NewBornGene ID™
Genetic Carrier Testing

"The doctor of the future will give no medication, but will interest his patients in the care of the human frame, diet and in the cause and prevention of disease."

- Thomas Alva Edison

NewbornGeneID™ Genetic Carrier Testing

NewBornGene ID™ is a non-invasive genetic test for men and women 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 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 disease "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 US[1]
- 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]

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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.

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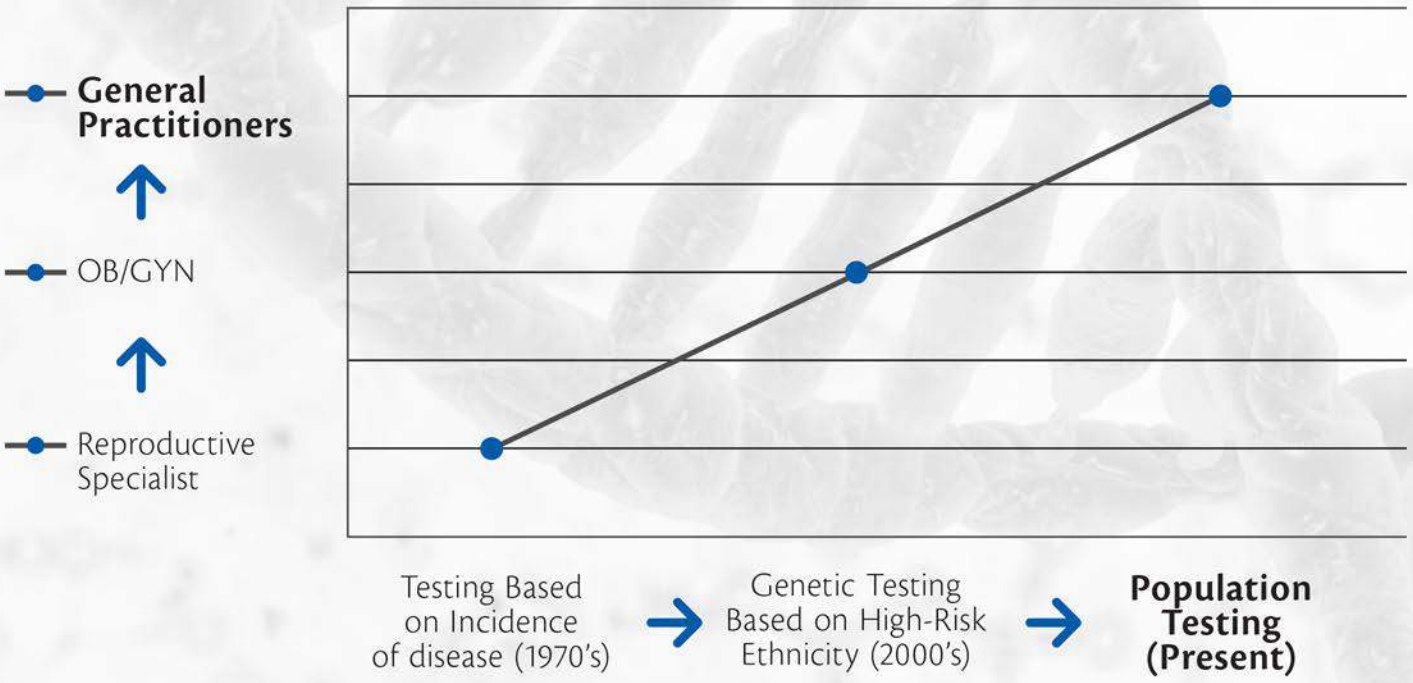
The Prevention Specialist

General Practitioners have been identified as one of the specialists that will offer most carrier screening tests[3]

New technology has created a paradigm shift in genetic testing, which has brought testing to General Practitioners



"The evidence strongly shows that it is in primary care that preventative interventions are best..." [4]

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

4 Starfield, B., SHI, L. and Macinko, J. (2005), Contribution of Primary Care to Health Systems and Health. Milbank Quarterly, 83: 457–502. doi: 10.1111/j.1468-0009.2005.00409.x

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Roughly 1 in 4 people in your practice may be 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 : 10
- Tay Sachs Disease
  - Ashkenazi Jewish – 1 : 27
  - Cajun – 1 : 30
  - French Canadian – 1 : 30

Patients from all countries and ethnicities are at risk for genetic diseases:

Mom is French Canadian

Dad is Caucasian

High risk of being a carrier for:

- Cystic Fibrosis
- Spinal Muscular Atrophy
- Tay-Sachs
- Phenylketonuria

Mom is African American

Dad is of Hispanic and Caucasian 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:

- Bloom Syndrome
- Canavan Disease
- Cystic Fibrosis
- Familial Dysautonomia
- Gaucher Disease
- Tay-Sachs Disease
- Maple Syrup Urine Disease Type 1A and 1B
- Mucolipidosis IV
- Niemann-Pick disease Type A
- Spinal Muscular Atrophy

Mom is of Caucasian and Cajun descent

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

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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 time[5]
- MD/PhD's on staff to answer any questions you may have about test results or communicating with patients

Simple (To Understand) Reports

- Approximately 20%-25% 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		Post-Conception
Conceive naturally	Using a sperm or egg donor who is not a carrier	Pre-Natal Screening
In vitro fertilization; testing the embryo for genetic diseases before it is implanted (PGD — Pre-implantation Genetic Diagnosis)	Adoption	
	Choose not to have children	

5 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.

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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 GeneID 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 and sign** Requisition and Consent forms
- **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 GeneID envelope, and place the GeneID 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.

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

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