Validated performance

The Vanadis® NIPT system is intended for screening conditions such as trisomies 21, 18 and 13. Sex determination is offered as an option for nonmedical purposes, only in countries where permitted. The accuracy of NIPT for screening other chromosomal conditions still needs to be demonstrated and is currently not recommended by international scientific societies.[3]

Noninvasive prenatal testing done on the Vanadis NIPT system can be offered to pregnant women after at least 10 weeks of gestation. Twin pregnancies may be analyzed with the Vanadis system*.

Clinical studies have demonstrated that the Vanadis NIPT system could improve detection and false positive rates, while minimizing the number of no-calls.

	T21	T18	T13
Detection Rate 95% CI	**100.0% (80/80)** 95.5%-100%	**91.4% (32/35)** 76.9%-98.2%	**100.0% (10/10)** 69.2%-100%
False Positive Rate 95% CI	**0.0% (0/666)** 0.0%-0.6%	**0.2% (2/1033)** 0.0%-0.7%	**0.1% (1/1033)** 0.0%-0.5%
Observed no-call rate: 0.94% (after first pass)			

Vanadis Clinical Performance[4]

Products comprising the Vanadis NIPT system are CE-marked *in vitro* diagnostic products in accordance with European directive 98/79/EC.

** There is limited clinical evidence of the sensitivity and specificity of the assay in this population.[4]*

Products may not be licensed in accordance with the laws in all countries, such as the United States. The reporting of fetal sex determination is an optional feature, not offered in countries where such reporting is not permitted such as India. Contact your local Revvity representative for availability.

The content is provided solely for informational purpose and does not constitute medical advice or intended to be used as healthcare recommendations.

References:
1. Gil MM. et al, Ultrasound Obstet Gynecol DOI: 10.1002/uog.17484
2. Dahl F. et al, Sci. Rep. 2018 Mar;8:4549. doi:10.1038/s41598-018-22606-0
3. Gregg et al. Genet Med. (2016) doi:10.1038/gim.2016.97
4. Vanadis Kit Insert, Version 4

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More women deserve the right to NIPT.

Vanadis® NIPT System
Noninvasive Prenatal Testing

For healthcare professionals

A whole new way to NIPT

Noninvasive prenatal testing (NIPT), based on the analysis of cell-free DNA (cfDNA), has demonstrated a superior performance for screening common trisomies. From a simple blood test, NIPT can detect trisomies 21 (Down syndrome), 18 (Edwards syndrome) and 13 (Patau syndrome) with very low rates of false negatives (<1%) and false positives (<1%), reducing the risk of fetal loss due to invasive procedures[1].

By enabling safe and early access to reliable results, NIPT has expanded rapidly worldwide – but its usage has often been limited to high-risk pregnancies due to the complexity, cost, and capacity of existing sequencing-based NIPT technologies.

Based on a breakthrough in advanced genetic analytics, the Vanadis NIPT system is a high-precision and cost-effective solution that reduces the complexity of cfDNA screening and increases access for women everywhere.

- High-precision assay to minimize the no-call rate
- Non-sequencing technology to enable wider use in local laboratories
- Cost-effective solution to help improve the global level of prenatal care

Understanding the benefits of a high-precision assay

By targeting thousands of chromosomal sequences, the Vanadis platform can count an average of 650,000 molecules per chromosome. High precision is achieved through high-yield counting and by eliminating PCR.

The high-precision of Vanadis NIPT, greatly reduces variation and tightens the Z-Score distribution. This allows for accurate screening of aneuploidies even in samples with lower fetal fractions and provides one of the lowest no-call rates among NIPTs. Figure 2 illustrates the benefits of utilizing a high-precision assay when analyzing samples with low fetal fractions.

Breakthrough technology with no sequencing, no PCR

The Vanadis NIPT system is an NIPT screening platform that enables targeted cfDNA analysis without PCR amplification, instead directly capturing target fragments and labeling them for counting[2]. Unlike complex sequencing-based platforms, Vanadis NIPT enables cost-efficient, high-performance screening for fetal aneuploidies using standard microplates, eliminating the need for DNA sequencing, microarrays, and microfluidics.

The Vanadis NIPT system's technology very precisely selects thousands of DNA fragments from target chromosomes using complementary probes. The probes are used together with DNA modification enzymes and DNA polymerase to create DNA circles that are then copied into long repeated DNA chains. The DNA chains collapse into spherical DNA objects that are labeled with chromosome-specific fluorophores and then imaged using a microplate scanner (see Figure 1).

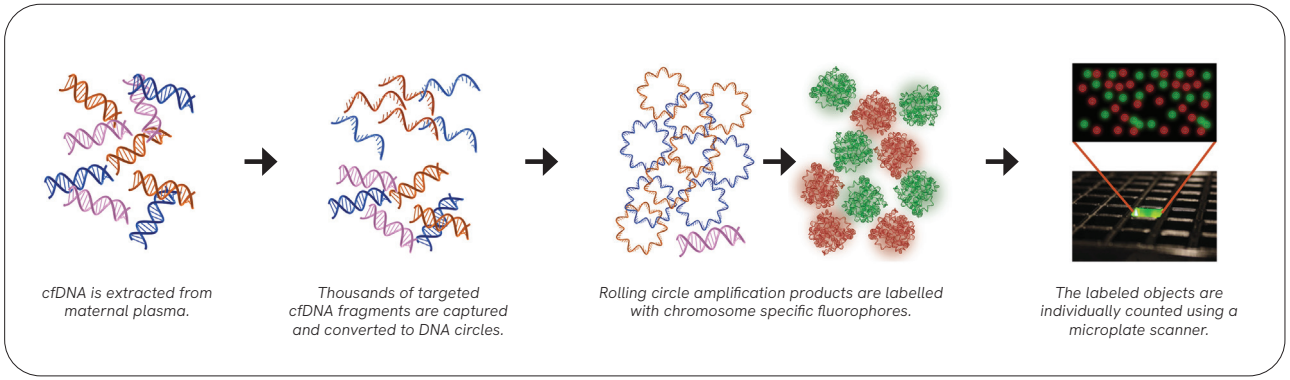

Figure 1: Vanadis NIPT technology

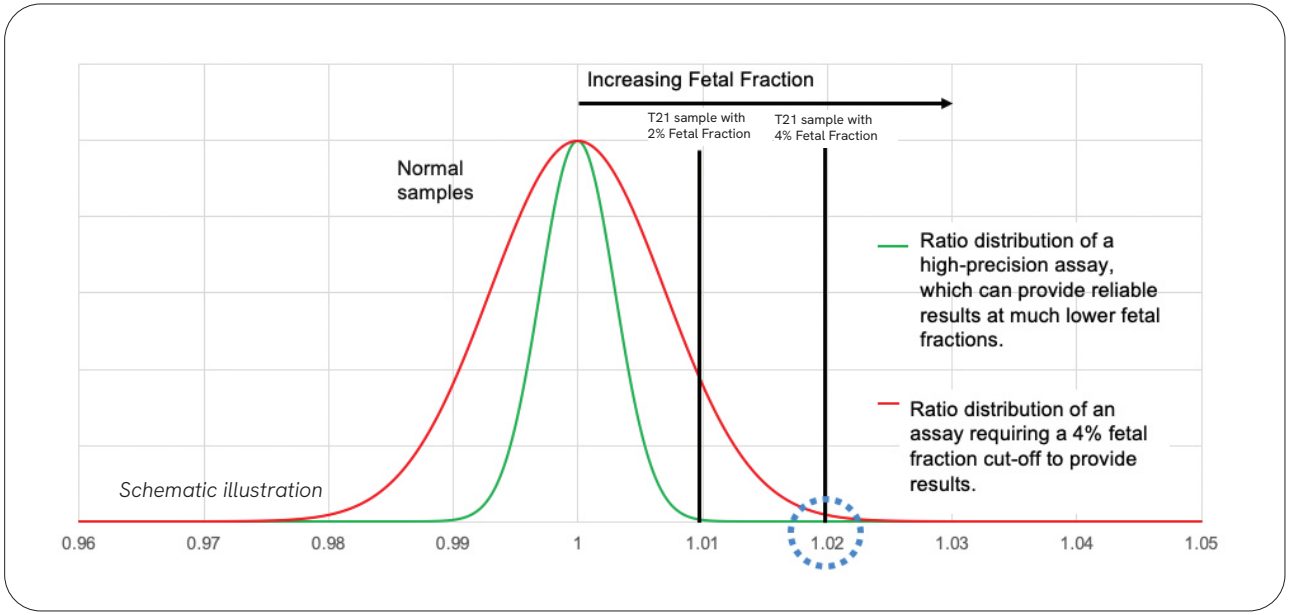

Figure 2: Chromosomal ratio (Chr21/ChrRef).