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Trinity Biotech Announces CLIA waiver of Rapid Syphilis Test

DUBLIN, Ireland (December 16, 2014).... Trinity Biotech plc. (Nasdaq: TRIB), a leading developer and manufacturer of diagnostic products for the point-of-care and clinical laboratory markets, today announced that a CLIA waiver has been received for Syphilis Health Check – a point-of-care rapid test for the detection of Syphilis.

CLIA waiver has been granted by the U.S. Food and Drug Administration (FDA) to Syphilis Health Check, which is the first ever waiver for a rapid screening test for syphilis available in the United States. The CLIA waiver has been granted to Diagnostics Direct, LLC who are retaining distribution rights for the product to the Physician's Office market, whilst Trinity Biotech will be the exclusive distributor for the U.S. Public Health and Hospital markets. Importantly, the waiver allows the test to be performed by untrained healthcare workers in a variety of non-traditional laboratory sites such as emergency rooms, health department clinics, community-based organisations, physicians' offices and other free standing counselling and testing locations. A copy of the press release issued by the FDA is included below.

Syphilis Health Check is a qualitative rapid membrane immune-chromatographic assay for the detection of *Treponema pallidum* (Syphilis) antibodies in human whole blood, serum and plasma. The test, which acts as a screening test, will primarily be performed in a CLIA waived setting using finger stick samples of whole blood only, with results being available in as little as 12 minutes. All positive tests should be followed up with further syphilis serological laboratory testing and clinical evaluation before final diagnosis.

Syphilis has been identified as a growing disease in the USA. According to the Centers for Disease Control and Prevention (CDC) there are approximately 55,000 new cases of primary and secondary syphilis in the USA each year. This growth is particularly prevalent amongst men who have sex with men (MSM), who now account for more than 75% of all new cases, with an increasing number occurring in the 15 to 24 age bracket. Early detection and treatment is central to limiting the spread of the disease and should help to reduce the risk of additional health issues in those who contract it.

William Smith, Executive Director of the National Coalition of STD Directors (NCSD) which represents state and local STD public health programs across the country commented, "NCSD has been working and advocating for years to bring this product to the wider marketplace that a CLIA waiver makes possible. We have done so because we have a public health emergency on our hands when it comes to increases in syphilis rates and now we have a point-of-care screening device that allows for timely and accurate test results to intervene sooner in people who are infected. It's a game changer and we are excited to get this test out into our member health department programs."

Commenting on today's news, Ronan O'Caoimh, CEO of Trinity Biotech, said "We are delighted that Syphilis Health Check has been CLIA waived. This is the only CLIA waived syphilis test now available in the USA and will become a major platform in combating the spread of syphilis, which has been increasing at an alarming rate over recent years. Early detection has been identified as a key step in this battle and this waiver now provides broader availability and easier access which should contribute to a higher rate of detection. Prior to the granting of this waiver there was no product for rapid syphilis screening testing in the USA. In addition, this test should act as an excellent companion product for our Uni-Gold rapid HIV test which itself is CLIA waived and services a similar patient demographic."

Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties including, but not limited to, the results of research and development efforts, the effect of regulation by the United States Food and Drug Administration and other agencies, the impact of competitive products, product development commercialisation and technological difficulties, and other risks detailed in the Company's periodic reports filed with the Securities and Exchange Commission.

Trinity Biotech 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. The 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, Germany, France and the U.K. 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

Press Release issued by the FDA

The following press release was issued by the FDA on December 15, 2014

The U.S. Food and Drug Administration today announced that it granted the first-ever waiver, under certain laboratory regulations, for a rapid screening test for syphilis, which will allow the Syphilis Health Check test to be used in a greater variety of health care settings.

According to the U.S. Centers for Disease Control and Prevention (CDC), about 55,000 people in the United States are newly infected with syphilis annually. During the 1990s, syphilis primarily occurred among heterosexual men and women of racial and ethnic minority groups; during the 2000s, however, cases increased among men who have sex with men (MSM). Men who have sex with men accounted for 75 percent of all primary and secondary syphilis cases in 2012.

This sexually transmitted infection, caused by the bacterium Treponema pallidum, can cause long- term complications or increase the likelihood of HIV transmission if not adequately treated. The syphilis bacterium can also infect the fetus of a woman during her pregnancy, causing infant death, developmental delays and seizures. CDC recommends that all pregnant women be tested for syphilis at the first prenatal visit. Those who are at high risk, live in areas with high rates of syphilis or were previously not tested should be tested in the third trimester and again at delivery. CDC also recommends screening at least once a year for syphilis for all sexually active homosexual, bisexual, and other men who have sex with men.

The FDA's waiver is related to the Clinical Laboratory Improvement Amendments (CLIA), federal standards that apply to clinical laboratory testing on humans, with certain exceptions. Because the FDA granted a waiver under CLIA, the Syphilis Health Check test can be distributed to a variety of nontraditional laboratory sites, including physicians' offices, emergency rooms, maternity wards, other health care facilities, health department clinics, outreach sites, community-based organizations and other freestanding counseling and testing sites. The waiver also allows untrained health care workers to perform the tests on patients.

"The broader availability and easier access to this test should contribute to a higher rate of detection of syphilis infection," said Alberto Gutierrez, Ph.D., director of the Office of In VitroDiagnostics and Radiological Health in FDA's Center for Devices and Radiological Health.
The test is performed by obtaining a sample of whole blood from a finger stick. Results are available in as little as 12 minutes and may be performed in the presence of the patient. All positive tests should be followed up with further syphilis serological laboratory testing and clinical evaluation before final diagnosis. The rapid result means that if a patient tests positive, a health care worker can obtain a second blood sample at the same office visit to confirm the test results through further lab testing. This increases the probability that patients, who might not return for a follow-up visit, will receive timely treatment.

The FDA first cleared the Syphilis Health Check test in 2011 and categorized it under CLIA as moderate- and high-complexity. The type of CLIA certificate a laboratory obtains depends upon the complexity of the tests it performs. CLIA regulations describe three levels of test complexity: waived tests, moderate complexity tests, and high complexity tests. The test was intended for use by prescription only to detect Treponema palladium antibodies in serum, plasma, and human whole blood.

The FDA granted a waiver under CLIA for the Syphilis Health Check test after the manufacturer submitted data demonstrating the test's ease of use and accuracy. The agency reviewed data for finger sticks of whole blood samples from 417 subjects collected over the course of four months at three testing sites representing typical CLIA-waived sites, such as doctor's offices. Twelve individuals not

trained in the use of the Syphilis Health Check test performed the tests on the study subjects. Results showed that the Syphilis Health Check test, when used by untrained operators, performed with high accuracy. This is critical if the test is to be allowed for use outside of moderate- and high-complexity laboratories.

With the issuance of the waiver, the Syphilis Health Check test can be used by more laboratories as an initial screening test or in conjunction with other appropriate laboratory tests and clinical findings to aid in the diagnosis of syphilis infection. However, the test is not intended for use in screening blood or plasma donors.

The Syphilis Health Check test is manufactured by VEDA LAB of Alencon, France for Diagnostics Direct, LLC, based in Cape May Court House, New Jersey. It is also distributed by Trinity Biotech USA, Inc., of Jamestown, New York.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.