THE ONLY

Carrier Screen WITH Reflex Single-Gene NIPT FOR

- Cystic Fibrosis
- Spinal Muscular Atrophy
- Sickle Cell Disease
- Thalassemias

98.5% SENSITIVE
99% SPECIFIC

COVERS ALL ACOG-RECOMMENDED[3] INHERITED DISORDERS

UNITY

POWERED BY Billion To One

UNITY™ is the only single-gene NIPT supported carrier screen that uses a single sample of the mother's blood

to determine a mother's carrier status *and* fetal risk for cystic fibrosis, spinal muscular atrophy, sickle cell disease, and thalassemias.

Identify high risk pregnancies early, easily, and accurately.

TRADITIONAL WORKFLOW

2 WEEKS

11% POSITIVE

2 - 4 WEEKS

2 - 6 WEEKS

CARRIER SCREEN
Test Maternal DNA

Mother is screened to see if she is a carrier for a condition.

FOLLOW-UPS
Paternal DNA

Coordinating **paternal DNA testing can be logistically and financially challenging.** 40% of US pregnancies are single mothers.

Invasive Diagnostic Tests

95% of women who are carriers DO NOT have an affected pregnancy.

UNITY™ WORKFLOW

2 WEEKS

<1% POSITIVE

UNITY™ reduces follow-up cases by **10X**

CARRIER SCREEN
Test Maternal DNA

IF POSITIVE
REFLEX NIPT
Test Cell-Free Fetal DNA

When a mother is identified as a carrier, **reflex NIPT is automatically performed** to determine whether the fetus is at increased risk for the condition.

UNITY™: ACCURACY YOU CAN COUNT ON

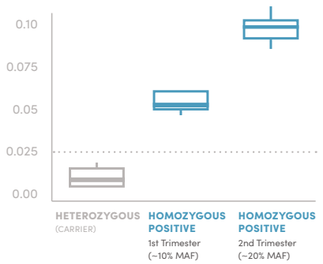
98.5+% sensitivity
99+% specificity [4]

- Carrier screening portion of UNITY is NGS based and meets the highest industry standards. We perform full gene sequencing on CFTR. We detect SMN1 silent carrier.
- NIPT portion of UNITY has >98.5% analytical sensitivity and >99% specificity.

100% accuracy in two clinical trials [4]

- At a **NIH-funded study with Baylor College of Medicine** [5], 50+ samples were processed and 15 "high risk" pregnancies were identified. Newborn screening confirmed all NIPT calls were correct.
- At a joint study with **Yashoda Hospital in India**, 200+ samples were processed and 27 "high risk" pregnancies were identified. Testing after birth confirmed all NIPT calls were correct.

HOW UNITY™ WORKS [4]



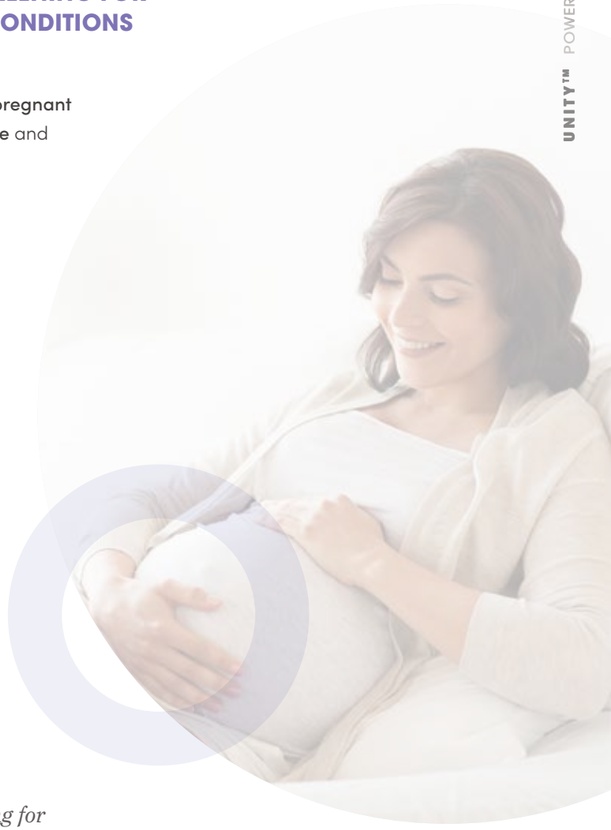
UNITY™ performs carrier testing on the pregnant mother using next-generation sequencing followed by confirmatory Sanger sequencing. For copy number variations, especially in SMA and alpha-thalassemia, digital MLPA is performed. If the result is positive, cell-free DNA is analyzed for the number of molecules with mutations and those without mutations by transforming next-generation sequencing data to digital molecular counts. BillionToOne is the **only NIPT provider for detecting recessive conditions without requiring paternal DNA**.

UNITY™ COVERS CARRIER SCREENING FOR ALL ACOG-RECOMMENDED CONDITIONS

UNITY™ provides carrier screening for **pregnant** and **non-pregnant** samples from **female** and **male** patients. Reflex single-gene NIPT [6] is available for **ACOG-recommended disorders**:

- Cystic fibrosis (CFTR)
- Spinal muscular atrophy (SMN1)
- Sickle cell disease (HBB)
- Alpha and beta-thalassemia (HBA1, HBA2, HBB)

In addition, expanded carrier screening (43 genes, NGS panel) is available for individuals of Ashkenazi Jewish, French Canadian, and Cajun descent. [7]



> *"In addition to existing guidance recommending universal screening for cystic fibrosis, all women should also be offered screening for spinal muscular atrophy (SMA).*
>
> — ACOG committee opinion 691, issued March 2017 [3]

UNITY™ IN SUMMARY

ACCURATE & NON-INVASIVE

- Accurately screen cell-free fetal DNA when the mother is identified as a carrier from the same blood sample
- Reduce the need for paternal screening and prenatal diagnosis by **over 90%**
- >98.5% sensitivity and >99% specificity [4]

EFFICIENT & CONVENIENT

- Reduce unnecessary clinic follow-up **by 90%**
- Access results in just 10 days, as early as week 10 of pregnancy [1]
- **Only one tube of maternal blood** needed [1]

AFFORDABLE & PATIENT-FRIENDLY

- **We accept all insurance including Medicaid.** We bill using existing CPT codes for carrier screening. Financial assistance program available for patients from all income level
- Access **complimentary genetic counseling** for all patients

COVERS ALL ACOG-RECOMMENDED DISORDERS

- Standard carrier screen performed for all ACOG-recommended disorders prior to reflex NIPT
- Screen every sample for SMA
- Expanded carrier screening for patients of Ashkenazi Jewish, French Canadian, and Cajun descent

UNITY™ IN YOUR PRACTICE

STEP 1 **Order UNITY™**

STEP 2 **Collect Blood Sample**
Collect just one tube of maternal blood [1].

STEP 3 **Ship Sample**
Ship the sample using pre-labeled kit.

STEP 4 **Receive Results in 2 Weeks**
Results sent to physician within 2 weeks. Access test results online.

STEP 5 **Access Complimentary Genetic Counseling**
Complimentary genetic counseling sessions are available for all patients.

IMPORTANT NOTE

While positive carrier testing results are confirmed by Sanger sequencing, reflex noninvasive prenatal tests based on cell-free DNA are not diagnostic. Irreversible pregnancy decisions should not be considered without further confirmatory diagnostic testing.

The carrier screen panel is designed to detect the most common pathogenic alleles for cystic fibrosis, spinal muscular atrophy, sickle cell disease, alpha-thalassemia, and beta-thalassemia. Sensitivity of carrier screening for these disorders is >95%. We currently do not offer single-gene NIPT reflex test on Tay-Sachs, Canavan disease or Familial dysautonomia. Single gene NIPT is not reported when the fetal fraction is <5% or when the amount of cell-free DNA in the blood sample is too low.

UNITY™ has been developed and its performance characteristics have been determined by BillionToOne, Inc. BillionToOne conducts all patient testing in its laboratory that is under the purview of the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. UNITY™ test has not been cleared or approved by the U.S. Food and Drug Administration. UNITY™ is currently not available in New York State.

UNITY by Billion To One

UNITY™ is performed by BillionToOne, the only combined carrier screen and single-gene NIPT provider that is able to detect recessive conditions. BillionToOne is a venture-backed, precision diagnostics company based in Menlo Park, California. BillionToOne's patent-pending molecular counter platform increases the resolution of cell-free DNA detection by over 1,000-fold.

CITATIONS

1. Small number of cases require a secondary draw, which include when the gestational age is under 10 weeks, the fetal fraction is less than 5%, or when the test is inconclusive
2. Committee Opinion No. 690 Summary: Carrier Screening in the Age of Genomic Medicine." 2017.Obstetrics and Gynecology 129 (3): 595–96.
3. Carrier Screening in the Age of Genomic Medicine. Committee Opinion 690. ACOG. Obstet Gynecol 2017;129:e35–40.
4. Tsao et al., 2019 "A novel high-throughput molecular counting method with single base-pair resolution enables accurate single-gene NIPT" [Preprint] Available from unityscreen.com/publication
5. Funded by the National Heart, Lung, and Blood Institute of the National Institute of Health under award number R43HL144322
6. Offered to pregnant women with singleton pregnancies ≥10 weeks gestation, excluding egg donors and surrogates.
7. Offered to Ashkenazi Jewish, French Canadian, or Cajun decent only. Reflex single-gene NIPT on Ashkenazi Jewish specific genes is currently not available

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