

California Prenatal Screening Program Changes Provider Support, Training & Educational Materials

Webinar 3 of 3

August 24, 2022

Welcome

Introduction: Lisa Feuchtbaum, Program & Policy Branch

Welcome: Richard Olney, Division Chief

Presenters:

- Program Changes/Workflow Walk Through
Robyn Jiménez, Chief, Prenatal Screening Section
- Q & A Session
Sara Goldman, Assistant Division Chief
- Training and Educational Materials
Faith Raider, Communication & Education Unit

Continuing Medical Education (CME)

- GDSP is accredited by the California Medical Association to provide Continuing Medical Education (CME) for physicians. **This webinar will constitute 1.5 AMA PRA Category 1 Credits™**
- The webinar recording will be on [PNS Program Webinars web page \(https://bit.ly/PNS_Webinars\)](https://bit.ly/PNS_Webinars). For CME credits, complete the evaluation survey found on this page
- CMEs may also be used for continuing education credits by other professional credentialing organizations (e.g., nursing, genetic counseling)

Welcome

Richard Olney, MD, MPH

Division Chief

Genetic Disease Screening Program

PNS Program moving to cell-free DNA (cfDNA)

You may have read about it...

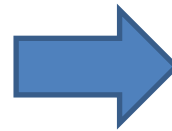


e-Newsletter: <https://tinyurl.com/GDSPOnline>

Revised PNS Program: Two Types of Screening

Current: Integrated Biochemical Screening

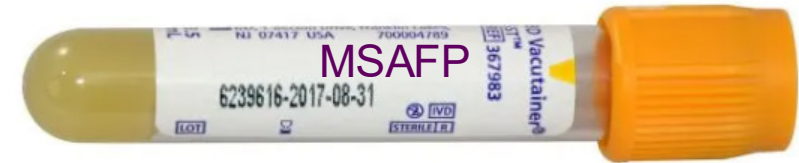
1st and 2nd trimester
maternal serum
specimens



Future: Two Types of Screening



Window: 10w 0d until term



Window: 15w 0d through 21w 0d

Revised PNS Program Changes

Robyn Jiménez, PhD

Chief

CA Prenatal Screening Program

Revised PNS Program: cfDNA

- Cell-free DNA (cfDNA) screening: primary screen for chromosomal anomalies
- Genetic screening examines fetal DNA circulating in maternal blood
- Screens for trisomy 21 (Down syndrome), trisomy 18, and trisomy 13 in singletons and twin pregnancies
- Includes fetal sex, if requested by the patient
- Offered at 10 weeks of gestation or later
- Lower false positive rate
- State PNS Program fee of \$232, includes follow-up services for referred patients to state-authorized Prenatal Diagnosis Centers

Amended State Regulations: CCR Title 17

Sections: 6520 – 6548

- The PNS Program has exclusivity in California to screen for trisomies 21, 18, and 13, as well as maternal serum AFP for neural tube defects
- The state currently has contracts with Natera, Quest Diagnostics, PerkinElmer and Kaiser Southern California Permanente Medical Group
- Natera & Quest Diagnostics will be available to the non-Kaiser providers at program launch. The third lab, PerkinElmer will come onboard later in the year
- No other labs operating in California may screen for trisomies 21, 18, and 13 using cfDNA methodologies

Three State-Contracted cfDNA Laboratories

- Provider choice of labs: Natera, Quest Diagnostics, & PerkinElmer
- Each lab has specific blood draw instructions
- Instructions are currently posted for Natera and Quest Diagnostics on program website
 - Draw blood in provider office;
 - Or send patient to blood draw station
- Kaiser providers should check with their internal systems

Natera Blood Draw Instructions For Providers

Page 1 of 2

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 call customer care at 650-434-4840, or email california@natera.com to request blood collection kits.
 - 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: 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. Go to the CalGenetic Portal (<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 (Vasistara SNP Based NIPT)'.
 - c. After completing the online form, select the SUBMIT button.
 - d. Print the California Prenatal Screening (PNS) Program Consent and cfDNA Order Confirmation on the PNS Program label stationery provided by the state program*.
 - i. When the screening order is printed on the label stationery, it will contain four PNS Program barcode stickers.
 1. Place one of the barcode stickers vertically on each of the blood collection tubes (you can use the sticker that says, "Extra label").
 2. Place an additional barcode sticker on a copy of the patient's insurance card.
 - ii. Obtain the patient's signature on the PNS Program Consent and cfDNA Order Confirmation.
 - e. Open the Natera blood collection kit.
 - i. Remove one barcode sticker from the Natera kit and affix it vertically on each blood collection tubes. Place stickers so they do not overlap.
 - ii. Remove one additional barcode sticker from the Natera kit and affix it to the upper right-hand corner of the printed *Consent and cfDNA Order Confirmation* in the box that says, "For lab use only, do not cover".
 - iii. If ordering additional tests from Natera using the same specimen, affix an additional Natera sticker on the upper right-hand corner of the Natera requisition form.

* To pre-order the PNS Program label stationery go to:
<https://www.cdph.ca.gov/Programs/CFH/DGDS/Pages/pns/orderingsupplies.aspx>

Last Updated 7-28-2022

California Prenatal Screening Program

Additional Information For Providers About California State-Contracted cfDNA Laboratories

NATERA LABORATORY

1. Methodology for cfDNA analysis?

SNP-based cfDNA screening reveals a baby's risk for severe genetic disorders. The test uses a unique single-nucleotide polymorphism (SNP)-based technology to analyze fetal/placental DNA obtained through a blood draw from the mother. This test can differentiate between maternal and fetal DNA to assess the risk of aneuploidies. The test also screens twin pregnancies for zygosity and fetal sex of each baby.
2. Can I have additional tests performed on the specimen I send for Prenatal Screening Program through Natera?
 - a. Additional tests can be ordered using the same specimen. These are:
 - i. Panorama CA Supplemental Panel: includes sex chromosome aneuploidies, Triploidy. Optional add-ons: 22q11.2 deletion syndrome, extended microdeletion panel
 - ii. Horizon Carrier Screen:
 1. Single gene options: CF, SMA, DMD
 2. Panel options: Horizon 4, Horizon 14, Horizon 27, Horizon 106, Horizon 274
 - b. Visit www.natera.com/CAPNS for ordering information and instructions.
3. How do patients consent to additional tests?
 - a. The physician must sign a separate requisition form indicating that they have consented the patient for additional testing. Patient consent language is included on the requisition form.
 - b. Visit www.natera.com/CAPNS to download the requisition form, or call 650-446-4095.
4. Are you CLIA-certified? Yes - CLIA# 05D1082992

Are you certified by California Laboratory Field Services (LFS)? Yes - CDF# 00337104
5. Where is the location of your lab(s) where my patients' specimens will be processed in California?

The performing lab for Natera is located at:
Natera, Inc.,
201 Industrial Rd.
San Carlos, CA 94070
6. 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.

These instructions are now available for viewing on the PNS Program Webpage a: <https://bit.ly/PNS4Providers>

Quest Blood Draw Instructions For Providers

Page 1 of 2

California Prenatal Screening (PNS) Program

Instructions FOR PROVIDERS on Ordering and Collecting cfDNA Screening Blood Specimens

QUEST DIAGNOSTICS LABORATORY

1. Locating a Quest Diagnostics Patient Service Center:
 - a. Quest Diagnostics has over 500 patient access points throughout Northern and Southern California.
 - b. Please use the link supplied below so that your patient can locate the nearest Patient Service Center (PSC) and schedule an appointment: <https://appointment.questdiagnostics.com/as-home>.
2. How to order the cfDNA Screen:
 - a. Visit the CalGenetic Portal (<https://calgenetic.cdph.ca.gov/>) to register and order the cfDNA screen (beginning September 19, 2022).
 - b. Select Quest Dx as the cfDNA Laboratory. The selection will say "Quest Dx (GDSP cfDNA Panel) CL: 94804005".
 - c. After completing the online form, select the SUBMIT button.
 - d. Print the California Prenatal Screening (PNS) Program *Consent and cfDNA Order Confirmation on the PNS Program label stationery* provided by the state program*.
 - i. When the screening order is printed on the stationery, it will contain four PNS Program barcodes stickers.
 - ii. Obtain the patient's signature on the PNS Program *Consent and cfDNA Order Confirmation*.
3. Specimen collection:
 - a. In-clinic collection instructions:
 - i. One barcode sticker should be affixed to a copy of the patient's insurance card.
 - ii. One barcode sticker should be affixed vertically on each blood collection tube.
 - b. Collection at a Quest Diagnostics Patient Service Center:
 - i. Ask the patient to make an appointment at their preferred Quest Diagnostics Patient Service Center location via the link below: <https://appointment.questdiagnostics.com/as-home>.
 - ii. The patient will be required to bring the following items:
 1. A signed PNS Program *Consent and cfDNA Order Confirmation* form and
 2. A copy of their insurance card with the affixed barcode sticker.
4. Does my patient need to do anything to prepare for the cfDNA screen (e.g., fast)?

No special preparation is needed.

* To pre-order the PNS Program label stationery go to:

<https://www.cdph.ca.gov/Programs/CFH/DGDS/Pages/pns/orderingsupplies.aspx>

Last Updated 7-28-2022

California Prenatal Screening (PNS) Program

Additional Information For Providers About California State-Contracted cfDNA Laboratories

QUEST DIAGNOSTICS LABORATORY

1. Methodology for cfDNA analysis?

The "GDSP cfDNA Panel" screening test from Quest Diagnostics utilizes an automated whole genome shotgun sequencing approach. A Z-score (the degree in which a data set differs from the expected outcome) is then bioinformatically generated to identify patients who are at a higher risk for a tested aneuploidy.
2. Can I have additional tests performed on the specimen I send for Prenatal Screening Program through your company?

At this time, Quest Diagnostics does not offer additional testing that can be performed on the cfDNA specimen.
3. Are you CLIA-certified? Yes
Are you certified by California Laboratory Field Services (LFS)? Yes

Laboratory Name	Quest Diagnostics
Federal CLIA #	CLIA 05D0643352
California Licensed CLIA Lab #	CDF-00002562

4. Where is the location of your lab(s) where my patients' specimens will be processed in California?

The performing lab for the "GDSP cfDNA Panel" from Quest Diagnostics is:
Quest Diagnostics San Juan Capistrano
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042

These instructions are now available for viewing on the PNS Program Webpage a: <https://bit.ly/PNS4Providers>

Provider Choice on cfDNA

State-Contracted Labs

- Providers decide which state-contracted labs they want to use
- The state pays the state-contracted cfDNA labs directly
- No fees for cfDNA screening charged to the patient if they have Medi-Cal or private insurance
- Medi-Cal and private insurance must cover the \$232 program fee
- PNS Program will invoice this fee to Medi-Cal or patient's insurance company
- Site-specific preexisting contracts or arrangements with existing cfDNA labs will no longer apply

cfDNA Case Management and Follow-up

- Screening results and interpretations will be standardized
- Case management will be provided by regional PNS Program coordinators, including results communications to providers
- Providers should contact the PNS Program coordinators for questions about test results and follow up services

Additional Screening Still Available

- The state cfDNA screening panel does not currently include screening for sex chromosome abnormalities or microdeletions
- Additional types of screening tests may be ordered outside the state PNS Program
- Any of the state-contracted labs who have this capacity can provide additional tests using the same specimen (currently, only Natera).
- The cost of additional screening services will not be covered by the state.
- Providers are responsible for pre and post-test counseling, patient consent and arranging any follow up diagnostic testing

Revised PNS Program: MSAFP Screening

Maternal serum AFP (MSAFP) will continue to be the primary screen for neural tube defects

Biochemical screening measures maternal serum alpha-fetoprotein (MSAFP)

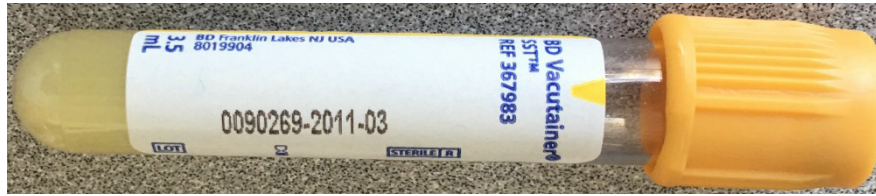
- Screens for anencephaly, open spina bifida, etc.
- Offered from 15 weeks 0 days through 21 weeks 0 days of gestation
- Fee is **\$85 for MSAFP**; includes follow-up services for referred patients to state-authorized PDC

MSAFP: What is the same?

MSAFP biochemical test

- Current blood collection kit
 - Can be ordered from the program website at no cost
- Patients can be directed to any blood collection location that has been used in the past
- Specimens are processed by regional CDPH state-contracted laboratories

MSAFP Blood Collection Kit (same as before)



3.5 mL serum separator tube(s)

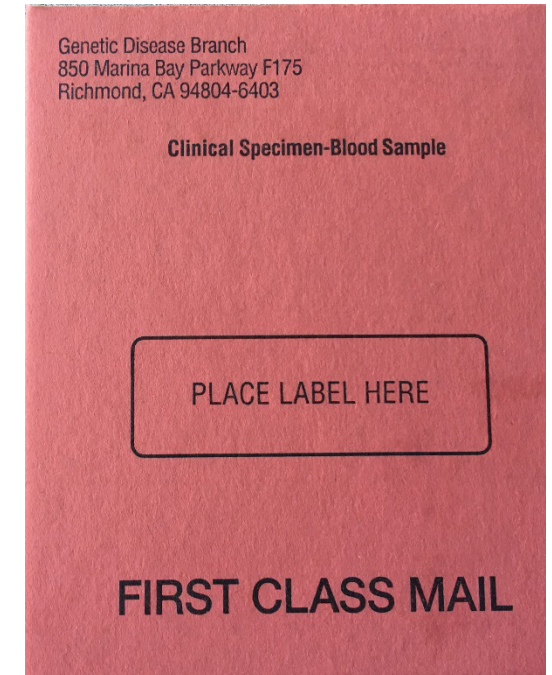


plastic
tray

absorbent
pouch



cardboard
mailing box



cfDNA & MSAFP: What Is New?

- Use of CalGenetic Portal for electronic ordering and viewing results
 - Replaces pre-printed, paper 1st & 2nd trimester test request forms
- For patients who consent, the provider uses new PNS Program stationery for printing the “Order and Consent Confirmation” form for both cfDNA and MSAFP screens.
- For patients who decline, the provider can use the cfDNA and MSAFP decline forms available on program website

California Prenatal Screening Program

Decline of MSAFP Screening Form

It is your choice whether you want prenatal screening offered by the California Prenatal Screening (PNS) Program. Your prenatal care provider will review the prenatal screening process and answer any questions you may have so you feel ready to make your decision. If you decide not to have one or both screenings offered by the PNS Program, you will sign and date a separate decline form for each of the two screenings.

Summary of key points to remember as you consider your final decision on whether you want one or both screenings offered by the PNS Program.

1. The PNS Program offers prenatal screening to identify these birth defects: neural tube defects through maternal serum alpha-fetoprotein or MSAFP screening. Screening is not 100% accurate in finding birth defects.
2. There are separate program fees for each of the two screenings, cfDNA screening and MSAFP screening. Medi-Cal and private insurance must cover all program fees, with only a few exceptions for self-insured employers and out-of-state health plans. If the fees are not covered, or you do not have Medi-Cal or health insurance, you must provide full payment.
3. If the screening result shows an increased chance of a birth defect, you can talk to your provider and decide if you want follow-up services. Follow-up services include genetic counseling to learn about follow-up options, an ultrasound examination, and diagnostic testing, either chorionic villus sampling or amniocentesis. It is possible to have normal results after diagnostic testing.
4. If your prenatal provider requests additional genetic screening or testing, outside of the PNS Program, separate test request forms and fees will be required. Follow-up services will not be available through the PNS Program for the additional screenings or testing.

If patient declines cell-free DNA or maternal serum alpha-fetoprotein screening

- Patient or patient's representative must sign and date the form.
- The provider must file the form in the patient's medical record and provide a copy of the signed form to the patient.

Maternal serum alpha-fetoprotein (MSAFP) Screening	
I Decline MSAFP Screening	I decline to have blood drawn for MSAFP screening offered by the California Prenatal Screening Program.
	Signed: _____ Date: _____
	Attestation that verbal decline from patient was received.
	Provider/Representative Name*: _____ Relationship to Patient*: _____
	(Please print) (Please print)



California Prenatal Screening Program

Decline of cfDNA Screening Form

It is your choice whether you want prenatal screening offered by the California Prenatal Screening (PNS) Program. Your prenatal care provider will review the prenatal screening process and answer any questions you may have so you feel ready to make your decision. If you decide not to have one or both screenings offered by the PNS Program, you will sign and date a separate decline form for each of the two screenings.

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1. The PNS Program offers prenatal screening to identify these birth defects: Down syndrome, trisomy 18, and trisomy 13 through cell-free DNA or cfDNA screening. Screening is not 100% accurate in finding birth defects.
2. There are separate program fees for each of the two screenings, cfDNA screening and MSAFP screening. Medi-Cal and private insurance must cover all program fees, with only a few exceptions for self-insured employers and out-of-state health plans. If the fees are not covered, or you do not have Medi-Cal or health insurance, you must provide full payment.
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cell-free DNA (cfDNA) Screening	
I Decline cfDNA Screening	I decline to have blood drawn for cfDNA screening offered by the California Prenatal Screening Program.
	Signed: _____ Date: _____
	Attestation that verbal decline from patient was received.
	Provider/Representative Name*: _____ Relationship to Patient*: _____
	(Please print) (Please print)

PNS Program: What is going away?

- Result mailers will NOT be sent to patients
- Biochemical integrated screening will NOT be offered
- Screening for Smith-Lemli-Opitz syndrome (SLOS) will NOT be done.
- NT ultrasound measurements (mm) will NOT be included on PNS screening orders

Supplies and Educational Materials

Supplies and printed ed materials are ordered online
(<https://bit.ly/PNSSupplies>)

- PNS Program label stationery for printing the MSAFP and cfDNA “Order and Consent Confirmation” forms
- MSAFP kits
- MSAFP labels



Screening Order and Results Workflow Process

Ordering a cfDNA screen

Clinician/delegate places
cfDNA order through
CalGenetic Portal

Clinician/delegate prints
confirmation page on label
stationery; patient or
representative signs
consent



Patient
consents

Patient
declines

The screenshot shows the 'WELCOME TO THE CALGENETIC PORTAL' page. It features the 'CALIFORNIA GDSP Genetic Disease Screening Program' logo. There is a 'Register/Sign In To Your Account' button and a 'New User?' link. The page also lists 'Services of the California Portal'.The screenshot shows the 'California Prenatal Screening Program Decline of cfDNA Screening Form'. It includes a 'Summary of key points to remember' section and a 'cell-free DNA (cfDNA)' section. The form has fields for 'Signed', 'Date', 'Attestation that verbal decline from patient was received', 'Provider/Representative Name', and 'Relationship to Patient'.The screenshot shows the 'Consent & cfDNA Order Confirmation' page. It includes a 'Patient' section with fields for 'Last Name', 'First Name', 'Medical Record #', 'Date of Birth', 'Patient Phone #', 'NFI/Donor Used?', and 'Number of Fetuses'. It also has an 'Order' section with fields for 'PNS Form #', 'Analysis Lab', 'Quest Dx (GDSP cfDNA Panel)', 'Estimated Due Date', 'Clinician Last', 'Clinician First', and 'Clinician Phone #'. There is a 'Patient Consent' section with a list of bullet points and a 'Patient/Authorized Person Signature' field. The page also includes a 'Blood Draw Facility' section with fields for 'Blood Draw Facility Name', 'Blood Draw Facility Phone #', 'Blood Draw Date', and 'Collector's Initials'. At the bottom, there is a 'Copy of insurance card' section with a barcode and a 'Blood draw tube' section with a barcode.

Provider/ patient discussion
about cfDNA PNS. Pre-
counseling recommended;
patient video on PNS website.

Patient signs decline form;
file in patient's chart

Links on CalGenetic
Portal help determine
appropriate cfDNA-lab
specific draw station and
location for the patient

Ordering a cfDNA screen

Consent & cfDNA Order Confirmation
California Prenatal Screening Program

For lab use only
(Do not cover)

Patient	Order
Last Name: Dominguez	PMS Form #: D-22-AM24-77
First Name: Jane	Analysis Lab: Quest Diagnostics
Medical Record #: 155053	CLIA #0000000000
Date of Birth: 10/12/1985	Estimated Due Date: 06/15/2022
Patient Phone #: 650.234.2487	Clinician Last: Williams
Referring Doctor Used? Yes	Clinician First: Nicholas
Number of Fetuses: 2	Clinician Phone #: 800.368.3468

Patient Consent

If you give consent to prenatal screening by signing below, your blood will be collected and sent to a state-licensed laboratory for prenatal screening.

- I understand the purpose of the California Prenatal Screening Program.
- I understand the release of medical and any other information about myself that is needed for my health insurance claim.
- I understand the purpose of medical benefits to the Genetic Disease Screening Program (GDSP) for the services provided to me.
- I understand the release of medical and any other information about myself that is needed for my health insurance claim.
- I understand any provider who is not a doctor will not be able to see through the California Prenatal Screening Program.

Consent

I, the undersigned, do hereby certify that the information provided is true and correct.

Signature: _____ Date: ____/____/____

Blood Draw Facility

Blood Draw Facility Name: _____ Blood Draw Facility Phone #: _____

Blood Draw Date: ____/____/____ Collector's Initials: ____/____

Copy of insurance card + Blood draw tube + Extra label / Do not remove x

Dominguez, S Dominguez, S Dominguez, S Dominguez, S

Collected on: ____/____/____ Collected on: ____/____/____ Collected on: ____/____/____ Collected on: ____/____/____



Patient Insurance Card

network health Network Health Medicare Explore (HMO)

This is your 2019 medical and prescription drug card.

Member: JANE M DOE Pharmacy Deductible: \$260

Member ID: 0000000000

Health Plan (000000) Rx BIN: 000000

Group 00000000 RxPCN: MD

MedicareRx RxGrp: NHPA

H5644 002



Patient takes eTRF, insurance card copy, and blood collection kit (Natera-only) to designated blood draw location

Patient's blood is drawn

Provider's chosen cfDNA laboratory receives and processes specimen



Draw station ships specimen, eTRF, and insurance information to designated cfDNA laboratory

Consent & cfDNA Order Confirmation
California Prenatal Screening Program

For lab use only
(Do not cover)

Patient	Order
Last Name: Dominguez	PMS Form #: D-22-AM24-77
First Name: Jane	Analysis Lab: Quest Diagnostics
Medical Record #: 155053	CLIA #0000000000
Date of Birth: 10/12/1985	Estimated Due Date: 06/15/2022
Patient Phone #: 650.234.2487	Clinician Last: Williams
Referring Doctor Used? Yes	Clinician First: Nicholas
Number of Fetuses: 2	Clinician Phone #: 800.368.3468

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- I understand the release of medical and any other information about myself that is needed for my health insurance claim.
- I understand any provider who is not a doctor will not be able to see through the California Prenatal Screening Program.

Consent

I, the undersigned, do hereby certify that the information provided is true and correct.

Signature: _____ Date: ____/____/____

Blood Draw Facility

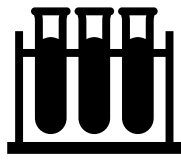
Blood Draw Facility Name: _____ Blood Draw Facility Phone #: _____

Blood Draw Date: ____/____/____ Collector's Initials: ____/____

Copy of insurance card + Blood draw tube + Extra label / Do not remove x

Dominguez, S Dominguez, S Dominguez, S Dominguez, S

Collected on: ____/____/____ Collected on: ____/____/____ Collected on: ____/____/____ Collected on: ____/____/____



network health Network Health Medicare Explore (HMO)

This is your 2019 medical and prescription drug card.

Member: JANE M DOE Pharmacy Deductible: \$260

Member ID: 0000000000

Health Plan (000000) Rx BIN: 000000

Group 00000000 RxPCN: MD

MedicareRx RxGrp: NHPA

H5644 002

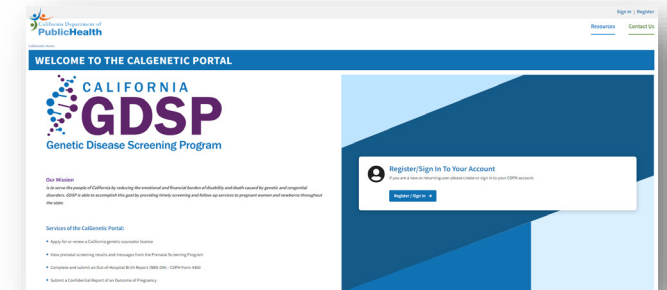
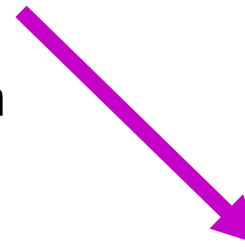
Ordering a cfDNA screen



cfDNA laboratory sends specimen data to PNS Program for standardization



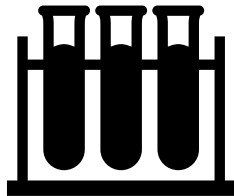
Paper result mailer sent to ordering provider



Screen Negative Results available on CalGenetic Portal real-time



Coordinator contacts ordering provider regarding any non-negative results



Patient is authorized for re-draw or follow-up services depending on non-negative result



Ordering an MSAFP screen

Clinician/delegate places
MSAFP order through
CalGenetic Portal

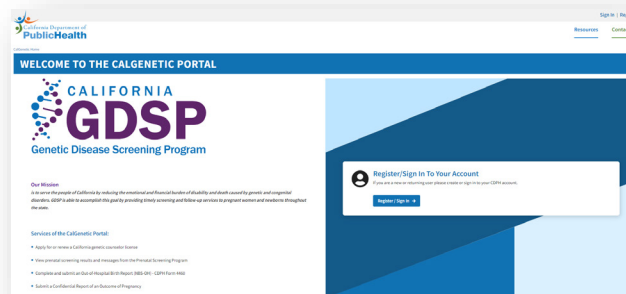
Clinician/delegate prints
order confirmation page on
label stationery; patient or
representative signs consent



Patient
consents

Patient
declines

Provider/ patient discussion about
MSAFP PNS screening. Pre-
counseling recommended; patient
video on PNS website.



**California Prenatal Screening Program
Decline of MSAFP Screening Form**

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If patient declines cell-free DNA or maternal serum alpha-fetoprotein screening

- Patient or patient's representative must sign and date the form.
- The provider must file the form in the patient's medical record and provide a copy of the signed form to the patient.

Maternal serum alpha-fetoprotein (MSAFP)

I decline to have blood drawn for MSAFP screening offered by the California Prenatal Screening Program.

Signed: _____ Date: _____

☐ Attestation that verbal decline from patient was received.

Provider/Representative Name: _____ Relationship to Patient: _____

(Please print) (Please print)

Patient signs decline
form; file in patient's chart

Consent & MSAFP Order Confirmation
California Prenatal Screening Program

Attach Accession Label
For state lab use only
Do not cover

Patient	Order
Last Name: Dominguez	PNS Form #: S 21 F234F 77
First Name: Jane	Clinician Last: Johansen
Medical Record #: 165253	Clinician First: Nicholas
Date of Birth: 10/12/1995	Clinician Phone #: (916) 354-3456
Patient Phone #: (415) 334-3267	

Patient Consent

If you give consent to prenatal screening by signing below, your blood will be collected and sent to a state-controlled laboratory for prenatal screening.

- I consent to participate in the California Prenatal Screening Program.
- I authorize the release of medical and any other information about myself needed for my health insurance claim.
- I authorize payment of medical benefits to the Genetic Disease Screening Program (GDSP) for the services provided to me.
- I consent to be billed directly for services provided to me if I do not have health insurance coverage or Medi-Cal.
- I agree my blood sample may be used for research by GDSP or GDSP-approved researchers, unless the box below is marked.
- ☐ I decline the use of my specimen for research.

Patient Signature: _____ Date: ____/____/____

☐ Attestation that verbal consent from patient was obtained:

Provider/Representative Name: _____ Relationship to Patient: _____

Based on Gestational Age, the recommended patient blood draw date range: 04/22/2022 - 05/23/2022

Blood Sample

Blood Draw Facility Name: _____ NAPS Lab Notes

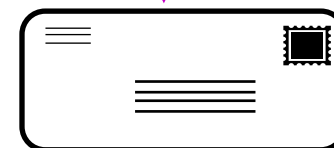
Collector's Initials: _____ Blood Draw Facility Phone #: _____

Copy of insurance card + Blood draw tube + Extra label ✓ Do not remove x

Dominguez, S Dominguez, S Dominguez, S Dominguez, S

5 21 F234F 77 5 21 F234F 77 5 21 F234F 77 5 21 F234F 77

Collected on: ____/____/____ Collected on: ____/____/____ Collected on: ____/____/____ Collected on: ____/____/____



USPS label and pre-paid
postage can be printed
for GDSP regional labs
from CalGenetic Portal



Ordering an MSAFP screen

Consent & MSAFP Order Confirmation
California Prenatal Screening Program

Health Insurance Label
For state lab use only
Do not use

Patient	Order
Last Name: Dominguez	Ref Name: 023 P23AP 77
First Name: Jane	Clinician Last: Johnson
Medical Record #: 180253	Clinician First: Maloney
Date of Birth: 05/12/1995	Clinician Phone: (865) 354-3406
Patient Phone: (408) 354-5087	

Patient Consent

I give you consent to prenatal screening by signing below, your blood will be collected and sent to a state contracted laboratory for prenatal screening.

- I consent to participate in the California Prenatal Screening Program.
- I authorize the release of medical and any other information about myself needed for my health insurance claim.
- I authorize payment of medical benefits to the Genetic Disease Screening Program (GDSP) for the services provided to me.
- I consent to be billed directly for services provided to me if I do not have health insurance coverage or third-party coverage.
- I agree my blood sample may be used for research by GDSP or GDSP-approved researchers, unless the box below is marked.
- ☐ I decline the use of my specimen for research.

Patient Signature: _____ **Date:** ☐ ☐ ☐ ☐

☐ Indication that verbal consent from patient was obtained

Provider/Representative Name: _____ **Relationship to Patient:** _____

Based on Gestational Age, the recommended patient blood draw date range: 04/22/2022 - 05/23/2022

Blood Sample

Blood Draw Facility Name: _____ **NAF's Lab Notes:** _____

Blood Draw Date: ☐ ☐ ☐ ☐ **Collector's Initials:** _____ **Blood Draw Facility Phone #:** _____

Copy of Insurance card: ☐ **Blood draw tube:** ☐ **Extra label:** ☐ **Do not remove:** ☐

Domestic: ☐ **Domestic:** ☐ **Domestic:** ☐ **Domestic:** ☐

023 P23AP 77 **023 P23AP 77** **023 P23AP 77** **023 P23AP 77**

Collected on: _____ **Collected on:** _____ **Collected on:** _____ **Collected on:** _____



Patient Insurance Card

network health
Network Health Medicare Explore (HMO)

This is your 2019 medical and prescription drug cost.

Member: JANE M DOE
Member ID: 000000000
Health Plan (000000)
Group (000000)

PC: <00>
Specialist: S30
Rx BEN: 000000
Rx PCTN: MD
Rx Grp: N00A

Pharmacy Deductible: \$200
Pharmacy Co-pay: \$30

155444 002



Patient's blood is drawn

Patient takes eTRF and insurance card copy to any blood collection location that draws for the PNS Program



GDSP regional laboratory receives and processes specimen



Consent & eTRF Order Confirmation
California Prenatal Screening Program

Health Insurance Label
For state lab use only
Do not use

Patient	Order
Last Name: Dominguez	Ref Name: 023 P23AP 77
First Name: Jane	Clinician Last: Johnson
Medical Record #: 180253	Clinician First: Maloney
Date of Birth: 05/12/1995	Clinician Phone: (865) 354-3406
Patient Phone: (408) 354-5087	

Patient Consent

I give you consent to prenatal screening by signing below, your blood will be collected and sent to a state contracted laboratory for prenatal screening.

- I consent to participate in the California Prenatal Screening Program.
- I authorize the release of medical and any other information about myself needed for my health insurance claim.
- I authorize payment of medical benefits to the Genetic Disease Screening Program (GDSP) for the services provided to me.
- I consent to be billed directly for services provided to me if I do not have health insurance coverage or third-party coverage.
- I agree my blood sample may be used for research by GDSP or GDSP-approved researchers, unless the box below is marked.
- ☐ I decline the use of my specimen for research.

Patient Signature: _____ **Date:** ☐ ☐ ☐ ☐

☐ Indication that verbal consent from patient was obtained

Provider/Representative Name: _____ **Relationship to Patient:** _____

Based on Gestational Age, the recommended patient blood draw date range: 04/22/2022 - 05/23/2022

Blood Sample

Blood Draw Facility Name: _____ **NAF's Lab Notes:** _____

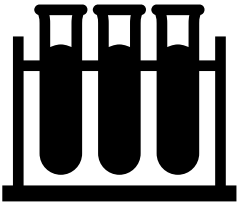
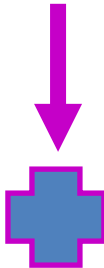
Blood Draw Date: ☐ ☐ ☐ ☐ **Collector's Initials:** _____ **Blood Draw Facility Phone #:** _____

Copy of Insurance card: ☐ **Blood draw tube:** ☐ **Extra label:** ☐ **Do not remove:** ☐

Domestic: ☐ **Domestic:** ☐ **Domestic:** ☐ **Domestic:** ☐

023 P23AP 77 **023 P23AP 77** **023 P23AP 77** **023 P23AP 77**

Collected on: _____ **Collected on:** _____ **Collected on:** _____ **Collected on:** _____



network health
Network Health Medicare Explore (HMO)

This is your 2019 medical and prescription drug cost.

Member: JANE M DOE
Member ID: 000000000
Health Plan (000000)
Group (000000)

PC: <00>
Specialist: S30
Rx BEN: 000000
Rx PCTN: MD
Rx Grp: N00A

Pharmacy Deductible: \$200
Pharmacy Co-pay: \$30

155444 002

Draw station ships specimen, eTRF, and insurance information to state MSAFP laboratory (labels provided for USPS on CalGenetic Portal)

Ordering an MSAFP screen



GDSP laboratory sends specimen data to PNS Program

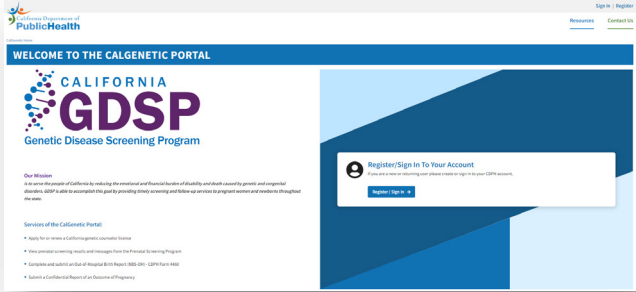
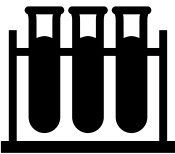


Paper result mailer sent to ordering provider



Coordinator contacts ordering provider regarding any non-negative results

Patient is authorized for re-draw or follow-up services depending on non-negative result



Screen Negative Results available on CalGenetic Portal real-time

Questions?

Write your questions in the Q&A box
Sara Goldman, Assistant Division Chief, GDSP

