HUMAN HEALTH

ENVIRONMENTAL HEALTH

PlGF 1-2-3

PERKINELMER PRE-ECLAMPSIA SCREENING SOLUTION

Not for distribution in the USA

PerkinElmer®
For the Better

PRE-ECLAMPSIA SCREENING THROUGHOUT PREGNANCY

Now you can obtain a valid assessment of the pre-eclampsia risk in every trimester

The Fetal Medicine Foundation
FMF approved

The PerkinElmer PlGF 1-2-3 assays are designed for use as an aid in screening for pre-eclampsia. The same assay result can be used as part of the T21 risk calculation.

In the 1st trimester, PlGF 1-2-3 helps identify high risk pregnancies so that preventive actions may be initiated during the 1st trimester.

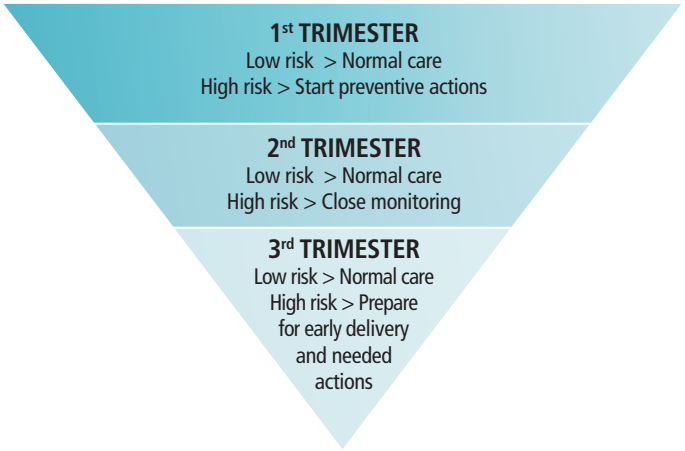
In the 2nd and 3rd trimesters, the same product allows reassessment of risk using cut-off values and helps to identify pregnancies where timely intervention can improve outcome.

The highly discriminating PlGF Marker

PlGF (Placental Growth Factor) has been shown to be the most discriminating biochemical marker for pre-eclampsia, and early-onset pre-eclampsia in particular [Levine et al. 2004].

In all three trimesters best results are obtained by using the PlGF test result together with results for other markers, such as maternal history and mean arterial blood pressure (MAP). The same combination of markers is suitable for use at every stage of pregnancy.

Screening in 1st, 2nd and 3rd trimesters using the same markers (Maternal history, PlGF 1-2-3, PAPP-A, MAP, uAD (if available)



Screening through pregnancy with the same combination of markers [Akolekar et al. 2013, Lai et al. 2013, Nicolaides 2014].
In the 1st trimester risk is calculated using dedicated software. In the 2nd and 3rd trimesters cut-off values for the markers are used.

FIRST TRIMESTER SCREENING IS KEY

Risk categories must be established and treatment started as early as possible

The main target of PE screening in the **1st trimester** (at 11-13 weeks) is to identify the high risk cases to be able to start preventive actions in time for it to be of maximum benefit [Akolekar et al. 2013, Roberge et al. 2012].

Screening with a protocol including serum PlGF measurement and use of a **dedicated risk calculation tool, such as PerkinElmer's Pre-eclampsia Predictor™**, makes it possible to establish reliable risk categories within the first trimester.

The proven efficacy of PlGF

According to a prospective study by Prof. Nicolaides's group at King's College Hospital, effective screening for early-onset PE at 11-13 weeks can be achieved in the first-trimester of pregnancy with a DR of about 95% and a FPR of 10%, when using a protocol including PlGF (see table) [Akolekar et al. 2013]. Further work by the group has shown the effectiveness of PlGF in combination with other markers later in pregnancy. [Garcia-Tizon Larroca et al. 2014, Lai et al. 2013]

Parameters	PE <34 weeks delivery		PE <37 weeks delivery		PE >37 weeks delivery	
History with:	FPR 5%	FPR 10%	FPR 5%	FPR 10%	FPR 5%	FPR 10%
PlGF	59.3%	72.4%	40.8%	54.4%	29.1%	40.1%
PAPP-A	43.6%	54.7%	37.3%	48.2%	31.5%	42.1%
PlGF & PAPP-A	60.3%	74.3%	42.8%	55.8%	30.4%	40.8%
PlGF, uAD & MAP	87.4%	95.8%	60.6%	77.3%	37.6%	52.9%
PAPP-A, uAD & MAP	81.8%	92.5%	52.5%	74.6%	36.0%	59.9%
PlGF, PAPP-A, uAD & MAP	93.4%	96.3%	61.1%	76.6%	37.8%	53.6%

Pre-eclampsia detection rates using various protocols. PlGF measurements were obtained using the DELFIA Xpress assay. [Akolekar et al. 2013]

uAD = Uterine Artery Doppler Pulsatility Index
MAP = Mean Arterial Blood Pressure
PAPP-A = Pregnancy-Associated Plasma Protein - A
PlGF = Placental Growth Factor

REFERENCES

Akolekar et al. (2013) Fetal Diagn Ther 33:8–15.
Roberge et al. (2012) Fetal Diagn Ther 31:141–146.
Koopmans et al. (2009) Lancet 374: 979–988.
Levine et al. (2004) N. Engl. J. Med. 350, 672–683.
Garcia-Tizon Larroca et al. (2014) Fetal Diagn Ther 36:9–17.
Lai et al. (2013) Fetal Diagn. Ther. 33, 164–172.
Nicolaides (2014): Webcast presented June 16th 2014 (Management of pre-eclampsia through the trimesters) available at www.perkinelmer.com/pre-eclampsia.
Hanses et al. (2014): Poster (Performance of a next generation PlGF 1-2-3 assay) at XXIV European Congress of Perinatal Medicine, Florence, June 2014.

EXPAND YOUR SCREENING CAPABILITIES TO 2T AND 3T

PlGF 1-2-3 helps you manage PE risk in the 2nd and 3rd trimester

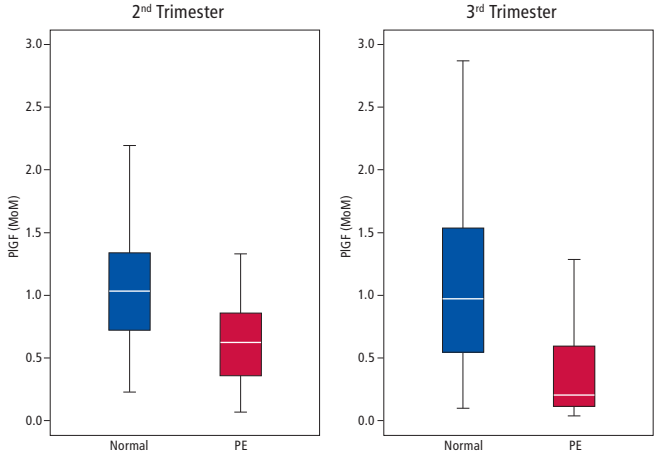
It has been shown in a prospective study that PlGF concentrations remain low throughout pregnancy when the risk of pre-eclampsia is high [Levine et al. 2004]. Using PlGF 1-2-3, comparison of PlGF MoMs with **cut-off values in combination with other markers** provides valuable additional information in both the **2nd and 3rd trimesters.**

Second trimester: Reassess and monitor risk

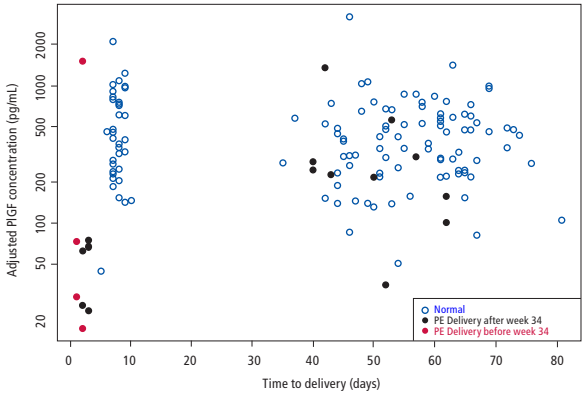
In the second trimester, PlGF 1-2-3 allows you to reassess the risk of pre-eclampsia in pregnancies already screened in the first trimester. In many cases it will then be possible to provide the reassurance that the risk is now reduced [Nicolaides 2014]. Additionally, 2nd trimester testing allows a first assessment of risk for those pregnancies not presenting in the 1st trimester.

Third trimester: Aid in Diagnosis

In the third trimester, PlGF 1-2-3 helps you identify those pregnancies that will develop pre-eclampsia. This enables you to improve perinatal outcome through the administration of antihypertensive medication and timely delivery.



PlGF MoM values for 2nd and 3rd trimester samples from normal pregnancies and pre-eclampsia pregnancies (120 normal pregnancy samples, 20 samples from pre-eclampsia pregnancies. Sampling at 19 - 23+6 and 30 - 33+6 weeks. PerkinElmer data).



A low PlGF value in the 3rd trimester is associated with a short time to delivery especially in PE cases requiring delivery before week 34 (120 normal pregnancy samples, all delivered after 34 weeks, 16 samples from pre-eclampsia pregnancies delivering after 34 weeks, 4 samples from pre-eclampsia pregnancies delivering before 34 weeks. Sampling at 30 - 33+6 weeks. PerkinElmer data).

Listen to Prof. Kypros Nicolaides' June 2014 lecture, Management of pre-eclampsia through the trimesters.
Free of charge webcast at www.perkinelmer.com/pre-eclampsia.

PlGF 1-2-3

- 1T, predict to prevent pre-eclampsia
- 2T, reassess and monitor
- 3T, aid in diagnosis

COMPLETE SCREENING SOLUTION

DELFIA Xpress and AutoDELFIA instruments

The PerkinElmer analyzers are already in routine use for aneuploidy screening in 52 countries. DELFIA assays for PlGF, Free hCGß, PAPP-A, hAFP, intact hCG and uE3 support high performance aneuploidy screening.

Key assays for pre-eclampsia and aneuploidy screening in 1T

The PlGF marker is used in risk assessment for both aneuploidy and pre-eclampsia. DELFIA® Xpress and DELFIA/AutoDELFIA PlGF 1-2-3 kits are CE-marked for both applications and are characterized by remarkably good sensitivity (low LoD and LoQ) [Hanses et al. 2014].

Pregnancy serum IVD PlGF controls

However sensitive the assay is, excellence in the QC materials used is critical to ensuring the integrity of results. For use with the PlGF 1-2-3 assay, PerkinElmer PlGF Controls is based on human pregnancy serum.

Software

PerkinElmer offers the first commercial 1st trimester pre-eclampsia risk calculation software Pre-eclampsia Predictor™. For Prenatal screening PerkinElmer offers LifeCycle™ software including aneuploidy risk calculation.

ORDERING INFORMATION

Product	Product Name
6007-0030/3C	DELFIA Xpress PlGF 1-2-3
B055-301	DELFIA/AutoDELFIA PlGF 1-2-3

The Fetal Medicine Foundation
FMF approved

funded by EU FP7
ASPRE project

SEVENTH FRAMEWORK PROGRAMME

ASPRE CHOOSES DELFIA® Xpress PlGF 1-2-3

- **The European multicentre trial on the role of Aspirin in prevention of pre-eclampsia**
- **Over 30.000 pregnancies screened with the PlGF 1-2-3 kit as part of the trial**
- **High risk pregnancies will be randomized for low dose Aspirin or placebo**

Product claims may differ from country to country based on regulations and product approvals. Please contact your country representative for further details. PerkinElmer products mentioned in this brochure are not available in the USA and Japan. Prior to registration, products are not available in China, Canada, certain Latin American countries and certain Asian countries. Please check availability with your local distributor.

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

PerkinElmer, Inc.
Wallac Oy
PO Box 10
20101 Turku, Finland
Phone: (+ 358) 22678-111
Fax: (+ 358) 22678-357

ISO 13485
ISO 9001
CMDCAS
ISO 14001
OHSAS 18001

PerkinElmer®
For the Better

For a complete listing of our global offices, visit www.perkinelmer.com/ContactUs

1599-9786-02, October 2015