CHEMBIO DIAGNOSTICS INC., A SUBSIDIARY OF BIOSYNEX, RECEIVES A GRANT FOR DEVELOPMENT OF A DPP CONGENITAL SYPHILIS ASSAY

Chembio Diagnostics, Inc. (Chembio), a wholly owned subsidiary of Biosynex, is a leading point-of-care diagnostics company focused on infectious diseases, today announced it was awarded a $1.5 million grant from the Bill & Melinda Gates Foundation for the development of a rapid point-of-care (POC) diagnostic test for congenital syphilis.

The diagnosis of congenital syphilis can be difficult due to maternal antibodies in newborns, so the diagnosis is often focused on maternal syphilis. Non-Treponemal and Treponemal pallidum IgM tests for newborns can be the most sensitive and specific tests for CS since they cannot cross the placental barrier. The current syphilis tests for newborns often result in over-treatment, delayed and/or missed diagnoses, and there is need for tests that are easy to use, high quality, rapid, and affordable in low and middle-income settings.

Chembio will undertake to develop a syphilis test assay based on its Dual Path Platform (DPP) technology and proprietary DPP Micro Reader II. The assay will be intended to simultaneously and separately detect Treponemal and Non-Treponemal IgM and IgA antibodies. The test should require only 10 µL of fingerstick blood, serum, or plasma and produce results in under 20 minutes.

Chembio has extensive experience in the field of rapid syphilis diagnostics through its successful development, validation, and commercialization of DPP HIV-Syphilis and DPP Syphilis Screen and Confirm. Additionally, Chembio has developed a new generation DPP Syphilis Treponema and Non-Treponema IgM and IgG antibodies with funding of the Centers for Disease Control and Prevention (CDC) and currently under FDA clinical trial in US.

Syphilis infections continue to be a significant health problem and are particularly threatening in high-risk groups and in people who are pregnant, where congenital syphilis can severely affect pregnancy outcome and infant morbidity. When a pregnant person has syphilis, the infection can spread in utero before the child is born. This transmission of syphilis can occur at any stage of pregnancy and can result in serious consequences for the newborn. Congenital syphilis may lead to stillbirth, premature birth, low birth weight, and a range of serious health issues, including bone deformities, brain and nerve problems like blindness or deafness.

In 2022, WHO estimated there were 700 000 congenital syphilis cases globally. These maternal syphilis cases led to an estimated 150 000 early fetal deaths and stillbirths, 70 000 neonatal deaths, 55 000 preterm or low-birth weight births, and 115 000 infants with clinical diagnosis of congenital syphilis. According to the Centers for Disease Control and Prevention, syphilis cases in the United States increased by nearly 80% between 2018 and 2022, creating a critical public health issue. The most alarming concerns center around the syphilis and congenital syphilis epidemics, signaling an urgent need for swift innovation and collaboration from all STI prevention partners. The timely identification and treatment of syphilis can decrease the transmission to others and result in better patient outcomes.

Javan Esfandiari, President of Chembio commented, *"We are excited to receive support from the Gates Foundation and look forward to developing a highly sensitive and highly specific test that will potentially enable physicians to diagnose and treat active syphilis in a timely manner in infant and mother. Early and reliable*

diagnosis and timely treatment can prevent transmission of syphilis as well as the development of severe complications".

Thierry Paper, Chief Science Technology Officer of Biosynex Group commented, *"We are honored to receive funding from the foundation and provide a solution for diagnostic of Congenital Syphilis which represents a major Public Health concern with no satisfactory solution to date".*

Next communication : Full-year revenue 2024 : Thursday 16 january 2025, after market.

Press coverage : https://www.biosynex.com/actualites/

About BIOSYNEX

Founded in 2005, the French laboratory BIOSYNEX is a leading health diagnostics group, specializing in rapid tests, biotherapy monitoring, and molecular biology.

As a forward-thinking player in the future of medicine, BIOSYNEX advocates for the improvement of healthcare pathways and offers innovative health solutions to a variety of users, including laboratories, hospitals, doctors, and the general public, aimed at enhancing overall patient care.
Following its significant contribution during the Covid-19 pandemic, BIOSYNEX has gained new international stature in the rapid diagnostics field, partly due to its dynamic external growth strategy. The Group now has research, production, and distribution subsidiaries in the United States, Europe, and Asia, supporting its two business units: BIOSYNEX PHARMACY and BIOSYNEX DIAGNOSTICS.

For the general public: The BIOSYNEX Pharmacy division, specialising in self-diagnostics and family health products, distributes a comprehensive range of well-established and recognised brands across a wide network of pharmacies and parapharmacies, focusing on prevention, diagnostics, and natural care.

For professionals: The BIOSYNEX Diagnostics division, a technology-driven business operating in high-growth sectors, develops and provides laboratories, hospitals, doctors, and nursing homes with in vitro diagnostic medical devices in the form of rapid diagnostic tests (RDTs and POC tests), molecular biology, and point-of-care (POC) products for screening, diagnosis, and prevention.

Based in Illkirch-Graffenstaden, Alsace, the BIOSYNEX Group employs over 500 people and has a presence in 95 countries. The Group achieved a turnover of €93 million in 2023. Listed on Euronext Growth Paris (FR0011005933 ALBIO), BIOSYNEX is eligible for PEA-PME.

For more information, visit www.biosynex.com.

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