

Information for Healthcare Professionals

# Preeclampsia and Gestational Diabetes

# KNOW THE RISK



PREGNANCY  
METABOLIC  
PROFILE



The first and only laboratory-developed test profile that utilizes glycosylated fibronectin (GlyFn) and a panel of additional biomarkers to accurately assess the risk for metabolic complications of pregnancy, specifically **preeclampsia (PE)** and **gestational diabetes (GDM)**.

## Common mechanisms and outcomes in PE and GDM

PE and GDM are the two most common metabolic causes of pregnancy complications, with serious consequences for both mother and child.<sup>1,2</sup> There is increasing evidence that these disorders share many features, including risk factors, underlying pathophysiology, and outcomes with respect to risk for subsequent disease.

- ✓ PE and GDM have similar risk factor profiles, particularly high BMI, which is thought to increase the risk of PE directly as well as indirectly through its association with GDM, which itself predisposes to PE.<sup>3-5</sup> Both PE and GDM are associated with elevated uric acid levels.<sup>6,7</sup>
- ✓ PE and GDM result in similar changes in a number of adipokines that regulate metabolic and vascular function.<sup>8</sup>
- ✓ Maternal insulin resistance is associated with PE and PE-associated inflammation.<sup>9,10</sup> Both PE and GDM increase the risk of subsequent type-2 diabetes.<sup>11,12</sup> Women with preexisting type-1 diabetes are at increased risk for PE.<sup>13,14</sup>
- ✓ A previous study demonstrated that treatment of GDM reduced the rate of PE by 30%, and the recent recommendation of low-dose aspirin for PE prevention may be translatable to GDM based upon the promising effects of salicylates on glycemic control in type-2 diabetes.<sup>15-18</sup>

These data support the concept that a large proportion of cases of PE and GDM represent variations in presentation of a common metabolic derangement.

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**GlyFn, a metabolic biomarker for detection of GDM and PE**, provides efficient identification of patients whose chances for successful pregnancy outcomes can be facilitated by cost-effective, standard interventions such as low-dose aspirin and nutritional counseling that can also reduce future healthcare expenses.

# GlyFn and PE

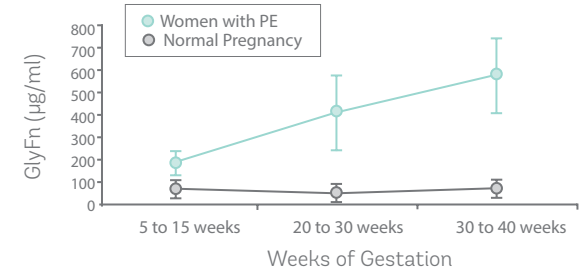
Fibronectin is known to regulate blood vessel organization, so that increased maternal serum levels may contribute directly to PE development.<sup>19</sup>

Recent studies indicate that a particular glycosylated version of fibronectin (GlyFn) is specifically associated with the risk of developing severe PE. Determination of GlyFn levels in maternal blood represents an improved method for detecting and monitoring PE.<sup>20</sup>

\* Data on file.

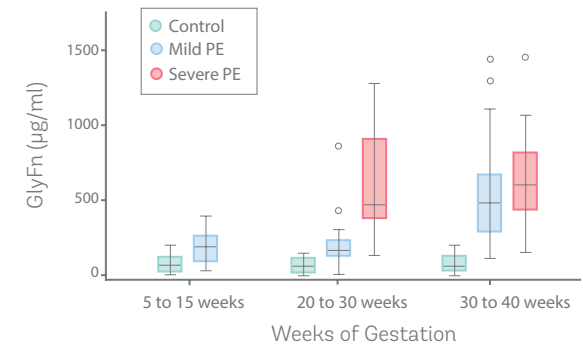
## GlyFn levels in PE are elevated as early as the second trimester

In a case-control study of 108 women, longitudinal comparison of normotensive women and women with PE showed that, within each trimester, GlyFn levels were significantly higher in patients with PE than in controls ( $p < 0.01$ ).<sup>20</sup>



## GlyFn levels are predictive of mild vs severe PE

In the same case-control study, increasing levels of GlyFn were also found to correlate with severity of PE.<sup>20</sup>



**PMP exhibits a sensitivity of 84% and a specificity of 97% for PE\***

Biomarker	Biomarker classification performance (95% CI)	
	Sensitivity (%)	Specificity (%)
Glycosylated fibronectin	80 (60-93)	97 (90-100)
PAPP A 2	36 (18-57)	94 (86-98)
Placental Lactogen	12 (3-31)	94 (86-98)
<b>PMP for PE</b>	<b>84 (64-95)</b>	<b>97 (90-100)</b>

# GlyFn and GDM

GlyFn is a pregnancy-specific biomarker for early identification of women at risk for GDM as early as the first trimester of pregnancy.<sup>23</sup>

The relative change in GlyFn concentrations in GDM is greater than the changes in HbA1c, CRP, and adiponectin, although all these biomarkers are associated with GDM status.\*

\* HbA1c used to identify existing type 1/2 diabetes.

\*\* Data on file.

**PMP exhibits  
a sensitivity of 78%  
and a specificity  
of 90% for GDM\*\***

Biomarker	Biomarker classification performance (95% CI)	
	Sensitivity (%)	Specificity (%)
Glycosylated fibronectin	81 (73-89)	90 (84-96)
Adiponectin	28 (19-37)	90 (84-96)
High-sensitivity CRP	16 (8-23)	91 (86-97)
<b>PMP for GDM</b>	<b>78 (69-86)</b>	<b>90 (84-96)</b>

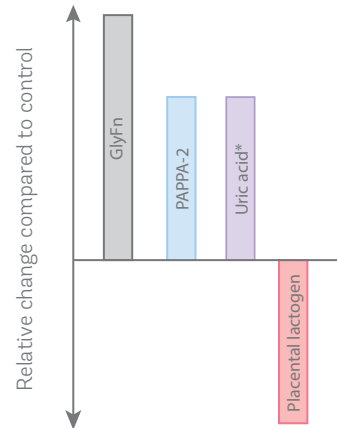


## Pregnancy Metabolic Profile: PE Test

In addition to GlyFn, the PE test panel includes pregnancy-associated plasma protein PAPP-A-2, placental lactogen, and uric acid\*, and employs an algorithm to estimate the risk of PE and potential adverse outcomes.

Placental lactogen is produced by the placenta, and maternal serum levels are decreased in PE, while PAPP-A-2 and uric acid levels are increased.<sup>21,22</sup>

\* Uric acid used for assessment of renal function.



### Who Should Be Tested for PE

Our PE test is recommended for pregnant patients who may have one or more of the following:

- ✓ Clinical assessment of increased risk for PE
- ✓ Nulliparous
- ✓ Family history of or previous hypertension  
PE-Family history of or preexisting type-1 or type-2 diabetes
- ✓ Clinically evaluated obesity

### When to Test for PE

- 1 Initial: 17-36 weeks
- 2 Follow up: 20-36 weeks

### Clinical Utility:<sup>20</sup>

- ✓ The PMP PE test provides the biochemical confirmation of PE.
- ✓ The test should be used in assessment of subjects suspected of PE, borderline blood pressure and proteinuria changes. The test is positive 2-4 weeks before the onset of symptoms.

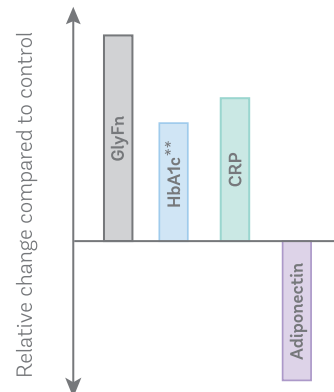
## Pregnancy Metabolic Profile: GDM Test

In addition to GlyFn, the GDM test panel includes hemoglobin HbA1c\*\*, C-reactive protein (CRP), adiponectin, and employs an algorithm to estimate the risk of GDM and potential adverse outcomes.

Maternal serum HbA1c levels indicate potential hyperglycemia often seen in GDM.

Elevated CRP levels are associated with GDM, as are decreased adiponectin levels.<sup>24-27</sup>

\*\* HbA1c used to identify existing type 1/2 diabetes.



### Who Should Be Tested for GDM

Our GDM test is recommended for pregnant patients who may have one or more of the following:

- ✓ Clinical assessment of increased risk for GDM
- ✓ Family history of or preexisting type-1 or type-2 diabetes
- ✓ History of GDM
- ✓ Presence of glycosuria
- ✓ History of abnormal glucose tolerance
- ✓ Overweight or obese prior to pregnancy

### When to Test for GDM

7-13 weeks

### Clinical Utility:<sup>23</sup>

- ✓ The PMP GDM test performed in the first trimester is more sensitive than the Glucose Challenge Test in predicting GDM.
- ✓ 90% of subjects with a positive PMP GDM test in the first trimester will test positive with the Oral Glucose Tolerance Test (OGTT) at 24-28 weeks gestation.



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**PregnancyMetabolicProfile.com**

Pursuant to applicable federal and/or state laboratory requirements, Diabetomics, Inc. has established and verified the accuracy and precision of its testing services.

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