



# The California Prenatal Screening Program

California Department of Public Health

Genetic Disease Screening Program



850 Marina Bay Parkway, F175, Richmond, CA 94804 | Phone: (510) 412-1502 | Fax: (510) 412-1547

## CALIFORNIA PRENATAL SCREENING PROGRAM EXPANSION

### FREQUENTLY ASKED QUESTIONS (As of March 30, 2009)

#### Program Overview

<p><b>What are the new Prenatal Screening options?</b></p>	<p>Screening options include:</p> <ul style="list-style-type: none"> <li>• <b>Quad Marker Screening:</b> One blood specimen drawn at 15 weeks – 20 weeks of pregnancy (current second trimester Program).</li> <li>• <b>Serum Integrated Screening:</b> Combines first trimester blood test results (10 weeks – 13 weeks 6 days) with second trimester blood test results.</li> <li>• <b>Full Integrated Screening:</b> Combines first and second trimester blood test results with NT results (Note: the Screening Program does not pay for NT ultrasounds).</li> </ul> <p><b>First Trimester Preliminary Risk Assessment:</b> Patients with first trimester blood specimens and NT will get a preliminary risk assessment for chromosomal abnormalities in the first trimester. This preliminary risk will be revised when the second trimester blood specimen is received.</p>
<p><b>Can health care providers continue to use commercial laboratories for first trimester and integrated screening?</b></p>	<p>By State statute and regulations, prenatal screening with maternal blood markers can only be performed by the California Prenatal Screening Program. Commercial laboratories will no longer perform similar screening in California.</p> <p>(Patients who have begun integrated or sequential screening should complete testing through the same laboratory.)</p>
<p><b>What are the key benefits of the expanded Program?</b></p>	<p>There are multiple Program benefits:</p> <ul style="list-style-type: none"> <li>• Integrated screening improves accuracy and detection rates for Down syndrome and Trisomy 18.</li> <li>• Earlier follow-up and diagnosis is possible with the inclusion of first trimester screening.</li> <li>• Patients will now have one unified standard of care for prenatal screening services.</li> <li>• The expanded Program is cost effective for California patients and their insurers.</li> <li>• Medi-Cal now covers NT ultrasound for Medi-Cal recipients.</li> <li>• The size and diversity of California’s population provides significant opportunities for future research on prenatal screening.</li> </ul>
<p><b>Since the Prenatal Screening Program is State run, will the Program be subject to revenue challenges because of the State budget?</b></p>	<p>Providers can feel confident in the continued operation and success of the California Prenatal Screening Program. Unlike General Fund-supported programs, we are largely supported by the fees we generate from prenatal and newborn screening. As long as providers continue to support the California Genetic Disease Screening Program, we will continue to provide a unified, high quality standard of care to California women.</p>
<p><b>How many women are screened each year through the Program?</b></p>	<p>In 2008, approximately 355,000 pregnant women in California were screened by the Program.</p>



# The California Prenatal Screening Program

California Department of Public Health

Genetic Disease Screening Program



850 Marina Bay Parkway, F175, Richmond, CA 94804 | Phone: (510) 412-1502 | Fax: (510) 412-1547

<b>Who developed the Program?</b>	The Program was developed by the Genetic Disease Screening Program, a division of the California Department of Public Health. The Prenatal Screening Program began in 1986.
-----------------------------------	---

## Clinical Questions

<b>What are the false positive rates for the new Program?</b>	<p>For women who are considering screening, a more useful number is the Screen Positive rate—what fraction of women have a positive result. The main predictor of the Screen Positive rate is the patient’s age; the table of positive rates by age is part of the Provider Handbook, which will be sent to providers in their start-up packets. This number answers the question: What is the chance that I would need to consider additional testing? The answer will be different for a 20-year old and a 50-year old.</p> <p>The False Positive rate [at any age] is numerically very close to the screen positive rate, because the incidence of all of the disorders for which we screen is very low. Therefore almost all Screen Positive results are “False”—in the sense that diagnosis will show that the fetus is unaffected.</p> <p>But this is a screening test, not a diagnostic test. Its goal is to identify a group of patients to offer the possibility of diagnostic procedures. The risk estimate itself is not “false”. In a large group of patients with a risk of 1:50, we would indeed find that about 1 in 50 of them did have an affected pregnancy.</p>
<b>Can I submit blood spot specimens to the Program, or do I need to use serum?</b>	The Program will only accept serum specimens. First trimester specimens MUST be centrifuged before being sent for analysis.
<b>Is there a risk assessment released for a first trimester serum specimen only (no NT)?</b>	<p>No. Risk assessments are only provided for first trimester serum specimens when accompanied with NT data. NT data includes:</p> <ul style="list-style-type: none"> <li>• A valid NT Practitioner ID number</li> <li>• The date of the NT exam</li> <li>• A CRL measurement (mm)</li> <li>• An NT measurement (mm)</li> <li>• An answer to: “Is this a twin pregnancy?” If this is a twin pregnancy, you must also provide chorionicity and CRL/NT for Fetus B (or “Unable to Measure”) on the Test Request Form.</li> </ul>
<b>Why doesn’t the Program use Beta hCG?</b>	Intact hCG is statistically best for our Program. It is measured in serum. Beta hCG works best as a single marker. It is measured in blood spots . Neither of these circumstances apply to our Program.
<b>Does the Program screen for Trisomy 13?</b>	In the first trimester, the analyte pattern for Trisomy 13 and Trisomy 18 is essentially the same. Most pregnancies with Trisomy 13 will be called “Screen Positive for Trisomy 18” and offered diagnostic procedures and either Trisomy 18 or Trisomy 13 will be identified. We did not want to complicate the issue by referring to Trisomy 18/13 screening in the first trimester and Trisomy 18 screening in the second trimester.



# The California Prenatal Screening Program

California Department of Public Health

Genetic Disease Screening Program



850 Marina Bay Parkway, F175, Richmond, CA 94804 | Phone: (510) 412-1502 | Fax: (510) 412-1547

<p><b>How often does a Screen Positive result in the 1st trimester become a Screen Negative result in the 2nd trimester?</b></p> <p><b>If a patient is Screen Positive in the 1<sup>st</sup> trimester and decides to draw a 2<sup>nd</sup> trimester specimen, how often will this patient be Screen Negative with Integrated Screening?</b></p>	<p>The answer depends on whether or not the fetus is affected with a chromosomal abnormality. After a 1st trimester positive result for Down syndrome, expected Integrated results are:</p> <table border="1" data-bbox="500 432 1336 627"> <thead> <tr> <th></th> <th>Unaffected</th> <th>Down syndrome</th> </tr> </thead> <tbody> <tr> <td><b>Stay Positive</b></td> <td>49%</td> <td>98%</td> </tr> <tr> <td><b>Recalculate to Negative</b></td> <td>51%</td> <td>2%</td> </tr> </tbody> </table> <p>After a 1st trimester positive result for trisomy 18, expected Integrated results are:</p> <table border="1" data-bbox="500 751 1336 947"> <thead> <tr> <th></th> <th>Unaffected</th> <th>Trisomy 18</th> </tr> </thead> <tbody> <tr> <td><b>Stay Positive</b></td> <td>40%</td> <td>95%</td> </tr> <tr> <td><b>Recalculate to Negative</b></td> <td>60%</td> <td>5%</td> </tr> </tbody> </table>		Unaffected	Down syndrome	<b>Stay Positive</b>	49%	98%	<b>Recalculate to Negative</b>	51%	2%		Unaffected	Trisomy 18	<b>Stay Positive</b>	40%	95%	<b>Recalculate to Negative</b>	60%	5%
	Unaffected	Down syndrome																	
<b>Stay Positive</b>	49%	98%																	
<b>Recalculate to Negative</b>	51%	2%																	
	Unaffected	Trisomy 18																	
<b>Stay Positive</b>	40%	95%																	
<b>Recalculate to Negative</b>	60%	5%																	
<p><b>If a patient is Screen Positive in the first trimester and discusses her options with her prenatal care provider, does the patient have to see a genetic counselor?</b></p>	<p>The patient has to be offered the referral to a Prenatal Diagnostic Center; however, she is not required to be seen in the first trimester. The patient may choose to be seen at a Prenatal Diagnostic Center in the second trimester. Patients always have the option to decline follow-up services. Patients can also accept genetic counseling and decline diagnostic tests at the Prenatal Diagnostic Center.</p>																		
<p><b>Are test results affected by whether diabetics are on oral agents?</b></p>	<p>As far as we know, the effect of oral agents on the serum markers has not been studied. We cannot adjust results when supporting data is unavailable or inconclusive. If diabetics are on oral medication, mark the insulin-dependent diabetic question as No.</p>																		
<p><b>What is the difference between light versus heavy smokers?</b></p>	<p>In the studies of the effect of smoking on Inhibin levels, the researchers said that there is not a dose-response effect. Rather, there is an on-off jump between the levels of nonsmokers and the levels of smokers.</p>																		
<p><b>Is there any data on the incidence of Down syndrome for maternal age between 15 and 20?</b></p>	<p>It is difficult to obtain data from minors. The data that we have comes from Europe, and considers women 18 years old and older.</p>																		
<p><b>Are there multiple risk assessments for twins?</b></p>	<p>There is only one risk assigned per pregnancy, not per fetus. However, the risk assessment will include the presence of twins.</p>																		



# The California Prenatal Screening Program

California Department of Public Health

Genetic Disease Screening Program



850 Marina Bay Parkway, F175, Richmond, CA 94804 | Phone: (510) 412-1502 | Fax: (510) 412-1547

## Costs and Coverage

<b>What is the cost? Is the Program cost effective?</b>	The new program is cost effective for California residents and their insurers, with one flat rate (\$162) that includes the initial blood test(s) for screening and any authorized follow-up services. The program offers follow-up services at State-approved Prenatal Diagnostic Centers for women with screen positive results in the first or second trimesters.
<b>Is CVS covered by the Program?</b>	Yes, diagnostic services such as Chorionic Villus Sampling (CVS) are covered for women who are Screen Positive for Down syndrome and/or Trisomy 18 in the first trimester.
<b>Is NT ultrasound covered by Medi-Cal?</b>	Effective April 1, 2009, Medi-Cal will reimburse a Nuchal Translucency exam using CPT Code 76813/14 if the NT Practitioner is credentialed by either NTQR or FMF. This will be included in the May 2009 Medi-Cal Program Bulletin.
<b>Is Medi-Cal only covering one ultrasound?</b>	Medi-Cal understands that the purpose of the NT ultrasound is limited and does not include a survey of fetal anatomy. Medi-Cal will cover both types of ultrasound after the Program begins if there is a medical indication.
<b>Is the gestational dating ultrasound covered by Medi-Cal?</b>	The provision of an early ultrasound for medical necessity – establishing an accurate gestational date – will continue to be reimbursed by Medi-Cal.
<b>Is there a particular reason that NT ultrasound is not covered by the Program?</b>	The Program is committed to covering diagnostic services for women who screen positive for certain birth defects. NT is an optional measurement that can contribute to the screening result. The Program has worked closely with Medi-Cal to cover the NT. Serum integrated screening is also a good option for women who do not have access to an NT ultrasound exam.
<b>If a woman has her blood drawn at the wrong time and needs to have her blood redrawn, is there an additional fee?</b>	No, the Program only charges one Prenatal Screening fee for all blood specimens in a given pregnancy. There may be a fee for drawing blood at the blood draw lab.
<b>If a woman screens positive in both the first and second trimesters, does the Program pay for both sets of genetic counseling?</b>	Yes, the Program will pay for both sessions of genetic counseling.
<b>Are Medi-Cal patients with presumptive eligibility covered under the new Program?</b>	Medi-Cal covers the Program fee for patients with presumptive eligibility in the first or second trimester.
<b>When does the patient (or insurer) get a bill for Program services?</b>	If a patient or her provider submits an insurance card when a blood specimen is submitted for screening, the insurer will be immediately billed by the Program. Please provide the patient's Medi-Cal number on the test form or send a copy of the patient's Medi-Cal card or insurance card with the blood specimen. Otherwise, a bill will be sent to the patient.



# The California Prenatal Screening Program

California Department of Public Health

Genetic Disease Screening Program



850 Marina Bay Parkway, F175, Richmond, CA 94804 | Phone: (510) 412-1502 | Fax: (510) 412-1547

## NT Ultrasound Logistics

<b>What is the NT process and when should the blood draw happen? What form do NT practitioners fill out and how should it be filled out?</b>	<p>The first trimester blood specimen is collected between 10 weeks 0 days and 13 weeks 2 days, and the NT exam must be done between 11 weeks 2 days and 14 weeks 2 days (CRL 45-84 mm).</p> <p>If the NT Practitioner is also doing the blood draw, or if the patient has the Test Request Form (for example, if she is going to have her blood drawn after the exam) the NT practitioner can write the NT exam data right on the Test Form that is being submitted with the specimen.</p> <p>To send the NT information to the patient's clinician, the NT Practitioner can write the NT exam data on the NT Exam Data Form (available on the GDSP website) and send this to the clinician.</p> <p>If a blood specimen has already been received by the Program, NT Practitioners who are SIS users (have undergone the eLearning and have access to SIS, the Program's computer system) can search for patients by Test Request Form number or Accession number and enter the NT exam data into the computer system for a Preliminary Risk Assessment.</p>
<b>What information is necessary for a valid NT?</b>	<p>For NT exam data to be used in screening, you must provide the following:</p> <ul style="list-style-type: none"><li>• A valid NT Practitioner ID number</li><li>• The date of the NT exam</li><li>• A CRL measurement (mm)</li><li>• An NT measurement (mm)</li><li>• An answer to: "Is this a twin pregnancy?" If this is a twin pregnancy, you must also provide chorionicity and CRL/NT for Fetus B (or "Unable to Measure") on the Test Request Form.</li></ul>
<b>How do NT credentialed practitioners provide their information to the Program, so they can be referred to by providers?</b>	<p>NTQR credentialed practitioner information is automatically sent to the Program. FMF credentialed practitioners who wish to be included can provide their information to Naomi Green at FMF, who will forward their information to the Program. NT practitioners can also contact Nerissa Wu via email (<a href="mailto:Nerissa.Wu@cdph.ca.gov">Nerissa.Wu@cdph.ca.gov</a>) with questions.</p>
<b>Will NT practitioners prioritize scheduling women over a certain age or with certain medical indications?</b>	<p>The Program cannot mandate that individual practitioners prioritize certain patients. However, some practices do choose to prioritize their scheduling.</p>



# The California Prenatal Screening Program

California Department of Public Health

Genetic Disease Screening Program



850 Marina Bay Parkway, F175, Richmond, CA 94804 | Phone: (510) 412-1502 | Fax: (510) 412-1547

## Form Logistics

<b>Does the Program allow the use of a stamp to fill out provider data on the new forms?</b>	Yes, but to facilitate the processing of the form please use a stamp designed specifically for the form. Small or misaligned lettering could slow down processing at the laboratory.
<b>Do providers have to include the patient's SSN on the new forms?</b>	No, it is not required. However, if possible please include at least the last four digits of the patient's SSN, which will facilitate the patient and specimen matching process by the Program's computer system.
<b>Does weight have to be exact on the form?</b>	No, approximate weight within a few pounds is fine.

## Provider Choice and Availability

<b>Are there sufficient CVS providers to meet demand under the new Program?</b>	There are state-approved CVS practitioners throughout the State, and there are an adequate number of CVS providers in the metropolitan areas, though pregnant women living outside these areas may be required to travel to the nearest location.
<b>Is NT practitioner capacity expected to increase over the next year?</b>	NTQR and FMF are working on offering more classes to NT practitioners, and are aware of the need for NT practitioners in California. Over time, we expect that the demand for NT practitioners will result in an increase in NT practitioners as more practitioners choose to become credentialed.

## Privacy

<b>How are patient privacy concerns being addressed?</b>	The expanded Program is HIPAA compliant. Also, the consent form (in the Patient Booklet) includes a check box for patients to opt out of having their blood specimen or information used for additional research. This should be noted by a similar check box on the Test Form.
--	---



# The California Prenatal Screening Program

California Department of Public Health

Genetic Disease Screening Program



850 Marina Bay Parkway, F175, Richmond, CA 94804 | Phone: (510) 412-1502 | Fax: (510) 412-1547

## Outreach and Resources

<b>What outreach is being performed in the provider community?</b>	The Genetic Disease Screening Program has performed a series of regional meetings in locations throughout California to educate providers on the scientific foundations of the new Program. In addition, announcement letters have been sent to the provider community outlining Program changes. Finally, the regional Prenatal Screening Program Coordinators are offering “in-services” to clinicians and their staff to explain the new Program and to provide educational materials.
<b>What resources are available for patients and providers?</b>	The following resources will be shared with providers: <ul style="list-style-type: none"><li>• <b>Patient Booklet:</b> Outlines the Program options for the patient and includes the Consent/Decline Form.</li><li>• <b>Pregnancy Wheel:</b> Provides a timeline for patients for prenatal screening and related activities</li><li>• <b>Two-Sided Summaries:</b> Overview of protocol changes for clinicians and support staff</li><li>• <b>Provider Handbook :</b> Details guidelines for the prenatal expansion and protocol changes for providers</li></ul> Beginning in March 2009, providers will also be able to find Program-related resources on the Prenatal Screening Program website, <a href="http://www.cdph.ca.gov/programs/pns">www.cdph.ca.gov/programs/pns</a>
<b>Are materials available in languages other than English?</b>	Yes. The printed patient booklet is available in English, Spanish, Chinese, Korean and Vietnamese. Other materials may be printed or available on the website.