FirstGene® – Multiple Prenatal Screen

Multiple Prenatal Screen

Myriad genetics®
prenatalsupport@myriad.com
(888) 268-6795

REQUIRED

Sample Collection Date:

_____/_____/_____

FirstGene barcode
Write number or apply sticker from kit here. Label date to the left.

Collect: (Three) 10mL STRECK tubes. **Required.**

Collect: (One) EDTA tube **Required.**

REQUIRED

Patient information

Myriad Genetics will use this information to contact the patient via e-mail, SMS and/or phone regarding payment, screen processing status, and online results access, or as otherwise outlined in the Informed Consent document. By submitting this requisition, I confirm that I have obtained the patient's express authorization to be contacted by Myriad through any of these means.

Patient e-mail address

Patient legal name (first) MI

Patient legal name (last)

Patient mobile number

Patient address

City State Zip

Sex at birth: ☐ Female ☐ Male
Sex assigned at birth is a label given to an individual at birth, typically "female" or "male".

____/____/____
Date of birth *(mm/dd/yyyy)*

Ethnicity, select all that apply:
- ☐ Northern European e.g. British, German
- ☐ Southern European e.g. Italian, Greek
- ☐ French Canadian or Cajun
- ☐ Ashkenazi Jewish
- ☐ Other/Mixed
- ☐ East Asian e.g. Chinese, Japanese
- ☐ South Asian e.g. Indian, Pakistani
- ☐ Southeast Asian e.g. Filipino, Vietnamese
- ☐ African or African American
- ☐ Hispanic
- ☐ Middle Eastern
- ☐ Native American
- ☐ Pacific Islander
- ☐ Unknown

REQUIRED

Clinic and provider information

Clinic name

Address

City, State, Zip

Phone

Fax

Ordering healthcare provider.
Select one or write in.

☐ _____
☐ _____
☐ _____
☐ _____
☐ _____

Authorization – Healthcare provider statement of medical necessity

By submitting this requisition, I confirm that I have obtained the patient's informed consent for the screening after pre-test counseling about the risks, benefits, and alternatives. The patient has had the opportunity to ask questions and has voluntarily decided to have this screen. Furthermore, I confirm that this Myriad screen is medically necessary for the patient. I understand that the definition of medical necessity may vary based on payer medical policy. I authorize the disease panel, the associated patient results, and report to be amended in accordance with payer medical policy.

Signature of healthcare provider ____/____/____ Date *(mm/dd/yyyy)*
This date will be deemed the date of service if an alternative collection date is not provided.

REQUIRED

Billing information - Select A, B, or C

Tests ordered will be processed and billed based on payer criteria.

☐ **Option A:** Bill to insurance *Attach a copy of the front and back of patient's insurance card.*

Policyholder's name

Relationship to insured:
☐ Self ☐ Spouse
☐ Child ☐ Other

Policyholder's sex at birth:
☐ Female ☐ Male

_____/_____/_____
Policyholder's date of birth *(mm/dd/yyyy)*

Authorization number
If obtained, please attach.

Member ID number

Insurance company name

Group number

☐ **Option B:** Bill to patient

☐ **Option C:** Bill to clinic

Pregnancy information

*FirstGene is **only** indicated for pregnant patients and singleton pregnancies.*
FirstGene is not available for pregnancies where a donor egg is used.
If there is a history of fetal demise and/or organ transplant, please contact Myriad.

REQUIRED Patient is pregnant? ☐ Yes Z34.90

Due Date:

____/____/____
(mm/dd/yyyy

____ft ___in Maternal height

_____lbs Maternal weight

NT Ultrasound date:

____/____/____
(mm/dd/yyyy)

____ mm NT

____ mm CRL

REQUIRED

Testing options – Patients must be at least 8 weeks pregnant.

☐ **FirstGene**

- Fetal aneuploidy analysis (trisomy 21, 18, 13)
- Fetal sex chromosome analysis (X, XXX, XXY, XYY)
- Fetal 22q11.2 deletion (DiGeorge syndrome)
- Recessive condition carrier screening (fetus and pregnant person)
- Fragile X syndrome carrier screening (pregnant person only)

Add to test:

☐ **Fetal RhD compatibility**
Add to test order for patients with a negative or unknown RH status.

Clinical indications – Codes are not exhaustive.

Describe relevant family history or prior testing

REQUIRED

- ☐ Advanced Maternal Age First Pregnancy O09.511, O09.512, O09.513
- ☐ Advanced Maternal Age Other Pregnancy O09.521, O09.522, O09.523
- ☐ Supervision of Other Normal Pregnancy Z34.81, Z34.82, Z34.83
- ☐ Supervision of Other High Risk Pregnancy O09.891, O09.892
- ☐ Carrier screening status Z31.430
- ☐ Partner genetic carrier screening Z31.440
- ☐ Chromosome screening Z36.0
- ☐ Abnormal ultrasound O28.3
- ☐ Abnormal serum screening O28.5
- ☐ Suspected chromosomal abnormality in fetus O35.05X1, O35.10X1
- ☐ Family history of inherited disease Z84.89
- ☐ Congenital malformations and chromosomal abnormalities Z82.79
- ☐ Intellectual disabilities Z81.0
- ☐ Consanguinity Z84.3
- ☐ Suspected chromosomal abnormality in previous pregnancy O35.2XX1
- ☐ History of genetic abnormality O09.291, O09.292, O09.293
- ☐ Other: _____

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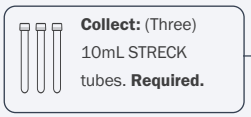
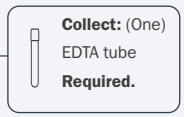
1. Confirm the information is complete and legible on the front and back.

2. Place this form in the kit along with the sample(s). Incomplete information may delay sample processing.



Collect: (Three) 10mL STRECK tubes. **Required.**



Collect: (One) EDTA tube **Required.**

Purpose

The FirstGene screen is a prenatal cell-free DNA (cfDNA) screen that uses a blood sample from a pregnant patient to concurrently assess:

- The pregnant patient's carrier status for certain single-gene conditions
- Fetal status regarding the same single-gene conditions
- Fetal chromosome screen regarding common chromosomal abnormalities
- Fetal RhD status and compatibility

The conditions assessed in the FirstGene screen can lead to health issues including birth defects, intellectual disabilities, and pregnancy complications. The severity of these can vary.

Benefits

Carrier screening results from the FirstGene screen may help the patient and healthcare provider by informing the need for obstetric oversight regarding current and future pathways. Carrier screening results may also benefit other family members. If the patient is identified as a carrier of a recessive condition, their biological relatives are more likely to test positive for the same mutation(s), thereby allowing them to discover previously unknown conditions and risks.

Fetal recessive disease and chromosomal risk assessments can help the patient make more informed medical management decisions. If it is early in pregnancy, they can pursue further testing to determine if the pregnancy is affected and receive guidance from their healthcare providers about how to best plan and prepare for birth.

Fetal RhD screening can help assess the risk for complications in pregnancy that can occur as a result of maternofetal rhesus incompatibility. Patients should speak with their healthcare provider to determine the most appropriate treatment options when there is a risk of maternofetal rhesus incompatibility.

What you might learn

With the FirstGene screen, fetal risk assessments use DNA from the pregnant patient as well as cfDNA to assess the risk of certain fetal chromosomal abnormalities and certain recessive conditions.

All "positive" results should be discussed with a healthcare provider to determine next steps, including considering pursuing diagnostic testing (such as chorionic villus sampling (CVS) and/or amniocentesis) and additional evaluation, as well as genetic counseling. While follow-up testing is recommended according to professional guidelines, the decision of whether to pursue additional testing belongs to the patient and should be made in consultation with their healthcare provider.

Negative results significantly reduce, but cannot eliminate, the risk for either the pregnant patient to be a carrier for the recessive conditions screened or the possibility of the pregnancy to be affected by one of the chromosomal or recessive conditions screened and do not guarantee a healthy pregnancy/child.

Risks

Genetic testing may reveal sensitive information about the patient's health and their family members, as well as their reproductive partner and their family members.

Results may provide information that can have an impact on the patient's medical decisions.

Results may lead to the patient's healthcare provider recommending additional testing and evaluation of the pregnancy or otherwise impact medical decisions.

Limitations

Prenatal screening may reveal sensitive information about the health of the pregnancy. The FirstGene fetal chromosome screen is designed to detect most pregnancies in which the fetus has one of the chromosome conditions listed above but does not detect or look for all known genetic diseases, syndromes, or birth defects.

The FirstGene carrier screen and fetal single gene screen are designed to detect deleterious mutations associated with recessive conditions. It cannot detect every mutation, nor does it look for all known genetic diseases or syndromes.

The FirstGene fetal RhD screen is designed to detect fetal RhD deletions. It cannot detect all genotypes associated with RhD negative status, nor does it look for all causes of maternofetal rhesus incompatibility.

As with all medical screening tests, there is a risk of error, including a false positive or false negative result.

Alternatives

There are various options available that provide insight into the carrier status of a pregnant person, the genetic health of the pregnancy, and maternofetal rhesus incompatibility. These should be discussed with the patient's healthcare provider.

Diagnostic testing, such as chorionic villus sampling (CVS) or amniocentesis, can provide definitive information about the genetic health of the pregnancy.

As all screening for genetic conditions and chromosome differences is completely voluntary, a patient has the right to decline all such tests.

Test component	Component details
Fetal chromosome screen	Fetal aneuploidy analysis (trisomy 21, 18, 13) Fetal sex chromosome analysis (X, XXX, XXY, XYY) Fetal 22q11.2 deletion (DiGeorge syndrome)
Fetal single gene screen	CFTR, PMM2, HBB, HEXA, ACADM, ASPA, DHCR7, PAH, ELP1, GAA, CPT2, PKHD1, MMUT, GALT, MMACHC, GNPTAB, CBS **only evaluated as reflex:** SMN1, HBA1/HBA2 (Hb Bart syndrome)
Patient carrier screen	CFTR, PMM2, HBB, HEXA, ACADM, ASPA, DHCR7, PAH, ELP1, GAA, CPT2, PKHD1, MMUT, GALT, MMACHC, GNPTAB, CBS, SMN1, HBA1/HBA2 (Hb Bart syndrome) FMR1 patient only
Optional: Fetal RhD screen	Fetal RhD compatibility for patients whose Rh status is negative or unknown

Authorized representative

By providing the below contact, I confirm that the patient has expressly consented to Myriad sharing the patient's protected health information, including screening results and billing information, with the person listed upon request. This authorization will expire 180 days from the date signed unless otherwise specified by the patient.

Name _____ Relationship _____