

The California Prenatal Screening Program



Sequential Integrated Screening
Serum Integrated Screening
Quad Marker Screening

Prenatal Care Provider Handbook

California Department of Public Health * Genetic Disease Screening Program

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Welcome to the California Prenatal Screening Program

The California Prenatal Screening Program is administered by the Genetic Disease Screening Program of the California Department of Public Health. The Program goal is to identify pregnant individuals at increased risk for specific birth defects so they can make informed decisions about their pregnancies. (California Code of Regulations Title 17, sections 6521-6532. Copies of these regulations are available from the Genetic Disease Screening Program.)

As a prenatal care provider, you play an important role by offering all pregnant individuals in California the opportunity to have prenatal screening for certain birth defects:

- **Down syndrome (DS; Trisomy 21; T21)**
- **Trisomy 18 (T18, Edwards Syndrome)**
- **Open Neural Tube Defects (NTD) and Abdominal Wall Defects (AWD)**
- **Smith-Lemli-Opitz syndrome (SLOS)**

What is California’s Prenatal Screening Program?

Prenatal screening offers blood tests to pregnant individuals to identify individuals who are at increased risk for carrying a fetus with a specific disorder. These blood tests can be drawn in the first and/or second trimester. Because **screening does not diagnose fetal defects, the Program provides diagnostic testing to individuals with screen positive results (increased risk)**. These individuals are referred for follow-up services at a State-approved Prenatal Diagnosis Center.

Types of screening: The Program offers several screening options:

Sequential Integrated Screening	Combines Nuchal Translucency (NT) ultrasound results with first and second trimester blood test results.
Serum Integrated Screening	Combines first trimester blood test results (drawn between 10 weeks 0 days – 13 weeks 6 days) with second trimester blood test results.
Quad Marker Screening	One blood specimen drawn between 15 weeks – 20 weeks of pregnancy (second trimester).

Screening results are reported as “Screen Negative” or “Screen Positive”.

A “**Screen Negative**” result indicates that the patient’s risk for the screened birth defects is low enough that the Program does not offer follow-up tests.

A “**Screen Positive**” result indicates that the patient is at **increased risk** for one or more of the screened birth defects and the Program will offer follow-up services.

The details of these screening options are presented in **Table 1** below.

Table 1. Blood Draws Required for Prenatal Screening by the California Prenatal Screening Program.

Type of Screening	1 st trimester draw	NT	2 nd trimester draw
Sequential Integrated Screening	YES	YES	YES
Serum Integrated Screening	YES	NO	YES
Quad Marker Screening	NO	NO	YES
Quad Marker + NT Screening	NO	YES	YES

The Prenatal Screening Program offers at no cost to the provider:

- Regional Coordinators to facilitate participation for patients and providers/clinicians.
- Patient education booklets with consent/refusal documents.
- First and Second Trimester Screening Forms (TRFs).
- Supplies to draw and mail serum samples.
- Follow-up services at State-approved Prenatal Diagnosis Centers (PDCs). The PDCs are independent perinatal clinics who are authorized to see state patients.
- Screen Positive patient education booklets.

Note: The California Prenatal Screening Program DOES NOT PAY for Nuchal Translucency ultrasound.

Role of Clinician – a Summary

Supplies: Order free patient education booklets, blood collection kits and First and Second Trimester Screening Forms by faxing an order form to (877) 984-8450 or by calling (877) 984-8650 toll-free or emailing, pnssupplies@cdph.ca.gov. See *Appendix I*.

Offer screening: Providers are obligated to offer the Prenatal Screening Program to all pregnant individuals who are seen before the 20th gestational week. Discuss with the patient which of the types of screening are available and appropriate for them considering their medical, pregnancy and family histories.

Consider Nuchal Translucency (NT) ultrasound referral for patient (optional): The California Prenatal Screening Program does not pay for NT. NT ultrasound measurements are accepted by the Program when provided by a credentialed NT Practitioner who is listed on the [California Prenatal Screening Program website](#).

Consent/refusal to participate: Have the patient read the booklet “The California Prenatal Screening Program” provided by the Genetic Disease Screening Program. After discussing and answering their questions, ask patient to sign the consent/refusal document in the patient education booklet. In addition, if they consent to participate, the patient may decline to have their specimen used for research. Place patient’s consent/refusal document in the patient’s medical record. If they decline to have their specimen used for research, this should be indicated on the “Patient Declined Research” field on the First and Second Trimester Screening Forms.

For patients who consent to prenatal screening:

Fully and accurately complete the First and/or Second Trimester Screening Form provided by the Genetic Disease Screening Program. See *page 15 and Appendix J*.

Use only ONE method of gestational dating. Dating by NT is the most accurate. If an NT ultrasound was not performed, ultrasound dating by CRL or BPD, if available, is next best for screening purposes. See *page 13*.

Timing of the test: First trimester specimens are drawn between 10 weeks 0 days and 13 weeks 6 days. **Second trimester specimens** are drawn between 15 weeks 0 days and 20 weeks 0 day of pregnancy. See *page 12 and Appendix F*.

Blood collection: Blood specimens may be collected by the clinician, or the patient may be sent to a blood collection facility. Read the instructions on the cover page of the First and Second Trimester Screening Form on how to collect and prepare the blood to mailed to the designated lab.

Note: *All specimens should be centrifuged per the instructions on the cover page of the First and Second Trimester Screening Forms. **First Trimester specimens that have not been centrifuged will not be analyzed.***

Results: You will receive the results by mail within 7-10 days of specimen collection.

A Prenatal Screening Coordinator calls the clinician if patient information needs verification or if the test result is *screen positive*.

Only a licensed health professional should explain a patient's result and assist the patient in deciding what action to take after a *screen positive* result.

The Prenatal Screening Coordinator assists the clinician in referring a patient with a *screen positive* result to a State-approved Prenatal Diagnosis Center (PDC) if that is the patient's decision. See current list of PDCs on the [California Prenatal Screening Program website](#).

Program fee: The current fee (2019) for the Prenatal Screening Program is \$221.60. This fee covers the blood test(s) as well as follow-up services when the result is *screen positive*. The Prenatal Screening Program fee is subject to change.

The fee DOES NOT cover the cost of the NT ultrasound.

Program billing: Enter the patient's Medi-Cal or insurance information on the First and/or Second Trimester Screening Form or send a copy of the patient's insurance card or Medi-Cal card with the specimen. The insurance company or Medi-Cal will be billed for the Prenatal Screening Program participation. If no insurance information is provided, the patient will receive a bill about 2 weeks after the first test. Because the Program cannot guarantee that insurance will cover the full cost of the screening, be sure to inform the patient of the charge for the Prenatal Screening Program. See *page 29*.

Provide the Program with patient insurance details to avoid unnecessary patient billing.

Clinician Obligations for patients who have prenatal screening:

- Report to the Genetic Disease Screening Program all cases of NTDs and/or chromosomal abnormalities diagnosed before one year of age, including stillborn.

- Complete the "Request for Pregnancy Outcome" form which is sent to clinicians regarding selected patients participating in the Program.

Find forms at: www.cdph.ca.gov/Programs/PSB/Pages/GeneticDiseaseScreening.aspx

Clinician Obligations for patients who have screen positive results:

- Verify all the patient data with the Prenatal Screening Coordinator when they call with non-negative results.
- After a first trimester *screen positive*, offer the patient a referral to a State-approved PDC or, if she declines a referral, a second trimester blood test.
- After a second trimester *screen positive*, offer a referral for follow-up at a State-approved PDC.
- Inform patients that they will be offered follow-up services **only** at a State-approved Prenatal Diagnosis Centers at no additional cost.

Patients' rights: The Prenatal Screening Program is voluntary, and patients have the right to decline screening or diagnostic services at any time.

Documentation: Your patient's decisions regarding screening and follow-up services should always be thoroughly documented in the patient's chart.

Serum Markers Used for Prenatal Screening

Alpha-fetoprotein (AFP)

AFP is a protein produced mainly in the fetal liver and released into the fetal serum and amniotic fluid. A small amount crosses the placenta and becomes measurable in the maternal serum towards the end of the first trimester. Levels rise steadily through the second trimester. In most fetuses affected with open spina bifida, anencephaly, or an abdominal wall defect, an increased amount of AFP enters the amniotic fluid and subsequently causes a higher than expected level of AFP in the maternal serum. In contrast, maternal serum AFP may be reduced in a pregnancy in which the fetus has Down syndrome, Trisomy 18, or SLOS.

Human chorionic gonadotropin (hCG)

Human chorionic gonadotropin is a hormone synthesized and secreted by the placenta. Levels of intact hCG are used in both the first and second trimester tests. The levels rise rapidly in early pregnancy and then decline between the 10th and the 20th week. Second trimester maternal serum levels may be higher in a pregnancy in which the fetus has Down syndrome. The level of hCG is often lower than expected in a pregnancy with a fetus affected with Trisomy 18 or SLOS.

Inhibin (Dimeric Inhibin-A; DIA; INH)

Dimeric Inhibin-A is a protein produced by the ovaries and fetal placenta. Levels rise during the first trimester, then decline after the 10th week of pregnancy and remain stable between the 15th and 20th week. Maternal levels of INH, on average, are twice as high in pregnancies affected by Down syndrome as compared to unaffected pregnancies.

Pregnancy-Associated Plasma Protein A (PAPP-A)

PAPP-A is produced by both the embryo and placenta during pregnancy. PAPP-A normally increases during gestation. Low levels during the first trimester may be associated with fetal chromosomal anomalies including Trisomies 13, 18 and 21. In addition, low PAPP-A levels in the first trimester may be associated with adverse pregnancy outcomes, including a baby that is smaller than expected at gestational age, premature delivery, preeclampsia, or stillbirth. A high PAPP-A level may predict a baby that is larger than expected at gestational age.

Unconjugated Estriol (uE3)

Unconjugated estriol is a hormone produced by the fetal adrenal glands, the fetal liver, and the placenta. Levels rise throughout a normal pregnancy. Maternal serum levels of uE3 may be lower in a pregnancy in which the fetus has Down syndrome or Trisomy 18. It is often very low in a pregnancy with a fetus affected with SLOS. Since it is only stable for 10 days, specimens in transit over 10 days will not have uE3 analytic values.

Non-Serum Marker Used for Prenatal Screening

Nuchal Translucency (NT) Ultrasound

Nuchal translucency (NT) measurements (nuchal fold) have proven to be very valuable in improving the detection of Down syndrome and Trisomy 18. When NT measurements are added to serum analytes for screening, detection rates are higher for Down syndrome and Trisomy 18.

The NT measurement generally increases with gestational age during the NT screening window. The expected range for NT thickness during the time period for an NT exam used in risk assessment (11 weeks 2 days to 14 weeks 2 days) is 1.2 – 2.7 mm. NT measurements of 3.0 mm or greater are associated with an increased risk of chromosomal or other abnormalities, even without serum markers.

NT Practitioners, certified by either the Nuchal Translucency Quality Review Program (NTQR) or the Fetal Medicine Foundation (FMF), must apply to participate in the California Prenatal Screening Program. A current list of accepted NT Practitioners is on the [Prenatal Screening website](#) as “Nuchal Translucency Practitioner List.”

The Prenatal Screening Program will *only* accept NT ultrasound information from credentialed practitioners listed with the Genetic Disease Screening Program of the California Department of Public Health. Credentialed practitioners that reside outside of California must directly notify the Genetic Disease Screening Program to be listed with the Prenatal Screening Program.

Multiple of the Median (MoM)

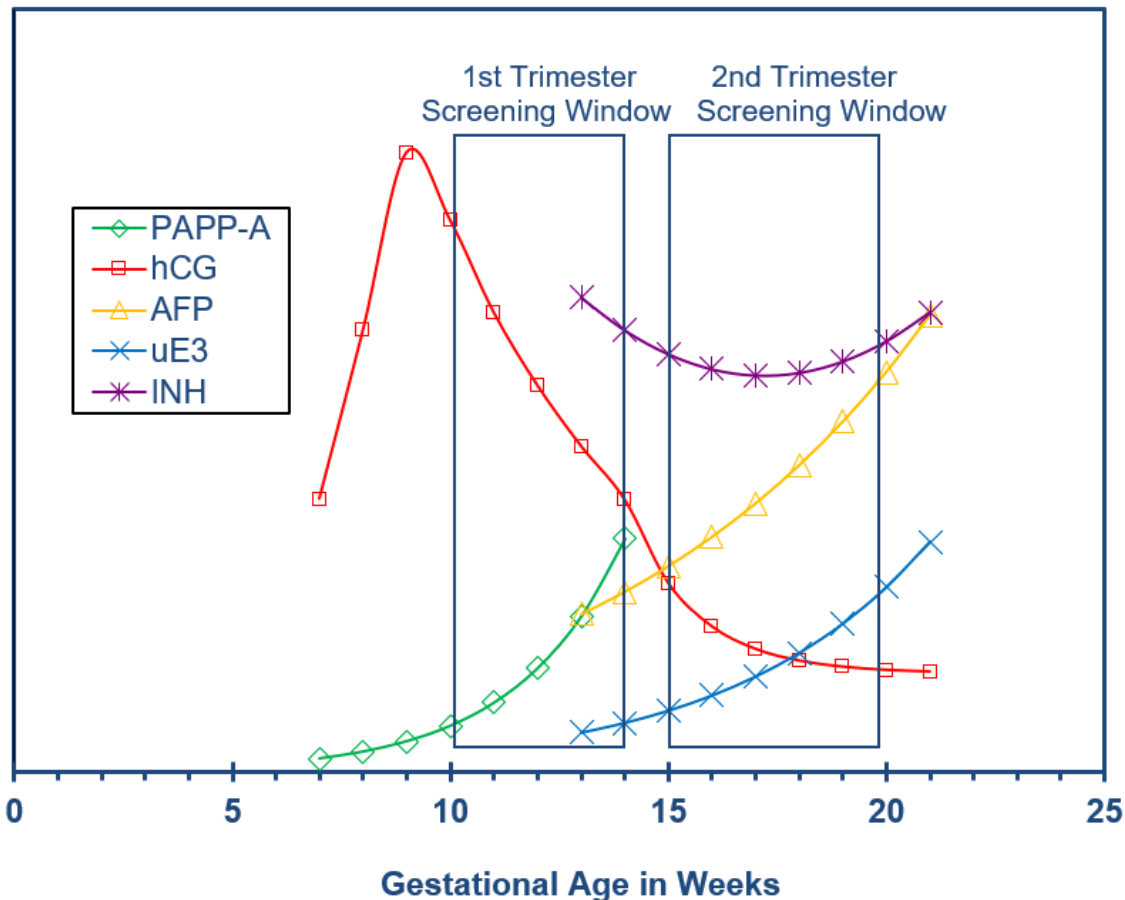
The concentrations of each serum marker change during the time window for screening, as shown in **Figure 1** on page 7. The Prenatal Screening Program has established the median concentrations of PAPP-A and First Trimester hCG for California's pregnant population for each day between 10 weeks 0 days and 13 weeks 6 days. The Program has also established medians for Second Trimester hCG, AFP, uE3 and INH for each day between 15 weeks 0 days and 20 weeks 0 days gestation.

For each blood specimen received, the analytic value for every serum marker tested is converted to a multiple of the median (MoM) based on the gestational age at blood collection. The median level for each day equals a MoM of 1.00. For example, an AFP result of 1.50 MoM means the patient has one and a half times the median level of AFP; an hCG result of 0.30 MoM means the patient has 30% of the median level of hCG. NT measurement values, when available, are also converted to MoMs.

MoMs are adjusted for patient race/ethnicity, weight, smoking status, and diabetic status to give a more accurate risk assessment.

The risk assessment for prenatal screening, resulting in *screen positive* and *screen negative* results, is determined by the MoMs, not the initial analytic value of the serum markers. **Therefore, the correct gestational age at blood collection is so important for prenatal screening.**

Figure 1. The Concentration of a Serum Marker Varies by Gestational Age



Markers Used for Different Birth Defects

Down syndrome and Trisomy 18: The MoMs for PAPP-A, hCG, AFP, uE3, INH and NT ultrasound measurements can be used in conjunction with the individual's age and other factors to calculate an individualized risk for Down syndrome and Trisomy 18. An individual's age is an essential component of the risk analysis because it is an important predictor of risk for these chromosomal abnormalities. See *page 24 and Appendices C, G and H for more information.*

Open Neural Tube Defects/Abdominal Wall Defects: The level of maternal serum AFP is used to calculate the AFP MoM. Risk assessment for NTD/AWD is based on the AFP MoM and whether the pregnancy has one fetus or twins. Some other conditions associated with an elevated maternal serum AFP are mentioned on page 21. See *Appendices C and D for more information.*

Smith-Lemli-Opitz syndrome: Measurements of the levels of AFP, hCG and uE3 are used to calculate the risk of having a fetus with SLOS. The most important analyte for SLOS detection is uE3; the patient's age is not a factor in the risk calculation. See *page 25 and Appendix C for more information.*

Prior to Offering Prenatal Screening

Important Questions

Clinicians should review a patient's medical and family history to determine if any of the following situations apply:

Does the patient have a history of?

- Birth Defects
- Genetic Disorders
- Multiple Miscarriages
- Teratogen Exposure
- Suspected Fetal Anomaly
- Diabetes
- Ovum Donor

Does the patient or their partner have a family history of birth defects or genetic disorders? Are they known carriers of genetic traits as Tay-Sachs, sickle cell or cystic fibrosis?

Is there a family history of an NTD?

Has the patient taken certain teratogens (one month prior to conception or during the first trimester) for seizures or any other indication? For example:

- Carbamazepine (Tegretol, Carbatrol, Atretol),
- Valproic Acid/Valproate/Divalproex (Depakene, Depakote)
- Oxcarbazepine (Trileptal)

Note: This is not a complete list.

If any one of the answers is yes:

The patient should be referred directly to a State-approved Prenatal Diagnosis Center for genetic counseling to assess risk and to discuss screening tests versus diagnostic tests. This pre-test genetic counseling is not covered by the Prenatal Screening Program. Many health plans and Medi-Cal cover genetic counseling for these indications.

The Prenatal Screening Program will pay for follow-up services only if the Prenatal Screening result is *screen positive*. Important Note: Do not order either a First or Second Trimester Prenatal Screening test if the patient is scheduled for, or has already had, an amniocentesis.

Did the patient have chorionic villus sampling (CVS)?

When the patient has already had or is scheduled for a karyotype from CVS, she should be offered screening for NTDs and SLOS in the second trimester. On the Second Trimester Screening Form, Field 13 asks "Has the patient had CVS?" If the "Yes" box is checked, the Prenatal Screening Program will only report risk for NTDs and SLOS, but not for chromosomal abnormalities, in the second trimester.

Is the pregnancy the result of a donated ovum?

If so, indicate this on the First and Second Trimester Screening Forms, including the age of the donor at time of donation. Even if the patient is using their own eggs, both the patient's

current age and age at time of egg preservation should still be reported. Two results will be calculated: one using the patient's date of birth and the other using the donor's age.

Is the pregnancy at risk of Zika virus infection?

If a pregnant patient has signs and symptoms of Zika virus disease, a travel history to an area with risk of Zika virus transmission, or a sexual partner's potential exposure, clinicians should follow [California Department of Public Health guidelines in *Zika Guidance for HCPs Caring for Pregnant Individuals and Newborns*](#).

Some Pregnancies are Not Eligible for Screening

Fetal reduction: Do not order Prenatal Screening. Individuals who have undergone procedures to reduce the number of fetuses usually have very high serum AFP levels and this prevents an accurate risk assessment. The effect of fetal reduction on PAPP-A, hCG, INH and uE3 is unknown. If a blood specimen is submitted, the results are considered invalid and no follow-up services are authorized.

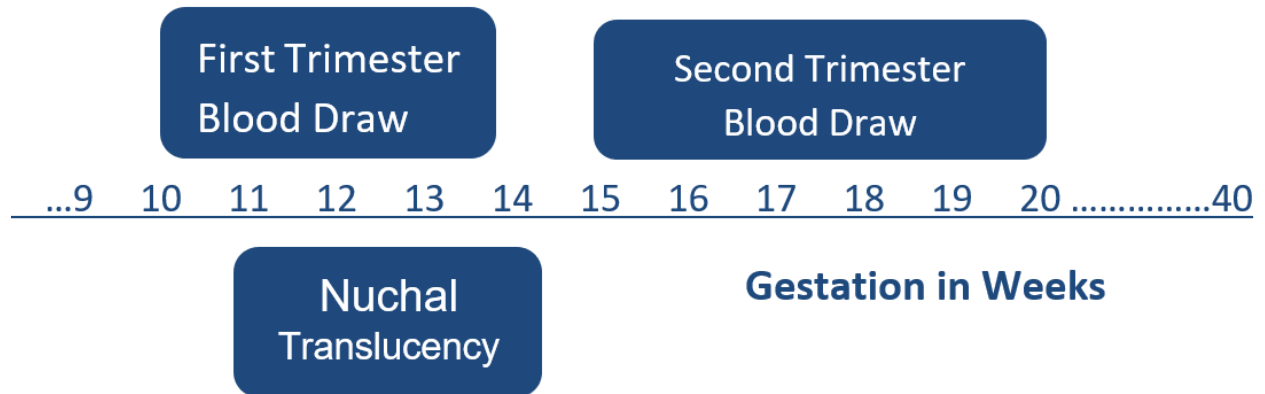
Multiple gestation of three or more fetuses: Do not order Prenatal Screening. Individuals who are carrying 3 or more fetuses usually have very high serum AFP levels, preventing an accurate risk assessment. The effect of multiple fetuses on PAPP-A, hCG, INH and uE3 is unknown. If a blood specimen is submitted, the results are considered invalid and no follow-up services are authorized.

A fetal loss **after 8 weeks gestation** makes this pregnancy ineligible for screening at any gestation.

A fetal loss **prior to 8 weeks gestation** makes the pregnancy ineligible for first trimester screening. The patient remains eligible for second trimester screening.

Timing for screening tests

Screening Timeline



First Trimester specimens can be drawn between 10 weeks 0 days and 13 weeks 6 days.

Second Trimester specimens can be drawn between 15 weeks, 0 days, and 20 weeks 0 days.

NT ultrasounds are done between 11 weeks 2 days and 14 weeks 2 days.

Good times for blood collection are during the 11th or 12th week of gestation for first trimester screening and during the 16th or 17th weeks of gestation for the second trimester screening. This schedule allows sufficient opportunity for follow-up diagnostic services if the Prenatal Screening result is *screen positive and gives some leeway for dating errors*. No risk assessment is provided for specimens collected before 10 weeks, after 20 weeks, or during the 14th week of gestation. Levels of both PAPP-A and hCG usually rise rapidly in the pregnant individual's blood for the **first 8 to 10 weeks**, then decrease and stabilize at a lower level for the remainder of the **pregnancy**.

Important: Screening late in each time window may compromise an individual's ability to make choices about follow-up services and pregnancy options.

Pregnancy Dating

Dating when NT Crown Rump Length (CRL) is available: Gestational age by NT CRL is the best dating method for screening, when the NT ultrasound is done by a credentialed NT Practitioner who is listed on the [California Prenatal Screening Program website](#).

NT ultrasound results may be given to the Program in one of three ways:

- If the blood specimen has already been processed at the screening lab, many of the approved NT practitioners have the ability to enter the NT and CRL measurements directly into the Program's computer system.
- When there is no blood specimen yet, the NT Practitioner can put the NT ultrasound information directly on the First Trimester Screening Form, if provided by the referring clinician.
- The NT Practitioner can send NT ultrasound results to the prenatal provider, who must put the NT information on the First or Second Trimester Screening Form.

Note: First Trimester Screening results REQUIRE NT CRL and NT measurements. The results are preliminary. A second trimester specimen should be drawn for sequential integrated results.

The Program fee does **NOT** cover the cost of an NT ultrasound.

Dating when ultrasound is available: If an NT ultrasound is not done, gestational age by ultrasound dating is the next best dating method, preferably with dating by biparietal diameter (BPD). Why use BPD for Prenatal Screening? In other obstetrical contexts, multiple dating parameters may be more useful, but for screening, BPD is better because:

- Studies show that fetuses with spina bifida often have smaller BPDs which results in a higher AFP MoM. The use of BPD increases the detection of open spina bifida by increasing the possibility that the AFP MoM will be over the cutoff of 2.50 MoM.
- Fetuses affected with Down syndrome often have shorter femurs and other long bones. Using femur length measurements instead of BPD could date the pregnancy earlier, thereby reducing the detection of Down syndrome.

See Appendix E for a more detailed description of ultrasound dating advantages.

Dating with LMP: If no ultrasound dating is available, last menstrual period (LMP) can be used as a method of dating for Prenatal Screening.

Exam dating: Exam dating is the least reliable dating for screening. It cannot be used with First Trimester analytes for Serum Integrated Screening. If no other method is available, it will be used for Second Trimester screening.

Corrections and updates to pregnancy dating: An individual will have different risk estimates for Down syndrome and Trisomy 18 depending on whether NT CRL, ultrasound, or LMP dating is used, even if the gestational ages are the same by all methods. Re-dating an LMP-dated or physical exam-dated pregnancy by ultrasound or

NT CRL may significantly change an individual's Down syndrome risk estimate and the new estimate provides a better risk assessment.

If ultrasound dating information becomes available after the Prenatal Screening sample has been submitted, clinicians are encouraged to call the Prenatal Screening Coordinator's phone number (printed on the results mailer) and request that the screening result be recalculated using the new dating.

Dating calculators: The Prenatal Screening Program has several tools available to clinicians at NO COST to calculate a patient's gestational age.

Prenatal Screening Program Time Window Calculator: This online tool is available on the [Program's website](#). This calculator provides time windows for drawing first and second trimester blood specimens and for obtaining a nuchal translucency ultrasound. Time windows displayed on this calculator can be printed for later use.

PNS Calculator Mobile App: This app is available for Android mobile devices from the Google Play Store and it is available for Apple mobile devices from the Apple App Store. Like the Time Window Calculator, the app provides time windows for drawing first and second trimester blood specimens and for obtaining a nuchal translucency ultrasound. The app does not have the innate ability to print calculated time windows.

Information Necessary for an Accurate Result

Prenatal Screening Test Request Form

The test request form is the primary source of patient information used to interpret a patient's screening test results. Clinicians are responsible for the accuracy of all information on Prenatal Screening Test Request Forms.

Incomplete or inaccurate information can delay results or cause an erroneous interpretation of results.

A First or Second Prenatal Screening Test Request Form must accompany each blood specimen. The cover page of the Form contains specific instructions for providing the required information. Please read and follow the directions exactly. (A sample of each Form is in *Appendix J*.)

Date of birth: A patient's age is used to determine an individualized risk for carrying a fetus with Down syndrome or Trisomy 18.

Gestational age: The median level of each analyte changes each day during pregnancy. It is important to choose the most accurate gestational dating method. NT CRL is the most accurate dating, followed by ultrasound dating based on BPD.

Weight: Heavier pregnant individuals have lower median values while lighter pregnant individuals have higher median values.

Race: Some races have different median values. For example: Black pregnant individuals have higher medians for AFP. Asian and Hispanic pregnant individuals have higher medians for uE3.

Number of fetuses: The level of each analyte is usually increased with a multiple gestation. Levels are approximately double for twins. However, since there are no established median values for more than two fetuses, pregnancies with more than 2 fetuses are not eligible for screening.

Diabetic status: The amount of maternal serum AFP is usually lower in patients diagnosed with diabetes prior to and during pregnancy.

Nicotine status: If a patient uses nicotine, it will affect one or more of the analytes. Currently, the effects of marijuana intake during pregnancy are unknown. The Prenatal Screening program does not screen for potential prenatal impacts of marijuana.

Ovum donor age: If an ovum donor age is provided, a separate risk assessment for the ovum donor can be calculated. It is important to provide the age of eggs at the time of donation, **even when the patient is using their own eggs** at the time of collection, to obtain a separate risk assessment.

Matching specimens for Integrated Screening

First and second trimester records must be matched to benefit from the improved detection rates of integrated screening. Data from both First and Second Trimester Test Request Forms are used for matching. It is important to enter the First Trimester Screening Form number on the Second Trimester Screening Form. The easiest method is to use the peel-off label provided on your (pink) copy of the First Trimester Screening test request form. **Affix the label or hand copy the First Trimester Screening Form number on to "Part A" of the Second Trimester Screening Form.**

Always include the following prenatal care provider information:

Name, California license number, NP, address & zip code, phone, and fax numbers. Stamps or labels can be used for this information if they are legible and efficiently correspond to the fields on the forms. Since the Program uses some Optical Character Recognition (OCR) technology for data entry, it is essential that you order a stamp that fits the clinician information area of the form. Be sure to provide a copy of the Screening Form when you order your stamp.

Sexual Orientation and Gender Identity Card (SOGI)

Effective July 1, 2018, the Prenatal Screening (PNS) Program must comply with Government Code Section 8310.8. Section 8310.8 states that all California state agencies collecting personal information must also include a questionnaire about sexual orientation and gender identity. A postage-paid card will be attached to all Test Request Forms (TRFs) beginning in 2018.

SOGI Card Instructions: tear off the card and give it directly to the patient. The patient can complete the information and mail it to the PNS Program. Submission of this card is **VOLUNTARY** and will not affect any prenatal risk assessment or results interpretation. This information is collected in aggregate and will not be traceable to individual patients and/or prenatal screening test results.

Blood collection and shipping

Prenatal blood collection kits, mailing supplies and First and Second Trimester Prenatal Screening Test Forms are supplied by the Genetic Disease Screening Program at no cost. See *Appendix I* for a description of Program supplies and materials.

Collection instructions are on the cover sheet of every First and Second Trimester Screening Test Request Form.

Specimens should be mailed as soon as possible after collection. Specimens held too long or delayed in transit over 10 days cannot be analyzed for uE3.

If unable to mail the specimen immediately, centrifuge and refrigerate until mailed. Do not freeze specimens.

Unlabeled, mislabeled, or improperly labeled specimens will not be analyzed. Hemolyzed specimens cannot be analyzed.

It is highly recommended that second trimester specimens be centrifuged.

First trimester specimens MUST be centrifuged to be analyzed.

Using General Logistics Systems US, Inc (GLS) courier service for specimens:

Provider offices and draw stations now have a special opportunity to use a courier, GLS, for specimen delivery to the California Prenatal Screening Program. While the post office can still be used to mail specimens, the Program would strongly encourage you to start using GLS.

There is ***no charge*** to clinicians or draw stations for GLS delivery services. If your office draws patients at least 3 days per week, GLS may be able to pick up samples for your facility. If not, individual pickups may be arranged by calling GLS Customer Service at 1-800-322-5555. Alternately, specimens can be dropped off at any GLS drop box. To find the locations of drop boxes in your area, go to the [GLS website](#), select “tools,” and then “drop box locations.” Enter your ZIP code to view the closest drop box locations.

The advantages of using GLS include:

- Just one day in transit, ensuring that blood analytes won't have expired on arrival
- Ability to track your specimen shipments online
- Faster turnaround for results

If you are interested in using this service, please visit the [Prenatal Screening Program's website](#), or contact the Prenatal Screening Program for further instructions.

Prenatal Screening Coordinators

Prenatal Screening Coordinator offices are located throughout California. Each prenatal care provider is assigned a coordinator by zip code. The prenatal care provider should look to the Coordinator as the primary source of information regarding the Program.

It is helpful to have a designated contact person in each clinician's office or clinic for the coordinator to call. Your coordinator's phone number is included on every result mailer.

A Prenatal Screening Coordinator will call your office when there is missing or incomplete information on the Test Request Form or to verify information for certain results such as positives, specimens drawn too early or too late, or any non-negative test result. See *Appendix B for a list of Prenatal Screening Coordinator offices.*

Clinicians should call their Prenatal Screening Coordinator when:

NT ultrasound information is received from a credentialed NT practitioner that is not on a First and/or Second Trimester Screening Test Request Form.

New or corrected information (such as a new gestational age by ultrasound) becomes available prior to 24 weeks gestation. (Results cannot be recalculated after 24 weeks.)

A result mailer has not been received by 10 days after blood collection.

There are any questions or concerns regarding the Program or a specific patient's Prenatal Screening result.

The office or clinic has a new clinician, address, phone, fax number, or email address.

Your coordinator's phone number are listed at the bottom of every result mailer.

Informing clinician of test results

Results for first and second trimester blood tests are communicated to the clinician in two ways:

- **Result Mailer.** Results are mailed after laboratory analysis is completed. Clinicians typically receive printed results within 7-10 days of blood collection.
- **Telephone Call.** A Prenatal Screening Coordinator calls the clinician's office with all results, except *screen negative*, generally on the same day the results are available. This is to verify information and facilitate redraws or referrals.

If no results are received by 10 days after blood draw, call the Prenatal Screening Coordinator!

Erroneous or missing information may lead to an incorrect screening result!

Other types of correspondence from the Program:

Document	Correspondence
Acknowledgement Letter	Sent to the clinician and to the patient when first trimester serum only (No results on NT ultrasound information provided).
Reminder Letter	Sent to the clinician if an expected second trimester specimen is not received by 17 weeks 3 days gestation.
New Result Mailer (Modified Mailer)	Sent to the clinician whenever the patient information changes, since this often modifies the MoM (multiple of the median) and may change the interpretation and/or risk assessment. For example, if the clinician calls in an NT ultrasound measurement when one was not previously reported, this will trigger a new result mailer. A corrected collection date or date of birth can change a result from <i>screen positive</i> to <i>screen negative</i> or vice versa.
Confirmation of Contact	Sent to the clinician to officially document verbal or fax communication between the Prenatal Screening Coordinator and the clinician or their staff. For example, the clinician agreed to a referral for prenatal diagnosis.
Patient Letter	Mailed to the patient three days after most result mailers are sent to the clinician, except for screen negative results. This letter serves as a “safety net” in case the clinician’s office is unsuccessful in contacting a patient about their result. The patient letter (in English and Spanish) instructs the patient to call their prenatal provider concerning their Prenatal Screening result.

Upon receipt of the Prenatal Screening Results mailer, verify the correctness of patient information. Call the Prenatal Screening Coordinator with any questions or to make any necessary corrections or changes.

Informing Your Patient of Their Blood Test Results

A health care professional should inform the patient of their test results, whether *screen negative* or *screen positive*. Please be certain that office staff who discuss screening results with patients understand the scope and purpose of the Prenatal Screening Program. Explaining the difference between screening and diagnosis before the blood test helps patients to better understand their results.

Information to Explain to Patients with a Screen Positive Result

- The Prenatal Screening test is not a diagnostic test and provides, the risk, or chance of carrying an affected fetus. A diagnostic test can give a definite answer about whether the fetus has a birth defect.
- A *screen positive* result does not mean that there is a problem, only that there is an increased risk for a problem and additional diagnostic tests are offered.
- The most common outcome of a *screen positive* result is an unaffected baby.

Guidelines to help reduce anxiety

- Do not leave anxiety-producing news of *screen positive* results on a patient's voice mail.
- Avoid calling *screen positive* results late on Friday or before holidays unless you have someone available to respond to questions.
- Do not use the inappropriate term "abnormal" result. Instead, say "*screen positive*" result.
- Encourage the patient to see a genetic counselor, at a State-approved Prenatal Diagnosis Center, to answer their questions and help them decide whether to have diagnostic tests. Assure the patient that CVS or amniocentesis is voluntary.
- Remind the patient that there is no charge for authorized follow-up services at a State-approved Prenatal Diagnosis Center. Services include genetic counseling, ultrasound and CVS, amniocentesis or cfDNA if indicated.
- Clinicians are advised to prepare patients for the possibility of a false positive test. Most individuals who test positive will have an unaffected baby.

Patients with a Screen Negative result information to help your patient

- A screen negative result means that the risk for these birth defects is low enough that diagnostic tests are not offered by the Program.
- A screen negative result does not guarantee an unaffected baby.
- The First Trimester blood test + NT ultrasound screens for Down syndrome and Trisomy 18 only. A Second Trimester blood test must be submitted to receive a refined risk for Down syndrome and Trisomy 18 and screening for NTD and SLOS.
- The Second Trimester blood test (Quad, Quad + NT, Serum Integrated or Integrated) is a screening test for Down syndrome, Trisomy 18, NTD and SLOS.
- The Prenatal Screening test only screens for certain birth defects. It is not a test for all birth defects.

Results and Interpretations for Screening Tests

Condition or Finding	Cutoffs for screen positive (1 st T)	Cutoffs for screen positive (2 nd Trimester)
<i>Down Syndrome</i>	≥ 1 in 100 for DS	For Quad Marker screen: ≥ 1 in 150 for DS For Quad + NT, Serum Integrated, or Sequential Integrated screen: ≥ 1 in 200 for DS
<i>Trisomy 18</i>	≥ 1 in 50 for T18	≥ 1 in 100 for T18
<i>NTD / AWD</i>	Not screened for in 1 st trimester	For Singleton: AFP MoM ≥ 2.50 For Twins: AFP MoM ≥ 4.50
<i>SLOS</i>	Not screened for in 1 st trimester	≥ 1 in 250 for SLOS
<i>Large NT Screen Positive</i>	NT ≥ 3.00 mm	Not screened for in the 2 nd trimester

First Trimester Results

Interpretation	Action Authorized
<i>1st Trimester Serum-only specimen (no valid NT, so no screening results)</i>	For screening results, report valid NT and/or draw 2 nd trimester specimen.
<i>“Preliminary risk assessment” (Screen Negative)</i>	Draw 2 nd trimester specimen for Sequential Integrated Screening.
<i>Screen Positive (Increased risk) for Down Syndrome and/or T 18</i>	Refer patient to a State-Approved Prenatal Diagnosis Center (PDC) OR draw a 2 nd T specimen for an Integrated Screening result.
<i>Large NT Screen Positive</i>	Refer patient to a State-Approved Prenatal Diagnosis Center (PDC).

Second Trimester Results (Quad Marker, Quad + NT, Serum Integrated and Sequential Integrated Cases)

Interpretation / Results	Action Authorized
<i>Screen Negative (for all conditions)</i>	No follow-up authorized by the Program. Do not draw another specimen.
<i>Screen Positive (for any condition or finding)</i>	Refer patient to a State-Approved Prenatal Diagnosis Center (PDC).
<i>Too Early, High AFP (Specimen drawn between 14 weeks 0 days and 14 weeks 6 days)</i>	Refer patient to a State-Approved Prenatal Diagnosis Center (PDC), or draw another 2 nd trimester specimen.
<i>Too Late, High AFP (Specimen drawn between 20 weeks 1 day and 21 weeks 0 days)</i>	Refer patient to a State-Approved Prenatal Diagnosis Center (PDC).

Results for Invalid Specimens

Interpretation	Cause	Action Authorized
<i>1st Trimester, Too Early</i>	The blood specimen was drawn prior to 10 weeks 0 days of gestation.	Draw another specimen in the correct date range for the 1 st and/or 2 nd trimester.
<i>1st Trimester, Too Late</i>	The blood specimen was drawn after 13 weeks 6 days of gestation.	Draw another specimen in the correct range for the 2 nd trimester.
<i>2nd Trimester, Too Early</i>	2 nd trimester specimen was drawn before 15 weeks 0 days.	Draw another specimen in the correct date range for the 2 nd trimester.
<i>2nd Trimester, Too Late</i>	2 nd trimester specimen was drawn after 20 weeks 0 days.	None. Do not draw another specimen.
<i>Unexpected specimen</i>	A second specimen was received after a valid specimen for the same trimester.	None. The results of an unauthorized test in the same trimester are not statistically valid.
<i>Inadequate specimen</i>	The blood specimen could not be analyzed (i.e. hemolyzed, broken tube) or as indicated by your Coordinator.	Draw another specimen in the 1 st and/or 2 nd trimester.
<i>Pregnancy not screenable</i>	Reasons include fetal reduction, fetal demise ≥ 8 weeks gestation, or more than 2 fetuses	None. Only submit another specimen if instructed by your Coordinator.
<i>Pregnancy not screenable (in the first trimester)</i>	Fetal demise <8 weeks gestation. 1 st trimester specimen is not valid.	None. Only submit another specimen if instructed by your Coordinator.
<i>Values inconsistent with pregnancy</i>	This result indicates the analyte levels appear to be inconsistent with pregnancy.	The clinician is asked to verify pregnancy status. Only submit another specimen if instructed by your Coordinator.

Explanation of Results

Screen Negative: No follow-up services authorized

Approximately 9 out of 10 patients have *screen negative* results. A negative result means that the patient's individual risk is low enough that diagnostic tests are not covered by the Prenatal Screening Program. No screening test can detect all birth defects and there is still a chance that the fetus has a birth defect. Clinicians always have the option of ordering diagnostic tests using other financial or insurance resources.

Screen Positive Down syndrome: Increased risk for Down syndrome

First Trimester + NT: The Prenatal Screening Program combines maternal age with PAPP-A, hCG and NT MoMs to determine an individualized midtrimester risk for Down syndrome. *Screen positive* patients may have high hCG and low PAPP-A levels and/or high NT measurements. The Down syndrome risk is calculated for a pregnancy with a single or twin gestation.

Quad, Quad + NT, Serum Integrated and Sequential Integrated: The Prenatal Screening Program combines maternal age with PAPP-A, AFP, INH, hCG, uE3 and NT MoMs to determine an individualized midtrimester risk for Down syndrome. *Screen positive* patients often have high hCG and INH levels. The Down syndrome risk is calculated for a pregnancy with a single or twin gestation. *Please see Appendix H for a summary of screen positive rates and detection rates.*

A common reason for a *screen positive* result for Down syndrome with Quad screening is overestimation of gestational age. *Screen positive* results may also be associated with some other chromosomal syndromes or with normal variation of pregnancy markers.

Note: When a 2nd trimester specimen is delayed more than 10 days between blood collection and analysis, there is no uE3 value reported due to the instability of the analyte. In these cases, the Down syndrome risk is calculated without uE3, but with all other available 1st and 2nd trimester analytes. Although the detection rate is slightly less, the risk assessment is accurate and reliable.

Screen Positive Trisomy 18: Increased risk for Trisomy 18

First Trimester + NT: The Prenatal Screening Program combines maternal age with PAPP-A and hCG to determine an individualized midtrimester risk for Trisomy 18. *Screen positive* patients may have low hCG and PAPP-A levels and/or high NT measurements.

Quad, Quad + NT, Serum Integrated and Sequential Integrated: The Prenatal Screening Program combines maternal age with PAPP-A, AFP, hCG, INH, uE3 and NT MoMs to determine an individualized midtrimester risk for Trisomy 18. Low levels of any or all of the analytes may be associated with increased risk for Trisomy 18. Very early pregnancy, some other chromosomal syndromes and normal variation may be associated with these screen positive results. *Please see Appendix H for a summary of screen positive rates and detection rates.*

Due to the potential for intrauterine growth restriction (IUGR) in a fetus with T18, certain criteria must be met to re-date the pregnancy with new ultrasound dating. Please contact your coordinator if you have a T18 positive patient with new ultrasound dating. The T18 risk is only calculated for a pregnancy with a twin gestation when NT information is available.

Screen positive NTD: Increased risk for an open NTD or AWD

The Prenatal Screening Program utilizes only the second trimester AFP analyte for this risk assessment. A patient is classified as *screen positive* and at increased risk for a fetus with an open NTD or AWD (see Appendix C) when the AFP value is elevated over the selected cutoff, which is currently ≥ 2.50 MoM for a pregnancy with a single fetus, or ≥ 4.50 MoM for a pregnancy with two fetuses.

Screen positive rate

Among program participants, 1% are initially *screen positive* for NTD.

Among individuals who have Prenatal Screening and diagnostic services, the Program identifies approximately 97% of fetuses with anencephaly, 80% with open spina bifida and 85% of AWDs (gastroschisis and omphalocele).

Other reasons for this *screen positive* result are underestimation of gestational age, multiple gestation, fetal demise, p.

Some apparently normal pregnancies have maternal serum AFP levels over the selected cutoff of 2.50 MoM. Elevation of AFP is frequently associated with a high-risk pregnancy even if no birth defect is found. An increased risk for low birth weight, preterm delivery and fetal demise is associated with otherwise unexplained high midtrimester maternal serum AFP values. See Appendix K. Early identification of these high-risk pregnancies may facilitate better obstetrical management. The Prenatal Screening Program does not cover costs associated with obstetrical management, additional testing, or treatment beyond prenatal diagnosis.

Screen positive SLOS: Increased risk for SLOS

The Prenatal Screening Program utilizes the second trimester analytes of AFP, hCG and uE3 MoMs to determine an individualized risk for Smith-Lemli-Opitz syndrome (SLOS). The most relevant finding is a very low uE3 value; AFP and hCG may also be low. The patient's age is not a factor in determining risk. A patient is classified as *screen positive* when the risk is ≥ 1 in 250. The most common findings with **S**LOS *screen positive* results are **c**ongenital anomalies and fetal **d**emise. That is why this is sometimes referred to as SCD screening, although the numeric risk is for SLOS.

Among program participants, about 0.2% are screen positive for SLOS. The Program identifies approximately 60% of the fetuses with SLOS assuming all screen positive individuals receive amniocentesis.

No SLOS risk assessment can be calculated when there is more than one fetus.

Follow-up Diagnostic Services

Follow-up services authorized by the California Prenatal Screening Program are only provided at State-approved Prenatal Diagnosis Centers (PDCs). *Please see the [Program's website](#) for a current list of State-approved PDCs.*

When follow-up services are authorized by the Program, the clinician is notified by a Prenatal Screening Coordinator. The clinician should contact the patient and offer a referral to a State-approved PDC for authorized services at no additional cost.

Authorized services for first trimester *screen positive cases* include genetic counseling, CVS (>15 weeks), amniocentesis (>15 weeks) and cfDNA if indicated.

Authorized services for second trimester *screen positive cases* include genetic counseling, ultrasound, amniocentesis and cfDNA if indicated. **The referral should be made as soon as possible to allow the patient access to all available follow-up services and options.**

No follow-up services are authorized after 24 weeks gestation.

Genetic Counseling

All patients receive counseling by a state-licensed genetic counselor. The counseling includes a family history and explanations of possible reasons for a *screen positive* result, as well as the risks, limitations, and benefits of diagnostic procedures.

Comprehensive Ultrasound

At State-approved PDCs, ultrasound examinations are performed by consultative sonologists. The ultrasound exam meets American College of Obstetrics and Gynecology, American Institute of Ultrasound in Medicine, and American College of Radiology standards. With services after 15 weeks, a comprehensive survey of fetal anatomy is performed to detect abnormalities associated with birth defects.

For cases without NT data, ultrasound information may indicate under- or over-estimation of gestational age. However, prenatal screening cases with gestational age dating by NT CRL, including second trimester cases, will not be re-dated after an ultrasound.

For second trimester screen positive results, if the ultrasound indicates a gestational age which changes the second trimester result, the Prenatal Screening coordinator is contacted by the PDC and then informs the clinician of the new result. A modified result mailer is issued by the Program. If, after ultrasound, the new result changes to screen negative or too late, no further services are authorized, and the coordinator notifies the clinician. If the ultrasound indicates that the blood was drawn too early for the second trimester, the clinician is asked to obtain another Prenatal Screening blood test at 15-20 weeks gestation.

Amniocentesis

If the ultrasound findings do not explain the second trimester screen positive results, or the findings suggest a chromosomal disorder, open NTD or AWD, amniocentesis is usually offered to the patient. The amniotic fluid is used to determine fetal karyotype, amniotic fluid AFP levels and the presence of acetylcholinesterase, if appropriate. If the Prenatal Screening result is screen positive for SLOS, the amniotic fluid is also tested for elevated levels of 7-DHC and 8-DHC.

CVS

In the first trimester, NT CRL is the only dating method used for screening results. CVS may be offered to the patient after first trimester screen positive results, depending on the patient's gestational age and the availability of CVS practitioners. CVS is only offered as a follow-up service in the first trimester when there is an NT result.

CVS or amniocentesis results are usually available within two weeks. The risk of miscarriage associated with CVS or amniocentesis is less than 1% at State-approved PDCs.

Cell Free Fetal DNA (cfDNA)/ Non-Invasive Prenatal Testing (NIPT)

Cell-free fetal DNA screening (cfDNA), also known as non-invasive prenatal testing (NIPT), is a very accurate screening test for the risk of certain chromosome abnormalities including Down syndrome, Trisomy 18, Trisomy 13, and some sex chromosome abnormalities. **Currently, cfDNA screening is covered as a follow-up service for singleton and twins** through the PNS Program for women at increased risk for chromosome abnormalities. This type of blood testing using fetal DNA is offered to first and second trimester patients with screen positive results for T21, T18, or Large NT who decline diagnostic testing. The Program does NOT pay for cfDNA as an initial screening test.

Reminder: cfDNA doesn't identify structural defects, such as Neural Tube Defects (NTDs) and cardiac defects. For individuals having cfDNA outside of the PNS Program, the usual 18-24-week scans and/or second trimester Quad serum screening tests for NTDs are recommended.

NOTE: Screen positive patients who have cfDNA outside the Program and obtain a negative cfDNA result are not authorized for follow-up services at a State-approved PDC.

If a birth defect is found...

The professional staff at the PDC discusses with the patient the type of defect found and how it may affect the fetus. Any available treatments are described. Options for continuing or terminating the pregnancy are discussed. Information is provided on support services for whatever decision the individual makes.

The cost of pregnancy management or termination is not covered by the Prenatal Screening Program.

See Appendix C for information about specific birth defects.

Reporting Birth Defects

State regulations (CCR, Title 17, Sections 6531 and 6532) requires that NTDs and or chromosome abnormalities found in fetuses or infants less than one year of age be reported to the Genetic Disease Screening Program. All cases of NTDs and chromosome abnormalities must be reported, even if the patient did not have Prenatal Screening or if the screening result was negative.

Reporting NTDs

The report should be made within 30 calendar days of the initial diagnosis on the form, *A Confidential Case Report of a NTD in a Fetus or an Infant Less than One Year of Age*, provided by the Genetic Disease Screening Program. Call a Prenatal Screening Coordinator to ask questions or to get copies of the form. Forms are also [available online](#).

Reporting chromosomal disorders

State regulations (CCR, Title 17, Section 6532) require the reporting of all cases of Down syndrome or other chromosomal disorders in a fetus or an infant under one year of age. California cytogenetic laboratories are responsible for this reporting. **However, clinicians become responsible for this reporting if they send the specimen to a laboratory outside of California.**

The report should be made within 30 calendar days of the initial diagnosis on the form, *A Confidential Case Report of a Chromosomal Defect in a Fetus, or an Infant Less Than One Year of Age*, provided by the Genetic Disease Screening Program. Call a Prenatal Screening Coordinator to ask questions or to get copies of the form.

Outcomes of pregnancy

State regulations (CCR, Title 17 Section 6527) require prenatal care providers to fill out an Outcome of Pregnancy form for screened individuals who had a Screen Positive Prenatal Screening test result or who have a pregnancy with a multiple gestation. The form is automatically mailed to the clinician who ordered the Prenatal Screening test just after the patient's due date. Clinicians should complete the form and return it to the address listed on the form as soon as possible. Some outcomes are requested on individuals who had screen negative test results to provide a comparison group for adverse outcomes.

COST/BILLING

Prenatal Screening Program fee

The current fee (2019) for the Prenatal Screening Program is \$221.60. This fee covers all blood tests (first and/or second trimester) plus authorized follow-up services at a State-approved Prenatal Diagnosis Center.

The fee is the same regardless of the number of specimens submitted or the number of analytes run.

Blood drawing and handling fees are not covered by the Prenatal Screening Program and will be charged to the patient or their insurance by the blood collection facility.

NT ultrasounds are NOT covered by the Prenatal Screening Program.

Insurance information

To avoid billing the patient unnecessarily, please enter the patient's Medi-Cal information on the First and/or Second Trimester Screening Test Request Form or submit a copy of the patient's insurance card with the First and/or Second Trimester Screening Test Request Form. This will allow the Prenatal Screening Program to directly bill the patient's insurer.

Medi-Cal information

For Medi-Cal patients, the Program will bill Medi-Cal directly if, on the Prenatal Screening Test Request Form, there is a patient birth date and a Medi-Cal ID number or a Presumptive Eligibility number. If a Medi-Cal patient receives a billing form from the Prenatal Screening Program, they should return the bill with their current Medi-Cal number written on it. For additional questions please call the PNS Billing number at (800) 597-0832.

If no insurance or Medi-Cal information

If no Medi-Cal or insurance coverage information is provided with the specimen, the Prenatal Screening Program will mail a bill and an insurance form to the patient. If the patient has insurance and wants us to bill their insurance company directly, they will need to fill out the insurance form and return it. Health insurance companies are required to cover Prenatal Screening according to California law (Health and Safety Code Sections 124977 (a) & (b)).

Special billing codes

Special billing codes are available for prepaid health plans, correctional facilities, military facilities, county health departments and other facilities who do not want patients to receive a bill directly. The organization obtaining the billing code is responsible for 100% payment. A billing code can be obtained by emailing the Prenatal Screening Program accounting office at pns@cdph.ca.gov. The billing code must be entered on the First and Second Prenatal Screening Test Request Form.