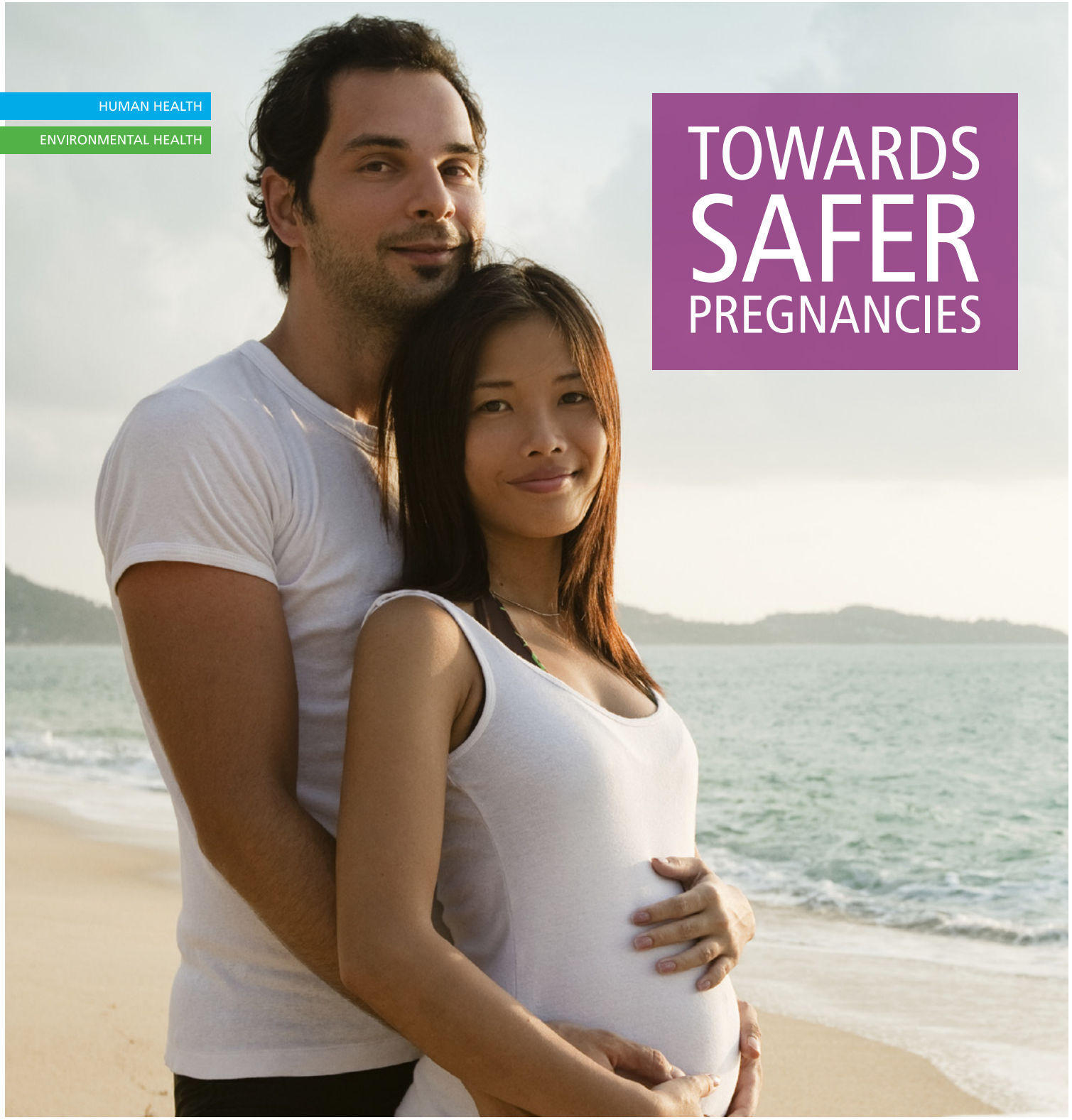
HUMAN HEALTH

ENVIRONMENTAL HEALTH



TOWARDS SAFER PREGNANCIES

SOLUTIONS FOR PRENATAL CARE

Brochure not for distribution in the USA

PerkinElmer®
For the Better

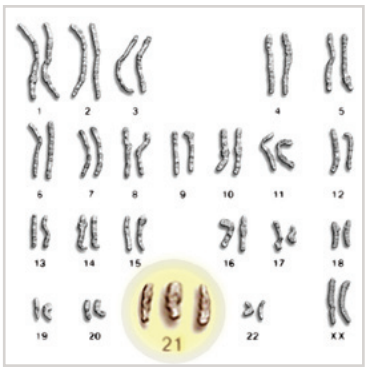
COMPLETE SYSTEMS TO MONITOR HEALTH DURING PREGNANCY

PerkinElmer is a global supplier recognized for its strong commitment to maternal health and newborn health. To help in the efficient deployment of pregnancy health care resources, we supply solutions for prenatal testing in which the focus is on early detection.

Prenatal testing for

- Assessing risk of chromosomal abnormality
- Diagnosing chromosomal abnormality
- Assessing risk of neural tube defect
- Monitoring fetal well-being
- Monitoring maternal health

Our products include maternal serum and blood spot assays, DNA tests, instruments, and data management and risk calculation software.



Monitoring pregnancy to further reduce infant mortality

As the established leader in systems for newborn screening, PerkinElmer has helped to save the lives of many babies. Our newborn screening tests have been used on more than 415 million children and in 2012 alone this led to the successful treatment of 20,154 of them.

Prematurity and maternal pre-eclampsia are, however, today's major causes of newborn mortality. To reduce these losses, intervention is needed before birth. PerkinElmer's latest products as well as those under development are designed to provide predictive support, identifying the pregnancies where intervention can benefit the outcome.

Risk assessment to allow considered actions and appropriate diagnostic measures

Effective screening for aneuploidies means fewer invasive procedures

In detecting chromosomal abnormalities, an optimal screening strategy leads to a reduction in invasive procedures such as amniocentesis, potentially benefiting both mother and child. Using the right combination of markers and high quality PerkinElmer assays, high detection rates can be achieved with low numbers of pregnancies screened positive.

Supporting your screening strategy

PerkinElmer 1st and 2nd trimester prenatal screening assays are ideal for most of the screening strategies practiced today, and support the needs of both laboratories and clinics. Automatic platforms available comprise DELFIA® Xpress and AutoDELFIA®, while VICTOR² D allows measurement of assays performed using semi-automatic instrumentation.

The Fetal Medicine Foundation
FMF approved

PerkinElmer first trimester assays for Free hCGß and PAPP-A on the VICTOR² D, AutoDELFIA and DELFIA Xpress platforms are approved by the Fetal Medicine Foundation (FMF)

Almost 8 million risk assessments made on the basis of PerkinElmer tests in 2012.

Fast reliable FTS

PerkinElmer offers reliable methods for combined first trimester screening (FTS). For clinics wishing to provide an OSCAR (one-stop clinic for assessment of risk) FTS service, the fast and convenient DELFIA Xpress has been widely adopted.

PlGF assay for pre-eclampsia and T21 screening

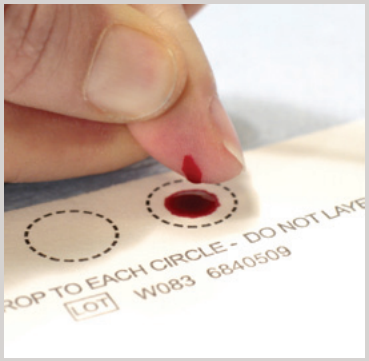
Now it is possible to screen for pre-eclampsia in the first trimester by measuring PlGF (placental growth factor). PlGF is the biochemistry marker of choice for assessing pre-eclampsia risk, and used together with the other FTS markers also improves the performance of T21 screening.

DRIED BLOOD SPOT ASSAY BRINGS MANY PRACTICAL BENEFITS

PerkinElmer's dried blood spot (DBS) assay supports easier access to prenatal screening in many regions. Approved by the FMF, the DELFIA/AutoDELFIA PAPP-A/Free hCGß Dual DBS assay provides simultaneous results for the first trimester aneuploidy markers.

DBS-based screening allows the same clinical performance as serum-based screening[1] and there are many practical benefits:

- The sampling process is simple - no phlebotomist is needed if the blood spot is taken from a finger-prick
- The blood spot is collected directly onto the sample card where it is associated with patient information
- Samples are dried and stable. No centrifugation or refrigeration of samples is necessary
- Transportation of samples is easy and inexpensive, and there is no risk of broken sample tubes during transport
- Biohazard risk is much reduced



Punching devices to meet your needs

As the global leader in newborn screening using dried blood spot samples, PerkinElmer offers a selection of punching devices for use with our assay instrumentation. Our assay instruments meet individual laboratory needs as to level of automation and throughput.

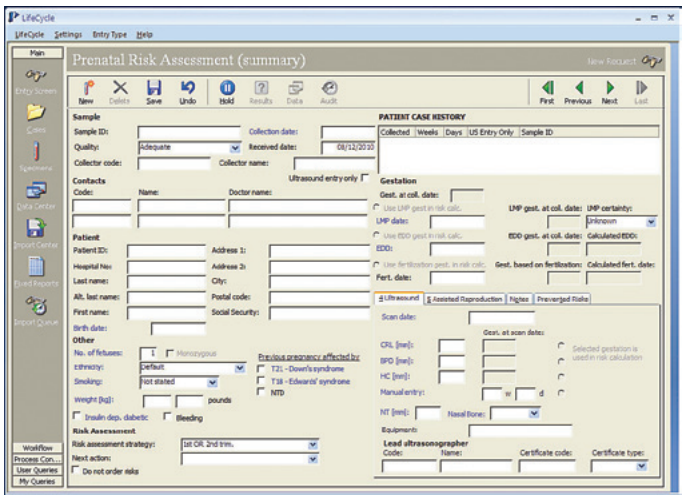
1. D Krantz, et al. Prenat Diagn (2011) 31:9.869-874.

Complete data management for prenatal risk assessment

LifeCycle™ is a comprehensive informatics and risk calculation package for maternal health monitoring and prenatal screening. It provides the support you need in managing an effective, high quality risk assessment program. Because the system has been thoroughly tested and all calculation methods, algorithms and values are supported by current published literature, LifeCycle will give you full confidence in your maternal risk assessment program.

LifeCycle™ allows you to:

- Improve performance by adjusting the software for local population variations
- Maintain control of your system with the statistical monitoring reports and tools
- Control your instrument work flow
- Use your database for research and follow-up
- Ensure rapid distribution of results with linking of multiple sites together



Screenshot of background information form.

Interconnectivity options

LifeCycle provides the connectivity options you need to make everyday screening operations more efficient. Direct connections are available to ultrasound applications and laboratory information systems. DELFIA Xpress also allows direct connectivity, so a wide choice of configurations is supported.

PRENATAL BOBS, A MORE INFORMATIVE OPTION THAN FISH AND QF-PCR FOR IVD LABS

Prenatal BoBs™ is a CE-marked IVD product based on BACs-on-Beads technology. It allows diagnostic testing when 1st or 2nd trimester screening has indicated a high risk of anomaly.

In addition to detecting copy number changes of chromosomes 13, 18, 21, X and Y, the product enables detection of 9 additional chromosomal regions in which a clear correlation between a loss and an adverse outcome has been demonstrated.[1] Copy number changes in these targeted microdeletion regions are not easily found with other commonly used methods. Also the microdeletion syndromes detected by Prenatal BoBs often are not inherited and do not display ultrasound abnormalities, so they may otherwise be missed in a prenatal setting.

1. OMIM: http://www.ncbi.nlm.nih.gov/omim/ #105830, #123450, #150230, #176270, #182290, #188400, #194050, #194190, and #247200

Low Input Material – Fast Results

Analysis using Prenatal BoBs can be performed with 50-250 ng genomic DNA, an amount which can be obtained from 3-5 mL of amniotic fluid or from 1 villus. Results are ready in 24-48 hours from the time of sampling.

How does Prenatal BoBs differ from other rapid diagnosis methods?

- Prenatal BoBs is a CE marked IVD test that enables high throughput analysis as tens of samples can be run simultaneously reducing the hands on time
- There are no unknown clinical significance results as there is a clear genotype-phenotype correlation for the microdeletion syndromes detected by Prenatal BoBs
- Robust assay with low quality DNA from various sample types
- The BACs-on-Beads technology enables multiplexing – in Prenatal BoBs 75 different BAC probes (similar to FISH probes) can be run simultaneously in one analysis

Aneuploidies	Cytoband
Trisomy 13: Patau Syndrome	Chr 13
Trisomy 18: Edwards Syndrome	Chr 18
Trisomy 21: Down Syndrome	Chr 21
Sex Chromosome Abnormalities	Chr X, Chr Y

Microdeletion Syndrome	Cytoband
DiGeorge Syndrome	22q11.2
DiGeorge 2 Syndrome	10p14
Williams-Beuren Syndrome	7q11.2
Prader-Willi Syndrome	15q11-q12
Angelman Syndrome	15q11-q12
Smith-Magenis Syndrome	17p11.2
Wolf-Hirschhorn Syndrome	4p16.3
Cri du Chat Syndrome	5p15.3-p15.2
Langer-Giedion Syndrome	8q23-q24
Miller-Dieker Syndrome	17p13.3

Why is it important to test for microdeletions included in Prenatal BoBs?

- Microdeletions may cause severe problems including severe learning disabilities (more severe than Down syndrome)
- Microdeletions are not detected by conventional karyotyping
- There is no visual evidence in ultrasound examination
- Microdeletions can be *de novo* mutations with no family history
- Microdeletion syndromes are not commonly detected with QF-PCR and standard FISH probes

ORDERING INFORMATION

3100-0020	Prenatal BoBs
1014-0020	Luminex 200 w/ xPonent
5012-0020	BoBsoft analysis software

NEW METHODS HELPING TO IMPROVE PREGNANCY OUTCOME

Prediction of pre-eclampsia in the first trimester

Pre-eclampsia is associated with high levels of infant and maternal mortality and morbidity. Early-onset pre-eclampsia (starting before 34 weeks of pregnancy) contributes most to the mortality and morbidity statistics. First trimester evaluation of pre-eclampsia risk is of benefit because it allows

- Increased surveillance of high risk pregnancies
- Earlier diagnosis of the clinical signs of the disease
- Earlier identification of the associated intra uterine growth restriction (IUGR)
- Treatment to delay or prevent the disease

Aspirin treatment effective against pre-eclampsia – but must be started early

Guidelines on pre-eclampsia prevention in various countries (e.g. Australia, Canada, France, Germany, Italy, UK) recommend the administration of low-dose aspirin in all pregnancies that are at risk, starting during the first trimester, or at least before week 16.

A recent metastudy with extremely well-defined inclusion criteria has shown that the initiation of low-dose aspirin prophylaxis at or before 16 weeks' gestation resulted in an 89% reduction of pre-eclampsia delivered before 37 weeks' gestation.[1]

1. Roberge et al. (2012) Fetal Diagn Ther 31:141–146.

Best screening performance achieved using PlGF in combination with other markers

PlGF (Placental Growth Factor) plays a role in placental development and has been shown to be the most discriminating biochemical marker for pre-eclampsia.[1] It is particularly discriminating for early-onset pre-eclampsia.

A major study has concluded that screening by maternal characteristics, biophysical and biochemical markers detected 96% of cases of PE requiring delivery before 34 weeks and 54% of all cases of PE at a fixed false-positive rate of 10%. Such high performance levels were obtained only when results for PlGF were included.[2]

1. Akolekar et al. (2011) Prenat Diagn 31: 66–74.
2. Akolekar et al. (2013) Fetal Diagn Ther 33:8–15.

A complete product range already available

In addition to the PlGF assay, available on DELFIA Xpress, AutoDELFIA and manual platforms, PerkinElmer supplies CE marked human pregnancy serum PlGF controls and Pre-eclampsia Predictor™ risk calculation software.

For more information see
www.perkinelmer.com/pre-eclampsia

RELIABLE SYSTEMS – RANDOM ACCESS, BATCH OR SEMI-AUTOMATIC

DELFIA Xpress random access platform

Kits available (with standard range)

6001-0010	DELFIA Xpress hAFP kit (1 –500 U/mL)
6002-0010	DELFIA Xpress Free hCGβ kit (2 – 200 ng/mL)
6003-0020	DELFIA Xpress PAPP-A kit (50 – 10 000 mU/L)
6004-0010	DELFIA Xpress hCG kit (5 – 5000 U/L)
6005-0010	DELFIA Xpress uE3 kit (0.6 – 50 nmol/L)
6007-0020/2C	DELFIA Xpress PlGF kit (18 – 4000 pg/mL)

Kit size

96 tests
(72-test kit versions are also available)

Degree of automation

Fully automated random access

Sample throughput

40 results per hour

Time to first result

30 min

AutoDELFIA automatic immunoassay system

Kits available (with standard range)

B096-101	AutoDELFIA hAFP kit (1 – 1000 U/mL)
B097-101	AutoDELFIA Free hCGβ kit (2 – 200 ng/mL)
B067-101	AutoDELFIA hAFP / Free hCGβ Dual kit (hAFP 1 – 500 U/mL, Free hCGβ 2 – 200 ng/mL)
B082-101	AutoDELFIA hCG kit (10 – 10 000 U/L)
B083-301	AutoDELFIA uE3 kit (0.6 – 50 nmol/L)
B098-201	AutoDELFIA PAPP-A kit (10 – 2000 mU/L)
B027-105	DELFIA/AutoDELFIA PAPP-A/Free hCGß Dual DBS kit (PAPP-A 0.1 – 22 U/L, Free hCGß 8 – 500 ng/mL)
B055-201	DELFIA/AutoDELFIA PlGF kit (18 – 4000 pg/mL)

Kit size

Serum assays, 96 tests

DBS assays, 480 tests

Degree of automation

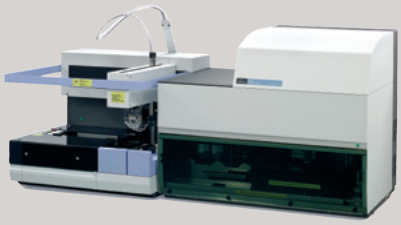
Fully automated batch-loading

Sample throughput

432 sample tubes and 8 different assays per batch

Results time

2-4 h



VICTOR² D fluorometer with sample processing instruments

Kits available (with standard range)

A096-101	DELFIA hAFP kit (1 – 1000 U/mL)
A097-101	DELFIA Free hCGβ kit (2 – 200 ng/mL)
A067-101	DELFIA hAFP / Free hCGβ Dual kit (hAFP 1 – 500 U/mL, Free hCGβ 2 – 200 ng/mL)
A082-101	DELFIA hCG kit (10 – 10 000 U/L)
A083-301	DELFIA uE3 kit (0.6 – 50 nmol/L)
A098-201	DELFIA PAPP-A kit (10 – 2000 mU/L)
B027-105	DELFIA/AutoDELFIA PAPP-A/Free hCGß Dual DBS kit (PAPP-A 0.1 – 22 U/L, Free hCGß 8 – 500 ng/mL)
B055-201	DELFIA/AutoDELFIA PlGF kit (18 - 4000 pg/mL)

Kit size

Serum assays, 96 tests

DBS assays, 480 tests

Degree of automation

Manual or semi-automatic assays

Sample throughput

96 results per microplate

Results time

2-4 h

DELFIA® ASSAYS ARE CLINICALLY VALIDATED

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

- Assays optimised for prenatal risk assessment
- All aneuploidy screening IVD assays CE marked 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, including the Echo PAPP-A study (France), CUBS (Scotland) and SURUSS (England).

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 hCGβ

PerkinElmer Free hCGβ kits are for the quantitative determination of the free beta subunit of human chorionic gonadotrophin (Free hCGβ) 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

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

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.

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

hAFP/Free hCGβ

PerkinElmer hAFP/Free hCGβ Dual kits are for the simultaneous quantitative determination of human alpha-fetoprotein (hAFP) and the free beta subunit of human chorionic gonadotrophin (Free hCGβ) 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 hCGβ

PAPP-A/Free hCGβ DBS

PerkinElmer PAPP-A/Free hCGβ 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 hCGβ) 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

PlGF

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

- Direct "sandwich" technique
- Intended for first trimester prediction of pre-eclampsia
- Same result also improves the performance of Down syndrome screening

Supporting the screening community

PerkinElmer is proud to support non-commercial resources such as the International Prenatal Screening Group (IPSG). Through its newsletter and website at http://www.leeds.ac.uk/idssg, the organization provides useful information on all aspects of screening during pregnancy.



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For information on availability of PerkinElmer products please contact your local representative.

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1244-1306-11, June 2013