

# The California Prenatal Screening Program

California Department of Public Health

Genetic Disease Screening Program

California Prenatal Screening Program Changes: Moving to cfDNA

Winter 2022

**The California Prenatal Screening Program will make cell-free DNA (cfDNA) screening available to all pregnant Californians, later in 2022.**

cfDNA will become the primary screen for trisomy 21, trisomy 18, and trisomy 13, replacing biochemical screening for trisomies 21 and 18, and will be available between 10 weeks 0 days and 21 weeks 0 days of pregnancy.

In addition to cfDNA, biochemical screening for maternal serum alpha-fetoprotein (MSAFP) for neural tube defects should continue to be offered in the second trimester (15 weeks 0 days to 21 weeks 0 days). The PNS program will continue to fund follow-up genetic counseling and diagnostic services for participants with screen-positive results through 24 weeks 0 days at state-approved Prenatal Diagnosis Centers.

cfDNA as a first-tier screen through the PNS program provides these benefits compared to biochemical screening: (1) cfDNA can report results for one additional aneuploidy (trisomy 13); (2) the gestational age window will allow screening as early as 10 weeks of gestation; and (3) cfDNA provides

higher sensitivity and lower false-positive rates, resulting in fewer screen-positive cases referred for follow-up diagnostic services.

Moving to cfDNA screening will make high-quality prenatal screening accessible for all pregnant individuals in California for the three most common autosomal trisomies at an affordable price covered by third-party payors and Medi-Cal.

Prenatal providers will have the choice of several state-contracted cfDNA laboratories/brands to conduct testing for patients.

The PNS program, at this time, will not include screening for sex chromosome abnormalities or microdeletions. Providers can order these screens, if they choose, as an additional lab which can be drawn at the same lab visit. The additional screens will require separate billing to the patient or their third-party payor and will not include follow-up services by the PNS program as they are not part of the approved PNS program.

The new program regulations will be promulgated through a Regulations Hearing later this spring. You will be provided with an announcement as soon as the final date and time are set.

**Follow PNS program changes at:**  
<https://www.cdph.ca.gov/pns>

**Coming Soon: Electronic Prenatal Screening Orders Through CalGenetic Portal**

A new electronic order requisition application on the CalGenetic Portal will be launched when cfDNA screening goes live. cfDNA and MSAFP screening will require providers to complete a separate electronic lab requisition form through the online portal. Providers will be required to obtain a signed patient consent document for each screen, which must accompany the sample sent to the testing laboratory. Training on how to order screening through the portal, obtain the patient consent, and collect samples will be available soon.

The CalGenetic Portal is already live and authenticated users can obtain secure online access to:

- 1) View patient prenatal screening results. The PNS program will continue to mail results but accessing them on the portal is quicker and easier for providers.
- 2) Submit Outcome of Pregnancy forms. These data are used to evaluate screening performance, and all data requests should be now entered on the portal.

The CalGenetic Portal is already a proven success! In the first six months more than 137,000 searches took place on the portal and over 53,000 prenatal screening results were viewed. All physicians and their delegates are encouraged to log into the portal and set up an account now.

<https://calgenetic.cdph.ca.gov/content/gdsp/en/my-account/homepage.html>

### **Certified Nurse Midwives and Nurse Practitioners Will Have Independent Portal Access**

Certified nurse midwives and nurse practitioners be able to independently access patient screening results in the CalGenetic Portal later this year and will no longer be required to be enrolled and managed in the portal as delegates of a physician.

When cfDNA screening is launched later in 2022, these providers will also be able to order cfDNA and MSAFP screening through the portal.

### **Stay Tuned for Trainings and New Educational Materials!**

The PNS program will be offering a series of educational webinars later this year to provide information and details about the new cfDNA screening, how to order screening through the online portal, how to obtain the required patient consent document, and other PNS program updates. The webinars will be recorded and posted on the program website. Short “how-to” videos will also be available on the website, as well as other provider training opportunities to learn more about the benefits and limitations of cfDNA screening. Stay tuned for further announcements.

Sign up for future PNS Program e-Newsletters at: <https://tinyurl.com/GDSPOnline>

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