## A whole new way to NIPT.





Vanadis<sup>®</sup> NIPT System

## 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 14,000 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.



Products may not be licensed in accordance with the laws in all countries, such as the United States. Please check with your local representative for availability.

# 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 14,000 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 Revvity, the world's leader in prenatal screening solutions

Products may not be licensed in accordance with the laws in all countries, such as the United States. Please check with your local representative for availability.

## 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.

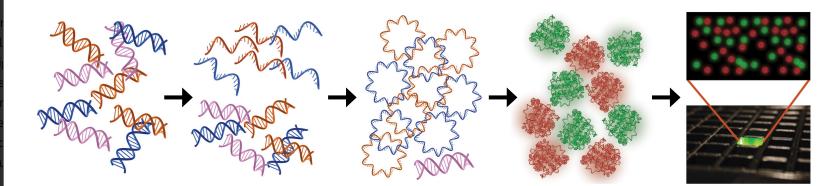
#### The cfDNA screening solution for all laboratories

Vanadis NIPT screening platform enables 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.



Products may not be licensed in accordance with the laws in all countries, such as the United States. Please check with your local representative for availability.

#### Groundbreaking cfDNA technology



cfDNA is extracted from maternal plasma. Thousands of targeted cfDNA fragments are captured and converted to DNA circles. Rolling circle amplification products are labelled with chromosome specific fluorophores. The labeled objects are individually counted using a microplate scanner.

Products may not be licensed in accordance with the laws in all countries, such as the United States. Please check with your local 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.

#### See the Vanadis NIPT workflow

5

# 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<sup>™</sup> 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 14,000 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.

States. Please check with your local 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.

Products may not be licensed in accordance with the laws in all countries, such as the United

Products may not be licensed in accordance with the laws in all countries, such as the United States. Please check with your local 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.

#### Automated workflow, from primary tube to final result

10 mL of 50 µL of cfDNA per sample Vanadis View® plate whole blood 1 sample per well Laboratory varies Contact rise 1 Contact rise 2 82..... Vanadis Extract® Cell-Free DNA Vanadis Core<sup>®</sup> Cell-Free DNA Vanadis View® LifeCycle™ Risk Calculation Software Molecule Counting Unit Extraction Unit Analysis Unit westy -----

Results available in 72 hours\*

## 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.

Products may not be licensed in accordance with the laws in all countries, such as the United States. Please check with your local representative for availability.

## Intuitive interface, leading risk-calculation software

The Vanadis NIPT system includes system software and trusted LifeCycle<sup>™</sup> 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 screeningprogram 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.



9 |

Products may not be licensed in accordance with the laws in all countries, such as the United States. Please check with your local representative for availability.

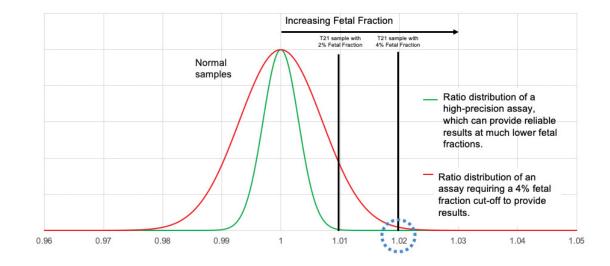
## With NIPT, precision is everything

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.

#### 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 to the right illustrates the benefits of utilizing a high-precision assay when analyzing samples with low fetal fractions.



Products may not be licensed in accordance with the laws in all countries, such as the United States. Please check with your local representative for availability.

#### Proven clinical performance

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

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

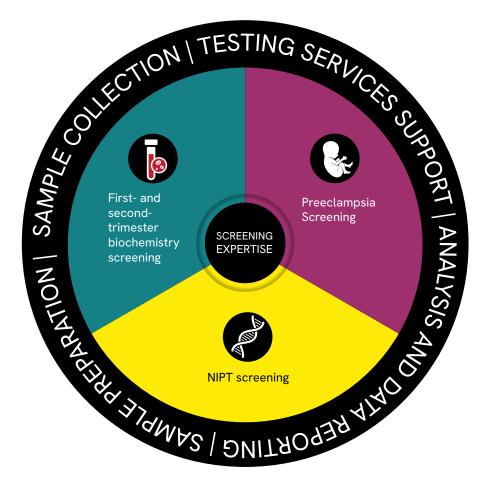
#### Source: Vanadis kit insert, version N°4

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 Revvity representative for availability.

Products may not be licensed in accordance with the laws in all countries, such as the United States. Please check with your local 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.



Products may not be licensed in accordance with the laws in all countries, such as the United States. Please check with your local representative for availability.



www.revvity.com



Revvity, Inc. 940 Winter Street Waltham, MA 02451 USA www.revvity.com

For a complete listing of our global offices, visit www.revvity.com Copyright ©2023, Revvity, Inc. All rights reserved.

1123446