Sonora Quest Laboratories™

A Subsidiary of Laboratory Sciences of Arizona

QNatal® Advanced

Noninvasive Prenatal Screening

Comprehensive screening for clearer insight

- A noninvasive 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
- 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 Sonora Quest Laboratories - a leader in genetic testing

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

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%

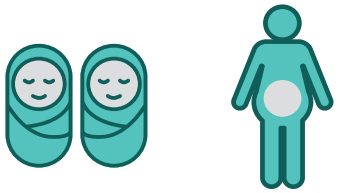
High overall positive predictive value (PPV)

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

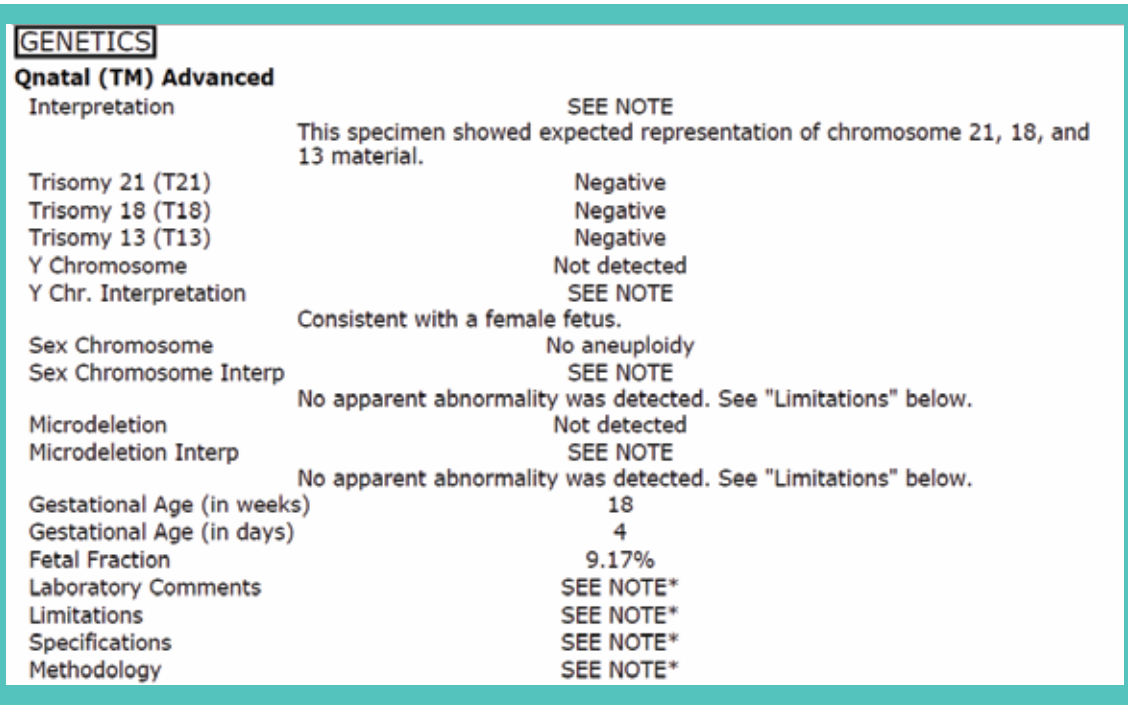


We support your patients and your practice

throughout the pregnancy journey

Quick results with simple, clear reporting

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



GENETICS

Qnatal (TM) Advanced

Interpretation	SEE NOTE
	This specimen showed expected representation of chromosome 21, 18, and 13 material.
Trisomy 21 (T21)	Negative
Trisomy 18 (T18)	Negative
Trisomy 13 (T13)	Negative
Y Chromosome	Not detected
Y Chr. Interpretation	SEE NOTE
	Consistent with a female fetus.
Sex Chromosome	No aneuploidy
Sex Chromosome Interp	SEE NOTE
	No apparent abnormality was detected. See "Limitations" below.
Microdeletion	Not detected
Microdeletion Interp	SEE NOTE
	No apparent abnormality was detected. See "Limitations" below.
Gestational Age (in weeks)	18
Gestational Age (in days)	4
Fetal Fraction	9.17%
Laboratory Comments	SEE NOTE*
Limitations	SEE NOTE*
Specifications	SEE NOTE*
Methodology	SEE NOTE*

Convenient blood draws

Sonora Quest has 75+ Patient Service Centers (PSCs) located throughout Arizona, including 15 inside Safeway stores, providing your patients the accessibility they need.

Access to genetic counselors

To speak to a genetic counselor call Quest Genomics Client Services* at 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

We offer 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 network.

A focus on innovation

With peer-reviewed publications and research studies, we continue 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.

*Available through one of our parent companies, Quest Diagnostics.

How to order

QNatal Advanced

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

Test Name	Test Code	CPT Code[a]	Specimen Requirements
QNatal® Advanced	906553	81420	Do not draw before 10 weeks gestation. 20 mL (16 mL min.) whole blood in TWO streck cell-free glass tubes; 10 mL in each tube. Supply #27859 (glass tubes with black and tan stopper). Store specimens at room temperature; do not refrigerate or freeze.

For more information, contact your **Sonora Quest Laboratories Account Manager**

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

[a]The CPT codes provided are based on AMA 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.

*Available through one of our parent companies, Quest Diagnostics.

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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