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Trinity Biotech Receives Regulatory Approval to Begin FDA-Cleared PreClara™ Preeclampsia Testing Service

New York State Department of Health (NYSDOH) clinical laboratory permit facilitates Q3 2025 launch of the FDA-cleared PreClara™ Ratio (sFlt-1/PlGF) biomarker test for hypertensive disorders of pregnancy.

DUBLIN, Ireland (August 14, 2025) - Trinity Biotech plc (Nasdaq: TRIB), a commercial-stage biotechnology company focused on human diagnostics and diabetes management solutions, including wearable biosensors, today announced that this week its New York, reference laboratory has received regulatory approval from the New York State Department of Health (NYSDOH) to begin providing the FDA-cleared PreClara™ Ratio (sFlt-1/PlGF) biomarker test for preeclampsia risk assessment. The service is planned to be rolled out in Q3 2025.

This approval marks a significant milestone in Trinity Biotech's maternal health strategy and strengthens its position in the U.S. diagnostics market. The PreClara™ test, provides clinicians with time-sensitive, clinically actionable insights to support informed decision-making for patients hospitalised with hypertensive disorders of pregnancy. Approximately 500,000 women in the United States are affected annually by hypertensive pregnancy disorders, a leading cause of maternal and neonatal complications. The PreClara™ Ratio test helps assess the likelihood of progression to severe preeclampsia, enabling more targeted and timely care for this high-risk population. Recent U.S.-based studies published in March 2025 demonstrated potential neonatal cost savings exceeding $10 million per 1,000 patients[1] when the test is incorporated into standard care, primarily through reduced preterm deliveries and NICU admissions.

The NYSDOH approval of the sFlt-1/PlGF testing service further lays critical groundwork for the anticipated commercial introduction of PrePsia™, Trinity Biotech's proprietary preeclampsia risk assessment technology designed for use in early pregnancy.

About Preeclampsia

Preeclampsia is a rapidly progressive hypertensive disorder affecting approximately **5-8% of pregnancies**[2], characterized by sudden onset high blood pressure and an associated sign of organ dysfunction like protein in the urine or severe headache. Early diagnosis and intervention are crucial, as preeclampsia significantly contributes to maternal morbidity, mortality, and premature births. In the United States, the condition already accounts for approximately 11%[3] of maternal deaths and 15%[4] of premature births, with cases nearly doubling since 2007[5].

PreClara Ratio (sFlt-1/PlGF) Intended Use

The PreClara Ratio (sFlt-1/PlGF) is to be used in conjunction with other laboratory tests and clinical assessments to aid in the risk assessment of pregnant women (singleton pregnancies between 23+0 and 34+6/7 weeks gestation) hospitalized for hypertensive disorders of pregnancy (preeclampsia, chronic hypertension with or without superimposed preeclampsia, or gestational hypertension) for progression to preeclampsia with severe features (as defined by American College of Obstetricians and Gynecologists)

within two weeks of presentation. The PreClara Ratio must be calculated using the B·R·A·H·M·S sFlt-1 KRYPTOR and the B·R·A·H·M·S PlGF plus KRYPTOR results measured on the B·R·A·H·M·S KRYPTOR analyzer.

[1] https://doi.org/10.1016/j.preghy.2025.101190
[2] https://www.preeclampsia.org/women-and-families
[3] https://doi.org/10.1097/aog.0000000000004361
[4] https://my.clevelandclinic.org/health/diseases/17952-preeclampsia
[5] https://doi.org/10.1001/jamanetworkopen.2022.28093

Forward-Looking Statements

This release includes statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"), including but not limited to statements related to Trinity Biotech's cash position, financial resources and potential for future growth, market acceptance and penetration of new or planned product offerings, and future recurring revenues and results of operations. Trinity Biotech claims the protection of the safe harbor for forward-looking statements contained in the Reform Act. These forward-looking statements are often characterized by the terms "may," "believes," "projects," "expects," "anticipates," or words of similar import, and do not reflect historical facts. Specific forward-looking statements contained in this release may be affected by risks and uncertainties, including, but not limited to, our ability to capitalize on the Waveform transaction and of our recent acquisitions, our continued listing on the Nasdaq Stock Market, our ability to achieve profitable operations in the future, the impact of the spread of COVID-19 and its variants, the possible pause and/or disruption in U.S. Government funding for HIV tests produced by Trinity Biotech, potential excess inventory levels and inventory imbalances at the company's distributors, losses or system failures with respect to Trinity Biotech's facilities or manufacturing operations, the effect of exchange rate fluctuations on international operations, fluctuations in quarterly operating results, dependence on suppliers, the market acceptance of Trinity Biotech's products and services, the continuing development of its products, required government approvals, risks associated with manufacturing and distributing its products on a commercial scale free of defects, risks related to the introduction of new instruments manufactured by third parties, risks associated with competing in the human diagnostic market, risks related to the protection of Trinity Biotech's intellectual property or claims of infringement of intellectual property asserted by third parties and risks related to condition of the United States economy and other risks detailed under "Risk Factors" in Trinity Biotech's annual report on Form 20-F for the fiscal year ended December 31, 2024 and Trinity Biotech's other periodic reports filed from time to time with the United States Securities and Exchange Commission. Forward-looking statements speak only as of the date the statements were made. Trinity Biotech does not undertake and specifically disclaims any obligation to update any forward-looking statements.

About Trinity Biotech

Trinity Biotech is a commercial stage biotechnology company focused on diabetes management solutions and human diagnostics, including wearable biosensors. The Company develops, acquires, manufactures and markets diagnostic systems, including both reagents and instrumentation, for the point-of-care and clinical laboratory segments of the diagnostic market and has recently entered the wearable biosensor industry, with the acquisition of the biosensor assets of Waveform Technologies Inc. and intends to develop a range of biosensor devices and related services, starting with a continuous glucose monitoring product. Our products are used to detect infectious diseases and to quantify the level of Haemoglobin A1c and other chemistry parameters in serum, plasma and whole blood. Trinity Biotech sells direct in the United States and through a network of international distributors and strategic partners in over 75 countries worldwide. For further information, please see the Company's website: www.trinitybiotech.com.