

New Lumella® GlyFN Pre-eclampsia Test Approved For Supply to NHS

AGHealth is pleased to announce that the Lumella® GlyFN pre-eclampsia test will be available to the NHS as of June 2021.

The Lumella® GlyFN test is a rapid point-of-care (POC) test that can assess the risk of pre-eclampsia. Pre-eclampsia affects about 6% of pregnancies in the UK and severe pre-eclampsia occurs in around 1-2% of pregnancies¹. Pre-eclampsia can progress unpredictably and can be fatal if untreated. Although maternal deaths due to pre-eclampsia in the UK is thankfully now rare, pre-eclampsia still remains a dangerous condition for both mother and baby. 8-10% of all preterm births result from hypertensive disorders, including pre-eclampsia¹. The severe complications be avoided with early treatment and careful management, which depends on early detection of pre-eclampsia.

Lumella® GlyFN is an accurate and inexpensive test kit which detects the early onset of pre-eclampsia, as early as 13 weeks of gestation; 7 weeks earlier than alternative tests. The test determines the concentration of Glycosylated Fibronectin (GlyFN), a robust biomarker which remains stable throughout pregnancy, except in pre-eclampsia when it has elevated levels. As a simple POC test, using Lumella® is easy and less invasive, only requiring a finger prick 5µl blood sample rather than venepuncture. The sample also does not require laboratory processing, avoiding further delays. Within 10 minutes Lumella® provides highly accurate results with 98.5% sensitivity and 92.8% specificity², resulting in a low rate of both false negative and false positive results. Studies have shown GlyFN to have the best overall diagnostic performance compared to other available biomarkers for pre-eclampsia (PIGF, PAPP2 and sFlt-1)²⁻⁴. This can reassure clinicians that women with suspected pre-eclampsia are receiving a more reliable and accurate diagnosis, and therefore the most appropriate management, in a fast and efficient way without compromising convenience for clinicians and comfort for women when using the Lumella® test.

AGHealth is highly selective over its product range, and only supports evidence-based devices that will lead to improved clinical outcomes and patient care. Continuing this mission to bring innovation to women's healthcare, we are pleased to announce that the diagnostic test Lumella® GlyFN is now available in the UK.

For more information, please get touch by emailing info@aghealth.co.uk

Alexander Fisher,
Managing Director

¹ Pre-eclampsia statistics. Tommy's Pregnancy Hub. (2020). [online]. [Accessed here](#).

² Glycosylated Fibronectin point-of-care test for diagnosis of pre-eclampsia in a low-resource setting: a prospective Southeast Asian population study. Nagalla et al. 2020. BJOG.

³ Maternal serum glycosylated fibronectin as a short-term predictor of preeclampsia: a prospective cohort study. Huhn, E. A. et al. 2020. BMC Pregnancy and Childbirth.

⁴ Maternal serum glycosylated fibronectin as a point-of-care biomarker for assessment of preeclampsia. Rasanen et al. 2015. AJOG.