Media Release

Roche Elecsys sFlt-1/PlGF ratio for preeclampsia receives FDA 510(k) clearance, offering a fast and reliable way to predict the risk of developing severe preeclampsia

- **Identifying patients at high risk of developing severe preeclampsia can lead to better prediction, earlier interventions and reduced adverse outcomes.[1]**
- **In the United States, preeclampsia has increased 25% in the last two decades and is a leading cause of maternal and infant illness and death,[2] disproportionately affecting Black women.[3]**
- **With an extensive U.S. installation base of more than 4,000 cobas® analyzers and a high degree of menu consolidation across various indications, clinicians are supported in making faster, more efficient clinical decisions.**

INDIANAPOLIS, February 13, 2025 – Roche announced today that the Roche Elecsys® sFlt-1/PlGF ratio for preeclampsia has received 510(k) clearance from the United States Food and Drug Administration (FDA). The ratio is a prognostic test intended to stratify hospitalized pregnant women with hypertensive disorders of pregnancy into low- and high-risk categories for developing severe preeclampsia within two weeks of testing. Identifying patients at high risk for severe preeclampsia can lead to better prediction, earlier interventions and reduced adverse outcomes.[1]

In the U.S., preeclampsia has increased 25% in the last two decades and is a leading cause of maternal and fetal illness and death.[2] Black women in particular experience higher rates of maternal and adverse fetal and neonatal outcomes than other racial and ethnic groups and are at greater risk for developing hypertensive disorders of pregnancy than other pregnant women.[3]

“There is a great need for highly reliable tools, such as the Elecsys sFlt-1/PlGF ratio, to address severe preeclampsia," said Brad Moore, president and CEO of Roche Diagnostics North America. “We are eager to partner with our customers so this prognostic test can help clinicians plan care and improve patient outcomes."

sFlt-1 and PlGF are key biomarkers in the formation of blood vessels during pregnancy. However, an angiogenic imbalance of these key biomarkers has been proven to play an important role in the development of preeclampsia. Their concentrations in maternal serum are altered even before the onset of the disease, making them a valuable tool for predicting preeclampsia progression.[4,5] Nearly 70% of women with a sFlt-1/PlGF ratio greater than 38 delivered their babies within two weeks.[1]

“The current clinical diagnostic criteria are poor in predicting, with accuracy, the development of preeclampsia among patients with hypertensive disorders of pregnancy," said Sarosh Rana, M.D., MPH, FACOG, University of Chicago Medicine. "The clearance of this ratio provides clinicians with an additional tool to predict the risk of severe preeclampsia and support clinical management by increasing surveillance in high-risk patients or prolonging pregnancy in low-risk patients, ultimately preventing adverse maternal, fetal and neonatal outcomes.”

Preeclampsia is defined as the new onset of hypertension and proteinuria after 20 weeks of gestation, or in the absence of proteinuria, new-onset hypertension and any of the following: thrombocytopenia, renal insufficiency, impaired liver function, pulmonary edema, or new onset of headache unresponsive to medication.[6] Preeclampsia can be treated only by removal of the placenta at delivery.[6] The clinical presentation of preeclampsia and the subsequent clinical course of the disorder can vary tremendously, making prediction, diagnosis and assessment of progression difficult.[6]

“The FDA clearance of the sFlt-1/PlGF ratio on Roche platforms is a major milestone in the quest to solve preeclampsia,” said Ravi Thadhani, M.D., MPH, executive vice president of Health Affairs at Emory University. “This test will give clinicians an additional tool to stratify women at highest risk for the development of severe preeclampsia. Preeclampsia biomarker testing has the potential to spur innovation in new therapies that are sorely needed for these patients.”

Preeclampsia and its symptoms, such as headaches, visual changes, epigastric pain, and shortness of breath,[6] have warning signs that are often overlooked and have devastating and lasting impact on mothers and babies if not properly managed.[7] Impacts can include maternal organ damage and an increased risk of future heart failure, preterm birth[6] and avoidable mental trauma.[8] Hospitalization is typically recommended to evaluate the potential for progression to severe disease. Standard diagnostic markers for preeclampsia are often nonspecific and may not accurately predict the severity of the condition or associated adverse outcomes in the subsequent days and weeks.[7]

The preeclampsia ratio aligns with Roche’s commitment to lead with science in order to develop transformational solutions that improve patient outcomes and simplify lab operations. Roche provides an unrivaled ability to scale access to testing at speed for those who need it most. With an extensive U.S. installation base of more than 4,000 **cobas**® analyzers and a high degree of menu consolidation across various indications, clinicians are supported in making faster, more efficient clinical decisions, providing the ability to scale testing at speed for even more women.

About Preeclampsia

Preeclampsia is a serious multi-system complication of pregnancy, occurring in 3% to 4% of pregnancies in the U.S., and remains one of the leading causes of maternal and perinatal morbidity and mortality worldwide.[7]

Preeclampsia can also have negative effects on the fetus and newborn, resulting in complications such as intrauterine growth restriction, low birth weight and stillbirth. These complications often necessitate early induction of labor or cesarean delivery, leading to preterm birth.[9]

Each year in the U.S., there are 4 million pregnancies, of which 120,000 to 160,000 are affected by preeclampsia. From 2017-2019, hypertensive disorders of pregnancy – including gestational hypertension, chronic hypertension, preeclampsia and superimposed preeclampsia – accounted for 6.3% of pregnancy-related deaths in the U.S.[10] In 2022, there were approximately 22 maternal deaths for every 100,000 live births in the U.S. – far above that of other high-income countries.[11]

About Elecsys sFlt-1/PlGF Ratio

The Elecsys sFlt-1/PlGF ratio for preeclampsia is an FDA-cleared test to clinically assess the progression of preeclampsia.[12] The preeclampsia ratio supports the management of pregnant patients with a singleton pregnancy, and is intended to help clinicians stratify hospitalized patients into low- and high-risk categories for developing severe preeclampsia within two weeks of presentation.[12] Identification of high-risk preeclampsia patients can lead to better prediction, earlier interventions and reduced adverse outcomes.[1,5,13]

The Elecsys sFlt-1 and Elecsys PlGF assays are provided in separate kits. The ratio must be calculated using Elecsys sFlt 1 and Elecsys PlGF results obtained on the same patient sample and the same cobas immunoassay analyzer per the intended use. The assay results should be used only in conjunction with information available from clinical evaluations and other standard-of-care procedures. The test result is not to be used to replace clinical judgment.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalized healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person, we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

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