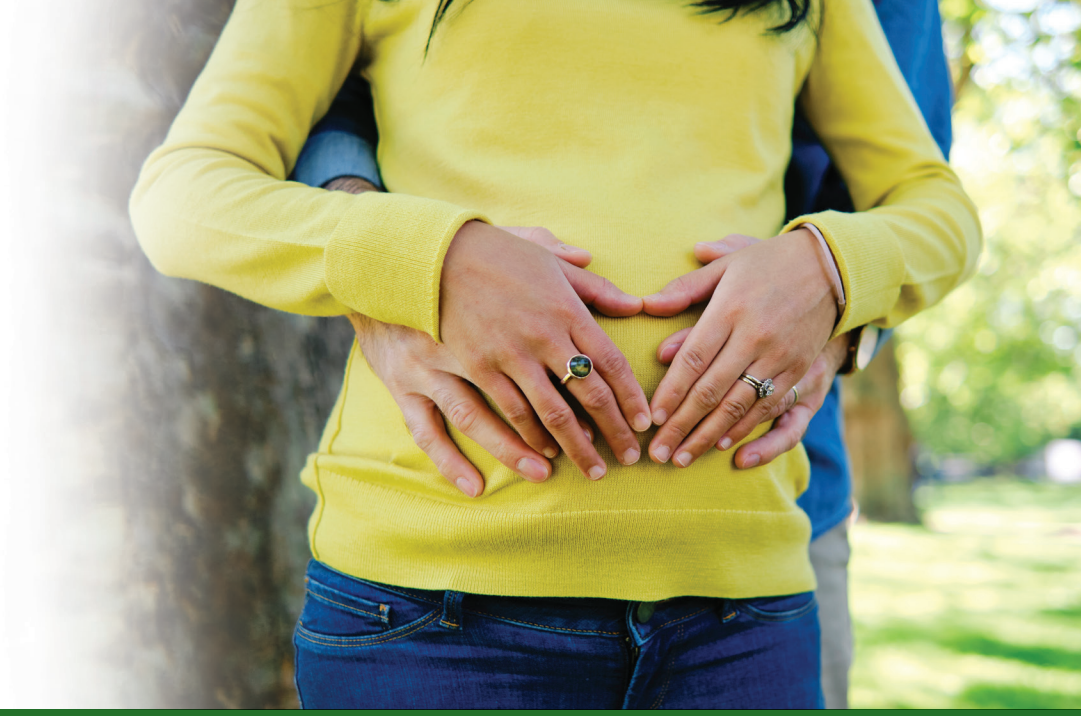
Quest Advanced® Women's Health

California Prenatal Screening Program



GDSP cfDNA Panel*

Available through the California Prenatal Screening Program

Important prenatal screening for all pregnant Californians

- An adapted version of our QNatal® Advanced offering
- A noninvasive prenatal cell-free DNA (cfDNA) screen
- Can be ordered as early as 10 weeks gestation
- Utilizes Next-Generation Sequencing (NGS) technology and advanced bioinformatics for high sensitivity and specificity*
- Low no-call rate[1]

The California Prenatal Screening (PNS) Program is a comprehensive public health service that makes prenatal screening available to all pregnant individuals in the state who want it. The GDSP cfDNA Panel is available as part of this program.

The GDSP cfDNA Panel provides the biological sex (male or female) and screens for:

Trisomies

Trisomy 21	Down syndrome
Trisomy 18	Edwards syndrome
Trisomy 13	Patau syndrome

Comprehensive insights from Quest Diagnostics®—**a leader in genetic testing**

Quest Diagnostics® has **over 30 years** of experience in providing prenatal screening and diagnostic testing to help you manage your patients' care more effectively. We offer **more than 900 genetic tests** using some of the newest technologies available today.

GDSP cfDNA Panel
Strong performance

High sensitivity and specificity during verification/validation testing and in the real world*

Verification/validation study

Prior to launch, the GDSP cfDNA Panel technology was verified and validated in a study of 2,752 pregnant women, showing high sensitivity and specificity.[2]

Screen	Sensitivity	Specificity
Singletons (n=2,637)		
90 of 90 trisomy 21	>99.9%	>99.9%
30 of 30 trisomy 18	>99.9%	>99.9%
21 of 21 trisomy 13	>99.9%	>99.9%
Twins (n=115)		
10 of 10 trisomy 21	>99.9%	>99.9%
4 of 4 trisomy 18	>99.9%	>99.9%
1 of 1 trisomy 13	>99.9%	>99.9%

Real world data

Study shows strong positive predictive value (PPV) in real world ~70,000 unique pregnancies[1]

Chromosome abnormality	GDSP cfDNA Panel PPV
Trisomy 21	98.1%
Trisomy 18	88.2%
Trisomy 13	59.3%

Easily order the GDSP cfDNA Panel through the **CalGenetic Portal**

1. Visit **https://calgenetic.cdph.ca.gov**
2. Select “Quest Dx (GDSP cfDNA Panel) CL: 94804005”
3. Instructions will be provided for printing the California PNS Program Consent and cfDNA Order Confirmation
4. Obtain the patient’s signature and date on the consent form
5. Copy the patient’s insurance card, affixing patient-specific barcodes
6. Draw the sample and send to Quest Diagnostics using Quest courier pickup

Please note, steps 5 and 6 only apply if the specimen is drawn on-site rather than utilizing a Quest Diagnostics Patient Service Center.

Test name	Specimen requirements
Quest Dx GDSP cfDNA Panel	• 10mL whole blood collected in 1 Streck tube at 10 weeks of gestation or later • Store specimens at room temperature; do not refrigerate or freeze

Screening test results will be provided through the CalGenetic Portal.
Results are typically available in 7-10 days. If you have any questions about the status of your order, please reach out to the California Department of Public Health Clinical Care Coordinators.

For more information on the **California PNS Program,** visit **https://www.cdph.ca.gov/Programs/CFH/DGDS/Pages/pns/healthcareprovider.aspx**

Quest Advanced®
Women's Health

Quest supports your patients and your practice throughout the pregnancy journey

Convenient blood draws

Quest Diagnostics has more than 400 Patient Service Centers (PSCs) in California, giving your patients the accessibility they need.

A full-service genetics laboratory

We offer a broad range of testing options that includes cytogenetic testing on amniocentesis and CVS specimens. If your patients need follow-up diagnostic testing, you can feel comfortable knowing the results will be analyzed by the same laboratory.

Access to genetic counselors

Quest has a team of genetic counselors ready to answer your questions. To reach a genetic counselor, call **1.866.GENE.INFO** (1.866.436.3463) Monday through Friday from 5:30 AM to 5:00 PM PT.

A focus on innovation

With peer-reviewed publications and research studies, Quest continues to innovate and help shape women's healthcare.

Additional screening and diagnostic tests including for Cystic fibrosis, Spinal muscular atrophy, Fragile X, and more, can be ordered directly from Quest Diagnostics via your Quanum® account, interfaced EHR, or Quest Diagnostics paper requisition. **For a full list of tests, please visit TestDirectory.QuestDiagnostics.com or call 1.866.MYQUEST (1.866.697.8378).**

For more information, visit **QuestWomensHealth.com/California**, contact your Quest Diagnostics sales representative, or call **1.866.MYQUEST** (1.866.697.8378)

*The GDSP (Genetic Disease Screening Program) cfDNA Panel is a cell-free DNA test that can screen for increased risk of trisomy 21, trisomy 18 and trisomy 13, which are fetal chromosomal abnormalities that may cause birth defects. It can also screen for fetal sex, if elected. Supplemental cfDNA screening is also available for sex chromosome aneuploidies (SCAs) and/or microdeletions. The GDSP cfDNA Panel, as well as the supplemental tests for SCA and/or microdeletions, are "screening" tests, not a diagnostic tests, and therefore all positive (i.e., increased risk) results should be followed by genetic counseling and further diagnostic testing and procedures, when clinically indicated. Pregnancy management decisions should not be based on the results of a cfDNA test alone. As with any test, there may be false positives or false negatives. The positive predictive value of the screening test varies by genetic marker, and may be lower for rare conditions. Performance data for the GDSP cfDNA Panel and for the supplemental screening tests may be obtained by contacting Quest Diagnostics at 1.866.GENE.INFO (1.866.436.3463). The GDSP cfDNA Panel and the supplemental screening tests are laboratory-developed tests that have been developed and validated, pursuant to the Clinical Laboratory Improvements Amendments of 1988 (CLIA), and as such they have not been reviewed by FDA.

References

1. Guy C, Haji-Sheikhi F, Rowland CM, et al. Prenatal cell-free DNA screening for fetal aneuploidy in pregnant women at average or high risk: Results from a large US clinical laboratory. *Mol Genet Genomic Med*. 2019;7(3):e545. doi:10.1002/mgg3.545 (finding a no-call rate of 3.5%; several authors affiliated with Quest Diagnostics); "No call rate" refers to the percentage of samples for which results could not be reported.
2. Anderson B et al. An automated, non-invasive prenatal screening assay (NIPS) for trisomy 21,18,13 in singleton and twin gestations [FIGO abstract FCS79.3.]. *Int J Gynaecol Obstet.* 2015;131(Suppl 5):E264. The study summarized in this abstract was used to validate QNatal Advanced prior to launch, and QNatal Advanced uses the same technology as the GDSP cfDNA Panel to screen for trisomies. Subsequent validation data is available upon request at 1.866.GENE.INFO (1.866.436.3463) Monday-Friday from 8:30 AM to 8:00 PM ET

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