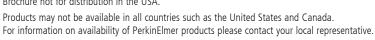


PRENATAL SCREENING SOLUTIONS FROM THE GLOBAL LEADER IN MATERNAL FETAL HEALTH

Brochure not for distribution in the USA.





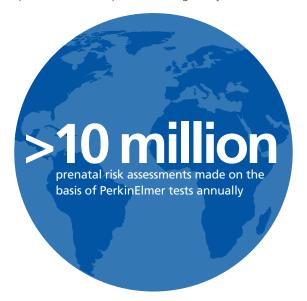


WORKING TOGETHER TOWARD IMPROVED PRENATAL CARE

Your total screening solution partner

When it comes to risk assessment and diagnosis 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.

PerkinElmer 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

PerkinElmer's prenatal screening assays are clinically validated and are ideal for all modern prenatal screening strategies. Using the right markers and PerkinElmer assays, combined with one of three scalable technology platforms and the industry-leading informatics of our LifeCycle® risk calculation software, laboratories and clinics can achieve high detection rates with low false positive rates. 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.

Innovative force in prenatal science

PerkinElmer 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 key professional organizations such as the Fetal Medicine Foundation.

99

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

Our screening solutions cover every stage of prenatal care:

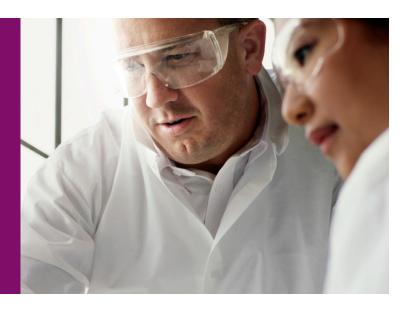
- Risk assessment of chromosomal abnormalities
- Risk assessment of neural tube defects
- Early prediction of pre-eclampsia
- Monitoring of maternal and fetal well-being







ACHIEVE MORE WITH PRENATAL SCREENING



Wide array of solutions for diverse screening needs

In detecting chromosomal abnormalities 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, DNA tests, instruments, and data management and risk calculation software.

Our prenatal screening solutions cover every stage of pregnancy

Whatever your preferred aneuploidy screening model, PerkinElmer 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 hCGB, PIGF 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	PIGF
Free hCGB	hAFP/Free hCGß Dual
AFP	PAPP-A/Free hCGß Dual DBS



2ND TRIMESTER

AFP	uE3	PIGF	
hCG	Inhibin-A*	riur	
Free hCGB	hAFP/Free hCGB Dual		

^{*} Inhibin-A only available on AutoDELFIA



3RD TRIMESTER

PIGF

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

PerkinElmer is the only company to offer four CE-marked assays – PAPP-A, free hCGB, PIGF 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 PIGF 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 sample shipments can be a challenge. Approved by the FMF, the DELFIA/AutoDELFIA PAPP-A/Free hCGB 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.

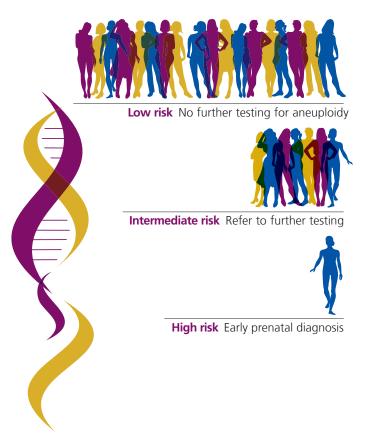
The Fetal Medicine Foundation

PerkinElmer first trimester assays for Free hCGß, PAPP-A, AFP and PIGF 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).

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.**



^{*}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-B human chorionic gonadotrophin, placental growth factor, and B-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 treatable 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.

PIGF – the most discriminating biomarker for pre-eclampsia

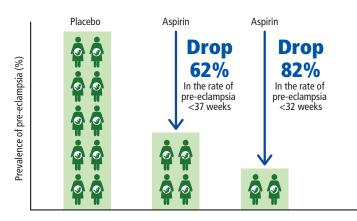
PIGF (Placental Growth Factor) has been shown to be the most discriminating biochemical marker for pre-eclampsia and early-onset pre-eclampsia in particular.

PerkinElmer's PIGF 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 PIGF 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 preeclampsia can be identified long before symptoms appear.

Aspirin treatment 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 treatment per 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 treatment 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

PerkinElmer 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

LifeCycleTM software is a globally used prenatal screening management offering. 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 PerkinElmer Risk Calculation Engine.

Flexible, reliable risk engine

At the heart of LifeCycleTM software is the PerkinElmer Risk Calculation Engine. This user-configurable engine features multiple risk calculation protocols where the user can use the built-in published parameters or their own parameters to optimize performance for the local population. All changes are fully audited. The engine also features performance monitoring tools to allow the user to assess performance as well as recommend parameter changes. Changes to screening parameters and equations can be tested before being taken into routine use.

Designed to evolve with the latest advances in screening

LifeCycleTM software and its risk calculation engine are designed to be easily updated with the latest screening parameters and allow the introduction of new algorithms as screening develops. Algorithms in cell-free DNA testing and pre-eclampsia screening (FMF/ASPRE algorithm) are included in LifeCycleTM software.



n Dashboard		LIFECYCLE 5	. 0			? Help O Logout SystemAdr		
Summary	₩ New ± Save # Hold	de Calculate and save ■Audit -	Report -	F Add specimen +				
© Patient	✓ Patient							
0	* PATIENT ID	LAST NAME		FIRST NAME		* BIRTH DATE		
Pregnancy	Q	Q.		Q.		■ 9.		
	ETHNICITY	SOCIAL SECURITY NUMBER		PHONE NO. 1				
Biochemistry	Default	• Q						
Ultrasound	◆ Pregnancy							
	LMP DATE	SMOKING STATUS		INSULIN DEP. DIABETIC		E00		
Gestation	₩	Not stated	•		*	■		
	NO. OF FETUSES	MONOZYGOUS		CHORIONICITY		CORRECTED BY CHORIONICITY		
Risks	1	0						
T21	▼ Biochemistry					∂ Unlink		
	* SAMPLE ID	* SPECIMEN COLLECTED		SPECIMEN RECEIVED		★ WEIGHT (KG)		
	Q	R		B				
	GEST, AT SAMPLE DATE (W+D)	GEST, AT SAMPLE DATE (W + D) SPECIMEN NOTES						
	TEST TEST STATUS	VALUE	UNIT	CORR. MOM	LAB	SITE		
Outcome	hCGb		ng/mL					
	PAPP-A		mU/L					
	Add test +					-		
	✓ Ultrasound							
	* SCAN DATE	CRL		BPD		HC		
	=							
	GEST, AT SAMPLE DATE (W+D)	CRL (#2)		BPD (#2)		HC (#2)		
	GEST, AT MANUAL ENTRY (W+1	SPECIMEN NOTES						
	TEST TEST STATUS	VALUE	UNIT	CORR. MOM	LAB	SITE		
	NT		mm					

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 laboratories 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 laboratory 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.

PerkinElmer 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 PerkinElmer DELFIA assays is widely acknowledged, and the assays have been used in numerous key international studies.

DELFIA® ASSAYS ARE CLINICALLY VALIDATED

PIGF 1-2-3™

PerkinElmer PIGF kits are for the quantitative determination of placental growth factor in maternal serum.

- Direct "sandwich" technique
- Intended throughout pregnancy prediction of pre-eclampsia
- 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

PerkinElmer 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 hCGB

PerkinElmer 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 β subunit of hCG
- Analytical sensitivity is typically better than 0.2 ng/mL
- No sample dilution needed

PAPP-A/Free hCGB DBS

PerkinElmer 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

PerkinElmer 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

PerkinElmer 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

PerkinElmer 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

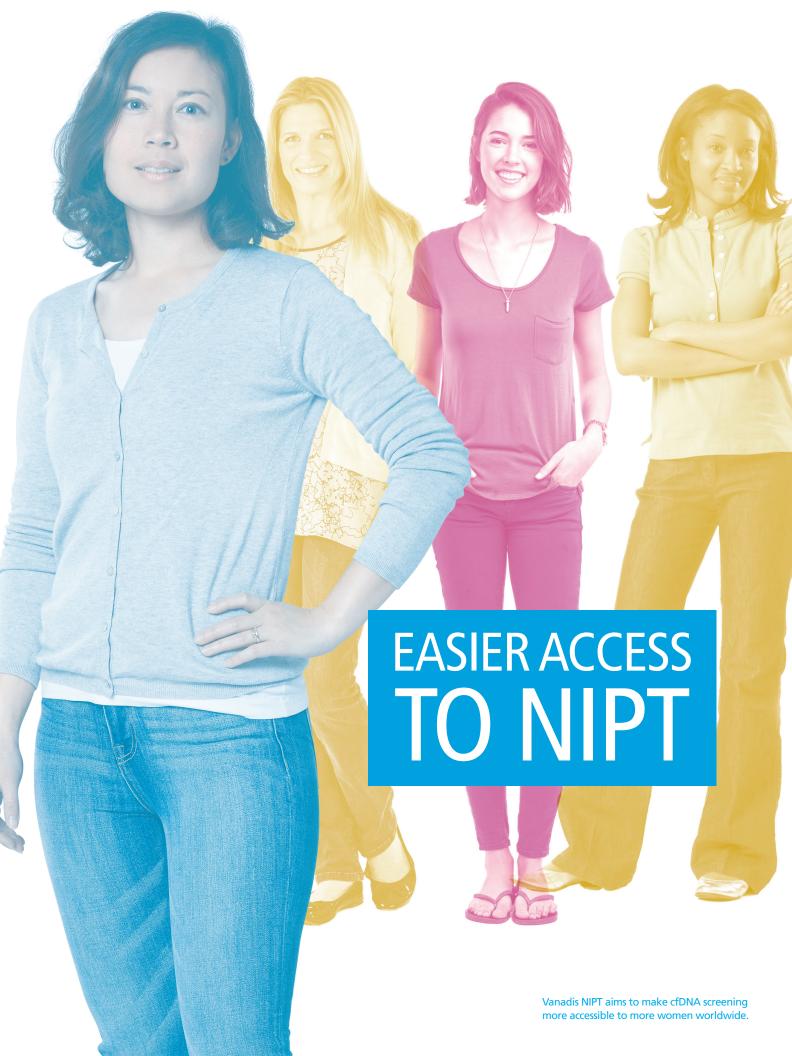
PerkinElmer Inhibin A kits are for the quatitative determination of dimeric human inhibin A in maternal serum.

- 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 hCGB

PerkinElmer hAFP/Free hCGß Dual kits are for the simultaneous quantitative determination of human alpha-feto-protein (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 hCGB



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.

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 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 20,000 samples per year to cope

20,000 samples per year to cope with an ever-increasing workload

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

Leading prenatal screening

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

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.

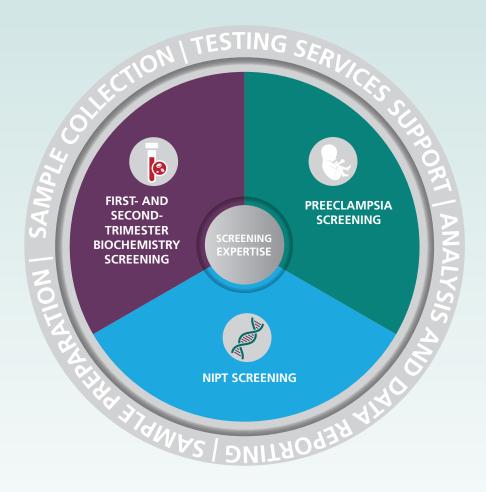
Vanadis NIPT	Detection Rate	False Positive Rate				
T21	100.0%	0.0%				
T18	88.9%	0.48%				
T13	100.0%	0.1%				
Observed no-call rate: 0.28 %						

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 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.



Products may not be available in all countries such as the United States and Canada. For information on availability of PerkinElmer products please contact your local representative.

PerkinElmer, Inc. 940 Winter Street Waltham, MA 02451 USA P: (800) 762-4000 or (+1) 203-925-4602 **www.perkinelmer.com**

