Quest Diagnostics®

QNatal® Advanced

Noninvasive Prenatal Screening

Comprehensive screening for clearer insight

- A non-invasive prenatal cell-free DNA (cfDNA) screen
- Can be ordered as early as 10 weeks gestation
- Utilizes Next-Generation Sequencing (NGS) technology and superior bioinformatics for high sensitivity, specificity, and PPV. See Important information on page 4*
- One of the lowest "no call" rates in the industry
- 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 chromosomes[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

Quality you can trust 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 patients' care more effectively. We offer **more than 900 genetic tests** using some of the newest technologies available today.

Alpha Labs

Comprehensive screening for clearer insight

For more information, email us at **alpha@alphalabs.ca**

1262 Don Mills Road, Toronto, ON M3B 2W7 Canada | **alphalabs.ca**

QNatal Advanced
Strong clinical performance

Superior sensitivity and specificity

QNatal Advanced was verified and validated in a study of 2,752 pregnant women, showing high sensitivity and specificity.[1]

Trisomy 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%
18 of 18 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%

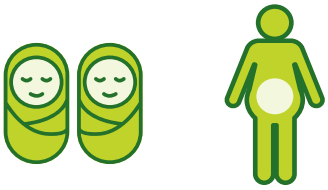
High overall positive predictive value (PPV)

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

[a]PPV for 22q11.2 deletion (DiGeorge) syndrome estimated at 69%-100% based on data presented at the 2020 ACMG Annual Clinical Genetics Meeting.

QNatal Advanced shows solid performance in both high- and average-risk populations, including twin pregnancies[2]

- Demonstrated in a real-world study including 69,794 unique pregnancies
- Validated technology and advanced bioinformatics for high PPV and a low “no call” rate
- Excellent analytical sensitivity and specificity for trisomy 21, 18, and 13
- Can be reliably performed on pregnancies conceived with donor eggs



Quest supports your patients and your practice throughout the pregnancy journey

Quick results with simple, clear reporting

Results are generally available in 7-10 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 the 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

Quest Diagnostics®

Convenient blood draws

Alpha Labs has Patient Service Centers (PSCs) located throughout Southwest Ontario, giving your patients the accessibility they need.

Access to genetic counselors

Quest has a team of genetic counselors ready to answer questions from ordering clinicians. To reach a genetic counselor, call **1.866.GENE.INFO** (1.866.436.3463) Monday through Friday from 8:30 AM to 8:00 PM ET.

A full-service genetics laboratory

Quest offers a broad range of testing options that includes everything from cytogenetic testing on amniocentesis, to 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 shape women's healthcare. As a lab-developed test, 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 Alpha Labs Patient Portal.

Specimen requirements

- 20 mL whole blood collected in 1 Cell-Free DNA Streck tube at 10 weeks gestation or later
- Store specimens at room temperature; do not refrigerate or freeze

For more information, contact Alpha Labs Customer Services at **clientsupport@alphalabs.ca**

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. 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.
2. 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. doi:10.1002/mgg3.545

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