

How Is The California Prenatal Screening Program Changing?

The future of CA PNS

Starting September 19, 2022, the California prenatal screening program (CA PNS) is transitioning to cell-free DNA (cfDNA) as the primary screening technology for trisomies 21, 18, and 13, as well as fetal sex (optional). Clinicians will be asked to follow new procedures for ordering and will receive cfDNA screening from the participating laboratory they select.

As a global leader in cfDNA testing, Natera is proud to be an approved noninvasive prenatal testing (NIPT) laboratory for CA PNS. We're partnering with CA clinicians to make the transition as smooth as possible for you and your patients.

Why cfDNA?



cfDNA are DNA fragments that are found in the blood. Placental cfDNA is present in a pregnant person's bloodstream and can be collected noninvasively with a blood draw for NIPT.

cfDNA-based NIPT offers higher sensitivity and specificity than older methods, such as maternal serum screening.¹⁻³ American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin 226 supports offering NIPT for all pregnancies and endorses it as the most sensitive and specific screening method for the common trisomies.⁴

What testing will be available?



All pregnant patients are eligible for CA PNS starting at 10 weeks gestation.

CA PNS conditions screened

Trisomies 21, 18, and 13

Fetal sex (optional)

Neural tube defect screening

Maternal serum alpha-fetoprotein (MSAFP) screening will still be available in the second trimester

Can additional conditions be screened?



You can order screening for additional conditions by filling out a supplementary requisition form.* When you order through Natera, your patient's CA PNS blood draw can be also used for supplemental NIPT and carrier screening, with no need for additional draws.

*Additional charge for supplemental testing. Diagnostic testing for conditions included in supplemental testing is not covered by CA PNS.

How will I order testing through CA PNS?



Starting September 19, 2022, the CalGenetic portal will replace your current Test Request Forms for all CA PNS orders. Visit <https://calgenetic.cdph.ca.gov> to create your user profile and register your office.

In the portal, you will be able to select your laboratory of choice and view your patients' results for trisomies 21, 18, and 13, and fetal sex (optional).

Why partner with Natera?



When you choose Natera for your CA PNS laboratory, you gain resources including:

- Optional supplemental NIPT and carrier screening from the same blood draw*
- Complimentary patient information sessions for supplemental NIPT and carrier screening* with Natera's board-certified genetic counselors
- Clinician access to Natera's genetic counselors for questions about tests and results
- Flexible phlebotomy services options
- Comprehensive patient educational materials



Learn more about NateraCore Services

<https://www.natera.com/womens-health/core-services/>

To learn more about Natera's SNP-based cfDNA testing technology and the tests we offer, visit [natera.com/CAPNS](https://www.natera.com/CAPNS) or reach out to california@natera.com.

To read about the upcoming CA PNS changes, visit <https://www.cdph.ca.gov/Programs/CFH/DGDS/Pages/pns/PNS-Program-Changes.aspx>

*Additional charge for supplemental testing. Diagnostic testing for conditions included in supplemental testing is not covered by CA PNS.

References

1. Norton M, et al. N Engl J Med. 2015;372(17):1589-1597.
2. Norton M, et al. Am J Obstet Gynecol. 2016;214(6):727 e1-e6.
3. DiNonno W, et al. J Clin Med Res. 2019;8(9).
4. Rose N, et al. Obstet Gynecol. 2020;136(4).

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The tests described have been developed and their performance characteristics determined by the CLIA-certified laboratory performing the test. The tests have not been cleared or approved by the US Food and Drug Administration (FDA). Although FDA is exercising enforcement discretion of premarket review and other regulations for laboratory-developed tests in the US, certification of the laboratory is required under CLIA to ensure the quality and validity of the tests. CAP accredited, ISO 13485 certified, and CLIA certified. © 2022 Natera, Inc. All Rights Reserved.
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