

California Prenatal Screening (PNS) Program



Instructions For Providers on Ordering and Collecting cfDNA Screening Blood Specimens

NATERA LABORATORY

1. How do I request blood collection kits from Natera?

- a. Either 1) call customer care at 650-434-4840, or 2) email california@natera.com to request blood collection kits. Phone number and email address are for providers only.
- b. Kits are free of charge and include prepaid shipping envelopes.

2. Where can I have the patient's blood specimen drawn?

- a. If blood collection services are not available at your clinic:
 - Please visit: https://my.natera.com/services/blood_draw, or call 650-446-4095.
 - ii. Please provide the Natera kit and printed requisition form(s) to the patient.

3. How do I order the cfDNA Screen?

- a. Visit the <u>CalGenetic Portal</u> (https://calgenetic.cdph.ca.gov/) to register and order the cfDNA screen (beginning September 19, 2022).
- b. Select Natera as the cfDNA Laboratory. The selection will say 'Natera (Vasistera SNP Based NIPT)'.
- c. After completing the online cfDNA order form, select the SUBMIT button.
- d. <u>Print</u> the California PNS Program *Consent and cfDNA Order Confirmation* on the PNS <u>Program label stationery</u> provided by the state program*.
 - i. After the screening order is printed on the state-supplied label stationery, please note that it will contain four PNS Program barcode labels.
 - ii. Place one barcode label on a copy of the patient's insurance card.
 - ** You do not need to use any of the additional PNS Program barcode labels to complete the Natera cfDNA order because Natera barcode labels are already on the Natera-supplied blood collection tubes.**
 - iii. Obtain the patient's signature on the PNS Program *Consent and cfDNA Order Confirmation*.
- e. Open the Natera blood collection kit.
 - Remove one barcode label from the Natera kit and <u>affix it to the upper right-hand</u> <u>corner of the printed PNS Program Consent and cfDNA Order</u> <u>Confirmation form</u>. Place in the box that says, "For lab use only, do not cover".

^{*} To pre-order the PNS Program label stationery and other program supplies go to:

PNS Program Supplies Ordering web page (https://bit.ly/PNSSupplies)

- ii. If ordering additional tests from Natera using the same specimen, affix an additional Natera sticker on the upper right-hand corner of the <u>Natera</u> requisition form.
- **4.** Does my patient need to do anything to prepare for the cfDNA screen (e.g., fast)? No special preparation for a patient is needed prior to their Natera cfDNA screen.

5. What kind of sample is needed (plasma, whole blood, etc.) and what volume should be collected?

- a. The cfDNA screen from Natera is performed using 10ml of whole blood collected in two cell-free DNA Streck tubes (20 ml total is required).
- b. Do not draw before 10 weeks gestation.
- c. Keep specimen at room temperature, do not refrigerate or freeze.

6. How long after the date of blood collection can specimens be tested?

Specimens should arrive at Natera within 8 days from date of collection.

7. How do I request shipping supplies from Natera?

a. A FedEx shipping envelope (Clinical Pak) with Natera's address printed on it will be available inside the blood collection kit.

8. How do I ship the blood collection kit?

- a. Place filled blood tubes, with completed labels, in the white tube holder.
- b. Place the white tube holder with blood tubes inside the biohazard bag.
- c. Place the biohazard bag in between the gel pack to cushion.
- d. Place the gel pack into the metallic (silver colored) envelope.
- e. Place the metallic envelope and the PNS Program Consent and cfDNA Order Confirmation form and the Natera requisition form (if ordering additional tests from Natera) inside the collection kit box.
- f. Place the cardboard mailer (original collection kit box) inside a FedEx Clinical Pak.
- g. Call 1-800-GO-FEDEX to arrange a pickup. A prepaid FedEx label is affixed to the Clinical Pak.

9. Disclaimer:

This test has been developed and its performance characteristics determined by the CLIA-certified laboratory performing the test. The test has not been cleared or approved by the US Food and Drug Administration (FDA). CAP accredited, ISO 13485 certified, and CLIA certified. © 2022 Natera, Inc. All Rights Reserved.

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