NTD Eurofins Attains New York State Department of Health (NYSDOH) Approval for the newest option to its MaternalFetalScreen^{SM} | T1 test – Y chromosome assessment

(Melville, NY – March 25, 2019) – NTD Eurofins, an innovative leader in prenatal screening, announced today that it has received approval from the New York State Department of Health (NYSDOH) for the addition of Y chromosome assessment to its MaternalFetalScreen^{SM} | T1 test. The approval from February 15, 2019 allows patients access to the MaternalFetalScreen^{SM} | T1 test with the Y chromosome option throughout the entire United States.

Terrence Hallahan PhD, Clinical Laboratory Director at NTD Eurofins, said the following about this new test; "It has long been known that maternal serum markers vary based on fetal gender. However, until recently there was no way to accurately assess fetal gender in the first trimester of pregnancy in order to make the necessary adjustments. Now, with the use of cell free fetal DNA we can accurately determine the presence of Y chromosome in the maternal circulation and based on that, adjust the serum markers accordingly. This provides an important refinement to the risk giving a more personalized risk assessment and removes gender bias when screening for various conditions."

Previous studies have shown differences in the median level of certain analytes based on fetal gender. Using real time PCR technology, NTD Eurofins can detect the presence of Y chromosome in the maternal plasma. The presence of a Y chromosome is predictive of a male fetus, while the absence of the Y chromosome most likely indicates the presence of a female fetus. Knowing whether the Y chromosome is present or not, allows NTD Eurofins to incorporate this information into the analyte MoM (multiple of the median) calculation, therefore providing a more personalized risk assessment.

MaternalFetalScreen^{SM} | T1 is the only test to combine first-trimester aneuploidy risk assessment with early onset preeclampsia (EOPE) in one report —providing patients with a comprehensive, personalized risk assessment as early as 10 weeks' gestation. Through the measurement of five serum markers, MaternalFetalScreen^{SM} | T1 casts a wide net for maternal and fetal issues, such as aneuploidy, preeclampsia, low birth weight, fetal loss and stillbirth. MoM adjustment factors have played a role in prenatal screening for over 30 years. The use of such adjustments allows individual analyte values to be compared to populations with similar clinical factors. For example, the maternal serum analyte MoM values for patients are adjusted for weight, ethnicity and diabetic status to allow for refinement of the patient specific risk.

For more information about MaternalFetalScreen^{SM} | T1 with the Y assessment or to order supplies, please contact your local Genetics Account Executive, or call 1-888-NTD-LABS (683-5227). To learn more about NTD Eurofins' comprehensive portfolio of prenatal and women's health test offerings, please visit www.ntd-eurofins.com.

References

The American Congress of Obstetricians and Gynecologists. Bipartisan legislation to prevent maternal deaths: promotes state maternal mortality review committees. 2 Mar 2017. Available at http://www.acog.org/About-ACOG/News-Room/News-Releases/2017/Bipartisan-Legislation-to-Prevent-Maternal-Deaths.

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About NTD Eurofins

For more than 30 years, Eurofins NTD has pioneered the research and development of prenatal screening protocols for open neural tube defects, Down syndrome, trisomy 13 and 18, and early onset preeclampsia screening. Today, Eurofins NTD serves universities, medical centers, hospitals, laboratories, obstetricians and maternal fetal medicine specialists worldwide—providing risk assessment services that help healthcare professionals and patients make more informed medical decisions.

NTD Eurofins is a 100 percent subsidiary of Eurofins Scientific (EUFI.PA), the global leader in bio-analytical testing, and one of the world leaders in genomic services. For more information, please visit www.eurofins.com and www.ntd-eurofins.com.

Eurofins – a global leader in bio-analysis

Eurofins Scientific through its subsidiaries (hereinafter sometimes “Eurofins” or “the Group”) believes it is a scientific leader in food, environment and pharmaceutical products testing and in agroscience CRO services. It is also one of the independent market leaders in certain testing and laboratory services for genomics, discovery pharmacology, forensics, CDMO, advanced material sciences and for supporting clinical studies. In addition, Eurofins is one of the emerging players in specialty clinical diagnostic testing in Europe and the USA. With about 45,000 staff in more than 800 laboratories across 47 countries, Eurofins offers a portfolio of over 200,000 analytical methods for evaluating the safety, identity, composition, authenticity, origin and purity of biological substances and products, as well as for innovative clinical diagnostic. The Group objective is to provide its customers with high-quality services, accurate results on time and expert advice by its highly qualified staff.

Eurofins is committed to pursuing its dynamic growth strategy by expanding both its technology portfolio and its geographic reach. Through R&D and acquisitions, the Group draws on the latest developments in the field of biotechnology and analytical chemistry to offer its clients unique analytical solutions and the most comprehensive range of testing methods.

As one of the most innovative and quality oriented international players in its industry, Eurofins is ideally positioned to support its clients’ increasingly stringent quality and safety standards and the expanding demands of regulatory authorities around the world.

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