

verifi[®]
prenatal test by



the reassurance of

knowing



Going to greater lengths for the answers that matter most.

The *verifi*[®] prenatal test by Pacific Rim provides reliable, comprehensive answers about the health of a developing fetus.

The *verifi*[®] test by Pacific Rim, represents a major advance in prenatal testing, providing accurate answers about fetal chromosomal health—without the risks associated with invasive procedures, such as amniocentesis or chorionic villus sampling (CVS). Performed as early as 10 weeks gestation, the *verifi*[®] test by Pacific Rim demonstrates superb sensitivity and specificity for the most prevalent trisomies.

Medical societies agree that all pregnant women should be offered prenatal screening and diagnosis for fetal abnormalities and that NIPT is a major advance in screening methodologies.¹⁻⁵



Test performance in most common chromosomal aneuploidies⁶

	N	Observed Sensitivity	95% CI	Observed Specificity	95% CI
T21 Down syndrome	577	99.14%	98.0–99.7	99.94%	99.90–99.97
T18 Edwards syndrome	175	98.31%	95.0–99.6	99.90%	99.86–99.93
T13 Patau syndrome	53	98.15%	90.0–99.9	99.95%	99.91–99.97

⁶Sex chromosome mosaicism cannot be distinguished by this method (the occurrence of which is <0.3%). Patients with such mosaicism will have a sex chromosome result reported and will fall into one of the six categories (Monosomy X, XXX, XXY, XYY, XX, XY).



The *verifi*[®] test by Pacific Rim can also detect sex chromosome aneuploidies in singleton pregnancies—at no extra charge.

<ul style="list-style-type: none"> • Monosomy X (Turner syndrome) • XXX (Triple X) • XXY (Klinefelters syndrome) 	<ul style="list-style-type: none"> • XYY (Jacobs syndrome) • Fetal sex (XX or XY)—aids in risk stratification of X-linked disorders such as hemophilia
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Test performance in most common sex aneuploidies*⁷

	N	Sensitivity	95% CI	Specificity	95% CI	Accuracy	95% CI
MX	508	95.0% (19/20)	75.1–99.9	99.0% (483/488)	97.6–99.7	-	-
XX	508	97.6% (243/249)	94.8–99.1	99.2% (257/259)	97.2–99.9	98.4%	96.9–99.3
XY	508	99.1% (227/229)	96.9–99.9	98.9% (276/279)	96.9–99.8	99.0%	97.7–99.7

XXX, XXY, XYY: Limited data of these more rare aneuploidies preclude performance calculations.

Expansion into twin pregnancies.

Recently, the *verifi*[®] prenatal test by Pacific Rim has been expanded to include the option to test for T21, T18 and T13 in both monozygotic and dizygotic twin pregnancies. A test for the presence of the Y chromosome can be ordered for twins as well.

Committed to research.

With its superior technology, the *verifi*[®] test by Pacific Rim provides clinical evidence showing across- the-genome analysis in a real-world population. The performance of the *verifi*[®] prenatal test by Pacific Rim was evaluated in a major scientific study in which more than 60 leading US medical research and teaching institutions participated. The study findings were reviewed and published in the preeminent journal read by obstetricians and gynecologists. A second study, published subsequently, presented the test’s performance under regular clinical conditions and found similar results.⁸

Intended use in singleton pregnancies

This screening test is intended for patients at 10 weeks or greater gestation with singleton pregnancies who meet any of the following criteria:

- Advanced maternal age (≥35 years at delivery)
- Positive serum screen
- Abnormal ultrasound
- History suggestive of increased risk for T21, T18, or T13, or sex chromosome aneuploidy

Intended use in twin pregnancies

This screening test is intended for patients at 10 weeks or greater gestation with twin pregnancies who meet any of the following criteria:

- Advanced maternal age (≥32 years at delivery)
- Positive serum screen
- Abnormal ultrasound
- History suggestive of increased risk for T21, T18, or T13

Taking a deeper look at the science of knowing.

The *verifi*[®] test by Pacific Rim advantage — A more stringent and optimized approach to genetic sequencing.

The *verifi*[®] prenatal test by Pacific Rim leverages the power of Massively Parallel Sequencing (MPS) across the whole genome. The industry's deepest sequencing approach combined with a highly optimized algorithm provides a clearer, more reliable answer than other methods.

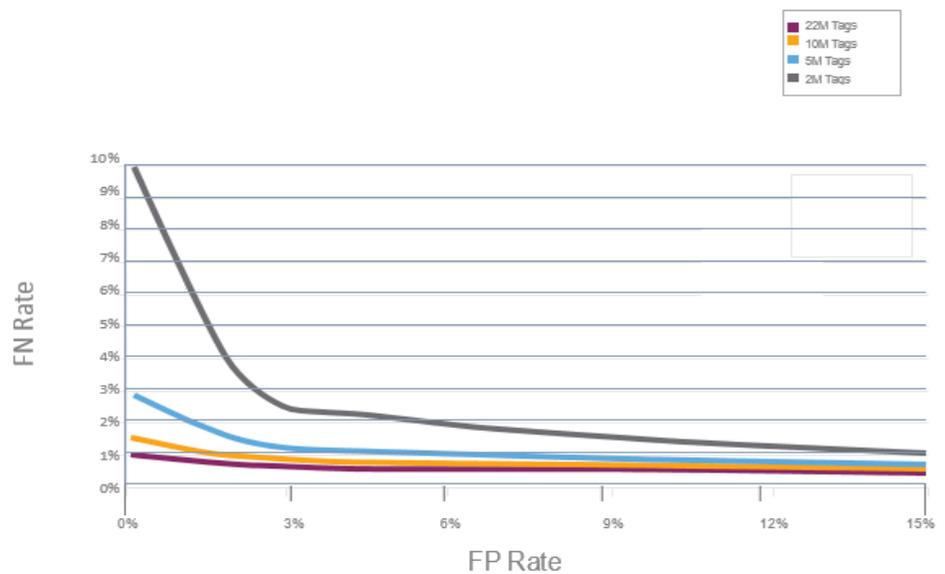
In the graph, shallower sequencing necessitates using fetal fraction (ff) estimates as compensation for weaker sequencing power. Without using ff estimates, the incidence of false negatives would be clinically unacceptable and result in higher numbers of sample rejections and delayed result time. The science of deeper sequencing



Other targeted non-invasive prenatal tests



verifi[®] prenatal test by Pacific Rim: whole genome sequencing



Utilizing the power of deeper sequencing, the *verifi*[®] test by Pacific Rim gives reassurance by:

- Eliminating unnecessary sample rejections
- Reducing the need for redraws
- Obviating requests for paternal samples
- Providing fast time to report (3–5 business days)⁹

The proof is in the data.

Our excellent NPV and PPV results are achieved without relying on variable ff estimates or other correction factors.⁶

	Positive Predictive Value	Negative Predictive Value
T21	0.970	0.999

The *verifi*[®] test by Pacific Rim with our enhanced SAFeR[™] algorithm increases the specific signal of aneuploid chromosomes and hence improves the overall accuracy of classifying affected samples. The test output provides definitive results, not a risk score, and it is not dependent on maternal age, maternal weight, gestational age (after 10 weeks) or ethnicity.



verifi[®] test by Pacific Rim	Available targeted sequencing tests
Definite, informative results	Ambiguous risk scores similar to serum screens
Lowest test failure rate (0.1%) ⁶	High failure rates (5%–10% or greater)
Not constrained by patient factors or paternal sample	May rely on patient factors or require paternal samples to improve accuracy
Accepts egg donors	May exclude egg donors

Shedding needed light on fetal chromosomes simply, safely, sooner.

An easy, non-invasive blood test delivering the answers you seek in just days.

The *verifi*[®] prenatal test by Pacific Rim is easy to order and needs only 1 tube of blood (just a 7mL sample). Simply ship the blood sample in its proprietary packaging to our CAP- accredited[†] clinical lab. Our easy-to-read reports are available to the ordering physician via fax, within just 3–5 business days.

The *verifi*[®] test by Pacific Rim report is well organized and easy to read

Basic reports contain results for chromosomes 21, 18 and 13. Test reports include one of three possible results for chromosomes 21, 18, and 13: *No Aneuploidy Detected*, *Aneuploidy Detected*, or *Aneuploidy Suspected (Borderline Value)*. If the sex chromosomes option is selected, results for Monosomy X, XXX, XXY and XYY will be included. (If no aneuploidies are detected, fetal sex will be reported.) Sex chromosomes will be reported as *No Aneuploidy Detected* or *Aneuploidy Detected*.

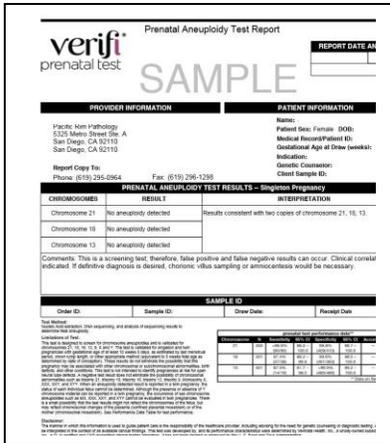
Know what a *verifi*[®] test by Pacific Rim case looks like.

High-risk patient considering an invasive procedure

38-year-old woman with history of infertility who conceived via *in vitro* fertilization (IVF)

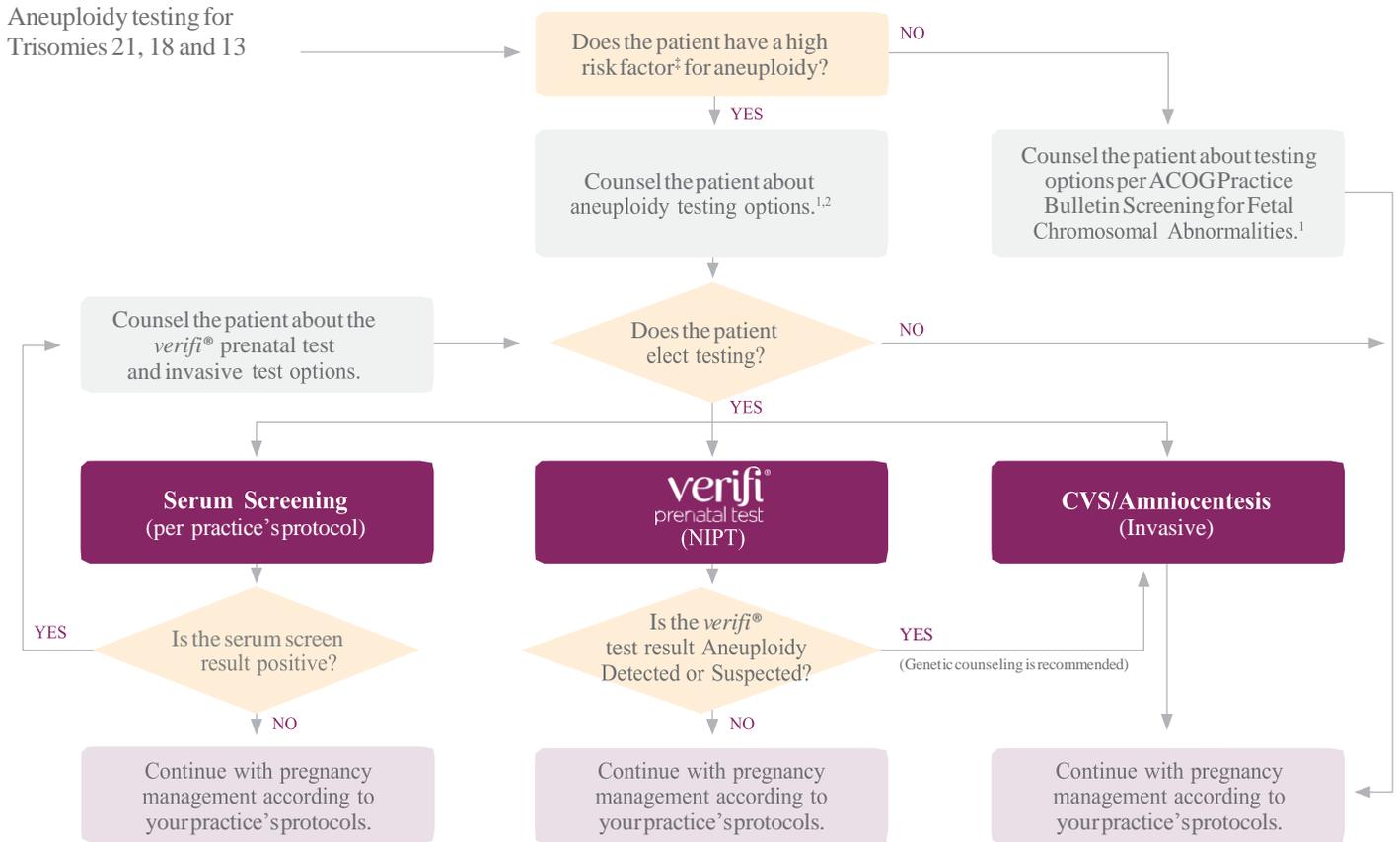
Genetic counseling to discuss testing options	<ul style="list-style-type: none"> – Screening – Invasive test—fearful of procedural loss – <i>verifi</i>[®] prenatal test by Pacific Rim – Ultrasound
Patient elects the <i>verifi</i> [®] prenatal test by Pacific Rim	<ul style="list-style-type: none"> – Chromosome 21—No Aneuploidy Detected – Chromosome 18—No Aneuploidy Detected – Chromosome 13—No Aneuploidy Detected – Normal ultrasound

Patient comfortable declining invasive testing due to high sensitivity of *verifi*[®] prenatal test by Pacific Rim and normal ultrasound result. Procedural risks avoided.



[†]College of American Pathologists.

Incorporating the *verifi*[®] prenatal test by Pacific Rim into practice



*This workflow was developed in adherence to the current ACOG/SMFM Committee Opinion No. 545, December 2012. Patient can choose/decline options based on clinical discussion with her provider.

Knowledgeable support for your practice.

Get started with the *verifi*[®] prenatal test by Pacific Rim today.

To learn more, contact one of our knowledgeable

Sales Representatives at 855.777.4327 or visit

www.pacificrimpathology.com

Disclaimer

The manner in which this information is used to guide patient care is the responsibility of the healthcare provider, including advising for the need for genetic counseling or additional diagnostic testing. Any diagnostic testing should be interpreted in the context of all available clinical findings.

This test was developed by, and its performance characteristics were determined by, YYYYY. It has not been cleared or approved by the U. S. Food and Drug Administration. Although laboratory-developed tests to date have not been subject to U.S. FDA regulation, certification of the laboratory is required under the Clinical Laboratory Improvement Amendments (CLIA) to ensure the quality and validity of the tests. Our laboratory is CAP-accredited and certified under CLIA as qualified to perform high-complexity clinical laboratory testing.

Limitations of test

The *verifi*[®] prenatal test by Pacific Rim is a highly accurate advanced screening test that is non-invasive. This test is designed to detect chromosome aneuploidies and is validated for chromosomes 21, 18, and 13, X and Y. The test is validated for singleton and twin pregnancies with gestational age of at least 10 weeks. Genetic counseling before and after testing is recommended. These results do not eliminate the possibility that this pregnancy may be associated with other chromosomal abnormalities, birth defects, or other complications. A negative test result does not preclude the presence of trisomy 21, trisomy 18, or trisomy 13, Monosomy X, XXX, XXY, and XYY. When an aneuploidy detected result is reported in a twin pregnancy, the status of each individual fetus cannot be determined. The presence or absence of Y chromosome material can be reported in a twin pregnancy; however, the occurrence of sex chromosome aneuploidies such as MX, XXX, XXY, and XYY, cannot be evaluated in twin pregnancies. There is a small possibility that the test results might not reflect the chromosomes of the fetus, but may reflect the chromosomal changes of the placenta (confined placental mosaicism), or of the mother (chromosomal mosaicism).

Results of "Aneuploidy Detected" or "Aneuploidy Suspected" are considered positive and patients should be offered invasive prenatal procedures for confirmation. Chorionic villus sampling and amniocentesis provide diagnostic information.

References

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Additional studies

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