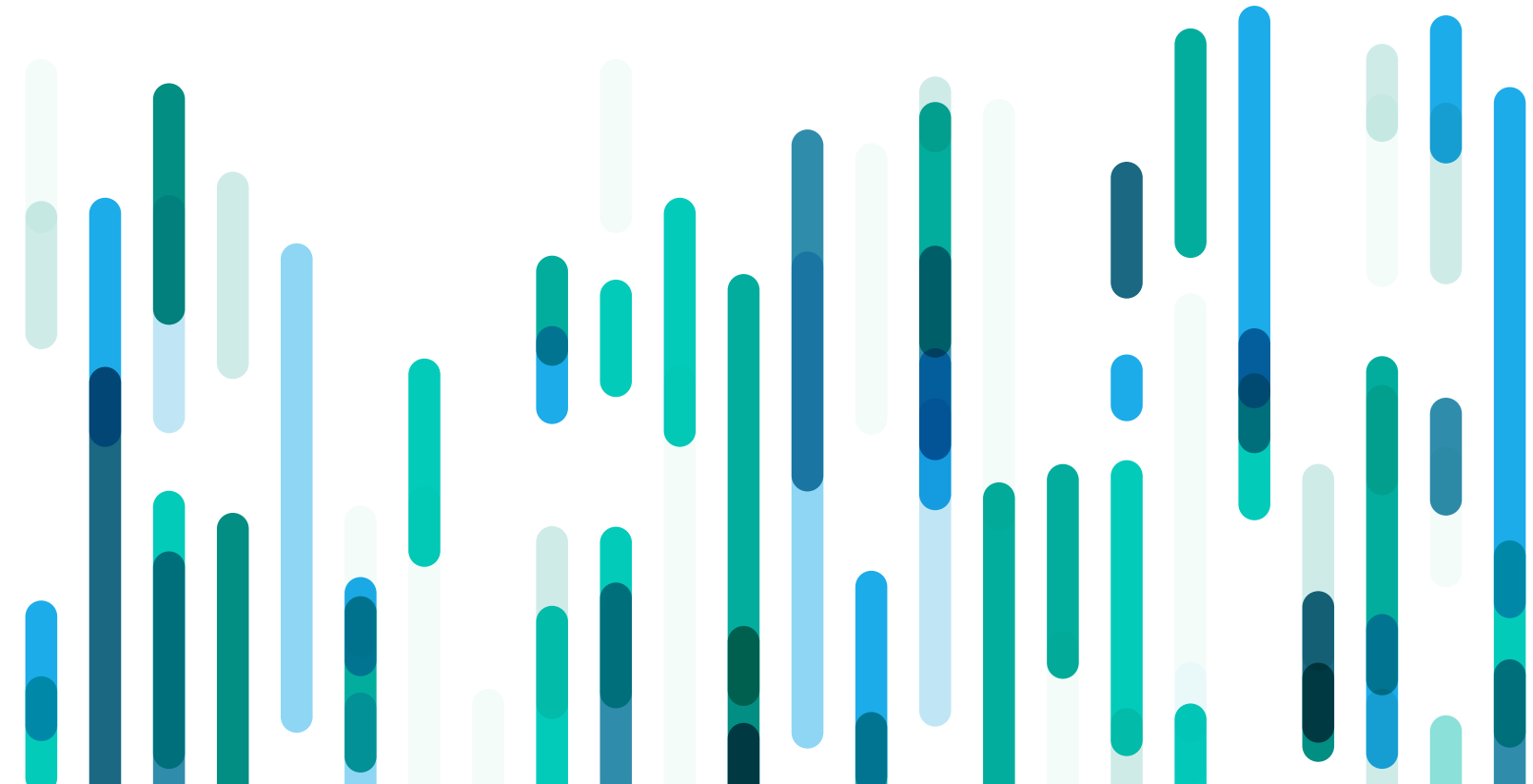
UNITY
by BILLIONTOONE

The new standard in prenatal care

One blood draw. Direct insights into fetal risk beyond aneuploidies.



What we do is different.

UNITY Fetal Risk Screen™ is the first-and-only NIPT for recessive conditions, aneuploidies, and beyond

TOP 10
clinical advancement of 2023 by AJHG[10]

~3x

Detects ~3x more affected pregnancies than traditional carrier screening[1]

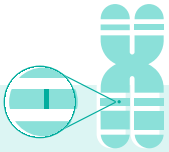
~58%

of male partners do not get tested. UNITY Fetal Risk Screen does not need the male partner's sample[2–4]

99%

Provide reassurance. 99% of patients are provided early reassurance their pregnancy has a low risk to be affected[1]

Expertise at fetal DNA quantification allows for first-and-only tests.



Aneuploidy
Easiest to detect

Microdeletion
Decreased accuracy

Recessive conditions
Requires extreme precision and sensitivity

- Cystic fibrosis
- Spinal muscular atrophy
- Hemoglobinopathies

10+ million base pairs — **1+ million** base pairs — **Single** base pairs

Conventional methods

QCT Technology

UNITY by BILLIONTOONE

It is difficult to efficiently identify at-risk pregnancies with traditional carrier screening

Prior to UNITY Fetal Risk Screen, it has not been technically possible to evaluate single-gene disorders from cell-free DNA (cfDNA). Instead, the only option was to generate a reproductive risk as a proxy (traditional carrier screening), rather than provide a true fetal risk.

Direct insights to the fetus are possible with QCT™ Technology

Quantitative Counting Templates™, patented by BillionToOne, quantify fetal DNA molecules from cfDNA down to a single base pair. This makes it possible to determine the fetal genotype in maternal blood, providing an individualized risk for pregnancy to be affected with the recessive condition the patient carries.

UNITY Complete.

Prenatal genetic testing designed for a general obstetric population

UNITY Complete®

UNITY Fetal Risk™ Screen

for recessive conditions

Carrier status is first determined. For positive maternal carriers, cell-free DNA from the same blood draw is analyzed to determine a precise fetal risk.

- Cystic Fibrosis
- Spinal Muscular Atrophy
- Sickle Cell Disease
- Alpha Thalassemia
- Beta Thalassemia
- Fragile X *(optional)*

UNITY Aneuploidy™ Screen

for chromosomal conditions

Determine the likelihood the fetus is affected with a serious chromosomal condition via cell-free DNA.

- Trisomies 13, 18, and 21
- Sex Chromosome Aneuploidies (Monosomy X, XXY, XYY, XXX)
- Zygosity *(included for twin pregnancies)*
- 22q11.2 microdeletion *(optional)*
- Fetal sex *(optional)*

Add-on to UNITY Complete

UNITY Fetal RhD™ NIPT

for non-alloimmunized RhD- pregnancies

Stratify which pregnancies may not need $Rh_o(D)$ immune globulin

UNITY Fetal Antigen™ NIPT

for alloimmunized pregnancies

Stratify which pregnancies will benefit from additional monitoring for Hemolytic Disease of the Fetus and Newborn

- Big C
- little c
- E
- D
- Fy^a (Duffy)
- K (Kell)

First-of-kind tests backed by clinical data.

2019

JUL 2019

UNITY

UNITY Fetal Risk Screen launches

OCT 2019

nature scientific reports

Analytical validity of single-gene NIPT with an estimated sensitivity of >98% and specificity of >99%[5]

UNITY Fetal Risk Screen | Analytical Validation

2022

MAR 2022

JME Journal of Medical Economics

The cost to detect one affected pregnancy by UNITY Fetal Risk Screen was 62% lower than traditional carrier screening[6]

UNITY Fetal Risk Screen | Health Economics Utility

APR 2022

American Journal of Hematology

Accurately identified all affected pregnancies as high risk at a greater than 9 in 10 risk

UNITY Fetal Risk Screen | Clinical Validation

DEC 2022

Genetics in Medicine

Top 10 of 2023 award by AJHG*[11]

99.4% NPV and >90% sensitivity in a high risk population[8]

UNITY Fetal Risk Screen | Clinical Validation

2023

AUG 2023

nature scientific reports

Analytical sensitivity and specificity of >99.9%[9]

UNITY Fetal RhD & Fetal Antigen tests | Clinical & Analytical Validation

SEPT 2023

PRENATAL DIAGNOSIS

Assay sensitivity of 96% and NPV of 99.8%. 100% of neonatal outcomes were confirmed to be affected via neonatal outcomes.[1]

UNITY Fetal Risk Screen | Clinical Validation

*American Journal of Human Genetics

UNITY Fetal Risk™ Screen.

Fetal risk for recessive conditions via cell-free DNA

UNITY Fetal Risk Screen leverages cell-free DNA to provide direct insights to the fetus, translating to **~3x increase in detection of affected pregnancies** compared to traditional carrier screening[1]

Conditions screened align to **ACOG recommendations**[11]

99% of patients will be reassured with a **reduced risk result**[1]

UNITY

BILLION TO ONE

PATIENT		SAMPLE		PROVIDER	
First Name	Jane	Sample Type	Blood	Provider	John Smith
Last Name	Doe	Date Collected	01/18/2023	Clinic Address	1035 O'Brien Drive Menlo Park, CA 94025
DOB	01/01/2000	Date Received	01/19/2023	Phone Number	650-460-2551
Ethnicity	Northern European/White	Accession ID	1234567X0000	Fax Number	883-915-0146
Gender	Female	Requisition ID	1234567X0000-1		
Gestational Age	10w4d	Date Reported	01/29/2023		
Medical Record #	N/A				

POSITIVE CARRIER

LOW RISK FETUS

CARRIER SCREENING

CONDITIONS SCREENED	MATERNAL CARRIER STATUS	FETAL RISK BY CELL-FREE DNA
Alpha-Thalassemia *(HBA1, HBA2)*	Negative	
Sickle Cell Disease / Beta-Thalassemia / Hemoglobinopathies *(HBB)*	Negative	
Cystic Fibrosis *(CFTR)*	POSITIVE c.1521_1523delCTT (p.Phe508del)	LOW RISK *See Results Below*
Spinal Muscular Atrophy *(SMN1)*	Negative 2 *SMN1* copies, SNP not present	

FETAL RISK WITH cfDNA

CONDITIONS SCREENED	FETAL RISK	Prior Risk (BEFORE cfDNA)	Post-Test Risk (AFTER cfDNA)	Fetal Fraction
Cystic Fibrosis	LOW	1 in 96 - 1 in 376	1 in 2800	9.9%

Fetal risk is provided **without male partner**

250,000+

UNITY Fetal Risk Screen Tests ordered[12]

For positive carriers, **risks can be clarified down to 1 in 5,000 and as high as 9 in 10**

**while report accurately reflects our test, it has been slightly modified for this purpose*

Provide reassurance to 99% of patients early in the pregnancy

TRADITIONAL CARRIER SCREEN

Up to 1 in 5
screen positive[13]

Male partner needed to provide a generic reproductive risk of 1 in 4

! >58% of male partners do not follow up with testing[2–4]

Most patients **will not pursue diagnostic testing** especially without a reproductive partner's results[14, 15]

Newborn screening can take weeks and requires follow up diagnostic testing

! Neonates are potentially missing the window of opportunity for many critical treatments

UNITY FETAL RISK SCREEN

Less than 1%
screen high risk

With earlier insights, diagnostic testing including Chorionic Villus Sampling, can be considered

UNITY

Know More. Know Early.

Timely treatment leads to optimal outcomes. **Provide peace of mind for 99% of pregnancies.**

UNITY Fetal Risk™ Screen.

Proven to maximize detection of affected pregnancies in a general obstetric population

PRENATAL DIAGNOSIS September 6, 2023

Performance of single-gene noninvasive prenatal testing for autosomal recessive conditions in a general population setting[1]

Study cohort

42,000+

cases collected from **811 unique practices** across **45 US states**

17.9% reflexed to sgNIPT

528

neonatal **outcomes** obtained

at least **75** outcomes per condition

Key results

96.0%

assay sensitivity

accurately detect affected pregnancies

99.8%

negative predictive value (NPV)

trust in a negative result

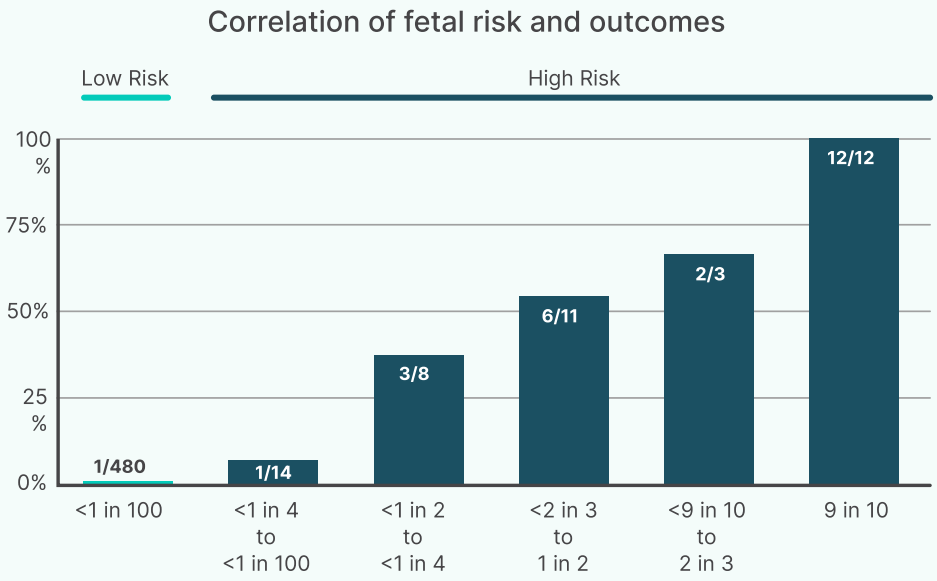
Conclusion

"This study builds upon earlier findings to confirm that carrier testing with reflex to sgNIPT is highly accurate for general population screening. Given this high accuracy and an NPV of 99.8%, **this workflow should be considered as an option for most of the general pregnant population.**"

The risk identified with UNITY Fetal Risk Screen is **strongly correlated** with the likelihood of an affected pregnancy

100% correlation of highest risk cases

All cases identified as a 9 in 10 risk were confirmed to have an affected child via neonatal outcomes



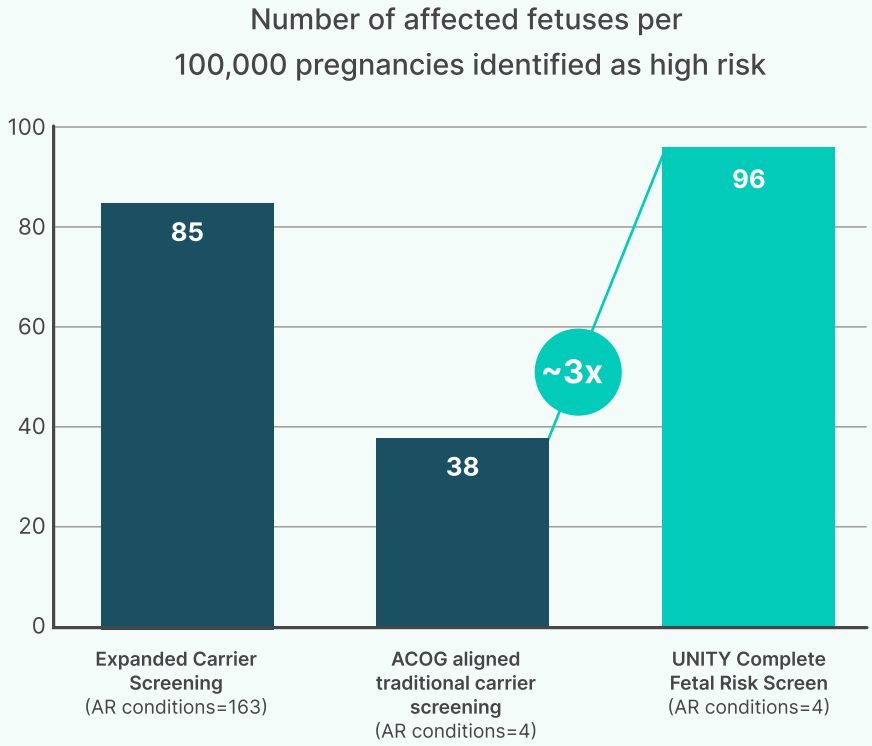
Detect **~3x more affected pregnancies** with UNITY Fetal Risk compared to traditional carrier screening

Detect more affected pregnancies

than traditional carrier screening in a real life scenario

Does not require a male partner sample

so is not limited by factors such as misattributed paternity (10%)[14] or lack of partner follow up (58%)[2–4]



UNITY Aneuploidy™ Screen.

Confidence in results with UNITY Aneuploidy

Optimized technology

- Leverages Next Generation Sequencing (NGS) coupled with QCT™ technology
- Expertise in fetal DNA quantification translates to high accuracy across all screened conditions

Designed for a general obstetric population

- Standard panel contains T21, T18, T13, Monosomy X, XXY, XYY, XXX. Aligns to ACOG recommended conditions.[16]
- Multiple add-ons accommodate varying clinical circumstances. Can be added-on at any point during the pregnancy, even after UNITY Aneuploidy is resulted.

Clinical Experience with UNITY Aneuploidy

Performance Characteristics of a Next Generation Sequencing-Based cfDNA Assay for Common Aneuploidies in a General Risk Population[17]

Mean test characteristics, n=114,707

MATERNAL AGE
29 years old

GESTATIONAL AGE
13.9 weeks

FETAL FRACTION
9.30% (1.5-39%*)

TURNAROUND TIME
5 days

	Trisomy 21	Trisomy 18	Trisomy 13	Combined Autosomes
Sensitivity	99.7%	99.5%	>99.9%	99.7%
Specificity	99.7%	>99.9%	>99.9%	99.9%
PPV	90.5%	97.6%	73.3%	90.8%
NPV	>99.9%	>99.9%	>99.9%	>99.9%

*1.5-39% represents the full distribution of fetal fraction

Add-ons to UNITY Aneuploidy Screen

22q11.2 Microdeletion Syndrome

Expertise in fetal quantification allows for accurate detection of 22q11.2 microdeletion

- Includes the full A-D region AND nested microdeletions
- >95% sensitivity and >99.9% specificity[18]

Twin Zygosity Determination

Identify which twin pregnancies may be monozygotic or dizygotic

UNITY Fetal RhD NIPT

nature scientific reports

Validation of a non-invasive prenatal test for fetal RhD, C, c, E, K, and Fy^a antigens

>99.9% **accuracy**

Sensitivity and specificity in detecting fetal D antigen[9]

~40% **fetal RhD "not detected"[19]**

RhD$^-$ pregnant patients can be reassured early pregnancy

TRADITIONAL WORKFLOW

Fetal RhD antigen status is unknown without invasive procedure

ALL RhD$^-$ mothers receive Rh_o(D) immune globulin

UNITY FETAL RhD NIPT

Fetal D-antigen presence/ absence determined as early as 10 weeks

40% fetal antigen not detected; Rh_o(D) immune globulin not indicated

Scan to learn more about the UNITY Fetal RhD and UNITY Fetal Antigen tests

Know more. Know early.

UNITY Complete® Fetal Risk Screen

One blood draw for multiple insights. No male partner sample required for an accurate fetal risk.

~10 weeks
One maternal blood draw

~11 weeks
UNITY Aneuploidy Results (+Add-ons)

~12 weeks
UNITY Fetal Risk Screen Results*

We are committed to making UNITY Complete® accessible and affordable for all

- We accept all insurances, including Medicaid
- We are in network with the majority of insurance plans

* Carrier and cell-free DNA for recessive conditions. Fetal Risk via cell-free DNA only performed if patient is determined to be a carrier

References

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