WOMEN'S HEALTH AND GENETICS

MaterniT® 21 PLUS Prenatal cfDNA Screening

Designed for every pregnant patient, because every pregnant patient matters

labcorp | Women's Health

MaterniT Prenatal cfDNA Screening

Pregnant patients present in many ways, and each pregnancy is unique. MaterniT prenatal cfDNA screening delivers results whether you are managing routine or high-risk pregnancies, which may include:

- Higher maternal weight
- Twins and multiple gestations, egg donor/IVF
- Complex family history
- Mosaicism

Results for all patients

Labcorp is your one-source laboratory, supporting your pregnant patients by combining expertise in prenatal screening, genetic counseling and diagnostic testing.

MaterniT helps you screen every patient with confidence, delivering ease of use for your practice and improved access to screening for your patients.

By definition, any screening test can produce a false positive result. After performing more than three million prenatal cfDNA screens over the last decade—including over 100,000 genome-wide and over 65,000 twin/triplet tests—we know that not all positive results are created equally.

The Mosaicism Ratio result, only available with MaterniT 21 PLUS (at no extra cost), helps differentiate between a positive result that is more likely to be a true positive, and one with an increased chance to be a false positive.[1]

Labcorp has performed more than 3 million prenatal cfDNA tests, including >100,000 genome-wide and >65,000 multifetal tests.

MaterniT 21 PLUS screening features

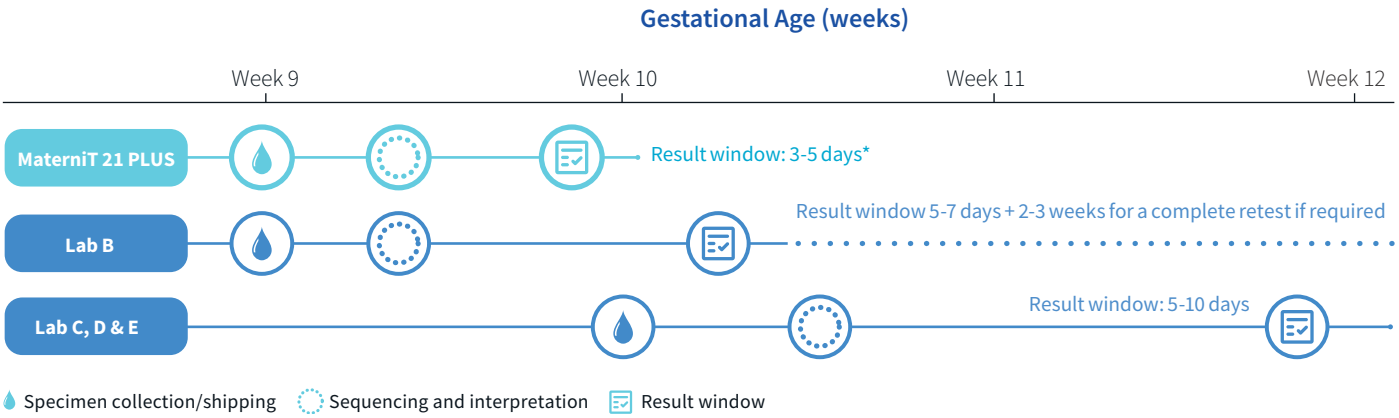
MaterniT 21 PLUS Core Test	Estimated Live Births Affected
Fetal sex (optional)	N/A
Trisomy 21 (Down syndrome)	1 in 700[2]
Trisomy 18 (Edwards syndrome)	1 in 5,000[3]
Trisomy 13 (Patau syndrome)	1 in 16,000[4]
SEX CHROMOSOME ANEUPLOIDIES* (SCA) opt-in, Singleton only	
45,X (Turner syndrome)*	1 in 2,500 (females)[5]
47,XXY (Klinefelter syndrome)*	1 in 650 (males)[6]
47,XXX (Triple X syndrome)*	1 in 1,000 (females)[7]
47,XYY (XYY syndrome)*	1 in 1,000 (males)[8]
ENHANCED SEQUENCING SERIES* (ESS) Clinically relevant microdeletions and trisomy opt-in	
22q (DiGeorge syndrome)*	1 in 4,000[9]
5p (Cri-du-chat syndrome)*	1 in 20,000 to 50,000[10]
1p36 deletion syndrome*	1 in 5,000 to 10,000[11]
15q (Prader-Willi syndrome)*	1 in 10,000 to 30,000[12]
15q (Angelman syndrome)*	1 in 12,000 to 20,000[13]
11q (Jacobsen syndrome)*	1 in 100,000[14]
8q (Langer-Giedion syndrome)*	Rare[15]
4p (Wolf-Hirschhorn syndrome)*	1 in 50,000[16]
Trisomy 16*	Rare (almost all cases result in miscarriage)[17]
Trisomy 22*	Rare (almost all cases result in miscarriage)[18]

* Reported as an additional finding; you may opt in to order this information.

MaterniT 21 PLUS will deliver highly sensitive and specific results earlier in pregnancy than other prenatal cfDNA screening

Rapid results, low failure rates. When time is critical, your choice is MaterniT 21 PLUS

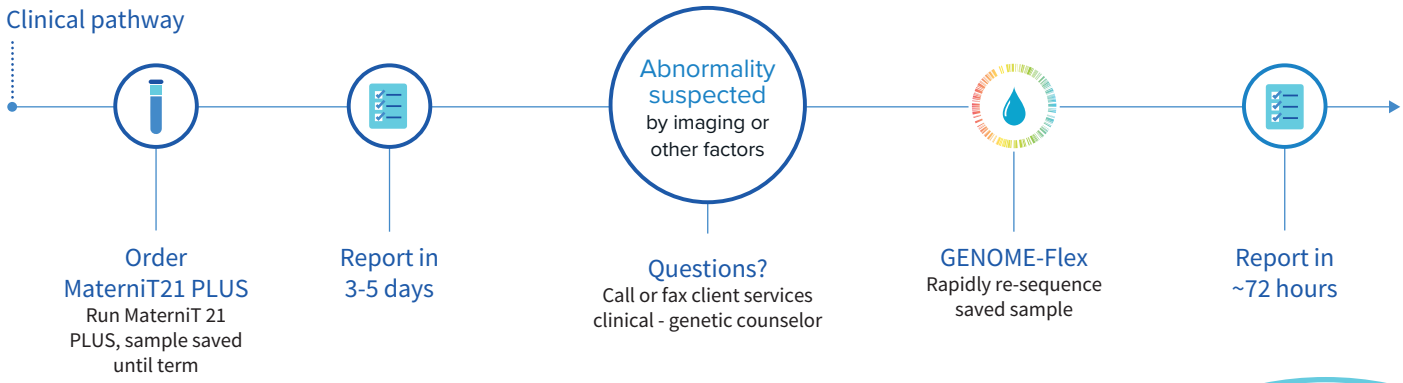
Test failures and patient redraws add unnecessary cost and time and may create anxiety for patients and healthcare providers if decisions are pushed later into pregnancy. MaterniT 21 PLUS has very low published non-reportable rates and will typically return results within 3-5 days starting at 9 weeks into pregnancy.



*Once sample is received at our lab in San Diego

GENOME-Flex high risk pathway

Once a prenatal cfDNA screen has been run and billed to insurance, future screening options for the provider become limited should anomalies be suspected later in pregnancy. A diagnostic procedure is recommended according to clinical practice and society guidelines, but this option may not be desired by the patient. MaterniT 21 PLUS provides an alternative pathway to rapidly resequence previously run MaterniT 21 PLUS samples using the deeper sequencing power of MaterniT GENOME. Often no redraw is required, results are available in approximately 72 hours, and a different insurance billing path is followed.



MaterniT, the clear choice in prenatal cfDNA screening

	MaterniT cfDNA	Your cfDNA
Core test: Trisomy 21, 18, 13 screening	✓	✓
Optional: Sex chromosome aneuploidy, Microdeletions (including 22q / Di George) and fetal sex	✓	?
Genome-wide screening for complex cases	✓	?
GENOME-Flex, a unique noninvasive prenatal testing pathway for genome-wide screening in high-risk patients	✓	?
IVF/egg donor gestations accepted	✓	?
New—Fetal sex and aneuploidy prediction for twins using Mosaicism Ratio[19]	✓	?
Triplets and higher order multifetal gestations accepted	✓	?
Refine PPV and identify potential false positive results with Mosaicism Ratio	✓	?
Successful results at high maternal weight and lower fetal fraction	✓	?
Closely aligned with society guidelines—prenatal screening, diagnostic testing and genetic counseling services from one lab partner	✓	?
Extensive maternal serum screening options, including MS-AFP	✓	?
Accompanied by a comprehensive comprehensive diagnostic portfolio, including Reveal SNP Microarray	✓	?
Online videos and resources for patients and providers	✓	?
Available nationwide, supported by more than 400 managed care plans, more than 2,000 patient service centers and more than 100 certified genetic counselors	✓	?

Draw as early as 9 weeks gestation

Rapid 3-5 day turnaround time†[20]

Low 0.9% overall[21]

1.87% samples drawn at 9 weeks[22]

2.4% in patients that weigh between 200-225 lbs[23]

2.66% in multifetal pregnancies[24]

†Turnaround time is from collection of specimen to issuance of report

Test Name	Test No.	Fetal Sex Opt-Out
MaterniT 21 PLUS Core (Trisomy 21, 18, 13, fetal sex)	**451927**	451951
MaterniT 21 PLUS Core + SCA* (Singletons only)	**451934**	452112
MaterniT 21 PLUS Core + ESS**	**451931**	452136
MaterniT 21 PLUS Core + ESS + SCA* (Singletons only)	**451937**	452122
GENOME-Flex (Add On) (Singletons only)	**452104**	n/a
GENOME-Flex (Add On) Redraw (Singletons only)	**452114**	n/a
MaterniT GENOME (Singletons only)	**451941**	452106

* Sex chromosome aneuploidies ** Enhanced sequencing series (microdeletions, trisomies 16 & 20)

References

1. Rafalko JM, Caldwell S, Tynan J, et al. Impact of mosaicism ratio on positive predictive value of cfDNA screening. *Prenat Diagn*. 2021;41(1):28-34. doi:10.1002/pd.5863
2. Down syndrome. https://medlineplus.gov/genetics/condition/down-syndrome/#frequency. Accessed November 29, 2023.
3. Trisomy 18. https://medlineplus.gov/genetics/condition/trisomy-18/#frequency. Accessed November 29, 2023.
4. Trisomy 13. https://medlineplus.gov/genetics/condition/trisomy-13/#frequency. Accessed December 1, 2023.
5. Turner Syndrome. https://www.genome.gov/Genetic-Disorders/Turner-Syndrome. Accessed December 5, 2023.
6. Klinefelter syndrome. https-://medlineplus.gov/genetics/condition/klinefelter-syndrome/#frequency. December 5, 2023.
7. Triple X syndrome. https://medlineplus.gov/genetics/condition/trisomy-x/#frequency. Accessed December 5, 2023.
8. 47,XYY syndrome. https://medlineplus.gov/genetics/condition/47xyy-syndrome/#frequency. Accessed December 5, 2023.
9. 22q deletion syndrome. https://my.clevelandclinic.org/health/diseases/21182-digeorge-syndrome. December 5, 2023.
10. Cri-du-chat syndrome. https://medlineplus.gov/genetics/condition/cri-du-chat-syndrome/#frequency. December 5, 2023.
11. 1p36 deletion syndrome. https://medlineplus.gov/genetics/condition/1p36-deletion-syndrome/#frequency. Accessed December 5, 2023.
12. Prader-Willi syndrome. https://medlineplus.gov/genetics/condition/prader-willi-syndrome/#frequency. Accessed December 5, 2023.
13. Angelman syndrome. https://medlineplus.gov/genetics/condition/angelman-syndrome/#frequency. Accessed December 5, 2023.
14. Jacobsen syndrome. https://medlineplus.gov/genetics/condition/jacobsen-syndrome/#frequency. Accessed December 5, 2023.
15. Trichorhinophalangeal syndrome type II. https://medlineplus.gov/genetics/condition/trichorhinophalangeal-syndrome-type-ii/#frequency. Accessed December 5, 2023.
16. Wolf-Hirschhorn syndrome. https://medlineplus.gov/genetics/condition/wolf-hirschhorn-syndrome/#frequency. Accessed December 5, 2023.
17. Disorders of Chromosome 16 Foundation. A brief (and basic) overview of Chromosome 16 disorders. http://www.trisomy16.org/about/what_are_doc16.html. Accessed December 5, 2023.
18. Heinrich T, Nanda I, Rehn M, et al. Live-born Trisomy 22: Patient Report and Review. *Mol Syndromol* 2012;3:262-269.
19. Rafalko J, Caldwell S, Soster E et al. Application of mosaicism ratio to multifetal gestations. *PLOS One*. 2021;16(3):e0248467. doi:10.1371/journal.pone.0248467.
20. Internal Data
21. Palomaki GE, Deciu C, Kloza EM, et al. DNA sequencing of maternal plasma reliably identifies trisomy 18 and trisomy 13, as well as Down syndrome: An international collaborative study. *Genet Med*. 2012;14(3):296-305.
22. Compton K, Soster E, Fanelli K, et al. A look at cell-free DNA performance at 9 weeks gestation, stratified by patient weight ranges. Clinical poster presented at NSGC annual conference. November 16, 2022. Nashville, Tennessee.
23. Wardrop J, McCullough R, Boomer T, et al. Maternal weight – impact on noninvasive prenatal testing (NIPT). Clinical poster presented at ACMG annual meeting. 2016. Tampa, Florida.
24. Dyr B, Boomer T, Almasri EA, et al. A new era in aneuploidy screening: cfDNA testing in >30,000 multifetal gestations: Experience at one clinical laboratory. *PLOS One*. 2019;14(8):e0220979.

Scan QR code, or visit **womenshealth.labcorp.com**
Call **877-821-7266** (within the US) / **858-202-9000** (outside US),
or contact your Labcorp representative for more information.

labcorp | Women's Health