UNITY
BY BILLIONTOONE

# FOR **SOME** + FOR **ALL**
# DETECT **BIG** + **SMALL**

The NIPT that screens for chromosome and single-gene conditions ACOG recommends for all pregnancies *plus* additional screening appropriate for some pregnancies.

# Screen for **common and severe** aneuploidies and recessive conditions.

ACOG recommended

## LARGE, CHROMOSOMAL aneuploidies*

INCIDENCE AT BIRTH [1-4]

| | |
|---|---|
| **trisomy 21** Down syndrome | **1 in 800** |
| **trisomy 18** Edwards syndrome | **1 in 5000** |
| **trisomy 13** Patau syndrome | **1 in 16,000** |
| **monosomy X** Turner syndrome | **1 in 2500** in females |
| **XXX** Triple X syndrome | **1 in 1000** in females |
| **XXY** Klinefelter syndrome | **1 in 500** in males |
| **XYY** Jacobs syndrome | **1 in 1000** in males |

## SMALL, SINGLE-GENE recessive conditions**

INCIDENCE AT BIRTH [5-10]

| | |
|---|---|
| **cystic fibrosis** | **1 in 3000** in Northern Europeans/ Ashkenazi Jewish |
| **spinal muscular atrophy** | **1 in 10,000** in general population |
| **sickle cell disease** | **1 in 365** in African Americans |
| **alpha thalassemia** | **1 in 10,000** in Asians |
| **beta thalassemia** | **1 in 50,000** in Asians |

## OPTIONAL RhD & other fetal antigens*

**C, c, D, E, Duffy (Fya), Kell (K)**

## OPTIONAL fetal sex*

* trisomy screening, fetal antigen screening, and fetal sex determination are also available for twin pregnancies

** carrier screening is also available separately for non-pregnant adults

# Simplify the prenatal genetic screening workflow with a **single blood draw**.

**Empowering pregnant patients as no partner sample is needed for fetal assessment.**

**maternal blood draw**

~10 weeks

**NIPT results for aneuploidies**

**+ fetal antigens (if added)**

~11 weeks

**Carrier status + NIPT results for recessive conditions***

~12 weeks

ANEUPLOIDIES

| CONDITION SCREENED | FETAL RISK | Risk *Before* NIPT | Risk *After* NIPT |
|---|---|---|---|
| Trisomy 21 | HIGH | 1 in 86 | 9 in 10 |

FETAL ANTIGENS optional, must be ordered with aneuploidy NIPT

| ANTIGEN SCREENED | SUMMARY OF RESULTS |
|---|---|
| RhD | Not Detected |

RECESSIVE CONDITIONS

| CONDITION SCREENED | MATERNAL CARRIER STATUS | | |
|---|---|---|---|
| Cystic fibrosis | POSITIVE | | |
| | FETAL RISK | Risk *Before* NIPT | Risk *After* NIPT |
| | LOW | 1 in 96 - 1 in 376 | 1 in 2000 |

Exemplary report results shown

* single-gene NIPT only performed for pregnant patients who are carriers

The NIPT that identifies fetal risks beyond chromosome abnormalities.

# aneuploidies

**Offer a highly accurate NIPT for aneuploidies, the standard of care to assess fetal risk for chromosome abnormalities.**

**Inform pregnancy management and birth preparations for potentially severe conditions:**

| | trisomy 21 | trisomy 18 | trisomy 13 |
|---|---|---|---|
| SENSITIVITY [11] | 99.8% (98.9% - 100%) | 99.9% (99.0% - 100%) | 99.1% (97.4% - 100%) |
| SPECIFICITY [11] | 99.9% (99.8% - 99.9%) | >99.9% | >99.9% |
| FALSE POSITIVE RATE [11] | <0.1% | <0.1% | <0.1% |

Trisomy screening & fetal sex are available for **twin pregnancies**

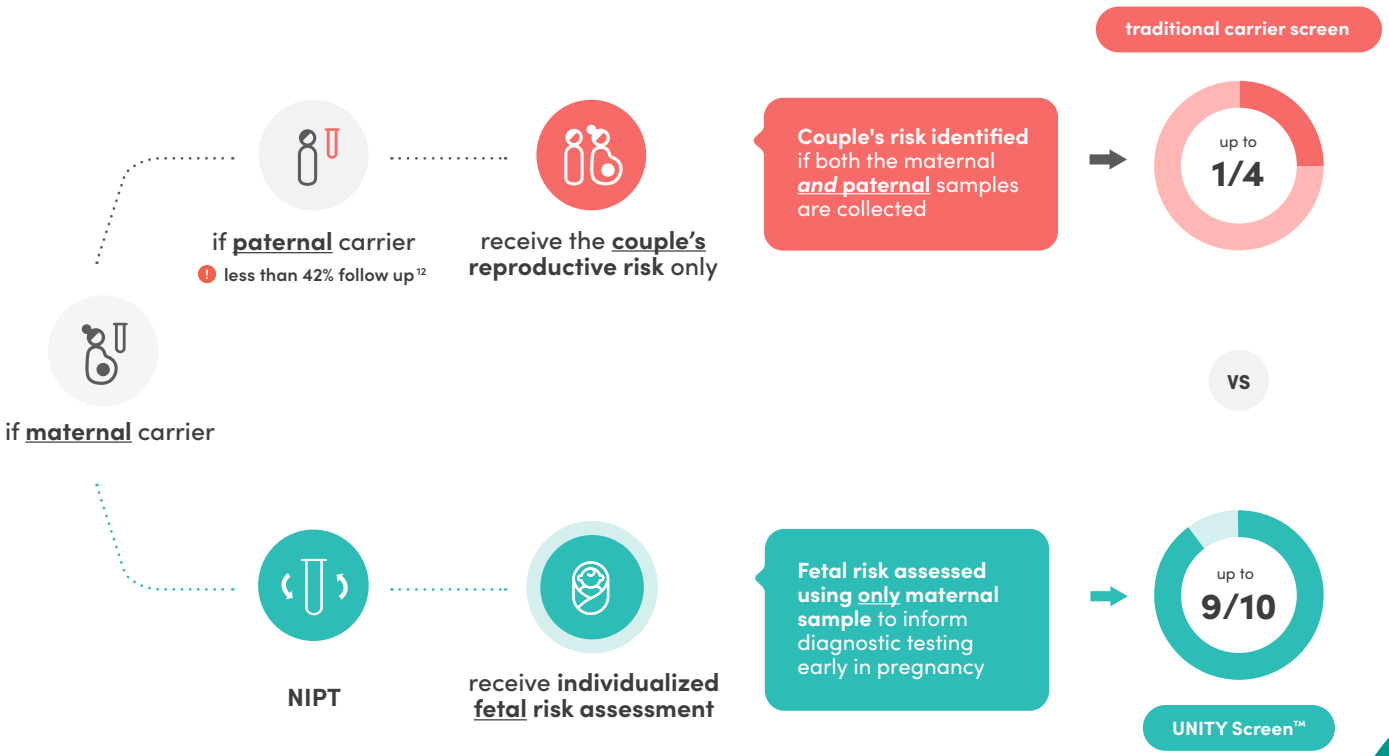
| | monosomy X | XXX | XXY | XYY |
|---|---|---|---|---|
| SENSITIVITY [11] | 97.7% (93.7% - 100%) | reported when detected | reported when detected | reported when detected |
| SPECIFICITY [11] | >99.9% | >99.9% | >99.9% | >99.9% |
| FALSE POSITIVE RATE [11] | <0.1% | <0.1% | <0.1% | <0.1% |

FOR ALL

# recessive conditions

Now assess fetal risk for recessive (single-gene) conditions, often an inequitable and inefficient process during pregnancy.

**Access an individualized, tailored fetal risk score of up to 9 in 10 rather than a calculated couple's risk of 1 in 4:**




FOR ALL

# clinical outcomes data

## New data[16] show the ability of UNITY Screen™ to efficiently identify pregnancies at risk for recessive conditions.

Our complete cohort consisted of 9151 pregnant individuals from 31 US states from over 240 providers. Of these, 1669 individuals (18.2%) were carriers for at least one condition and had single-gene NIPT. NIPT results were compared to newborn outcomes obtained from parent survey responses or provider reports for a cohort of 191 pregnancies.

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### 93.3%*

**SENSITIVITY for single-gene NIPT**

Identify more high-risk pregnancies for reported carriers than carrier screening alone.

* Single-gene NIPT correctly identified 14/15 affected fetuses as high-risk.

### ~2X*

**POSITIVE predictive value**

Of those high-risk pregnancies, half were affected at birth. This is nearly double the couple's calculated reproductive risk of 1 in 4 derived from traditional carrier screening.

* Of 29 high-risk results, 14 were affected, resulting in a PPV of 48.3%.

### 99.4%*

**NEGATIVE predictive value**

Provides confidence that a low-risk result most likely means the fetus is not at risk.

* Of 162 low-risk results, 161 were unaffected, resulting in an NPV of 99.4% (95%CI: 96.0, 99.9%).

**UNITY Screen™ is not a diagnostic test. Any high-risk fetal result should be followed up with a diagnostic test such as an amniocentesis.**

## Single-gene variations call for tiny scale quantification.

**see how our tech works**

Proprietary molecular counting technology (Quantitative Counting Templates™, or QCTs) is used to count DNA fragments (molecules) to detect conditions caused by tiny single-gene variations that code for recessive conditions or presence of fetal antigens.

**This quantification enables fetal risk assessment from small amounts of cfDNA floating in the bloodstream from the gene in question.**

# RhD & other fetal antigens

Plus, screen for presence of D antigen or other red blood cell antigens.

**>99.9% sensitivity & specificity[13]**

**Administer Rho(D) immune globulin with more certainty:**

**Learn fetal RhD status early in pregnancy to inform the need for Rho(D) immune globulin for pregnant patients who are RhD negative.**

**40%**[14] of RhD negative patients will carry RhD negative fetuses and may not need Rho(D) immune globulin.

**Streamline management for up to 65%**[15] **of alloimmunized patients:**

**Non-invasive fetal antigen screening for C, c, E, D, Duffy (Fya), and Kell (K) informs care for patients at risk for Hemolytic Disease of the Fetus and Newborn.**

Only about **35%** of fetuses will express the antigen of concern.

FOR **SOME**

# Resources to **Support** Your Practice

## GENETIC COUNSELING

Pre- and post-test patient counseling
On-call medical science liaisons to answer clinical questions

## CLIENT SERVICES

Patient billing questions
Mobile phlebotomy
Kit shipping and logistics
EMR integration

## PROVIDER PORTAL

Full view of order history and status of results
View and download patient results
Release results to patient

## PATIENT PORTAL

All results with fetal sex available separately
Sharable fetal sex results
FAQs and educational materials


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