



NewBornGene ID™
Genetic Carrier Testing

NewBornGene ID™

lets you leverage **cutting edge technology** and the **latest science** to reduce the incidence of devastating inherited diseases

NewBornGene ID™

is a noninvasive genetic test for women and men of reproductive age who are planning to start or expand their family




The test can identify your patients who are “Carriers” for devastating genetic diseases such as cystic fibrosis, spinal muscular atrophy, sickle-cell anemia and Tay-Sachs



**DEVASTATING
HEREDITARY
CONDITIONS
OFTEN OCCUR
WITHOUT
WARNING**



**A SIMPLE TEST IN YOUR OFFICE CAN INFORM
YOUR PATIENTS IF THEY ARE AT AN INCREASED RISK**



NewBornGene ID™ is a non-invasive genetic test which can identify your patients who are “carriers” for more than 60 devastating diseases

Did you Know

- 🧬 American College of Medical Genetics (ACMG), and American College of Obstetricians and Gynecologists (ACOG), recommend Carrier Screening for **ALL** patients of reproductive age looking to start or expand their family
- 🧬 Roughly 1 in 4 people in your practice are carriers for an inherited genetic disease
- 🧬 Genetic diseases “carriers” display no symptoms and therefore are not identifiable without testing
- 🧬 Many people only find out that they are carriers when they have a child who inherits the disease
- 🧬 Approximately 80% of all hereditary recessive diseases occur in families with no known history of the disease
- 🧬 Genetic diseases account for 20% of infant mortality and 18% of infant hospitalizations in the US¹
- 🧬 Many of these diseases can be prevented by simply identifying high-risk couples and taking steps to mitigate reproductive risk
- 🧬 Carrier Screening works! In targeted populations where testing is widespread, the incidence of disease has been reduced by as much as 90%²

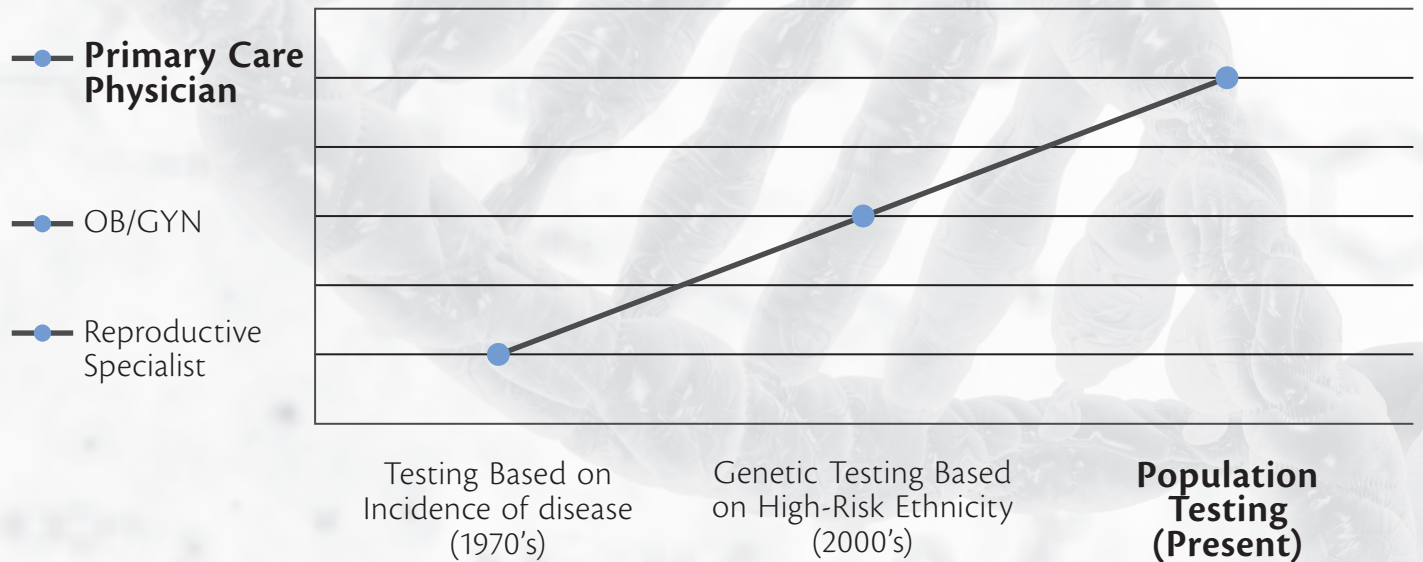
1 Lazarin, Gabriel A., and Imran S. Haque. “Expanded carrier screening: A review of early implementation and literature.” *Seminars in Perinatology*. WB Saunders, 2015


2 Mitchell, John J., et al. “Twenty-year outcome analysis of genetic screening programs for Tay-Sachs and beta-thalassemia disease carriers in high schools.” *American journal of human genetics* 59.4 (1996): 793.



Primary Care Physicians have been identified as one of the specialties that will offer most carrier screening tests³

New technology has created a paradigm shift in genetic testing, which has brought testing to the Primary Care Physician



 Primary Care Physicians are the front line of patient care and disease prevention




 As genetic testing has become more affordable and more widespread, it has become another tool in the Primary Care Physician's Toolkit

³ Edwards, Janice G., et al. "Expanded Carrier Screening in Reproductive Medicine—Points to Consider: A Joint Statement of the American College of Medical Genetics and Genomics, American College of Obstetricians and Gynecologists, National Society of Genetic Counselors, Perinatal Quality Foundation, and Society for Maternal-Fetal Medicine." *Obstetrics & Gynecology* 125.3 (2015): 653-662.



Roughly 1 in 4 people in your practice are carriers for an inherited genetic disease such as:

Cystic Fibrosis

-  Caucasian – 1 : 25
-  Ashkenazi Jewish – 1 : 24
-  Hispanic – 1 : 58




Spinal Muscular Atrophy

-  General Population – 1 : 40

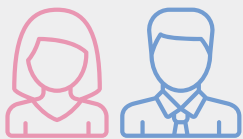
Sickle-Cell Anemia

-  African-American – 1 : 14

Tay Sachs Disease

-  Ashkenazi Jewish – 1 : 27
-  Cajun – 1 : 30
-  French Canadian – 1 : 70




Patient Profiles

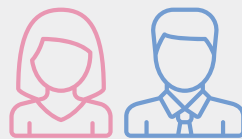


Mom is French Canadian

Dad is Caucasian

High risk of being a carrier for:

-  Cystic Fibrosis
-  Spinal Muscular Atrophy
-  Tay-Sachs

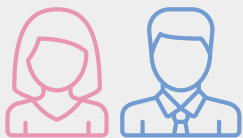


Mom is African American

Dad is of Hispanic and French descent

High risk of being a carrier for:






-  Cystic Fibrosis
-  Spinal Muscular Atrophy
-  Sickle-Cell Anemia
-  Alpha Thalassemia
-  Beta Thalassemia

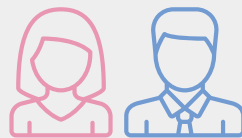


Mom is Ashkenazi Jewish

Dad is Ashkenazi Jewish

High risk of being a carrier for:



-  Cystic Fibrosis
-  Tay-Sachs
-  Canavan Disease
-  Niemann-Pick (type A)
-  Bloom Syndrome
-  Fanconi Anemia (group C)
-  Mucopolidosis IV
-  Gaucher Disease
-  Spinal Muscular Atrophy



Mom is Caucasian and French Canadian

Dad is from Greece

High risk of being a carrier for:

-  Cystic Fibrosis
-  Spinal Muscular Atrophy
-  Tay-Sachs
-  Sickle-Cell Anemia
-  Alpha Thalassemia
-  Beta Thalassemia



NewBornGene ID™
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Simple Testing Process:

- It is easy to identify appropriate patients:
 - Most Commercial and Medicaid insurances cover Carrier testing as a “Population Based” test
- Testing is Non-Invasive, utilizing a mouth rinse that takes just 20-30 seconds
- Easy to Interpret Results returned in approximately 2 weeks after insurance verification
- Studies show that patients remember their results and act on them at the appropriate time⁴
- MD/PhD’s on staff to answer any questions you may have about test results or communicating with patients

What to do with the Results?

- Approximately 15%-20% of patients will test “positive” as a carrier
- Patients who test positive should have their partner tested
- If both partners test positive for the same disease, they should be referred to a Genetic Counselor and/or Reproductive Specialist

Family Planning Options include:

Pre-Conception

- Conceive Naturally
- In-Vitro Fertilization with Pre-Implantation Diagnosis (PGD)
- Utilize an Egg or Sperm Donor
- Adoption
- Choose not to have (additional) children

Post-Conception

- Pre-Natal Screening

⁴ Mitchell, John J., et al. “Twenty-year outcome analysis of genetic screening programs for Tay-Sachs and beta-thalassemia disease carriers in high schools.” American journal of human genetics 59.4 (1996): 793.



Collection Process

- 🧬 **Identify appropriate patients** who are considering having children by reaching out to them using our screening pad, poster, email or discussing carrier testing with patients in the office
- 🧬 **Educate** patients about testing. This can be done verbally, by displaying the GenelD brochures and/or by showing them the brief **NewBornGene ID™** video
- 🧬 **Collect the patient's DNA** sample using the mouthwash and tube included in each kit (full collection instructions included in each kit)
- 🧬 **Fill out** Requisition and Consent forms and signed by the patient and doctor
- 🧬 **Include** any medical records and a signed letter of medical necessity
- 🧬 **Write** the patients name and initials on the collection tube
- 🧬 **Place** the sample and forms into the GenelD envelope, and place the GenelD envelope into the FedEx envelope
- 🧬 **Attach** our prepaid label
- 🧬 **Call FedEx** to schedule a pickup

We will take over from here...



The Benefits of Using Next-Generation Sequencing

The advent of Next-Generation Sequencing (also called “Massively Parallel Sequencing”) has led to significant reductions in the cost of genetic testing. As the name “Massively Parallel” indicates, it is able to read millions of sections of DNA at the same time. The cost reduction has also enabled significant improvements in genetic testing. Cost considerations tied to traditional genotyping mean that most other companies offering carrier testing are forced to limit their test to include only the most common mutations. This significantly increases the likelihood of false negatives.

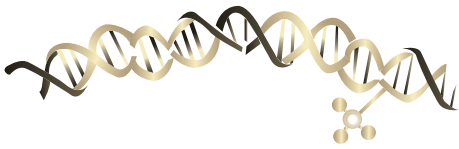
GenelD uses Next-Generation Sequencing to look for thousands of different mutations, reducing the likelihood of false negatives.



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A Division of GeneID Lab



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