Advanced screening for healthier pregnancies.

revvity

Prenatal screening solutions

Brochure not for distribution in the USA.

Working together toward improved prenatal care

Your total screening solution partner

When it comes to risk assessment and screening of prenatal aneuploidy and pre-eclampsia, early detection is essential. Accurate results, based on clinically validated assays and comprehensive population screening data, not only ensure more informed choices with minimal subsequent testing and invasive procedures. They also give women the confidence they need to plan and manage their pregnancies without unnecessary uncertainty or distress.

Revvity supports laboratories and clinics with optimized screening programs for a wide range of pregnancy complications. Through early assessment of pregnancy risks, we aim to improve the level of prenatal care globally.

Empower your screening strategy

Revvity's prenatal screening assays are all clinically validated and can be run on any of our 3 scaleable platforms. Using the right markers combined with LifeCycle™, our industry leading risk calculation software, laboratories can offer optimised screening to all patients. Our screening solutions are also used in many international prenatal and maternal health studies, including ASPRE, a ground-breaking study into the role of aspirin in the prevention of pre-eclampsia.

funded by EU FP7 ASPRE project

The Fetal Medicine Foundation

Innovative force in prenatal science

Revvity is committed to advancing the science and practice of prenatal screening and diagnostics through our cooperation with leading researchers in prenatal medicine and our active involvement in pioneering studies. In addition to continually developing innovative assays, screening equipment and informatics software, we invest significant resources in expanding the capabilities of laboratories and clinics with solutions that will shape the future of prenatal care.

Today our assays on the AutoDELFIA™, DELFIA™Xpress and Victor 2D platforms provide effective prenatal risk assessment for millions of mothers globally and are approved by the Fetal Medicine Foundation.

Our screening solutions cover monitoring of maternal and fetal well-being, such as:

- Risk assessment of common aneuploidies
- Risk assessment of neural tube defects
- Early prediction of pre-eclampsia

"For an increasing number of pregnancy complications, a risk classification as early as in the 12th week can make all the difference in improving outcomes."

– Professor Kypros Nicolaides

Achieve more with prenatal screening

Wide array of solutions for diverse screening needs

In detecting common aneuploidies and other pregnancy complications, choosing the optimal screening strategy can lead to a significant reduction in invasive procedures such as amniocentesis, as well as provide effective detection.

Whether your laboratory specializes in automated high throughput prenatal screening or clinic-level random access screening, we meet the needs of your screening program from sample to report. Our complete selection of prenatal screening solutions includes maternal serum and blood spot assays, NIPT screening, instruments, and data management and risk calculation software.

Our prenatal screening solutions cover every stage of pregnancy

Whatever your preferred aneuploidy screening model, Revvity assays offer tailored solutions that meet all your screening needs in the first and second trimester. In the first trimester, our four CE-marked assays – PAPP-A, free hCGß, PlGF and AFP – provide effective screening for aneuploidy, either using the combined or expanded combined model when ultrasound is available, or the 1T QUAD biochemistry-only model. In the second trimester, our assay solutions enable you to run the cost-effective Double test or enhance your screening performance using the Triple test or 2T QUAD test.

Three trimesters, three platforms, endless screening solution possibilities.

1ST TRIMESTER

PAPP-A	PlGF
Free hCGß	hAFP/Free hCGß Dual
AFP	PAPP-A/Free hCGß Dual DBS

2ND TRIMESTER

AFP	uE3	PlGF
hCG	Inhibin-A*	
Free hCGß	hAFP/Free hCGß Dual	

* Inhibin-A only available on AutoDELFIA

3RD TRIMESTER

PlGF

1T QUAD – effective 1st trimester aneuploidy screening even when NT is not available

Revvity offers four CE-marked assays – PAPP-A, free hCGß, PlGF and AFP – for first-trimester screening of Down Syndrome. Together these assays enable accurate screening in the first trimester, even in the absence of Nuchal Translucency (NT) measurement.

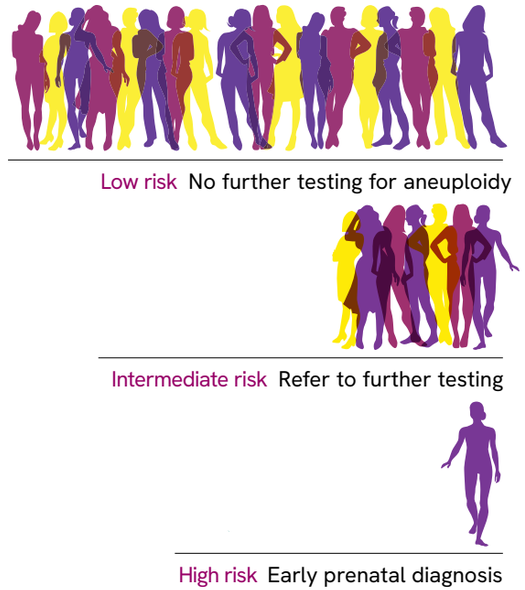
1T QUAD has been shown to provide effective aneuploidy screening even when NT measurement is not available.* In fact, with 1T QUAD, you can achieve similar performance to 2T QUAD test already in the first trimester.**

The PlGF assay is CE-marked for both Down syndrome and pre-eclampsia screening, which means that the same measurement can be used for both risk assessments.

DBS – reach more women with your screening program

Our dried blood spot (DBS) assay supports easier access to prenatal screening in regions where serum sample shipments can be a challenge. Approved by the FMF, the DELFIA/AutoDELFIA PAPP-A/Free hCGß Dual DBS assay provides simultaneous results for the first trimester aneuploidy markers.

DBS is an effective solution to prenatal screening for several reasons. To begin with, the sampling process is simple and no phlebotomist is needed as the blood spot can be taken from a finger-prick. The blood spot is also collected directly onto the sample card where it is associated with patient information, there is no need for centrifugation or refrigeration of samples. Furthermore, the transportation of dried and stable samples is easy and inexpensive, while also eliminating biohazard risks such as broken sample tubes.



Contingent screening – focus your resources more effectively

Our screening solutions support contingent screening strategies that categorize pregnant women into three risk categories based on their individual risk in the first-tier screening test. Women in the high-risk category are offered invasive testing, to ensure early prenatal diagnosis, while women at low risk of pregnancy complications require no further testing. Those women with a risk between the two cut-offs are referred to additional testing, e.g. second trimester serum screening, NT or cfDNA testing.

Contingent screening is a cost-effective way to select women in the medium risk category for cfDNA testing if the use of NIPT is limited by cost or availability.*** If ultrasound testing is not readily available, 1T QUAD can be used as the first-tier screening for all women, with women in the medium risk category being directed to NT measurement.**

The Fetal Medicine Foundation
FMF approved

Revvity first trimester assays for Free hCGß, PAPP-A, AFP and PlGF on the AutoDELFIA and DELFIA Xpress platforms and DELFIA/Auto DELFIA PAPP-A/Free hCGß Dual DBS assay are approved by the Fetal Medicine Foundation (FMF).

*Huang T, Dennis A, Meschino WS, Rashid S, Mak-Tam E, Cuckle H. First trimester screening for Down syndrome using nuchal translucency, maternal serum pregnancy-associated plasma protein A, free-ß human chorionic gonadotrophin, placental growth factor, and □-fetoprotein. Prenat Diagn. 2015 Jul;35(7):709-16
**Johnson J, Pastuck M, Metcalfe A, Connors G, Krause R, Wilson D, Cuckle H. First-trimester Down syndrome screening using additional serum markers with and without nuchal translucency and cell-free DNA. Prenat Diagn. 2013 Nov;33(11):1044-9.
***Cuckle H, Benn P, Pergament E. Maternal cfDNA screening for Down syndrome - a cost sensitivity analysis. Prenat Diagn. 2013 Jul;33(7):636-42.

First trimester is key

Prevent pre-eclampsia through early prediction & intervention

Early-onset pre-eclampsia, which results in premature delivery before gestational week 34, is approximately three times more prevalent than Down syndrome. Compared with Down syndrome, however, it is not yet as widely included in first trimester screening strategies, despite being a significant and prevetable cause of preterm birth.

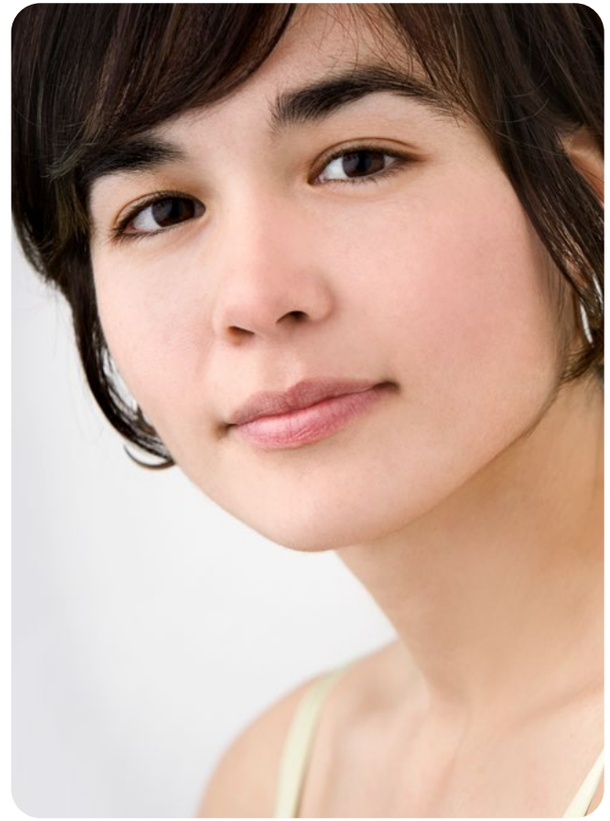
The consensus among caregivers and researchers is that timing matters more than ever in pre-eclampsia treatment. The earlier you identify women at high risk for pre-eclampsia, the better the outcome for mother and child.

PlGF – the most discriminating biomarker for pre-eclampsia

PlGF (Placental Growth Factor) has been shown to be the most differentiating biochemical marker for pre-eclampsia and early-onset pre-eclampsia in particular.

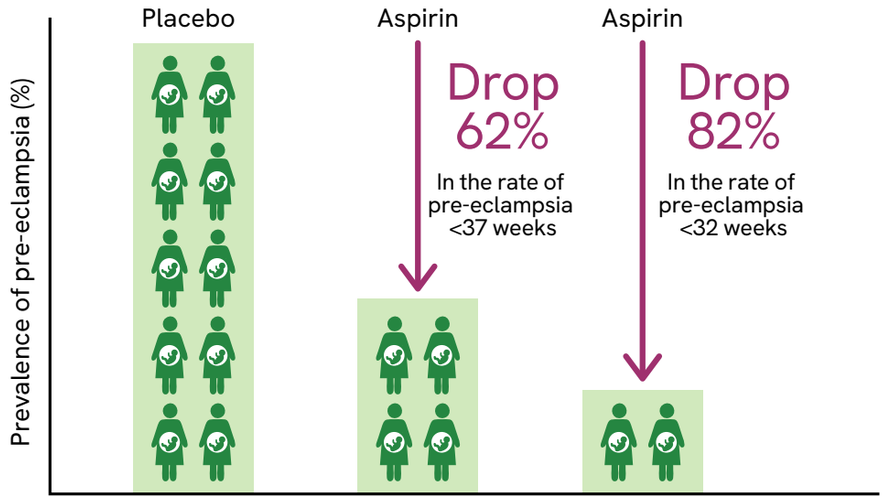
Revvity's PlGF 1-2-3 assay is the most sensitive first trimester screening assay for pre-eclampsia to date and therefore the choice for the ground-breaking ASPRE study (Rolnik et al, 2017).

When the PlGF 1-2-3 assay is used in combination with a comprehensive first trimester screening program including maternal medical history, mean arterial blood pressure and if available, uterine artery Doppler ultrasound, women at high risk for pre-eclampsia can be identified long before symptoms appear.



Aspirin prophylaxis works, if started early

The ASPRE trial results showed that the rate of developing early onset pre-eclampsia dropped by 82% and preterm pre-eclampsia by 62% among those women who received 150 mg aspirin at night and were at high risk of developing the disease. A secondary analysis proves that if we exclude the patients suffering with known chronic blood pressure, the therapy with aspirin allows to almost eradicate preterm pre-eclampsia for patients that are compliant with the aspirin in 90% of the cases.



Daniel L. Rolnik et al. Aspirin versus Placebo in Pregnancies at High Risk for Preterm Preeclampsia. DOI: 10.1056/NEJMoa1704559, New England J Med June 2017

Revvity does not endorse or make recommendations with respect to research, medication, or treatments. All information presented is for informational purposes only and is not intended as medical advice.

Software that evolves with your screening program

LifeCycle – Leading prenatal screening management software

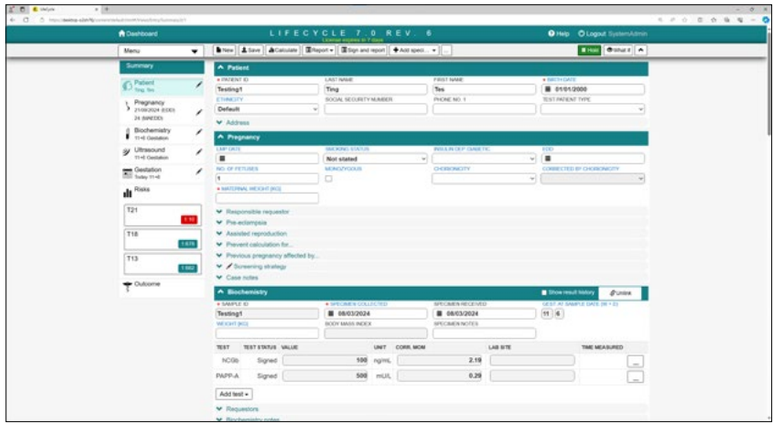
LifeCycle for Prenatal screening is trusted by over 800 users for screening pregnancies globally. The latest browser-based platform features multiple user-configurable entry screens, simplified workflow, advanced searching and a performance monitoring dashboard as well as the proven LifeCycle Risk Calculation Engine.

Flexible, reliable risk engine

At the heart of LifeCycle software is the LifeCycle Risk Calculation Engine. The risk calculation engine contains the following risk protocols for all your prenatal screening requirements:

- Trisomy 13, 18, 21 – using biochemical markers or NIPT
- Preeclampsia
- NTD
- SLOS
- 1T Turners syndrome

The risk calculation engine is fully configurable, so the user can update and optimise parameters for tailored population screening.



Three screening platforms for all lab capabilities

VICTOR™ 2D 1420-020 fluorometer with sample processing instruments

Ideal measurement platform for low volume clinics or laboratories. Compact, easy to use and reliable, Victor 2D provides start-up screening programs with the right balance of cost-effectiveness and control.

Capabilities

- Manual or semi-automated system
- Batch loading, 96-well format
- Easy to use and reliable measurement device
- Time to results 2–4 h
- Serum and dried blood spot assays
- Easy to use and reliable
- Easy to expand the analyte panel

Ideal solution for small to mid-size and start-up labs having <1000 samples/year.

DELFIA™ Xpress 6000-0010 random access platform

Fast and reliable DELFIA Xpress represents an ideal solution for clinics wishing to implement an OSCAR (One Stop Clinic for Assesment of Risk) approach.

Capabilities

- Full automation with rapid, easy-to-use software design
- Random access
- First result in 30 min, 40 results per hour
- Serum assays
- Supports connectivity with LifeCycle and 3rd party software

Compact instrument for clinic or lab having <10000 samples/year.

AutoDELFIA™ automatic 1235-5220 immunoassay system

Fully automatic screening platform for sensitive and precise quantitation. Combining versatility with ease of use. Supported by widest available range of prenatal analytes on any platform.

Capabilities

- Fully automated
- Batch loading
- 432 sample tubes, up to 8 different assays per run
- Time to results 2-4 h
- User-friendly instrument software
- Serum and dried blood spot assays
- Supports connectivity with LifeCycle™ and 3rd party software

High throughput for laboratories running >10000 samples/year.

All instrument platforms are FMF approved

DELFIA Assays are clincally validated

Revvity maternal serum biochemistry assays are based on the robust and sensitive DELFIA™ chemistry with measurement by time-resolved fluorometry.

- Assays optimized for prenatal risk assessment
- All screening assays are CE-IVD marked, aneuploidy screening assays under Annex 2, List B (Medium risk products)
- Extensive internal QC
- Low lot-to-lot variation

The high performance of Revvity DELFIA assays is widely acknowledged, and the assays have been used in numerous key international studies.

PlGF 1-2-3™*

Revvity PlGF kits are for the quantitative determination of placental growth factor in maternal serum.

- Direct “sandwich” technique
- Intended throughout pregnancy prediction of pre-eclampsia and aid in diagnosis and short-term prediction
- Can also be used to improve the performance of Down syndrome screening in the first trimester
- Limit of Detection (LoD) determined as 3.0 pg/mL with 95 % probability

PAPP-A

Revvity PAPP-A kits are for the quantitative determination of pregnancy associated plasma protein A (PAPP-A) in maternal serum. These assays are based on two monoclonal antibodies directed against two antigenic determinants on the PAPP-A/proMBP complex.

- Specific for PAPP-A/proMBP complex
- Analytical sensitivity typically better than 5 mU/L for AutoDELFIA assay
- Extensive measurement range up to 10,000 mU/L

Free hCGß

Revvity Free hCGß kits are for the quantitative determination of the free beta subunit of human chorionic gonadotrophin (Free hCGß) in maternal serum.

- Assay detects only the free ß subunit of hCG
- Analytical sensitivity is typically better than 0.2 ng/mL
- No sample dilution needed

sFlt-1*

- Direct “sandwich” technique
- Intended for aid in diagnosis of pre-eclampsia 20 weeks onwards together with PlGF 1-2-3
- Limit of Detection (LoD) determined as 3.8 pg/mL

* DELFIA Xpress PlGF and s-Flt-1 are NICE approved

PAPP-A/Free hCGß DBS

Revvity PAPP-A/Free hCGß Dual DBS kits are for the simultaneous quantitative determination of pregnancy associated plasma protein A (PAPP-A) and the free beta subunit of human chorionic gonadotrophin (Free hCGß) in maternal dried blood spots.

- Direct “sandwich” technique with two different labels
- Two analyte results from one assay
- Easier sampling, and easier storage and transportation of samples

hAFP

Revvity hAFP kits are for the quantitative determination of human alpha-fetoprotein (hAFP) in maternal serum and amniotic fluid.

- Direct “sandwich” technique
- Analytical sensitivity is typically better than 0.1 U/mL

uE3

Revvity uE3 kits are for the quantitative determination of human unconjugated estriol (uE3) in serum. These solid phase, time-resolved fluoroimmunoassays are based on the competition between Eu-labeled estriol and sample estriol for the limited number of binding sites on uE3-specific antibodies.

- Minimal cross-reactivity with other estrogen metabolites
- Analytical sensitivity is typically better than 0.2 nmol/L

Total hCG

Revvity hCG kits are for the quantitative determination of human chorionic gonadotrophin (hCG) in maternal serum.

- Direct “sandwich” technique
- Analytical sensitivity is typically better than 0.5 U/L

Inhibin A

Revvity Inhibin A kits are for the quatitative determination of dimeric human inhibin A in maternal serum.

- Two monoclonal antibodies directed against two separate antigenic determinants on the dimeric Inhibin A molecule
- Improves screening performance significantly in second trimester
- Limit of Detection (LoD) determined as 5.7 pg/mL

hAFP/Free hCGß

Revvity hAFP/Free hCGß Dual kits are for the simultaneous quantitative determination of human alpha-fetoprotein (hAFP) and the free beta subunit of human chorionic gonadotrophin (Free hCGß) in maternal serum.

- Direct “sandwich” technique with two different labels
- Two analyte results from one assay
- Analytical sensitivity is typically better than 0.1 U/mL for hAFP and 0.2 ng/mL for Free hCGß

Vanadis NIPT: Easier access to NIPT

With our -IVD marked 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 the need for PCR amplification and gene sequencing, and is so easy to use that one lab technician can handle up to 14,000 samples per year. Walkaway automation streamlines the process from the loading of samples until the delivery of final results.

With NIPT, precision is everything

By targeting thousands of chromosomal sequences, the Vanadis platform can count an average of 650,000 molecules per chromosome. The high precision achieved through incorporating high-yield counting and eliminating PCR enables you to analyze all samples for common aneuploidies without eliminating those with low fetal fraction.

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

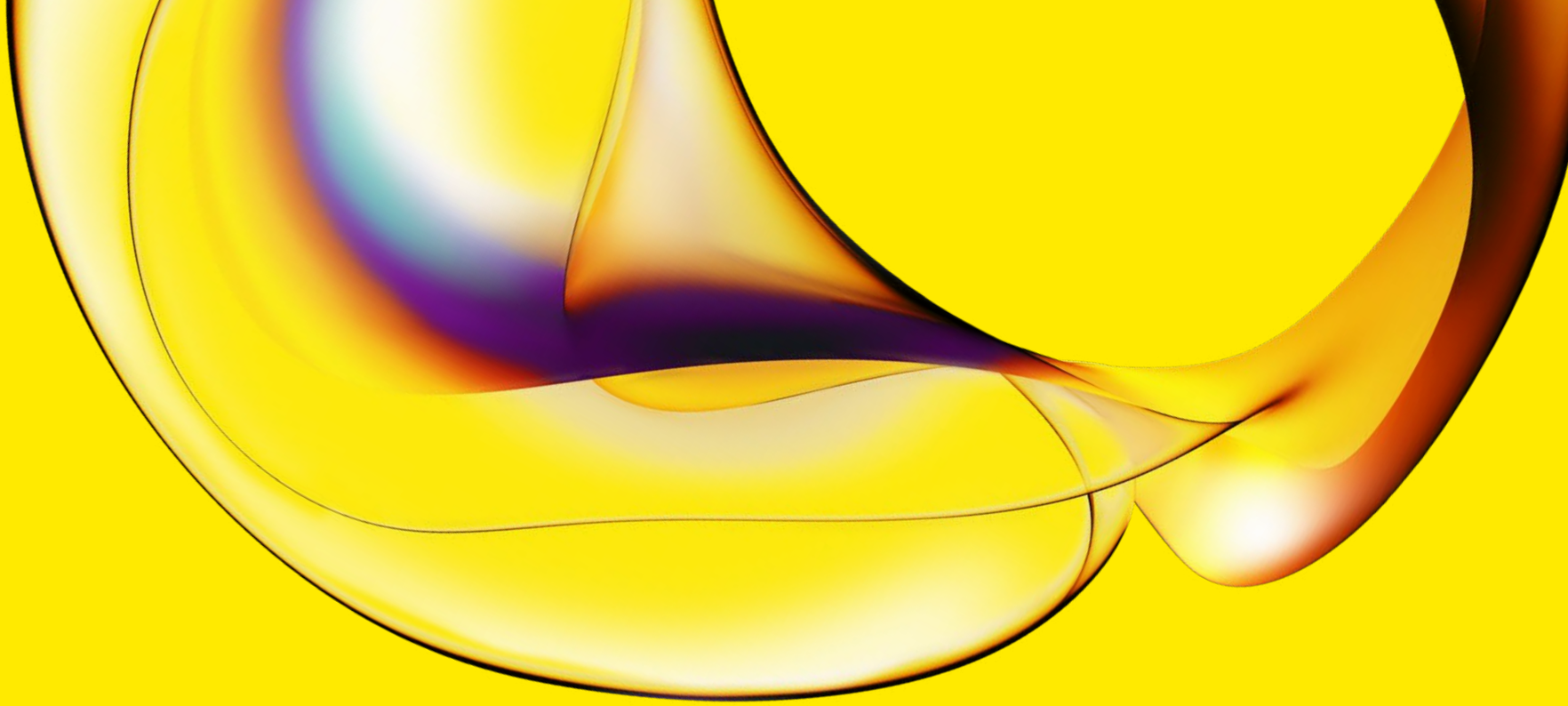
Proven Clinical Performance

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

	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

Products comprising the Vanadis NIPT system are CE-marked *in vitro* diagnostic products. 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.



www.revvity.com

Revvity, Inc.
940 Winter Street, Waltham, MA 02451 USA
(800) 762-4000 | www.revvity.com

For a complete listing of our global offices, visit www.revvity.com

1167356