PRESS RELEASE

Groundbreaking study shows that a simple, rapid PlGF test can accurately risk stratify pregnant women with suspected pre-eclampsia[1].

08:00 (CET) Rome, Italy, October 8th, 2012 – Alere Inc. (NYSE: ALR) is pleased to announce the results of a study, presented today at the 20th FIGO World Congress of Obstetrics and Gynecology, which demonstrate that a simple blood test measuring placental growth factor (PlGF) can help to quantify risk in women when pre-eclampsia is first suspected. The level of PlGF in blood is already known to be an important marker for placental and foetal wellbeing as well as the placenta's ability to sustain the pregnancy.[2]

This UK-based, multi-centre study known as PELICAN used the Alere Triage® PLGF test to measure PlGF levels in 625 women with suspected pre-eclampsia in their first clinic visit. In women presenting before 35 weeks gestation who were managed in accordance with standard clinical protocols, a high PlGF level was strongly correlated with low risk for required delivery in the next 14 days. In fact, 96% of women with a normal test result were correctly diagnosed as not at risk.[1] Conversely, a low PlGF level accurately identified women at high risk for preterm delivery, and 94% of women with an abnormal test result went on to require early delivery.[1]

Professor of Obstetric Medicine at the University of Oxford and PELICAN investigator, Christopher Redman commented, "Pre-eclampsia is notoriously unpredictable. Reliable tests that can be used in the clinical setting, when pre-eclampsia is first suspected, would be a notable breakthrough in the management of this life-threatening condition. The PELICAN data have demonstrated that PlGF testing before 35 weeks enables physicians to categorise women into low and high risk for disease progression and to adjust clinical management appropriately."

Pre-eclampsia is a dangerous condition that can develop during pregnancy and, if left untreated, may lead to significant maternal organ damage, foetal growth restriction and, in some cases, foetal or maternal death.[3–5] Deterioration in women with suspected pre-eclampsia can be rapid and unpredictable, requiring costly and frequent clinical assessment to determine if early delivery is medically necessary. Current diagnostic methods for assessing risk include

measurement of maternal blood pressure, identifying the presence of protein in the urine, and laboratory blood testing for maternal organ damage. These methods are generally poor in determining a woman's level of risk and often result in over-management and unnecessary costs.

Remarking on the PELICAN results, Andrew Shennan, Professor of Obstetrics at King's College London and study investigator, stated, "The appropriate management of women with suspected pre-eclampsia presenting before 35 weeks is known to be extremely complex. Many women are admitted, treated or even delivered inappropriately. What is more worrying is that a substantial number of cases are missed altogether. At last, with the Alere Triage® PLGF Test, we have a simple and reliable tool guiding clinicians to target women who will benefit from these interventions, whilst limiting unnecessary healthcare expenditures incurred by managing women at low risk for needing preterm delivery."

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References

1. Redman C, Shennan A, Myers J. Placental Growth Factor and the Clinical Management of Pre-eclampsia. FIGO 2012.
2. Taylor RN, Grimwood J, Taylor RS, et al. Longitudinal serum concentrations of placental growth factor: evidence for abnormal placental angiogenesis in pathologic pregnancies. Am J Obstet Gynecol 2003;188:177–82.
3. Centre for Maternal and Child Enquiries (CMACE). Saving Mothers' Lives: reviewing maternal deaths to make motherhood safer: 2006–08. The Eighth Report on Confidential Enquiries into Maternal Deaths in the United Kingdom. BJOG 2011;118(Suppl 1):1–203.
4. EURO-PERISTAT Project, with SCPE, EUROCAT, EURONEOSTAT. European Perinatal Health Report. 2008. Available at: www.europeristat.com
5. Douglas KA, Redman CWG. Eclampsia in the United Kingdom. BMJ 1994;309:1395–1400.

About Alere Triage® PLGF

The Alere Triage® PLGF test is currently available for use as an aid in the diagnosis of pre-eclampsia in women with suspected pre-eclampsia before 35 weeks gestation. An expanded indication for use as an aid in risk stratification for required preterm delivery will soon be CE marked. The product is not available for sale or distribution in the United States. The Alere Triage® PLGF test takes 15 minutes to deliver a result from a maternal plasma specimen.

About Alere

By developing new capabilities in near-patient diagnosis, monitoring and health management, Alere enables individuals to take charge of improving their health and quality of life at home.

Alere's global leading products and services, as well as its new product development efforts, focus on cardiology, infectious disease, toxicology, diabetes, oncology and women's health. Alere is headquartered in Waltham, Massachusetts.

For additional information on Alere, please visit www.alere.com

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