

CALIFORNIA CONGENITAL SYPHILIS SURVEILLANCE AND CASE MANAGEMENT

*Protocols, Forms, Instructions and Tools for Implementing
Congenital Syphilis (CS) Surveillance and Disease Intervention
Case Management in California Local Health Jurisdictions*

Prepared by the California Department of Public Health,
Sexually Transmitted Disease Control Branch, June 2015



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Acronyms used in this document

CaIREDIE	California Reportable Disease Information Exchange
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CIA	Chemiluminescence Immunoassay
CS	Congenital Syphilis
CSF	Cerebral Spinal Fluid
CSF-VDRL	Cerebral Spinal Fluid – Venereal Disease Research Laboratory
DFA	Direct Fluorescent Antibody
DFA-TP	Direct Fluorescent Antibody – <i>Treponema pallidum</i>
DIS	Disease Intervention Specialist (or equivalent)
EGA	Estimated Gestational Age
EIA	Enzyme Immunoassay
FTA-Abs	Fluorescent treponemal antibody-absorption
HDFU	Health Department Follow-up
ICCR	Intra/Inter-State Communication Control Record
IR	Interview Record
LHJ	Local Health Jurisdiction
LMP	Last Menstrual Period
MBIA	Microbead Immunoassay
RPR	Rapid Plasma Reagin
STD	Sexually Transmitted Disease
STS	Serologic Test for Syphilis
TP-PA	Treponemal Pallidum Particle Agglutination assay
VDRL	Venereal Disease Research Laboratory
WBC	White Blood Cells

Section 1: Disease Intervention Protocol for CS Prevention and Case Management

The following protocol was developed by the California Department of Public Health (CDPH) Sexually Transmitted Disease (STD) Control Branch to guide California Local Health Jurisdictions (LHJ) in managing reactive serologic tests for syphilis in women of child-bearing age and infants. Questions should be directed to your field office manager.

Please note that the use of the title “Disease Intervention Specialist” (DIS) throughout this document applies to all equivalent classifications, including but not limited to Communicable Disease Investigators and Public Health Nurses.

A. Surveillance Case Definition for CS

A **confirmed case** of CS is an infant or child in whom *Treponema pallidum* is identified by any of the following:

- A. darkfield microscopy of lesions, body fluids, or neonatal nasal discharge;
- B. polymerase chain reaction (PCR) or other equivalent direct molecular methods of lesions, neonatal discharge, placenta, umbilical cord, or autopsy material;
- C. immunohistochemistry (IHC) or special stains (e.g., silver staining) of specimens from lesions, placenta, umbilical cord, or autopsy material

A **presumptive case** of CS is either of the following:

- A. any infant whose mother had untreated or inadequately treated syphilis at the time of delivery, regardless of the findings in the infant or child;
- B. any infant or child who has a reactive non-treponemal test for syphilis and any one of the following:
 - a. evidence of CS on physical examination;¹
 - b. evidence of CS on long bone X-ray;
 - c. reactive Cerebrospinal Fluid (CSF)-VDRL;
 - d. elevated CSF white blood cell count or protein (without other cause);²

¹ Signs of CS in an infant or a child < 2 years of age may include condyloma lata, snuffles, syphilitic skin rash, hepatosplenomegaly, jaundice due to syphilitic hepatitis, pseudoparalysis, or edema from nephrotic syndrome or malnutrition. Stigmata in an older child may include interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinson’s teeth, saddle nose, rhagades or Clutton’s joints.

² For infants 30 days old or less, CSF white blood cell (WBC) count > 15 WBC/mm³ and CSF protein >120 mg/dL are considered abnormal. For infants/children more than 30 days old, CSF WBC count > 5 WBC/mm³ and protein > 40 mg/dL are considered abnormal, regardless of CSF serology.

A **syphilitic stillbirth** is defined as a fetal death 1) that occurs after a 20-week gestation, or 2) in which the fetus weighs greater than 500g and the mother had untreated or inadequately treated syphilis at the time of delivery.

Adequate treatment³ for syphilis in pregnant females is as follows:

Stage of syphilis	Recommended Regimen	Dose/Route	Timing
Primary, Secondary, and Early Latent	Benzathine Penicillin G	2.4 million units IM ⁴	Administered 30 days or more prior to delivery
Late Latent and Latent of Unknown Duration	Benzathine Penicillin G	7.2 million units, administered as 3 doses of 2.4 million units IM each, at 1-week intervals	First dose administered 30 days or more prior to delivery, AND all doses received

Prepared by the California Department of Public Health

B. Managing Reactive Serologic Tests for Syphilis (STS) in Women

Reactive STS reported to the local health department for women of child-bearing age (45 years of age or younger) are classified as “Red” on the Reactor Alert System, and prioritized for immediate follow up.

Syphilis History Search and Entry

As with all syphilis case reports, a syphilis history search⁵ should be done for the woman to check for history of infection and determine whether the reactive STS is indicative of a new case or a follow-up titer from a prior infection. All reactive STS for women should be prioritized for CalREDIE entry.

If history is found, and the STS appears to be for a serofast patient or a decreasing follow-up titer, then the newly reported test should either be 1) attached to the most recent incident, or 2) entered into CalREDIE as a new incident, if no prior incident exists. These incidents should be closed with a Resolution Status of “Previously Reported”.

Biologic false positive tests (BFPs), or reactive RPR/VDRL with a negative confirmatory test, in women of child-bearing age should be entered into CalREDIE so that an accurate history can be obtained for future pregnancies. BFPs should be closed with a Resolution Status of “Not a Case.”

³ 2015 CDC STD Treatment Guidelines. <http://www.cdc.gov/std/tg2015/default.htm>

⁴ Pregnant women allergic to penicillin should be treated with penicillin after desensitization. There are no alternative regimens for syphilis treatment in pregnancy.

⁵ Syphilis history searches can be conducted in CalREDIE and/or a local reactor system.

Assignment and Verification of Clinical Information

If the reactive STS is indicative of a new case of syphilis (i.e., four-fold rise in titer or no history of syphilis), a new CalREDIE incident should be created and assigned to DIS for investigation. Per usual protocol for syphilis follow-up, DIS should contact the reporting medical provider to obtain needed information, including pregnancy status, syphilis history, confirmatory test results, plans for follow-up and treatment, and syphilis stage. This information should be entered into CalREDIE appropriately.

Management of Non-Pregnant Female Syphilis Cases

Case management of non-pregnant female syphilis cases should be conducted with the same prioritization as any other syphilis case.

- Early syphilis cases (710, 720, 730) should be interviewed and sex partners within the interview period should be contacted for testing and treatment. Cases should be closed within 30 days of the interview with the original patient.
- Late syphilis cases (740, 745, 750) do not require interview. All three treatment doses should be confirmed and the case closed within 30 days of treatment completion. Providers should be faxed the following:
 - Cover Letter (see [Appendix A](#) for a sample) and
 - Guidelines for Clinical Management of Late Latent Syphilis ([Appendix B](#)).

Management of Pregnant Syphilis Cases

All pregnant syphilis cases should be interviewed and receive partner services, regardless of syphilis stage.

DIS should make the determination of whether the pregnant patient was adequately treated. Adequate treatment in pregnancy is defined in [Section 1.A](#).

For a pregnant female who **was** adequately treated:

- Document pregnancy status, treatment and interview in CalREDIE appropriately
- Fax the following documents to the medical provider:
 - Cover Letter (see [Appendix A](#) for a sample),
 - Evaluation and Management of Pregnant Women with Syphilis ([Appendix C](#)), and
 - Guidelines for Evaluation and Management of Neonates Exposed to Syphilis ([Appendix D](#)).

For a pregnant female who **was not** adequately treated:

- In the mother's incident:
 - Document pregnancy status, treatment and interview appropriately
 - Add infant as a contact and use "Create Incident" to generate his/her own incident
- In the infant incident:
 - Change the Disease Condition to "Congenital Syphilis"
 - Complete the *California CS Case Investigation and Report*
 - If no lab information is available for the infant, classify him/her as a probable CS case. If lab information is available, follow instructions in [Section 1.C](#). If the infant has not been born, keep the case open until lab information is available.
 - See the *CS Case Classification Algorithm* for classification criteria.
- Fax the following documents to the medical provider:
 - Cover Letter (see [Appendix A](#) for a sample),
 - Evaluation and Management of Pregnant Women with Syphilis ([Appendix C](#)), and
 - Guidelines for Evaluation and Management of Neonates Exposed to Syphilis ([Appendix D](#)).
- Alert the local STD Control Officer.
- Contact the provider to confirm receipt of the documentation and to answer questions about prevention or next steps for the infant.

C. Managing Reactive STS in Delivery Blood and Infants

The health department obtains information about infants through reactive STS reported by labs or providers. If testing is not done or results are negative, the health department will not receive notification of the infant's test results, even if the mother was treated for syphilis during pregnancy. Adequate treatment in pregnancy is defined in [Section 1.A](#).

For a reactive STS for an infant or a reactive delivery blood, where the mother **was** adequately treated:

- Contact the medical provider to collect information on any infant test results, maternal results at delivery, etc. Appropriate methods of obtaining information include a phone call with the medical provider, review of faxed infant medical records, or review of infant medical records through a field visit to the delivery hospital.
- Fax the following to reporting medical providers:
 - Cover Letter (see [Appendix A](#) for a sample),
 - Evaluation and Management of Pregnant Women with Syphilis ([Appendix C](#)), and
 - Guidelines for Evaluation and Management of Neonates Exposed to Syphilis ([Appendix D](#)).

- If the infant has lab results or clinical signs consistent with CS⁶:
 - Complete the *California CS Case Investigation and Report* in CalREDIE
 - Classify the infant according to the *CS Case Classification Algorithm*.
- Mothers who were not reported or investigated during pregnancy should be contacted for interview, partner services, and a risk assessment of CS with prior births.

For a reactive STS for an infant or a reactive delivery blood, where the mother **was not** adequately treated:

- Contact the medical provider to collect information on any infant test results, maternal results at delivery, etc. Appropriate methods of obtaining information include a phone call with the medical provider, review of faxed infant medical records, or review of infant medical records through a field visit to the delivery hospital.
- Fax the following to reporting medical providers:
 - Cover Letter (see [Appendix A](#) for a sample),
 - Evaluation and Management of Pregnant Women with Syphilis ([Appendix C](#)), and
 - Guidelines for Evaluation and Management of Neonates Exposed to Syphilis ([Appendix D](#)).
- For mothers who were reported and investigated during pregnancy:
 - In the mother's incident -
 - Add the infant as a contact and use "Create Incident" to turn the infant into his/her own incident
 - In the baby's incident -
 - Change the Disease Condition to "Congenital Syphilis"
 - Complete the *California CS Case Investigation and Report*
 - Classify the infant according to the *CS Case Classification Algorithm*.
- For mothers who were not reported or investigated during pregnancy:
 - Create and assign mother's incident for interview and partner services
 - Add the baby as a contact and use "Create Incident" to turn the baby into his/her own incident
 - In the baby's incident -
 - Change the Disease Condition to "Congenital Syphilis"
 - Complete the *California CS Case Investigation and Report*
 - Classify the infant according to the *CS Case Classification Algorithm*.

⁶ Although uncommon, some infants develop signs of CS despite adequate treatment during pregnancy.

D. Managing Suspected Syphilitic Stillbirths

A syphilitic stillbirth⁷ is most often identified by the health department through laboratory reports or confidential morbidity reports on the mother. Syphilitic stillbirths are identified by investigators either during case investigation of the mother, through a delivery blood test from the mother, or other serologic testing on the mother. Occasionally, a provider may contact the health department to report a syphilitic stillbirth.

These cases should be managed in the same way as a case report for an infant:

- Contact the medical provider to collect information on any fetal test results, maternal results at delivery, etc. Appropriate methods of obtaining information include a phone call with the medical provider, review of faxed medical records, or review of medical records through a field visit to the delivery hospital.
- Fax the following to reporting medical providers:
 - Cover Letter (see [Appendix A](#) for a sample),
 - Evaluation and Management of Pregnant women with Syphilis ([Appendix C](#))
- For mothers who were reported and investigated during pregnancy:
 - In the mother's incident -
 - Add the infant as a contact and use "Create Incident" to turn the infant into his/her own incident
 - In the infant's incident -
 - Change the Disease Condition to "Congenital Syphilis"
 - Complete the *California CS Case Investigation and Report*
 - Classify the infant according to the *CS Case Classification Algorithm*.
- For mothers who were not reported or investigated during pregnancy:
 - Create and assign mother's incident for interview and partner services -
 - Add the infant as a contact and use "Create Incident" to turn the infant into his/her own incident.
 - In the infant's incident:
 - Change the Disease Condition to "Congenital Syphilis"
 - Complete the *California CS Case Investigation and Report*
 - Classify the infant according to the *CS Case Classification Algorithm*.

E. Case Closure, Case Review and Document Submission

For pregnant women who are adequately treated during pregnancy, the mother's case should be closed 30 days following the initiation of treatment. This will enable investigators to confirm that the mother was adequately treated at least 30 days prior to delivery.

⁷ A syphilitic stillbirth is defined as a fetal death in which the mother had untreated or inadequately treated syphilis at the time of delivery of either a fetus after a 20-week gestation or a fetus weighing >500g.

For presumptive or confirmed CS cases and syphilitic stillbirths, close the case within 30 days of delivery of the infant or fetal death. Once investigation and documentation are completed, the case should be reviewed by a front line supervisor.

Upon closure, the following should be complete in CalREDIE:

- Congenital Syphilis incident
 - Health Department Follow-up tab with dispositions
 - California CS Case Investigation and Report
 - Resolution Status: “Closed by LHD”
- Mother’s incident
 - Health Department Follow-up tab with dispositions
 - Syphilis History Report in the Electronic Filing Cabinet
 - Syphilis Interview Record
 - STD Contacts, with appropriate partner linkages in CalREDIE
 - Resolution Status: “Closed by LHD”

Section 2: California Congenital Syphilis (CS) Case Investigation and Reporting Form Instructions and Algorithm

Note: These instructions accompany the California Congenital Syphilis (CS) Case Investigation and Reporting Form, CDPH 9049 (4/4/2013). This form is adapted from the CDC 73.126 form. For additional information about CS case investigations, please refer to the CDC’s CS Case Investigation and Reporting Form Instructions.⁸

A. General Instructions

1. Use a pencil or ballpoint pen to complete forms. Avoid felt tip markers since they result in poor copies.
2. Fill in one digit per dashed line.
3. Mark only one box per question unless otherwise noted.
4. Boxes should be marked with an X.
5. Dates should be written in MM/DD/YYYY format. Months and days less than 10 should be preceded with a 0, for example, May should be recorded as 05. If the day is not known, record the known month and year values and record the day as 15. If the entire date is unknown, mark the Unknown box with an X.
6. On all questions, unknowns should be marked with an X in the unknown box.
7. Do not write in more dates than there are places to write in dates. These dates will be disregarded at CDPH and CDC.
8. Do not write additional information in the margins or spaces. This information will be disregarded at CDPH and CDC. For example, if a test result is pending, indicate that the result is unknown. Do not write pending in the margin.
9. Skip patterns are directions that appear next to some answers (Go to Q...) and direct you to the next question to be answered. Observe these directions and do not complete a question that you have been directed to skip. Data entered where an item should have been skipped will be disregarded at CDPH and CDC.

⁸ <http://www.cdc.gov/std/Program/forms/>

10. Except for skip patterns and where specifically mentioned in these instructions, all questions should be completed. LHJs with missing data will be contacted for correct information.
11. Footnotes mentioned in these instructions and on the reporting form are located on the back of each form.

B. Reporting Form Items

Case ID No.: The CS ID Number assigned to the case by ICCR Headquarters.

Update (2/10/15): LHJs are no longer required to obtain this ID number from ICCR Headquarters.

Part I. Maternal Information

1. Report Date to Health Department: This is the date when the first information about the infant or child came to the attention of the health department or STD program. This answer should never be blank. If the date is not known, mark the Unknown box. ***The report date should never be before the infant's delivery date.***
- 2,3. Reporting State, Reporting County: The state (California) and county reporting the CS case. The reporting county should be the county of residence for the mother or, in the case of a mother from Mexico or other foreign country, the county in which the infant was born. If the case is identified in one jurisdiction, and the mother's jurisdiction of residence is in another jurisdiction, the case should be forwarded to the jurisdiction of residence.
4. Country of residence: This should correspond to the country of legal residence of the mother. It should be left blank if the mother's residence is in the U.S.
- 5,6,7,8. Residence State, County, City and Zip Code: These should correspond to the U.S. state, county and zip code in which the mother resides. For cities that are also local health jurisdictions (e.g., City of Long Beach, City of Berkeley), the city in which the mother resides should be included. For cities that are within county health jurisdictions, city can be left blank.
9. Mother's date of birth: Write the mother's date of birth. If this date is not known, mark the Unknown box.
10. Mother's ethnicity: Mark the appropriate box to denote the mother's ethnicity (Hispanic/Latina or Non-Hispanic/Latina). Do not leave this answer blank. If mother's ethnicity is not known, mark the Unknown box.
11. Mother's race: Check ***all that apply*** to denote the mother's race. If the mother's race is not known, mark the Unknown box.

12. Did mother have prenatal care?: Mark the appropriate box to show whether the mother had **at least one prenatal care visit** before delivery in the U.S. , at least one prenatal care visit outside of the U.S., no prenatal care, or unknown. A prenatal care visit does not include medical care for reasons unrelated to prenatal services, such as visits to an emergency room, a minor emergency clinic, or an STD clinic. This question does not ask for an assessment of the quality of prenatal care. If the answer is No or Unknown, proceed to Question 15; do not complete Questions 13 or 14.
13. Date of first prenatal visit: If the answer to Question 12 is Yes, show the date of the first prenatal visit; do not leave this answer blank. If the day is unknown, write 15 in the corresponding blank. For example, if the date of the first prenatal visit was in January, but the day is unknown, enter 01/15/2012. If the entire date is unknown, mark the Unknown box. Do not answer this question if the answer to Question 12 is No or Unknown.
14. Number of prenatal visits: If the answer to Question 12 is Yes, show the number of prenatal visits before delivery; do not leave this answer blank. If the number of visits is not known, mark the Unknown box. Do not answer this question if the answer to Question 12 is No or Unknown.
15. Maternal non-treponemal test: Mark the appropriate box to show whether mother had an RPR/VDRL in pregnancy, at delivery, or within 3 days of delivery. Do not leave this answer blank.
16. Dates and results of maternal non-treponemal tests: This question should be completed if the answer to Question 15 is Yes. Space is provided for the four tests done closest to the time of diagnosis of the infant or child. (In most cases this will be near the date of delivery but could be earlier or later). List the date closest to the time of diagnosis of the infant or child at **a.** and go backward in time. All four lines do not need to be completed. Fill in dates as previously instructed. Mark the appropriate box to show the results of each non-treponemal test. Fill in titers (if reactive) in spaces provided beginning immediately to the right of the colon. For example, a titer of 1:8 is recorded 1:8_ _ _ . Do not fill in the remaining spaces. Rewriting a 1: is not necessary. If the titer is unknown, record the titer as 9999.

NOTE: Every date entered in Question 16 should have a result box marked. Do not complete this section if the answer to Question 15 is No or Unknown.

17. Maternal confirmatory treponemal test: Mark the appropriate box to show whether the mother had a confirmatory test (e.g., TP-PA, FTA-Abs, EIA, CIA, MBIA) and whether the test was reactive or nonreactive. If the result of the treponemal test is not known or it is not known whether a treponemal test was done, mark the Unknown box. If there are multiple treponemal tests performed, use the date of the first positive treponemal test.

18. Darkfield/DFA examination at delivery: Mark the appropriate box if the mother had a darkfield or direct fluorescent antibody (DFA) examination of a lesion or lesions at the time of delivery and show whether results were positive or negative. If the results of the darkfield or DFA examination are not known or it is not known whether a darkfield or DFA examination was done at the time of delivery, mark the Unknown box.
19. Mother's last treatment for syphilis **before** delivery: *Mark one appropriate box to show when the mother was last treated for syphilis **before** the date of delivery* and indicate the date of treatment in the space provided. For example, if the mother was treated for syphilis before this pregnancy and was treated again during pregnancy, then the last treatment was during pregnancy. Follow the skip patterns: If the mother was last treated before pregnancy, proceed to Question 20. If the mother was treated during pregnancy, proceed to Question 21. If the mother was not treated before delivery, mark the box for No treatment and proceed to Question 22. If the date of the mother's last treatment is not known, mark the Unknown box, leave the date of treatment blank, then proceed to Question 22.

NOTE: Instances may arise where the mother was treated adequately for syphilis but was given additional treatment later as a "preventive measure" without evidence that she had been exposed to syphilis or had a new or recurrent syphilis infection. If this later treatment would be considered inadequate because it was a non-penicillin therapy or was too close to the time of delivery, do not record this treatment as the last treatment in pregnancy. Consider the earlier adequate treatment as the last treatment for syphilis before the date of delivery.

20. Mother's last treatment was **before** pregnancy: Mark one appropriate box to denote the adequacy of treatment **before** pregnancy. If the answer is Yes, adequate, proceed to Question 22; do not answer Question 21. If the answer is No, treatment not appropriate for stage or Unknown, proceed to Question 22; do not answer Question 21. This question should be answered only if the answer to Question 19 is Before pregnancy.

NOTE: Adequate therapy in a pregnant female is defined in [Section 1.A](#).⁹

21. Mother's last treatment was **during** pregnancy: Mark one appropriate box to denote the adequacy of treatment during pregnancy. This question should be answered if the answer to Question 19 is During pregnancy. Do not answer this question if the answer to Question 19 was not During pregnancy.

NOTE: Adequate therapy in a pregnant female is defined in [Section 1.A](#).

⁹ For more details on treatment, see the STD Treatment Guidelines, available at www.cdc.gov/std/treatment/.

Part II. Infant Information

22. Date of delivery: Write the date of delivery of the infant or child (infant's or child's birthdate). Do not leave this answer blank.
23. Vital status: Show the vital status of the infant or child at the time of this case report and investigation. Do not leave this answer blank. If the infant or child is alive, proceed to Question 24. If the infant or child was born alive then died, proceed to Question 24. If the infant was stillborn, proceed to Question 26. If the vital status is not known, proceed to Question 25.

NOTE: A syphilitic stillbirth is a fetal death in which the mother had untreated or inadequately treated syphilis at delivery of a fetus after a 20 week gestation or weighing >500 grams.

24. Date of death: Complete this question only if the infant or child died after birth. If the date of death is not known, mark the Unknown box. Do not complete this question if the infant was stillborn.
25. Sex: Denote the sex of the infant or child. Do not leave this answer blank unless the infant was stillborn.
26. Birth weight: Write the birth weight in grams, not pounds and ounces or kilograms. Do not use decimal points. Write a 0 in the first space if the infant weighed less than 1000 grams. For example, a birth weight of 750 grams should be written as 0 7 5 0. If the hospital recorded the weight in pounds and ounces, convert the weight to grams using the formula: 1 pound = 454 grams, 1 ounce = 28 grams. For example, a birth weight of 6 pounds, 11 ounces = 3,032 grams. If the weight is listed in kilograms, multiply kilograms x 1000 = grams. For example, 2.5 kilograms = 2500 grams. Do not leave this answer blank. If the answer is not known, mark the Unknown box.
27. Estimated gestational age (EGA): Show the gestational age in weeks. If a fraction of a week is also recorded, round the gestational age to the nearest whole number. For example, 40 2/7 weeks should be recorded as 40. Gestational age is usually available in the delivery record or can be calculated from the maternal due date. The Dubowitz exam (done by hospital staff) or sonogram results are acceptable if the last menstrual period (LMP) or the due date is not recorded. If the infant is called term without a specified number of weeks, LMP, or due date, then show the estimated gestational age as 40. Do not leave this answer blank. If the gestational age is not known, mark the Unknown box.

NOTE: If the infant was stillborn, proceed to Question 40. Do not answer Questions 31-39.

28. Infant/child reactive non-treponemal test for syphilis (e.g., RPR, VDRL): Mark the appropriate box to show whether the infant or child has had any reactive non-treponemal tests for syphilis at any time. If the child had a reactive blood test for syphilis, mark Yes, serum, regardless of the cord blood test results. If the only reactive treponemal test on the infant was cord blood, mark Yes, cord blood only. Do not leave this answer blank (unless the infant was stillborn). If the answer to this question is No or Unknown, proceed to Question 29. If the answer to this question is Yes, fill in the date and the titer of the infant/child's first reactive non-treponemal test for syphilis. For titer, fill in the spaces beginning immediately to the right of the colon. For example, a titer of 1:8 is recorded 1:8 _ _ . Do not fill in the remaining spaces with 9s or 0s. Rewriting a 1: is not necessary. If the titer is unknown leave this section blank.
29. Infant/child reactive treponemal test for syphilis (e.g., TP-PA, FTA-Abs, EIA, CIA, MBIA): Mark the appropriate box to show whether the infant or child has had any reactive treponemal tests for syphilis at any time. If the child had a reactive blood test for syphilis, mark Yes, serum, regardless of the cord blood test results. If the only reactive treponemal test on the infant was cord blood, mark Yes, cord blood only. Do not leave this answer blank (unless the infant was stillborn). If the answer to this question is No or Unknown, proceed to Question 30. If the answer to this question is Yes, fill in the date of the infant/child's first reactive treponemal test for syphilis.
30. Infant/child has classic signs of CS: Mark the appropriate box to show whether the infant or child had any classic signs of CS. Do not leave this answer blank (unless the infant was stillborn). If the presence of classic signs is not known, mark the Unknown box.
- NOTE: Signs of CS (usually in an infant or child <2 years old) include: condyloma lata, snuffles, syphilitic skin rash, hepatosplenomegaly, jaundice/hepatitis, pseudoparalysis, or edema (nephrotic syndrome and/or malnutrition). Stigmata in an older child might include: interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinson's teeth, saddle nose, rhagades, or Clutton's joints.*
31. Infant/child had darkfield examination or DFA-TP: Mark the appropriate box to show whether a darkfield examination or DFA-TP was done and the result. Please note: the DFA-TP is not the FTA-ABS. A DFA test is performed on lesion material using a fluorescent stain for *T. pallidum* is not a serologic test. Do not leave this answer blank (unless the infant was stillborn). If the result of the darkfield or DFA-TP examination is not known or it is not known whether a darkfield or DFA-TP examination was done, mark the Unknown box.

32. Infant/child had long bone X-rays: Mark the appropriate box to show whether long bone X-rays were done and the results. Evidence of osteochondritis or periostitis is consistent with CS. Do not leave this answer blank (unless the infant was stillborn). If the results of the long bone X-rays are not known or it is not known whether long bone X-rays were done, mark the Unknown box.
33. Infant/child had CSF-VDRL: Mark the appropriate box to show whether a CSF-VDRL was done and the results. Do not leave this answer blank (unless the infant was stillborn). If the result of the CSF-VDRL is not known or it is not known whether a CSF-VDRL was done, mark the Unknown box.
34. Infant/child had CSF cell count or CSF protein: Mark the appropriate box to show whether the CSF cell count and protein were done and the results. Note that results are recorded as elevated or not elevated. Do not leave this answer blank (unless the infant was stillborn). If the results of the CSF cell count and protein are not known or it is not known whether the CSF cell count and protein were done, mark the Unknown box.
- NOTE: In the immediate newborn period, interpretation of these results may be difficult; normal values vary with the gestational age and are higher in preterm infants. For infants 30 days old or less, CSF white blood cell (WBC) count > 15 WBC/mm³ and CSF protein >120 mg/DL are considered abnormal. For infants/children more than 30 days old, CSF WBC count > 5 WBC/mm³ and protein > 40 mg/dL is considered abnormal, regardless of CSF serology.*
35. Infant/child treatment: Mark the appropriate box to show whether treatment was given and what was administered.

Part III. CS Case Classification

36. Classification: For assistance in making a case classification, see the surveillance case definition and the *CS Case Classification Algorithm*. Mark the appropriate box to show the classification: Not a case, Confirmed case, Syphilitic stillbirth, or Probable case. Do not leave this answer blank.

Appendices

[Appendix A](#): Sample Cover Letter for Provider Faxes

[Appendix B](#): Guidelines for Clinical Management of Late Latent Syphilis

[Appendix C](#): Evaluation and Management of Pregnant Women with Syphilis

[Appendix D](#): Guidelines for Evaluation and Management of Neonates Exposed to Syphilis

[Appendix E](#): Quick Reference: Local Health Jurisdiction Management of Reactive Serologic Tests for Syphilis in Women and Infants

Appendix A: Sample Cover Letter for Provider Faxes

Dear _____

We recently received a syphilis case report for your patient:

NAME: _____

DATE OF BIRTH: _____

Initial review indicates that no further Health Department investigation is required for this patient. However, we are providing you with the following documents, should they be of assistance to you in the management of this case, her infant (if applicable) and her partners.

Check attached documents

- Evaluation and Management of Pregnant Women with Syphilis
- Guidelines for Evaluation and Management of Neonates Exposed to Syphilis
- Guidelines for Clinical Management of Late Latent Syphilis

Please be aware that the Health Department conducts case investigations and offers partner services to all early cases of syphilis and all pregnant female cases of syphilis, regardless of stage, as a measure of controlling syphilis transmission in the community. We do not conduct these activities for non-pregnant late cases (cases who appear to have been detected >1 year after their infection).

Please feel free to contact us if you have any questions.

Thank you,

[Health Department signature here]

For more detail on diagnosis, treatment and management of STDs, refer to the [STD Treatment Guidelines](http://www.cdc.gov/std/tg2015/default.htm) (<http://www.cdc.gov/std/tg2015/default.htm>).

For further questions, contact the California STD Control Branch clinician warm line at (510) 620-3400.

Appendix B: Guidelines for Clinical Management of Late Latent Syphilis

Management of cases diagnosed with late latent and latent syphilis of unknown duration necessitates a longer duration of follow-up than those with primary, secondary or early latent syphilis. All patients diagnosed with syphilis should also be tested for HIV.

Treatment

All patients should have a titer on or close to day of treatment; this titer is important as it will be compared to follow-up titers to assess treatment response.

Recommended regimen for Late Latent Syphilis

- Benzathine penicillin G 7.2 million units total, administered as 3 doses of 2.4 million units intramuscular at 1-week intervals.
- Alternative regimens can be used for non-pregnant patients with allergy to penicillin:
 - Doxycycline 100 mg orally twice daily for 28 days, OR
 - Tetracycline 500 mg orally four times per day for 28 days
- Efficacy of alternative regimens is not well established and has not been studied in HIV-infected patients. Close follow-up is essential.
- Pregnant women allergic to penicillin should be treated with penicillin after desensitization.

Follow-up

- Follow-up serologic tests should be performed using the same test type (RPR or VDRL). RPR titer results cannot be compared to VDRL titer results as RPR titers are frequently slightly higher.
- Serologic titer should be obtained at 6, 12 and 24 months.
- Fourfold drop in titer is expected by 12-24 months (if initially high > 1:16).
- HIV-infected patients should be evaluated clinically and serologically at 6, 12, 18, and 24 months.

Partner Management

All sex partners of pregnant female syphilis cases should be evaluated clinically and serologically with treatment provided based on contact management guidelines, regardless of syphilis stage. See CDC 2015 STD Treatment Guidelines (<http://www.cdc.gov/std/tg2015/default.htm>) for detailed information on management of sex partners.

For more detail on diagnosis, treatment and management of STDs, refer to the STD Treatment Guidelines (www.cdc.gov/std/treatment).

For further questions, contact the California STD Control Branch clinician warm line at (510) 620-3400.

Appendix C: Evaluation and Management of Pregnant Women with Syphilis

Congenital syphilis is a preventable condition; failure to detect and appropriately treat maternal syphilis can result in serious sequelae for the fetus and infant. Routine syphilis screening of pregnant women and appropriate management of syphilis in pregnancy are two critical components of congenital syphilis prevention. All patients diagnosed with syphilis should also be tested for HIV.

Syphilis Screening in Pregnancy

- **ALL** pregnant women should be screened for syphilis at their first prenatal visit.
- Women at high risk for syphilis and women who live in areas with high syphilis morbidity should be re-tested for syphilis between 28 and 32 weeks and at delivery. Contact your local health department to find out about areas with high syphilis morbidity.
- Stat RPR should be performed at delivery for women with no prenatal care.
- No infant or mother should leave the hospital without having maternal syphilis status documented at least once either during pregnancy or at delivery.
- Any woman who delivers a stillborn fetus should be tested for syphilis.
- Pregnant women who are seropositive should be considered infected unless they have documentation of adequate treatment with appropriate serologic response to treatment and titers are low and stable.
 - Women with prior adequate treatment, appropriate response to treatment and low serofast titers (VDRL<1:2; RPR<1:4) may not require retreatment.
 - Women with persistent higher antibody titers may indicate reinfection.

Management of Syphilis in Pregnancy

Staging

For treatment, follow-up and partner management purposes, syphilis has been divided into a series of stages:

- Primary infection is characterized by an ulcer or chancre.
- Secondary infection has numerous manifestations including: rash, constitutional symptoms, lymphadenopathy, mucous patches, condyloma lata, and alopecia.
- Latent infection is detected by serologic testing and has no clinical manifestations
 - Early latent syphilis: criteria demonstrate infection acquired in past year
 - Late latent syphilis or latent syphilis of unknown duration: do not meet criteria for infection within past year
- Tertiary infection is characterized by gummas, aortitis, iritis, and other clinical manifestations
- Neurosyphilis can occur at any stage of syphilis.

See CDC 2015 STD Treatment Guidelines (<http://www.cdc.gov/std/tg2015/default.htm>) for detailed information on syphilis staging and criteria to distinguish early latent infection from late latent syphilis and latent syphilis of unknown duration.

Ultrasound

Women diagnosed with syphilis after 20 weeks of pregnancy should have an ultrasound to evaluate for signs of congenital syphilis. Sonographic signs of fetal syphilis (i.e., ascites, hepatomegaly, hydrops, fetal anemia or thickened placenta) may indicate greater risk of fetal treatment failure. Ultrasound evaluation should not delay maternal treatment.

Treatment

All women should have a titer on or close to the day of treatment. This titer is important as it will be compared to follow-up titers to assess treatment response.

Recommended regimen for Primary, Secondary and Early Latent Syphilis

Benzathine Penicillin G 2.4 million units intramuscular in a single dose
(Some specialists recommend a second dose of benzathine penicillin G 2.4 million units intramuscular 1 week after the initial dose for pregnant women with primary, secondary, or early latent syphilis.)

Recommended regimen for Late Latent Syphilis or Latent Syphilis of Unknown Duration

Benzathine penicillin G 7.2 million units, administered as 3 doses of 2.4 million units intramuscular at 1-week intervals
(Missed doses are not acceptable; pregnant women who miss any dose of therapy should repeat the full course of treatment.)

Recommended regimen for Neurosyphilis

Aqueous crystalline penicillin G 18-24 million units daily, administered as 3-4 million units intravenous every 4 hours for 10-14 days
(Some specialists provide additional treatment with 2.4 million units of benzathine penicillin G once per week for up to 3 weeks after completion of neurosyphilis treatment for patients with late latent syphilis or latent syphilis of unknown duration.)

- Pregnant women allergic to penicillin should be treated with penicillin after desensitization.
- Treatment in the second half of pregnancy may precipitate the Jarisch-Herxheimer reaction, possibly including uterine contractions, preterm labor, and/or fetal distress. Women should be advised to seek obstetric attention for fever, contractions, or decrease in fetal movement.

Follow-up

Follow-up serologic tests should be performed using the same test type (RPR or VDRL). RPR titer results cannot be compared to VDRL titer results as RPR titers are frequently slightly higher.

- All women should have repeat serologic titers at 28-32 weeks' gestation and at delivery.
- It is acceptable to repeat serologic titers monthly for women at high risk for reinfection or if in geographic region with high syphilis prevalence.
- Follow-up intervals for primary or secondary syphilis:
 - Clinical exam at approximately 1 week to confirm symptom improvement.
 - Serologic titer at 6 and 12 months. Expect a fourfold drop in titers at 6-12 months.
- Follow-up intervals for latent infection:
 - Serologic titer at 6, 12 and 24 months. Expect a fourfold drop in titer by 12-24 months (if initially high > 1:16).

HIV-infected patients need closer follow-up intervals. See CDC 2015 STD Treatment Guidelines for details.

Partner Management

- All sex partners of pregnant women with syphilis should be evaluated clinically and serologically with treatment provided based on contact management guidelines, regardless of syphilis stage. See CDC 2015 STD Treatment Guidelines (www.cdc.gov/std/tg2015/default.htm) for detailed information on management of sex partners.
- Sexual partner management is critical to prevent reinfection of the pregnant women.

Evaluation of Additional Family Members

Pregnant women with syphilis who have children from prior pregnancies should be advised to discuss syphilis screening of these children with their primary care provider.

For more detail on diagnosis, treatment and management of STDs, refer to the STD Treatment Guidelines (<http://www.cdc.gov/std/tg2015/default.htm>).

For further questions, contact the California STD Control Branch clinician warm line at (510) 620-3400.

Appendix D: Guidelines for Evaluation and Management of Neonates Exposed to Syphilis

Babies born to mothers with positive syphilis tests are at risk for congenital syphilis. Maternal evidence of syphilis includes reactive non-treponemal and treponemal syphilis serology tests or positive darkfield or other direct test of suspicious lesions. This guidance is intended for infants who may have been exposed to syphilis.

Initial Evaluation

Serologic testing

- **Recommended.** A quantitative non-treponemal serologic test (e.g., RPR or VDRL) should be performed on the infant's serum. For accurate comparison to the maternal titer at delivery, the same test should be conducted preferably by the same laboratory.
- **Not Recommended.**
 - Umbilical cord blood is not recommended as it can be contaminated with maternal blood leading to a false positive result.
 - Treponemal testing (e.g., TP-PA, FTA-ABS, EIA, CIA, MBIA) is not useful, as results cannot be quantified for comparison to maternal titer at delivery.
 - Commercially available IgM tests are not recommended due to limitations in sensitivity and specificity.

Physical exam

- All infants born to women who have reactive serologic tests for syphilis should be examined thoroughly for evidence of congenital syphilis (e.g., nonimmune hydrops, jaundice, hepatosplenomegaly, rhinitis, skin rash, and pseudoparalysis of an extremity).

Darkfield microscopic examination

- Darkfield microscopic examination of suspicious lesions or body fluids (e.g., nasal discharge) are also recommended.

Pathologic exam of placenta or umbilical cord

- Pathologic examination of the placenta or umbilical cord using specific fluorescent anti-treponemal antibody staining is suggested.

Further evaluation

Further evaluation depends on findings from the initial evaluation of the infant, as well as maternal history, including treatment and titers. See the [CDC 2015 STD Treatment Guidelines](http://www.cdc.gov/std/tg2015/default.htm) (<http://www.cdc.gov/std/tg2015/default.htm>) for details.

- Cerebrospinal fluid (CSF) examination for VDRL, cell count, and protein.
- Complete blood count (CBC) with differential and platelet count.
- Additional tests as clinically indicated: long bone radiographs, chest radiograph, liver function tests, cranial ultrasound, ophthalmologic exam and auditory brainstem response.

Treatment

Treatment decisions are made on the basis of 1) identification of syphilis in the mother; 2) adequacy of maternal treatment; 3) presence of clinical, laboratory, or radiographic evidence of syphilis in the infant; and 4) comparison of maternal (at delivery) and infant non-treponemal serologic titers. See [CDC 2015 STD Treatment Guidelines](http://www.cdc.gov/std/tg2015/default.htm) (<http://www.cdc.gov/std/tg2015/default.htm>) for treatment recommendations and drug regimens.

Follow up

- All seroreactive infants (or infants whose mothers were seroreactive at delivery) should receive follow-up examinations and serologic testing with a non-treponemal test every 2–3 months until the test becomes nonreactive or the titer has decreased fourfold.
- Non-treponemal antibody titers should decline by age 3 months and should be nonreactive by age 6 months if the infant is not infected or was infected but adequately treated.

For more detail on diagnosis, treatment and management of STDs, refer to the [STD Treatment Guidelines](http://www.cdc.gov/std/tg2015/default.htm) (<http://www.cdc.gov/std/tg2015/default.htm>).

For further questions, contact the California STD Control Branch clinician warm line at (510) 620-3400.

Appendix E: LHJ Management of Reactive Serologic Tests for Syphilis in Women of Child-Bearing Age

	Maternal Case Determination	MEDICAL PROVIDER	LOCAL HEALTH JURISDICTION		
		Case Management	Case Management	Forms/CalREDIE UDF Tab Completion	Timing of Case Closure
Non-pregnant female, Adequately treated	Not a case ¹	None	None	None	n/a
	Early Syphilis	Report, Treat (BICx1)	Confirm Treatment, Interview, Partner Services	<u>Mother's incident</u> : IR, Clinical/Lab <u>Partner(s) incident</u> : HDFU <u>Provider</u> : none	30 days after OP interview
	Late Syphilis	Report, Treat (BICx3)	Confirm Treatment	<u>Mother's incident</u> : n/a <u>Partner(s) incident</u> : n/a <u>Provider</u> : Faxes A,B	30 days after confirmation of all 3 shots
Non-pregnant female, Inadequately treated ²	Not a case ¹	None	None	None	n/a
	Early Syphilis	Report, Treat (BICx1)	Confirm Treatment, Interview, Partner Services	<u>Mother's incident</u> : IR, Clinical/Lab <u>Partner(s) incident</u> : HDFU <u>Provider</u> : none	30 days after OP interview
	Late Syphilis	Report, Treat (BICx3)	Confirm Treatment	<u>Mother's incident</u> : n/a <u>Partner(s) incident</u> : n/a <u>Provider</u> : Faxes A,B	30 days after confirmation of all 3 shots
Pregnant female, Adequately treated	Not a case ¹	None	None	None	n/a
	Early Syphilis	<u>Mother</u> : Report, Treat (BICx1) <u>Infant</u> : Evaluate and treat, as indicated	Confirm Treatment, Interview, Partner Services	<u>Mothers incident</u> : IR, Clinical/Lab <u>Partner(s) incident</u> : HDFU <u>Provider</u> : Faxes A, C, D	30 days after OP interview
	Late Syphilis	<u>Mother</u> : Report, Treat (BICx3) <u>Infant</u> : Evaluate and treat, as indicated Manage steady partners and children associated with prior pregnancies.	Confirm Treatment, Interview, Partner Services	<u>Mother's incident</u> : IR, Clinical/Lab <u>Partner(s) incident</u> : HDFU <u>Provider</u> : Faxes A, C, D	30 days after confirmation of all 3 shots
Pregnant female, Inadequately treated ²	Not a case ¹	None	None	None	n/a
	Early Syphilis	<u>Mother</u> : Report, Treat (BICx1) <u>Infant</u> : Evaluate and treat, as indicated	Confirm treatment of mother and infant, Interview mother, Partner Services	<u>Mother's incident</u> : IR, Clinical/Lab <u>Partner(s) incident</u> : HDFU <u>Provider</u> : Faxes A, C, D <u>Infant's incident</u> :HDFU ³ , Lab, CS Form	30 days after delivery or stillbirth
	Late Syphilis	<u>Mother</u> : Report, Treat (BICx3) <u>Infant</u> : Evaluate and treat, as indicated Manage steady partners and children associated with prior pregnancies.	Confirm treatment of mother and infant, Interview mother, Partner Services	<u>Mother's incident</u> : IR, Clinical/Lab <u>Partner(s) incident</u> : HDFU <u>Provider</u> : Faxes A, C, D <u>Infant's incident</u> :HDFU ³ , Lab, CS Form	30 days after delivery or stillbirth

¹ Not a case includes serofast; ² Adequate treatment as defined in Section 1.A.; ³ Complete HDFU for live births only.

LHJ = Local Health Jurisdiction, BIC = Bicillin-LA, CS = Congenital Syphilis, HDFU=Health Department Follow-up, IR = Interview Record, OP = Original Patient. Provider Faxes referenced are from the CS Protocol: A = Cover Letter, B = "Guidelines for Clinical Management of Late Latent Syphilis", C = "Evaluation and Management of Pregnant Women with Syphilis", D = "Guidelines for Evaluation and Management of Neonates Exposed to Syphilis"
CS Form = California Congenital Syphilis Case Investigation and Report

Prepared by the California Department of Public Health

Appendix F: LHJ Management of Reactive Serologic Tests for Syphilis in Infants

	Maternal Case Determination	MEDICAL PROVIDER	LOCAL HEALTH JURISDICTION		Timing of Case Closure
		Case Management	Case Management	Forms/CalREDIE UDF Tab Completion	
Positive infant serology, regardless of maternal serology	Not a case ¹	None	Confirm mother is not a case	None	30 days after delivery
	Early Syphilis	<u>Mother</u> : Report, Treat (BICx1) <u>Infant</u> : Evaluate and treat, as indicated	Confirm treatment of mother and infant, Interview mother, Partner Services	<u>Mother's incident</u> : IR, Clinical/Lab <u>Partner(s) incident</u> : HDFU <u>Infant's incident</u> : HDFU ² , Lab, CS Form <u>Provider</u> : Faxes A, C, D Document maternal incarceration history in past 12 months and, for binational cases, date of mother's first US prenatal visit on the infant HDFU tab under 'Other locating'.	30 days after delivery or stillbirth
	Late Syphilis	<u>Mother</u> : Report, Treat (BICx3) <u>Infant</u> : Evaluate and treat, as indicated Manage steady partners and children associated with previous pregnancies	Confirm treatment of mother and infant, Interview mother, Partner Services	<u>Mother's incident</u> : IR, Clinical/Lab <u>Partner(s) incident</u> : HDFU <u>Infant's incident</u> : HDFU ² , Lab, CS Form <u>Provider</u> : Faxes A, C, D Document maternal incarceration history in past 12 months and, for binational cases, date of mother's first US prenatal visit on the infant HDFU tab under 'Other locating'.	30 days after delivery or stillbirth
Positive delivery blood on mother, with negative infant serology	Not a case ³	None	Confirm mother is not a case	None	r/a
	Early Syphilis	<u>Mother</u> : Report, Treat (BICx1) <u>Infant</u> : Evaluate and treat, as indicated	Confirm treatment of mother and infant, Interview mother, Partner Services	<u>Mother's incident</u> : IR, Clinical/Lab <u>Partner(s) incident</u> : HDFU <u>Infant's incident</u> : HDFU ² , Lab, CS Form <u>Provider</u> : Faxes A, C, D Document maternal incarceration history in past 12 months and, for binational cases, date of mother's first US prenatal visit on the infant HDFU under 'Other locating'.	30 days after delivery or stillbirth
	Late Syphilis	<u>Mother</u> : Report, Treat (BICx3) <u>Infant</u> : Evaluate and treat, as indicated Manage steady partners and children associated with previous pregnancies	Confirm treatment of mother and infant, Interview mother, Partner Services	<u>Mother's incident</u> : IR, Clinical/Lab <u>Partner(s) incident</u> : HDFU <u>Infant's incident</u> : HDFU ² , Lab, CS Form <u>Provider</u> : Faxes A, C, D Document maternal incarceration history in past 12 months and, for binational cases, date of mother's first US prenatal visit on the infant HDFU under 'Other locating'.	30 days after delivery or stillbirth

¹ Maternal transfer of antibodies; ² Complete HDFU for live births only; ³ Previous treatment of mother or biologic false positive test.

LHJ = Local Health Jurisdiction, BIC = Bicillin-LA, CS = Congenital Syphilis, HDFU=Health Department Follow-up Tab, IR = Interview Record. Provider Faxes referenced are from the CS Protocol: A = Cover Letter, B = "Guidelines for Clinical Management of Late Latent Syphilis", C = "Evaluation and Management of Pregnant Women with Syphilis", D = "Guidelines for Evaluation and Management of Neonates Exposed to Syphilis"

CS Form = California Congenital Syphilis Case Investigation and Report

Prepared by the California Department of Public Health