QNatal® Advanced

Noninvasive Prenatal Screening

Comprehensive screening with easy-to-read results

- A noninvasive prenatal cell-free DNA (cfDNA) screen
- Can be ordered as early as 10 weeks gestation
- Utilizes next-generation sequencing (NGS) technology and advanced bioinformatics for high sensitivity and specificity.
  See *Important information on page 4
- Low no-call rate[1]
- Can choose to opt out of fetal sex and/or microdeletion reporting

QNatal® Advanced screens for:

Trisomies

Trisomy 21	Down syndrome
Trisomy 18	Edwards syndrome
Trisomy 13	Patau syndrome

Sex chromosome aneuploidies[a]

45,X	Turner syndrome
47,XXY	Klinefelter syndrome
47,XXX	Triple X syndrome
47,XYY	XYY syndrome

Microdeletions[a,b]

22q	DiGeorge syndrome
5p	Cri-du-chat syndrome
1p36	1p36 deletion syndrome
15q	Angelman/Prader-Willi syndromes
11q	Jacobsen syndrome
8q	Langer-Giedion syndrome
4p	Wolf-Hirschhorn syndrome

Fetal sex[b]

[a] Will be reported as additional finding when detected.
[b] Can opt out of receiving results for microdeletions and/or fetal sex.

Comprehensive insights from Quest Diagnostics®—a leader in genetic testing

Quest Diagnostics® has **over 30 years** of experience in providing prenatal screening and diagnostic testing to help you manage your patient's care more effectively. We offer **more than 900 genetic tests** using some of the newest technologies available today.

QNatal Advanced

Strong lab performance

High sensitivity and specificity during verification/validation testing and in the real world*

QNatal Advanced verification/ validation study

Prior to launch, the QNatal Advanced technology was verified and validated in a study of 2,752 pregnant women, showing high sensitivity and specificity.[2]

Screen	Sensitivity	Specificity
Singletons (n=2,637)		
90 of 90 trisomy 21	>99.9%	>99.9%
30 of 30 trisomy 18	>99.9%	>99.9%
21 of 21 trisomy 13	>99.9%	>99.9%
1 of 1 sex aneuploidies	>99.9%	>99.9%
371 of 372 fetal sex	>99.7% accuracy	
Twins (n=115)		
10 of 10 trisomy 21	>99.9%	>99.9%
4 of 4 trisomy 18	>99.9%	>99.9%
1 of 1 trisomy 13	>99.9%	>99.9%

Real world data

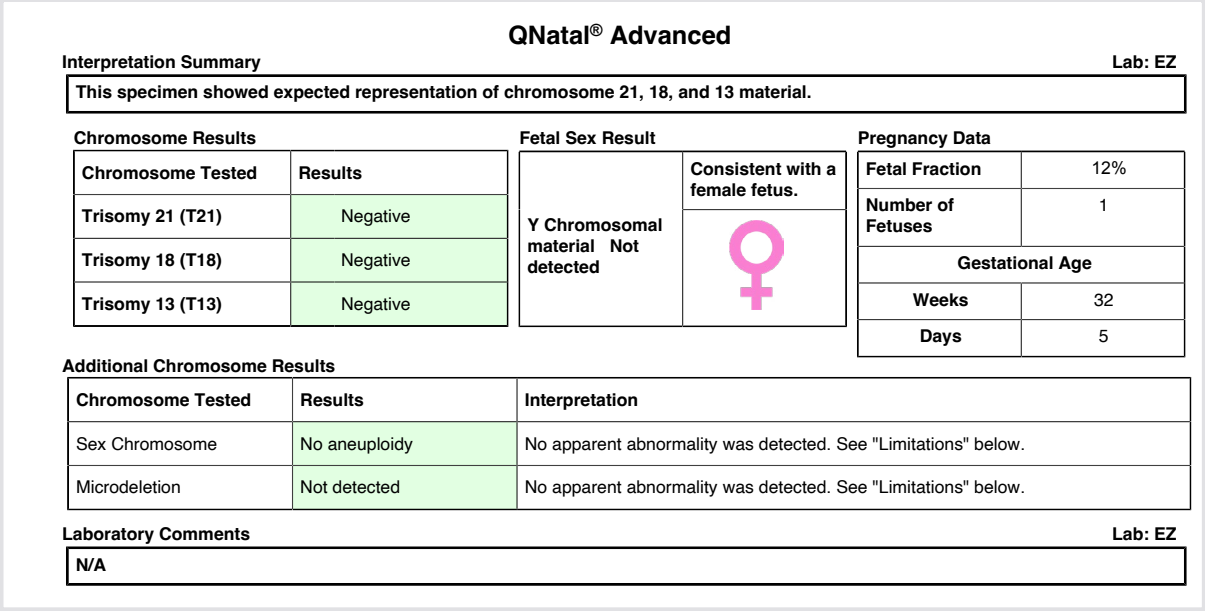
Study shows strong positive predictive value (PPV) in real world ~70,000 unique pregnancies.[1]

Chromosome abnormality	QNatal Advanced PPV
Trisomy 21	98.1%
Trisomy 18	88.2%
Trisomy 13	59.3%
Sex chromosome aneuploidy	69%
Microdeletions	75%

Quest supports your patients and your practice throughout the pregnancy journey

Quick results with simple, easy-to-read reporting

Results are generally available in 5-7 days. Reports are easy to read, with clear positive or negative results for the trisomies. As recommended by ACMG, fetal fraction is included on all reports, and all positive results for trisomies include age-adjusted PPV.



QNatal® Advanced

Interpretation Summary — **Lab: EZ**

This specimen showed expected representation of chromosome 21, 18, and 13 material.

Chromosome Results

Chromosome Tested	Results
Trisomy 21 (T21)	Negative
Trisomy 18 (T18)	Negative
Trisomy 13 (T13)	Negative

Fetal Sex Result

Y Chromosomal material Not detected	Consistent with a female fetus. ♀

Pregnancy Data

Fetal Fraction	12%
Number of Fetuses	1
Gestational Age	
Weeks	32
Days	5

Additional Chromosome Results

Chromosome Tested	Results	Interpretation
Sex Chromosome	No aneuploidy	No apparent abnormality was detected. See "Limitations" below.
Microdeletion	Not detected	No apparent abnormality was detected. See "Limitations" below.

Laboratory Comments — **Lab: EZ**

N/A

Convenient blood draws

Quest Diagnostics has nearly 2,000 Patient Service Centers (PSCs) located throughout the US, giving your patients the accessibility they need.

Access to genetic counselors

Our Genomics Client Services team are ready to assist you with test selection and result interpretation support, and your patients with post-test consultation on any Quest genetic test result.

Call **1.866.GENE.INFO** (1.866.436.3463).

A full-service genetics laboratory

We offer a broad range of testing options that includes cytogenetic testing on amniocentesis and CVS specimens. If your patients need follow-up diagnostic testing, you can feel comfortable knowing the results will be analyzed by the same laboratory.

A focus on innovation

With peer-reviewed publications and research studies, Quest continues to innovate and help Qshape women's healthcare. As a lab-developed Qtest, QNatal Advanced continues to evolve as more women are tested and technology advances.

How to order QNatal Advanced

Easily order QNatal Advanced and other pregnancy-related testing through your EMR or Quanum® Lab Services Manager.

Test name	Test code	CPT code	Specimen requirements
QNatal® Advanced	92777	81420	• 10mL (minimum 8mL) whole blood in 1 cell-free DNA Streck tube at 10 weeks gestation or later • Store specimens at room temperature; do not refrigerate or freeze

Understanding costs

Patient Navigators

Patient Navigators will work directly with your patients to answer any billing questions about their prenatal genetic screenings, clarify costs, and assist with financial assistance applications, for patients who qualify.

Your patients can access Patient Navigators via phone and email: Call **1.888.445.5011** or email **PatientNavigators@QuestDiagnostics.com**

Prior authorization (PA) services for all QNatal Advanced orders

Orders are routed automatically to our Specialty Testing Services (STS) team who work with a patient's health plan to determine coverage and need for prior authorization.

For questions specific to prior authorization, call **1.888.445.5011**

Flexible financial options

For patients with insurance—with coverage and appropriate ICD-10 diagnosis codes, patients can pay as little as $0 based on their insurance plan

For the insured who experience a denial—if the health plan denies QNatal Advanced as a "non-covered service," the patient should pay no more than $300

For patients without insurance—uninsured patient price (UPP) available in all states for qualified patients; alternative UPP pricing is available in FL, NH, MA, ME, RI, VT, and TX

79% of insured patients pay less than $99,[a] and our convenient, interactive cost estimator provides an estimated out-of-pocket responsibility in real time.

[a] Based on full-year 2022 claims analysis.

For more information, contact your **Quest Diagnostics account representative** or visit **QNatal.com**

For clinician consultation on test results, call **Genomic Client Services** at **1.866.GENE.INFO (1.866.436.3463)** Monday-Friday from 8:30 AM to 8:00 PM ET

***Important information**

QNatal® Advanced is a cell-free DNA test that screens for increased risk of certain fetal chromosomal abnormalities that may cause birth defects, including Trisomy 21 (Down Syndrome), Trisomy 18, Trisomy 13, and certain sex chromosome abnormalities (i.e., 45,X, 47,XXY, 47,XXX, and 47,XYY). In addition, if selected as an option, QNatal Advanced can screen for certain microdeletions (i.e., 22q, 5p, 1p36, 15q, 11q, 8q, and 4p) that may cause birth defects, and/or for fetal sex. This test does not assess the risk of fetal anomalies such as neural tube defects or ventral wall defects. QNatal Advanced is not recommended before 10 weeks gestation due to a significantly increased risk of a failed result.QNatal is a "screening" test, not a diagnostic test, and therefore all positive/increased risk results should be followed by genetic counseling and further diagnostic testing and procedures, when clinically indicated. Pregnancy management decisions should not be based on the results of a cfDNA test alone.

As with any test, there may be false positives or false negatives. The positive predictive value of the screening test varies by genetic marker, and may be lower for rare conditions. Performance data for the QNatal Advanced may be obtained by contacting Quest Diagnostics at 1.866.GENE.INFO (1.866.436.3463).QNatal Advanced is a laboratory developed test that has been developed and validated, pursuant to the Clinical Laboratory Improvements Amendments of 1988 (CLIA), and as such it has not been reviewed by FDA.

References

1. Guy C, Haji-Sheikhi F, Rowland CM, et al. Prenatal cell-free DNA screening for fetal aneuploidy in pregnant women at average or high risk: Results from a large US clinical laboratory. *Mol Genet Genomic Med*. 2019;7(3):e545. Finding of a no-call rate of 3.5%; several authors affiliated with Quest Diagnostics. "No call rate" refers to the percentage of samples for which results could not be reported. doi:10.1002/mgg3.545
2. Anderson B et al. An automated, non-invasive prenatal screening assay (NIPS) for trisomy 21,18,13 in singleton and twin gestations [FIGO abstract FCS79.3.]. *Int J Gynaecol Obstet.* 2015;131(Suppl 5):E264. The study summarized in this abstract was used to verify/validate QNatal Advanced prior to launch. Subsequent validation data related to updates are available upon request at 1.866.GENE.INFO (1.866.436.3463). Data from the Anderson study regarding the sex chromosome aneuploidies and microdeletions are also available upon request. Twin pregnancies were included in the study but less data is available for twin pregnancies than singleton pregnancies.

Image content features models and is intended for illustrative purposes only. Test codes may vary by location. Please contact your local laboratory for more information.

The CPT® codes provided are based on American Medical Association guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

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