



WOMEN'S HEALTH AND GENETICS

Labcorp Genetic Carrier Screening

Comprehensive insights for every
reproductive journey



Advancing patient care through a comprehensive continuum of testing, workflow solutions, and expert support

Early detection changes outcomes. When you have comprehensive genetic insights integrated with seamless follow-up care, you can identify risks earlier, manage pregnancies more effectively, and improve neonatal outcomes.

Labcorp Genetic Carrier Screening delivers this integrated approach, connecting screening, diagnostic testing, and expert genetic counseling in one streamlined ecosystem. Fewer handoffs. Less administrative burden. More time for patient care.

The case for broad, ethnic-neutral carrier screening

- “Carrier screening paradigms should be ethnic and population neutral and more inclusive of diverse populations...”¹ – American College of Medical Genetics and Genomics (ACMG)
- Carrier screening for cystic fibrosis (CF), spinal muscular atrophy, and the hemoglobinopathies (sickle cell disease, beta and alpha thalassemia) “should be offered to all women who are considering pregnancy or are currently pregnant.”²⁻³ – American College of Obstetricians and Gynecologists (ACOG)
- Approximately 1% to 2% of all couples are at risk of having a child affected with a severe recessive genetic disorder⁴

Beyond ethnicity and family history

The absence of family history for genetic disease is not an indicator of decreased risk for having an affected child. For example, more than 80% of infants with CF are born to families with no prior family history.⁵

People may not know their family history or ethnic background⁶

Everyone carries three to five genetic variants that, if inherited by a child from both parents, could lead to a genetic disorder⁷



Comprehensive options for provider-patient shared decision-making

With both ethnic-neutral and multi-ethnic panel options, Labcorp Carrier Screening reflects the evolving needs of providers, patients, and the latest society recommendations.

Panel	Panel Description	Gene Count
Inheritest CF/SMA Panel	Screens for cystic fibrosis and spinal muscular atrophy, two of the more common genetic disorders recommended for general population carrier screening by medical societies ²	2
Inheritest Core Panel	Screens for cystic fibrosis, spinal muscular atrophy, and fragile X syndrome, some of the more common genetic disorders	3
Labcorp 14-Gene Carrier Panel	Includes disorders associated with ethnicities listed in ACOG recommendations	14/13*
Labcorp High Frequency Carrier Panel	Includes 110 of the 113 genes included in the ACMG Tier 3 category (> 1/200 carrier frequency)	110/96*
Labcorp 100 PLUS Carrier Panel	Includes analysis of more than 100 clinically relevant genetic disorders	142/136*
Labcorp 300 PLUS Carrier Panel	Covers more than 300 clinically relevant genetic disorders, including all the genes in the 14-Gene and 100 PLUS Panels as well as additional genes in the ACMG Tier 3 category, focusing on high-frequency disorders	349/327*
Labcorp 500 PLUS Carrier Panel	Expanded coverage of more than 500 clinically relevant genetic disorders, including all genes on the 300 PLUS Panel	574/530*
Labcorp 790 PLUS Panel/700 PLUS Panel	Expanded coverage of more than 790 clinically-relevant genetic disorders, including all genes on the 500 PLUS Panel	794/719*

*Number of genes on a panel without X-linked disorders

Clinically relevant gene coverage

More than 790 disorders covered by Labcorp Carrier Screening were thoughtfully selected by our clinical and scientific team, taking into consideration:

- ACOG and ACMG society guidance and practice resources
- Inclusion of multiple known recessive and X-linked genes causing each disorder when possible
- Disorders that can affect quality of life, require medical management, or decrease life expectancy
- Disorders that may be severe and of early onset, those which are degenerative and progressive, and those which can cause intellectual disability, visual impairment, deafness or hearing loss
- Metabolic disorders that may benefit from early medical intervention

Cutting-edge science and methodology

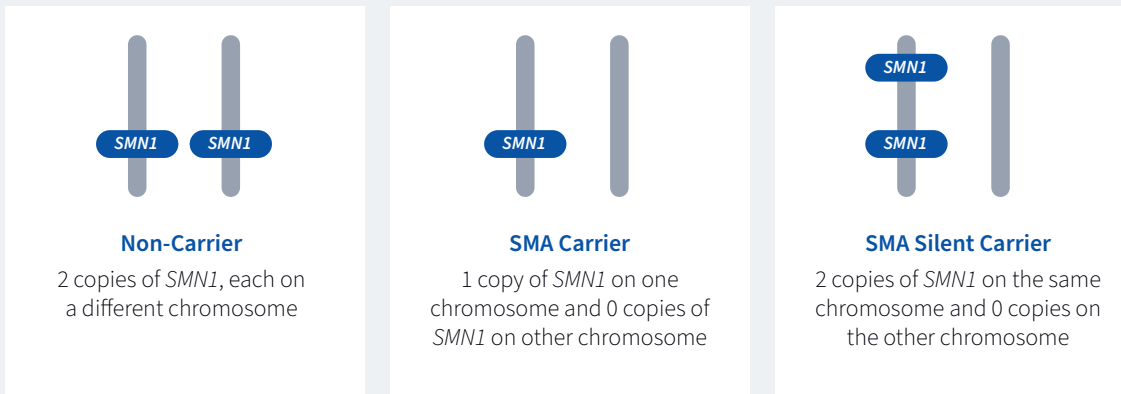
Advanced sequencing technology and appropriate confirmations for greater accuracy

- Full-gene sequencing with 99% detection rates for most genes, and deletion/duplication analysis (copy number variant [CNV] calling)
- Positive results are confirmed with an orthogonal technology consistent with ACMG guidelines to deliver optimal sensitivity and specificity

Enhanced SNP analysis to identify patients at risk to be silent (2+0) SMA carriers

- Potential identification of more couples at risk for having a child with SMA⁸
- Enhanced residual risk estimates to inform genetic counseling and support patient education⁸
- Improved prenatal and neonatal management, including early diagnosis and early referral for new therapies

SMN1 gene in normal and carrier states

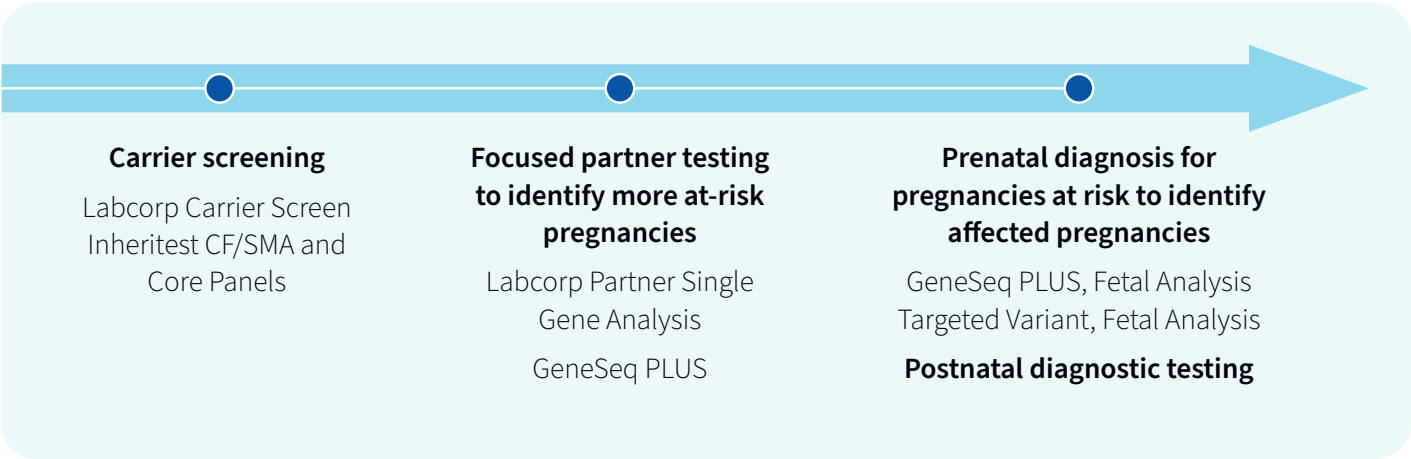


One fast result for fragile X risk assessment

Comprehensive and integrated fragile X analysis with CGG and AGG repeats reported at the same time.



Continuity of care and streamlined workflows



Our testing continuum delivers an efficient process flow for all patient backgrounds and needs, helping to save time and reduce anxiety for your patients.

Comprehensive partner testing

If your patient's result is positive, a comprehensive analysis of a requested gene can be performed for the partner with Labcorp Partner Single Gene Analysis or GeneSeq PLUS (for CF/SMA or Core panels).

- This analysis, recommended by ACMG,¹ helps identify more carriers and a greater number of potentially at-risk pregnancies compared to panel testing
- Available for most genes in the Labcorp panels*[†]
- Reports variants including pathogenic, likely pathogenic, deletions and duplications, contributing to high detection rates
- Screening in the presence of family history

*GeneSeq PLUS is not available for SMA. Please order Spinal Muscular Atrophy (SMA) for follow-up partner testing.

[†] Full-gene sequencing for HBA1/HBA2, CYP21A2, GBA, and FMR1 is not currently available.



Reporting options

Labcorp Reproductive Risk Summary provides a couple's risk assessment by combining carrier results from each partner. The summary is affixed to an individual carrier report.**

- The summary can be ordered for either or both partner(s) via test code 898196 but will only be issued to the patient for whom it is ordered
- Both members of the couple must be tested with a Labcorp Carrier Panel, or a panel and a Labcorp Partner Single Gene Analysis
- The summary must be ordered with a carrier panel/test. It cannot be ordered on its own
- Contact client services to add the summary to any order that has already been resulted out



Results unmasking

We offer the ability to unmask results for panels that include 15 or more genes without the need for a new sample and at no additional cost.†

Prenatal diagnosis

Our end-to-end continuum of patient care saves time and reduces anxiety. Once an at-risk pregnancy is identified, prenatal diagnostic testing is available for most genes in the Labcorp Carrier Screening panels to deliver insights regarding the baby's possible condition.

Prenatal diagnosis is available:






- When both a patient and partner are found to be carriers of the same disorder, or a patient is a carrier for an X-linked disorder
- When a patient is a carrier for a recessive disorder and the partner is unavailable for testing

**Please note test requisition includes an attestation that by providing a partner's name and DOB, consent to the creation of a merged summary has been obtained from both partners. For clients utilizing an EMR, Ask at Order Entry (AOE) questions have been created to collect the partner's name and DOB in addition to attestation of consent and authorizations.

† Subject to restrictions based on the original sample receipt date.






Supporting your practice

Physician services and ease-of-use solutions help streamline your workflow, saving valuable time and allowing you to focus on patient care.

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 - **Connectivity solutions:** Interfaces with hundreds of EMR/LIS solutions to help your practice with test ordering and results delivery
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 - **Results reporting:** Turnaround time of 10-21 days (from date of sample pickup)
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 - **Genetic counseling:** A broad menu of comprehensive and customizable genetic counseling services for prenatal, preconception and infertility
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 - **Labcorp Link™:** View, share, manage and analyze lab results. Anytime, anywhere
- 
 - **Labcorp Diagnostic Assistant™:** Provides the most complete view of a patient’s lab results history while delivering actionable, evidence-based guidelines and lab-based clinical insights to facilitate informed clinical decision-making

Supporting your patients

Patients can benefit from our network of genetic counseling services, broad managed care coverage, and convenient options for sample collection as well as educational resources and out-of-pocket cost transparency.

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 - **More than 2,000 patient service centers:** For convenient access to specimen collection sites including select Walgreens locations. Convenient home diagnostic test collection service in collaboration with Getlabs
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 - **Extensive in-network coverage:** Labcorp is in network with most major health plans, helping your patients maximize their benefits and save on out-of-pocket costs. Based on our internal billing data, most patients pay \$0
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 - **Genetic counseling:** A national network of over 100 board-certified and state-licensed genetic counselors dedicated to patient care. Visit our online scheduler at womenshealth.labcorp.com or call 855-422-2557
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 - **iGeniE:** Our innovative digital assistant is designed to help simplify your process for pre-test education and deliver carrier screening results to your patients
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 - **Patient Engagement Program:** Individualized support to help patients understand their insurance and out-of-pocket costs. We have flexible programs to meet individual patient needs because we believe our tests should be accessible for all. Send your patients to womenshealth.labcorp.com/estimatemycost or have them call us toll-free (within the U.S.) 844-799-3243. We will take it from there

Comprehensive genetic counseling services

Access genetic counselors

- National network of board-certified and state-licensed genetic counselors
- Testing supported by team of scientists, including 15 lab directors and ~35 lab-based genetic counselors, as well as 100+ genetic counselors dedicated to direct interaction with patients
- In-person and telegenetics (telephone and televideo) services
- Counseling in many languages

Personalized patient support

- Comprehensive genetic counseling (reproductive, including prenatal and fertility)
- Genetic results counseling and results reporting including iGeniE
- Genetic education video series
- Scheduling services and text message reminders
- Donor risk assessment

Labcorp has been a leader in providing genetic counseling services for more than 25 years



Test No.	Test Name	No. of Genes
481758	Inheritest CF/SMA Panel	2
481776	Inheritest Core Panel	3
898123	Carrier Panel 12;5 Genes	5
898549	Carrier Panel J;6 Genes	6
898099	Labcorp 14-gene Carrier Panel	14
898154	Labcorp 13-gene Carrier Panel (No X-Linked)	13
898100	Labcorp High Frequency Carrier Panel	110
898155	Labcorp High Frequency Carrier Panel (No X-Linked)	96
898101	Labcorp 100 PLUS Carrier Panel	142
898156	Labcorp 100 PLUS Carrier Panel (No X-Linked)	136
898102	Labcorp 300 PLUS Carrier Panel	349
898157	Labcorp 300 PLUS Carrier Panel (No X-Linked)	327
898103	Labcorp 500 PLUS Carrier Panel	574
898158	Labcorp 500 PLUS Carrier Panel (No X-Linked)	530
898104	Labcorp 790 PLUS Carrier Panel	794
898585	Labcorp 700 PLUS Carrier Panel (No X-Linked)	719
898105	Labcorp Partner Single Gene Analysis	Most genes
898196	Labcorp Reproductive Risk Summary*	N/A
Order w/AOE	Labcorp Carrier Opt-in Panel	10/11
482370	GeneSeq PLUS (partner testing for Inheritest panels)	Most genes
482389	GeneSeq PLUS, Fetal Analysis	Most genes
482552	Targeted Variant Analysis	Most genes
482534	Targeted Variant, Fetal Analysis	Most genes

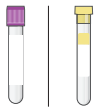
*Not available for Inheritest CF/SMA and Core panels.

Continuity of care, pioneering science and seamless workflow

Labcorp delivers continuity of care for your patients, from carrier screening to prenatal cell-free DNA screening (NIPT) to prenatal and pediatric diagnostic testing.

We provide the scientific expertise you need and the customer experience patients want.

Blood:



- **Inheritest panels, GeneSeq PLUS and Targeted Variant Analysis:** 4 mL whole blood in lavender-top (EDTA) tube or yellow-top (ACD-A) tube

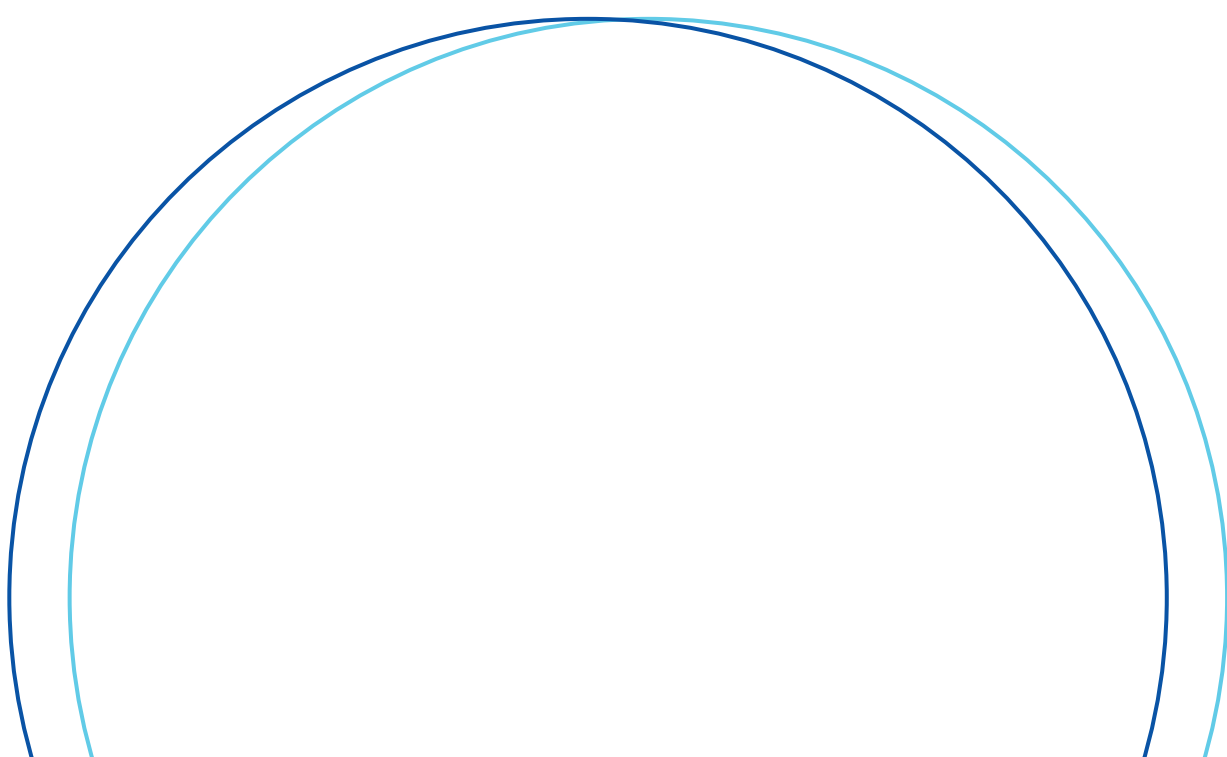


- **Labcorp Carrier Panels and Labcorp Partner Single Gene Analysis:** 4 mL whole blood in lavender-top (EDTA) tube

Saliva:



- Saliva specimens are accepted in Oragene®•Dx saliva collection kits. To order saliva kits, please contact your sales representative or client services at 800-848-4436.





To view all available panels and disorders included in Labcorp Carrier Screening, please visit womenshealth.labcorp.com/providers/carrier-screening.

References

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Learn more about our genetic counseling services at:

womenshealth.labcorp.com/providers/services/genetic-counseling

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