

Advancing Accurate Risk Assessment & Clinical Management of Preeclampsia

Introducing the Lumella[®] GlyFN rapid point-of care test



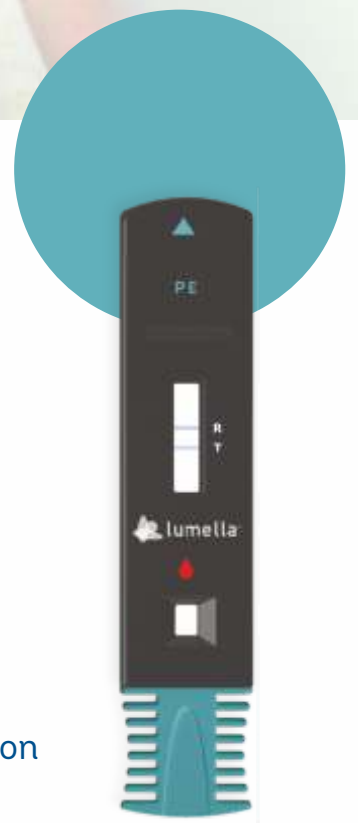


Early Symptoms of Preeclampsia are often too Ambiguous for Accurate Clinical Stratification

- Clinical presentations often involve uncertain indications of hypertension and proteinuria
- Less than 40% of women exhibit both hypertension and proteinuria before the development of overt preeclampsia
- Preeclampsia progression is unpredictable and often complicated by adverse outcomes

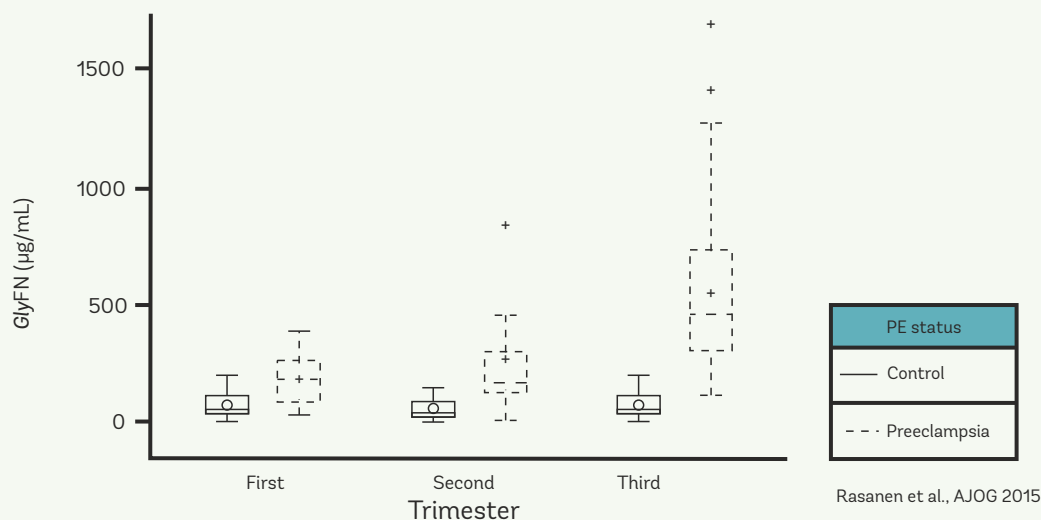
“ Biochemical markers can improve accurate clinical stratification and expectant management ” - Dr. Michael Gravett, Dept of Obgyn, University

of Washington Medical Centre, Seattle, USA



Glycosylated Fibronectin (GlyFN) Levels are Elevated in Preeclampsia*

In an observational cohort of 107 pregnant women, 45 normotensive and 62 diagnosed with preeclampsia, glycosylated fibronectin (GlyFN) levels were elevated as early as the first trimester ($p < 0.001$).



*Rasanen et al. Maternal serum glycosylated fibronectin as a point-of care biomarker for assessment of preeclampsia. *American Journal of Obstetrics and Gynecology* 2015;212:82.e1-9

The Lumella® GlyFN Point-of Care Test Accurately Estimates Risk in Women with Suspected Preeclampsia

In a prospective, observational study (SUPERIOR study, 2016-2018), conducted in India among a cohort of 599 women suspected of preeclampsia, GlyFN as a single biochemical marker showed the highest test performance for risk stratification of preeclampsia.

Normal GlyFN	50-250 µg/mL	Correlated with normal pregnancy with high sensitivity of 98.2% and high Negative Predictive Value of 99.4%
Positive GlyFN	351-600 µg/mL	Correlated with biochemical diagnosis of preeclampsia with 98% Positive Predictive Value
High Positive GlyFN	> 600 µg/mL	Correlated with risk of severe preeclampsia with 99% Positive Predictive Value

The Lumella[®] GlyFN Test is Intended as an Aid in the Diagnosis of Preeclampsia in Women with Suspected Preeclampsia.

Testing period: Gestational age 13-37 weeks



- New-onset hypertension
- New-onset proteinuria
- Severe headache
- Changes in vision
- Abdominal pain
- Fetal growth restriction

Introducing the Lumella[®] GlyFN Point-of Care Test

- Measures glycosylated fibronectin (GlyFN)
- Uses 5 µL finger prick blood sample
- Results in 10 minutes

Clinical Interpretation of Test Results

GlyFN range	Test Result	Interpretation
50-250 µg/mL	Normal	99.4% Negative Predictive Value for normal pregnancy
251-350 µg/mL	Abnormal	Mild or Developing Preeclampsia, repeat testing in 2 weeks
351-600 µg/mL	Positive	98% Positive Predictive Value for diagnosis of preeclampsia
>600 µg/mL	High Positive	High risk of severe preeclampsia and adverse outcomes



DiabetOmics, Inc.
 2345 NE Overlook Drive #140, Hillsboro, OR 97006, USA.
 6-3-349/17 Dwarakapuri, Hyderabad - 500 082, India.
 For Queries, email us at : enquiry@diabetomics.com



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Contact Information:
 Ruchi Tiwari
 GenWorks Health Pvt Ltd
 Unit 522-524, 5th Floor, Gamma Block Sigma
 Tech Park, Ramagondanahalli Varthur Road,
 Bangalore - 560066
 Ph no. +91 96204 06263
ruchi.tiwari@genworkshealth.com