

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 <u>california@natera.com</u> 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:
  - i. Please visit: <u>https://my.natera.com/services/blood\_draw</u>, 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 '<u>Natera (Vasistera SNP</u> <u>Based NIPT)'.</u>
- 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* <u>on the PNS</u> <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. <u>Place one barcode label</u> 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: <u>PNS Program Supplies Ordering web page</u> (https://bit.ly/PNSSupplies)

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- 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 CLIAcertified 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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