

Early detection of Pre-eclampsia

GPBB



DIANEONATAL®

Glycogen Phosphorylase Isoenzyme BB

DIANEONATAL® POCT



Background

Pre-eclampsia is a medical condition in pregnant women, characterized by high blood pressure and proteinuria (significant amounts of protein in the urine). In Western Europe, 5-7% of all pregnant women suffer from pre-eclampsia, about 50.000 worldwide die from pre-eclampsia every year. An early biomarker could help diagnose the condition in time and lower the risks for mother and child significantly.

New Possibilities

Diagenics SE has now developed a method to measure a new biomarker for pre-eclampsia: Glycogen Phosphorylase isoenzyme BB (GPBB). This enzyme is specific for heart, brain and placental tissue, and in case of an ischemia it is immediately released into the blood stream - much earlier than any necrosis marker.

Studies

Diagenics SE owns the proprietary antibodies to this enzyme and has already developed a product line for the early diagnosis of pre-eclampsia: Dianeonatal. Currently ongoing and further studies will increase our knowledge related to the diagnosis of pre-eclampsia.

Product

Dianeonatal POCT [DN - P3] is a diagnostic which measures GPBB concentration as an aid to diagnose pre-eclampsia early and reliable by the detection of GPBB in human blood or plasma.

Format

A point of care test (POCT) for early and reliable detection of pre-eclampsia, based on the marker Glycogen Phosphorylase isoenzyme BB (GPBB).

Mode of Operation

Dianeonatal POCT qualitatively detects the enzyme GPBB indicating placental ischemia. Utilizing whole blood or plasma, the Dianeonatal POCT gives a solid answer on a patient's state shortly after symptom onset.

System

As a lateral flow test, the enzyme based immunoassay provides reliable results within 15 minutes.

CE-Approved

Time of approval: Q4/2014

Partner

The CE-certified production partner for the Dianeonatal POCT system is VEDA.LAB, France.



DIANEONATAL® ELISA



Product

The Dianeonatal ELISA (Enzyme Linked Immuno Sorbent Assay) [DN-E2] is a diagnostic device to measure GPBB as an aid for the specific and early detection of pre-eclampsia.

Format

ELISA for the measurement of Glycogen Phosphorylase isoenzyme BB (GPBB) as an aid to reliably detect pre-eclampsia.

Mode of Operation

The Dianeonatal ELISA quantitatively detects the enzyme GPBB which is released into the blood from ischemic placenta cells. Abnormally elevated GPBB blood levels shortly after typical symptom onset indicate a pre-eclampsia.

System

96-well micro titer plates, enzyme immunoassay (Sandwich ELISA) that is compatible with standard ELISA reader systems.

CE-Approved

Time of approval: Q1/2014

Partner

The CE-certified production partner for the Dianeonatal ELISA system is Viro-Immun GmbH, Germany.

DIANEONATAL® READER



Product

After having performed a Dianeonatal POCT, the respective test stripe is inserted into the device holder of the Dianeonatal Reader [DX-R1].

The reader analyzes the POCT within 1 minute regarding test and control line.

The intensity of the test line is measured and translated into the GPBB concentration of the analyzed sample. The results are displayed and documented.

Format

An optical reader to document and store the result of the POCT (Point-of-care-test).

CE-Approved

Time of approval: tba

Partner

The CE-certified production partner for the Dianeonatal Reader is the company opTricon GmbH, Germany.

* The test result should only be interpreted by medical specialists in conjunction with the patient's history, clinical symptoms and other medical investigations according to the latest guideline for pre-eclampsia. Also considering the guideline for pre-eclampsia differential diagnostic procedures should be used to eliminate myocardial infarction and/or stroke, two conditions that can also cause high GPBB levels.

CLINICAL EVALUATION

GPBB assessment in patients with pre-eclampsia

Patient Group	Control (N=33)	Pre-eclampsia (N=74)	SGA (N=28)
Maternal age, y*	23 (15-34)	25.5 (15-43)	21.5 (16-39)
Para (nullipara), %	21.2	52.7	35.7
Gestational age at blood sampling, wk*	30.1 (20.3-36.9)	30.3 (22.6-36.7)	33.6 (20.3-36.7)
Gestational age at delivery, wk*	39.6 (37.6-42.0)	30.9 (22.9-36.7)	33.8 (20.9-36.9)
Infant sex (male), %	51.5	51.4	17.9
SGA neonates, %	0.0	50.0	100.0

SGA indicates small-for-gestational age; *data are median (range)

Source: Glycogen Phosphorylase Isoenzyme BB Plasma Concentration Is Elevated in Pregnancy and Pre-term Preeclampsia, American Heart Association, 2012 (excerpt)

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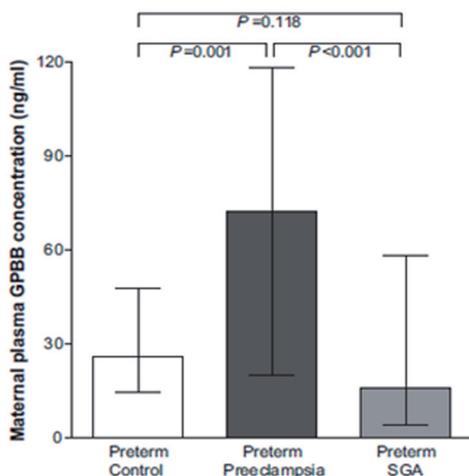
Background:

Glycogen phosphorylase is a key enzyme in glycolysis. Released with myocardial ischemia, blood concentration of glycogen phosphorylase isoenzyme BB (GPBB) is a marker of acute coronary syndromes. Pregnancy imposes metabolic stress, and preeclampsia is associated with cardiac complications. However, plasma GPBB concentration during pregnancy is unknown. This study was conducted to determine maternal plasma GPBB concentration in normal pregnancy and in pre-eclampsia.

Conclusions:

Cases of preterm (but not term) preeclampsia had higher median plasma GPBB concentrations than gestational age-matched normal pregnancy cases. (...) There is physiological elevation of plasma GPBB concentration during pregnancy; an increase in maternal plasma GPBB is a novel phenotype of preterm preeclampsia. It is strongly suggested that these changes are attributed to GPBB of placental origin.

Contact



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