PROPATH
A Sonic Healthcare Anatomic Pathology Practice

Genetic Carrier and Prenatal Screening Requisition

ACCESSION LABEL

PATIENT INFORMATION

Last Name | M.I. | Biological Sex: Female ○ Male ○

First Name

Street Address | Apt #

City | State | Zip Code

Date of Birth | Medical Record # | Patient Phone # ( ) –

PAYMENT AND INSURANCE

☐ Self-Pay ☐ Medicaid ☐ Client Bill ☐ Bill Insurance — Attach copy of front and back of insurance card

Insurance Name

Subscriber Name | ID #

Group # | Preauthorization #

SAMPLE COLLECTION — (Complete A, B, and C)

A. Collection Date (MM/DD/YYYY): _____

B. Collection Time: _____

C. Write patient's full name and date of birth on all tubes

CLINICIAN SIGNATURE

I will supply information to the patient regarding genetic testing, including: the manner of collection, use, retention, maintenance, and disclosure of the patient's sample and the results of the genetic testing; and the benefits, risks, and limitations of the laboratory test requested; and I will answer any of the patient's questions. I understand that the patient must give voluntary consent for genetic testing to be performed. Any testing ordered is medically necessary for the diagnosis or detection of disease, illness, impairment, symptom, syndrome, or disorder, and the results will be used in the medical management and treatment decisions for the patient. **Physicians (or other individuals authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment of the patient.**

Clinician Signature | Date

PATIENT SIGNATURE FOR INFORMED CONSENT AND FINANCIAL RESPONSIBILITY

I authorize Sonic Healthcare USA and its affiliates ("Sonic") to conduct genetic testing and to collect, obtain, use, maintain, and retain a sample and the results of the testing for that purpose. I authorize the laboratory to disclose my medical information, including the results of my genetic testing, to the ordering clinician or healthcare provider for treatment purposes; Metis Genetics, LLC for purposes of genetic counseling when appropriate; and my health plan/insurance carrier and its authorized representatives as necessary for reimbursement unless otherwise indicated.

I have had the opportunity to ask questions and discuss the capabilities, limitations, and possible risks of the test(s) with my healthcare provider and have been made aware of the availability of genetic counseling.

I accept full financial responsibility for any payment obligation associated with my test(s). I understand that I am responsible for any applicable copayment, coinsurance, or deductible as specified by my health plan, including any costs relating to out-of-network, non-covered, or non-authorized services. I understand that Sonic and its affiliates will bill my health plan as required by my insurer, and in accordance with its policies, unless otherwise notified. If applicable, I authorize Sonic to appeal any coverage denial made by my insurer on my behalf. I understand to direct all cost estimates and coverage inquiries to my insurer or, if I am uninsured, to Sonic and its affiliates. I further authorize my health plan/insurance carrier to directly pay Sonic and its affiliates for services rendered. I understand that I may be responsible for portions of this test not covered by my insurance. ***New York and Nevada residents must file a separate consent form(s).***

Patient Signature | Date

Non-Invasive Prenatal Screening (NIPS)

Collect ONE Streck tube

[1] Singletons Only [2] Fetal Sex Not Reported

Please select ONLY ONE of the below test options
If twins, only test code W907 or W906 is appropriate.

With Fetal Sex

- ○ **W905** NIPS w/ SCA[1+] (Trisomies 21, 18, 13, w/ Sex Chromosome Aneuploidies)
- ○ **W907** NIPS, Twin[+] (Trisomies 21, 18, 13)
- ○ **W913** NIPS+ w/ Microdeletions[1+>] (Trisomies 21, 18, 13, w/ Sex Chromosome Aneuploidies and Microdeletions)

Without Fetal Sex

- ○ **W906** NIPS[2+] (Trisomies 21, 18, 13)
- ○ **W910** NIPS w/ SCA[1,2+] (Trisomies 21, 18, 13, w/ Sex Chromosome Aneuploidies)
- ○ **W915** NIPS+ w/ Microdeletions[1,2+>] (Trisomies 21, 18, 13, w/ Microdeletions)

○ Other Code: _____

NIPS Clinical Information (Required)

Number of Fetuses: ○ (S)ingleton ○ (T)wins **Maternal Weight (lbs):** _____

Estimated Date of Delivery (EDD): ___/___/___ **Maternal Height (in):** _____

IVF Pregnancy: ○ Y ○ N **Patient/donor egg retrieval age:** _____ years

NIPS Commonly Utilized ICD Codes (Required)

- ○ **O09.291** Other poor reproductive or obstetric history, 1st tri
- ○ **O09.511** Elderly primigravida, 1st tri
- ○ **O09.519** Elderly primigravida, unsp tri
- ○ **O09.521** Elderly multigravida, 1st tri
- ○ **O09.529** Elderly multigravida, unsp tri
- ○ **O28.3** Abnormal ultrasonic finding
- ○ **O28.5** Abnormal chromosomal and genetic finding
- ○ **O35.1XX0** (Suspected) chromosomal abnormality in fetus
- ○ **Z13.79** Other genetic screening
- ○ **Z33.1** Pregnant state, incidental
- ○ **Z34.01** Normal first pregnancy, 1st tri
- ○ **Z34.81** Other normal pregnancy, 1st tri
- ○ **Z34.90** Other normal pregnancy, unsp, unsp tri
- ○ **Z36.9** Antenatal screening, unsp
- ○ **Z82.79** Family history of congenital anomalies
- ○ **Other** (please specify code): _____

For test and panel details, please visit www.SonicReproductiveHealth.com

Sonic Healthcare
Reproductive Health
Prenatal

Genetic Carrier Screening (CS)

Collect TWO EDTA purple-top tubes/test

- ○ **E2720** Hemoglobin Electrophoresis[*]
- ○ **W139** CF 139[+]
- ○ **W199** Fragile X Screen w/ Reflex Methylation[+*]
- ○ **W220** SMA[@#]
- ○ **W801** Basic Trio, Female[+>*] (CF139, SMA, FX)
- ○ **W802** Basic Duo, Female/Male[+>] (CF139, SMA)
- ○ **W557** Ashkenazi Jewish Panel, Female[+] (39 genes)
- ○ **W558** Ashkenazi Jewish Panel, Male[+] (37 genes)
- ○ **W559** Classic Panel, Female (24 genes)[+>]
- ○ **W560** Classic Panel, Male (22 genes)[+]
- ○ **W555** Complete Panel, Female (157 genes)[+>]
- ○ **W556** Complete Panel, Male (147 genes)[+]
- ○ Other Code: _____

CS Clinical Information (Required)

Patient Ethnicity: ☐ African American (AA) ☐ Caucasian (W) ☐ Hispanic (H) ☐ Asian (AS) ☐ Jewish (Ashkenazi) (J) ☐ Other (O): _____ ☐ Not Specified (NS)

Indication:

☐ Abnormal US (US) ☐ Egg/Sperm Donor (DO) ☐ Consanguinity (CO) ☐ Infertility (IN) ☐ Partner Known Carrier (PC) ☐ Patient Known Carrier (PT) ☐ Family History (HX)

Family History Present: ○ Y ○ N **If Yes, Indicate Relative:**

☐ Sibling ☐ Parent ☐ Grandparent ☐ Aunt/Uncle ☐ Niece/Nephew ☐ Cousin

Relative is: ☐ Affected by Or ☐ Carrier of _____

Is patient or partner pregnant? ○ Patient ○ Partner ○ Neither

CS Commonly Utilized ICD Codes (Required)

- ○ **E28.39** Other primary ovarian failure
- ○ **Z31.430** Encounter of female for testing for genetic disease carrier status for procreative mgmt
- ○ **Z31.440** Encounter of male for testing for genetic disease carrier status for procreative mgmt
- ○ **Z81.0** Family history of intellectual disabilities
- ○ **Z82.69** Family history of other diseases of the musculoskeletal system and connective tissue
- ○ **Z84.81** Family history of carrier of genetic disease
- ○ Other (please specify code): _____

[*] Includes alpha-thalassemia, beta-thalassemia and sickle cell disease plus other hemoglobinopathies.

\+ Not covered by Medicare
@ Medicare Limited Coverage
# Medicare Frequency Limit
> More than one CPT code will be billed
* Reflex testing may be performed with additional charge

[38773]

Sonic Healthcare
Reproductive Health
Prenatal

PRENATAL TESTING SOLUTIONS

Non-Invasive Prenatal Screening

What is NIPS?

NIPS is a non-invasive blood test that screens for chromosome conditions in the pregnancy. These conditions are uncommon, do not usually run in the family, and can happen in any pregnancy. NIPS can be performed based on a single blood draw beginning at 10 weeks gestation. Collecting your blood sample for NIPS poses no threat to your baby.

What does NIPS test for?

Chromosome Conditions

- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)

Additional testing options are available, including fetal sex. Limitations and indications for screening for additional conditions should be discussed with your provider.

How accurate is NIPS?

NIPS is a screening test. While uncommon, some people may receive a positive result when the pregnancy is unaffected or a negative result when the pregnancy is affected. Testing for rarer conditions may negatively impact accuracy and increase the probability of a positive result being a false positive.[1] Any high-risk results should be confirmed with diagnostic laboratory testing.

Carrier Screening

What is a carrier?

A carrier is a person who has a genetic change, or mutation in their DNA, but, in most cases, does not have any associated health problems.

What does reproductive carrier screening test for?

Our test will help identify carriers for the main genetic disorders:

- Cystic Fibrosis (CF)
- Spinal Muscular Atrophy (SMA)
- Fragile X Syndrome (FX)*
- Hemoglobinopathy Screening (such as sickle cell anemia)
- Ashkenazi Jewish Panel
- Expanded Carrier Panel Options

Why test for these conditions?

CF, SMA, and FX are three of the most commonly inherited conditions. People are usually unaware that they are carriers and often do not have a history of these conditions in their family.

- CF is one of the most common life-limiting genetic conditions.
- SMA is the most common genetic cause of death in children under the age of two.
- FX is the most common form of inherited intellectual disability.

Results

Your results will be delivered to your provider, and he or she will discuss them with you. They will also be available to you in your SonicMyAccess™ patient portal.

Finding out about a genetic condition can raise important concerns around pregnancy planning and care. **If it is determined you have a high-risk pregnancy, a licensed genetic counselor will reach out to you to provide education about what your results mean.***

*Patients must be enrolled with SonicMyAccess™ and confirm their enrollment with our genetic counseling service to have the benefit of this offering.

For patient resources and consent forms, please visit www.SonicReproductiveHealth.com

Important Test Information
NIPS is a screening test, therefore false-negative or false-positive results can occur. Carrier conditions including but not limited to blood transfusion, organ transplantation, bone marrow transplant, certain surgical procedures, stem cell therapy, malignancy, or genetic mosaicism can affect test accuracy. Pregnancy-related conditions such as fetal or placental genetic mosaicism, nonviable twin, or fetal demise can decrease test accuracy. There are exceptional and uncommon situations, which is why NIPS should be regarded as a screening test. There is a small, well-defined possibility that NIPS will not reflect the actual chromosome status of the fetus. A "high-probability" result should be confirmed by invasive genetic testing before taking irreversible steps in the management of the pregnancy. A "low-probability" result may still warrant invasive genetic testing if there are other indicators of a fetal chromosome disorder. NIPS does not detect all genetic defects or non-genetic or structural birth defects. Conclusions about the fetal condition and pregnancy management decisions should not be solely based on the results of this screening test alone.

It is important to note that no pre-conception **carrier screen** is able to detect every mutation that might cause a genetic condition. The test does not detect every mutation that can cause cystic fibrosis, spinal muscular atrophy, and fragile X syndrome, or mutations in other genes responsible for other disorders. If no mutation is found, the risk of the patient being a carrier for these conditions is greatly reduced; however, the possibility cannot be eliminated. The patient's ethnicity may also affect carrier risk.

NIPS was developed and its performance characteristics determined by Sonic Reference Laboratory (SRL). It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. SRL is qualified to perform high-complexity testing under the Clinical Laboratory Improvement Amendments (CLIA).

*Routine reproductive carrier screening for FX in male patients is not recommended.

References

1. https://www.ajog.org/article/S0002-9378(17)31187-0/pdf

Advancing **Personalized Reproductive Care** With an Inclusive and Empowered Approach