *(ELHLCWI)* ☐ 1 - Yes   ☐ 0 - No

     c. Head nodding: *(ELHHEAD)* ☐ 1 - Yes   ☐ 0 - No

     d. Central cyanosis: *(ELHCENTR)* ☐ 1 - Yes   ☐ 0 - No

     e. Unable to feed *(must be observed by examiner)*:   *(ELHFEED)* ☐ 1 - Yes   ☐ 0 - No

     f. Vomiting everything *(must be observed by examiner)*:   *(ELHVOM)* ☐ 1 - Yes   ☐ 0 - No

     g. Lethargy or impaired consciousness:

           0-0 - A: Alert and awake
           1-1 - V: Responds to voice
           2-2 - P: Responds to pain
           3-3 - U: Unresponsive
           9-9 - Pharmacologically sedated

     (ELHLETH)

     NOTE: Wait for > 30 minutes after any convulsion before carrying out assessment of consciousness.

     h. Did child have convulsions?   *(ELHCONV)* ☐ 1 - Yes   ☐ 0 - No

       i. If Yes, what kind *(check all that apply)*?

       (ELHMCONV) ☐ Multiple *(>2 episodes)*   *(ELHPCONV)* ☐ Prolonged *(>15 minutes)*   *(ELHSCONV)* ☐ Single brief *(<15 minutes)*

     i. Does the child have <u>severe</u> or <u>very severe</u> pneumonia?   *(ELHPNEUM)* ☐ 1 - Yes   ☐ 0 - No

       Answer is pre-populated based on responses to Q16a-g and Q16h.i. indicating multiple or prolonged convulsions.
       *Severe or very severe pneumonia is defined as having **cough or difficulty breathing** (i.e. 16a is Yes) **AND ONE or MORE***
       responses in 16b-g checked Yes or multiple or prolonged convulsions in 16h.i.

Eligibility for PERCH

ELIG
1=Yes
0=No

17. Is this child eligible for PERCH?   *(ELHELIG)* ☐ 1 - Yes   ☐ 0 - No

     Answer is populated after the form is saved based on responses to inclusion and exclusion criteria.
     If answers to Q7-9 and Q19 are Yes, and Q10-12, Q15, and Q16i are No, and Q9b is not UNK, and Q19b is not blank, then child is eligible for PERCH.

     For Q17 to be Yes (child is eligible) after saving the form, ensure Section C is completed. If child is not eligible, answer N/A to Q19.

18. Section B Comments:

(ELHBCOMM)

Section B Staff Code: (ELHBSTAF)

Section C:
Consent and Enrollment for PERCH

19. **Has consent been obtained?** *(ELHCONNA)* ☐ 9 - N/A   *(ELHCONS)* ☐ 1 - Yes   ☐ 0 - No

Must be Yes to continue enrollment.
If No, mark the reason why not in Q15c below.

a. If Yes, child's date of birth: *(When date of birth is uncertain,*
    <u>always</u> *estimate the date and check 'Date uncertain' box)*

_DOB   Date of birth: *(ELHDOB)* ⬚   *(ddMMMyyyy)*   *(ELHDOBUN)* ☐ 8 - Date uncertain

b. If Yes, date and time of enrollment:

ENRLDATE   Date of enrollment: *(ELHENRDT)* ⬚   *(ddMMMyyyy)*   Time of enrollment: *(ELHENRTM)* ⬚   *(hh:mm)*

ENRL
1=Yes
0=No

c. If No, reason why not: *(ELHNOC)*

| 01-01 - Refused consent |
| 99-99 - Other |

Other, specify: *(ELHNOCSP)* ⬚   Code: *(ELHNOCCO)* ⬚

20. Section C Comments:

(ELHCCOMM)

Section C Staff Code: (ELHCSTAF)

Initial QC by: (ELHINQC)

Supervisor Staff Code: (ELHSUPER)

Supervisor Verification Date: (ELHVERDT)   *(ddMMMyyyy)*

CRF 03: Clinical History (CHX)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

Date of clinical history: *(CHXDT)* [　　　　] *(ddMMMyyyy)*

CURRENT HEALTH STATUS

_FEVER
1=Yes
0=No

_ILL_DURATION
(days)

Symptom	Symptom present?	If Yes, duration in days *(xx)* *(1=today)*
a. Fever:	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXFEV)*	*(CHXFEVD)*
b. Cough:	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXCOU)*	*(CHXCOUD)*
c. Difficulty breathing:	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXDIF)*	*(CHXDIFD)*
d. Wheeze:	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXWHZ)*	*(CHXWHZD)*
e. Unable to feed:	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXFEED)*	*(CHXFEEDD)*
f. Runny nose:	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXRUN)*	*(CHXRUND)*
g. Ear discharge:	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXEAR)*	*(CHXEARD)*
h. Vomiting:	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXVOM)*	*(CHXVOMD)*
i. Diarrhea ($\geq$3 abnormally loose or watery stools per day):	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXDIA)*	*(CHXDIAD)*
i. If Yes, was there blood in the stool?	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXDIABL)*	
j. Has the child had abnormal sleepiness or been difficult to wake?	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXABN)*	*(CHXABND)*

Symptom	Symptom code	Symptom present?	If Yes, duration in days *(xx)* *(1=today)*
k. Other: *(CHXOTASP)*	*(CHXOTACO)*	1-1 - Yes / 0-0 - No / 9-9 - NR *(CHXOTHA)*	*(CHXOTHAD)*

l. Other: *(CHXOTBSP)* [   ] *(CHXOTBCO)* [   ]   *(CHXOTHBD)* [   ]

(CHXOTHB)
```
1-1 - Yes
0-0 - No
9-9 - NR
```

NOTE: If a <u>control</u> develops difficulty breathing, is unable to drink/breastfeed, or becomes very lethargic, child should be taken to hospital/clinic to be seen.

MEDICATIONS (prior to hospital presentation)

2. Was the child given any medication for this illness in the past 48 hours?
   (If No or UNK, go to Q3.)

(CHXMED)
```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - N/A
```
(N/A for non-ill controls)

Medication	Given?

a. Anti-malarials?

(CHXANTI)
```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```

b. Antibiotics:

(CHXABX)
```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```

c. Fever medication/Analgesics/Antipyretics:

(CHXFEVMD)
```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```

d. Bronchodilators:

(CHXBRON)
```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```

e. Traditional medicine?

(CHXTRAD)
```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```

3. Did the child get antibiotics at the referral hospital before being sent to study hospital?

(CHXABREF)
```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - N/A
```

   a. If Yes, route of administration:

(CHXRTE)
```
01-01 - IV
02-02 - IM
03-03 - PO
08-08 - UNK
09-09 - NR
*Additional Options Listed Below
```

   Other, specify: *(CHXRTESP)* [   ]   Code: *(CHXRTECO)* [   ]

   b. Did the child get steroids at the referral hospital before being sent to the study hospital?

(CHXSTREF)
```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - N/A
```

PAST MEDICAL HISTORY

4. Has the child been admitted to a hospital since birth?
   (If No or UNK, go to Q5.)

(CHXADM)
```
1-1 - Yes
0-0 - No
8-8 - UNK
```
If Yes, # of admissions: *(CHXADMN)* [   ] *(xx)*

   a. If Yes, was the child ever admitted for Pneumonia?

(CHXADMP)
```
1-1 - Yes
0-0 - No
8-8 - UNK
```
If Yes, # of admissions: *(CHXADMPN)* [   ] *(xx)*

5. Has the child ever been diagnosed with wheezing or asthma?

1-1 - Yes
0-0 - No
8-8 - UNK
(CHXWHZDX)

   a. If Yes, are wheezing medications regularly taken at home?

1-1 - Yes
0-0 - No
8-8 - UNK
(CHXWHZRX)

6. Has the child had measles in the past month?

_HIV_EXPOSED
1=Exposed, infected
2=Exposed, uninfected
3=Unexposed, uninfected
4=Presumably unexposed, uninfected
5=Unknown exposure, uninfected
6=Exposed, unknown HIV status
7=Unexposed, unknown HIV status
8=Unknown exposure, unknown HIV status

1-1 - Yes
0-0 - No
8-8 - UNK
(CHXMEAS)

HIV

HIV Exposure

Maternal HIV - History
   During Pregnancy

7a. Was the mother known to be HIV positive *during* pregnancy with this child?

1-1 - Yes
0-0 - No
8-8 - UNK
(CHXDPHIV)

   7ai. Source of HIV status during pregnancy *(check all that apply)*: *(CHXDPSRP)* ☐ Self-report *(CHXDPDOC)* ☐ Documented test results

   7aii. If HIV positive, does the mother receive HAART?

1-1 - Yes
0-0 - No
8-8 - UNK
(CHXDPART)

     If Yes, for how long?*(CHXDPDMY)* ☐ Days ☐ Months *(CHXDPDUR)* ⌐_____ *(xx)* *(CHXDPUNK)* ☐ 8 - UNK
☐ Years

   7aiii. Does the child receive prophylactic nevirapine (NVP)?

1-1 - Yes
0-0 - No
8-8 - UNK
(CHXNVPCH)

     If Yes, indicate duration:*(CHXNVPWM)* ☐ 1 - Weeks *(CHXNVPDU)* ⌐_____ *(xx)* *(CHXNVPUN)* ☐ 8 - UNK
☐ 2 - Months

   7aiv. Does the child receive prophylactic Cotrimoxazole (Bactrim, Septrin)?

1-1 - Yes
0-0 - No
8-8 - UNK
(CHXPROPH)

     If Yes, indicate duration:*(CHXMTHWK)* ☐ 1 - Weeks *(CHXPROD)* ⌐_____ *(xx)* *(CHXPRODU)* ☐ 8 - UNK
☐ 2 - Months

   After Pregnancy
   (Only required if 7a is No or UNK)

7b. Has the mother received a positive HIV result since the birth of this child?

1-1 - Yes
0-0 - No
8-8 - UNK
(CHXAPHIV)

   7bi. Source of post-partum HIV status *(check all that apply)*: *(CHXAPSRP)* ☐ Self-report *(CHXAPDOC)* ☐ Documented test results within the last 6 months

   7bii. If HIV positive, does the mother receive HAART?

1-1 - Yes
0-0 - No
8-8 - UNK
(CHXAPART)

     If Yes, for how long?*(CHXAPDMY)* ☐ Days ☐ Months *(CHXAPDUR)* ⌐_____ *(xx)* *(CHXAPDUN)* ☐ 8 - UNK
☐ Years

Maternal HIV - Test Results
Only required if 7a and 7b are No or UNK

7c. Was the mother tested for HIV at the PERCH Clinic?

1-1 - Yes
0-0 - No
2-2 - Refused
9-9 - N/A
(CHXPCTST)

7ci. If Yes, Maternal RVD test results:

(CHXMRVD)
- 1-1 - Positive
- 2-2 - Negative
- 3-3 - Indeterminate

Child HIV

8. Is the child known to be HIV positive?
(If No or UNK, go to Q9)

If Yes, child is HIV positive, answer the following questions: (CHXCHIV)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

8a. Does the child receive HAART? (CHXART)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

8ai. If Yes, date HAART initiated: (CHXARTDT) _____ (CHXARTUN) ☐ 8 - UNK
(ddMMMyyyy)

8b. Has the child attended a HAART clinic in the past 3 months? (CHXARTCL)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

8c. Has the child had CD4 cell counts measured in the past 3 months? (CHXCD4CT)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

If Yes, record the most recent CD4 results:

8ci. Date of CD4 test: (CHXCD4DT) _____ (CHXCD4UN) ☐ 8 - UNK
(ddMMMyyyy)

8cii. CD4 number: (CHXCD4N) _____ *(xxxx)* (CHXCD4NU) ☐ 8 - UNK
/mm^3

8ciii. CD4 percent: (CHXCD4P) _____ *(xx.xx)* % (CHXCD4PU) ☐ 8 - UNK

TUBERCULOSIS

9. Is the child living in the same household with someone on TB treatment?
(If No or UNK, go to Q10.) (CHXTBC)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

a. If Yes, how long has the TB contact been on treatment? (CHXTBCD) _____ *(xx) (months)* (CHXTBDUN) ☐ 8 - UNK

b. If Yes, how was the TB diagnosed? (CHXTBCDX)
- 01-01 - CXR
- 02-02 - AFB positive sputum
- 03-03 - Clinical
- 04-04 - TB skin test (if close contact is another child)
- 08-08 - UNK
- *Additional Options Listed Below

Other, specify:(CHXCDXOT) _____ Code:(CHXCDXCO) _____

c. If Yes, what regimen is the contact being treated with? (CHXTBCRG) ☐ 1 - Oral medications   ☐ 2 - Oral and injectables   ☐ 8 - UNK

10. Has this child ever been diagnosed with TB? (CHXTB) ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

a. If Yes, has this child ever received TB treatment? (CHXTBTRT) ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

i. If Yes, current TB treatment status: (CHXTBCUR)
- 1-1 - On treatment
- 2-2 - Completed treatment
- 3-3 - Defaulted
- 8-8 - UNK

11. Has the child had noticeable weight loss or failed to gain weight? (CHXTBWGT) ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

OTHER UNDERLYING CONDITIONS

12. Did your child drink paraffin in the past 48 hours? (CHXPARA)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

a. If Yes, how many days ago? *(1=today)* (CHXPARAD) _____ *(xx)* (CHXPARAU) ☐ 8 - UNK

b. If Yes, did someone see the child drink the paraffin?

1-1 - Yes
0-0 - No
8-8 - UNK

(CHXPARDR)

13. Thalassemia?

1-1 - Yes
0-0 - No
8-8 - UNK

(CHXTHAL)

Initial QC by: *(CHXINQC)*

Additional Selection Options for CHX

Antibiotic route of admin
99-99 - Other

TB contact diagnosis
99-99 - Other

CRF 03: Immunization History (IMM)

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

IMMUNIZATION HISTORY

14. Does the child have their immunization records with them? *(IMMREC)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

15. Has the child had Vitamin A supplements in the last 6 months? *(IMMVITA)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

16. Has the child had any of the following vaccinations? *(IMMVAX)* ☐ 8 - UNK *(for all vaccinations)*

Vaccine	Dose	Yes/No/UNK	Date Received (ddMMMyyyy)	Date Estimated
a. BCG	1.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM1A)*	*(IMM1ADT)*	*(IMM1AEST)* ☐
b. DTP-HiB(Combact-Hib)	1.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM1B)*	*(IMM1BDT)*	*(IMM1BEST)* ☐
	2.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM2B)*	*(IMM2BDT)*	*(IMM2BEST)* ☐
	3.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM3B)*	*(IMM3BDT)*	*(IMM3BEST)* ☐
	4.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM4B)*	*(IMM4BDT)*	*(IMM4BEST)* ☐
c. DTP only	1.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM1C)*	*(IMM1CDT)*	*(IMM1CEST)* ☐
	2.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM2C)*	*(IMM2CDT)*	*(IMM2CEST)* ☐
	3.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM3C)*	*(IMM3CDT)*	*(IMM3CEST)* ☐
	4.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM4C)*	*(IMM4CDT)*	*(IMM4CEST)* ☐
d. DTaP only	1.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM1D)*	*(IMM1DDT)*	*(IMM1DEST)* ☐
	2.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM2D)*	*(IMM2DDT)*	*(IMM2DEST)* ☐
	3.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM3D)*	*(IMM3DDT)*	*(IMM3DEST)* ☐

_DTP_VAX_STATUS
(incorporates all DTP formulations)
2=Fully vaccinated
1=Partially vaccinated 0=Not vaccinated

_HIB_VAX_STATUS
(incorporates all Hib formulations)
2=Fully vaccinated
1=Partially vaccinated
0=Not vaccinated

Vaccine	Dose	Yes/No/UNK		
	4. (IMM4D)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM4DDT)	(IMM4DEST) ☐
	5. (IMM5D)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM5DDT)	(IMM5DEST) ☐
e. DTP-HepB	1. (IMM1E)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM1EDT)	(IMM1EEST) ☐
	2. (IMM2E)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM2EDT)	(IMM2EEST) ☐
	3. (IMM3E)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM3EDT)	(IMM3EEST) ☐
f. DTP-HiB-HepB (Penta)	1. (IMM1F)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM1FDT)	(IMM1FEST) ☐
	2. (IMM2F)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM2FDT)	(IMM2FEST) ☐
	3. (IMM3F)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM3FDT)	(IMM3FEST) ☐
g. DTaP-HiB-IPV (Pentaxim)	1. (IMM1G)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM1GDT)	(IMM1GEST) ☐
	2. (IMM2G)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM2GDT)	(IMM2GEST) ☐
	3. (IMM3G)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM3GDT)	(IMM3GEST) ☐
	4. (IMM4G)	1-1 - Yes 0-0 - No 8-8 - UNK	(IMM4GDT)	(IMM4GEST) ☐
Vaccine	**Dose**	**Yes/No/UNK**		
h. HepB	1. (IMM1H)	1-1 - Yes 0-0 - No 8-8 - UNK		
	2. (IMM2H)	1-1 - Yes 0-0 - No 8-8 - UNK		
	3. (IMM3H)	1-1 - Yes 0-0 - No 8-8 - UNK		
i. HIB	1. (IMM1I)	1-1 - Yes 0-0 - No 8-8 - UNK		

	2.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM2I)*				
	3.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM3I)*				
	4.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM4I)*				
j. OPV	1.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM1J)*	*(IMM1JDT)*		*(IMM1JEST)* ☐	
	2.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM2J)*	*(IMM2JDT)*		*(IMM2JEST)* ☐	
	3.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM3J)*	*(IMM3JDT)*		*(IMM3JEST)* ☐	
	4.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM4J)*	*(IMM4JDT)*		*(IMM4JEST)* ☐	
	5.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM5J)*	*(IMM5JDT)*		*(IMM5JEST)* ☐	
k. PCV	1.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM1K)*	*(IMM1KDT)*		*(IMM1KEST)* ☐	
	2.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM2K)*	*(IMM2KDT)*		*(IMM2KEST)* ☐	
	3.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM3K)*	*(IMM3KDT)*		*(IMM3KEST)* ☐	
	4.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM4K)*	*(IMM4KDT)*		*(IMM4KEST)* ☐	
l. Rotavirus	1.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM1L)*				
	2.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM2L)*				
	3.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM3L)*				
m. Japanese Encephalitis	1.	1-1 - Yes 0-0 - No 8-8 - UNK *(IMM1M)*				

_PCV_VAX_STATUS
2=Fully vaccinated
1=Partially vaccinated
0=Not vaccinated

Vaccine	Dose	Yes/No/UNK	Date Received (ddMMMyyyy)	Date Estimated
	2.	1-1 - Yes 0-0 - No 8-8 - UNK (IMM2M)		
	3.	1-1 - Yes 0-0 - No 8-8 - UNK (IMM3M)		
n. Measles	1.	1-1 - Yes 0-0 - No 8-8 - UNK (IMM1N)	(IMM1NDT)	(IMM1NEST) ☐
	2.	1-1 - Yes 0-0 - No 8-8 - UNK (IMM2N)	(IMM2NDT)	(IMM2NEST) ☐
	3.	1-1 - Yes 0-0 - No 8-8 - UNK (IMM3N)	(IMM3NDT)	(IMM3NEST) ☐
o. MMR	1.	1-1 - Yes 0-0 - No 8-8 - UNK (IMM1O)		
p. Influenza (for the current season)	1.	1-1 - Yes 0-0 - No 8-8 - UNK (IMM1P)	(IMM1PDT)	(IMM1PEST) ☐
	2.	1-1 - Yes 0-0 - No 8-8 - UNK (IMM2P)	(IMM2PDT)	(IMM2PEST) ☐
q. MR	1.	1-1 - Yes 0-0 - No 8-8 - UNK (IMM1Q)	(IMM1QDT)	(IMM1QEST) ☐

17. If the child is <9 months of age, has the <u>mother</u> had any of the following vaccinations during her pregnancy with this child?
    UNK if Unknown for all vaccinations
    N/A if child > 9 months
    If Yes, list the date of the last dose if more than one.

(IMMMVAX) ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK ☐ 9 - N/A

Vaccine	Yes/No/UNK	Date of last dose (ddMMMyyyy)	Date Estimated
a. Influenza (for the current flu season)	1-1 - Yes 0-0 - No 8-8 - UNK (IMMFL)	(IMMFLDT)	(IMMFLEST) ☐
b. DTaP	1-1 - Yes 0-0 - No 8-8 - UNK (IMMDT)	(IMMDTDT)	(IMMDTEST) ☐
c. PCV	1-1 - Yes 0-0 - No 8-8 - UNK (IMMPC)	(IMMPCDT)	(IMMPCEST) ☐
d. PPS-23	1-1 - Yes 0-0 - No 8-8 - UNK (IMMPP)	(IMMPPDT)	(IMMPPEST) ☐

Comments:

(IMMCOMM)

Interviewer's Staff Code: (IMMSTAFF)

Initial QC by: (IMMINQC)

Supervisor's Staff Code: (IMMSUPER)

Supervisor Verification Date: (IMMVERIF) (ddMMMyyyy)

CRF 04: Case Clinical Assessment (CSA)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

Date of assessment: (CSAASDT) _____ *(ddMMMyyyy)*

1. Time of assessment: (CSAASSTM) _____ *(hh:mm)*

2. Where is child being assessed?

```
01-01 - Hospital
02-02 - Clinic
99-99 - Other
```
(CSALOCAT)

Other, specify:(CSALOCSP) _____   Code:(CSAASCO) _____

3. Was child referred from another health clinic/hospital?

```
1-1 - Yes
0-0 - No
8-8 - UNK
```
(CSAREFER)

  a. Clinic/hospital name:(CSAHOS) _____   Code:(CSAHOSCO) _____

_LENANTHRO (Height for age)
1=outlier low (z-score <-6 SDs)
2=severe (>=-6 SDs and <-3 SDs)
3=moderate (>=-3 SDs and <-2 SDs)
4=normal (>=-2 SDs and <=+6 SDs)
5=outlier high (>+6 SDs)

_WEIANTHRO (Weight for age)
1=outlier low (z-score <-6 SDs)
2=severe (>=-6 SDs and <-3 SDs)
3=moderate (>=-3 SDs and <-2 SDs)
4=normal (>=-2 SDs and <=+5 SDs)
5=outlier high (>+5 SDs)

_WFHANTHRO (Weight for height)
1=outlier low (z-score <-5 SDs)
2=severe (>=-5 SDs and <-3 SDs)
3=moderate (>=-3 SDs and <-2 SDs)
4=normal (>=-2 SDs and <=+2 SDs)
5=overweight(> +2 SDs and <=+5 SDs)
6=outlier high (>+5 SDs)

_FEVER
1=Yes
0=No

NUTRITION/HYDRATION STATUS/VITAL SIGNS

4. Temperature (axillary): (CSATEMP) _____ *(xx.x)* °C   (CSATEMPU) ☐ 8 - UNK

5. Height/length: (CSAHELE) _____ *(xxx.x)* cm   (CSAHELEU) ☐ 8 - UNK

6. Was the child weighed alone? (CSACWEIG) ☐ 1 - Yes   ☐ 0 - No

  If No, child's weight will be calculated from questions 7 and 8.
  The calculated field will be read only.

6a. Weight of child: (CSAWCHIL) _____ *(xx.x)* kg   (CSAWCU) ☐ 8 - UNK   (CSACWCAL) _____ *(xx.x)* kg

7. Weight of mother and child: (CSAWMCHI) _____ *(xxx.x)* kg   (CSAWMCHU) ☐ 8 - UNK

8. Weight of mother: (CSAWMOTH) _____ *(xxx.x)* kg   (CSAWMOTU) ☐ 8 - UNK

9. Mid-upper arm circumference (MUAC): (CSAARMCI) _____ *(xxx)* mm   (CSAARMCU) ☐ 8 - UNK   ☐ 9 - N/A

_ACANTHRO (Arm circumference for age)
1=outlier low (z-score <-5 SDs)
2=severe (>=-5 SDs and <-3 SDs)
3=moderate (>=-3 SDs and <-2 SDs)
4=normal (>=-2 SDs and <=+5 SDs)
5=outlier high (>+5 SDs)

_TACHYCARDIA
1=Yes
0=No

10. Heart rate: (CSAHR) _____ *(xxx)* beats per minute   (CSAHRU) ☐ 8 - UNK

14. Pedal edema:

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSAPEDED)

15. Skin turgor:

```
1-1 - Normal
2-2 - Reduced
8-8 - UNK
9-9 - NR
```
(CSASKIN)

16. Capillary refill time: (CSACRT) _____ *(x)*   (CSACRTUN) ☐ 8 - UNK   ☐ 9 - NR

17. Cool peripheries (cool hands and feet):

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSAPERIF)

18. Weak peripheral pulses (Radial/Dorsalis pedis pulse):

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSAWEAKP)

19. Gallop rhythm:

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSAGALLO)

20. Tender liver mass (With/without hepatomegaly):

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSALIVER)

RESPIRATORY SIGNS (in addition to those recorded on CRF 01)

_COUGH
1=Yes
0=No

21. Observed cough:

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSAOBSC)

    a. If Yes, is it a barking cough?

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSABARKC)

22. Stridor:

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSASTRID)

    a. If Yes, is the stridor still present when the child is quiet (not crying)?

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSASTRQ)

23. Grunting:

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSAGRUNT)

24. Nasal flaring:

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSANFLAR)

25. Deep breathing:

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSADPBRE)

26. Is there an audible wheeze?

```
1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
```
(CSAAUDWH)

27. Does the child have any of the following findings on chest auscultation?

Findings:	Left side	Right side
_WHEEZE 1=Yes 0=No a. Wheeze	1-1 - Yes 0-0 - No 8-8 - UNK 9-9 - NR *(CSAWHLT)*	1-1 - Yes 0-0 - No 8-8 - UNK 9-9 - NR *(CSAWHRT)*
_CRACK 1=Yes 0=No b. Crackles/Crepitations:	1-1 - Yes 0-0 - No 8-8 - UNK 9-9 - NR *(CSACRLT)*	1-1 - Yes 0-0 - No 8-8 - UNK 9-9 - NR *(CSACRRT)*
c. Decreased breath sounds:	1-1 - Yes 0-0 - No 8-8 - UNK 9-9 - NR *(CSADBRLT)*	1-1 - Yes 0-0 - No 8-8 - UNK 9-9 - NR *(CSADBRRT)*

d. Bronchial breath sounds:

(CSABROLT)	(CSABRORT)
1-1 - Yes 0-0 - No 8-8 - UNK 9-9 - NR	1-1 - Yes 0-0 - No 8-8 - UNK 9-9 - NR

e. Auscultation findings were done by: *(CSAAUSBY)*

01-01 - Hospital staff
02-02 - PERCH staff
08-08 - UNK
09-09 - NR
99-99 - Other

Other, specify: *(CSAAUSSP)* _____ Code: *(CSAAUSCO)* _____

28. Clubbing: *(CSACLUBB)*

1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR

29. Was a digital stethoscope recording taken? *(CSADIGST)*

1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR

a. If Yes, enter the sound file record number: *(CSASOUND)* _____ (DDMMYY-xxxxx)

b. Time of recording: *(CSARECTM)* _____ *(hh:mm)*

c. Digital auscultation comments: *(CSAUSCOM)*

MISCELLANEOUS SIGNS

30. Jaundice: *(CSAJAUND)*

1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR

31. Bulging fontanelle (if < 18 months): *(CSABFONT)*

01-01 - Yes
00-00 - No
08-08 - UNK
09-09 - NR
10-10 - N/A

32. Rash: *(CSARASH)*

1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR

a. If Yes, type of rash? *(check one)* *(CSARASHT)*

01-01 - Petechial (size of individual lesions < 3 mm)
02-02 - Purpural (size of individual lesions > = 3 mm)
03-03 - Measles
04-04 - Chicken pox
08-08 - UNK
*Additional Options Listed Below

Other, specify: *(CSARASSP)* _____ Code: *(CSARASCO)* _____

33a. Clinical *pneumonia* diagnosis made by hospital staff on admission *(check one)*: *(CSAPNDX)*

1-1 - Non-severe pneumonia/Pneumonia not otherwise specified
2-2 - Severe pneumonia
3-3 - Very severe pneumonia
4-4 - No pneumonia diagnosis
9-9 - Not available/Not done by hospital

_ADMDX   33b. **Other** clinical diagnosis made by hospital staff on admission *(check all that apply)*:

(CSAPULTB) ☐ Pulmonary TB   *(CSAPARAF)* ☐ Paraffin ingestion

(CSAEXTB) ☐ Extrapulmonary TB   *(CSASEVAN)* ☐ Severe anaemia

(CSABRRSV) ☐ Bronchiolitis/RSV   *(CSASCELL)* ☐ Sickle cell disease

(CSAASTHM) ☐ Asthma/Reactive   *(CSAMALN)* ☐ Severe malnutrition
Airway Disease (RAD)

(CSAMEASL) ☐ Measles   *(CSABRONC)* ☐ Bronchitis

(CSAMALAR) ☐ Malaria   *(CSADDELA)* ☐ Developmental
                                      delay/Cerebral palsy

(CSAMENIN) ☐ Meningitis   *(CSAOT1DX)* ☐ Other   *(CSADX1SP)* Other, specify: _____   Code: *(CSAOT1CO)* _____

(CSAGAST) ☐ Gastroenteritis   *(CSAOT2DX)* ☐ Other   *(CSADX2SP)* Other, specify: _____   Code: *(CSAOT2CO)* _____

(CSAHIV) ☐ HIV   *(CSAOT3DX)* ☐ Other   *(CSADX3SP)* Other, specify: _____   Code: *(CSAOT3CO)* _____

(CSAPRSEP) ☐ Presumptive   *(CSANA)* ☐ Not available/Not
septicaemia   done by hospital

                                     (CSAPNEON) ☐ Pneumonia
                                      diagnosis only

Comments: *(CSACOMM)*

Form Completed By Staff Code: *(CSACBSCO)* _____

Initial QC by: *(CSAINQC)* _____

Supervisor Staff Code: *(CSASUPCO)* _____

Supervisor Verification Date: *(CSAVERDT)* _____ *(ddMMMyyyy)*

Additional Selection Options for CSA

Rash type
09-09 - NR
99-99 - Other

CRF 04A: Control Clinical Assessment (COA)

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

Date of assessment: *(COAASDT)* ☐ *(ddMMMyyyy)*

NUTRITION/HYDRATION STATUS/VITAL SIGNS

1. Were any signs or symptoms of illness in the last 48 hours reported?

1-1 - Yes
0-0 - No
8-8 - UNK
(COASIGNS)

_FEVER
1=Yes
0=No

   a. If Yes, temperature: *(COATEMP)* ☐ *(xx.x)* °C   Source: *(COATEMPT)*   *(COATEMPU)* ☐ 8 - UNK

1-1 - Axilary
2-2 - Rectal

_LENANTHRO (Height for age)
1=outlier low (z-score <-6 SDs)
2=severe (>=-6 SDs and <-3 SDs)
3=moderate (>=-3 SDs and <-2 SDs)
4=normal (>=-2 SDs and <=+6 SDs)
5=outlier high (>+6 SDs)

2. Height/length: *(COAHELE)* ☐ *(xxx.x)* *(COAHELEU)* ☐ 8 - UNK cm

3. Was the child weighed alone? *(COACWEIG)* ☐ 1 - Yes   ☐ 0 - No

   If No, child's weight will be calculated from questions 4 and 5.
   The calculated field will be read only.

3a. Weight of child: *(COAWCHIL)* ☐ *(xx.x)* *(COAWCU)* ☐ 8 - UNK   *(COACWCAL)* ☐ *(xx.x)* kg kg

4. Weight of mother and child: *(COAWMCHI)* ☐ *(xxx.x)* kg *(COAWMCHU)* ☐ 8 - UNK

5. Weight of mother: *(COAWMOTH)* ☐ *(xxx.x)* kg *(COAWMOTU)* ☐ 8 - UNK

_WEIANTHRO (Weight for age)
1=outlier low (z-score <-6 SDs)
2=severe (>=-6 SDs and <-3 SDs)
3=moderate (>=-3 SDs and <-2 SDs)
4=normal (>=-2 SDs and <=+5 SDs)
5=outlier high (>+5 SDs)

6. Mid-upper arm circumference (MUAC): *(COAARMCI)* ☐ *(xxx)* mm *(COAARMCU)* ☐ 8 - UNK ☐ 9 - N/A

7. Respiratory rate *(# of breaths counted in 60 seconds)*: *(COARR)* ☐ *(xxx) per min* *(COARRNA)* ☐ 8 - UNK

_WFHANTHRO (Weight for height)
1=outlier low (z-score <-5 SDs)
2=severe (>=-5 SDs and <-3 SDs)
3=moderate (>=-3 SDs and <-2 SDs)
4=normal (>=-2 SDs and <=+2 SDs)
5=overweight(> +2 SDs and <=+5 SDs)
6=outlier high (>+5 SDs)

RESPIRATORY SIGNS

_COUGH
1=Yes
0=No

8. Observed cough?

1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
(COAOBSC)

_ACANTHRO (Arm circumference for age)
1=outlier low (z-score <-5 SDs)
2=severe (>=-5 SDs and <-3 SDs)
3=moderate (>=-3 SDs and <-2 SDs)
4=normal (>=-2 SDs and <=+5 SDs)
5=outlier high (>+5 SDs)

9. Was a digital stethoscope recording taken?

1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR
(COADIGST)

   a. If Yes, enter the sound file record number: *(COASOUND)* ☐ *(DDMMYY-xxxxx)*

   b. Time of recording: *(COARECTM)* ☐ *(hh:mm)*

   c. Digital auscultation comments:

(COAUSCOM)

10. Clubbing:

1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR

(COACLUBB)

MISCELLANEOUS SIGNS

11. Rash:

1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - NR

(COARASH)

a. If Yes, type of rash? *(check one)*

01-01 - Petechial (size of individual lesions < 3 mm)
02-02 - Purpural (size of individual lesions > = 3 mm)
03-03 - Measles
04-04 - Chicken pox
08-08 - UNK
*Additional Options Listed Below

(COARASHT)

Other, specify: *(COARASSP)*   Code: *(COARASCO)*

Comments: *(COACOMM)*

Form Completed By Staff Code: *(COACBSCO)*

Initial QC by: *(COAINQC)*

Supervisor Staff Code: *(COASUPCO)*

Supervisor Verification Date: *(COAVERDT)*   *(ddMMMyyyy)*

Additional Selection Options for COA

Rash type
09-09 - NR
99-99 - Other

CRF 05: Demographics and Household (RFA)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

Visit date: *(RFAVISDT)* ☐ *(ddMMMyyyy)*

1. Are you a primary caregiver for this child? *(RFAPRMCG)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

2. What is your relationship to him or her *(choose one)*?

```
01-01 - Mother
02-02 - Father
03-03 - Grandmother
04-04 - Grandfather
05-05 - Brother
*Additional Options Listed Below
```
(RFARELAT)

If Other, specify: *(RFAOTSP)* ☐ *(RFAOTSCO)* Code: ☐

DEMOGRAPHICS

3. Mother's ethnic group *(choose one)*:

```
01-01 - Giriama
02-02 - Chonyi
03-03 - Kauma
04-04 - Kambe
05-05 - Luo
*Additional Options Listed Below
```
(RFAMETH)

If Other, specify: *(RFAMEOSP)* ☐ *(RFAMEOCO)* Code: ☐

4. Father's ethnic group *(choose one)*:

```
01-01 - Giriama
02-02 - Chonyi
03-03 - Kauma
04-04 - Kambe
05-05 - Luo
*Additional Options Listed Below
```
(RFAFETH)

If Other, specify: *(RFAFEOSP)* ☐ *(RFAFEOCO)* Code: ☐

5. Has the child been previously enrolled as a PERCH case or control? *(check all that apply)*

(RFAPENRN) ☐ 0 - No ☐ 8 - UNK *(RFAPENRC)* ☐ Case *(RFAPENCN)* ☐ Control

(If No or UNK, skip to Q6)

If previously enrolled:

    a. 1st previous PERCH participant ID: *(RFAPE1ID)* ☐

    b. 2nd previous PERCH participant ID: *(RFAPE2ID)* ☐

    c. 3rd previous PERCH participant ID: *(RFAPE3ID)* ☐

6. Was the child enrolled in any <u>intervention</u> studies in the past year? *(RFAENINT)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

(i.e. has the child received medicines, vaccines, vitamins, etc. as part of a study?)

(If No or UNK, skip to Q7)

If Yes, please provide the name of the other studies and the associated ID numbers:

Study name: 8 - UNK   ID number in the other study: 8 - UNK

(or description of intervention if name UNK)

(RFAST1NM) a1.	*(RFAS1NMU)* ☐	*(RFAST1ID)* b1.	*(RFAS1IDU)* ☐
(RFAST2NM) a2.	*(RFAS2NMU)* ☐	*(RFAST2ID)* b2.	*(RFAS2IDU)* ☐
(RFAST3NM) a3.	*(RFAS3NMU)* ☐	*(RFAST3ID)* b3.	*(RFAS3IDU)* ☐
(RFAST4NM) a4.	*(RFAS4NMU)* ☐	*(RFAST4ID)* b4.	*(RFAS4IDU)* ☐

HOUSEHOLD INFORMATION

7. Is the biological mother of child still alive?

(RFAMLIVE)
```
1-1 - Yes
0-0 - No
8-8 - UNK
```

If Yes, record the mother's age: (RFAMAGE) _____ (xx) years   (RFAMAGEU) ☐ 8 - UNK

If No, estimate the mother's age at the time of the child's birth: (RFAMAGEB) _____ (xx) years   (RFAMAGBU) ☐ 8 - UNK

(Estimate using major events if needed.)

8. How many years of formal education has the mother /primary caregiver completed? (RFAMED) _____ (xx) years   (RFAMEDUN) ☐ 8 - UNK

9. What type of school did the mother / primary caregiver attend?

(check all that apply)   _MOTHEDUC

(RFAMEDU) ☐ Unknown   0=No formal education
1=Religious education
(RFAMSCHN) ☐ No formal education   2=Formal education
3=College and beyond
(RFAMEDF) ☐ Formal education

(RFAMEDR) ☐ Religious education

(RFAMEDC) ☐ College (and beyond)

10. Does the mother/primary caregiver belong to any social group? (RFAMSOCG) ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

11. Is the father of the child still alive? (RFAFLIVE) ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

(If No, skip to Q15)

12. How many years of formal education has the father completed? (RFAFED) _____ (xx) years   (RFAFEDUN) ☐ 8 - UNK

13. What type of school did the father attend?

(check all that apply)

(RFAFEDU) ☐ Unknown

(RFAFSCHN) ☐ No formal education

(RFAFEDF) ☐ Formal education

(RFAFEDR) ☐ Religious education

(RFAFEDC) ☐ College (and beyond)

14. How many current wives does the father have? (RFAFWIFE) _____ (xx)   (RFAFWFUN) ☐ 8 - UNK

a. If more than one wife, what is the order number of the child's mother? (RFAFWFOR) _____ (xx)   (RFAFWFOU) ☐ 8 - UNK

(1 = first wife, 2 = second wife, etc.)

For Qs 15-17, respond for the most common living situations of the child during the past 12 months.

15. How many (total) people usually live in the same household as the child? (RFALVHSH) _____ (xxx)   (RFALVHSU) ☐ 8 - UNK

(Defined as sharing a cooking pot/area)

16. How many children aged 0-10 years (including study child) live in the same household? (RFALHCHD) _____ (xx)   (RFALVHCU) ☐ 8 - UNK

17. How many people usually slept in the same room as this child in the last month (including the study child)? (RFASLPMT) _____ (xx)   (RFASLPMU) ☐ 8 - UNK

18. For people usually sleeping in the same room as this child, record the following details: (RFASLUNK) ☐ 8 - UNK

Person #	a. Relationship to child	b. Age (xxx)	c. Sleep in same bed?	d. Had a cough in the last month?
1	(RFASLP1R) 1-1 - Mother / 2-2 - Father / 3-3 - Sibling / 4-4 - Other child / 5-5 - Other adult	(RFASL1AG) _____	(RFASL1SB) 1-1 - Yes / 0-0 - No / 8-8 - UNK	(RFA1CGH) 1-1 - Yes / 0-0 - No / 8-8 - UNK
2	(RFASLP2R) 1-1 - Mother / 2-2 - Father / 3-3 - Sibling / 4-4 - Other child / 5-5 - Other adult	(RFASL2AG) _____	(RFASL2SB) 1-1 - Yes / 0-0 - No / 8-8 - UNK	(RFA2CGH) 1-1 - Yes / 0-0 - No / 8-8 - UNK

3

(RFASLP3R)
- 1-1 - Mother
- 2-2 - Father
- 3-3 - Sibling
- 4-4 - Other child
- 5-5 - Other adult

(RFASL3AG) [ ]

(RFASL3SB)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

(RFA3CGH)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

4

(RFASLP4R)
- 1-1 - Mother
- 2-2 - Father
- 3-3 - Sibling
- 4-4 - Other child
- 5-5 - Other adult

(RFASL4AG) [ ]

(RFASL4SB)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

(RFA4CGH)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

5

(RFASLP5R)
- 1-1 - Mother
- 2-2 - Father
- 3-3 - Sibling
- 4-4 - Other child
- 5-5 - Other adult

(RFASL5AG) [ ]

(RFASL5SB)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

(RFA5CGH)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

6

(RFASLP6R)
- 1-1 - Mother
- 2-2 - Father
- 3-3 - Sibling
- 4-4 - Other child
- 5-5 - Other adult

(RFASL6AG) [ ]

(RFASL6SB)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

(RFA6CGH)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

7

(RFASLP7R)
- 1-1 - Mother
- 2-2 - Father
- 3-3 - Sibling
- 4-4 - Other child
- 5-5 - Other adult

(RFASL7AG) [ ]

(RFASL7SB)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

(RFA7CGH)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

8

(RFASLP8R)
- 1-1 - Mother
- 2-2 - Father
- 3-3 - Sibling
- 4-4 - Other child
- 5-5 - Other adult

(RFASL8AG) [ ]

(RFASL8SB)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

(RFA8CGH)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

9

(RFASLP9R)
- 1-1 - Mother
- 2-2 - Father
- 3-3 - Sibling
- 4-4 - Other child
- 5-5 - Other adult

(RFASL9AG) [ ]

(RFASL9SB)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

(RFA9CGH)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

10

(RFASL10R)
- 1-1 - Mother
- 2-2 - Father
- 3-3 - Sibling
- 4-4 - Other child
- 5-5 - Other adult

(RFAS10AG) [ ]

(RFAS10SB)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

(RFA10CGH)
- 1-1 - Yes
- 0-0 - No
- 8-8 - UNK

19. How many live deliveries has the mother had?   (RFALIVDE) [ ] (xx)   (RFALVDUN) ☐ 8 - UNK

(Including the study child; twins counts as one.)

(If 1 or more, answer Q19a; otherwise skip to Q20)

    a. Of the live deliveries reported in Q19, how many of her children have died?   (RFALVDDD) [ ] (xx)   (RFALVDDU) ☐ 8 - UNK

20. Does this child attend out of home care (nursery/preschool/family care/creche)?   (RFADAYCR) ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

(Must include at least 2 other children for at least 4 hours per day, 3 days a week)

Initial QC by: (RFAINQC) [   ]

Additional Selection Options for RFA

Relationship to child
06-06 - Sister
07-07 - Aunt
09-09 - Uncle
10-10 - Other Relative
11-11 - Maid / Babysitter
08-08 - UNK
99-99 - Other

Mother ethnic group
06-06 - Digo
07-07 - Duruma
08-08 - Jibana
09-09 - Rabai
10-10 - Ribe
11-11 - Swahili
12-12 - Ajuran
13-13 - Arab
14-14 - Asian
15-15 - Bajun
16-16 - Basuba
17-17 - Beni/Sange
18-18 - Boran
19-19 - Dogodia
20-20 - El molo
21-21 - Embu
22-22 - Gabbra
23-23 - Gosha
24-24 - Gurreh
25-25 - Hawaiyah
26-26 - Kalenjin
27-27 - Kamba
28-28 - Kikuyu
29-29 - Kisii
30-30 - Kuria
31-31 - Luhya
32-32 - Masai
33-33 - Mbere
34-34 - Meru
35-35 - Mnubi
36-36 - Ndorobo
37-37 - Nemps
38-38 - Ogaden
39-39 - Orma/Saraja
40-40 - Pokomo
41-41 - Rendille
42-42 - Sakuye
43-43 - Samburu
44-44 - Shiraz
45-45 - Somali
46-46 - Taita
47-47 - Taveta
48-48 - Teso
49-49 - Tharak
50-50 - Turkana
51-51 - Xhosa
52-52 - Zulu
53-53 - Coloured
54-54 - Sotho
55-55 - Bemba
56-56 - Lozi
57-57 - Chewa
58-58 - Tonga
59-59 - Lunda
60-60 - Luvale
61-61 - Kaonde
62-62 - Mandinka
63-63 - Wollof
64-64 - Fula
65-65 - Serahule
66-66 - Jola
67-67 - Aku
68-68 - Manjago
69-69 - Serere
70-70 - Ndebele
71-71 - Vietnamese
72-72 - Bambara
73-73 - Malinke
74-74 - Sarakole
75-75 - Peuhl
76-76 - Bobo
77-77 - Senoufo
78-78 - Minianka
79-79 - Bozo
80-80 - Somono
81-81 - Dogon
82-82 - Sonrhai
83-83 - Maure
84-84 - Tamachek
85-85 - Samoko
86-86 - Dafing

87-87 - Thai
88-88 - Lao
89-89 - Cambodian
90-90 - Bangladeshi
91-91 - Soli
98-98 - UNK
99-99 - Other

CRF 05: Environment and Healthcare (RFB)

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

ENVIRONMENT & SANITATION

21. What is the **main** source of drinking water for child's household? *(check one)*

```
01-01 - Piped into house (indoor tap water)
02-02 - Piped into yard/compound/property
03-03 - Bought (tank, bottles, etc.)
04-04 - Outdoor / Public tap
05-05 - Borehole
*Additional Options Listed Below
```
(RFBWATER)

If Other, specify:　*(RFBWTRSP)* _____　*(RFBWTRCO)* Code: ___

22. Where is the nearest drinking water source? *(check one)*

```
01-01 - Inside house
02-02 - Inside compound <= 5 m of house
03-03 - Inside compound > 5 m of house
04-04 - Outside compound
08-08 - UNK
*Additional Options Listed Below
```
(RFBWTSRC)

If Outside compound is checked, time to reach in minutes:　*(RFBWMIN)* ____ *(xxx)*　*(RFBWTMU)* ☐ 8 - UNK

If Other, specify:　*(RFBWTOSP)* _____　*(RFBNWTCO)* Code: ___

23. What is the **main** source of water for washing hands in your household? *(check one)*

```
01-01 - Piped into house (indoor tap water)
02-02 - Piped into yard / property
03-03 - Outdoor / Public tap
04-04 - Public well
05-05 - Rainwater
*Additional Options Listed Below
```
(RFBMHWTR)

(If piped into house, skip Q24 and go to Q25)

If piped into house, how many working taps/sinks with running water are located inside your house?　*(RFBMSINK)* ____ *(x)*　*(RFBMSNKU)* ☐ 8 - UNK

If Other, specify:　*(RFBMWOSP)* _____　*(RFBMWOCO)* Code: ___

24. How long does it take to reach the water source used for washing hands?　*(RFBHWMWT)* ____ *(xxx) mins*　*(RFBHWMUN)* ☐ 8 - UNK

25. In the last 24 hours, have you used soap and water to wash your hands?　*(RFBSOAP)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

26. Does your household have a shared basin with standing water for washing hands?　*(RFBSHRBA)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

If Yes, how many times per day is the water changed?　*(RFBSHRCH)* ____ *(xx)*　*(RFBSRCHU)* ☐ 8 - UNK

(if <1 time per day, put 0)

27. How often does your household run out of water for washing hands? *(check one)*

```
1-1 - More than 10 days every month
2-2 - 5-10 days every month
3-3 - 1-4 days per month
4-4 - Occasionally but not every month
5-5 - Never
*Additional Options Listed Below
```
(RFBNOWTR)

28. How concerned are you about the cost of water used for washing hands? *(check one)*

```
1-1 - Not at all concerned
2-2 - Somewhat concerned
3-3 - Very concerned
8-8 - UNK
```
(RFBCSTWT)

29. What are the **floors** in the child's house primarily made of? *(check one)*　*(RFBFLOOR)*

```
01-01 - Natural floor (sand/earth/dung)
02-02 - Rudimentary floor (wood/palm/bamboo)
03-03 - Finished floor (wood/tiles/cement/carpet)
08-08 - UNK
99-99 - Other
```

If Other, specify: *(RFBFLRSP)* [   ] *(RFBFLRCO)* Code: [   ]

30. What are the <u>walls</u> in the child's house primarily made of? *(check one)*

> 01-01 - Bricks
> 02-02 - Tin / iron sheeting
> 03-03 - Mud / mud stick / bamboo / traditional
> 04-04 - Cement / concrete / coral
> 05-05 - Wood
> *Additional Options Listed Below
> *(RFBWALLS)*

If Other, specify: *(RFBWALSP)* [   ] *(RFBWALCO)* Code: [   ]

31. What is the <u>roof</u> in the child's house primarily made of? *(check one)*

> 01-01 - Thatch
> 02-02 - Tin / iron sheeting / metal / corrugated
> 03-03 - Cement / concrete
> 04-04 - Wood
> 05-05 - Tiled
> *Additional Options Listed Below
> *(RFBROOF)*

If Other, specify: *(RFBROFSP)* [   ] *(RFBROFCO)* Code: [   ]

32. What type of toilet does the child's house have? *(check one)*

> 01-01 - Flush toilet
> 02-02 - Modern toilet without flush
> 03-03 - Ventilated, well-kept pit latrine
> 04-04 - Open pit latrine
> 05-05 - Bucket system
> *Additional Options Listed Below
> *(RFBTLET)*

If Other, specify: *(RFBTLTSP)* [   ] *(RFBTLTCO)* Code: [   ]

For Q33-39, respond for the most common situation for the child.
  *For <u>controls</u>, ask about **during the past month.***
  *For <u>cases</u>, ask about the month **before** the child became ill with pneumonia symptoms since the period when they were ill might have been atypical for the family.*

33. Describe the type of cooking fuel you used *in the past month?* *(RFBCKFNA)* ☐ 9 - N/A

a.   What was the <u>main</u> cooking fuel? *(check one)*

> 01-01 - Animal dung
> 02-02 - Crop wastes
> 03-03 - Wood
> 04-04 - Straw / shrubs / grass
> 05-05 - Charcoal
> *Additional Options Listed Below
> *(RFBCKFL)*

If Other, specify: *(RFBCKFSP)* [   ] *(RFBCKFCO)* Code: [   ]

b.   What <u>other</u> fuel types did you use? *(check all that apply)*

Animal dung:	*(RFBFANDU)*	☐
Crop wastes:	*(RFBFCWST)*	☐
Wood:	*(RFBFWOOD)*	☐
Straw/shrubs/grass:	*(RFBFSTRA)*	☐
Charcoal:	*(RFBFCHAR)*	☐
Coal/ignite:	*(RFBFCOAL)*	☐
Kerosene/paraffin:	*(RFBFKROS)*	☐
Gas:	*(RFBFGAS)*	☐
Electricity:	*(RFBFELEC)*	☐
Other:	*(RFBFOTHR)*	☐

If Other, specify: *(RFBFOTSP)* [   ] *(RFBFOTCO)* Code: [   ]

If animal dung, crop wastes, wood, straw/shrubs/grass, charcoal, coal/ignite, or kerosene/paraffin was checked as the <u>main</u> fuel source in Q33 above, please answer Q34. Otherwise, skip to Q38.

34. What was the main stove type that you used for cooking?   *(RFBSTOVE)*
   (check one)

| 01-01 - Stove: Traditional open |
| 02-02 - Stove: Enclosed |
| 03-03 - Stove: Advanced type (modern design, may have fan to improve combustion) |
| 04-04 - 3-stone fire |
| 05-05 - Kerosene wick |
| *Additional Options Listed Below |

If Other, specify: *(RFBSTVSP)* [　　　　　　　] *(RFBSTVCO)* Code: [　　　]

If 3-stone fire, Kerosene wick or Pressurized kerosene are selected, skip to Q35.

    a. If you used a stove or open fire, does it have a functioning chimney or hood?

| 1-1 - Yes |
| 0-0 - No |
| 8-8 - UNK |
| 9-9 - N/A |

(RFBCHMNY)

35. Where did you usually cook with fuel *in the past month? (check one)*

| 1-1 - In the house, but in a room separate from living / sleeping area |
| 2-2 - In the house, part of the living / sleeping area |
| 3-3 - Outside the house or in a separate building |
| 8-8 - UNK |

(RFBFLMNT)

36. How many open windows does the room have where the cooking is done? *(RFBWINDO)* [　　　] *(x)* *(RFBWINDU)* ☐ 8 - UNK ☐ 9 - N/A

37. Typically, where was the study child when the mother/caretaker was cooking with fuel *in the past month (before the child became ill)?*
    (check one)

(RFBLCCHC)

| 1-1 - On her back |
| 2-2 - In the cooking area, but not on her back |
| 3-3 - Not in the cooking area (e.g. outside, in another room, etc.) |
| 8-8 - UNK |

38. What was the main method used to light your home when it was dark *in the past month? (check one)*

| 01-01 - None (did not light home) |
| 02-02 - Used light from cooking stove |
| 03-03 - Candles |
| 04-04 - Kerosene (paraffin) wick lamp |
| 05-05 - Kerosene (paraffin) pressure lamp |
| *Additional Options Listed Below |

(RFBLTHOM)

    If Other, specify: *(RFBLTHSP)* [　　　　　　　　] *(RFBLTHCO)* Code: [　　]

39. Did you use a fire to heat your home *in the past month?* *(RFBFIRE)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

    a. If Yes, how often?

| 1-1 - Everyday |
| 2-2 - Most days (16-29 days) |
| 3-3 - Many days (5-15 days) |
| 4-4 - Few days (<5 days) |
| 8-8 - UNK |

(RFBFRTMS)

40. Does anyone who lives in the same household as the child smoke cigarettes? *(RFBSMOKE)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

41. Does your household have any mosquito nets that can be used while sleeping? *(RFBMSQNT)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

    If Yes, answer Q41a-b. If No, or UNK, skip to Q42.

    a. Did this child sleep under the mosquito net last night? *(RFBMQTSL)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

    b. Does this child usually sleep under a mosquito net? *(RFBMQTUS)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

HEALTHCARE UTILIZATION

42. Record the *usual* travel time to the following locations by the *usual* mode of transport and the *usual* costs associated with this travel.

Location:	i. How long does it usually take *(minutes)?*		ii. How much does transportation usually cost? *(in local currency, one way)*	
a. Nearest health post/clinic	*(RFBTMCLI)* [　　] *(xxx)*	*(RFBTMCLU)* ☐ 8 - UNK	*(RFBCSTCL)* [　　] *(xxxxxx)*	*(RFBCSTCU)* ☐ 8 - UNK ☐ 9 - N/A
b. Study hospital	*(RFBSHMIN)* [　　] *(xxx)*	*(RFBSHSUN)* ☐ 8 - UNK	*(RFBSHCST)* [　　] *(xxxxxx)*	*(RFBSHCTU)* ☐ 8 - UNK ☐ 9 - N/A
c. Is the study hospital the nearest hospital?	1-1 - Yes / 0-0 - No / 8-8 - UNK *(RFBSHSPN)*			

d. Nearest hospital *(If nearest hospital is the study hospital, answer N/A)*	(RFBNRHSL) [____] *(xxx)*	(RFBNHSPU) ☐ 8 - UNK ☐ 9 - N/A	(RFBCSTNH) [____] *(xxxxxx)*	(RFBCSTHU) ☐ 8 - UNK ☐ 9 - N/A

*For **Cases** only, ask Q43-44. For **Controls** skip to Q45.*

43. How long did it take to get to the study hospital for this admission *(minutes)*?   (RFBTMADM) [____]   *(xxx)*   (RFBTMAUN) ☐ 8 - UNK

44. How much was the cost of transportation for <u>this</u> hospital admission *(one way)*?   (RFBCSTH) [____]   *(xxxxxx)*   (RFBCSHU) ☐ 8 - UNK   ☐ 9 - N/A

Initial QC by: (RFBINQC) [_____]

Additional Selection Options for RFB

Main source of water
06-06 - Open well in house or yard
07-07 - Covered well in house or yard
09-09 - Open public well
10-10 - Covered public well
11-11 - Deep tube well
12-12 - Shallow tube well
13-13 - Protected spring
14-14 - Unprotected spring
15-15 - Dam or earth pan
16-16 - Rainwater
17-17 - River, stream, pond, or lake water
99-99 - Other
08-08 - UNK

Location of water
99-99 - Other

Main hand wash water
06-06 - River, stream, pond, or lake water
07-07 - Pumped from ground through borehole
09-09 - Protected spring
10-10 - Unprotected spring
11-11 - Tube well
12-12 - Covered well in house or yard
99-99 - Other
08-08 - UNK

Run out of water
8-8 - UNK

Material of walls
06-06 - Plaster
07-07 - Stone
08-08 - UNK
99-99 - Other

Material of roof
06-06 - Asbestos
08-08 - UNK
99-99 - Other

Type of toilet
06-06 - None / outdoors
08-08 - UNK
99-99 - Other

Type of cooking fuel
06-06 - Coal / ignite
07-07 - Kerosene / paraffin
09-09 - Gas
10-10 - Electricity
08-08 - UNK
99-99 - Other

Stove type
06-06 - Pressurized kerosene
08-08 - UNK
99-99 - Other

Light home
06-06 - Gas
07-07 - Electricity
09-09 - Battery powered lamp
10-10 - Solar
08-08 - UNK
99-99 - Other

CRF 05: Household Income and Birth Milestones (RFC)

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

HOUSEHOLD INCOME & ASSETS

		If other, specify:	Other Code:
45. What is the occupation of the head of household?	*(RFC5OC)* 01-01 - Football player / Sports coach / Gym instructor 02-02 - Brand ambassador / Sales consultant / Marketer 03-03 - Driver: Taxi / Bus / Track / Motorbike / Train / Courier 04-04 - Domestic worker / Child-minder / Care giver / Washing-lady 05-05 - Shop assistant / Cashier *Additional Options Listed Below	*(RFC5OCSP)*	*(RFC5OCCO)*
46. Father's occupation *(if not head of household)*:	01-01 - Teacher 02-02 - Student 03-03 - Rice farmer 04-04 - Plant farmer (e.g., corn, sugarcane) 05-05 - Animal farmer (e.g., fish, pig, cow) *Additional Options Listed Below *(RFC6DAD)*	*(RFC6DASP)*	*(RFC6DACO)*
47. Mother's/primary care giver's occupation:	01-01 - Teacher 02-02 - Student 03-03 - Rice farmer 04-04 - Plant farmer (e.g., corn, sugarcane) 05-05 - Animal farmer (e.g., fish, pig, cow) *Additional Options Listed Below *(RFC6MOM)*	*(RFC6MOSP)*	*(RFC6MOCO)*
45. What is the occupation of the head of household?	01-01 - Farmer 02-02 - House Wife 03-03 - Watchman, Security, Caretaker 04-04 - Waiter, Barkeeper, Cook 05-05 - Nanny, Cleaner, Maid, Laundress *Additional Options Listed Below *(RFC2OC)*	*(RFC2OCSP)*	*(RFC2OCCO)*
46. Father's occupation *(if not head of household)*:	01-01 - Farmer 02-02 - House Wife 03-03 - Watchman, Security, Caretaker 04-04 - Waiter, Barkeeper, Cook 05-05 - Nanny, Cleaner, Maid, Laundress *Additional Options Listed Below *(RFC2DAD)*	*(RFC2DASP)*	*(RFC2DACO)*
47. Mother's/primary care giver's occupation:	01-01 - Farmer 02-02 - House Wife 03-03 - Watchman, Security, Caretaker 04-04 - Waiter, Barkeeper, Cook 05-05 - Nanny, Cleaner, Maid, Laundress *Additional Options Listed Below *(RFC2MOM)*	*(RFC2MOSP)*	*(RFC2MOCO)*
45. What is the occupation of the head of household?	001-001 - Administrator 002-002 - Craftsman 003-003 - Animal Farming 004-004 - Driver 005-005 - Trader *Additional Options Listed Below *(RFC3OC)*	*(RFC3OCSP)*	*(RFC3OCCO)*
47. Mother's/primary care giver's occupation:	001-001 - Administrator 002-002 - Craftsman 003-003 - Animal Farming 004-004 - Driver 005-005 - Trader *Additional Options Listed Below *(RFC3MOM)*	*(RFC3MOSP)*	*(RFC3MOCO)*

45. What is the occupation of the head of household?

001-001 - Teacher, Up to School / Madrasha / Tutor
002-002 - Religious Leader / Religious Worker
003-003 - Painter / Sculptor
004-004 - Barber / Hair Dresser
005-005 - Tailor / Dress Maker / Sewer
*Additional Options Listed Below
(RFC8OC)

(RFC8OCSP) _____ *(RFC8OCCO)* ___

46. Father's occupation (*if not head of household*):

001-001 - Teacher, Up to School / Madrasha / Tutor
002-002 - Religious Leader / Religious Worker
003-003 - Painter / Sculptor
004-004 - Barber / Hair Dresser
005-005 - Tailor / Dress Maker / Sewer
*Additional Options Listed Below
(RFC8DAD)

(RFC8DASP) _____ *(RFC8DACO)* ___

47. Mother's/primary care giver's occupation:

001-001 - Teacher, Up to School / Madrasha / Tutor
002-002 - Religious Leader / Religious Worker
003-003 - Painter / Sculptor
004-004 - Barber / Hair Dresser
005-005 - Tailor / Dress Maker / Sewer
*Additional Options Listed Below
(RFC8MOM)

(RFC8MOSP) _____ *(RFC8MOCO)* ___

45. What is the occupation of the head of household?

01-01 - Businessman
02-02 - Small business
03-03 - Manager
04-04 - Accountant
05-05 - Clerk
*Additional Options Listed Below
(RFC9OC)

(RFC9OCSP) _____ *(RFC9OCCO)* ___

46. Father's occupation (*if not head of household*):

01-01 - Businessman
02-02 - Small business
03-03 - Manager
04-04 - Accountant
05-05 - Clerk
*Additional Options Listed Below
(RFC9DAD)

(RFC9DASP) _____ *(RFC9DACO)* ___

47. Mother's/primary care giver's occupation:

01-01 - Businessman
02-02 - Small business
03-03 - Manager
04-04 - Accountant
05-05 - Clerk
*Additional Options Listed Below
(RFC9MOM)

(RFC9MOSP) _____ *(RFC9MOCO)* ___

48. What was the weekly/monthly cash income of the household last month?

01-0 - 500 Rand
02-501 - 1,000 Rand
03-1,001 - 3,000 Rand
04-3,001 - 5,000 Rand
05-5,001 - 15,000 Rand
*Additional Options Listed Below
(RFCINCOM)

49. Ask mother/primary caregiver: Do you regularly earn any income yourself? *(RFCMOMI)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

50. Is the child receiving a "child grant"? *(RFCCGRNT)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

51. Does your household have any of the following which are in working order? (*check all that apply*) *(RFCWRKU)* ☐ 8 - UNK

(RFCWELEC) ☐ Electricity   *(RFCWTELE)* ☐ Television   *(RFCWBICY)* ☐ Bicycle / rickshaw
(RFCWGENR) ☐ Generator   *(RFCWSATV)* ☐ Satellite TV/DS TV *(RFCWBOAT)* ☐ Boat with a motor
(RFCWAC) ☐ Air conditioner   *(RFCWRADI)* ☐ Radio   *(RFCWCANO)* ☐ Canoe
(RFCWELCF) ☐ Electric fan   *(RFCWMPHN)* ☐ Mobile phone   *(RFCWSEWM)* ☐ Sewing machine
(RFCWCOMP) ☐ Computer   *(RFCWEIRN)* ☐ Electric iron   *(RFCWWTRH)* ☐ Water heater
(RFCWFRIG) ☐ Refrigerator   *(RFCWATCH)* ☐ Watch   *(RFCWWASH)* ☐ Washing machine
(RFCWANCT) ☐ Animal-drawn cart *(RFCWCMRA)* ☐ Camera   *(RFCWNON)* ☐ None of these
(RFCWCLK) ☐ Clock   *(RFCWCAR)* ☐ Car / truck
(RFCWDVD) ☐ DVD/Video player *(RFCWMCYC)* ☐ Motorcycle / scooter

52. Does anyone in the household own any of the following livestock?

(*For all that apply, check and enter how many are owned.
Confirm by observation where possible and appropriate.*)

Livestock	Check all that apply	i. If checked, how many owned? (xxxx)	8 - UNK
a. Cattle	(RFCCATTL) ☐	(RFCCATLN) [ ]	(RFCCATLU) ☐
b. Sheep	(RFCSHEEP) ☐	(RFCSHEPN) [ ]	(RFCSHEPU) ☐
c. Goats	(RFCGOAT) ☐	(RFCGOATN) [ ]	(RFCGOATU) ☐
d. Horses	(RFCHORSE) ☐	(RFCHORSN) [ ]	(RFCHORSU) ☐
e. Donkeys	(RFCDONKY) ☐	(RFCDNKYN) [ ]	(RFCDNKYU) ☐
f. Pigs	(RFCPIG) ☐	(RFCPIGNM) [ ]	(RFCPIGUN) ☐
g. Chickens	(RFCCHKEN) ☐	(RFCHKENM) [ ]	(RFCHKENU) ☐
h. None of these	(RFCNOLIV) ☐		

53. Does your household own at least five items of furniture? (RFCFURNT) ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

Furniture	Check all that apply
a. Table	(RFCTABLE) ☐
b. Chair	(RFCCHAIR) ☐
c. Sofa	(RFCSOFA) ☐
d. Bed	(RFCBED) ☐
e. Armoire	(RFCARMOR) ☐
f. Cabinet	(RFCABINE) ☐

54. Does any member of this household own agricultural land? (RFCAGLND) ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

a. If Yes, specify how many acres? (RFCACRES) [ ] (xxxx) (RFCAGLDU) ☐ 8 - UNK

BIRTH AND DELIVERY MILESTONES

55. Place of birth:

01-01 - Hospital
02-02 - Clinic
03-03 - Home
99-99 - Other
08-08 - UNK
(RFCPLBRT) ▬

If Other, specify: (RFCPLBSP) [ ] Code: (RFCPLBCO) [ ]

56. Mode of delivery:

1-1 - Vaginal
2-2 - C-section
8-8 - UNK
(RFCMODEB) ▬

57. Gestational age: (RFCGAGE) [ ] (xx) weeks (RFCGAGEU) ☐ 8 - UNK

58. Was this child premature (<37 weeks recorded) at birth? (RFCPREMI) ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

59. How much did the child weigh at birth? (RFCWTBRT) [ ] (x.xx) kg (RFCWTBUN) ☐ 8 - UNK

a. If exact weight is unknown, what was the child's size at birth?

1-1 - Small
2-2 - Medium
3-3 - Large
8-8 - UNK
(RFCBSIZE) ▬

60. How was the child fed since s/he was born?

	Given at any stage?	i. If Yes, age first started (Enter 0 if from birth) months	Unknown	ii. If stopped, age stopped (Check N/A if still continuing) months	Unknown / N/A
a. Breastfeeding	(RFCBSTFD) 1-1 - Yes 0-0 - No 8-8 - UNK ▬	(RFCBSTST) [ ] (xx)	(RFCBSTSU) ☐ 8 - UNK	(RFCBSTSP) [ ] (xx)	(RFCBSTPU) ☐ 8 - UNK ☐ 9 - N/A
b. Infant formula	(RFCINFOR)	(RFCINFST) [ ] (xx)	(RFCINFSU) ☐ 8 - UNK	(RFCINFSP) [ ] (xx)	(RFCINFPU) ☐ 8 - UNK ☐ 9 - N/A

_BFDURAT (months)

_TOTEXCLU (months)

	1-1 - Yes 0-0 - No 8-8 - UNK				

c. Any liquids other than breast milk (e.g. water, tea) or semi-solid food (e.g. pap)

(RFCLIQID)
1-1 - Yes
0-0 - No
8-8 - UNK

(RFCLQSST) _____ *(xx)*   *(RFCLQSTU)* ☐ 8 - UNK   *(RFCLQSSP)* _____ *(xx)*   *(RFCLQSPU)* ☐ 8 - UNK   ☐ 9 - N/A

d. Solid food   *(RFCSFOOD)*
1-1 - Yes
0-0 - No
8-8 - UNK

(RFCSFODS) _____ *(xx)*   *(RFCSFODU)* ☐ 8 - UNK   *(RFCSFODP)* _____ *(xx)*   *(RFCSFDPU)* ☐ 8 - UNK   ☐ 9 - N/A

_TOTEXCLU (months)

_BFDURAT (months)

61. Was the child breastfed?   *(RFCBSFED)* ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

a. For how many months was the child <u>exclusively</u> breastfed?   *(RFCEXBST)* _____ *(xx)* months   *(RFCEXBSU)* ☐ 8 - UNK

b. For how many months was the child breastfed?   *(RFCMNBST)* _____ *(xx)* months   *(RFCMNBSU)* ☐ 8 - UNK

c. Was the child breastfed in the week before illness (or the week before enrollment for <u>controls</u>)?

1-1 - Exclusive
2-2 - Mixed
3-3 - None
8-8 - UNK

(RFCBSTIL)

Comments: *(RFCCOMM)*

Staff Code: *(RFCFCBCO)* _____

Initial QC by: *(RFCINQC)* _____

Supervisor Staff Code: *(RFCSUPCO)* _____

Supervisor Verification Date: *(RFCVERDT)* _____ *(ddMMMyyyy)*

Additional Selection Options for RFC

South Africa head occup.
06-06 - Labour/Carpentry/Builder/Plumber/Welder/Mechanic/Printer/Worker (general, factory, warehouse)
07-07 - Nurse / Doctor
08-08 - Teacher
09-09 - Temporary jobs / Piece jobs
10-10 - Tuck shop / Spaza / Vendor
11-11 - Food industry: Baker / Chef / Waiter / Waitress
12-12 - Security guard / Policeman / Fireman / Traffic officer / Soldier
13-13 - Car park attendant / Car guard
14-14 - Administrator / Clerk / Teller / PA / RA / Receptionist / Data capturer / Call centre agent
15-15 - Hair stylist / Beautician
16-16 - Tradiational healer
17-17- Pensioner
18-18 - Self employed
19-19 - Unemployed
20-20 - UNK
21-21 - Other
97-97 - N/A

Thailand father occup.
06-06 - Housewife
07-07 - Office worker
09-09 - Factory worker
10-10 - Food vendor
11-11 - Vendor (non-food)
12-12 - Shop or store worker / sales
13-13 - Shop owner
14-14 - Other small business owner
15-15 - Retired
16-16 - Government officer
17-17 - Monk
18-18 - Police / guard
19-19 - Military
20-20 - Construction
21-21 - Artisan (e.g., carpenter, mechanic, repairer)
22-22 - Dressmaker / tailor
23-23 - Beauty salon / barber
24-24 - Health care worker
25-25 - Maid or cleaning person
26-26 - Driver
27-27 - Unemployed
28-28 - Day laborer
08-08 - UNK
97-97 - N/A
99-99 - Other

Gambia head occupation
06-06 - Shop Keeper, Petty Trader
07-07 - Business Man / Woman, Contractor
08-08 - Weaver, Tye And Dye, Tailor
09-09 - Food / Drug Seller, Hawker, Donkey / Horse Cart Driver
10-10 - Hairdresser, Photographer
11-11 - Carpenter, Blacksmith, Painter, Driver, Mechanic, Baker
12-12 - Plumber, Masoner, Architect, Labourer
13-13 - Technician, Welder, Electrician
14-14 - Artist, Operator, DJ
15-15 - Soldier, Police, Fire Brigade, Immigration, Prison Officer
16-16 - Librarian, Teacher
17-17 - Student
18-18 - Traditional Birth Attendant / Village Health Worker, Primary Health Care Worker
19-19 - Nurse, Medical Assistant, Pharmacy Assistant, Health Inspector
20-20 - Traditional Healer, Marabout
21-21 - Doctor, Dentist, Scientist
22-22 - Veterinary Administrator, Agricultural Worker
23-23 - Gardener, Hunter, Forest Scouts, Shepherd, Butcher
24-24 - Supervisor, Revenue Collector, Account Assistant
25-25 - Fieldworker, Research Officer, Social Worker
26-26 - Secretary, Bank Employee, Receptionist, Cashier, Post Master
27-27 - Accountant, Manager, Auditor
28-28 - Religious Leader
29-29 - Journalist
30-30 - Lawyer, Judge
31-31 - Fisherman, Spray Man, Wine Tapper, Bee Keeper
32-32 - Other Civil Servant
33-33 - Messenger, Dock / Factory Worker
34-34 - Unemployed, Retired
97-97 - N/A
98-98 - Other
99-99 - UNK

Mali head occupation
006-006 - Farmer
007-007 - Koranic School
008-008 - Teacher
009-009 - Pupil/Student
010-010 - Security Guard
011-011 - Nurse
012-012 - Engineer
013-013 - Judge
014-014 - Unskilled Worker
015-015 - Spiritual Healer/Muslim Leader

016-016 - Doctor
017-017 - Housewife
018-018 - Housekeeper
019-019 - Skilled Worker
020-020 - Fisherman
021-021 - Office Assistant
022-022 - Retired
023-023 - Unemployed
024-024 - Technician
025-025 - Traditional Healer
026-026 - Other
097-097 - N/A
098-098 - UNK

Matlab head occupation
006-006 - Blacksmith / Potter
007-007 - Cobbler / Repairing Worker
008-008 - Plumber
009-009 - Goldsmith (Jeweler, Precious Metal Worker)
010-010 - Carpenter / Mason
011-011 - Student
012-012 - Beggar
013-013 - Housewife / Homemaker
014-014 - Retired
015-015 - Boatman / Rickshaw / Van Puller
016-016 - Teacher, College & University / Madrasha
017-017 - Agriculture Related, works in own land only / not share cropper
018-018 - Agriculture Related, works in own land / share cropper also
019-019 - Agriculture Related, share cropper / does not own agricultural land
020-020 - Fishing / Fish Business, Employer / Self Employed
021-021 - Fishing / Fish Business, Labor / Employee
022-022 - Engineer / Architect / Computer Programmer
023-023 - Fishery / Agriculture / Veterinary Graduate
024-024 - Advocate
025-025 - Deed Writer
026-026 - Physician / Dentist Graduate
027-027 - Nurse / Midwife / Paramedic
028-028 - Village Doctor / Quack / Traditional Healer (Herbal)
029-029 - Spiritual Healer
030-030 - Homeopathy / Herbal (Graduate)
031-031 - Supervisor / Clerical Supervisor
032-032 - Executive / Manager / Officer
033-033 - Housekeeping / Maid
034-034 - Security Guard / Peon / Caretaker / Attendant / Daily Wager / Porter
035-035 - Office Assistant / Clerical Worker / Field Worker / Service Worker
036-036 - Industry / Factory / Port Worker / Garments
037-037 - Driver / Vehicle Owner and Driver
038-038 - Foreign Service (Working Abroad)
039-039 - Poultry / Fishery / Agriculture / Dairy Farm Worker
040-040 - Wood Preparation Worker
041-041 - Construction Worker / Manual Day Labor
042-042 - Bicycle / Rickshaw / Any Push Cart Mechanics
043-043 - Electrician / Automobile / Radio / TV / Mobile / Welding / Lathe Machine Operator
044-044 - Businessman, Shop (Retail / Wholesale) Poultry
045-045 - Hawker (Mobile) / Small Business
046-046 - Large Business / Company / Industrialist
047-047 - Restaurant Business
048-048 - Ice Cream Factory / Paper Packer / Paper Box / Bakery / Muri Factory
049-049 - Handicrafts / Bamboo / Cane Tools Maker, etc.
050-050 - Contractor / Supplier
051-051 - Jewelry Business
052-052 - Child
053-053 - Housekeeping Supervisors (Parents having no specific jobs but taking care of whole family)
054-054 - Unemployed / Jobless / Looking for Job
055-055 - Disabled / Elderly
097-097 - N/A
098-098 - UNK
099-099 - Other

Dhaka head occupation
06-06 - Messenger
07-07 - Driver / Helper
08-08 - Sweeper / Ward boy / Cleaner
09-09 - Other
10-10 - Rickshaw / Push-cart puller
11-11 - Day labourer
12-12 - Skilled labourer (e.g., tailor, plumber, transport mechanic)
13-13 - Farmer
14-14 - Office in any Organization
15-15 - Teacher
16-16 - Clergy
17-17 - Garments worker
18-18 - Maidservant / servant
19-19 - Landlord
20-20 - Hawker
21-21 - Professional (e.g., doctor, engineer, lawyer, architect)
22-22 - Barber / hair dresser
23-23 - Fisherman
24-24 - Mill / factory worker
25-25 - Electrician
26-26 - Craftsman not labourer elsewhere classified
27-27 - Security forces (e.g., Army, police, private security)
28-28 - Unskilled labourer

29-29 - Cook
30-30 - Line man (e.g., gas, T&T, Wasa)
31-31 - Sales man / woman
32-32 - Paramedic (e.g., nurse, FWV, MA, SACMO)
33-33 - Municipality health worker (e.g., MHW, HA, FWA)
34-34 - Trained TBA
35-35 - Untrained TBA
36-36 - Termination attendant
37-37 - Allopath quack
38-38 - Pharmacist
39-39 - Traditional practitioner
40-40 - Homeopath practitioner
41-41 - Home maker (houseman / housewife)
42-42 - Student
43-43 - Dependent
88-88 - UNK
97-97 - N/A

Monthly income
06-> 15,000 Rand
07-0 - 1,000 baht
09-1,001 - 2,000 baht
10-2,001 - 4,000 baht
11-4,001 - 7,000 baht
12->7,000 baht
08-08 - UNK

CRF 06: Case Specimen Collection: Blood NP/OP Urine (CBU)

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

If no blood, NP/OP, or urine specimens were taken, submit a Missing Forms Request.

1. Child's weight category *(check one)*: *(CBUWEIGH)* ☐ 1: <= 1 kg   ☐ 2: > 1 kg to < 3 kg   ☐ 3: >= 3 kg

Child's Weight	Total Volume	Blood Culture Bottle Volume	EDTA Tube #1 (CBC) Volume	EDTA Tube #2 (PCR) Volume	Plain/ Red Top Tube Volume
≤ 1 kg	3 ml	1 mL	0.5 mL	1 mL	0.5 mL
> 1 kg to < 3 kg	4.5 mL	2 mL	0.5 mL	1 mL	1 mL
≥ 3 kg	5 mL	2 mL	0.5 mL	1.5 mL	1 mL

In instances of limited blood volume, the following guidance applies in decreasing order of priority:
1) Blood cultures
   CBC
   malaria slides (for endemic sites)
   HIV serology (for high prevalence sites)
2) Purple top tube for PCR, etc., (up to 1 mL max.)
3) If there is sufficient volume, any remaining blood should be placed in the red top tube

*Volume may vary based on local requirements for CBC and risk factor tests.

When *< 3 mL of blood* is collected from a patient, the following guidelines may be used:

Total Volume Available	Blood Culture Bottle Volume	EDTA Tube #1 (CBC*) Volume	EDTA Tube #2 (PCR) Volume	Plain/ Red Top Tube Volume
< 1 mL	all	0 mL	0 mL	0 mL
1 to < 2 mL	1 mL	0.5* mL	0 - 0.5 mL	0 mL
2 to < 3 mL	1 mL	0.5* mL	0.5 - 1 mL	Any remaining volume

2. Enrollment category *(check one)*:

(CBUENRCW) ☐	Child had wheeze at admission AND the case defining signs of severe pneumonia resolved after 1 dose of bronchodilator treatment (< 2 yrs old) or after 1 - 3 doses (≥ 2 to < 5 yrs old).	→	**Modified protocol: Collect blood and swabs only. Do not collect other specimens.**
(CBUENRCN) ☐	Either (a) child did not have wheeze, (b) child had very severe pneumonia, or (c) signs of severe pneumonia persisted after complete course of bronchodilator therapy.	→	**Proceed with standard protocol.**

3.	Were the following samples collected?	Reason, if not collected:	Date (ddMMMyyyy) & Time: (24hr clock)		Collecte
a. Blood culture	*(CBUBCCOL)* 1-1 - Yes, at study facility 2-2 - Yes, at referring facility 3-3 - Not collected	Reason code:*(CBUBRCO)* 01-01 - Parent/Guardian refused 02-02 - Child died prior to specimen collection 03-03 - Insufficient blood volume 04-04 - All EDTA blood being collected in one tube 05-05 - Child discharged *Additional Options Listed Below	Date:*(CBUBCDT)*	*(CBUBCDTU)* ☐ 8 - UNK	Initials:*(CBUBC*
	If Yes, blood culture was collected, enter blood culture bottle weight on CRF 20.				
		Other:*(CBUBCSP)*	Time:*(CBUBCTM)*	*(CBUBCTMU)* ☐ 8 - UNK	Staff code:*(CBU*
		Other specify code:*(CBUBOTCO)*			
b. EDTA tube #1 (CBC)	1-1 - Yes 0-0 - No *(CBUEDTA1)*	Reason code:*(CBUED1CO)*	Date:*(CBUED1DT)*	*(CBUE1DTU)* ☐ 8 - UNK	Initials:*(CBUED*

		Reason code:	Date/Time		
		01-01 - Parent/Guardian refused 02-02 - Child died prior to specimen collection 03-03 - Insufficient blood volume 04-04 - All EDTA blood being collected in one tube 05-05 - Child discharged *Additional Options Listed Below			
		Other:*(CBUED1SP)*	Time:*(CBUED1TM)*	*(CBUE1TMU)* ☐ 8 - UNK	Staff code:*(CBU*
		Other specify code:*(CBUE1TCO)*			
c. EDTA tube #2 (PCR) *(CBUEDTA2)*	1-1 - Yes 0-0 - No	Reason code:*(CBUED2CO)* 01-01 - Parent/Guardian refused 02-02 - Child died prior to specimen collection 03-03 - Insufficient blood volume 04-04 - All EDTA blood being collected in one tube 05-05 - Child discharged *Additional Options Listed Below	Date:*(CBUED2DT)*	*(CBUE2DTU)* ☐ 8 - UNK	Initials:*(CBUED*
		Other:*(CBUED2SP)*	Time:*(CBUED2TM)*	*(CBUE2TMU)* ☐ 8 - UNK	Staff code:*(CBU*
		Other specify code:*(CBUE2TCO)*			
d. Plain / red top tube *(CBUPLAIN)*	1-1 - Yes 0-0 - No	Reason code:*(CBUPLRCO)* 01-01 - Parent/Guardian refused 02-02 - Child died prior to specimen collection 03-03 - Insufficient blood volume 04-04 - All EDTA blood being collected in one tube 05-05 - Child discharged *Additional Options Listed Below	Date:*(CBUPLDT)*	*(CBUPLDTU)* ☐ 8 - UNK	Initials:*(CBUPLI*
		Other:*(CBUPLSP)*	Time:*(CBUPLTM)*	*(CBUPLTMU)* ☐ 8 - UNK	Staff code:*(CBU*
		Other specify code:*(CBUPLCO)*			

4.	Were the following samples collected?	Reason, if not collected:	Date (ddMMMyyyy) & Time: *(24hr clock)*		Collecte
a. NPS-VTM *(CBUNPSVT)*	1-1 - Yes 0-0 - No	Reason code:*(CBUNVRCO)* 01-01 - Parent/Guardian refused 02-02 - Child died prior to specimen collection 03-03 - Insufficient blood volume 04-04 - All EDTA blood being collected in one tube 05-05 - Child discharged *Additional Options Listed Below	Date:*(CBUNVDT)*	*(CBUNVDTU)* ☐ 8 - UNK	Initials:*(CBUNV*
		Other:*(CBUNVSP)*	Time:*(CBUNVTM)*	*(CBUNVTMU)* ☐ 8 - UNK	Staff code:*(CBU*
		Other specify code:*(CBUNVCO)*			
b. OPS *(CBUOPS)*	1-1 - Yes 0-0 - No	Reason code:*(CBUOPRCO)* 01-01 - Parent/Guardian refused 02-02 - Child died prior to specimen collection 03-03 - Insufficient blood volume 04-04 - All EDTA blood being collected in one tube 05-05 - Child discharged *Additional Options Listed Below	Date:*(CBUOPSDT)*	*(CBUOPDTU)* ☐ 8 - UNK	Initials:*(CBUOPI*
		Other:*(CBUOPSP)*	Time:*(CBUOPSTM)*	*(CBUOPTMU)* ☐ 8 - UNK	Staff code:*(CBU*
		Other specify code:*(CBUOPCO)*			

c. NPS-STGG	1-1 - Yes 0-0 - No (CBUNPSST)	Reason code: (CBUNSRCO) 01-01 - Parent/Guardian refused 02-02 - Child died prior to specimen collection 03-03 - Insufficient blood volume 04-04 - All EDTA blood being collected in one tube 05-05 - Child discharged *Additional Options Listed Below	Date: (CBUNSDT)	(CBUNSDTU) ☐ 8 - UNK	Initials: (CBUNSI)
		Other: (CBUNSSP)	Time: (CBUNSTM)	(CBUNSTMU) ☐ 8 - UNK	Staff code: (CBU
		Other specify code: (CBUNSCO)			

*Flocked NP swab and OP swab should be put together in one VTM vial (one barcode label only).

⁺Rayon NP swab should be put in STGG vial.

5.	Was the following sample collected?	Reason, if not collected:	Date (ddMMMyyyy) & Time: (24hr clock)		Collecte
a. Urine	(CBUUCOL) 1-1 - Yes, sterile cup 2-2 - Yes, urine bag or catheter 0-0 - No	Reason code: (CBUURCO) 01-01 - Parent/Guardian refused 02-02 - Child died prior to specimen collection 03-03 - Insufficient blood volume 04-04 - All EDTA blood being collected in one tube 05-05 - Child discharged *Additional Options Listed Below	Date: (CBUURDT)	(CBUUDTU) ☐ 8 - UNK	Initials: (CBUUI)
		Other: (CBUUSP)	Time: (CBUUTM)	(CBUUTMU) ☐ 8 - UNK	Staff code: (CBU
		Other specify code: (CBUUCO)			

Comments:

(CBUCOMM)

Initial QC by: (CBUINQC)

Supervisor Staff Code: (CBUSCO)

Supervisor Verification Date: (CBUSDT) (ddMMMyyyy)

Additional Selection Options for CBU

Reason code:
07-07 - Child could not produce specimen
08-08 - UNK
09-09 - Not applicable
99-99 - Other (give reason and enter other specify code)

CRF 06A: Control Specimen Collection: Blood NP/OP Urine (COB)

Web Version: 1.0; 5.04; 06JUN13

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

If no blood, NP/OP, or urine specimens were collected, submit a Missing Forms Request.

Date specimens collected: *(COBFORDT)* [   ] *(ddMMMyyyy)*

Volume of Blood Collection Guidelines:

EDTA Volume	Plain/Red Top Volume	Total Volume
2 mL	2 mL	4 mL

In instances where less than the minimum volume is obtained, at least 1 mL should be collected in the EDTA tube.

1. Staff code of person collecting specimens: *(COBCBYCO)* [   ]

	2. Were the following samples collected?	Reason, if not collected:	Time of specimen collection: *(24hr clock)*
a. EDTA tube	1-1 - Yes 0-0 - No *(COBEDTA)*	01-01 - Parent/Guardian refused 02-02 - Phlebotomist unable to collect blood 05-05 - Child discharged 07-07 - Child could not produce specimen 08-08 - UNK *Additional Options Listed Below Reason code: *(COBEDCO)*	Time: *(COBEDTM)* [ ]
		Other: *(COBEDSP)* [ ]	
		Other specify code: *(COBETCO)* [ ]	
b. Plain / red top tube	1-1 - Yes 0-0 - No *(COBPLAIN)*	01-01 - Parent/Guardian refused 02-02 - Phlebotomist unable to collect blood 05-05 - Child discharged 07-07 - Child could not produce specimen 08-08 - UNK *Additional Options Listed Below Reason code: *(COBPLRCO)*	Time: *(COBPLTM)* [ ]
		Other: *(COBPLSP)* [ ]	
		Other specify code: *(COBPLCO)* [ ]	
c. Dried blood spot **Collect only for HIV PCR testing**	1-1 - Yes 0-0 - No 9-9 - N/A *(COBBLSPO)*	01-01 - Parent/Guardian refused 02-02 - Phlebotomist unable to collect blood 05-05 - Child discharged 07-07 - Child could not produce specimen 08-08 - UNK *Additional Options Listed Below Reason code: *(COBBLCO)*	Time: *(COBBLTM)* [ ]
		Other: *(COBBLSP)* [ ]	
		Other specify code: *(COBBLTCO)* [ ]	

	3. Were the following samples collected?	Reason, if not collected:	Time of specimen collection: *(24hr clock)*	
a. NPS-VTM	1-1 - Yes 0-0 - No *(COBNPSVT)*	Reason code: *(COBNVRCO)* 01-01 - Parent/Guardian refused 02-02 - Phlebotomist unable to collect blood 05-05 - Child discharged 07-07 - Child could not produce specimen 08-08 - UNK *Additional Options Listed Below	Time: *(COBNVTM)* [ ]	*(CC UNK
		Other: *(COBNVSP)* [ ]		

		Other specify code: *(COBNVCO)*		
b. OPS	*(COBOPS)* 1-1 - Yes 0-0 - No	Reason code: *(COBOPRCO)* 01-01 - Parent/Guardian refused 02-02 - Phlebotomist unable to collect blood 05-05 - Child discharged 07-07 - Child could not produce specimen 08-08 - UNK *Additional Options Listed Below	Time: *(COBOPSTM)*	*(CC* *UNK*
		Other: *(COBOPSP)*		
		Other specify code: *(COBOPCO)*		
c. NPS-STGG	*(COBNPSST)* 1-1 - Yes 0-0 - No	Reason code: *(COBNSRCO)* 01-01 - Parent/Guardian refused 02-02 - Phlebotomist unable to collect blood 05-05 - Child discharged 07-07 - Child could not produce specimen 08-08 - UNK *Additional Options Listed Below	Time: *(COBNSTM)*	*(CC* *UNK*
		Other: *(COBNSSP)*		
		Other specify code: *(COBNSCO)*		
d. Urine	*(COBUCOL)* 1-1 - Yes, sterile cup 2-2 - Yes, urine bag 0-0 - No	Reason code: *(COBURCO)* 01-01 - Parent/Guardian refused 02-02 - Phlebotomist unable to collect blood 05-05 - Child discharged 07-07 - Child could not produce specimen 08-08 - UNK *Additional Options Listed Below	Time: *(COBUTM)*	*(CC* *UNK*
		Other: *(COBUSP)*	Date of urine collection if different from date above: *(COBURIDT)*	
		Other specify code: *(COBUSCO)*		

*Flocked NP swab and OP swab should be put together in one VTM vial (one barcode label only).

⁺Rayon NP swab should be put in STGG vial.

Comments:

(COBCOMM)

Initial QC by: *(COBINQC)*

Supervisor Staff Code: *(COBSCO)*

Supervisor Verification Date: *(COBSDT)* *(ddMMMyyyy)*

Additional Selection Options for COB

Reason code:
99-99 - Other (give reason or enter the other specify code if available)

CRF 07: Case Specimen Collection: Induced Sputum (CIS)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

Do not complete this form if case is in the "modified protocol" category.
- *Induced sputum should be collected <u>within 24 hours of admission</u> whenever possible.*
- *If induced sputum is not collected within 24 hours, a gastric aspirate specimen should be obtained. Attempts should still be made to obtain induced sputum after 24 hours post-admission.*

SECTION A - FIRST INDUCED SPUTUM (IS)

1. Was an endotracheal tube (ETT) aspirate collected from an intubated patient? *(CISETTAS)* ☐ 1 - Yes ☐ 0 - No
   [Note: If an endotracheal tube (ETT) aspirate was collected from an intubated patient, skip to question 3.]

2. At the initial assessment, does the child have any of the following contraindications to IS collection: *(CISCONNA)* ☐ 9 - N/A

   (N/A should only be selected if the subject died before contraindications could be assessed for specimen collection)

   a. Oxygen saturation < 92% on supplemental oxygen: *(CISOXSAT)* ☐ 1 - Yes ☐ 0 - No

   b. Inability to protect airways: *(CISINABI)* ☐ 1 - Yes ☐ 0 - No

   c. Severe bronchospasm: *(CISSBRON)* ☐ 1 - Yes ☐ 0 - No

   d. Seizure within the past 24 hours: *(CISSEIZ)* ☐ 1 - Yes ☐ 0 - No

   e. Deemed inappropriate by the clinician for another reason: *(CISINAPP)* ☐ 1 - Yes ☐ 0 - No

   If the answer to any of the above is Yes, <u>do not</u> collect induced sputum at this time.
   Wait and evaluate the child again at a later point.

3. Was IS or ETT aspirate collected <u>within 24 hrs</u> of admission? *(CISISWIT)* ☐ 1 - Yes ☐ 0 - No
   (If Yes, skip to Q5)

   If <u>No</u>, reason not collected *(check all that apply)*:

   (CISWCMET) ☐ Child met one or more clinical contraindications

   (CISWPGR) ☐ Parent/guardian refused

   (CISWCDIE) ☐ Child died prior to collection of specimen

   (CISWOTHE) ☐ Other   *(CISWOSP)* Specify: _____   *(CISWOCO)* Code: _____

   (CISWUNKU) ☐ Unknown

4. Was IS or ETT aspirate collected more than <u>24 hrs</u> after admission? *(CISISAFT)* ☐ 1 - Yes ☐ 0 - No

   If <u>No</u>, reason not collected *(check all that apply)*:

   (CISACMET) ☐ Child met one or more clinical contraindications

   (CISAPGR) ☐ Parent/guardian refused

   (CISACDIE) ☐ Child died prior to collection of specimen

   (CISAOTHE) ☐ Other   *(CISAOSP)* Specify: _____   *(CISAOCO)* Code: _____

   (CISAUNKU) ☐ Unknown

5. Was a gastric aspirate specimen collected? *(CISGASAS)* ☐ 1 - Yes ☐ 0 - No

   If <u>No</u>, reason not collected *(check all that apply)*:

   (CISGANAP) ☐ Not applicable, induced sputum was collected before gastric aspirate was considered.

   (If Not applicable is selected, skip remainder of reasons)

   (CISGCMET) ☐ Child met one or more clinical contraindications

   (CISGPGR) ☐ Parent/guardian refused

   (CISGCDIE) ☐ Child died prior to collection of specimen

(CISGOTHE) ☐ Other   (CISGOSP) Specify: [＿＿＿＿＿＿]   (CISGOCO) Code: [＿＿]

(CISGUNKU) ☐ Unknown

If no specimen was collected (Q 3-5 are 'No'), this form is complete. Sign and date at end.

- *If an ETT aspirate was collected (Q1='Yes'), complete CRF 07ETT.*
- *If an IS was collected, continue with completion of this form.*
- *If a Gastric Aspirate was collected (Q5='Yes'), complete CRF 07GA.*

6. Was an IS sample collected?   (CISFISC) ☐ 1 - Yes   ☐ 0 - No

   First IS collection

   a. Date/time of first IS collection: (CISAISDT) [＿＿＿＿] (ddMMMyyyy) (CISFISTM) [＿＿＿＿] (hh:mm) (24 hr clock)

   b. Staff code: (CISFISCO) [＿＿＿＿]

   c. Enter IS specimen ID (scan barcode label): (CISAISID) [＿＿＿＿]

SAFETY MONITORING

7. List any clinical findings that are relevant to this procedure: (CISLISTA) [＿＿＿＿＿＿＿＿＿＿]

8. Was the induced sputum procedure stopped because oxygen saturation levels dropped below 88%?

(CISSTOPA) ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

9. Record the following clinical measures:

Time point	i. Oxygen requirement (XX.X, L/min) (N/A if not on O2)	ii. Oxygen saturation (%)	iii. Respiratory Rate (per minute)	iv. Conscious Level (check one)
A. Immediately prior to IS procedure	(CISORIPA) [＿＿＿] (xx.x)	(CISOSIPA) [＿＿＿] (xxx)	(CISREIPA) [＿＿＿] (xxx)	(CISCLIPA) 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
	(CISRIPAU) ☐ 8 - UNK ☐ 9 - N/A	(CISSIPAU) ☐ 8 - UNK ☐ 9 - NR	(CISEIPAU) ☐ 8 - UNK ☐ 9 - N/A	
B. Immediately following IS procedure	(CISORIFA) [＿＿＿] (xx.x)	(CISOSIFA) [＿＿＿] (xxx)	(CISREIFA) [＿＿＿] (xxx)	(CISCLIFA) 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
	(CISRIFAU) ☐ 8 - UNK ☐ 9 - N/A	(CISSIFAU) ☐ 8 - UNK ☐ 9 - NR	(CISEIFAU) ☐ 8 - UNK ☐ 9 - N/A	
C. 30 minutes after IS procedure	(CISORTMA) [＿＿＿] (xx.x)	(CISOSTMA) [＿＿＿] (xxx)	(CISRETMA) [＿＿＿] (xxx)	(CISCLTMA) 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
	(CISRTMAU) ☐ 8 - UNK ☐ 9 - N/A	(CISSTMAU) ☐ 8 - UNK ☐ 9 - NR	(CISETMAU) ☐ 8 - UNK ☐ 9 - N/A	

D. 2 hours after IS procedure	(CISORTHA) [＿＿] (xx.x)	(CISOSTHA) [＿＿] (xxx)	(CISRETHA) [＿＿] (xxx)	(CISCLTHA) 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
	(CISRTHAU) ☐ 8 - UNK ☐ 9 - N/A	(CISSTHAU) ☐ 8 - UNK ☐ 9 - NR	(CISETHAU) ☐ 8 - UNK ☐ 9 - N/A	
E. 4 hours after IS procedure	(CISORFHA) [＿＿] (xx.x)	(CISOSFHA) [＿＿] (xxx)	(CISREFHA) [＿＿] (xxx)	(CISCLFHA) 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
	(CISRFHAU) ☐ 8 - UNK ☐ 9 - N/A	(CISSFHAU) ☐ 8 - UNK ☐ 9 - NR	(CISEFHAU) ☐ 8 - UNK ☐ 9 - N/A	

10. Were any of the following observed <u>within four hours</u> following the induced sputum procedure?	1 - Yes	0 - No	8 - UNK
a. Drop in oxygen saturation to below 92%, resulting in increased supply of supplemental oxygen for 10 minutes or more	(CISASATB) ☐	☐	☐
b. New onset of unconsciousness or prostration	(CISANEWO) ☐	☐	☐
c. New requirement for bronchodilator or increased frequency of bronchodilator treatment	(CISAINCR) ☐	☐	☐
d. Death	(CISADEAT) ☐	☐	☐

If any response above is marked Yes, notify the local safety monitor and complete CRF 16 (Case SAE).

SECTION B - ADDITIONAL INDUCED SPUTUM

11. Was an additional induced sputum specimen collected during hospitalization?   (CISADDIS) ☐ 1 - Yes ☐ 0 - No

(If No, sign and end form.)

   a. If Yes, specify reason *(check all that apply)*:   (CISTB) Suspected TB ☐   (CISTREAT) Treatment failure ☐   (CISROUTI) Routine ☐

   b. Date/time of additional IS collection: (CISBISDT) [＿＿] (ddMMMyyyy)   (CISBISTM) [＿＿] (hh:mm) (24 hr clock)

   c. Staff code: (CISBSTCO) [＿＿]

   d. Enter IS specimen ID (scan barcode label):   (CISBISID) [＿＿]

SAFETY MONITORING

12. List any clinical findings that are relevant to this procedure: *(CISLISTB)* [＿＿]

13. Was the induced sputum procedure stopped because oxygen saturation levels dropped below 88%?

(CISSTOPB) ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

14. Record the following clinical measures:

Time point	i. Oxygen requirement *(XX.X, L/min)* *(N/A if not on O2)*	ii. Oxygen saturation *(%)*	iii. Respiratory Rate *(per minute)*	iv. Conscious Level *(check one)*

A. Immediately prior to IS procedure	*(CISORIPB)* [_____] *(xx.x)*	*(CISOSIPB)* [_____] *(xxx)*	*(CISREIPB)* [_____] *(xxx)*	*(CISCLIPB)* 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
	(CISRIPBU) ☐ 8 - UNK ☐ 9 - N/A	*(CISSIPBU)* ☐ 8 - UNK ☐ 9 - NR	*(CISEIPBU)* ☐ 8 - UNK ☐ 9 - N/A	
B. Immediately following IS procedure	*(CISORIFB)* [_____] *(xx.x)*	*(CISOSIFB)* [_____] *(xxx)*	*(CISREIFB)* [_____] *(xxx)*	*(CISCLIFB)* 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
	(CISRIFBU) ☐ 8 - UNK ☐ 9 - N/A	*(CISSIFBU)* ☐ 8 - UNK ☐ 9 - NR	*(CISEIFBU)* ☐ 8 - UNK ☐ 9 - N/A	
C. 30 minutes after IS procedure	*(CISORTMB)* [_____] *(xx.x)*	*(CISOSTMB)* [_____] *(xxx)*	*(CISRETMB)* [_____] *(xxx)*	*(CISCLTMB)* 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
	(CISRTMBU) ☐ 8 - UNK ☐ 9 - N/A	*(CISSTMBU)* ☐ 8 - UNK ☐ 9 - NR	*(CISETMBU)* ☐ 8 - UNK ☐ 9 - N/A	
D. 2 hours after IS procedure	*(CISORTHB)* [_____] *(xx.x)*	*(CISOSTHB)* [_____] *(xxx)*	*(CISRETHB)* [_____] *(xxx)*	*(CISCLTHB)* 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
	(CISRTHBU) ☐ 8 - UNK ☐ 9 - N/A	*(CISSTHBU)* ☐ 8 - UNK ☐ 9 - NR	*(CISETHBU)* ☐ 8 - UNK ☐ 9 - N/A	
E. 4 hours after IS procedure	*(CISORFHB)* [_____] *(xx.x)*	*(CISOSFHB)* [_____] *(xxx)*	*(CISREFHB)* [_____] *(xxx)*	*(CISCLFHB)* 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
	(CISRFHBU) ☐ 8 - UNK ☐ 9 - N/A	*(CISSFHBU)* ☐ 8 - UNK ☐ 9 - NR	*(CISEFHBU)* ☐ 8 - UNK ☐ 9 - N/A	

15. Were any of the following observed <u>within four hours</u> following the second induced sputum procedure?	1 - Yes	0 - No	8 - UNK
a. Drop in oxygen saturation to below 92%, resulting in increased supply of supplemental oxygen for 10 minutes or more	*(CISBSATB)* ☐	☐	☐
b. New onset of unconsciousness or prostration	*(CISBNEWO)* ☐	☐	☐
c. New requirement for bronchodilator or increased frequency of bronchodilator treatment	*(CISBINCR)* ☐	☐	☐
d. Death	*(CISBDEAT)* ☐	☐	☐

If any response above is marked Yes, notify the local safety monitor and complete CRF 16 (Case SAE).

Comments:*(CISCOMM)*

Section A Signature

Form Completed by Staff Code: *(CISFCACO)*

Supervisor Staff Code: *(CISSU1CO)*

Supervisor Verification Date: *(CISVE1DT)*   *(ddMMMyyyy)*

Section B Signature

Supervisor Staff Code: *(CISSU2CO)*

Supervisor Verification Date: *(CISVE2DT)*   *(ddMMMyyyy)*

Initial QC by: *(CISINQC)*

Additional Selection Options for CIS

Conscious prior IS A
9-9 - Pharmacologically sedated

CRF 07ETT: Case - ETT Specimen (SEA)

Segment *(PROTSEG)*:

Specimen number *(SPECNUM)*:

Date specimen collected: *(SEACLDT)* _____ *(ddMMMyyyy)*

1. Time of ETT aspirate collection: *(SEAETTM)* _____ *(hh:mm) (24 hour clock)* *(SEAETTUK)* ☐ 8 - UNK

2. Specimen collected by Staff Code: *(SEAETCO)* _____

3. ETT aspirate specimen ID (scan barcode label): *(SEAETTID)* _____

Comments:*(SEACOMM)*

Initial QC by: *(SEAINQC)* _____

Supervisor Staff Code: *(SEASCO)* _____

Supervisor Verification Date: *(SEASDT)* _____ *(ddMMMyyyy)*

Additional Selection Options for SEA

Specimen number (*SPECNUM*) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15

CRF 07GA: Case - Gastric Aspirate (SGA)

Segment *(PROTSEG)*:
Specimen number *(SPECNUM)*:

Date specimen collected: *(SGAGADT)* _____ *(ddMMMyyyy)*

1. Time of gastric aspirate collection: *(SGAGATM)* _____ *(hh:mm) (24 hour clock)* *(SGATMUKN)* ☐ 8 - UNK

2. Specimen collected by Staff Code: *(SGASPCO)* _____

3. Gastric aspirate specimen ID(scan barcode label): *(SGASPID)* _____

Comments:*(SGACOMM)*

Initial QC by: *(SGAINQC)* _____

Supervisor Staff Code: *(SGASSCO)* _____

Supervisor Verification Date: *(SGASUPDT)* _____ *(ddMMMyyyy)*

Additional Selection Options for SGA

Specimen number (*SPECNUM*) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15

CRF 08: Case CXR (CXR)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

If no CXR is taken, submit a Missing Forms Request.

Date of CXR:*(CXRDT)*   *(ddMMMyyyy)*

1. Time of CXR:*(CXRTM)*   *(24 hour clock)*

2. Is this the initial or a follow-up CXR?   *(CXRINOFU)* ☐ 1 - Initial   ☐ 2 - Follow-up

3. Was an antero-posterior or postero-anterior view image taken? *(CXRANPOS)* ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK
   (If No or UNK, go to Q4)

     If Yes, specimen ID (scan barcode label):   *(CXRAPSID)*

     a. Indicate which view:

1-1 - AP
2-2 - PA
8-8 - UNK

(CXRVIEW)

     b. Indicate position:

1-1 - Supine
2-2 - Upright
9-8 - UNK

(CXRPOSAP)

     c. Captured on inspiration?

1-1 - Yes
0-0 - No
8-8 - UNK

(CXRINSAP)

     d. Quality of image:

1-1 - Good
2-2 - Fair
3-3 - Poor/Uninterpretable
8-8 - UNK

(CXRQUAAP)

4. Was a lateral view image taken?   *(CXRLATER)* ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK
   (If No or UNK, go to Q5)

     If Yes, specimen ID (scan barcode label):   *(CXRLASID)*

     a. Indicate position:

1-1 - Supine
2-2 - Upright
9-8 - UNK

(CXRPOSLA)

     b. Captured on inspiration?

1-1 - Yes
0-0 - No
8-8 - UNK

(CXRINSLA)

     c. Quality of image:

1-1 - Good
2-2 - Fair
3-3 - Poor/Uninterpretable
8-8 - UNK

(CXRQUALA)

5. Was a decubitus image taken?   *(CXRDECUB)* ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK
   (If No or UNK, go to Q6)

     If Yes, specimen ID (scan barcode label):   *(CXRDESID)*

     a. Captured on inspiration?

1-1 - Yes
0-0 - No
8-8 - UNK

(CXRINSDE)

     b. Quality of image:

1-1 - Good
2-2 - Fair
3-3 - Poor/Uninterpretable
8-8 - UNK

(CXRQUADE)

6. CXR interpretation *(mark all that apply)*:

(CXRNORMA) ☐ a. Normal

(CXRABCES) ☐ b. Abscess

(CXRAIRBR) ☐ c. Air bronchogram

(CXRALVEO) ☐ d. Alveolar infiltrate

(CXRATELE) ☐ e. Atelectasis

(CXRBRONC) ☐ f. Bronchial thickening/peribroncial cuffing

(CXRCARDI) ☐ g. Cardiomegaly

(CXRCONSO) ☐ h. Consolidation

-> i. If checked, do the findings indicate eligibility for lung tap?*(CXRELILT)*　　☐ 1 - Yes　☐ 0 - No　☐ 8 - UNK

1. If child is eligible for a lung tap, was the procedure done? *(CXRLUNGT)*　☐ 1 - Yes　☐ 0 - No

If No, reason not collected *(check all that apply)*:

(CXRUNKNO) ☐ Unknown

(CXRCLCON) ☐ Child met one or more clinical contradictions

(CXRREFUS) ☐ Parent/guardian refused

(CXRDEATH) ☐ Child died prior to collection of specimen

(CXROTHER) ☐ Other 　　　Other, specify:*(CXROTHSP)* 　　　Code:*(CXROTHCO)*

(CXRHYPER) ☐ i. Hyperinflation

(CXRINTER) ☐ j. Interstital infiltrate

(CXRLYMPH) ☐ k. Lymphadenopathy or mass

(CXROTHAB) ☐ l. Other abnormalities

(CXRPLEFF) ☐ m. Pleural effusion

(CXRPNATO) ☐ n. Pneumatocoeles

(CXRPNOTH) ☐ o. Pneumothorax

(CXRPULMO) ☐ p. Pulmonary edema

(CXRRETIC) ☐ q. Reticulonodular infiltrate

(CXRUNINT) ☐ r. Unknown/uninterpretable

7. Is the film quality adequate?

1-1 - Adequate
2-2 - Suboptimal
3-3 - Poor/Uninterpretable
8-8 - UNK

(CXRQUFIL)

8. Does this film contain significant pathology?

1-1 - Yes
0-0 - No
8-8 - UNK

(CXRPATHO)

9. Primary end-point consolidation?　Right:

1-1 - Yes
0-0 - No
8-8 - UNK

(CXRPREPR)

Left:

1-1 - Yes
0-0 - No
8-8 - UNK

(CXRPREPL)

10. Other consolidation/infiltrate?　Right:

1-1 - Yes
0-0 - No
8-8 - UNK

(CXROTCIR)

Left:

1-1 - Yes
0-0 - No
8-8 - UNK

(CXROTCIL)

11. Pleural fluid?

Right:

1-1 - Yes
0-0 - No
8-8 - UNK

(CXRPLFLR)

Left:

1-1 - Yes
0-0 - No
8-8 - UNK

(CXRPLFLL)

_CXRFIN_5 12. Conclusion *(check one)*:
1=Primary endpoint pneumonia only
2=Other infiltrate only
3=Both PEP and other infiltrate
4=Normal
5=Uninterpretable

1-1 - Primary end-point consolidation or pleural effusion
2-2 - Other consolidation/infiltrate
3-3 - No consolidation/infiltrate/effusion
4-4 - Uninterpretable

(CXRCONCL)

Comments:*(CXRCOMM)*

_CXRFINCAT_5
1=Abnormal
0=Normal
5=Uninterpretable

Form Completed by Staff Code: *(CXRSTFCO)*

Initial QC by: *(CXRINQC)*

Supervisor Staff Code: *(CXRSUPCO)*

Supervisor Verification Date: *(CXRSVEDT)* *(ddMMMyyyy)*

CRF 08A: Chest X-Ray Evaluation (CXE)

Chest X-ray ID Number *(CXRIMGID):*

1. Primary consolidation:

1-1 - Yes (right)
2-2 - Yes (left)
3-3 - Yes (bilateral)
4-4 - No
5-5 - Uninterpretable for primary consolidation

(CXEPRIMC)

2. Other infiltrate:

1-1 - Yes (right)
2-2 - Yes (left)
3-3 - Yes (bilateral)
4-4 - No
5-5 - Uninterpretable for other infiltrate

(CXEOTHER)

3. Pleural fluid:

1-1 - Yes (right)
2-2 - Yes (left)
3-3 - Yes (bilateral)
4-4 - No

(CXEPLFL)

4. Do you have any concerns about the right/left orientation of this image?

1-1 - Yes
0-0 - No

(CXEORIEN)

5. Conclusion:

_CXRFIN_5
1=Primary endpoint pneumonia only
2=Other infiltrate only
3=Both PEP and other infiltrate
4=Normal
5=Uninterpretable

_CXRFINCAT_5
1=Abnormal
0=Normal
5=Uninterpretable

1-1 - Primary endpoint pneumonia only
2-2 - Other infiltrate only
3-3 - Both PEP and other infiltrate
4-4 - Normal
5-5 - Uninterpretable

(CXECONCL)

1-1a. PEP without other infiltrate
2-1b. PEP and uninterpretable for other infiltrate
3-2a. Other infiltrate without PEP
4-2b. Other infiltrate and uninterpretable for PEP
5-5a. Uninterpretable for PEP only
*Additional Options Listed Below

(CXECONCB)

(CXECONCH) ☐ **This conclusion is confirmed and final.**

Comments:

(CXECOMM)

Additional Selection Options for CXE

Conclusion B

6-5b. Uninterpretable for other infiltrate only

7-5c. Uninterpretable for any findings

CRF 09: Case Specimen Collection: Lung Aspirate (CLA)

Segment *(PROTSEG)*:

Specimen number *(SPECNUM)*:

1. At the initial assessment, does the child have any of the following contraindications to LA collection:

   a. Presence of pneumatocoeles on CXR: *(CLAPPCXR)* ☐ 1 - Yes ☐ 0 - No

   b. Post measles pneumonia: *(CLAPMPNE)* ☐ 1 - Yes ☐ 0 - No

If the answer to any of the above is Yes, do not collect a lung aspirate at this time.
Wait and evaluate the child again at a later point.

Date specimen collected: *(CLALADT)* ☐ *(ddMMMyyyy)*

LUNG ASPIRATE

2. Time of lung aspirate collection: *(CLALATM)* ☐ *(hh:mm) (24 hour clock)*

3. Collection performed by: *(CLACOPER)* ☐ Staff Code: *(CLAPERCO)* ☐

4. Lung aspirate specimen ID (scan barcode label): *(CLASPEID)* ☐

Record the following clinical measures:

Time point	i. Oxygen requirement *(XX.X, L/min)* *(N/A if not on O2)*	ii. Oxygen saturation *(%)*	iii. Respiratory Rate *(per minute)* and Haemoptysis	iv. Conscious Level *(check one)*
A. Immediately prior to LA procedure	*(CLAORIMP)* ☐ *(xx.x)*	*(CLAOSIP)* ☐ *(xxx)*	*(CLARRIP)* ☐ *(xxx)*	*(CLACLIP)* 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
(CLAIPTM) ☐ *(hh:mm)*	*(CLAORIPU)* ☐ 8 - UNK ☐ 9 - N/A	*(CLAOSIPU)* ☐ 8 - UNK ☐ 9 - NR	*(CLARRIPU)* ☐ 8 - UNK ☐ 9 - N/A	
			Haemoptysis: *(CLAHMIP)* ☐ 1 - Yes ☐ 0 - No	
B. Immediately following LA procedure	*(CLAORIF)* ☐ *(xx.x)*	*(CLAOSIF)* ☐ *(xxx)*	*(CLARRIF)* ☐ *(xxx)*	*(CLACLIF)* 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
(CLAIFTM) ☐ *(hh:mm)*	*(CLAORIFU)* ☐ 8 - UNK ☐ 9 - N/A	*(CLAOSIFU)* ☐ 8 - UNK ☐ 9 - NR	*(CLARRIFU)* ☐ 8 - UNK ☐ 9 - N/A	
			Haemoptysis: *(CLAHMIF)* ☐ 1 - Yes ☐ 0 - No	
C. 15 minutes following LA procedure	*(CLAOR15F)* ☐ *(xx.x)*	*(CLAOS15F)* ☐ *(xxx)*	*(CLARR15F)* ☐ *(xxx)*	*(CLACL15F)* 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
(CLA15FTM) ☐ *(hh:mm)*	*(CLAOR15U)* ☐ 8 - UNK ☐ 9 - N/A	*(CLAOS15U)* ☐ 8 - UNK ☐ 9 - NR	*(CLARR15U)* ☐ 8 - UNK ☐ 9 - N/A	
			Haemoptysis: *(CLAHM15F)* ☐ 1 - Yes ☐ 0 - No	

D. 30 minutes following LA procedure	(CLAOR30F) _____ (xx.x)	(CLAOS30F) _____ (xxx)	(CLARR30F) _____ (xxx)	(CLACL30F) 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
(CLA30FTM) _____ (hh:mm)	(CLAOR30U) ☐ 8 - UNK ☐ 9 - N/A	(CLAOS30U) ☐ 8 - UNK ☐ 9 - NR	(CLARR30U) ☐ 8 - UNK ☐ 9 - N/A	
			Haemoptysis:(CLAHM30F) ☐ 1 - Yes ☐ 0 - No	
E. 2 hours after LA procedure	(CLAOR2HF) _____ (xx.x)	(CLAOS2HF) _____ (xxx)	(CLARR2HF) _____ (xxx)	(CLACL2HF) 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
(CLA2HFTM) _____ (hh:mm)	(CLAOR2HU) ☐ 8 - UNK ☐ 9 - N/A	(CLAOS2HU) ☐ 8 - UNK ☐ 9 - NR	(CLARR2HU) ☐ 8 - UNK ☐ 9 - N/A	
			Haemoptysis:(CLAHM2HF) ☐ 1 - Yes ☐ 0 - No	
F. 4 hours after LA procedure	(CLAOR4HF) _____ (xx.x)	(CLAOS4HF) _____ (xxx)	(CLARR4HF) _____ (xxx)	(CLACL4HF) 0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below
(CLA4HFTM) _____ (hh:mm)	(CLAOR4HU) ☐ 8 - UNK ☐ 9 - N/A	(CLAOS4HU) ☐ 8 - UNK ☐ 9 - NR	(CLARR4HU) ☐ 8 - UNK ☐ 9 - N/A	
			Haemoptysis:(CLAHM4HF) ☐ 1 - Yes ☐ 0 - No	

5. Safety Monitoring: Were any of the following observed <u>within four hours</u> following the lung aspirate procedure?	
a. Drop in oxygen saturation below 92%, resulting in increased supply of supplemental oxygen for 10 minutes or more (CLAOXSAT)	1-1 – Yes 0-0 – No 8-8 – UNK
b. New onset of unconsciousness or prostration (CLAUNCON)	1-1 – Yes 0-0 – No 8-8 – UNK
c. New requirement for bronchodilator or increased frequency of bronchodilator treatment (CLARBRON)	1-1 – Yes 0-0 – No 8-8 – UNK
d. Pneumothorax (CLAPNUEM)	1-1 – Yes 0-0 – No 8-8 – UNK
e. Significant haemoptysis (>5mls) at any time following lung aspirate, during the hospitalization (CLAHAEMO)	1-1 – Yes 0-0 – No 8-8 – UNK
f. Death during hospitalization (CLADEATH)	1-1 – Yes 0-0 – No 8-8 – UNK

If any response above is marked YES, notify the local safety monitor and complete CRF 16 (Case SAE).

Note: Beyond the first four hours of surveillance, if the child develops a pneumothorax or dies at any time during hospitalization, the event must be reported to the local safety monitor and CRF 16 (Case SAE) must be completed.

Comments:*(CLACOMM)*

Initial QC by: *(CLAINQC)*

Supervisor Staff Code: *(CLASUPCO)*

Supervisor Verification Date: *(CLAVERDT)*   *(ddMMMyyyy)*

Additional Selection Options for CLA

Specimen number (SPECNUM) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15

Conscious prior LA
9-9 - Pharmacologically sedated

CRF 10: Case - Pleural Fluid (SPF)

Segment *(PROTSEG)*:
Specimen number *(SPECNUM)*:

Date specimen collected: *(SPFPFDT)* _____ *(ddMMMyyyy)*

1. Time of pleural fluid collection: *(SPFPFTM)* _____ *(hh:mm)* *(24 hour clock)* *(SPFTMUNK)* ☐ 8 - UNK

2. Specimen collected by Staff Code: *(SPFSPCO)* |

3. Pleural fluid specimen ID (scan barcode label): *(SPFSPID)* |

Comments:*(SPFCOMM)*

Initial QC by: *(SPFINQC)* _____

Supervisor Staff Code: *(SPFSSCO)* _____

Supervisor Verification Date: *(SPFSUPDT)* _____ *(ddMMMyyyy)*

Additional Selection Options for SPF

Specimen number (*SPECNUM*) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15

CRF 11: Case Admission Medications (CAM)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

1. Were antibiotics administered at the study hospital on the day of admission? *(CAMABADM)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

   If Yes, check all that apply:

Antibiotic	Administered	Mode of Administration
a. Penicillin	*(CAMPENIC)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMPENM)*
b. Amoxicillin (Ampicillin)	*(CAMAMOX)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMAMOXM)*
c. Amoxicillin/Clavulanate (Augmentin)	*(CAMAMCLA)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMAMCLM)*
d. Cotrimoxazole (Bactrim, Septrin)	*(CAMCOTRI)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMCOTRM)*
e. Cefuroxime (2nd gen. Cephalosporin)	*(CAMCEFUR)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMCEFUM)*
f. Ceftriaxone (3rd gen. Cephalosporin)	*(CAMCEFTR)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMCEFTM)*
g. Ganciclovir	*(CAMGANCI)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMGANCM)*
h. Macrolide (Azithromycin, Erythromycin)	*(CAMACRO)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMACROM)*
i. Aminoglycoside (Gentamicin)	*(CAMAMINO)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMAMINM)*
j. Chloramphenicol	*(CAMCHLOR)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMCHLOM)*
k. Ciprofloxacin (Quinolone)	*(CAMCIPRO)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMCIPRM)*
l. Cloxacillin	*(CAMCLOX)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMCLOXM)*

Antibiotic	Other Code	Administered	Mode of Administration
m. Other antibiotic: *(CAMOABSP)*	*(CAMOTHCO)*	*(CAMOTHAB)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CAMOTHM)*

n. Date and time **first** antibiotic was administered in the study hospital:

(CAM1ABDT) Date: _____ (CAM1DUNK) ☐ 8 - UNK (CAM1ABTM) Time: _____ (hh:mm) (24 hour (CAM1UNK) ☐ 8 - UNK
(ddMMMyyyy)   clock)

Was antibiotic administered <u>before</u> collection of each of the following specimens?

_PRABXBC
1=Yes
0=No

o. Blood culture

| 1-1 - Yes |
| 0-0 - No |
| 8-8 - UNK |
| 9-9 - N/A |
(CAMBEFBC)

_PRABXNP
1=Yes
0=No

p. NPS-VTM, OPS, NPS-STGG

| 1-1 - Yes |
| 0-0 - No |
| 8-8 - UNK |
| 9-9 - N/A |
(CAMBEFNP)

_PRABXUR
1=Yes
0=No

q. Urine

| 1-1 - Yes |
| 0-0 - No |
| 8-8 - UNK |
| 9-9 - N/A |
(CAMBEFUR)

_PRABXIS
1=Yes
0=No

r. Induced sputum

| 1-1 - Yes |
| 0-0 - No |
| 8-8 - UNK |
| 9-9 - N/A |
(CAMBEFIS)

2. Was a medication to treat influenza administered on the day of admission? (CAMINFLU) ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

If Yes, check all that apply:

a.(CAMOSELT) ☐ Oseltamivir

b.(CAMZANAM) ☐ Zanamivir

c.(CAMOTMED) ☐ Other (CAMOTMSP) Specify: _____ (CAMINFCO) Code: _____

d. Date and time **first** influenza medication was administered:

(CAMINFDT) Date: _____ (CAMIDUNK) ☐ 8 - UNK (CAMINFTM) Time: _____ (hh:mm) (24 hour (CAMINUNK) ☐ 8 - UNK
(ddMMMyyyy)   clock)

3. Were steroids administered on the day of admission? (CAMSTERO) ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

a. If Yes, specify type:

| 1-1 - Oral |
| 2-2 - Inhaled |
| 3-3 - Intramuscular |
| 4-4 - Intravenous |
| 8-8 - UNK |
(CAMSTYPE)

b. Date **first** dose of steroids was administered: (CAMSTEDT) _____ (ddMMMyyyy)

4. Have bronchodilators been administered on the day of admission? (CAMBRONC) ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK
(*as part of bronchodilator challenge or otherwise*)

5. Were medications to treat TB administered on the day of admission? (CAMTBMED) ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

If Yes, check all that apply:

Medication	Administered	Mode of Administration
a. Fixed Drug Combinations	(CAMTBFIX) ☐	1-1 - Oral / 2-2 - Parenteral / 8-8 - UNK (CAMFIXM)
b. INH	(CAMTBINH) ☐	1-1 - Oral / 2-2 - Parenteral / 8-8 - UNK (CAMINHM)
c. Ethambutol	(CAMTBETH) ☐	1-1 - Oral / 2-2 - Parenteral / 8-8 - UNK (CAMETHM)

d. Rifampin   *(CAMTBRIF)* ☐

(CAMRIFAM)
```
1-1 - Oral
2-2 - Parenteral
8-8 - UNK
```

e. Pyrazinamide   *(CAMTBPYR)* ☐

(CAMPYRAM)
```
1-1 - Oral
2-2 - Parenteral
8-8 - UNK
```

	Medication	**Other Code**	**Administered**	**Mode of Administration**

f. Other medication: *(CAMTBOCO)* [ ]   *(CAMTBOTA)* ☐

(CAMTBOSP) [ ]

(CAMOTHTM)
```
1-1 - Oral
2-2 - Parenteral
8-8 - UNK
```

g. Date <u>first</u> TB medication was administered: *(CAMTBDT)* [ ] *(ddMMMyyyy)*

Comments:

(CAMCOMM) [ ]

Form completed by Staff Code: *(CAMSTAFF)* [ ]

Initial QC by: *(CAMINQC)* [ ]

Supervisor Staff Code: *(CAMSUPER)* [ ]

Supervisor Verification Date: *(CAMSUPDT)* [ ] *(ddMMMyyyy)*

CRF 12: Case 24/48-Hour Follow-up (CFU)
Select variables included in _clin dataset with
24-hour or 48-hour indication (see below)

Web Version: 1.0; 6.03; 16APR13

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

Visit date: *(CFUVISDT)* [ ] *(ddMMMyyyy)*

Complete this form on each of the two days following admission.

1. Check which post-admission assessment is being performed: *(CFUVIDAY)* [ ] 1 - 24 hours [ ] 2 - 48 hours

2. Time of assessment: *(CFUVISTM)* [ ] *(hh:mm) (24 hour clock)*

3. Location of assessment: *(CFULOCAT)* [ ] 1 - Hospital [ ] 2 - Clinic [ ] 3 - Home

4. Temperature: *(CFUTEMP)* [ ] *(xx.x)* ˚C
   Source: *(CFUTEMPT)* [ ]
   1-1 - Axillary
   2-2 - Rectal
   (CFUTSTAT) [ ] 8 - UNK

5. Respiratory rate (# of breaths counted in 60 seconds): *(CFURR)* [ ] *(xxx)* per minute *(CFURRNA)* [ ] 8 - UNK [ ] 9 - N/A

6. Is child on O_2? *(If No or Unknown, skip to Q7)*:
   CFUOXTGN24
   CFUOXTGN48
   (CFUOXTGN) [ ]
   1-1 - Yes
   0-0 - No
   8-8 - UNK

   a. If Yes, oxygen delivery flow rate? *(CFUOXFLO)* [ ] *(xx.x)* L/min *(CFUOUNK)* [ ] 8 - UNK

7. Is child receiving mechanical ventilation?
   (CFUMVENT) [ ]
   1-1 - Yes
   0-0 - No
   8-8 - UNK

8. Pulse oximetry *(on room air whenever possible)*: *(CFUPLSOX)* [ ] % *(CFUPOUNK)* [ ] 8 - UNK
   CFUPLSOX24
   CFUPLSOX48
   a. Measured when child was on:
   CFUAIRTP24
   CFUAIRTP48
   (CFUAIRTP) [ ]
   1-1 - O2
   2-2 - Room air
   8-8 - UNK

CLINICAL STATUS

9. On exam today, does the child have any of the following signs?	
a. Lower chest wall indrawing: *(CFULCWI)*	1-1 - Yes 0-0 - No 8-8 - UNK
b. Head nodding: *(CFUHEAD)*	1-1 - Yes 0-0 - No 8-8 - UNK
c. Central cyanosis: *(CFUCENTR)*	1-1 - Yes 0-0 - No 8-8 - UNK
d. Unable to feed: *(CFUFEED)*	1-1 - Yes 0-0 - No 8-8 - UNK
e. Vomiting everything: *(CFUVOM)*	1-1 - Yes 0-0 - No 8-8 - UNK
f. Lethargy, or unconsciousness: *(CFULETH)*	0-0 - A: Alert & awake 1-1 - V: Responds to voice 2-2 - P: Responds to pain 3-3 - U: Unresponsive 8-8 - UNK *Additional Options Listed Below

If V, P or U are ticked, the child has lethargy or impaired consciousness.

<u>NOTE</u>: *wait for >30 minutes after any convulsion before carrying out assessment of consciousness level.*

10. Did the child have convulsions since the last assessment?

<table>
<tr><td>1-1 - Yes
0-0 - No
8-8 - UNK</td></tr>
</table>

(CFUCONV)

    a. If Yes, what kind (*check all that apply*):

(CFUMCONV) ☐ Multiple (≥2 episodes)   *(CFUPCONV)* ☐ Prolonged (≥15 minutes)   *(CFUSCONV)* ☐ Single brief (<15 minutes)

11. What is the WHO pneumonia severity classification?

<table>
<tr><td>1-1 - Very severe
2-2 - Severe
3-3 - Neither
8-8 - UNK</td></tr>
</table>

(CFUPNEUM)

MEDICATION

12. Has any additional medication for <u>treatment of wheeze</u> been administered since enrollment? *(CFUMEDW)* ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

    (other than any bronchodilator challenge doses administered at enrollment)

13. Which antibiotics is the child currently on, including medication added during this assessment? *(check all that apply):*

Antibiotic:	Administered:	Mode of administration?
a. Penicillin:	*(CFUPENIC)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUPENM)*
b. Amoxicillin (Ampicillin):	*(CFUAMAD)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUAMOXM)*
c. Amoxicillin & Clavulonate (Augmentin):	*(CFUAMCLA)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUAMCLM)*
d. Cotrimoxizole (Bactrim, Septrin):	*(CFUCOTRI)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUCOTRM)*
e. Cefuroxime (2nd gen. Cephalosporin):	*(CFUCEFUR)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUCEFUM)*
f. Ceftriaxone (3rd gen. Cephalosporin):	*(CFUCEFTR)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUCEFTM)*
g. Macrolide (Azithromycin, Erythromycin):	*(CFUACRO)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUACROM)*
h. Aminoglycoside (Gentamicin):	*(CFUAMINO)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUAMINM)*
i. Cloxacillin:	*(CFUCLOX)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUCLOXM)*
j. Chloramphenicol:	*(CFUCHLOR)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUCHLOM)*
k. Ganciclovir:	*(CFUGANCI)* ☐	1-1 - Oral 2-2 - Parenteral 8-8 - UNK *(CFUGANCM)*

Antibiotic: Code: Administered: Mode of Administration:

l. Any Quinolone: *(CFUQUISP)* [_____] *(CFUQUICO)* [_____] *(CFUQUINO)* ☐

(CFUQUINM)
| 1-1 - Oral |
| 2-2 - Parenteral |
| 8-8 - UNK |

m. Other antibiotic: *(CFUATBSP)* [_____] *(CFUABXCO)* [_____] *(CFUABXAD)* ☐

(CFUABXM)
| 1-1 - Oral |
| 2-2 - Parenteral |
| 8-8 - UNK |

14. If antibiotics were changed since last assessment, specify why: *(CFUABXCH)*

| 01-01 - New findings on CXR |
| 02-02 - Changed to oral antibiotics |
| 03-03 - Changed because of diagnostic test result |
| 04-04 - Allergic reaction to medication |
| 05-05 - Not responding to initial therapy |
| *Additional Options Listed Below |

Other, specify: *(CFUANTSP)* [_____] *(CFUABCCO)* Code: [_____]

15. Was a medication to treat influenza (e.g. oseltamavir) added since the last assessment?

(CFUFMED) ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

16. Since admission (or last assessment) has the child been started on medication to treat or prevent PCP?

(CFUPCPMD)
| 1-1 - Yes |
| 0-0 - No |
| 8-8 - UNK |

(If Yes, answer questions below; if No or UNK, skip to Q17)

a. Why started?

(CFUPCPST)
| 1-1 - PCP preventive therapy (if checked, answer Q16b, skip Q16c and proceed to Q17) |
| 2-2 - PCP treatment (if checked, answer both Q16b and Q16c) |

Medication:	Administered:	Why started?	
b. Cotrimoxazole (Septrin, Bactrim):	*(CFUCORTM)* ☐	01-01 - Clinical suspicion of PCP 02-02 - Lab test results suggest PCP 03-03 - Newly recognized risk factor, e.g. HIV 04-04 - Prevention of PCP 08-08 - UNK *Additional Options Listed Below *(CFUCORTR)*	
		Other, specify: *(CFUCORSP)* [_____]	Code: *(CFUCORCO)* [_____]
c. Corticosteroids:	*(CFUCSTRD)* ☐	01-01 - Clinical suspicion of PCP 02-02 - Lab test results suggest PCP 03-03 - Newly recognized risk factor, e.g. HIV 08-08 - UNK 99-99 - Other *(CFUCSTDR)*	
		Other, specify: *(CFUCSTSP)* [_____]	Code: *(CFUCSTCO)* [_____]

17. Have any TB meds been started since the last assessment?

(CFUTBMED)
| 1-1 - Yes |
| 0-0 - No |
| 8-8 - UNK |

a. If Yes, why started? *(Check all that apply)*

Unknown: *(CFUTBMUN)* ☐

Contact history: *(CFUTBCHX)* ☐

CXR: *(CFUTBCXR)* ☐

Clinical suspicion: *(CFUTBCLI)* ☐

Diagnostic test: *(CFUTBDTS)* ☐

TB skin test: *(CFUTBTST)* ☐

  i. What is the TST result? *(CFUTBSMM)* [_____] *(xx)* mm

Other: *(CFUTBOTH)* ☐

i. Other, specify: *(CFUTBOSP)* [_____] Code: *(CFUTBOCO)* [_____]

Comments *(CFUCOMM)*

Form completed by Staff Code: *(CFUSTAFF)*

Initial QC by: *(CFUINQC)*

Supervisor Staff Code: *(CFUSUPER)*

Supervisor Verification Date: *(CFUSUPDT)* *(ddMMMyyyy)*

Additional Selection Options for CFU

Lethargy
9-9 - Pharmacologically sedated

Antibiotic change
06-06 - Stock (out of initial antibiotics)
08-08 - UNK
09-09 - N/A
99-99 - Other

Cotrimoxazole reason
99-99 - Other

CRF 13: Case Discharge (CDC)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

1. Date of discharge: *(CDCDISDT)* ☐ *(ddMMMyyyy)*

_HOSPDIED
1=Yes
0=No

```
1-1 - Discharged home: not moribund
2-2 - Discharged home: moribund
3-3 - Left against medical advice: not moribund
4-4 - Left against medical advice: moribund
5-5 - Died (skip to Q5 and complete CRF 17 Case Mortality)
*Additional Options Listed Below
```

2. Discharge status *(check one)*: *(CDCSTATU)*

```
01-01 - For higher level facility
02-02 - To be closer to home
03-03 - Convalescent care for patient in moribund state (i.e, lower level facility)
08-08 - UNK
99-99 - Other
```

a. Reason for transfer? *(CDCTREAS)*

Other, specify: *(CDCTROSP)* ☐   Code: *(CDCTROCO)* ☐

3. Respiratory rate *(# of breaths counted in 60 seconds)*: *(CDCRR)* ☐ *(xxx) per minute*   *(CDCRRNA)* ☐ 8 - UNK   ☐ 9 - N/A

4. Pulse oximetry *(on room air whenever possible - record from digit)*: *(CDCPLSOX)* ☐ *(xxx) %* *(CDCPOUNK)* ☐ 8 - UNK

5. Were antibiotics changed since last assessment? *(CDCABXCH)* ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

a. If Yes, why? *(Check all that apply)*

(CDCANCXR) ☐ New findings on CXR   *(CDCNRESP)* ☐ Not responding to initial therapy   *(CDCIVPO)* ☐ Change from IV to PO medication

(CDCALLER) ☐ Allergic reaction to med   *(CDCSTOCK)* ☐ Stock-out of initial antibiotics

(CDCANOTH) ☐ Other   Other, specify: *(CDCANTSP)* ☐   Code: *(CDCABCCO)* ☐

6. Was medication to treat influenza (e.g., oseltamavir) added since last assessment? *(CDCCFUFM)*   ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

7. Were any TB meds started since last assessment? *(CDCTBMED)*   ☐ 1 - Yes   ☐ 0 - No   ☐ 8 - UNK

a. If Yes, why? *(Check all that apply)*

(CDCTBCHX) ☐ Contact history   *(CDCTBUN)* ☐ 8 - UNK

(CDCTBCXR) ☐ CXR finding

(CDCTBCLI) ☐ Clinical suspicion

(CDCTBTST) ☐ TB skin test   If checked-> i. What is the TST result? *(CDCTSTRT)* ☐ *(xx) mm* *(CDCTSTUN)* ☐ 8 - UNK

(CDCTBDTS) ☐ Diagnostic test

(CDCTBOTH) ☐ Other   Other, specify: *(CDCTBOSP)* ☐   Code: *(CDCTBOCO)* ☐

8. Since last assessment has the child been started on medication to treat or prevent PCP? *(CDCPCPMD)*

```
1-1 - Yes
0-0 - No
8-8 - UNK
```

(If Yes, answer questions below; if No or UNK, skip to Q9)

a. Why started?

```
1-1 - PCP preventive therapy (if checked, answer Q8b, skip Q8c and proceed to Q9)
2-2 - PCP treatment (if checked, answer both Q8b and Q8c)
```

(CDCPCPST)

Medication:	Administered:	Why started?	

b. Cotrimoxazole (Septrin, Bactrim):	(CDCCORTM) ☐	*(CDCCORTR)* 01-01 - Clinical suspicion of PCP 02-02 - Lab test results suggest PCP 03-03 - Newly recognized risk factor, e.g. HIV 04-04 - Prevention of PCP 08-08 - UNK *Additional Options Listed Below		
		Other, specify: *(CDCCORSP)*	Code: *(CDCCORCO)*	
c. Corticosteroids:	(CDCCSTRD) ☐	*(CDCCSTDR)* 01-01 - Clinical suspicion of PCP 02-02 - Lab test results suggest PCP 03-03 - Newly recognized risk factor, e.g. HIV 08-08 - UNK 99-99 - Other		
		Other, specify: *(CDCCSTSP)*	Code: *(CDCCSTCO)*	

9. Discharge diagnoses *(check all that apply):*　　*(CDCDIAUN)* ☐ 8 - UNK　　**_DISCHDX**

(CDCPNEAA) ☐　Pneumonia　　　　　　　*(CDCMALAA)* ☐　Malaria

(CDCBRONA) ☐　Bronchiolitis (Acute)　　　*(CDCMALNA)* ☐　Malnutrition

(CDCLRTIA) ☐　Lower respiratory tract infection　*(CDCMENIA)* ☐　Meningitis

(CDCAFEBA) ☐　Afebrile seizure disorder　　*(CDCMUCOA)* ☐　Mucocutaneous candidiasis

(CDCANUNA) ☐　Anaemia - cause unknown　　*(CDCNEONA)* ☐　Neonatal sepsis

(CDCANHFA) ☐　Anaemic heart failure　　　*(CDCOSTEA)* ☐　Osteomyelitis (Acute)

(CDCASTHA) ☐　Asthma (Acute)　　　　　　*(CDCOTITA)* ☐　Otitis media

(CDCBIASA) ☐　Birth asphyxia　　　　　　*(CDCPCPPA)* ☐　PCP pneumonia

(CDCCELLA) ☐　Cellulitis　　　　　　　　*(CDCPNEXA)* ☐　Pneumothorax - primary and secondary

(CDCCEREA) ☐　Cerebral palsy　　　　　　*(CDCPOISA)* ☐　Poisoning

(CDCCOHDA) ☐　Congenital heart disease　　*(clinically suspected or echo-diagnosed)*

(CDCCOABA) ☐　Congenital abnormality　　*(excluding congenital heart disease)*

(CDCDIARA) ☐　Diarrhoeal disease (Acute)　*(CDCPREMA)* ☐　Prematurity

(CDCDYSEA) ☐　Dysentery　　　　　　　*(CDCPROTA)* ☐　Protein energy malnutrition

(CDCEMPYA) ☐　Empyema thoracis　　　　*(CDCPULMA)* ☐　Pulmonary TB

(CDCEPILA) ☐　Epilepsy　　　　　　　　*(CDCSEARA)* ☐　Septic arthritis

(CDCFAILA) ☐　Failure to thrive　　　　　*(CDCSEAEA)* ☐　Septicaemia

(CDCFEBRA) ☐　Febrile convulsion (Acute)　*(CDCSICAA)* ☐　Sickle cell anaemia

(CDCGASTA) ☐　Gastroenteritis　　　　　*(CDCSICDA)* ☐　Sickle cell disease

(CDCHELMA) ☐　Helminthiasis　　　　　　*(CDCSKINA)* ☐　Skin sepsis

(CDCHIVA) ☐　HIV　　　　　　　　　　*(CDCURINA)* ☐　Urinary tract infection

(CDCIMMUA) ☐　Immunosuppression　　　*(CDCURTIA)* ☐　Upper respiratory tract infection

(CDCOTHAA) ☐　Other　Other, specify: *(CDCOAASP)*　　　　　Code: *(CDCOAACO)*

(CDCOTHBA) ☐　Other　Other, specify: *(CDCOBASP)*　　　　　Code: *(CDCOBACO)*

(CDCOTHCA) ☐　Other　Other, specify: *(CDCOCASP)*　　　　　Code: *(CDCOCACO)*

10. All other concurrent conditions *(check all that apply):*　*(CDCCONUN)* ☐ 8 - UNK　　*(CDCNONEB)* ☐ 9 - NONE

(CDCPNEAB) ☐　Pneumonia　　　　　　　*(CDCMALAB)* ☐　Malaria

(CDCBRONB) ☐　Bronchiolitis (Acute)　　　*(CDCMALNB)* ☐　Malnutrition

(CDCLRTIB) ☐　Lower respiratory tract infection　*(CDCMENIB)* ☐　Meningitis

(CDCAFEBB) ☐　Afebrile seizure disorder　　*(CDCMUCOB)* ☐　Mucocutaneous candidiasis

(CDCANUNB) ☐　Anaemia - cause unknown　　*(CDCNEONB)* ☐　Neonatal sepsis

(CDCANHFB) ☐　Anaemic heart failure　　　*(CDCOSTEB)* ☐　Osteomyelitis (Acute)

(CDCASTHB) ☐ Asthma (Acute)	*(CDCOTITB)* ☐ Otitis media
(CDCBIASB) ☐ Birth asphyxia	*(CDCPCPPB)* ☐ PCP pneumonia
(CDCCELLB) ☐ Cellulitis	*(CDCPNEXB)* ☐ Pneumothorax - primary and secondary
(CDCCEREB) ☐ Cerebral palsy	*(CDCPOISB)* ☐ Poisoning
(CDCCOHDB) ☐ Congenital heart disease	*(clinically suspected or echo-diagnosed)*
(CDCCOABB) ☐ Congenital abnormality	*(excluding congenital heart disease)*
(CDCDIARB) ☐ Diarrhoeal disease (Acute)	*(CDCPREMB)* ☐ Prematurity
(CDCDYSEB) ☐ Dysentery	*(CDCPROTB)* ☐ Protein energy malnutrition
(CDCEMPYB) ☐ Empyema thoracis	*(CDCPULMB)* ☐ Pulmonary TB
(CDCEPILB) ☐ Epilepsy	*(CDCSEARB)* ☐ Septic arthritis
(CDCFAILB) ☐ Failure to thrive	*(CDCSEAEB)* ☐ Septicaemia
(CDCFEBRB) ☐ Febrile convulsion (Acute)	*(CDCSICAB)* ☐ Sickle cell anaemia
(CDCGASTB) ☐ Gastroenteritis	*(CDCSICDB)* ☐ Sickle cell disease
(CDCHELMB) ☐ Helminthiasis	*(CDCSKINB)* ☐ Skin sepsis
(CDCHIVB) ☐ HIV	*(CDCURINB)* ☐ Urinary tract infection
(CDCIMMUB) ☐ Immunosuppression	*(CDCURTIB)* ☐ Upper respiratory tract infection

(CDCOTHDB) ☐ Other   Other, specify:*(CDCODBSP)* [＿＿＿＿＿＿]   Code:*(CDCODBCO)* [＿＿]

(CDCOTHEB) ☐ Other   Other, specify:*(CDCOEBSP)* [＿＿＿＿＿＿]   Code:*(CDCOEBCO)* [＿＿]

(CDCOTHFB) ☐ Other   Other, specify:*(CDCOFBSP)* [＿＿＿＿＿＿]   Code:*(CDCOFBCO)* [＿＿]

Comments:*(CDCCOMM)*

[＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿]

Form Completed by Staff Code:*(CDCFCBCO)* [＿＿＿]

Initial QC by:*(CDCINQC)* [＿＿＿＿＿]

Supervisor Staff Code:*(CDCSUPCO)* [＿＿＿]

Supervisor Verification Date:*(CDCVERDT)* [＿＿＿]   *(ddMMMyyyy)*

Additional Selection Options for CDC

2. Discharge status *(check one)*:
6-6 - Transferred (if transferred, complete Q2a)

Cotrimoxazole reason
99-99 - Other

CRF 14: Case 30-Day Follow-up (CSF)

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

NOTE: This form does not need to be completed if the child died prior to discharge.

Date of follow-up: *(CSFFUDT)* [ ] *(ddMMMyyyy)*

1. Was a follow-up interview conducted? *(CSFINTER)* ☐ 1 - Yes ☐ 0 - No

   At least two attempts must be made to contact the patient. A phone interview is only acceptable if an in person visit is not possible.

   a. If Yes, location of follow-up:

01-01 - Facility
02-02 - By phone
03-03 - At child's home
08-08 - UNK
99-99 - Other

   (CSFLOC)

   Other, specify: *(CSFFUSP)* [ ]   Code: *(CSFFUCO)* [ ]

   b. If No, provide reason for no follow-up interview:

   (CSFNOFOL)
01-01 - Child out-migrated or moved to unknown address
02-02 - Child travelled out of study area
03-03 - Parent refused
04-04 - Unable to locate child during follow-up period
05-05 - Child died after discharge
*Additional Options Listed Below

   Other, specify: *(CSFNOSP)* [ ]   Cod [ ]

2. Who was interviewed? *(check all that apply, if not Unknown)*

   (CSFINTU) ☐ Unknown

   (CSFINTMO) ☐ Mother

   (CSFINTFA) ☐ Father

   (CSFINTCA) ☐ Caregiver (non-parent)

   (CSFINTOR) ☐ Other relative
   or household
   member (non-caregiver)

   (CSFINTNE) ☐ Neighbor

   (CSFINTOT) ☐ Other   Other, specify: *(CSFINTSP)* [ ]   Code: *(CSFINTCO)* [ ]

_DIED
1=Yes
0=No

3. Child's vital status:

1-1 - Living
2-2 - Deceased
8-8 - UNK

   (CSFVITST)

4. Was child observed?

1-1 - Yes
0-0 - No
8-8 - UNK

   (CSFCHOBS)

5. Height/length: *(CSFHELE)* [ ] *(xxx.x) cm*   *(CSFHELEU)* ☐ 8 - UNK

6. Weight: *(CSFWEIGH)* [ ] *(xx.x) kg*   *(CSFWEIGU)* ☐ 8 - UNK

7. Mid-upper arm circumference (MUAC): *(CSFARMCI)* [ ] *(xxx) mm*   *(CSFARMCU)* ☐ 8 - UNK ☐ 9 - N/A

8. Respiratory rate *(# of breaths counted in 60 seconds)*: *(CSFRR)* [ ] *(xxx) per minute*   *(CSFRRNA)* ☐ 8 - UNK ☐ 9 - N/A

9. If in facility, pulse oximetry *(on room air whenever possible; record from digit)*: *(CSFPLSOX)* [ ] *(xxx) %*   *(CSFPOUNK)* ☐ 8 - UNK ☐ 9 - N/A

10. Was convalescent blood collected?
    (plain/red top tube - collect 4 mL; minimum 2 mL)

1-1 - Yes
0-0 - No
8-8 - UNK

    (CSFBLCOL)

    If Yes, complete Q10 a-c and fill out CRF 19.
    If No, complete Q10d.

    a. Date of blood collection: *(CSFBLCDT)* [ ] *(ddMMMyyyy)*

    b. Time of blood collection: *(CSFBLCTM)* [ ] *(hh:mm) (24 hour clock)*

c. Blood specimen ID (scan barcode label): *(CSFBSPID)*

d. Reason why not? *(CSFREACB)*

01-01 - Parent refused
02-02 - Phlebotomist unable to collect blood
08-08 - UNK
99-99 - Other

Other, specify:*(CSFRECSP)*   Code:

Question 11 is For HIV-positive cases only:

11. Was EDTA blood obtained for CD4 testing?

1-1 - Yes
0-0 - No
8-8 - UNK
9-9 - N/A

(CSFEDTA)

If Yes, complete Q11 a and fill out CRF 19.
If No, complete Q11 b.

a. EDTA blood specimen ID (barcode label): *(CSFESPID)*

b. Reason why not? *(CSFREAED)*   Other, specify:*(CSFEOSP)*

01-01 - Parent refused
02-02 - CD4 count obtained from Patient Support Center/ART Treatment clinic
08-08 - UNK
99-99 - Other

12. Urine collected?

1-1 - Yes
0-0 - No
8-8 - UNK

(CSFURINE)

If Yes, complete Q12 a-d and fill out CRF 19.
If No, complete Q 12e.

a. Date of urine collection: *(CSFURIDT)*   *(ddMMMyyyy)*

b. Time of urine collection: *(CSFURITM)*   *(hh:mm) (24 hour clock)*

c. Urine specimen ID (scan barcode label): *(CSFURIID)*

d. Container collected in: *(CSFURCOL)*

1-1 - Sterile cup
2-2 - Urine bag

e. Reason why not? *(CSFREAUR)*

01-01 - Parent refused
02-02 - Child did not void
08-08 - UNK
99-99 - Other

Other, specify:*(CSFURISP)*   Code:

Comments:*(CSFCOMM)*

Collection Performed By Staff Code: *(CSFCOSCO)*

Initial QC by: *(CSFINQC)*

Supervisor Staff Code: *(CSFSUPCO)*

Supervisor Verification Date: *(CSFVERDT)*   *(ddMMMyyyy)*

Additional Selection Options for CSF

Reason for no follow-up
08-08 - UNK
99-99 - Other

CRF 15: Case Specimen Collection: Consent (CPC)

Segment *(PROTSEG)*:

(CPCCONSE) ☐ **Please check this box which confirms that a consent form was signed for the lung biopsy**

CRF 15: Case Specimen Collection: Post-Mortem Lung Biopsy (CPM)

Web Version: 1.0; 1.02; 16APR13

Segment *(PROTSEG)*:

Date of lung biopsy:*(CPMLBDT)* [ ] *(ddMMMyyyy)*

Percutaneous Needle Biopsy

1. Time of postmortem lung biopsy or pleural aspiration: *(CPMLBTM)* [ ] *(hh:mm)* *(24 hr clock)* *(CPM1UNK)* ☐ 8 - UNK

2. Death-biopsy (or aspiration) interval in hours: *(CPMDBINT)* [ ] *(xx)* *(CPM2UNK)* ☐ 8 - UNK

3. Procedure performed by Staff Code: *(CPMPSTCO)* [ ]

4. Was at least one lung biopsy successfully collected? *(CPMLBCOL)* ☐ 1 - Yes   ☐ 0 - No

   (If Yes, skip to Q6. If No, complete questions 5 a-b below and then end form.)

5. Only if unable to take any core biopsies (Q4 is No), attempt pleural aspiration. If antemortem chest x-ray was done, target aspiration from any effusion if present, or area of consolidation.

   Was pleural fluid/aspirate taken from:

   a. Right Lung: *(CPMRLUNG)* ☐ 1 - Yes   ☐ 0 - No   Specimen ID (scan barcode label):*(CPMRLBID)* [ ]

   b. Left Lung: *(CPMLLUNG)* ☐ 1 - Yes   ☐ 0 - No   Specimen ID (scan barcode label):*(CPMLLBID)* [ ]

6. What was the site of disease as diagnosed by clinical exam and chest x-ray?

1-1 - Localised (lobar pneumonia)
2-2 - Diffuse disease
8-8 - Unknown

   (CPMSITE)

   (If 1 - Localised is selected complete Q7. If 2 - Diffuse disease or 8 - Unknown is selected, skip to Q8.)

7. Sampling Protocol for **Localised (Lobar) Pneumonia**: (To minimize contamination, please collect the samples in the order specified below)

   Note: if collection difficult, prioritise 1 sample for microbiology, 1 sample for histology and 1 sample to be stored in RNAlater as indicated by underlining below (Sample types b,e,g):

   a) Site(s) of Disease *(check all that apply)*   *(CPMRUL)* ☐ Right Upper Lobe (RUL)   *(CPMRML)* ☐ Right Middle Lower (RML)   *(CPMRLL)* ☐ Right Lower Lobe (RLL)   *(CPMLUL)* ☐ Left Upper Lobe (LUL)   *(CPMLLL)* ☐ Left Lower Lobe (LLL)

Sample Type	Tube	Specimen ID (scan barcode label):
b) Microbiology core from a **diseased lobe** Core collected?*(CPMLM1ST)* ☐ 1 - Yes ☐ 0 - No	**Tube M1**	*(CPMLM1ID)* [ ]
c) Microbiology core from a **diseased lobe** Core collected?*(CPMLM2ST)* ☐ 1 - Yes ☐ 0 - No	**Tube M2**	*(CPMLM2ID)* [ ]
d) Microbiology core from a **diseased lobe** Core collected?*(CPMLM3ST)* ☐ 1 - Yes ☐ 0 - No	**Tube M3**	*(CPMLM3ID)* [ ]
e) RNAlater sample from a **diseased lobe** Core collected?*(CPMLR1ST)* ☐ 1 - Yes ☐ 0 - No	**Tube R7**	*(CPMLR7ID)* [ ]
f) RNAlater sample from a **diseased lobe** Core collected?*(CPMLR7ST)* ☐ 1 - Yes ☐ 0 - No	**Tube R8**	*(CPMLR8ID)* [ ]
g) Histology core from a **diseased lobe** Core collected?*(CPMLH1ST)* ☐ 1 - Yes ☐ 0 - No	**Tube H11**	*(CPMLH1ID)* [ ]
h) Histology core from a **diseased lobe** Core collected?*(CPMLH2ST)* ☐ 1 - Yes ☐ 0 - No	**Tube H12**	*(CPMLH2ID)* [ ]
i) Histology core from a **non-diseased lobe of diseased lung** Core collected?*(CPMLH3ST)* ☐ 1 - Yes ☐ 0 - No	**Tube H13**	*(CPMLH3ID)* [ ]

j) Frozen tissue core from a **diseased lobe** Core collected?*(CPMLF1ST)* ☐ 1 - Yes ☐ 0 - No	**Tube F16**	*(CPMLF1ID)*
k) Microbiology core from a **non-diseased lung** (If right lung is diseased take core from LUL; if left lung is diseased, take core from RUL) Core collected?*(CPMLM4ST)* ☐ 1 - Yes ☐ 0 - No	**Tube M4**	*(CPMLM4ID)*
l) Microbiology core from a **non-diseased lung** (If right lung is diseased take core from LUL; if left lung is diseased, take core from RUL) Core collected?*(CPMLM5ST)* ☐ 1 - Yes ☐ 0 - No	**Tube M5**	*(CPMLM5ID)*
m) Microbiology core from a **non-diseased lung** (If right lung is diseased take core from LUL; if left lung is diseased, take core from RUL) Core collected?*(CPMLM6ST)* ☐ 1 - Yes ☐ 0 - No	**Tube M6**	*(CPMLM6ID)*
n) RNAlater sample from a **non-diseased lung** (If right lung is diseased take core from LUL; if left lung is diseased, take core from RUL) Core collected?*(CPMLR9ST)* ☐ 1 - Yes ☐ 0 - No	**Tube R9**	*(CPMLR9ID)*
o) RNAlater sample from a **non-diseased lung** (If right lung is diseased take core from LUL; if left lung is diseased, take core from RUL) Core collected?*(CPMLR4ST)* ☐ 1 - Yes ☐ 0 - No	**Tube R10**	*(CPMLR4ID)*
p) Histology core from a **non-diseased lung** (If right lung is diseased take core from LUL; if left lung is diseased, take core from RUL) Core collected?*(CPMLH4ST)* ☐ 1 - Yes ☐ 0 - No	**Tube H14**	*(CPMLH4ID)*
q) Histology core from a **non-diseased lung** (If right lung is diseased take core from LUL; if left lung is diseased, take core from RUL) Core collected?*(CPMLH5ST)* ☐ 1 - Yes ☐ 0 - No	**Tube H15**	*(CPMLH5ID)*

8. Sampling Protocol for **Diffuse Disease** OR if the site of disease (Q6) is **Unknown:**
(To minimize contamination, please collect the samples in the order specified below)

Note: if collection difficult, prioritise 1 sample for microbiology, 1 sample for histology and 1 sample to be stored in RNAlater as indicated by underlining below (Sample types a,d,f):

Sample Type	Tube	Specimen ID (scan barcode label):
a) Microbiology core from **RUL** Core collected?*(CPMDM1ST)* ☐ 1 - Yes ☐ 0 - No	**Tube M1**	*(CPMDM1ID)*
b) Microbiology core from **RLL** Core collected?*(CPMDM2ST)* ☐ 1 - Yes ☐ 0 - No	**Tube M2**	*(CPMDM2ID)*
c) Microbiology core from **RUL** Core collected?*(CPMDM3ST)* ☐ 1 - Yes ☐ 0 - No	**Tube M3**	*(CPMDM3ID)*
d) RNAlater sample from **RUL** Core collected?*(CPMDR7ST)* ☐ 1 - Yes ☐ 0 - No	**Tube R7**	*(CPMDR7ID)*

e) RNAlater sample from **RLL**
Core collected?*(CPMDR8ST)* ☐ 1 - Yes ☐ 0 - No   **Tube R8** *(CPMDR8ID)* _____

f) Histology core from **RUL**
Core collected?*(CPMDH1ST)* ☐ 1 - Yes ☐ 0 - No   **Tube H11** *(CPMDH1ID)* _____

g) Histology core from **RML**
Core collected?*(CPMDH2ST)* ☐ 1 - Yes ☐ 0 - No   **Tube H12** *(CPMDH2ID)* _____

h) Histology core from **RLL**
Core collected?*(CPMDH3ST)* ☐ 1 - Yes ☐ 0 - No   **Tube H13** *(CPMDH3ID)* _____

i) Frozen tissue core from **RUL**
Core collected?*(CPMDF1ST)* ☐ 1 - Yes ☐ 0 - No   **Tube F16** *(CPMDF1ID)* _____

j) Microbiology core from **LUL**
Core collected?*(CPMDM4ST)* ☐ 1 - Yes ☐ 0 - No   **Tube M4** *(CPMDM4ID)* _____

k) Microbiology core from **LLL**
Core collected?*(CPMDM5ST)* ☐ 1 - Yes ☐ 0 - No   **Tube M5** *(CPMDM5ID)* _____

l) Microbiology core from **LUL**
Core collected?*(CPMDM6ST)* ☐ 1 - Yes ☐ 0 - No   **Tube M6** *(CPMDM6ID)* _____

m) RNAlater sample from **LUL**
Core collected?*(CPMDR9ST)* ☐ 1 - Yes ☐ 0 - No   **Tube R9** *(CPMDR9ID)* _____

n) RNAlater sample from **LLL**
Core collected?*(CPMDR4ST)* ☐ 1 - Yes ☐ 0 - No   **Tube R10** *(CPMDR4ID)* _____

o) Histology core from **LUL**
Core collected?*(CPMDH4ST)* ☐ 1 - Yes ☐ 0 - No   **Tube H14** *(CPMDH4ID)* _____

p) Histology core from **LLL**
Core collected?*(CPMDH5ST)* ☐ 1 - Yes ☐ 0 - No   **Tube H15** *(CPMDH5ID)* _____

Comments:*(CPMCOMM)* _____

Initial QC by: *(CPMINQC)* _____

Supervisor Staff Code: *(CPMSUPCO)* _____

Supervisor Verification Date: *(CPMSUPDT)* _____ *(ddMMMyyyy)*

CRF 16: Case Serious Adverse Event (SAE)

Web Version: 1.0; 4.00; 25JUL13

Segment *(PROTSEG)*:

SAE event number *(SAEEVNUM)*:

1. Date of SAE: *(SAESAEDT)* [_____] *(ddMMMyyyy)*

2. Date of birth: *(SAEBRDT)* [_____] *(ddMMMyyyy)*

3. Is this the initial or final report of this SAE?

   1-1 - Initial
   2-2 - Final
   (SAEIFREP)

   The final report must have 'Final' selected.

4. Time of SAE onset: *(SAEONSTM)* [_____] *(hh:mm) (24 hour clock)* *(SAEONTMU)* ☐ 8 - UNK

5. Did the child have a lung aspirate or was there an attempt to collect this specimen? *(SAELUASP)* ☐ 1 - Yes ☐ 0 - No

   a. If Yes, date/time: *(SAEYLADT)* [_____] *(ddMMMyyyy)* *(SAEYLATM)* [_____] *(hh:mm) (24 hour clock)*

6. Did the child have induced sputum collected or was there an attempt to collect this specimen? *(SAEISPUT)* ☐ 1 - Yes ☐ 0 - No

   a. If Yes, date/time: *(SAEISPDT)* [_____] *(ddMMMyyyy)* *(SAEISPTM)* [_____] *(hh:mm) (24 hour clock)*

7. Specify event and any complications *(check all that apply)*:

Event Description	During the severe pneumonia episode:	Within 4 hrs after lung aspirate:	Within 4 hrs after induced sputum:
a. Death related to PERCH procedures	*(SAEDREPE)* ☐	*(SAEDRELA)* ☐	*(SAEDREIS)* ☐
b. Drop in oxygen saturation to below 92% resulting in increased supply of supplemental oxygen for 10 minutes or more	*(SAEOXSPE)* ☐	*(SAEOXSLA)* ☐	*(SAEOXSIS)* ☐
c. New onset of unconsciousness or prostration	*(SAEUNCPE)* ☐	*(SAEUNCLA)* ☐	*(SAEUNCIS)* ☐
d. New requirement for bronchodilators or increased frequency of bronchodilator treatment	*(SAEBROPE)* ☐	*(SAEBROLA)* ☐	*(SAEBROIS)* ☐
e. Pneumothorax at any time following lung aspirate, during the hospitalization	*(SAEPNEPE)* ☐	*(SAEPNELA)* ☐	*(SAEPNEIS)* ☐
f. Significant haemoptysis (>5mls) at any time following lung aspirate, during the hospitalization	*(SAEHAEPE)* ☐	*(SAEHAELA)* ☐	*(SAEHAEIS)* ☐
g. Other, specify:*(SAEOEDSP)* [_____]	*(SAEOTHPE)* ☐	*(SAEOTHLA)* ☐	*(SAEOTHIS)* ☐
Code:*(SAEEDCO)* [_____]			

8. Relatedness to study procedure:

   a. SAE relatedness to lung aspirate:

   1-1 - Definitely related
   2-2 - Probably related
   3-3 - Possibly related
   4-4 - Probably not related/unlikely
   5-5 - Definitely not related
   (SAERELLA)

   b. SAE relatedness to induced sputum:

   1-1 - Definitely related
   2-2 - Probably related
   3-3 - Possibly related
   4-4 - Probably not related/unlikely
   5-5 - Definitely not related
   (SAERELIS)

   c. SAE relatedness to other study procedure:
   (N/A if other study procedure not done)

   1-1 - Definitely related
   2-2 - Probably related
   3-3 - Possibly related
   4-4 - Probably not related/unlikely
   5-5 - Definitely not related
   (SAERELOP)   *(SAEOTRNA)* ☐ 9 - N/A

   i. Specify other study procedure: *(SAERELSP)* [_____]

Code: *(SAERELCO)* [_____]

d. If Definitely not related to any study procedure, specify probable cause: *(SAEDNRSP)* [_____]

Code: *(SAEDNRCO)* [_____]

9. SAE severity:

| 1-1 - Mild |
| 2-2 - Moderate |
| 3-3 - Severe |

(SAESEV) [▬▬▬▬▬]

10. SAE outcome at initial reporting: *(check one)*

| 1-1 - Resolved |
| 2-2 - Resolved with sequelae |
| 3-3 - Continuing |
| 4-4 - Death |
| 8-8 - UNK |

Date of death/Date resolved: *(SAERESDT)* [_____] *(ddMMMyyyy)*

(SAERESOL) [▬▬▬▬▬]

If '2 - Resolved with sequelae' or '3 - Continuing': Explain in comments

11. Is the child continuing to participate in the PERCH study? *(SAECONTI)* ☐ 1 - Yes ☐ 0 - No

12. Clinical narrative of SAE: *(SAECLNAR)*
[_____]

ALL SAEs MUST BE FOLLOWED TO RESOLUTION. IF NOT RESOLVED, REASSESS THE SAE UNTIL FINAL RESOLUTION.

13. Final SAE outcome:

| 1-1 - Resolved |
| 2-2 - Resolved with sequelae |
| 3-3 - Continuing |
| 4-4 - Death |
| 8-8 - UNK |

Date of death/Date resolved: *(SAEREFDT)* [_____] *(ddMMMyyyy)*

(SAERESOF) [▬▬▬▬▬]

If '2 - Resolved with sequelae' or '3 - Continuing': Explain in comments

14. SAE final comments: *(SAECOMM)*
[_____]

Form Completed By Staff Code: *(SAESTACO)* [_____]

Local Safety Monitor: *(SAELSMCO)* [_____]

Initial QC by: *(SAEINQC)* [_____]

Supervisor Staff Code: *(SAESUPCO)* [_____]

Supervisor Verification Date: *(SAEVERDT)* [_____] *(ddMMMyyyy)*

Additional Selection Options for SAE

SAE event number (*SAEEVNUM*) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15

CRF 17: Case Mortality (CMR)

Segment *(PROTSEG)*:

_HOSPDIED
1=Yes
0=No

Date of death: *(CMRDTHDT)* [ ] *(ddMMMyyyy)*

1. Did the child die at the **study facility**?*(CMRLOCAT)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

If Yes, complete Section A. If No or UNK, skip to Section B.

a. If Yes, where did the child die?*(CMRLOCDH)* ☐ 1 - Kamalapur ☐ 2 - Dhaka Hospital

_DIED
1=Yes
0=No

Section A. Complete this section for deaths that occurred <u>at the study facility</u>.

2. Time of death: *(CMRDTHTM)* [ ] *(hh:mm) (24 hour clock) (CMRTMUNK)* ☐ 8 - UNK

3. Indicate the immediate cause of death from the medical record (*select one*):

> 01-01 - Pneumonia
> 02-02 - Gastroenteritis
> 03-03 - Malaria
> 04-04 - Dehydration/shock
> 05-05 - Meningitis
> *Additional Options Listed Below

(CMRCAUSA) [____]

Other, specify:*(CMRCAOSP)* [_____] Code:*(CMRCAOCO)* [____]

4. Indicate other causes of death listed on the medical record (*check all that apply*): *(CMROAUNK)* ☐ 8 - UNK ☐ 9 - NONE

(CMRPNEUA) ☐ Pneumonia *(CMRMENA)* ☐ Meningitis

(CMRGASTA) ☐ Gastroenteritis *(CMRMALNA)* ☐ Malnutrition

(CMRMALA) ☐ Malaria *(CMRHIVA)* ☐ HIV

(CMRDEHYA) ☐ Dehydration/shock *(CMRSEPA)* ☐ Sepsis (any cause)

(CMROTHA) ☐ Other Other, specify:*(CMROTASP)* [_____] Code:*(CMROTACO)* [____]

PERCUTANEOUS LUNG BIOPSY CONSENT

5. Did parent/caregiver give consent for a post-mortem lung biopsy?

> 1-1 - Yes
> 0-0 - No
> 2-2 - Consent not sought
> 8-8 - UNK

(CMRLNGBI) [____]

If Yes, complete CRF 15 CASE SPECIMEN COLLECTION: LUNG BIOPSY.

If No, what is parent/caregiver's reason for refusing consent?*(CMRCNTSP)* [_____]

Section B. Complete this section for deaths that were <u>not known</u> to occur at the study facility.

6. Where did the child die?

> 01-01 - Other facility
> 02-02 - Home
> 99-99 - Other
> 08-08 - UNK

(CMROTLOC) [____]

Other facility, specify:*(CMROFCSP)* [_____] Other facility, Code:*(CMROFCCO)* [____]

Other location, specify:*(CMRLOCSP)* [_____] Other location, Code:*(CMRLOCCO)* [____]

7. Is a death certificate available?

> 1-1 - Yes
> 0-0 - No
> 8-8 - UNK

(CMRDTHCR) [____]

If Yes, answer Q7a and Q7b, then skip to end.
If No or UNK, skip to Q8.

7a. Immediate cause of death (*select one*):

> 01-01 - Pneumonia
> 02-02 - Gastroenteritis
> 03-03 - Malaria
> 04-04 - Dehydration/shock
> 05-05 - Meningitis
> *Additional Options Listed Below

(CMRCAUSB) [____]

Other, specify:*(CMRCBOSP)* [_____] Code:*(CMRCBOCO)* [____]

7b. Other causes of death *(CMROBUNK)* ☐ 8 - UNK   ☐ 9 - NONE
    (check all that apply):

(CMRPNEUB) ☐   Pneumonia   *(CMRMENB)* ☐   Meningitis

(CMRGASTB) ☐   Gastroenteritis   *(CMRMALNB)* ☐   Malnutrition

(CMRMALB) ☐   Malaria   *(CMRHIVB)* ☐   HIV

(CMRDEHYB) ☐   Dehydration/shock   *(CMRSEPB)* ☐   Sepsis (any cause)

(CMROTHB) ☐   Other   Other, specify:*(CMROTBSP)* [   ]   Code:*(CMROTBCO)* [   ]

If No death certificate is available (or UNK), answer Q8.

8. Was the family interviewed
   regarding the cause of death?

                     1-1 - Yes
                     0-0 - No
                     8-8 - UNK
           (CMRFAMIN)

If Yes, ask the parent/caregiver Q8a and Q8b.
If No or UNK, skip to Q9.

8a. What did the doctor or nurse   *(CMRDRUNA)* ☐ 8 - UNK   ☐ 9
say   - N/A
    was the cause of death?
    (check all that apply)

(CMRPNEUC) ☐   Pneumonia   *(CMRMENC)* ☐   Meningitis

(CMRGASTC) ☐
Gastroenteritis   *(CMRMALNC)* ☐   Malnutrition

(CMRMALC) ☐   Malaria   *(CMRHIVC)* ☐   HIV

(CMRDEHYC) ☐
Dehydration/shock   *(CMRSEPC)* ☐   Sepsis (any cause)

(CMROTC1) ☐   Other   Other, specify:*(CMROC1SP)*   Code:*(CMROC1CO)*
                                   [   ]   [   ]

(CMROTC2) ☐   Other   Other, specify:*(CMROC2SP)*   Code:*(CMROC2CO)*
                                   [   ]   [   ]

(CMROTC3) ☐   Other   Other, specify:*(CMROC3SP)*   Code:*(CMROC3CO)*
                                   [   ]   [   ]

8b. What do you think is the cause of death?   *(CMRINUNK)* ☐ 8 - UNK
    (check all that apply)

(CMRPNEUD) ☐   Pneumonia   *(CMRMEND)* ☐   Meningitis

(CMRGASTD) ☐   Gastroenteritis   *(CMRMALND)* ☐   Malnutrition

(CMRMALD) ☐   Malaria   *(CMRHIVD)* ☐   HIV

(CMRDEHYD) ☐   Dehydration/shock   *(CMRSEPD)* ☐   Sepsis (any cause)

(CMROTD1) ☐   Other   Other, specify:*(CMROD1SP)* [   ]   Code:*(CMROD1CO)* [   ]

(CMROTD2) ☐   Other   Other, specify:*(CMROD2SP)* [   ]   Code:*(CMROD2CO)* [   ]

(CMROTD3) ☐   Other   Other, specify:*(CMROD3SP)* [   ]   Code:*(CMROD3CO)* [   ]

If No death certificate is available (or UNK), answer Q9.

9. Is cause of death available
   from another source?

                   1-1 - Yes
                   0-0 - No
                   8-8 - UNK
         (CMROTSOC)

If Yes, answer Q9a-c.
If No or UNK, skip to end.

9a. Source *(select one)*:

                                      01-01 - Medical record (from other non-study facility)
                                      02-02 - Verbal autopsy
                                      08-08 - UNK
                                      99-99 - Other
                       (CMRSOURC)

Other, specify:*(CMROSCSP)* [   ]   Code:*(CMROSCCO)* [   ]

9b. Immediate cause of death (*select one*):

| 01-01 - Pneumonia |
| 02-02 - Gastroenteritis |
| 03-03 - Malaria |
| 04-04 - Dehydration/shock |
| 05-05 - Meningitis |
| *Additional Options Listed Below |

(CMRCAUSE)

Other, specify: *(CMRCEOSP)* _____ Code: *(CMRCEOCO)* _____

9c. Other causes of death   *(CMROEUNK)* ☐ 8 - UNK   ☐ 9 - NONE
   (*check all that apply*):

(CMRPNEUE) ☐ Pneumonia   *(CMRMENE)* ☐ Meningitis

(CMRGASTE) ☐ Gastroenteritis   *(CMRMALNE)* ☐ Malnutrition

(CMRMALE) ☐ Malaria   *(CMRHIVE)* ☐ HIV

(CMRDEHYE) ☐ Dehydration/shock   *(CMRSEPE)* ☐ Sepsis (any cause)

(CMROTHE) ☐ Other   Other, specify: *(CMROTESP)* _____ Code: *(CMROTECO)* _____

Comments:

(CMRCOMM)

Interviewer's Code: *(CMRINTCO)* _____

Initial QC by: *(CMRINQC)* _____

Supervisor Staff Code: *(CMRVERCO)* _____

Supervisor Verification Date: *(CMRVERDT)* _____ *(ddMMMyyyy)*

Additional Selection Options for CMR

Immediate cause A
06-06 - Malnutrition
07-07 - HIV
09-09 - Sepsis (any cause)
08-08 - UNK
99-99 - Other

CRF 18: Study Completion/Termination (SCT)

Segment *(PROTSEG)*:

Date of termination: *(SCTERMDT)* [＿＿＿＿＿＿] *(ddMMMyyyy)*

1. Did the child complete all applicable *(SCTCOMPL)* ☐ 1 - Yes ☐ 0 - No
   study protocol assessments?

    a. If No, indicate the reason(s) the child terminated the study early: *(check all that apply)*

(SCTWITCO) ☐ Primary caregiver withdrew consent

(SCTDIED) ☐ Died

(SCTSTREG) ☐ Failure to comply with study regulations

(SCTMOVED) ☐ Moved from the area

(SCTLOCAT) ☐ Could not locate for follow-up

(SCTOTHER) ☐ Other, specify: *(SCTOTHSP)* [＿＿＿＿＿＿＿＿＿＿] Code: *(SCTOTCOD)* [＿＿＿]

(SCTERUNK) ☐ 8 - UNK

Comments:

(SCTCOMM) [＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿]

Form completed by Staff Code: *(SCTSTAFF)* [＿＿＿＿]

Initial QC by: *(SCTINQC)* [＿＿＿＿＿＿]

Supervisor Staff Code: *(SCTSUPER)* [＿＿＿＿]

Supervisor Verification Date: *(SCTREVDT)* [＿＿＿＿] *(ddMMMyyyy)*

CRF 19: Lab Reception (LSR)

Segment *(PROTSEG)*:

Specimen type *(SPECTYP)*:

Date specimen received: *(LSRSPCDT)* [　　　　　] *(ddMMMyyyy)*

1. Specimen ID (scan barcode label): *(LSRSPCID)* [　　　　　]

3. Time received in laboratory: *(LSRRECTM)* [　　　] *(hh:mm)* (24 hour clock)

4. Specimen volume: *(LSRSPVOL)* [　　　] *(xxxxx)* μL　　*(LSRVOLNA)* ☐ 9 - N/A　(for blood culture, dried blood spot, NP/OP swabs, and slides only)

5. Status *(LSRSPSTA)* ☐ 1 - Accepted for processing　☐ 2 - Rejected

　If Rejected, specify reason below (check all that apply):
　Contact clinic immediately if any apply.

a.	Specimen unlabeled	*(LSRSPUNL)* ☐
b.	Specimen ID does not match ID on requisition form	*(LSRSPMAT)* ☐
c.	Blood is hemolyzed or anti-coagulated specimen contains clots	*(LSRSPQUA)* ☐
d.	Specimen container is leaking	*(LSRSPLEA)* ☐

　e.　Other　　　　*(LSRSPOTH)* ☐　　Other, specify: *(LSRROTSP)* [　　　　　]　　Other Code: *(LSRRJOCO)* [　　]

6. Was specimen transported under appropriate conditions and time frame? *(LSRSTRAN)* ☐ 1 - Yes　☐ 0 - No　☐ 8 - UNK

7. Person Receiving Specimen Staff Code: *(LSRSTAFF)* [　　　]

Comments:

(LSRCOMM) [　　　　　　　　　　　　　　　　]

Initial QC by: *(LSRINQC)* [　　　　　　　]

Supervisor Code: *(LSRSUPER)* [　　　]

Supervisor Verification Date: *(LSRVERDT)* [　　　] *(ddMMMyyyy)*

Additional Selection Options for LSR

Specimen type *(SPECTYP)* (key field):
01-1A - Blood Culture Bottle
02-1B - Plain/Red Top Tube
03-1C - EDTA case tube #1
04-1D - EDTA case tube #2
05-1E - EDTA control tube #1
06-1F - EDTA control tube #2
08-1H - Malaria Slide
09-1I - HIV Rapid Test
10-1J - Dried Blood Spot
11-2A - 30 Day Follow up Plain Tube
12-2B - 30 Day Follow up EDTA (CD4)
13-3A - NP STGG Swab
14-3B - NP VTM and OP Swab
15-3B - NP VTM Swab ONLY
16-3B - OP Swab ONLY
17-4A - Induced Sputum
18-4B - Second Induced Sputum
19-5A - ETT Specimen
20-5B - Second ETT Specimen
21-6A - Gastric Aspirate
22-6B - Second Gastric Aspirate
23-6C - Third Gastric Aspirate
24-7A - Urine
25-7B - 30 Day Follow up Urine
26-8A - Pleural Fluid
27-8B - Second Pleural Fluid
28-9A -Lung Aspirate
29-6D - Fourth Gastric Aspirate
30-6E - Fifth Gastric Aspirate

CRF 19OTH: Lab Reception: Other Specimen (LSO)

Segment *(PROTSEG)*
Specimen number *(SPECNUM)*

Date specimen received: *(LSOSPCDT)* [　　　] *(ddMMMyyyy)*

1. Specimen ID (scan barcode label): *(LSOSPCID)* [　　　]

2. Other Specimen Type:

Other, specify: *(LSOOTHSP)* [　　　]   Code: *(LSOOTHCO)* [　　　]

3. Time received in laboratory: *(LSORECTM)* [　　　] *(hh:mm)* (24 hour clock)

4. Specimen volume: *(LSOSPVOL)* [　　　] *(xxxx)* µL   *(LSOVOLNA)* ☐ 9 - N/A

5. Status *(LSOSPSTA)* ☐ 1 - Accepted for processing   ☐ 2 - Rejected

If Rejected, specify reason below (check all that apply):
Contact clinic immediately if any apply.

a.	Specimen unlabeled	*(LSOSPUNL)* ☐
b.	Specimen ID does not match ID on requisition form	*(LSOSPMAT)* ☐
c.	Blood is hemolyzed or anti-coagulated specimen contains clots	*(LSOSPQUA)* ☐
d.	Specimen container is leaking	*(LSOSPLEA)* ☐

e. Other   *(LSOSPOTH)* ☐   Other, specify: *(LSOROTSP)* [　　　]   Other Code: *(LSORJOCO)* [　　　]

6. Was specimen transported under appropriate conditions and time frame? *(LSOSTRAN)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

7. Person Receiving Specimen Staff Code: *(LSOSTAFF)* [　　　]

Comments:

(LSOCOMM) [　　　]

Initial QC by: *(LSOINQC)* [　　　]

Supervisor Code: *(LSOSUPER)* [　　　]

Supervisor Verification Date: *(LSOVERDT)* [　　　] *(ddMMMyyyy)*

Additional Selection Options for LSO

Specimen number (SPECNUM) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15

CRF 19PM: Lab Reception: Post Mortem Specimen (LSP)

Segment *(PROTSEG)*:

PM Specimen type *(PMSPECTY)*:

Date specimen received: *(LSPSPCDT)* [　　　　] *(ddMMMyyyy)*

1. Specimen ID (scan barcode label): *(LSPSPCID)* [　　　　]

3. Time received in laboratory: *(LSPRECTM)* [　　　　] *(hh:mm)* (24 hour clock)

4. Specimen Volume: *(LSPSPVOL)* [　　　　] *(xxxxx)* µL

Volume should be recorded for the pleural aspirates only.

5. Status: *(LSPSPSTA)* ☐ 1 - Accepted for processing   ☐ 2 - Rejected

   If Rejected, specify reason below (check all that apply):
   Contact study personnel immediately if any apply.

a.*(LSPSPUNL)* ☐	Specimen unlabeled
b.*(LSPSPMAT)* ☐	Specimen ID does not match ID on requisition form
c.*(LSPSPLEA)* ☐	Specimen container is leaking

   d.*(LSPSPOTH)* ☐ Other   Other, specify:*(LSPROTSP)* [　　　　]   Other Code:*(LSPRJOCO)* [　　]

6. Was specimen transported under appropriate conditions and time frame? *(LSPSTRAN)* ☐ 1 - Yes ☐ 0 - No ☐ 8 - UNK

7. Person Receiving Specimen Staff Code: *(LSPSTAFF)* [　　　　]

Comments:

(LSPCOMM) [　　　　　　　　　　　　　　]

Initial QC by: *(LSPINQC)* [　　　　]

Supervisor Code: *(LSPSUPER)* [　　　　]

Supervisor Verification Date: *(LSPVERDT)* [　　　　] *(ddMMMyyyy)*

Additional Selection Options for LSP

PM Specimen type _(PMSPECTY)_ (key field):
01-M1 - Microbiology Core 1
02-M2 - Microbiology Core 2
03-M3 - Microbiology Core 3
04-M4 - Microbiology Core 4
05-M5 - Microbiology Core 5
06-M6 - Microbiology Core 6
07-R7 - RNAlater Sample 1
08-R8 - RNAlater Sample 2
09-R9 - RNAlater Sample 3
10-R10 - RNAlater Sample 4
11-H11 - Histology Core 1
12-H12 - Histology Core 2
13-H13 - Histology Core 3
14-H14 - Histology Core 4
15-H15 - Histology Core 5
16-F16 - Frozen Tissue Sample
17-PR - Pleural Aspirate - Right Lung
18-PL - Pleural Aspirate - Left Lung

CRF 20: Lab Result: Blood Culture (LRB)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

If no blood specimen was taken, submit a Missing Forms Request.

1. Specimen ID (scan barcode label): *(LRBSPCID)* [   ]

2. a. Date the blood culture bottle was placed in BACTEC/BacT/ALERT: *(LRBBACDT)* [   ] *(ddMMMyyyy)*

   Time the blood culture bottle was placed in BACTEC/BacT/ALERT: *(LRBBACTI)* [   ] *(hh:mm) (24 hour clock)*

   Time the blood culture bottle was placed in BACTEC/BacT/ALERT: *(LRBSAFTI)* [   ] *(hh:mm) (24 hour clock)*

   b. Technician's Staff Code: *(LRBSTAFF)* [   ]

3. Sample volume:

   _BLD_VOL

   a. Weight of bottle prior to specimen collection: *(LRBPRIWT)* [   ] *(xxx.xx)* grams

   b. Weight of bottle after collection/ at time of reception in lab: *(LRBPSTWT)* [   ] *(xxx.xx)* grams

4. Results reporting:

_AVAIL_BCX
1=Yes
0=No

   a. Alarm positive? *(LRBALARM)* ☐ 1 - Yes   ☐ 2 - No, negative at 5 days   *(stop here and end form)*

5. Time to positive (from blood culture machine): *(LRBPOSHR)* [   ] *(xxx.x)* hrs

6. Description of any organism by Gram stain of blood culture broth *(check all that apply)*:

   Gram stain performed? *(LRBGRAMS)* ☐ 1 - Yes   ☐ 0 - No

a.	No organisms seen	*(LRBNOORG)* ☐
b.	Gram-negative rods (GNR)	*(LRBGNR)* ☐
c.	Gram-positive cocci in clusters (GPC clusters)	*(LRBGPCCL)* ☐
d.	Gram-negative coccobacilli (GNCB)	*(LRBGNCB)* ☐
e.	Gram-positive cocci in chains (GPC chains)	*(LRBGPCCH)* ☐
f.	Gram-negative diplococci (GNDC)	*(LRBGNDC)* ☐
g.	Gram-positive cocci single cells (GPC singles)	*(LRBGPCSI)* ☐
h.	Gram-negative cocci (GNC)	*(LRBGNC)* ☐
i.	Gram-positive rods (GPR)	*(LRBGPR)* ☐
j.	Gram-positive diplococci (GPDC)	*(LRBGPDC)* ☐
k.	Yeasts or other fungal elements	*(LRBYEAST)* ☐

Reminder: Binax result should be performed only on samples that are:

- *BACTEC or BacT/ALERT alarm positive, gram stain negative, and sub-culture negative (no growth on 24 hour plates)*
  -or-
- *BACTEC or BacT/ALERT alarm positive, streptococci positive on gram stain, and sub-culture negative (no growth on 24 hour plates)*

7. Binax result *(check one)*: *(LRBBINAX)* ☐ 1 - Positive   ☐ 2 - Negative   ☐ 3 - Indeterminate   ☐ 9 - Not done

8. Description of sub-culture growth results: *(LRBSUBCU)* ☐ 1 - Growth   ☐ 2 - No growth

   (If no growth, stop here and end form.)

9. Organism identification:

_ANYBAC_ALL_BCX
_ANYBAC_NONCONTAM_BCX
1=Yes
0=No

	Organism Code	Isolate ID (scan barcode label)	Isolate ID N/A N/A ONLY if organism is a contaminant	Organism Confirmation
a. Organism 1	*(LRB01ORG)* [ ]	*(LRB01ISO)* [ ]	*(LRB01INA)* ☐ 9 - N/A	1-1: C - Confirmed 2-2: U - Updated 3-3: NC - Not confirmed *(LRB01CON)*

&ORG._BCX (Positive for indiv. organism; see organism dictionary for organism codes)
1=Positive
0=Negative

b. Organism 2	*(LRB02ORG)*	*(LRB02ISO)*	*(LRB02INA)* ☐ 9 - N/A		*(LRB02CON)* 1-1: C - Confirmed 2-2: U - Updated 3-3: NC - Not confirmed
c. Organism 3	*(LRB03ORG)*	*(LRB03ISO)*	*(LRB03INA)* ☐ 9 - N/A		*(LRB03CON)* 1-1: C - Confirmed 2-2: U - Updated 3-3: NC - Not confirmed

10. Antibiotic Susceptibility Testing:
   Note: **1 = Susceptible; 2 = Intermediate; 3 = Resistant**

Antibiotic code:	Organism 1 Zone of inhibition in mm (xx):	Organism 1 S/I/R Code:	Organism 2 Zone of inhibition in mm (xx):	Organism 2 S/I/R Code:	Organism 3 Zone of inhibition in mm (xx):	Organism 3 S/I/R Code:
a. **AMC** (Amoxicillin / Clavulanic acid)	*(LRB01AMC)*	*(LRB1AMCI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB02AMC)*	*(LRB2AMCI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB03AMC)*	*(LRB3AMCI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
b. **AMP** (Ampicillin)	*(LRB01AMP)*	*(LRB1AMPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB02AMP)*	*(LRB2AMPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB03AMP)*	*(LRB3AMPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
c. **CAZ** (Ceftazidimine)	*(LRB01CAZ)*	*(LRB1CAZI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB02CAZ)*	*(LRB2CAZI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB03CAZ)*	*(LRB3CAZI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
d. **CH** (Chloramphenicol)	*(LRB01CH)*	*(LRB1CHI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB02CH)*	*(LRB2CHI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB03CH)*	*(LRB3CHI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
e. **CIP** (Ciprofloxacin)	*(LRB01CIP)*	*(LRB1CIPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB02CIP)*	*(LRB2CIPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB03CIP)*	*(LRB3CIPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
f. **CN** (Gentamicin)	*(LRB01CN)*	*(LRB1CNI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB02CN)*	*(LRB2CNI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB03CN)*	*(LRB3CNI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
g. **CRO** (Ceftriaxone)	*(LRB01CRO)*	*(LRB1CROI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB02CRO)*	*(LRB2CROI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB03CRO)*	*(LRB3CROI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
h. **CTX** (Cefotaxime)	*(LRB01CTX)*	*(LRB1CTXI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB02CTX)*	*(LRB2CTXI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB03CTX)*	*(LRB3CTXI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
i. **DA** (Clindamycin)	*(LRB01DA)*	*(LRB1DAI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB02DA)*	*(LRB2DAI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB03DA)*	*(LRB3DAI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
j. **ERY** (Erythromycin)	*(LRB01ERY)*	*(LRB1ERYI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB02ERY)*	*(LRB2ERYI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRB03ERY)*	*(LRB3ERYI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
k. **FOX** (Cefoxitin)	*(LRB01FOX)*	*(LRB1FOXI)*	*(LRB02FOX)*	*(LRB2FOXI)*	*(LRB03FOX)*	*(LRB3FOXI)*

	Antibiotic Code:	Organism 1 Zone of inhibition in mm (xx):	Organism 1 S/I/R Code:	Organism 2 Zone of inhibition in mm (xx):	Organism 2 S/I/R Code:	Organism 3 Zone of inhibition in mm (xx):	Organism 3 S/I/R Code:
			1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant		1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant		1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
l. **IPM** (Imipenem)	*(LRB01IPM)*	*(LRB1IPMI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant		*(LRB02IPM)*	*(LRB2IPMI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB03IPM)*	*(LRB3IPMI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
m. **OX** (Oxacillin)	*(LRB01OX)*	*(LRB1OXI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant		*(LRB02OX)*	*(LRB2OXI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB03OX)*	*(LRB3OXI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
n. **P** (Penicillin)	*(LRB01P)*	*(LRB1PI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant		*(LRB02P)*	*(LRB2PI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB03P)*	*(LRB3PI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
o. **SXT** (Cotrimoxazole)	*(LRB01SXT)*	*(LRB1SXTI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant		*(LRB02SXT)*	*(LRB2SXTI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB03SXT)*	*(LRB3SXTI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
p. **TET** (Tetracycline)	*(LRB01TET)*	*(LRB1TETI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant		*(LRB02TET)*	*(LRB2TETI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB03TET)*	*(LRB3TETI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
q. **VA** (Vancomycin)	*(LRB01VA)*	*(LRB1VAI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant		*(LRB02VA)*	*(LRB2VAI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB03VA)*	*(LRB3VAI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant

Other Antibiotic, Specify:	Antibiotic Code:	Organism 1 Zone of inhibition in mm (xx):	Organism 1 S/I/R Code:	Organism 2 Zone of inhibition in mm (xx):	Organism 2 S/I/R Code:	Organism 3 Zone of inhibition in mm (xx):	Organism 3 S/I/R Code:
r. Other *(LRBOT1SP)*	*(LRBOTH1D)*	*(LRB1OT1D)*	*(LRB1OT1I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB2OT1D)*	*(LRB2OT1I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB3OT1D)*	*(LRB3OT1I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant
s. Other *(LRBOT2SP)*	*(LRBOTH2D)*	*(LRB1OT2D)*	*(LRB1OT2I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB2OT2D)*	*(LRB2OT2I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB3OT2D)*	*(LRB3OT2I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant
t. Other *(LRBOT3SP)*	*(LRBOTH3D)*	*(LRB1OT3D)*	*(LRB1OT3I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB2OT3D)*	*(LRB2OT3I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	*(LRB3OT3D)*	*(LRB3OT3I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant

	Organism 1	Organism 2	Organism 3
u. **Beta lactamase**	*(LRB01BPN)* ☐ 1 - Positive ☐ 2 - Negative	*(LRB02BPN)* ☐ 1 - Positive ☐ 2 - Negative	*(LRB03BPN)* ☐ 1 - Positive ☐ 2 - Negative

11. MIC Etest® results for *S. pneumoniae* isloates that are resistant (R) or intermediate (I) to oxacillin disk diffusion testing.

MIC Etest® performed? *(LRBSPNET)* ☐ 1 - Yes ☐ 0 - No ☐ 9 - N/A *(If No or N/A, skip to Question 12.)*

a) Penicillin Etest® results *(LRBPENSI)* ☐ < ☐ > *(LRBPENRS)* [　　　　] *(xx.xxx) µg/mL*

b) *(LRBETDRG)* ☐ Ceftriaxone ☐ Cefotaxime *(LRBETSIG)* ☐ < ☐ > *(LRBETRST)* [　　　　] *(xx.xxx) µg/mL*

12. Screening for Extended Spectrum ß-Lactamase (ESBL) Production done?

(LRBESBL) ☐ 1 - Yes ☐ 0 - No

If Yes, results of additional phenotypic testing:

(LRBESBLC) ☐ 1 - ESBL confirmed   ☐ 2 - ESBL not confirmed

Comments:

(LRBCOMM)

Technician Reporting Final Results Staff Code: *(LRBTECH)*

Initial QC by: *(LRBINQC)*

Supervisor Staff Code: *(LRBSUPER)*

Supervisor Verification Date: *(LRBVERDT)*   *(ddMMMyyyy)*

CRF 20: Lab Result: Blood Culture: Additional Tests (LRE)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

(Question 11) 'MIC Etest® performed?' was answered Yes; for results for *S. pneumoniae* isolates that are resistant (R) or intermediate (I) to oxacillin disk diffusion testing. Please answer the following questions:

      c. Clindamycin Dtest® results *(LRECLNRS)* ☐ 1 - Positive   ☐ 2 - Negative

13. MIC Etest® results for *S. aureus* isolates that are resistant (R) or intermediate (I) to cefoxitin disk diffusion testing.

    MIC Etest® performed? *(LRESANET)* ☐ 1 - Yes   ☐ 0 - No   ☐ 9 - N/A

      a. Vancomycin Etest® results *(LREVNSSI)* ☐ <   ☐ >   *(LREVNSRS)* [＿＿＿＿＿] *(xx.xxx) µg/mL*

      b. Clindamycin Dtest® results *(LRECNSRS)* ☐ 1 - Positive   ☐ 2 - Negative

14. Was *S. pneumoniae* isolated?

(LRESPISO) ☐ 1 - Yes   ☐ 0 - No

    If Yes, what serotypes were identified:

a. *(LRE1SERP)* [＿＿＿＿＿]

b. *(LRE2SERP)* [＿＿＿＿＿]

c. *(LRE3SERP)* [＿＿＿＿＿]

d. *(LRE4SERP)* [＿＿＿＿＿]

See _pneu_st dataset and supporting documentation

15. Was *H. influenzae* isolated?

(LREHIISO) ☐ 1 - Yes   ☐ 0 - No

    If Yes, what serotype was identified:

a. *(LRE5SERI)* [＿＿＿＿＿]

Comments:

(LRECOMM) [   ]

Technician Reporting Final Results Staff Code: *(LRETECH)* [＿＿＿＿]

Initial QC by: *(LREINQC)* [＿＿＿＿＿＿＿]

Supervisor Staff Code: *(LRESUPER)* [＿＿＿＿]

Supervisor Verification Date: *(LREVERDT)* [＿＿＿＿] *(ddMMMyyyy)*

CRF 21: Lab Result: Pneumococcal PCR (LRP)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

If no specimen was taken, submit a Missing Forms Request.

1. Nucleic acid extract aliquot ID (scan barcode label):*(LRPSPCID)*

2. Date of nucleic acid extraction:*(LRPNAEDT)* *(ddMMMyyyy)*

3. Volume of blood extracted:*(LRPBLVOL)* *(xxx)* µL

4. Technician who performed extraction Staff Code:*(LPRETECH)*

5. Date of PCR run:*(LRPPCRDT)* *(ddMMMyyyy)*

6. Technician who performed PCR run Staff Code:*(LPRPTECH)*

Comments:*(LRPCOMM)*

Initial QC by:(LRPINQC)

Supervisor Staff Code:(LRPSUPER)

Supervisor Verification Date:(LRPVERDT) *(ddMMMyyyy)*

CRF 22: Lab Result:Antibiotic Activity (LAA)

Segment *(PROTSEG)*

LAA specimen type *(LAASPTYP)*

1. Specimen ID (scan barcode label): *(LAAANTID)*

2. Technician's Staff Code: *(LAATECCO)*

3. Date result was read: *(LAARSTDT)* *(ddMMMyyyy)*

_ABXSERUM 4. Diameter of zone of inhibition: *(LAAINHZN)* *(xx)* mm
1=Positive
0=Negative

Comments:*(LAACOMM)*

InitialQC by: *(LAAINQC)*

Supervisor Staff Code: *(LAASSCO)*

Supervisor Verification Date: *(LAASUPDT)* *(ddMMMyyyy)*

Additional Selection Options for LAA

LAA specimen type *(LAASPTYP)* (key field):
1-1 - Serum
2-2 - Urine

CRF 23: Lab Reception: Core Blood Tests (LRC)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

If no core blood tests were done, submit a Missing Forms Request.

CBC

(LRCCBCND) ☐ CBC not done, skip to next section

Date and time received in laboratory: *(LRCSPEDT)* ⬚ *(ddMMMyyyy)*   *(LRCSPETM)* ⬚ *(hh:mm)*

1. Date of test: *(LRCCBCDT)* ⬚ *(ddMMMyyyy)*

2. Specimen ID (scan barcode label): *(LRCCBCID)* ⬚

3. Technician's Staff Code: *(LRBCBCTE)* ⬚

4. CBC Results:

Variable		Result	
a. Hemoglobin:	*(LRCCBCA)*	⬚	*(xx.x)* g/dL
b. Hematocrit:	*(LRCCBCB)*	⬚	*(xx.x)* %
c. MCV:	*(LRCCBCC)*	⬚	*(xxx.x)* fL
d. MCH:	*(LRCCBCD)*	⬚	*(xx.x)* Pg
e. MPV:	*(LRCCBCE)*	⬚	*(xx.x)* fL
f. Platelets:	*(LRCCBCF)*	⬚	*(xxxx)* x10³/μL
g. WBC:	*(LRCCBCG)*	⬚	*(xxx.x)* x10³/μL
h. Neutrophils:	*(LRCCBCH)*	⬚	*(xx.x)* %
i. Lymphocytes:	*(LRCCBCI)*	⬚	*(xx.x)* %
j. Monocytes:	*(LRCCBCJ)*	⬚	*(xx.x)* %
k. Eosinophils:	*(LRCCBCK)*	⬚	*(xx.x)* %
l. Basophils:	*(LRCCBCL)*	⬚	*(xx.x)* %
m. Band Cells:	*(LRCCBCM)*	⬚	*(xx.x)* %
n. RBC:	*(LRCCBCN)*	⬚	*(x.xx)* x10⁶/μL
o. MCHC:	*(LRCCBCO)*	⬚	*(xxx.xx)* g/dL

g. WBC: _LEUKOCYTOSIS   _LEUKOPENIA
1=Yes   1=Yes
0=No   0=No

HIV ANTIBODY TEST

(LRCHIVND) ☐ HIV Antibody test not done, if applicable indicate reason why and then skip to next section

If HIV antibody test not done, indicate the reason why: *(LRCHIVRE)* ☐ 1 - Child known to be positive   ☐ 2 - Testing was refused   ☐ 9 - Other

Other, specify: *(LRCHIVSP)* ⬚   Code: *(LRCHIVCO)* ⬚

5. Date of test: *(LRCHIVDT)* ⬚ *(ddMMMyyyy)*

6. Specimen ID (scan barcode label): *(LRCHIVID)* ⬚

7. Technician's Staff Code: *(LRCHIVTE)* ⬚

8. HIV antibody test final result:

_HIV
1=Positive
0=Negative
8=Unknown

| 1-1 - Positive |
| 2-2 - Negative |
| 3-3 - Indeterminate |
| 4-4 - Invalid |

(LRCHIVRS)

   a. If <u>positive</u>, is the child <18 months old?   *(LRCHIVPO)* ☐ 1 - Yes   ☐ 0 - No
   (If Yes, HIV PCR test should be done.)

HIV PCR TEST
(for HIV antibody-positive children less than 18 months old)

(LRCPCRND) ☐ HIV PCR test not done, skip to next section

9. Date of test: *(LRCPCRDT)* ⬚ *(ddMMMyyyy)*

10. PCR test result: *(LRCPCRRS)* ☐ 1 - Positive ☐ 2 - Negative

11. Technician's Staff Code: *(LRCPCRTE)* _____

CD4 TEST *(LRCCD4ND)* ☐ CD4 not done, skip to next section

12. Date of test: *(LRCCD4DT)* _____ *(ddMMMyyyy)*

13. CD4 test result:

   a. Absolute count: *(LRCCD4AB)* _____ *(xxxx)* cells/µL *(LRCCD4AN)* ☐ 9 - Not done

   b. CD4 percent: *(LRCCD4P)* _____ *(xx.xx)* % *(LRCCD4PN)* ☐ 9 - Not done

14. Technician's Staff Code: *(LRCCD4TE)* _____

SICKLE CELL TEST
[THALASSEMIA TESTING for Thailand] *(LRCSICND)* ☐ Sickle cell testing not done, skip to next section

15. Date of test: *(LRCSICDT)* _____ *(ddMMMyyyy)*

16. Specimen ID (scan barcode label): *(LRCSICID)* _____

17. Technician's Staff Code: *(LRCSICTE)* _____

18 a. Solubility testing results: *(LRCSICSR)* ☐ 1 - Positive ☐ 2 - Negative ☐ 9 - N/A

   18 b. Test result/HB type:

   ```
   09-09 - N/A
   01-01 - AA
   02-02 - AF
   03-03 - AS
   04-04 - EA
   *Additional Options Listed Below
   ```

   (LRCSICRS) ▮

   Other, specify: *(LRCSICSP)* _____ Code: *(LRCSICCO)* _____

   18 c. Hemoglobin Fractions:

   A *(LRCHFA)* _____ *(xx.x)* % *(LRCHFAN)* ☐ 9 - N/A F *(LRCHFF)* _____ *(xx.x)* % *(LRCHFFN)* ☐ 9 - N/A

   A2 *(LRCHF2A)* _____ *(xx.x)* % *(LRCHF2AN)* ☐ 9 - N/A Cs *(LRCHFCS)* _____ *(xx.x)* % *(LRCHFCSN)* ☐ 9 - N/A

   E *(LRCHFE)* _____ *(xx.x)* % *(LRCHFEN)* ☐ 9 - N/A H *(LRCHFH)* _____ *(xx.x)* % *(LRCHFHN)* ☐ 9 - N/A

MALARIA TESTING *(LRCMALND)* ☐ Malaria testing not done, skip to next section

19. Date of test: *(LRCMALDT)* _____ *(ddMMMyyyy)*

20. Specimen ID (scan barcode label): *(LRCMALID)* _____

21. Technician's Staff Code: *(LRCMALTE)* _____

22. Type of test (check one. If both tests were done, check the one that was done first.): *(LRCMALTP)* ☐ 1 - Rapid Antigen Detection ☐ 2 - Microscopy

   a. Test result: *(LRCMALRS)* ☐ 1 - Positive ☐ 2 - Negative

   23a. If Positive, species: *(LRCMASND)* ☐ Speciation not done, skip to next section

      i. *P. falciparum* *(LRCMALPF)* ☐ 1 - Yes ☐ 0 - No

      ii. *P. vivax* *(LRCMALPV)* ☐ 1 - Yes ☐ 0 - No

      iii. *P. ovale* *(LRCMALPO)* ☐ 1 - Yes ☐ 0 - No

      iv. *P. malariae* *(LRCMALPM)* ☐ 1 - Yes ☐ 0 - No

   23b. Quantification *(LRCMALQU)* ☐ 9 - Not done

      i. Parasitaemia *(LRCMALPA)* _____ *(xxxx)* *(LRCMALWB)* ☐ 1 - per 200 WBC ☐ 2 - per 500 WBC

      ii. Density *(LRCMALD)* _____ *(xxxxxx)* /µL *(LRCMALWR)* ☐ 1 - using white cell count ☐ 2 - using red cell count

CRP Testing *(LRCCRPND)* ☐ CRP testing not done, end form

24. Date of test: *(LRCCRPDT)* _____ *(ddMMMyyyy)*

25. Specimen ID (scan barcode label): *(LRCCRPID)* _____

26. Technician's Staff Code: *(LRCCRPTE)* _____

27. Test result: (LRCCRPRS) [＿＿＿] *(xxx.xx)* mg/L

30-DAY FOLLOW-UP CD4 TEST *(LRCCDFND)* ☐ CD4 not done, skip to next section.

28. Date of test *(LRCCDFDT)* [＿＿＿] *(ddMMMyyyy)*

29. CD4 test result:

    a. Absolute count: *(LRCCDFAB)* [＿＿＿] *(xxxx)* cells/uL   *(LRCCDFAN)* ☐ 9 - Not done

    b. CD4 percent: *(LRCCDFUP)* [＿＿＿] *(xx.xx)* %   *(LRCCDFPN)* ☐ 9 - Not done

30. Technician's Staff Code: *(LRCCDFTE)* [＿＿＿]

Comments:

[   ]

(LRCCOMM)

Initial QC by: *(LRCINQC)* [＿＿＿]

Supervisor Staff Code: *(LRCSUPER)* [＿＿＿]

Supervisor Verification Date: *(LRCVERIF)* [＿＿＿] *(ddMMMyyyy)*

Additional Selection Options for LRC

Sickle cell result
05-05 - EF
06-06 - SC
07-07 - SS
08-08 - A2A
10-10 - EE
11-11 - EFA
12-12 - C A2A H
13-13 - A2F
14-14 - A2FA
15-15 - A2A H
16-16 - AE Barts
17-17 - AC
99-99 - Other

CRF 23: Lab Reception: Core Blood Tests (LRD)

Segment *(PROTSEG)*

Visit Number *(VISNO)*

If no core blood tests were done, submit a Missing Forms Request.

CBC

(LRDCBCND) ☐ CBC not done, skip to next section

Date and time received in laboratory: *(LRDSPEDT)* ☐ *(ddMMMyyyy)*   *(LRDSPETM)* ☐ *(hh:mm)*

1. Date of test: *(LRDCBCDT)* ☐ *(ddMMMyyyy)*

2. Specimen ID (scan barcode label): *(LRDCBCID)* ☐

3. Technician's Staff Code: *(LRDCBCTE)* ☐

4. CBC Results:

Variable		Result
a. Hemoglobin:	*(LRDCBCA)*	*(xx.x)* g/dL
b. Hematocrit:	*(LRDCBCB)*	*(xx.x)* %
c. MCV:	*(LRDCBCC)*	*(xxx.x)* fL
d. MCH:	*(LRDCBCD)*	*(xx.x)* Pg
e. MPV:	*(LRDCBCE)*	*(xx.x)* fL
f. Platelets:	*(LRDCBCF)*	*(xxxx)* x10^3/µL
g. WBC:	*(LRDCBCG)*	*(xxx.x)* x10^3/µL
h. Neutrophils:	*(LRDCBCH)*	*(xx.x)* %
i. Lymphocytes:	*(LRDCBCI)*	*(xx.x)* %
j. Monocytes:	*(LRDCBCJ)*	*(xx.x)* %
k. Eosinophils:	*(LRDCBCK)*	*(xx.x)* %
l. Basophils:	*(LRDCBCL)*	*(xx.x)* %
m. Band Cells:	*(LRDCBCM)*	*(xx.x)* %
n. RBC:	*(LRDCBCN)*	*(x.xx)* x10^6/µL
o. MCHC:	*(LRDCBCO)*	*(xxx.xx)* g/dL

_LEUKOCYTOSIS
1=Yes
0=No

_LEUKOPENIA
1=Yes
0=No

HIV ANTIBODY TEST

(LRDHIVND) ☐ HIV Antibody test not done, if applicable indicate reason why and then skip to next section

If HIV antibody test not done, indicate the reason why: *(LRDHIVRE)* ☐ 1 - Child known to be positive   ☐ 2 - Testing was refused   ☐ 9 - Other

Other, specify: *(LRDHIVSP)* ☐   Code: *(LRDHIVCO)* ☐

5. Date of test: *(LRDHIVDT)* ☐ *(ddMMMyyyy)*

6. Specimen ID (scan barcode label): *(LRDHIVID)* ☐

7. Technician's Staff Code: *(LRDHIVTE)* ☐

8. HIV antibody test final result:

```
1-1 - Positive
2-2 - Negative
3-3 - Indeterminate
4-4 - Invalid
```
(LRDHIVRS)

_HIV
1=Positive
0=Negative
8=Unknown

   a. If <u>positive</u>, is the child <18 months old?   *(LRDHIVPO)* ☐ 1 - Yes   ☐ 0 - No
   (If Yes, HIV PCR test should be done.)

HIV PCR TEST
(for HIV antibody-positive children less than 18 months old)

(LRDPCRND) ☐ HIV PCR test not done, skip to next section

9. Date of test: *(LRDPCRDT)* ☐ *(ddMMMyyyy)*

10. PCR test result: *(LRDPCRRS)* ☐ 1 - Positive ☐ 2 - Negative

11. Technician's Staff Code: *(LRDPCRTE)* _____

CD4 TEST *(LRDCD4ND)* ☐ CD4 not done, skip to next section

12. Date of test: *(LRDCD4DT)* _____ *(ddMMMyyyy)*

13. CD4 test result:

    a. Absolute count: *(LRDCD4AB)* _____ *(xxxx)* cells/μL   *(LRDCD4AN)* ☐ 9 - Not done

    b. CD4 percent: *(LRDCD4P)* _____ *(xx.xx)* %   *(LRDCD4PN)* ☐ 9 - Not done

14. Technician's Staff Code: *(LRDCD4TE)* _____

SICKLE CELL TEST
[THALASSEMIA TESTING for Thailand] *(LRDSICND)* ☐ Sickle cell testing not done, skip to next section

15. Date of test: *(LRDSICDT)* _____ *(ddMMMyyyy)*

16. Specimen ID (scan barcode label): *(LRDSICID)* _____

17. Technician's Staff Code: *(LRDSICTE)* _____

18 a. Solubility testing results: *(LRDSICSR)* ☐ 1 - Positive ☐ 2 - Negative ☐ 9 - N/A

    18 b. Test result/HB type:

> 09-09 - N/A
> 01-01 - AA
> 02-02 - AF
> 03-03 - AS
> 04-04 - EA
> *Additional Options Listed Below

(LRDSICRS) ▮

    Other, specify: *(LRDSICSP)* _____ Code: *(LRDSICCO)* _____

    18 c. Hemoglobin Fractions:

A *(LRDHFA)* _____ *(xx.x)* % *(LRDHFAN)* ☐ 9 - N/A   F *(LRDHFF)* _____ *(xx.x)* % *(LRDHFFN)* ☐ 9 - N/A

A2 *(LRDHF2A)* _____ *(xx.x)* % *(LRDHF2AN)* ☐ 9 - N/A   Cs *(LRDHFCS)* _____ *(xx.x)* % *(LRDHFCSN)* ☐ 9 - N/A

E *(LRDHFE)* _____ *(xx.x)* % *(LRDHFEN)* ☐ 9 - N/A   H *(LRDHFH)* _____ *(xx.x)* % *(LRDHFHN)* ☐ 9 - N/A

MALARIA TESTING *(LRDMALND)* ☐ Malaria testing not done, skip to next section

19. Date of test: *(LRDMALDT)* _____ *(ddMMMyyyy)*

20. Specimen ID (scan barcode label): *(LRDMALID)* _____

21. Technician's Staff Code: *(LRDMALTE)* _____

22. Type of test (check one. If both tests were done, check the one that was done first.): *(LRDMALTP)* ☐ 1 - Rapid Antigen Detection ☐ 2 - Microscopy

    a. Test result: *(LRDMALRS)* ☐ 1 - Positive ☐ 2 - Negative

      23a. If Positive, species: *(LRDMASND)* ☐ Speciation not done, skip to next section

        i. *P. falciparum* *(LRDMALPF)* ☐ 1 - Yes ☐ 0 - No

        ii. *P. vivax* *(LRDMALPV)* ☐ 1 - Yes ☐ 0 - No

        iii. *P. ovale* *(LRDMALPO)* ☐ 1 - Yes ☐ 0 - No

        iv. *P. malariae* *(LRDMALPM)* ☐ 1 - Yes ☐ 0 - No

      23b. Quantification *(LRDMALQU)* ☐ 9 - Not done

        i. Parasitaemia *(LRDMALPA)* _____ *(xxxx)*   *(LRDMALWB)* ☐ 1 - per 200 WBC ☐ 2 - per 500 WBC

        ii. Density *(LRDMALD)* _____ *(xxxxxx)* /μL *(LRDMALWR)* ☐ 1 - using white cell count ☐ 2 - using red cell count

CRP Testing *(LRDCRPND)* ☐ CRP testing not done, end form

24. Date of test: *(LRDCRPDT)* _____ *(ddMMMyyyy)*

25. Specimen ID (scan barcode label): *(LRDCRPID)* _____

26. Technician's Staff Code: *(LRDCRPTE)* _____

27. Test result: *(LRDCRPRS)* [ ] *(xxx.xx)* mg/L

30-DAY FOLLOW-UP CD4 TEST *(LRDCDFND)* ☐ 9 - Not done   CD4 not done, skip to next section.

28. Date of test *(LRDCDFDT)* [ ] *(ddMMMyyyy)*

29. CD4 test result:

    a. CD4 percent: *(LRDCDFUP)* [ ] *(xx.xx)* %   *(LRDCDFPN)* ☐ 9 - Not done

    a. Absolute count: *(LRDCDFAB)* [ ] *(xxxx)* cells/uL   *(LRDCDFAN)* ☐ 9 - Not done

30. Technician's Staff Code: *(LRDCDFTE)* [ ]

Comments:

(LRDCOMM) [ ]

Initial QC by: *(LRDINQC)* [ ]

Supervisor Staff Code: *(LRDSUPER)* [ ]

Supervisor Verification Date: *(LRDVERIF)* [ ] *(ddMMMyyyy)*

CRF 24: Lab Result: NP Culture (LRN)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

If no specimen was taken, submit a Missing Forms Request.

1. Specimen ID (scan barcode label): *(LRNSPID)*

2. Date/time put up for culture: *(LRNCULDT)* *(ddMMMyyyy)* *(LRNCULTM)* *(hh:mm)* (24 hour clock)

Identification of pneumococcal colonies _PNEU_NPCX 1=Yes 0=No	a. If Yes, optochin zone diameter (mm):	b. Bile soluble? (only do if optochin zone is 9-13 mm):	c. Serotype (skip if not yet available):	d. Isolate ID (scan barcode label):
3. Was a pneumococcal colony identified? 1-1 - Yes 0-0 - No *(If No, end form)(LRN1PCOL)*	*(LRN1OZD)* *(xx)*	*(LRN1BILE)* 0-0 - No 1-1 - Yes 9-9 - Not done	*(LRN1SERO)* See _pneu_st dataset and supporting documentation	*(LRN1ISID)*
4. Was a second pneumococcal colony identified? *(If No, end form)(LRN2PCOL)* 1-1 - Yes 0-0 - No	*(LRN2OZD)* *(xx)*	*(LRN2BILE)* 0-0 - No 1-1 - Yes 9-9 - Not done	*(LRN2SERO)*	*(LRN2ISID)*
5. Was a third pneumococcal colony identified? *(If No, end form)(LRN3PCOL)* 1-1 - Yes 0-0 - No	*(LRN3OZD)* *(xx)*	*(LRN3BILE)* 0-0 - No 1-1 - Yes 9-9 - Not done	*(LRN3SERO)*	*(LRN3ISID)*
6. Was a fourth pneumococcal colony identified? *(If No, end form)(LRN4PCOL)* 1-1 - Yes 0-0 - No	*(LRN4OZD)* *(xx)*	*(LRN4BILE)* 0-0 - No 1-1 - Yes 9-9 - Not done	*(LRN4SERO)*	*(LRN4ISID)*

Comments:*(LRNCOMM)*

Initial QC by: *(LRNINQC)*

Supervisor Staff Code: *(LRNSUPER)*

Supervisor Verification Date: *(LRNVDT)* *(ddMMMyyyy)*

CRF 25: Lab Result: Multiplex PCR (LRM)

Segment *(PROTSEG)*:
Specimen number *(SPECNUM)*:

If no specimen was taken, submit a Missing Forms Request.

1. Date of nucleic acid extraction: *(LRMNAEDT)* _____ *(ddMMMyyyy)*

2. Nucleic acid extract aliquot ID (scan barcode label): *(LRMSPCID)* _____

3. Technician who performed extraction Staff Code: *(LRMETECH)* _____

4. Specimen type *(select one)*: *(LRMSPTYP)*

01-01 - NP flocked swab/OP swab
02-02 - Induced sputum
03-03 - Lung aspirate
04-04 - NP flocked swab only
05-05 - ETT aspirate
*Additional Options Listed Below

5. Date of PCR Run: *(LRMPCRDT)* _____ *(ddMMMyyyy)*

6. Technician who performed run Staff Code: *(LRMPTECH)* _____

Comments: *(LRMCOMM)*

Initial QC by: *(LRMINQC)* _____

Supervisor Staff Code: *(LRMSUPER)* _____

Supervisor Verification Date: *(LRMVERDT)* _____ *(ddMMMyyyy)*

Additional Selection Options for LRM

Specimen number (SPECNUM) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15

Specimen type (select one):
07-07 - OP swab only
08-08 - Pleural fluid
09-09 - M2: Microbiology Core 2
10-10 - M5: Microbiology Core 5
11-11 - PR: Pleural Aspirate Right Lung
12-12 - PL: Pleural Aspirate Left Lung

CRF 26: Lab Result: Induced Sputum Micro-Culture (LRS)

Web Version: 1.0; 6.03; 16APR13

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

If no induced sputum specimen was taken, submit a Missing Forms Request.

Quality Assessment and Gram Stain

1. a. Date: *(LRSGSTDT)* _____ *(ddMMMyyyy)*

   b. Time: *(LRSGSTTM)* _____ *(hh:mm)* *(24 hour clock)*

2. Specimen ID (scan barcode label): *(LRSSPCID)* _____

3. Specimen type:
   (LRSSPTYP)
   | 1-1 - Induced sputum |
   | 2-2 - ETT aspirate |

   _SQCAT

4. Technician's Staff Code: *(LRSGSTCO)* _____

5. Number of neutrophils per representative low powered field (x10 objective)? *(check one)*
   (LRSNEUT)
   | 1-1 - <10 |
   | 2-2 - 10-25 |
   | 3-3 - >25 |

   _BARTT

6. Mucus seen? *(check one)*
   (LRSMUCUS)
   | 1-1 - Yes |
   | 0-0 - No |

7. Number of epithelial cells per representative low powered field (x10 objective)? *(check one)*
   (LRSEPITH)
   | 1-1 - <10 |
   | 2-2 - 10-25 |
   | 3-3 - >25 |

Induced Sputum Gram Stain

8. Description of any organism by Gram stain:
   Check the appropriate quantification box for Q8a-j below.

   If no organisms were seen, check here and skip to Q9: *(LRSNOORG)* ☐ No organisms seen (NOS)

	Organism	Not Seen	Scanty	1+	2+	3+
a.	Gram-negative rods (GNR)	*(LRSGNR)* ☐	☐	☐	☐	☐
b.	Gram-positive cocci in clusters (GPC clusters)	*(LRSGPCCL)* ☐	☐	☐	☐	☐
c.	Gram-negative coccobacilli (GNCB)	*(LRSGNCB)* ☐	☐	☐	☐	☐
d.	Gram-positive cocci in chains (GPC chains)	*(LRSGPCCH)* ☐	☐	☐	☐	☐
e.	Gram-negative diplococci (GNDC)	*(LRSGNDC)* ☐	☐	☐	☐	☐
f.	Gram-positive cocci single cells (GPC singles)	*(LRSGPCSI)* ☐	☐	☐	☐	☐
g.	Gram-negative cocci (GNC)	*(LRSGNC)* ☐	☐	☐	☐	☐
h.	Gram-positive rods (GPR)	*(LRSGPR)* ☐	☐	☐	☐	☐
i.	Gram-positive diplococci (GPDC)	*(LRSGPDC)* ☐	☐	☐	☐	☐
j.	Yeasts or other fungal elements	*(LRSYEAST)* ☐	☐	☐	☐	☐

Culture of Induced Sputum

9. Date/time put up for culture: *(LRSISPDT)* _____ *(ddMMMyyyy)* *(LRSISPTM)* _____ *(hh:mm)* *(24 hour clock)*

10. Technician's Staff Code: *(LRSISPCO)* _____

11. Final culture result:
    (LRSSPRST)
    | 1-1 - Growth (proceed) |
    | 2-2 - No growth (Stop here and end form) |

12. Organism identification and quantification:

	Organism Code	Quantity *(Select one)*	Isolate ID (scan barcode label)	Organism Confirmation

_ANYBAC_NONCONTAM_ISCX
_ANYBAC_NONCONTAM_ISCX2
1=Yes
0=No

a. Oropharyngeal flora		4-4 - Scanty 1-1 - 1+ 2-2 - 2+ 3-3 - 3+ 0-0 - None (LRSOROFQ)		

_&ORG._ISCX (Positive for indiv. organism)
_&ORG._ISCX2 (Positive w/ high stringency criteria)
_&ORG._ISCXG (Positive w/ compatible gram stain)

| b. Organism 1 | (LRS01ORG) | 4-4 - Scanty
1-1 - 1+
2-2 - 2+
3-3 - 3+
(LRS1ORGQ) | (LRS01ISO) | 1-1: C - Confirmed
2-2: U - Updated
3-3: NC - Not confirmed
(LRS01CON) |

(See organism dictionary for organism codes)
1=Positive
0=Negative)

| c. Organism 2 | (LRS02ORG) | 4-4 - Scanty
1-1 - 1+
2-2 - 2+
3-3 - 3+
(LRS2ORGQ) | (LRS02ISO) | 1-1: C - Confirmed
2-2: U - Updated
3-3: NC - Not confirmed
(LRS02CON) |
| d. Organism 3 | (LRS03ORG) | 4-4 - Scanty
1-1 - 1+
2-2 - 2+
3-3 - 3+
(LRS3ORGQ) | (LRS03ISO) | 1-1: C - Confirmed
2-2: U - Updated
3-3: NC - Not confirmed
(LRS03CON) |

_&ORG._ISCXQ (Quantity for indiv. organism)
(See organism dictionary for organism codes)
0=Negative
1=1+
2=2+
3=3+
4=Scanty

| e. Organism 4 | (LRS04ORG) | 4-4 - Scanty
1-1 - 1+
2-2 - 2+
3-3 - 3+
(LRS4ORGQ) | (LRS04ISO) | 1-1: C - Confirmed
2-2: U - Updated
3-3: NC - Not confirmed
(LRS04CON) |

13. Antibiotic Susceptibility Testing:
Note: 1: S = Susceptible; 2: I = Intermediate; 3: R = Resistant

Antibiotic Code:	Organism 1 Zone of inhibition in mm (xx):	Organism 1 S/I/R Code:	Organism 2 Zone of inhibition in mm (xx):	Organism 2 S/I/R Code:	Organism 3 Zone of inhibition in mm (xx):	Organism 3 S/I/R Code:	Organism 4 Zone of inhibition in mm (xx):
a. AMC (Amoxicillin / Clavulanic acid)	(LRS01AMC)	(LRS1AMCI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02AMC)	(LRS2AMCI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03AMC)	(LRS3AMCI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04A...
b. AMP (Ampicillin)	(LRS01AMP)	(LRS1AMPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02AMP)	(LRS2AMPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03AMP)	(LRS3AMPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04A...
c. CAZ (Ceftazidimine)	(LRS01CAZ)	(LRS1CAZI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02CAZ)	(LRS2CAZI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03CAZ)	(LRS3CAZI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04C...
d. CH (Chloramphenicol)	(LRS01CH)	(LRS1CHI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02CH)	(LRS2CHI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03CH)	(LRS3CHI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04C...
e. CIP (Ciprofloxacin)	(LRS01CIP)	(LRS1CIPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02CIP)	(LRS2CIPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03CIP)	(LRS3CIPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04C...
f. CN (Gentamicin)	(LRS01CN)	(LRS1CNI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02CN)	(LRS2CNI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03CN)	(LRS3CNI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04C...
g. CRO (Ceftriaxone)	(LRS01CRO)	(LRS1CROI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02CRO)	(LRS2CROI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03CRO)	(LRS3CROI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04C...

		(LRS01CTX)	(LRS1CTXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02CTX)	(LRS2CTXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03CTX)	(LRS3CTXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04C
h.	**CTX** (Cefotaxime)	(LRS01CTX)	(LRS1CTXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02CTX)	(LRS2CTXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03CTX)	(LRS3CTXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04C
i.	**DA** (Clindamycin)	(LRS01DA)	(LRS1DAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02DA)	(LRS2DAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03DA)	(LRS3DAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04D
j.	**ERY** (Erythromycin)	(LRS01ERY)	(LRS1ERYI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02ERY)	(LRS2ERYI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03ERY)	(LRS3ERYI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04E
k.	**FOX** (Cefoxitin)	(LRS01FOX)	(LRS1FOXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02FOX)	(LRS2FOXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03FOX)	(LRS3FOXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04F
l.	**IPM** (Imipenem)	(LRS01IPM)	(LRS1IPMI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02IPM)	(LRS2IPMI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03IPM)	(LRS3IPMI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04I
m.	**OX** (Oxacillin)	(LRS01OX)	(LRS1OXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02OX)	(LRS2OXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03OX)	(LRS3OXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04O
n.	**P** (Penicillin)	(LRS01P)	(LRS1PI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02P)	(LRS2PI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03P)	(LRS3PI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04P
o.	**SXT** (Cotrimoxazole)	(LRS01SXT)	(LRS1SXTI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02SXT)	(LRS2SXTI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03SXT)	(LRS3SXTI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04S
p.	**TET** (Tetracycline)	(LRS01TET)	(LRS1TETI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02TET)	(LRS2TETI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03TET)	(LRS3TETI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04T
q.	**VA** (Vancomycin)	(LRS01VA)	(LRS1VAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS02VA)	(LRS2VAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS03VA)	(LRS3VAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRS04V

Other Antibiotic, Specify:	Antibiotic Code:	Organism 1 Zone of inhibition in mm (xx):	Organism 1 S/I/R Code:	Organism 2 Zone of inhibition in mm (xx):	Organism 2 S/I/R Code:	Organism 3 Zone of inhibition in mm (xx):	Organism 3 S/I/R Code:	
r. Other (LRSOT1SP)	(LRSOTH1D)	(LRS1OT1D)	(LRS1OT1I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	(LRS2OT1D)	(LRS2OT1I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	(LRS3OT1D)	(LRS3OT1I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	
s. Other (LRSOT2SP)	(LRSOTH2D)	(LRS1OT2D)	(LRS1OT2I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	(LRS2OT2D)	(LRS2OT2I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	(LRS3OT2D)	(LRS3OT2I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	
t. Other (LRSOT3SP)	(LRSOTH3D)	(LRS1OT3D)	(LRS1OT3I)	(LRS2OT3D)	(LRS2OT3I)	(LRS3OT3D)	(LRS3OT3I)	

1-1: S - Susceptible 2-2: I - Intermediate 3-3: R- Resistant	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant

Organism 1   **Organism 2**   **Organism 3**

u. **Beta lactamase**   *(LRS01BPN)* ☐ 1 - Positive ☐ 2 - Negative   *(LRS02BPN)* ☐ 1 - Positive ☐ 2 - Negative   *(LRS03BPN)* ☐ 1 - Positive ☐ 2 - Negative   *(LRS04BP* ☐ Negative

14. MIC Etest® results for *S. pneumoniae* isloates that are resistant (R) or intermediate (I) to oxacillin disk diffusion testing.

MIC Etest® performed? *(LRSSPNET)* ☐ 1 - Yes ☐ 0 - No ☐ 9 - N/A   *(If No or N/A, skip to Question 15)*

a) Penicillin Etest® results   *(LRSPENSI)* ☐ < ☐ > *(LRSPENRS)* [　　　] *(xx.xxx) µg/mL*

b)*(LRSETDRG)* ☐ Ceftriaxone ☐ Cefotaxime   *(LRSETSIG)* ☐ < ☐ > *(LRSETRST)* [　　　] *(xx.xxx) µg/mL*

15. Screening for Extended Spectrum ß-Lactamase (ESBL) Production done?

(LRSESBL) ☐ 1 - Yes ☐ 0 - No

a. If Yes, results of additional phenotypic testing:

(LRSESBLC) ☐ 1 - ESBL confirmed ☐ 2 - ESBL not confirmed

Comments:

(LRSCOMM) [　　　　　　　　　　　　　　]

Technician Reporting Final Results Staff Code: *(LRSTECCO)* [　　　]

Initial QC by: *(LRSINQC)* [　　　　　　]

Supervisor Staff Code: *(LRSSUPER)* [　　　]

Supervisor Verification Date: *(LRSVERDT)* [　　　] *(ddMMMyyyy)*

CRF 26: Lab Result: Induced Sputum: Additional Tests (LRT)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

16. Was *S. pneumoniae* isolated?

(LRTSPISO) ☐ 1 - Yes   ☐ 0 - No

If Yes, what serotypes were identified:

a. *(LRT1SERP)* _____

b. *(LRT2SERP)* _____

c. *(LRT3SERP)* _____

d. *(LRT4SERP)* _____

See _pneu_st
dataset
and supporting
documentation

17. Was *H. influenzae* isolated?

(LRTHIISO) ☐ 1 - Yes   ☐ 0 - No

If Yes, what serotype was identified:

a. *(LRT5SERI)* _____

Comments:

(LRTCOMM)

Technician Reporting Final Results Staff Code: *(LRTTECH)* _____

Initial QC by: *(LRTINQC)* _____

Supervisor Staff Code: *(LRTSUPER)* _____

Supervisor Verification Date: *(LRTVERDT)* _____ *(ddMMMyyyy)*

CRF 27: Lab Results: TB Testing (CTB)

Segment *(PROTSEG)*:

Specimen type *(TBSPECTY)*:

1. Date tested or sent to reference lab: *(CTBTESDT)* [ ] *(ddMMMyyyy)*

2. Specimen ID (scan barcode label): *(CTBTBSID)* [ ]

3. Technician's staff code: *(CTBTECCO)* [ ]

4. Volume of specimen sent for TB staining and culture: *(CTBSPVOL)* [ ] *(xxxxx)* µL

ACID-FAST BACILLI SMEAR

5. Results *(select one)*:

1-1 - Negative; No AFB per 100 oil immersion fields
2-2 - Scanty; 1 - 9 AFB per 100 oil immersion fields
3-3 - Positive 1+; 10 - 99 AFB per 100 oil immersion fields
4-4 - Positive 2+; 1 - 10 AFB per oil immersion field
5-5 - Positive 3+; > 10 AFB per oil immersion field
*Additional Options Listed Below

(CTBSMEAR)

If Scanty, enter # of AFB: *(CTBAFBN)* [ ] *(x)*

CULTURE

(CTBCULND) ☐ Culture not done *(skip to end)*

6. Mycobacterium tuberculosis isolated?

1-1 - Yes
0-0 - No
2-2 - Contaminated specimen

(CTBMYTBI)

7. Other mycobacterium isolated?

1-1 - Yes
0-0 - No
2-2 - Contaminated specimen

(CTBMTBOT)

7a-b. If Yes, enter the following information:

Organism Code   Specimen ID (scan barcode label):

a. *(CTBOR1CO)* [ ]   *(CTBOR1ID)* [ ]

b. *(CTBOR2CO)* [ ]   *(CTBOR2ID)* [ ]

8. Susceptibility testing:

Note: **1: S = Susceptible; 2: I = Intermediate; 3: R = Resistant**

Antibiotic	Mycobacterium tuberculosis S/I/R Code:	Organism A S/I/R Code:	Organism B S/I/R Code:
a. Isoniazid:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMISOI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBAISOI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBISOI)*
b. Pyrazinamide:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMPYRI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBAPYRI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBPYRI)*
c. Ethambutol:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMETHI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBAETHI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBETHI)*
d. Amikacin:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMAMKI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBAAMKI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBAMKI)*
e. Capreomycin:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMCAPI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBACAPI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBCAPI)*

	Mycobacterium tuberculosis S/I/R Code	Organism A S/I/R Code	Organism B S/I/R Code
f. Ethionamide:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMETAI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBAETAI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBETAI)*
g. Rifampicin:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMRIFI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBARIFI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBRIFI)*
h. Streptomycin:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMSTRI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBASTRI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBSTRI)*
i. Ofloxacin:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMOFLI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBAOFLI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBOFLI)*
j. Kanamycin:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMKANI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBAKANI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBKANI)*
k. Cycloserine:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMCYCI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBACYCI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBCYCI)*
l. PAS:	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBMPASI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBAPASI)*	1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant *(CTBBPASI)*

Other Antibiotic, Specify:	Antibiotic Code:	Mycobacterium tuberculosis S/I/R Code:	Organism A S/I/R Code:	Organism B S/I/R Code:
m. Other *(CTBOT1SP)*	*(CTBOT1CO)*	*(CTBMOT1I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(CTBAOT1I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(CTBBOT1I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
n. Other *(CTBOT2SP)*	*(CTBOT2CO)*	*(CTBMOT2I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(CTBAOT2I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(CTBBOT2I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
o. Other *(CTBOT3SP)*	*(CTBOT3CO)*	*(CTBMOT3I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(CTBAOT3I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(CTBBOT3I)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant

Comments: *(CTBCOMM)*

Initial QC by: *(CTBINQC)*

Supervisor Staff Code: *(CTBSUPCO)*

Supervisor Verification Date: *(CTBVERDT)* *(ddMMMyyyy)*

Additional Selection Options for CTB

Specimen type *(TBSPECTY)* (key field):
01-01 - Initial induced sputum
02-02 - Pleural fluid
03-03 - Gastric aspirate
04-04 - ETT specimen
05-05 - Lung aspirate
07-07 - Second induced sputum
08-08 - Second pleural fluid
09-09 - Second gastric aspirate
10-10 - Second ETT specimen
11-11 - Third gastric aspirate
12-12 - Fourth gastric aspirate
13-13 - Fifth gastric aspirate
14-14 - M3: Microbiology Core 3
15-15 - M6: Microbiology Core 6
16-16 - PR: Pleural Aspirate Right Lung
17-17 - PL: Pleural Aspirate Left Lung

Acid-fast bacilli smear
6-6 - Not Done; Microscopy not done

CRF 28: Lab Result: Pleural Fluid - Lung Aspirate (LRF)

Segment *(PROTSEG)*:

Specimen number *(SPECNUM)*:

If no pleural fluid/lung aspirate specimen was taken, submit a Missing Forms Request.

1. Date/time put up for culture: *(LRFGSTDT)* _____ *(ddMMMyyyy)* *(LRFGSTTM)* _____ *(hh:mm)* *(24 hour clock)*

2. Specimen ID (scan barcode label): *(LRFSPCID)* _____

3. Specimen type *(check one)*:

   | 1-1 - Pleural fluid |
   | 2-2 - Lung aspirate |

   (LRFSPTYP)

   3a. If pleural fluid, select all that apply: *(LRFPFPUR)* ☐ purulent *(LRFPFBLO)* ☐ bloody *(LRFPFCLE)* ☐ clear

4. Technician's Staff Code: *(LRFPLECO)* _____

Gram Stain

5. Description of any organism by Gram stain:

   Check the appropriate quantification box for Q5a-j below.

   If no organisms were seen, check here and skip to Q6: *(LRFNOORG)* ☐ No organisms seen (NOS)

	Organism		Not Seen	Scanty	1+	2+	3+
a.	Gram-negative rods (GNR)	*(LRFGNR)* ☐	☐	☐	☐	☐
b.	Gram-positive cocci in clusters (GPC clusters)	*(LRFGPCCL)* ☐	☐	☐	☐	☐
c.	Gram-negative coccobacilli (GNCB)	*(LRFGNCB)* ☐	☐	☐	☐	☐
d.	Gram-positive cocci in chains (GPC chains)	*(LRFGPCCH)* ☐	☐	☐	☐	☐
e.	Gram-negative diplococci (GNDC)	*(LRFGNDC)* ☐	☐	☐	☐	☐
f.	Gram-positive cocci single cells (GPC singles)	*(LRFGPCSI)* ☐	☐	☐	☐	☐
g.	Gram-negative cocci (GNC)	*(LRFGNC)* ☐	☐	☐	☐	☐
h.	Gram-positive rods (GPR)	*(LRFGPR)* ☐	☐	☐	☐	☐
i.	Gram-positive diplococci (GPDC)	*(LRFGPDC)* ☐	☐	☐	☐	☐
j.	Yeasts or other fungal elements	*(LRFYEAST)* ☐	☐	☐	☐	☐
k.	Leukocytes	*(LRFLEUKO)* ☐	☐	☐	☐	☐

Bacterial Culture

6. Aerobic Plate: Was growth observed up to 96 hours? *(LRF96HOU)* ☐ 1 - Yes ☐ 0 - No

7. Anerobic Plate: Was growth observed at 48 hours? *(LRF48HOU)* ☐ 1 - Yes ☐ 0 - No

8. Was broth positive? *(LRFBRPOS)* ☐ 1 - Yes ☐ 0 - No

If the answer to Q6, Q7 AND Q8 are No, please skip to Q13.

9. Organism identification and quantification:

		Organism Code	Found In	Isolate ID (scan barcode label)	Organism Confirmation	Organ
_AVAIL_PFCX _AVAIL_LACX 1=Yes 0=No	a. Mixed skin flora		1-1 - Solid Media 2-2 - Broth 3-3 - Both 9-9 - N/A *(LRFSKFLL)*			
_&ORG._PFCX _&ORG._LACX (Positive for indiv. organism; See organism dictionary for organism code) 1=Positive 0=Negative	b. Organism 1	*(LRF01ORG)* _____	1-1 - Solid Media 2-2 - Broth 3-3 - Both *(LRF1ORGL)*	*(LRF01ISO)* _____	1-1: C - Confirmed 2-2: U - Updated 3-3: NC - Not confirmed *(LRF01CON)*	4-4 - Sc 1-1 - 1+ 2-2 - 2+ 3-3 - 3+ *(LRF01OQ*

c. Organism 2	(LRF02ORG)	1-1 - Solid Media 2-2 - Broth 3-3 - Both (LRF2ORGL)	(LRF02ISO)	1-1: C - Confirmed 2-2: U - Updated 3-3: NC - Not confirmed (LRF02CON)
d. Organism 3	(LRF03ORG)	1-1 - Solid Media 2-2 - Broth 3-3 - Both (LRF3ORGL)	(LRF03ISO)	1-1: C - Confirmed 2-2: U - Updated 3-3: NC - Not confirmed (LRF03CON)
e. Organism 4	(LRF04ORG)	1-1 - Solid Media 2-2 - Broth 3-3 - Both (LRF4ORGL)	(LRF04ISO)	1-1: C - Confirmed 2-2: U - Updated 3-3: NC - Not confirmed (LRF04CON)

10. Antibiotic Susceptibility Testing:

Note: **1: S = Susceptible; 2: I = Intermediate; 3: R = Resistant**

Antibiotic Code:	Organism 1 Zone of inhibition in mm (xx):	Organism 1 S/I/R Code:	Organism 2 Zone of inhibition in mm (xx):	Organism 2 S/I/R Code:	Organism 3 Zone of inhibition in mm (xx):	Organism 3 S/I/R Code:	Organism Zone inhib in (x
a. **AMC** (Amoxicillin / Clavulanic acid)	(LRF01AMC)	(LRF1AMCI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF02AMC)	(LRF2AMCI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03AMC)	(LRF3AMCI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04
b. **AMP** (Ampicillin)	(LRF01AMP)	(LRF1AMPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF02AMP)	(LRF2AMPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03AMP)	(LRF3AMPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04
c. **CAZ** (Ceftazidimine)	(LRF01CAZ)	(LRF1CAZI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF02CAZ)	(LRF2CAZI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03CAZ)	(LRF3CAZI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04
d. **CH** (Chloramphenicol)	(LRF01CH)	(LRF1CHI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF02CH)	(LRF2CHI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03CH)	(LRF3CHI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04
e. **CIP** (Ciprofloxacin)	(LRF01CIP)	(LRF1CIPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF02CIP)	(LRF2CIPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03CIP)	(LRF3CIPI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04
f. **CN** (Gentamicin)	(LRF01CN)	(LRF1CNI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF02CN)	(LRF2CNI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03CN)	(LRF3CNI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04
g. **CRO** (Ceftriaxone)	(LRF01CRO)	(LRF1CROI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF02CRO)	(LRF2CROI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03CRO)	(LRF3CROI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04
h. **CTX** (Cefotaxime)	(LRF01CTX)	(LRF1CTXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF02CTX)	(LRF2CTXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03CTX)	(LRF3CTXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04
i. **DA** (Clindamycin)	(LRF01DA)	(LRF1DAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF02DA)	(LRF2DAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03DA)	(LRF3DAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04
j. **ERY** (Erythromycin)	(LRF01ERY)	(LRF1ERYI)	(LRF02ERY)	(LRF2ERYI)	(LRF03ERY)	(LRF3ERYI)	(LRF04

	Antibiotic Code	Organism 1 Zone	Organism 1 S/I/R Code	Organism 2 Zone	Organism 2 S/I/R Code	Organism 3 Zone	Organism 3 S/I/R Code	Organism 4
			1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant		1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant		1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	
k. FOX (Cefoxitin)	(LRF01FOX)	(LRF02FOX)	(LRF1FOXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF2FOXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03FOX)	(LRF3FOXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04...)
l. IPM (Imipenem)	(LRF01IPM)	(LRF02IPM)	(LRF1IPMI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF2IPMI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03IPM)	(LRF3IPMI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04...)
m. OX (Oxacillin)	(LRF01OX)	(LRF02OX)	(LRF1OXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF2OXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03OX)	(LRF3OXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04...)
n. P (Penicillin)	(LRF01P)	(LRF02P)	(LRF1PI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF2PI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03P)	(LRF3PI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04...)
o. SXT (Cotrimoxazole)	(LRF01SXT)	(LRF02SXT)	(LRF1SXTI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF2SXTI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03SXT)	(LRF3SXTI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04...)
p. TET (Tetracycline)	(LRF01TET)	(LRF02TET)	(LRF1TETI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF2TETI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03TET)	(LRF3TETI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04...)
q. VA (Vancomycin)	(LRF01VA)	(LRF02VA)	(LRF1VAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF2VAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF03VA)	(LRF3VAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF04...)

Other Antibiotic, Specify:	Antibiotic Code:	Organism 1 Zone of inhibition in mm (xx):	Organism 1 S/I/R Code:	Organism 2 Zone of inhibition in mm (xx):	Organism 2 S/I/R Code:	Organism 3 Zone of inhibition in mm (xx):	Organism 3 S/I/R Code:
r. Other (LRFOT1SP)	(LRFOTH1D)	(LRF1OT1D)	(LRF1OT1I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF2OT1D)	(LRF2OT1I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF3OT1D)	(LRF3OT1I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
s. Other (LRFOT2SP)	(LRFOTH2D)	(LRF1OT2D)	(LRF1OT2I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF2OT2D)	(LRF2OT2I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF3OT2D)	(LRF3OT2I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
t. Other (LRFOT3SP)	(LRFOTH3D)	(LRF1OT3D)	(LRF1OT3I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF2OT3D)	(LRF2OT3I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRF3OT3D)	(LRF3OT3I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant

	Organism 1	Organism 2	Organism 3	
u. Beta lactamase	(LRF01BPN) ☐ 1 - Positive ☐ 2 - Negative	(LRF02BPN) ☐ 1 - Positive ☐ 2 - Negative	(LRF03BPN) ☐ 1 - Positive ☐ 2 - Negative	(LRF04B...) ☐

11. MIC Etest® results for *S. pneumoniae* isloates that are resistant (R) or intermediate (I) to oxacillin disk diffusion testing.

MIC Etest® performed? (LRFSPNET) ☐ 1 - Yes ☐ 0 - No ☐ 9 - N/A *(If No or N/A, skip to Question 12)*

a) Penicillin Etest® results (LRFPENSI) ☐ < ☐ > (LRFPENRS) [____] *(xx.xxx) µg/mL*

b)*(LRFETDRG)* ☐ Ceftriaxone ☐ Cefotaxime *(LRFETSIG)* ☐ < ☐ > *(LRFETRST)* ⬚ *(xx.xxx) µg/mL*

12. Screening for Extended Spectrum ß-Lactamase (ESBL) Production done?

(LRFESBL) ☐ 1 - Yes ☐ 0 - No

    a. If Yes, results of additional phenotypic testing:

(LRFESBLC) ☐ 1 - ESBL confirmed ☐ 2 - ESBL not confirmed

Chemistry - Pleural Fluid Only

13. Results:

Variable:	Result:	
a. Protein	*(LRFPROTE)* ⬚	*(xx.x)* g/dL
b. Glucose	*(LRFGLUCO)* ⬚	*(xx.x)* mmol/L
c. Not Done	*(LRFCHEND)* ☐	

14. Technician's Staff Code: *(LRFCHECO)* ⬚

BinaxNOW Pneumococcal Antigen Testing - Pleural Fluid Only

_AVAIL_PFBINAX
1=Yes
0=No

15. Technician's Staff Code: *(LRFBINCO)* ⬚

_PNEU_PFBINAX
1=Positive
0=Negative

16. Test result: *(LRFBINAX)* ☐ 1 - Positive ☐ 2 - Negative ☐ 3 - Indeterminate ☐ 9 - Not done

Comments:

(LRFCOMM)

Initial QC by: *(LRFINQC)* ⬚

Supervisor Staff Code: *(LRFSUPER)* ⬚

Supervisor Verification Date: *(LRFVERDT)* ⬚ *(ddMMMyyyy)*

Additional Selection Options for LRF

Specimen number (*SPECNUM*) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15

CRF 28: Lab Result: Pleural Fluid: Additional Tests (LRG)

Segment *(PROTSEG)*:

Specimen number *(SPECNUM)*:

(Question 11) 'MIC Etest® performed?' was answered Yes; for results for *S. pneumoniae* isolates that are resistant (R) or intermediate (I) to oxacillin disk diffusion testing. Please answer the following questions:

    c. Clindamycin Dtest® results *(LRGCLNRS)* ☐ 1 - Positive ☐ 2 - Negative

17. MIC Etest® results for *S. aureus* isolates that are resistant (R) or intermediate (I) to cefoxitin disk diffusion testing.

    MIC Etest® performed? *(LRGSANET)* ☐ 1 - Yes ☐ 0 - No ☐ 9 - N/A

    a. Vancomycin Etest® results *(LRGVNSSI)* ☐ < ☐ >   *(LRGVNSRS)* [ ] *(xx.xxx) µg/mL*

    b. Clindamycin Dtest® results *(LRGCNSRS)* ☐ 1 - Positive ☐ 2 - Negative

18. Was *S. pneumoniae* isolated?

(LRGSPISO) ☐ 1 - Yes ☐ 0 - No

    If Yes, what serotypes were identified:

a. *(LRG1SERP)* [ ]

b. *(LRG2SERP)* [ ]

c. *(LRG3SERP)* [ ]

d. *(LRG4SERP)* [ ]

See _pneu_st dataset and supporting documentation

19. Was *H. influenzae* isolated?

(LRGHIISO) ☐ 1 - Yes ☐ 0 - No

    If Yes, what serotype was identified:

a. *(LRG5SERI)* [ ]

Comments:

(LRGCOMM) [ ]

Technician Reporting Final Results Staff Code: *(LRGTECH)* [ ]

Initial QC by: *(LRGINQC)* [ ]

Supervisor Staff Code: *(LRGSUPER)* [ ]

Supervisor Verification Date: *(LRGVERDT)* [ ] *(ddMMMyyyy)*

Additional Selection Options for LRG

Specimen number (*SPECNUM*) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15

CRF 29: Lab Result: PCP Staining/Fluor Results (LPC)

Segment *(PROTSEG)*:

Specimen type *(LPCSPECT)*:

1. Specimen ID (scan barcode label): *(LPCSPID)*

2. Date/time test performed: *(LPCTSTDT)*   *(ddMMMyyyy)*

         (LPCTSTTM)   *(hh:mm) (24 hour clock)*

3. Technician's Staff Code: *(LPCSPCO)*

4. Type of test *(check one)*: *(LPCTSTTP)* ☐ 1 - Immunofluorescence   ☐ 2 - Toluidine blue staining

5. Test result *(check one)*: *(LPCTRSLT)* ☐ 1 - Positive   ☐ 2 - Negative

     If Positive *(check one)*:

> 1-1 + (<10 cysts per field)
> 2-2 + (11-100 cysts per field)
> 3-3 + (101-1000 cysts per field)
> 4-4 + (>1000 cysts per field)

(LPCCYSTN)

Comments:*(LPCCOMM)*

Initial QC by: *(LPCINQC)*

Supervisor Staff Code: *(LPCSSCO)*

Supervisor Verification Date: *(LPCSUPDT)*   *(ddMMMyyyy)*

Additional Selection Options for LPC

Specimen type (LPCSPECT) (key field):
1-1 - Induced sputum
2-2 - Pleural fluid
3-3 - Lung aspirate
4-4 - ETT aspirate

CRF 30: Participant Event (DEV)

Segment *(PROTSEG)*:

Event number *(EVENTNUM)*:

Indicate which best categorizes the study participant event:

1. Category *(check one)*:*(DEVCAT)*   Other, specify:*(DEVCATSP)*   Code:*(DEVCATCO)*

01-01 - Safety
02-02 - Informed consent
03-03 - Protocol implementation
99-99 - Other

Code:*(DEVDESCO)*

2. Description of event:*(DEVDESCR)*

3. Corrective action taken:*(DEVACTIO)*   Code:*(DEVACTCO)*   *(DEVACTNA)* ☐ 9 - N/A

4. Event start date:*(DEVSTADT)* _____ *(ddMMMyyyy)*

5. Event end date:*(DEVENDDT)* _____ *(ddMMMyyyy)*

6. Date reported to ERC, if required:*(DEVREPDT)* _____ *(ddMMMyyyy)* *(DEVREPNA)* ☐ 9 - N/A

Comments:*(DEVCOMM)*

Form Completed by Staff Code: (DEVSTACO) _____

Initial QC by: (DEVINQC) _____

Supervisor Staff Code: (DEVSUPCO) _____

Supervisor Verification Date: (DEVVERDT) _____ *(ddMMMyyyy)*

Additional Selection Options for DEV

Event number (*EVENTNUM*) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15
16-16
17-17
18-18
19-19
20-20
21-21
22-22
23-23
24-24
25-25

CRF 30A: Site Event (SDE)

Event number *(EVENTNUM)*:

1. Description of event:*(SDEDESCR)*　　　　　　　　　　　Code:*(SDEDESCO)*

2. Data that may be affected:*(SDEDATAF)*　　　　　　　　　Code:*(SDEDATCO)*

3. Corrective action taken:*(SDEACTIO)*　　　　　Code:*(SDEACTCO)*　　　*(SDEACTNA)* ☐ 9 - N/A

4. Event start date:*(SDESTADT)* ☐ *(ddMMMyyyy)*

5. Event end date:*(SDEENDDT)* ☐ *(ddMMMyyyy)*

6. Date reported to local ERC, if required:*(SDEREPDT)* ☐ *(ddMMMyyyy)* *(SDEREPNA)* ☐ 9 - N/A

Comments:*(SDECOMM)*

Form Completed by Staff Code: (SDESTACO)

Initial QC by: *(SDEINQC)*

Supervisor Staff Code: *(SDESUPCO)*

Supervisor Verification Date: *(SDEVERDT)* *(ddMMMyyyy)*

Additional Selection Options for SDE

Event number (*EVENTNUM*) (key field):
01-01
02-02
03-03
04-04
05-05
06-06
07-07
08-08
09-09
10-10
11-11
12-12
13-13
14-14
15-15
16-16
17-17
18-18
19-19
20-20
21-21
22-22
23-23
24-24
25-25

CRF 31: Case Pre-Screening (CPS)

Reporting period *(RPERIDD)*:

To be completed once a month

1. If reporting period start and end dates are not the first and last day of the month, record them here: *(CPSDTNA)* ☐ 9 - N/A

    a. Start date: *(CPSSTDT)* ☐☐☐☐☐ *(ddMMMyyyy)*

    b. End date: *(CPSENDDT)* ☐☐☐☐☐ *(ddMMMyyyy)*

PART A: Pre-Screening

2. Total under-five admissions (all days, all hours):   *(CPSU5ADM)* ☐☐☐☐ *(xxxx)*   *(CPSU5AUN)* ☐ 8 - UNK

    a. Provide a brief description of the source of the above data: *(CPSU5ASP)*

2i. Total under-five admissions that were admitted to the hospital: *(CPSU5HOS)* ☐☐☐☐ *(xxxx)*   *(CPSU5HUN)* ☐ 8 - UNK

    a. Provide a brief description of the source of the above data: *(CPSU5HSP)*

3. Total under-five admissions who met the clinical screening trigger: *(CPSU5ATG)* ☐☐☐☐ *(xxxx)*   *(CPSTRGUN)* ☐ 8 - UNK

    a. Provide a brief description of the source of the above data: *(CPSTRGSP)*

4. Total under-five admissions during hours of screening: *(CPSU5SCR)* ☐☐☐☐ *(xxxx)*   *(CPSUSCUN)* ☐ 8 - UNK   ☐ 9 - N/A

    a. Provide a brief description of the source of the above data: *(CPSSCRSP)*

5. Total under-five admissions during the hours of screening
   who met the clinical screening trigger: *(CPSSCTRG)* [____] *(xxxx)*   *(CPSSCTUN)* ☐ 8 - UNK   ☐ 9 - N/A

   a. Provide a brief description of the source of the above data: *(CPSSCTSP)*

6. Number of <u>all</u> patient screened (all ages): *(CPSNUMSC)* [____] *(xxxx)*   *(CPSNUMUN)* ☐ 8 - UNK   ☐ 9 - N/A
   (check NA if all screened are entered in EDC)

7. Number of <u>admitted</u> patient screened (all ages): *(CPSNUMAD)* [____] *(xxxx)*   *(CPSADMUN)* ☐ 8 - UNK   ☐ 9 - N/A
   (check NA if all screened are entered in EDC)

   a. If applicable, please provide additional information
   to describe why Q3 or Q5, as applicable, does not equal Q7
   (i.e., explain why some hospitalized age-eligible children
   who met the clinical screening trigger were not screened). *(CPSNUMSP)*

PART B: For sites that do not submit CRF 01 for <u>INELIGIBLE or NON-ENROLLED</u> subjects

8. Of Q7 (screened and admitted), how many were eligible? *(CPSNUELI)* [____] *(xxxx)*   *(CPSNUEUN)* ☐ 8 - UNK

   a. Of Q7 (screened and admitted), for how many was eligibility unknown? *(CPSNUUNK)* [____] *(xxxx)*   *(CPSEUUNK)* ☐ 8 - UNK

9. Of Q8 (screened and eligible), how many were not enrolled
   for each of the reasons below:

   a. Refused consent *(CPSCNSNT)* [____] *(xxxx)*   *(CPSCNSUN)* ☐ 8 - UNK

   b. Died *(CPSDIED)* [____] *(xxxx)*   *(CPSDIEUN)* ☐ 8 - UNK

   c. Met quota *(CPSQUOT)* [____] *(xxxx)*   *(CPSQUOUN)* ☐ 8 - UNK

   d. Other *(CPSEOT)* [____] *(xxxx)*   *(CPSEOTUN)* ☐ 8 - UNK

    (CPSEOTSP) Other, specify: [____]   *(CPSEOTCO)* Code:

10. Of Q6 (all patients screened) <u>who were ineligible</u>,
    how many were excluded for each of the reasons below:

   a. Not from catchment area *(CPSCATCH)* [____] *(xxxx)*   *(CPSCATUN)* ☐ 8 - UNK

   b. Not age-eligible *(CPSAGEIN)* [____] *(xxxx)*   *(CPSAGEUN)* ☐ 8 - UNK

   c. No cough or difficulty breathing *(CPSNOCOU)* [____] *(xxxx)*   *(CPSNOCUN)* ☐ 8 - UNK

   d. No signs of severe or very severe pneumonia *(CPSNOPNE)* [____] *(xxxx)*   *(CPSNOPUN)* ☐ 8 - UNK

e. Not admitted to hospital   *(CPSNOTAD)* ☐ *(xxxx)*   *(CPSNOAUN)* ☐ 8 - UNK

f. Hospitalized within the past 14 days   *(CPSHOSP)* ☐ *(xxxx)*   *(CPSHOSUN)* ☐ 8 - UNK

g. PERCH case within past 30 days   *(CPSPREV)* ☐ *(xxxx)*   *(CPSPCHUN)* ☐ 8 - UNK

h. LCWI resolved after BD challenge (severe cases only)   *(CPSLCRES)* ☐ *(xxxx)*   *(CPSLRSUN)* ☐ 8 - UNK

i. Other   *(CPSIOTH)* ☐ *(xxxx)*   *(CPSIOTUN)* ☐ 8 - UNK

(CPSIOTSP) Other, specify   *(CPSIOTCO)* Code:

Comments:

(CPSCOMM)

Form Completed by Staff Code: *(CPSSTACO)*

Initial QC by: *(CPSINQC)*

Supervisor Staff Code: *(CPSSUPCO)*

Supervisor Verification Date: *(CPSVERDT)* *(ddMMMyyyy)*

Additional Selection Options for CPS

Reporting period *(RPERDD)* (key field):
01-June - 2011
02-July - 2011
03-August - 2011
04-September - 2011
05-October - 2011
06-November - 2011
07-December - 2011
08-January - 2012
09-February - 2012
10-March - 2012
11-April - 2012
12-May - 2012
13-June - 2012
14-July - 2012
15-August - 2012
16-September - 2012
17-October - 2012
18-November - 2012
19-December - 2012
20-January - 2013
21-February - 2013
22-March - 2013
23-April - 2013
24-May - 2013
25-June - 2013
26-July - 2013
27-August - 2013
28-September - 2013
29-October - 2013
30-November - 2013
31-December - 2013
32-January - 2014
33-February - 2014
34-March - 2014
35-April - 2014
36-May - 2014
37-June - 2014
38-July - 2014
39-August - 2014
40-September - 2014
41-October - 2014
42-November - 2014
43-December - 2014

CRF 31Ai: EPI Control Screening (CPE)

Reporting period *(RPERIDD)*:

To be completed once a month

1. If reporting period start and end dates are not the first and last day of the month, record them here: *(CPEDTNA)* ☐ 9 - N/A

a. Start date: *(CPESTDT)* ☐☐☐☐☐ *(ddMMMyyyy)*

b. End date: *(CPEENDDT)* ☐☐☐☐☐ *(ddMMMyyyy)*

PART A: Pre-Screening

2. Number of households visited <u>with an age-eligible child</u> for screening: *(CPEAGEEL)* ☐☐☐☐ *(xxxx)*   *(CPEEAGUN)* ☐ 8 - UNK

3. Of Q2 above (i.e., households with an age-eligible child), record the number of controls that <u>were not screened</u> (i.e., Screening Form CRF 01A was not completed) because:

    a. Guardian could not be located: *(CPENOLOC)* ☐☐☐☐ *(xxxx)*   *(CPENOLUN)* ☐ 8 - UNK   ☐ 9 - N/A

    b. Child out of town: *(CPETOWN)* ☐☐☐☐ *(xxxx)*   *(CPETOWUN)* ☐ 8 - UNK   ☐ 9 - N/A

    c. They declined to be screened for PERCH: *(CPEDEC)* ☐☐☐☐ *(xxxx)*   *(CPEDECUN)* ☐ 8 - UNK   ☐ 9 - N/A

    d. They did not appear at the clinic/hospital for enrollment: *(CPENOSHO)* ☐☐☐☐ *(xxxx)*   *(CPENOSUN)* ☐ 8 - UNK   ☐ 9 - N/A

    e. Other: *(CPENSOTH)* ☐☐☐☐ *(xxxx)*   *(CPENSOUN)* ☐ 8 - UNK   ☐ 9 - N/A

    (CPENSOSP) Other, specify: ☐☐☐☐☐   *(CPENSOCO)* Code: ☐☐☐

PART B: For sites that do not submit CRF 01A for <u>INELIGIBLE or NON-ENROLLED</u> screened subjects

4. Record the number of children screened: *(CPENUMSC)* ☐☐☐☐ *(xxxx)*   *(CPENUMUN)* ☐ 8 - UNK   ☐ 9 - N/A

5. Of Q4 (screened), how many were <u>eligible</u> but did not have CRF 01A entered into EDC? *(CPEELI)* ☐☐☐☐ *(xxxx)*   *(CPEELIUN)* ☐ 8 - UNK   ☐ 9 - N/A

Of Q5, record how many were not enrolled for each of the reasons below:

    a. Refused consent: *(CPECNSNT)* ☐☐☐☐ *(xxxx)*   *(CPECNSUN)* ☐ 8 - UNK

    b. Met quota: *(CPEQUOT)* ☐☐☐☐ *(xxxx)*   *(CPEQUOUN)* ☐ 8 - UNK

    c. Other: *(CPEEOT)* ☐☐☐☐ *(xxxx)*   *(CPEEOTUN)* ☐ 8 - UNK

    (CPEEOTSP) Other, specify: ☐☐☐☐☐   *(CPEEOTCO)* Code: ☐☐☐

6. Of Q4 (screened), how many were <u>ineligible</u> and did not have CRF 01A entered into EDC? *(CPEINELI)* ☐☐☐☐ *(xxxx)*   *(CPEIELUN)* ☐ 8 - UNK   ☐ 9 - N/A

Of Q6, record how many were ineligible for each of the reasons below:

    a. Not from catchment area: *(CPECATCH)* ☐☐☐☐ *(xxxx)*   *(CPECATUN)* ☐ 8 - UNK

    b. Not age-eligible: *(CPEAGEIN)* ☐☐☐☐ *(xxxx)*   *(CPEAGEUN)* ☐ 8 - UNK

    c. Hospitalized within the past 14 days: *(CPEHOSP)* ☐☐☐☐ *(xxxx)*   *(CPEHOSUN)* ☐ 8 - UNK

    d. PERCH case within past 30 days: *(CPEPREV)* ☐☐☐☐ *(xxxx)*   *(CPEPCHUN)* ☐ 8 - UNK

    e. Too sick (requires hospitalization): *(CPEILL)* ☐☐☐☐ *(xxxx)*   *(CPEILLUN)* ☐ 8 - UNK

    f. Other: *(CPEIOTH)* ☐☐☐☐ *(xxxx)*   *(CPEIOTUN)* ☐ 8 - UNK

(CPEIOTSP) Other, specify:

(CPEIOTCO) Code:

Comments:

(CPECOMM)

Form Completed by Staff Code: *(CPESTACO)*

Initial QC by: *(CPEINQC)*

Supervisor Staff Code: *(CPESUPCO)*

Supervisor Verification Date: *(CPEVERDT)* *(ddMMMyyyy)*

Additional Selection Options for CPE

Reporting period *(RPERDD)* (key field):
01-June - 2011
02-July - 2011
03-August - 2011
04-September - 2011
05-October - 2011
06-November - 2011
07-December - 2011
08-January - 2012
09-February - 2012
10-March - 2012
11-April - 2012
12-May - 2012
13-June - 2012
14-July - 2012
15-August - 2012
16-September - 2012
17-October - 2012
18-November - 2012
19-December - 2012
20-January - 2013
21-February - 2013
22-March - 2013
23-April - 2013
24-May - 2013
25-June - 2013
26-July - 2013
27-August - 2013
28-September - 2013
29-October - 2013
30-November - 2013
31-December - 2013
32-January - 2014
33-February - 2014
34-March - 2014
35-April - 2014
36-May - 2014
37-June - 2014
38-July - 2014
39-August - 2014
40-September - 2014
41-October - 2014
42-November - 2014
43-December - 2014

CRF 31Aii: DSS Control Pre-Screening (CPH)

Reporting period *(RPERIDD)*:

To be completed once a month

1. If reporting period start and end dates are not the first and last day of the month, record them here: *(CPHDTNA)* ☐ 9 - N/A

a. Start date: *(CPHSTDT)* ☐ *(ddMMMyyyy)*

b. End date: *(CPHENDDT)* ☐ *(ddMMMyyyy)*

PART A: Pre-Screening

2. Number of controls approached or attempted to enroll in PERCH: *(CPHAPPRO)* ☐ *(xxxx)* *(CPHAPPRU)* ☐ 8 - UNK ☐ 9 - N/A

   a. Number of controls approached from birth registry *(CPHAPPRB)* ☐ *(xxxx)* *(CPHAPPBU)* ☐ 8 - UNK ☐ 9 - N/A

3. Of Q2, record the number of controls that were <u>not</u> screened (i.e., Screening Form CRF01A was not completed/entered into the EDC) because:

   a. Could not be located (moved or not found at home after repeated visits) *(CPHLOCAT)* ☐ *(xxxx)* *(CPHLOCUN)* ☐ 8 - UNK ☐ 9 - N/A

   b. Declined to be screened *(CPHDECLN)* ☐ *(xxxx)* *(CPHDECUN)* ☐ 8 - UNK ☐ 9 - N/A

   c. Did not appear at the clinic/hospital for enrollment *(CPHAPEAR)* ☐ *(xxxx)* *(CPHAPEUN)* ☐ 8 - UNK ☐ 9 - N/A

   d. Died *(CPHDIED)* ☐ *(xxxx)* *(CPHDIEUN)* ☐ 8 - UNK ☐ 9 - N/A

   e. Incorrect DSS records (e.g. wrong age or address) *(CPHWRECD)* ☐ *(xxxx)* *(CPHWRDUN)* ☐ 8 - UNK ☐ 9 - N/A

   f. Withdrew from surveillance *(CPHWDREW)* ☐ *(xxxx)* *(CPHWDRUN)* ☐ 8 - UNK ☐ 9 - N/A

   g. Recently provided specimens for surveillance or other studies *(CPHSPECS)* ☐ *(xxxx)* *(CPHSPEUN)* ☐ 8 - UNK ☐ 9 - N/A

   h. Enrolled in another study that prevents PERCH enrollment *(CPHOENRL)* ☐ *(xxxx)* *(CPHOENUN)* ☐ 8 - UNK ☐ 9 - N/A

   i. Other *(CPHNOTH)* ☐ *(xxxx)* *(CPHNOTUN)* ☐ 8 - UNK

   (CPHNOTSP) Other, specify: *(CPHNOTCO)* Code: ☐

PART B: For sites that do not submit CRF01A for <u>INELIGIBLE or NON-ENROLLED</u> subjects

4. Record the number of children screened: *(CPHSCTRG)* ☐ *(xxxx)* *(CPHSCTUN)* ☐ 8 - UNK ☐ 9 - N/A

5. Of Q4 (screened), how many were <u>eligible</u> but did not have CRF01A entered into EDC? *(CPHNUELI)* ☐ *(xxxx)* *(CPHNUEUN)* ☐ 8 - UNK ☐ 9 - N/A

Of Q5, record how many were not enrolled for each of the reasons below:

   a. Refused consent *(CPHCNSNT)* ☐ *(xxxx)* *(CPHCNSUN)* ☐ 8 - UNK

   b. Met quota *(CPHQUOT)* ☐ *(xxxx)* *(CPHQUOUN)* ☐ 8 - UNK

   c. Other *(CPHEOT)* ☐ *(xxxx)* *(CPHEOTUN)* ☐ 8 - UNK

   (CPHEOTSP) Other, specify: *(CPHEOTCO)* Code: ☐

6. Of Q4 (screened) how many were <u>ineligible</u>, and did not have CRF01A entered into EDC? *(CPHSCINE)* ☐ *(xxxx)* *(CPHSCIUN)* ☐ 8 - UNK ☐ 9 - N/A

Of Q6, record how many were ineligible for each of the reasons below:

   a. Not from catchment area *(CPHCATCH)* ☐ *(xxxx)* *(CPHCATUN)* ☐ 8 - UNK

   b. Not age-eligible *(CPHAGEIN)* ☐ *(xxxx)* *(CPHAGEUN)* ☐ 8 - UNK

   c. Hospitalized within the past 14 days *(CPHHOSP)* ☐ *(xxxx)* *(CPHHOSUN)* ☐ 8 - UNK

d. PERCH case within past 30 days   *(CPHBPREV)* [ ] *(xxxx)*   *(CPHBPCUN)* ☐ 8 - UNK

e. Too sick (requires hospitalization)   *(CPHSICK)* [ ] *(xxxx)*   *(CPHSICUN)* ☐ 8 - UNK

f. Other   *(CPHIOTH)* [ ] *(xxxx)*   *(CPHIOTUN)* ☐ 8 - UNK

(CPHIOTSP) Other, specify: [ ]   *(CPHIOTCO)* Code: [ ]

Comments:

(CPHCOMM) [ ]

Form Completed by Staff Code: *(CPHSTACO)* [ ]

Initial QC by: *(CPHINQC)* [ ]

Supervisor Staff Code: *(CPHSUPCO)* [ ]

Supervisor Verification Date: *(CPHVERDT)* [ ] *(ddMMMyyyy)*

Additional Selection Options for CPH

Reporting period *(RPERDD)* **(key field):**
01-June - 2011
02-July - 2011
03-August - 2011
04-September - 2011
05-October - 2011
06-November - 2011
07-December - 2011
08-January - 2012
09-February - 2012
10-March - 2012
11-April - 2012
12-May - 2012
13-June - 2012
14-July - 2012
15-August - 2012
16-September - 2012
17-October - 2012
18-November - 2012
19-December - 2012
20-January - 2013
21-February - 2013
22-March - 2013
23-April - 2013
24-May - 2013
25-June - 2013
26-July - 2013
27-August - 2013
28-September - 2013
29-October - 2013
30-November - 2013
31-December - 2013
32-January - 2014
33-February - 2014
34-March - 2014
35-April - 2014
36-May - 2014
37-June - 2014
38-July - 2014
39-August - 2014
40-September - 2014
41-October - 2014
42-November - 2014
43-December - 2014

CRF 31B: HIV+ Control Screen (CPP)

Reporting period *(RPERIDD)*:

To be completed once a month to describe
HIV-Infected Control Recruitment

1. If reporting period start and end dates are not the *(CPPDTNA)* ☐ 9 - N/A
first and last day of the month, record them here:

a. Start date: *(CPPSTDT)* [   ] *(ddMMMyyyy)*

b. End date: *(CPPENDDT)* [   ] *(ddMMMyyyy)*

PART A: Pre-Screening

2. Number of potentially eligible (i.e., in target age group) *(CPPAGEEL)* [   ] *(xxxx)*   *(CPPEAGUN)* ☐ 8 - UNK
HIV-infected controls that were identified for screening:

3. Of Q2, record the number of controls that were <u>not</u> screened
(i.e., Screening Form CRF01B was not completed/entered into
EDC) because:

a. Declined to be screened: *(CPPDEC)* [   ] *(xxxx)*   *(CPPDECUN)* ☐ 8 - UNK ☐ 9 - N/A

b. Guardian could not be located: *(CPPNOLOC)* [   ] *(xxxx)*   *(CPPNOLUN)* ☐ 8 - UNK ☐ 9 - N/A

c. Enrolled in another study that prevents PERCH enrollment: *(CPPSTUDY)* [   ] *(xxxx)*   *(CPPSTYUN)* ☐ 8 - UNK ☐ 9 - N/A

d. Enrolled as PERCH control within past 3 months: *(CPPPRE)* [   ] *(xxxx)*   *(CPPPREUN)* ☐ 8 - UNK ☐ 9 - N/A

e. Other: *(CPPNSOTH)* [   ] *(xxxx)*   *(CPPNSOUN)* ☐ 8 - UNK ☐ 9 - N/A

(CPPNSOSP) Other, specify: *(CPPNSOCO)* Code: [   ]
[   ]

PART B: For sites that do not submit CRF 01B for <u>INELIGIBLE or NON-ENROLLED</u> screened subjects

4. Record the number of children screened: *(CPPNUMSC)* [   ] *(xxxx)*   *(CPPNUMUN)* ☐ 8 - UNK ☐ 9 - N/A

5. Of Q4 (screened), how many were <u>eligible</u> *(CPPELI)* [   ] *(xxxx)*   *(CPPELIUN)* ☐ 8 - UNK ☐ 9 - N/A
but did not have CRF 01B entered into EDC?

Of Q5, record how many were not enrolled for each of the
reasons below:

a. Refused consent: *(CPPCNSNT)* [   ] *(xxxx)*   *(CPPCNSUN)* ☐ 8 - UNK

b. Met quota: *(CPPQUOT)* [   ] *(xxxx)*   *(CPPQUOUN)* ☐ 8 - UNK

c. Other: *(CPPEOT)* [   ] *(xxxx)*   *(CPPEOTUN)* ☐ 8 - UNK

(CPPEOTSP) Other, specify: *(CPPEOTCO)* Code: [   ]
[   ]

6. Of Q4 (screened), how many were <u>ineligible</u> *(CPPINELI)* [   ] *(xxxx)*   *(CPPIELUN)* ☐ 8 - UNK ☐ 9 - N/A
and did not have CRF 01B entered into EDC?

Of Q6, record how many were ineligible for each of the reasons
below:

a. Not from catchment area: *(CPPCATCH)* [   ] *(xxxx)*   *(CPPCATUN)* ☐ 8 - UNK

b. Not age-eligible: *(CPPAGEIN)* [   ] *(xxxx)*   *(CPPAGEUN)* ☐ 8 - UNK

c. Hospitalized within the past 14 days: *(CPPHOSP)* [   ] *(xxxx)*   *(CPPHOSUN)* ☐ 8 - UNK

d. PERCH case within past 30 days: *(CPPPREV)* [   ] *(xxxx)*   *(CPPPCHUN)* ☐ 8 - UNK

e. Too sick (requires hospitalization): *(CPPILL)* [   ] *(xxxx)*   *(CPPILLUN)* ☐ 8 - UNK

f. Enrolled as PERCH control within past 3 months: *(CPPICTL)* [   ] *(xxxx)*   *(CPPICTUN)* ☐ 8 - UNK

g. Other: *(CPPIOTH)* [   ] *(xxxx)*   *(CPPIOTUN)* ☐ 8 - UNK

(CPPIOTSP) Other, specify:

(CPPIOTCO) Code:

Comments:

(CPPCOMM)

Form Completed by Staff Code: *(CPPSTACO)*

Initial QC by: *(CPPINQC)*

Supervisor Staff Code: *(CPPSUPCO)*

Supervisor Verification Date: *(CPPVERDT)* *(ddMMMyyyy)*

Additional Selection Options for CPP

Reporting period *(RPERDD)* (key field):
01-June - 2011
02-July - 2011
03-August - 2011
04-September - 2011
05-October - 2011
06-November - 2011
07-December - 2011
08-January - 2012
09-February - 2012
10-March - 2012
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23-April - 2013
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27-August - 2013
28-September - 2013
29-October - 2013
30-November - 2013
31-December - 2013
32-January - 2014
33-February - 2014
34-March - 2014
35-April - 2014
36-May - 2014
37-June - 2014
38-July - 2014
39-August - 2014
40-September - 2014
41-October - 2014
42-November - 2014
43-December - 2014

CRF 32: Lab Result: Post-Mortem Lung Biopsy (LRL)

Web Version: 1.0; 2.01; 16APR13

Segment *(PROTSEG)*:

PM Specimen type micro *(PM SPECMI)*:

1. Date/time put up for culture: *(LRLGSTDT)* ☐ *(ddMMMyyyy)* *(LRLGSTTM)* ☐ *(hh:mm)* *(24 hour clock)*

2. Specimen ID (scan barcode label): *(LRLSLCID)* ☐

3. Technician's Staff Code: *(LRLLUBCO)* ☐

Gram Stain

4. Description of any organism by Gram stain:
   Check the appropriate quantification box for Q4a-k below.

(LRLNOORG) ☐ No organisms seen (NOS) *(LRLGSNA)* ☐ N/A (Gram stain not done - *skip to Q5*)

	Organism	Not Seen	Scanty	1+	2+	3+
a.	Gram-negative rods (GNR)	*(LRLGNR)* ☐	☐	☐	☐	☐
b.	Gram-positive cocci in clusters (GPC clusters)	*(LRLGPCCL)* ☐	☐	☐	☐	☐
c.	Gram-negative coccobacilli (GNCB)	*(LRLGNCB)* ☐	☐	☐	☐	☐
d.	Gram-positive cocci in chains (GPC chains)	*(LRLGPCCH)* ☐	☐	☐	☐	☐
e.	Gram-negative diplococci (GNDC)	*(LRLGNDC)* ☐	☐	☐	☐	☐
f.	Gram-positive cocci single cells (GPC singles)	*(LRLGPCSI)* ☐	☐	☐	☐	☐
g.	Gram-negative cocci (GNC)	*(LRLGNC)* ☐	☐	☐	☐	☐
h.	Gram-positive rods (GPR)	*(LRLGPR)* ☐	☐	☐	☐	☐
i.	Gram-positive diplococci (GPDC)	*(LRLGPDC)* ☐	☐	☐	☐	☐
j.	Yeasts or other fungal elements	*(LRLYEAST)* ☐	☐	☐	☐	☐
k.	Leukocytes	*(LRLLEUKO)* ☐	☐	☐	☐	☐

Bacterial Culture

5. Aerobic Plate: Was growth observed up to 96 hours? *(LRL96HOU)* ☐ 0 - No ☐ 1 - Yes ☐ 9 - Not done

6. Anerobic Plate: Was growth observed at 48 hours? *(LRL48HOU)* ☐ 0 - No ☐ 1 - Yes ☐ 9 - Not done

7. Was broth positive? *(LRLBRPOS)* ☐ 0 - No ☐ 1 - Yes ☐ 9 - Not done

If the answers to Q5, Q6 AND Q7 are No or Not done, please end form.

8. Bacterial culture organism identification and quantification:

	Organism Code	Found In	Organism Quantity	Isolate ID (scan barcode label)	Organ Confirm
a. Mixed skin flora*		1-1 - Solid Media 2-2 - Broth 3-3 - Both 9-9 - Not seen *(LRLSKFLL)* ▬			
b. Organism 1	*(LRL01ORG)* ☐	1-1 - Solid Media 2-2 - Broth 3-3 - Both *(LRL1ORGL)* ▬	4-4 - Scanty 1-1 - 1+ 2-2 - 2+ 3-3 - 3+ *(LRL01OQT)* ▬	*(LRL01ISO)* ☐	1-1: C 2-2: U 3-3: NC *(LRL01CON)* ▬
c. Organism 2	*(LRL02ORG)* ☐	1-1 - Solid Media 2-2 - Broth 3-3 - Both *(LRL2ORGL)* ▬	4-4 - Scanty 1-1 - 1+ 2-2 - 2+ 3-3 - 3+ *(LRL02OQT)* ▬	*(LRL02ISO)* ☐	1-1: C 2-2: U 3-3: NC *(LRL02CON)* ▬

| d. Organism 3 | (LRL03ORG) ___ | (LRL3ORGL) | 1-1 - Solid Media
2-2 - Broth
3-3 - Both | (LRL03OQT) | 4-4 - Scanty
1-1 - 1+
2-2 - 2+
3-3 - 3+ | (LRL03ISO) ___ | (LRL03CON) | 1-1: C
2-2: U
3-3: NC |
| e. Organism 4 | (LRL04ORG) ___ | (LRL4ORGL) | 1-1 - Solid Media
2-2 - Broth
3-3 - Both | (LRL04OQT) | 4-4 - Scanty
1-1 - 1+
2-2 - 2+
3-3 - 3+ | (LRL04ISO) ___ | (LRL04CON) | 1-1: C
2-2: U
3-3: NC |

Includes S. epidermidis and many species of Corynebacteria, Propionibacteria, Micrococci and Mycobacteria. See SOP for complete list.

9. Bacterial culture antibiotic susceptibility testing: *(LRLBASNA)* ☐ N/A (not done)

Antibiotic Code:	Organism 1 Zone of inhibition in mm (xx):	Organism 1 S/I/R Code:	Organism 2 Zone of inhibition in mm (xx):	Organism 2 S/I/R Code:	Organism 3 Zone of inhibition in mm (xx):	Organism 3 S/I/R Code:	Organism 4 Zone of inhibition in mm (xx):
a. **AMC** (Amoxicillin / Clavulanic acid)	*(LRL01AMC)*	*(LRL1AMCI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL02AMC)*	*(LRL2AMCI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL03AMC)*	*(LRL3AMCI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL04A...)*
b. **AMP** (Ampicillin)	*(LRL01AMP)*	*(LRL1AMPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL02AMP)*	*(LRL2AMPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL03AMP)*	*(LRL3AMPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL04A...)*
c. **CAZ** (Ceftazidimine)	*(LRL01CAZ)*	*(LRL1CAZI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL02CAZ)*	*(LRL2CAZI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL03CAZ)*	*(LRL3CAZI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL04C...)*
d. **CH** (Chloramphenicol)	*(LRL01CH)*	*(LRL1CHI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL02CH)*	*(LRL2CHI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL03CH)*	*(LRL3CHI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL04C...)*
e. **CIP** (Ciprofloxacin)	*(LRL01CIP)*	*(LRL1CIPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL02CIP)*	*(LRL2CIPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL03CIP)*	*(LRL3CIPI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL04C...)*
f. **CN** (Gentamicin)	*(LRL01CN)*	*(LRL1CNI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL02CN)*	*(LRL2CNI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL03CN)*	*(LRL3CNI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL04C...)*
g. **CRO** (Ceftriaxone)	*(LRL01CRO)*	*(LRL1CROI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL02CRO)*	*(LRL2CROI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL03CRO)*	*(LRL3CROI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL04C...)*
h. **CTX** (Cefotaxime)	*(LRL01CTX)*	*(LRL1CTXI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL02CTX)*	*(LRL2CTXI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL03CTX)*	*(LRL3CTXI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL04C...)*
i. **DA** (Clindamycin)	*(LRL01DA)*	*(LRL1DAI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL02DA)*	*(LRL2DAI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL03DA)*	*(LRL3DAI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL04D...)*
j. **ERY** (Erythromycin)	*(LRL01ERY)*	*(LRL1ERYI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL02ERY)*	*(LRL2ERYI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL03ERY)*	*(LRL3ERYI)* 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	*(LRL04E...)*

	Organism 1	Organism 1 S/I/R	Organism 2	Organism 2 S/I/R	Organism 3	Organism 3 S/I/R	Organism 4
k. **FOX** (Cefoxitin)	(LRL01FOX)	(LRL1FOXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL02FOX)	(LRL2FOXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL03FOX)	(LRL3FOXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL04F...
l. **IPM** (Imipenem)	(LRL01IPM)	(LRL1IPMI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL02IPM)	(LRL2IPMI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL03IPM)	(LRL3IPMI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL04I...
m. **OX** (Oxacillin)	(LRL01OX)	(LRL1OXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL02OX)	(LRL2OXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL03OX)	(LRL3OXI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL04O...
n. **P** (Penicillin)	(LRL01P)	(LRL1PI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL02P)	(LRL2PI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL03P)	(LRL3PI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL04P...
o. **SXT** (Cotrimoxazole)	(LRL01SXT)	(LRL1SXTI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL02SXT)	(LRL2SXTI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL03SXT)	(LRL3SXTI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL04S...
p. **TET** (Tetracycline)	(LRL01TET)	(LRL1TETI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL02TET)	(LRL2TETI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL03TET)	(LRL3TETI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL04T...
q. **VA** (Vancomycin)	(LRL01VA)	(LRL1VAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL02VA)	(LRL2VAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL03VA)	(LRL3VAI) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL04V...

Other Antibiotic, Specify:	Antibiotic Code:	Organism 1 Zone of inhibition in mm (xx):	Organism 1 S/I/R Code:	Organism 2 Zone of inhibition in mm (xx):	Organism 2 S/I/R Code:	Organism 3 Zone of inhibition in mm (xx):	Organism 3 S/I/R Code:
r. Other (LRLOT1SP)	(LRLOTH1D)	(LRL1OT1D)	(LRL1OT1I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL2OT1D)	(LRL2OT1I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL3OT1D)	(LRL3OT1I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
s. Other (LRLOT2SP)	(LRLOTH2D)	(LRL1OT2D)	(LRL1OT2I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL2OT2D)	(LRL2OT2I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL3OT2D)	(LRL3OT2I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant
t. Other (LRLOT3SP)	(LRLOTH3D)	(LRL1OT3D)	(LRL1OT3I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL2OT3D)	(LRL2OT3I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant	(LRL3OT3D)	(LRL3OT3I) 1-1: S - Susceptible 2-2: I - Intermediate 3-3: R - Resistant

	Organism 1	Organism 2	Organism 3	
u. **Beta lactamase**	(LRL01BPN) ☐ 1 - Positive ☐ 2 - Negative	(LRL02BPN) ☐ 1 - Positive ☐ 2 - Negative	(LRL03BPN) ☐ 1 - Positive ☐ 2 - Negative	(LRL04BP... ☐ ...Negative

10. MIC Etest® results for *S. pneumoniae* isloates that are resistant (R) or intermediate (I) to oxacillin disk diffusion testing.

MIC Etest® performed? (LRLSPNET) ☐ 1 - Yes ☐ 0 - No ☐ 9 - N/A *(If No or N/A, skip to Question 11)*

a) Penicillin Etest® results (LRLPENSI) ☐ < ☐ > (LRLPENRS) _____ *(xx.xxx) µg/mL*

b) (LRLETDRG) ☐ Ceftriaxone ☐ Cefotaxime (LRLETSIG) ☐ < ☐ > (LRLETRST) _____ *(xx.xxx) µg/mL*

11. Screening for Extended Spectrum ß-Lactamase (ESBL) Production done?

(LRLESBL) ☐ 1 - Yes ☐ 0 - No

a. If Yes, results of additional phenotypic testing:

(LRLESBLC) ☐ 1 - ESBL confirmed   ☐ 2 - ESBL not confirmed

Comments:

(LRLCOMM)

Initial QC by: (LRLINQC)

Supervisor Staff Code: (LRLSUPER)

Supervisor Verification Date: (LRLVERDT)   (ddMMMyyyy)

Additional Selection Options for LRL

PM Specimen type micro *(PM SPECM)* **(key field):**
01-M1 - Microbiology Core 1
04-M4 - Microbiology Core 4
17-PR - Pleural Aspirate - Right Lung
18-PL - Pleural Aspirate - Left Lung

CRF 32: Lab Result: Post-Mortem Lung Biopsy: Additional Tests (LRK)

Segment *(PROTSEG)*:

PM Specimen type micro *(PMSPECMI)*:

12. Was *S. pneumoniae* isolated?

(LRKSPISO) ☐ 1 - Yes   ☐ 0 - No

    If Yes, what serotypes were identified:

a. *(LRK1SERP)* _____

b. *(LRK2SERP)* _____

c. *(LRK3SERP)* _____

d. *(LRK4SERP)* _____

13. Was *H. influenzae* isolated?

(LRKHIISO) ☐ 1 - Yes   ☐ 0 - No

    If Yes, what serotype was identified:

a. *(LRK5SERI)* _____

Comments:

(LRKCOMM)

Technician Reporting Final Results Staff Code: *(LRKTECH)* _____

Initial QC by: *(LRKINQC)* _____

Supervisor Staff Code: *(LRKSUPER)* _____

Supervisor Verification Date: *(LRKVERDT)* _____ *(ddMMMyyyy)*

Additional Selection Options for LRK

PM Specimen type micro *(PM SPECM I)* **(key field):**
01-M1 - Microbiology Core 1
04-M4 - Microbiology Core 4
17-PR - Pleural Aspirate - Right Lung
18-PL - Pleural Aspirate - Left Lung

CRF 33: Histology Result: Post-Mortem Lung Biopsy (HRL)

Web Version: 1.0; 1.01; 16APR13

Segment *(PROTSEG):*

1. Biopsy information

Biopsy available?	Specimen ID (scan barcode label):	Specimen quality *(check one)*:	Does biopsy show lung tissue?
a. H11?*(HRLH11BA)* ☐ 1 - Yes ☐ 0 - No	*(HRLH11ID)* _____	*(HRLH11SQ)* ☐ 1 - Good quality core ☐ 2 - Poor/small/disrupted	*(HRLH11LT)* ☐ 1 - Yes ☐ 0 - No
b. H12?*(HRLH12BA)* ☐ 1 - Yes ☐ 0 - No	*(HRLH12ID)* _____	*(HRLH12SQ)* ☐ 1 - Good quality core ☐ 2 - Poor/small/disrupted	*(HRLH12LT)* ☐ 1 - Yes ☐ 0 - No
c. H13?*(HRLH13BA)* ☐ 1 - Yes ☐ 0 - No	*(HRLH13ID)* _____	*(HRLH13SQ)* ☐ 1 - Good quality core ☐ 2 - Poor/small/disrupted	*(HRLH13LT)* ☐ 1 - Yes ☐ 0 - No
d. H14?*(HRLH14BA)* ☐ 1 - Yes ☐ 0 - No	*(HRLH14ID)* _____	*(HRLH14SQ)* ☐ 1 - Good quality core ☐ 2 - Poor/small/disrupted	*(HRLH14LT)* ☐ 1 - Yes ☐ 0 - No
e. H15?*(HRLH15BA)* ☐ 1 - Yes ☐ 0 - No	*(HRLH15ID)* _____	*(HRLH15SQ)* ☐ 1 - Good quality core ☐ 2 - Poor/small/disrupted	*(HRLH15LT)* ☐ 1 - Yes ☐ 0 - No

MICROSCOPY (GENERAL QUESTIONS FOR CASE)

(HRLMSCND) ☐ 9 - Not done

2. Appearances: Do biopsies show abnormal/pathological features?

(HRLABPAT) ☐ 1 - No pathological appearances - Normal lung   ☐ 2 - Pathology identified

3. Special Stains performed on biopsies

(HRLSPSTA) ☐ 1 - None (H+E only)   ☐ 2 - Yes: Specify

If Yes, specify:

(HRLSTASP)

4. Histological Findings

	Pathological Feature	Present or Not (Check box if present)
a.	Pulmonary edema	*(HRLPULM)* ☐
b.	Pyogenic pneumonia (neutrophilic consolidation)	*(HRLPNEUM)* ☐
c.	Lymphocytic infiltration of alveolar walls	*(HRLYMINF)* ☐
d.	Tuberculosis	*(HRLTB)* ☐
e.	Granulomas	*(HRLGRANU)* ☐
f.	Viral inclusion bodies	*(HRLVIRAL)* ☐
g.	Hyaline membrane formation	*(HRLHYALI)* ☐
h.	Specific pathogen identified	*(HRLSPATH)* ☐
	If identified, type/s of pathogen code/s:	1.*(HRLPATH1)* ____
	(e.g. Fungi/Pneumocystis jiroveci/Viral inclusions/TB)	2.*(HRLPATH2)* ____
		3.*(HRLPATH3)* ____
i.	Other pathological features	*(HRLOTPAT)* ☐
	If identified, type/s of feature/s:	

	1.*(HRLOTPA1)*		
	2.*(HRLOTPA2)*		
	Special Stains Positive? **If positive, state:**	*(HRLSTPOS)* ☐	
j.	Gram Stain	*(HRLGRMST)* ☐	
	If positive: Gram positive organisms	*(HRLGRPOS)* ☐	
	Gram negative organisms	*(HRLGRNEG)* ☐	
k.	Silver Stain	*(HRLSILST)* ☐	
l.	ZN Stain	*(HRLZNSTA)* ☐	
m.	Other Stain	*(HRLOTHST)* ☐	
	Other, specify:*(HRLOSTSP)*		

Histology Report: (Summary report of Case across all available biopsies)

5. Histology Report:

(HRLSUMM)

6. Final Diagnosis:

(HRLFDIAG)

7. Examining Pathologist Staff Code: *(HRLEXPAT)*

8. Date: *(HRLDT)* *(ddMMMyyyy)*

Comments:

(HRLCOMM)

Technician's Staff Code: *(HRLTECH)*

Initial QC by: *(HRLINQC)*

Supervisor Staff Code: *(HRLSUPER)*

Supervisor Verification Date: *(HRLVERDT)* *(ddMMMyyyy)*