The new standard in prenatal care.

Fetal risk assessment for up to 14 recessive and X-linked genes, aneuploidies, and more — all from a single maternal blood draw.

The leader in cfDNA screening for recessive conditions.

Industry-Leading Performance

6 years
in clinical practice since the launch of UNITY Fetal Risk Screen in 2019

>500,000 tests
ordered[1]

>95% sensitivity
for identifying affected fetuses[2]

99.8% NPV
negative predictive value[3]

Scientific Excellence

5 publications
in peer-reviewed journals

42,000+ pregnancies
clinically validated for a general obstetric population[3]

QCT™ technology
the only clinically validated cfDNA testing method for direct fetal risk assessment of recessive conditions[4]

Streamlined, Patient-Centric Workflow

1 test
single blood draw

2 panels
to suit your patient's needs

~2 weeks
from testing to results

Where others stop, we keep going.

UNITY Complete® is the **first-and-only clinically validated NIPT** to analyze cell-free DNA for a direct fetal risk assessment — including recessive conditions, aneuploidies, and more — all from a single maternal blood sample.[3,5]

Partner testing is available, but not required to produce an accurate fetal risk assessment.

UNITY Complete®

UNITY Fetal Risk™ Screen
for up to 14 recessive and X-linked genes

- Cystic Fibrosis[i]
- Spinal Muscular Atrophy
- Sickle Cell Disease
- Alpha-Thalassemia
- Beta-Thalassemia

ACOG-aligned screening for a general obstetric population

- Canavan Disease[i]
- MCAD Deficiency
- Tay Sachs Disease[i]
- Familial Dysautonomia[i]
- Smith-Lemli-Opitz Syndrome
- PMM2-Congenital Disorder of Glycosylation
- DMD-Associated Dystrophinopathies[ii]
- PAH Deficiency (Phenylketonuria)
- Fragile X Syndrome[ii]

UNITY Aneuploidy™ Screen
for chromosomal conditions

- Trisomy21[iii]
- Trisomy18[iii]
- Trisomy13[iii]
- Sex Chromosome Aneuploidies: XO, XXY, XYY, XXX
- Zygosity *included for twins*
- 22q11.2 Microdeletion Syndrome[iii] *optional*
- Fetal Sex[iii] *optional*

Maternal carrier screening with reflex to NIPT for single gene conditions, when indicated. Personalized fetal risk provided for current pregnancy.

Add-On

UNITY Fetal Antigen™ Tests
for RhD & fetal antigen status

UNITY Fetal RhD NIPT[iii]
for non-alloimmunized RhD- pregnancies

Provides fetal RhD status to guide medical management

UNITY Fetal Antigen NIPT[iii]
for alloimmunized pregnancies

Provides fetal antigen status to guide medical management for hemolytic disease of fetus and newborn (HDFN) risk

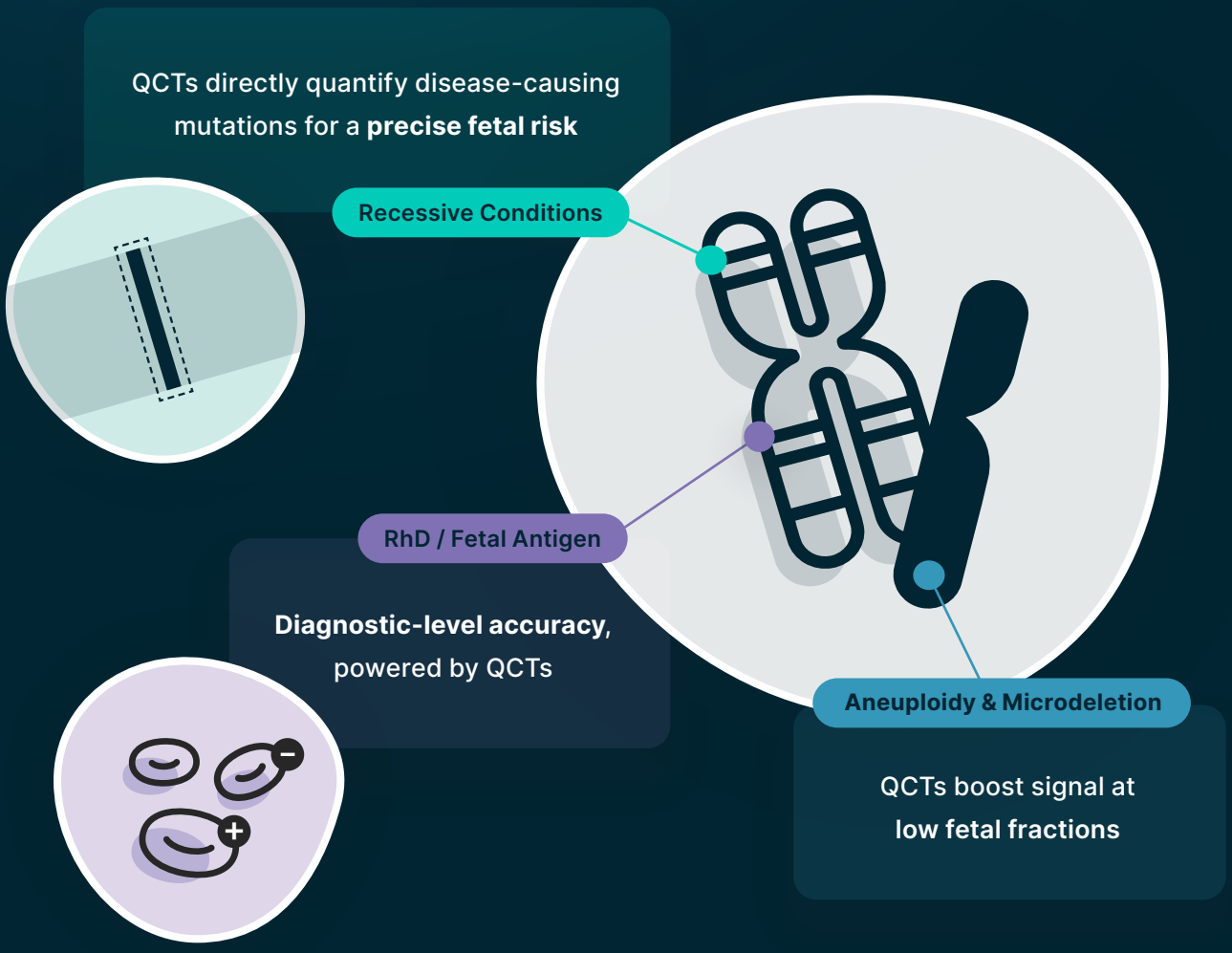
- big C
- little c
- D
- E
- Fy[a] Duffy)
- K (Kell)

MCAD: Medium-Chain Acyl-CoA Dehydrogenase
PMM2: Phosphomannomutase 2
DMD: Duchenne Muscular Dystrophy
PAH: Phenylalanine Hydroxylase

i. ACOG recommended screening for Ashkenazi Jewish patients
ii. Fetal risk assessment via cfDNA is clarified via fetal sex only
iii. Available for mono and dizygotic twins

Direct insights to the fetus are possible with QCT™ technology.

Exclusive to UNITY, Quantitative Counting Template™ (QCT) technology does what other technologies cannot: precisely quantify the disease-causing mutation in cfDNA to deliver a direct fetal risk assessment for up to 14 recessive and X-linked genes with >95% sensitivity[2].



First-of-kind tests backed by clinical data.

TOP 10
clinical advancement of 2023 by AJHG[11]

nature scientific reports

FR A

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

OCT 2019

JME Journal of Medical Economics

FR H

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

MAR 2022

American Journal of Hematology

FR H

Accurately identified all sickle cell affected pregnancies as high risk at a greater than 9 in 10 risk[7]

APR 2022

Genetics in Medicine

FR C

99.4% NPV and >90% sensitivity[4]

DEC 2022

PRENATAL DIAGNOSIS

FR C

Assay sensitivity of 96% and NPV of 99.8%. 9-out-of-10 results were confirmed to be affected via neonatal outcomes[3]

SEP 2023

nature scientific reports

Rh FA C A

Analytical sensitivity and specificity of >99.9%[8]

AUG 2023

Annals of Gynecology and Obstetrics Research

AP C

99.7% sensitivity & 99.9% specificity for autosomal trisomies. 80% of patients were <35 years[9]

MAY 2024

OBSTETRICS & GYNECOLOGY

FA C

100% concordance with 465 neonatal outcomes[10]

JUL 2024

OBSTETRICS & GYNECOLOGY

Rh C

100% concordance with 401 clinical outcomes 5 *RHD(Ψ)* + 5 *RHD-CE-D* hybrid genes detected in non-alloimmunized RhD-neg patients[11]

APR 2025

Journal of Cystic Fibrosis

FR C

Retrospective review of >100,000 consecutive general-risk pregnant patients. 100% sensitivity, >99% NPV, ~60% PPV in the *CFTR* gene[12]

SEP 2025

Product

- FR UNITY Fetal Risk Screen
- AP UNITY Aneuploidy NIPT
- FA UNITY Fetal Antigen NIPT
- Rh UNITY Fetal RhD NIPT

Publication Scope

- A Analytical Validation
- C Clinical Validation
- H Health Economics Utility

Dive into our clinical validation.

UNITY Fetal Risk™ Screen

Simplified workflow. Superior Insights.
Designed with obstetric healthcare providers in mind.

Traditional Carrier Screening

Maternal blood draw to determine carrier status

Partner sample is required for reproductive risk

Less than 50% of partners complete carrier screening[13]

Couples receive a maximum **reproductive risk of 25%**

Less than 5% of high-risk couples pursue **diagnostic testing**[13]

UNITY Fetal Risk Screen

Maternal blood draw to determine carrier status **and fetal risk** for recessive conditions

Personalized fetal risk provided for this specific pregnancy (up to 9 in 10 or down to 1 in 10,000)[3]

More than 35% of high-risk couples pursue diagnostic testing[4]

While partner testing is accepted, it is not required for an accurate fetal risk assessment.

Trusted by providers nationwide with over 1 million UNITY tests ordered[14].

Example Report

Dual panel flexibility in a single test

	Patient Carrier Status	cfDNA Fetal Risk Status
ACOG Guideline Panel		
Alpha-Thalassemia *HBA1* *HBA2*	Negative	N/A
Cystic Fibrosis *CFTR*	POSITIVE	Low Risk
Sickle Cell Disease / Beta-Thalassemia / Hemoglobinopathies *HBB*	Negative	N/A
Spinal Muscular Atrophy *SMN1*	Negative	N/A
Fragile X syndrome *FMR1*	Negative 32 / 30 repeats	N/A
***Plus* Panel**		
Canavan Disease *ASPA*	Negative	N/A
DMD-Associated Dystrophinopathies *DMD*	Negative	N/A
Familial Dysautonomia *ELP1*	Negative	N/A
Medium-Chain Acyl-CoA Dehydrogenase Deficiency *ACADM*	Negative	N/A
Phenylalanine Hydroxylase Deficiency *PAH*	Negative	N/A
***PMM2*-Congenital Disorder of Glycosylation** *PMM2*	Negative	N/A
Smith-Lemli-Opitz Syndrome *DHCR7*	POSITIVE	HIGH RISK
Tay Sachs Disease *HEXA*	Negative	N/A

Fetal risk **specific to this pregnancy** is assessed without a partner sample:

For positive carriers, fetal risks can be clarified down to **1 in 10,000...**

Risk *Before* cfDNA	Fetal Risk *After* cfDNA	
1 in 100 - 1 in 472	1 in 10,000	Low Risk

L

99% of patients will receive a reassuring, low fetal risk result[3]

... or up to **9 in 10:**

Risk *Before* cfDNA	Fetal Risk *After* cfDNA	
1 in 284 - 1 in 732	9 in 10	HIGH RISK

Early detection can make a difference.

Conditions Screened	Carrier Frequency[15]	Available Interventions
Cystic Fibrosis	1 in 29-38	
Spinal Muscular Atrophy	1 in 54	
Sickle Cell Disease	1 in 8-33	
Alpha-Thalassemia	1 in 112	
Beta-Thalassemia	1 in 33	
Canavan Disease	1 in 44-439	
DMD-Associated Dystrophinopathies	1 in 717	
Familial Dysautonomia	1 in 35-402	
Medium-Chain Acyl-CoA Dehydrogenase Deficiency	1 in 67	
PMM2-Congenital Disorder of Glycosylation	1 in 70	
Phenylalanine Hydroxylase Deficiency (PKU)	1 in 79	
Smith-Lemli-Opitz Syndrome	1 in 71	
Tay Sachs Disease	1 in 28-193	
Fragile X Syndrome	1 in 201	

Gene or Enzyme Therapies

Early detection enables access to therapies that may significantly improve outcomes

Dietary Modifications

May improve outcomes and help alleviate symptoms

Multidisciplinary Care

Early detection connects families with specialists for immediate postnatal care

Early Intervention Programs

Intervention programs and IEPs support development with demonstrated benefits

Risks shown are for general population. Ranges reflect carrier frequencies of specific populations with high prevalence of the condition (ex, Black, Ashkenazi Jewish).

Quantify fetal cfDNA for a precise fetal risk.

UNITY Fetal Risk Screen delivers highly accurate fetal risk assessment for inherited conditions in the general pregnant population and is able to identify affected pregnancies with both homozygous or heterozygous variants.

By both sequencing and directly quantifying disease-causing mutations in cfDNA from a single maternal blood sample, UNITY Fetal Risk Screen **detects approximately three times more affected pregnancies compared to traditional carrier screening**.

This efficient workflow removes barriers associated with partner testing and provides personalized fetal risk assessment early in pregnancy, making it an ideal solution for routine prenatal care across diverse patient populations.

Published in 2023
PRENATAL
DIAGNOSIS

Performance of single-gene noninvasive prenatal testing for autosomal recessive conditions in a general populations setting[3]

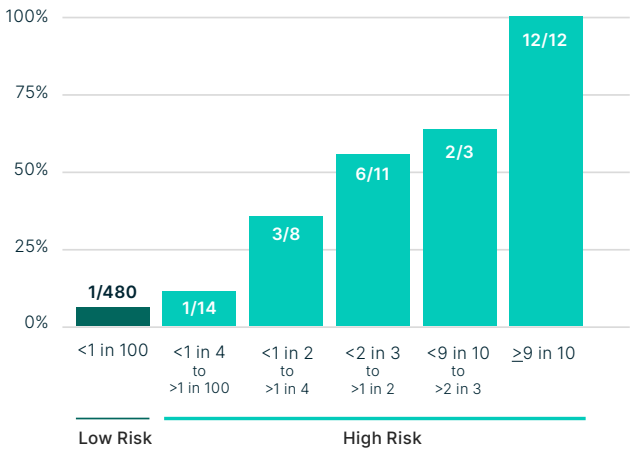
96.0% **sensitivity** Accuracy in detecting affected pregnancies with homozygous and heterozygous variants

99.8% **NPV** **(negative predictive value)** Trust in a negative result

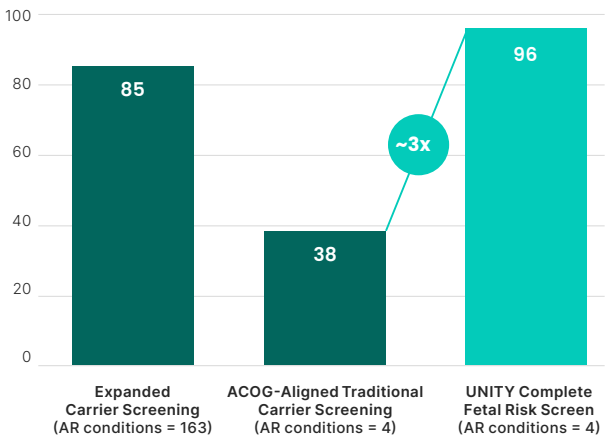
All cases identified as a **9 in 10 risk** in the study cohort were confirmed to have an affected child.

UNITY overcomes challenges of traditional carrier screening, **including lack of partner follow-up** (58%) and **misattributed paternity** (~10%) — providing patients with timely and accurate fetal risk assessment.[13, 16, 17]

Proportion of pregnancies confirmed to have an affected child



Number of affected fetuses per 100,000 pregnancies identified as high risk



UNITY Aneuploidy™ Screen

Optimized technology.
Designed for a general obstetric population.

UNITY Aneuploidy Screen harnesses NGS (next generation sequencing), QCT, and SNP technology to deliver precise and highly accurate fetal risk assessment for chromosomal abnormalities.

- Aligned to current ACOG recommendations for aneuploidy screening
- Standard panel includes T21, T18, T13, XO, XXY, XYY, and XXX
- Zygosity included for all twin pregnancies to determine mono- versus dizygotic pregnancies and individual fetal sex

Published in 2024

Annals of Gynecology and Obstetrics Research

Performance Characteristics of a Next Generation Sequencing-Based cfDNA Assay for Common Aneuploidies in a General Risk Population[9]

Mean Test Characteristics
n = 114,707

Maternal Age
29 years old

Gestational Age
13.9 weeks

Fetal Fraction
9.30% min 1.5%; max 39%

Average TAT
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%**

Expand your aneuploidy screening to accommodate diverse clinical needs with **flexible add-on options** that can be requested at any point during pregnancy, even post initial results.

Add-On

22q11.2 Microdeletion Syndrome

- Highly accurate detection through precise fetal cfDNA quantification
- Screens the full A-D region and certain nested microdeletions[16]
- 95% sensitivity, >99.9% specificity, and 80% positive predictive value (PPV)[16]

UNITY Fetal RhD & Antigen™ NIPT

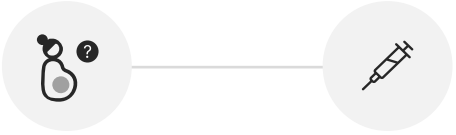
200,000+ Fetal RhD and Antigen tests performed since 2020[11].

Add-On

UNITY Fetal RhD NIPT
for non-alloimmunized RhD- pregnancies

Detects the presence or absence of the *RHD* gene deletion, common deletions, *RHD-CD-D* hybrid gene, and *RHD(Ψ)* via cfDNA[8,10]

Traditional Workflow



Fetal RhD antigen status is **often unknown** without invasive procedure

All RhD negative mothers receive RH_0(D) immune globulin

UNITY Fetal RhD NIPT

Determines fetal RhD antigen status

40% of fetuses are identified as RhD negative; Rh_0(D) immune globulin not indicated[18]

Add-On

UNITY Fetal Antigen NIPT
for alloimmunized pregnancies

Detects fetal antigen status for big C, little c, D, E, Fya (Duffy), and K (Kell) antigen(s)

>99.9% sensitivity[10]

>99.9% specificity[10]

100% concordance with neonatal outcomes[10]

Scan to learn more

Your patients, our priority.

UNITY Complete streamlines testing through a single maternal blood draw, reducing the complexity of multiple clinic visits, partner testing, and numerous insurance bills and co-pays.

Patient-Centric Experience

- **Convenient self-service portal:** Track test progress and view results.
- **Educational support:** On-demand videos and resources.
- **Complimentary genetic counseling:** Virtual visits with our genetic counselors to review their results.
- **Transparent, friendly billing practices:** Our US-based team contacts patients about balances before billing. One bill, one copay — no surprises.

Affordable for All

- **Wide insurance coverage:** In-network with the majority of insurance plans, covering over 200 million lives.
- **$0 for all Medicaid patients:** 45% of UNITY patients have Medicaid[19].
- **~80% of commercially insured patients pay less than $200** for two tests (UNITY Fetal Risk Screen + Aneuploidy)[19].

Streamlined Provider Workflow

- **Single order:** One TRF for all UNITY Complete tests.
- **Portal or EHR integration:** Easy ordering and fast results via EHR or provider portal.
- **Actionable results:** Clear, reliable insights for confident clinical decisions.

1. Data on file as of May 2025. **2.** For autosomal recessive conditions, the clinical sensitivity refers to the estimated clinical detection rate of highrisk fetuses by cfDNA fetal risk assessment. For X-linked conditions, for which cfDNA testing is only clarified via fetal sex, the clinical sensitivity refers to carrier screening detection and does not account for de novo mutations **3.** Wynn J, et al. Performance of single-gene noninvasive prenatal testing for autosomal recessive conditions in a general population setting. ***Prenat Diagn***. 2023 Sep; 43(10):1344-1354. doi:10.1002/pd.6427. Epub 2023 Sep 6. PMID: 37674263. **4.** Tsao, D. S., et al. (2019). A novel high-throughput molecular counting method with single base-pair resolution enables accurate single-gene NIPT. *Scientific Reports*, 9, 14382. https://doi.org/10.1038/s41598-019-50378-8. **5.** Tsao, D. S., et al. (2019). A novel high-throughput molecular counting method with single base-pair resolution enables accurate single-gene NIPT. ***Scientific Reports***, 9, 14382. https://doi.org/10.1038/s41598-019-50378-8. **6.** Riku S. et al. (2022) Reflex single-gene non-invasive prenatal testing is associated with markedly better detection of fetuses affected with single-gene recessive disorders at lower cost, Journal of Medical Economics, 25:1, 403-411 DOI: 10.1080/13696998.2022.2053384. **7.** Westin, E.R., et al. (2022), Validation of single-gene noninvasive prenatal testing for sickle cell disease. Am J Hematol, 97: E270-E273. doi:10.1002/ajh.26570. **8.** Alford, Brian, et al. "Validation of a non-invasive prenatal test for fetal RhD, C, c, E, K and Fya antigens." *Scientific Reports* 13.1 (2023): 12786.. **9.** Wynn J, et al. Performance Characteristics of a Next Generation Sequencing-Based cfDNA Assay for Common Aneuploidies in a General Risk Population. Ann Gynecol Obstetr. Res. 2024; 7(1): 102. **10.** Rego, Shannon, et al. "Cell-free DNA analysis for the determination of fetal red blood cell antigen genotype in individuals with alloimmunized pregnancies." Obstetrics & Gynecology (2022): 10-1097. **11.** Mateus-Nino, Julio F., et al. "Clinical performance of cell-free DNA for fetal RhD detection in RhD-negative pregnant individuals in the United States." Obstetrics & Gynecology 145.4 (2025): 402-408. **12.** Wynn, J., et al. "Routine cell-free DNA prenatal screening identifies pregnancies at high risk for cystic fibrosis that may benefit from fetal therapy." *Journal of Cystic Fibrosis* (2025). **13.** Strauss, T S et al. "Barriers to completion of expanded carrier screening in an inner city population." Genetics in medicine : official journal of the American College of Medical Genetics vol. 25,7 (2023): 100858. doi:10.1016/j.gim.2023.100858 **14.** Internal data on file. Aug 2025. **15.** Carrier screening in the age of genomic medicine. Committee Opinion No. 690. American College of Obstetricians and Gynecologists. ***Obstet Gynecol*** 2017;129:e35-40. **16.** Hull, L E et al. "Association of Patient and Site-of-Care Characteristics With Reproductive Carrier Screening Timing in a Large Integrated Health System." JAMA network open vol. 5,11 e2240829. 1 Nov. 2022, doi:10.1001jamanetworkopen.2022.40829 **17.** Carlotti, K et al. "Perceived barriers to paternal expanded carrier screening following a positive maternal result: To screen or not to screen." ***Journal of Genetic Counseling*** Vol. 30,2 (2021): 470-477. doi:10.1002/jgc4.1333 Ghiossi CE, Goldberg JD, Haque IS, Lazarin GA, Wong KK. Clinical Utility of Expanded Carrier Screening: Reproductive Behaviors of At-Risk Couples. *J Genet Couns*. 2018 Jun;27(3):616-625. doi: 10.1007/s10897-017-0160-1. Epub 2017 Sep 27. PMID: 28956228; PMCID: PMC5943379. **18.** Prevention of Rh D Alloimmunization. Obstetrics & Gynecology 130(2):p e57-e70, August 2017. DOI: 10.1097/AOG.0000000000002232. **19.** BillionToOne, Inc. (2024). Internal billing data on file.

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