Vanadis® NIPT System
Noninvasive Prenatal Testing

PerkinElmer®
For the Better

EASIER ACCESS TO NIPT

Vanadis NIPT: Precision Technology from the World's Leader in Prenatal Testing

With our high-throughput Vanadis® NIPT solution, we're taking much of the complexity out of cell-free DNA (cfDNA) testing, making it accessible to more women – and more cost-effective for your laboratory. This breakthrough technology eliminates PCR amplification and gene sequencing, and it's so easy to use that one lab technician can handle up to 20,000 samples per year. Walkaway automation streamlines the process from primary tube to final results. And it complies with European regulations for *in vitro* diagnostics products as it's CE-IVD marked.

What Makes the Vanadis NIPT System Unique?

Breakthrough technology, eliminating PCR and sequencing to provide cfDNA testing to any laboratory

A scalable platform, allowing a single technician to run up to 20,000 samples per year to cope with an ever-increasing workload

Leading prenatal screening software for risk calculation, supporting the implementation of all screening models

Walkaway automation, enabling a streamlined workflow for greater efficiency

Easy-to-use system with full traceability of both samples and reagents

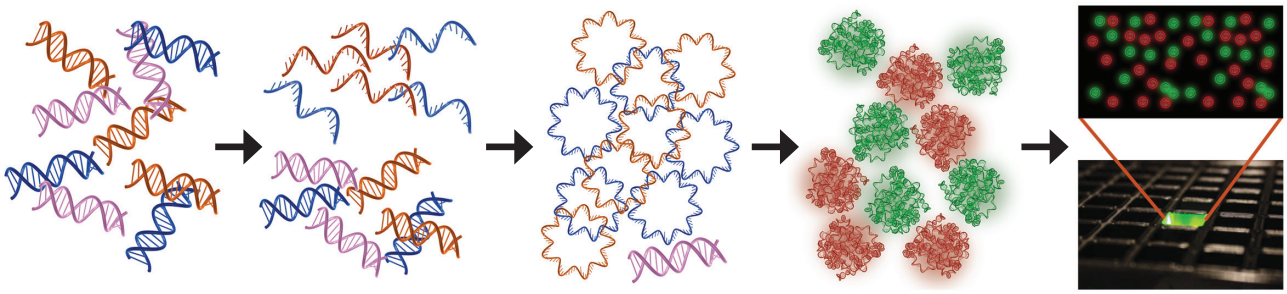
Service and support from PerkinElmer, the world's leader in prenatal screening solutions

BREAKTHROUGH TECHNOLOGY WITH NO PCR, NO SEQUENCING

Unlike complex, expensive sequencing-based platforms, Vanadis NIPT enables cost-efficient, high-performance screening for fetal aneuploidies using standard microplates and automated sample processing – from primary blood tube to final reporting. Highly precise, the Vanadis NIPT system converts target chromosomes into spherical fluorescent DNA objects that simplify data analysis.

The cfDNA Screening Solution for All Laboratories

Vanadis is the only NIPT screening platform to enable targeted cfDNA analysis without PCR, instead directly capturing target fragments and labeling them for counting. A proprietary nanofilter plate then captures labeled molecules for imaging, eliminating the need for data-intensive steps such as DNA sequencing, microarrays, and microfluidics.



cfDNA is extracted from maternal plasma.

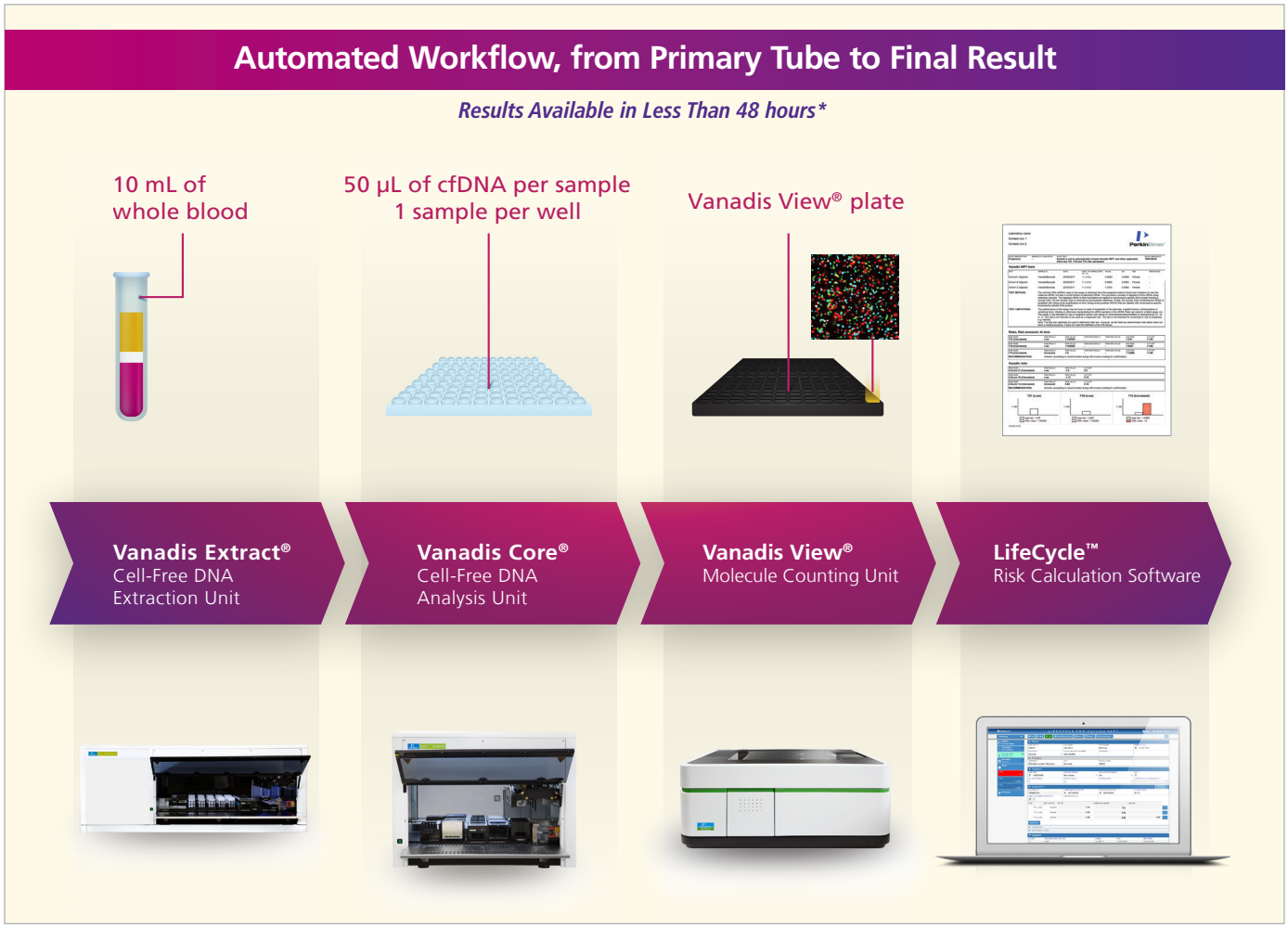
Thousands of targeted cfDNA fragments are captured and converted to DNA circles.

Rolling circle replication products are labelled with chromosome specific fluorophores.

The labeled objects are individually counted using a microplate scanner.

Walkaway Automation for Greater Efficiency

With Vanadis technology, all the critical steps are automated, starting with pipetting steps to reduce manual errors. Plasma volumes are monitored by camera to avoid contamination by the buffy coat, and samples and reagents are barcoded for complete tracking throughout the workflow. Software guides you through the process, with user-friendly touchscreens, and the software enables remote workflow management for ease of use. LifeCycle™ software connects to your LIMS systems to reduce manual errors and simplify data management.



Minimum Hands-on Time

Apart from sample centrifugation steps, hands-on time can be as little as 40 minutes, depending on the number of samples being tested.

	Vanadis Extract®	Vanadis Core®	Vanadis View®	Total
48 Samples	20 minutes	~20 minutes	3 minutes	~40 minutes
84 Samples	40 minutes	~20 minutes	3 minutes	~60 minutes

Scalable Throughput to Support Evolving Needs

The Vanadis system was developed to offer maximum flexibility to laboratories whose workload encompasses from 2,000 to 20,000 samples per year. What's more, no minimum number of samples is needed to start extraction, so labs can get started using the Vanadis system right away.

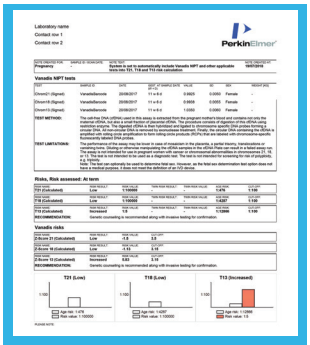
* For 48 samples

EASY TO LEARN, EASY TO USE

Automated plasma pipetting helps avoid contamination.

Reagents and samples are barcoded to enable complete traceability.

Intuitive software guides you through the process.



Patient reports can be customized to suit your reporting needs.

INTUITIVE INTERFACE, LEADING RISK-CALCULATION SOFTWARE

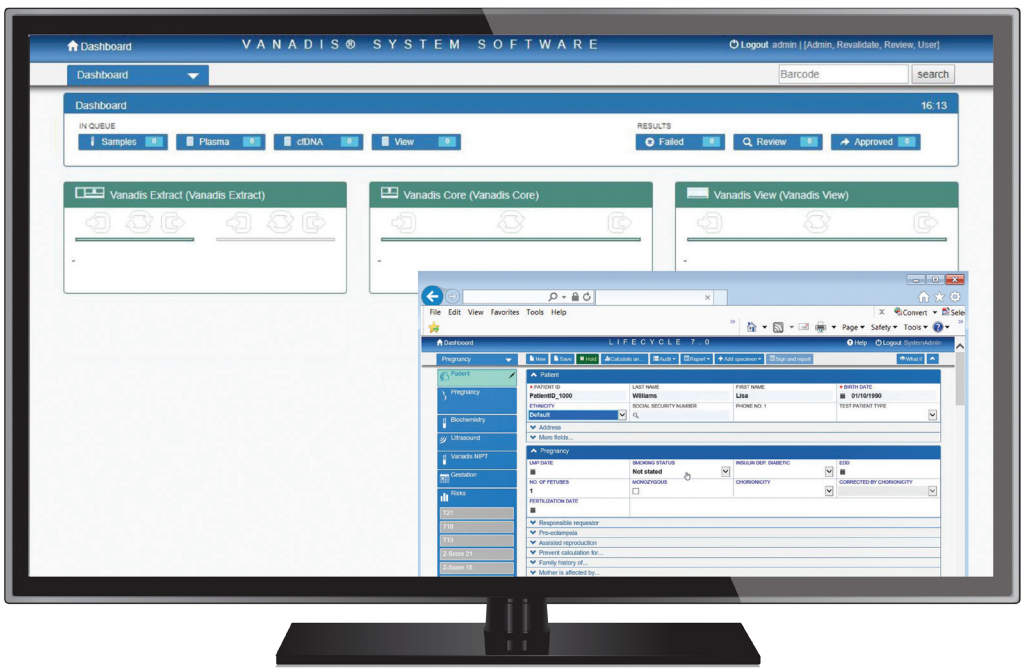
The Vanadis NIPT system includes system software and trusted LifeCycle™ software, the complete data management solution for prenatal screening laboratories. With a sleek, simple, flexible user interface and a performance-monitoring dashboard that enables access from any current Web browser, these technologies provide the reliability and support laboratories can rely on.

To start your run, simply load your instrument, following the intuitive guides in the software. The run starts automatically after the instrument detects that all samples, reagents, and consumables are in place. Software guides and monitors your workflow – including sample identification and processing, demographic data entry, results acceptance, risk calculation, quality assessment, and reporting.

The performance dashboard enables monitoring of marker and screening-program performance, so you can check:

- Images of tubes, reagents, and consumables used
- Positioning of plates
- Number of samples per batch
- Performance statistics
- Quality control and review

The whole application is underpinned by our flexible, trusted Risk Calculation Engine, which ensures optimal risk-calculation results with powerful algorithms. For example, LifeCycle software enables the use of additional biomarkers for risk assessment and other screening solutions and also connects to laboratory information systems.



WITH NIPT, PRECISION IS EVERYTHING

By targeting thousands of chromosomal sequences, the Vanadis platform can count an average of 650,000 molecules per chromosome, for high precision. As an example, to obtain 650,000 sequencing reads from chromosome 21 using sequencing-based technologies, a total of approximately 50 million sequencing reads would be needed, since chromosome 21 only constitutes 1.36% of the genome.

The high precision achieved through incorporating high-yield counting and eliminating PCR enables you to analyze all samples without eliminating those with low fetal fraction.

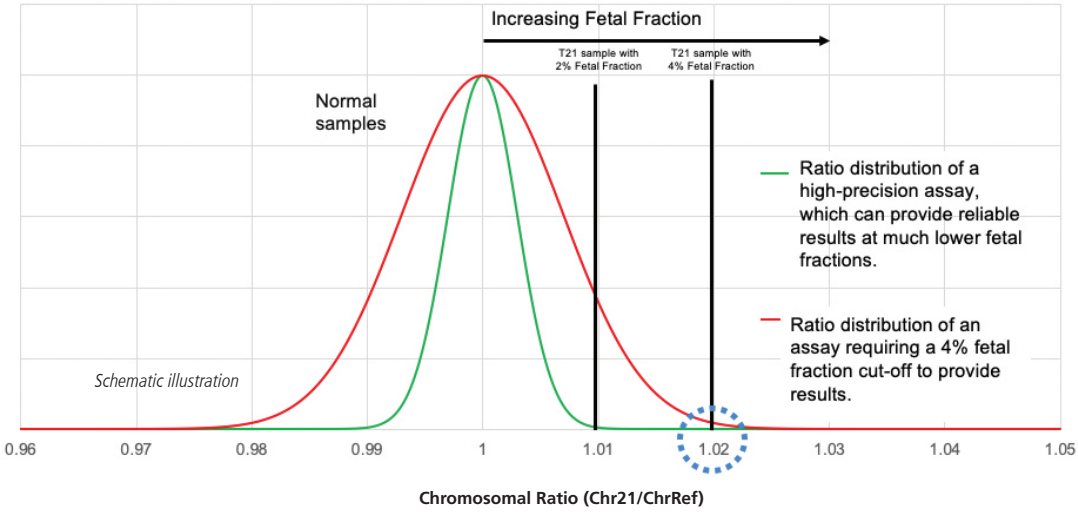
More Pregnant Women Deserve Answers

"With our Vanadis platform, we're taking the technical complexity out of NIPT while breaking down the cost barriers. This will enable more women to gain access to NIPT and improve the level of prenatal care on a global level."

Olle Ericsson
General Manager, Vanadis

Understanding the Benefits of a High-Precision Assay

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. The figure below illustrates the benefits of utilizing a high-precision assay when analyzing samples with low fetal fractions.



Proven Clinical Performance

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

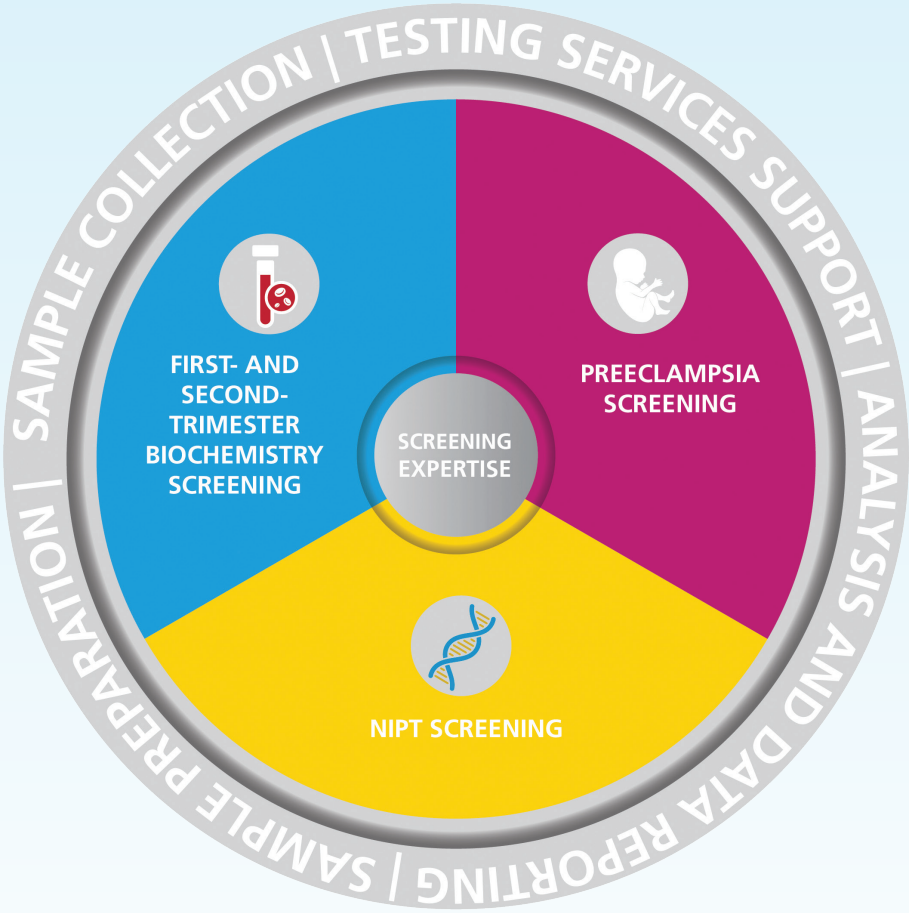
	T21	T18	T13
Detection Rate 95% CI	**100.0% (80/80)** 95.5%-100%	**91.4% (32/35)** 76.9%-98.2%	**100.0% (10/10)** 69.2%-100%
False Positive Rate 95% CI	**0.0% (0/666)** 0.0%-0.6%	**0.2% (2/1033)** 0.0%-0.7%	**0.1% (1/1033)** 0.0%-0.5%
Observed no-call rate: 0.94% (after first pass)			

Source: Vanadis kit insert, version N°4

Products comprising the Vanadis NIPT system are CE-marked in vitro diagnostic products and clinical validation studies have been reviewed by a Notified Body. Vanadis NIPT is used for screening for the risk of trisomy 21, 18, and/or 13. 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 PerkinElmer representative for availability.

A COMPLETE SOLUTION FROM THE LEADER IN PRENATAL TESTING

From sample collection to analysis to support and testing services, we can be your single source for all your screening solutions.



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