Trinity Biotech Announces CE Mark of its Covid-19 IgG ELISA Antibody Test

DUBLIN, Ireland, Jan. 05, 2021 — Trinity Biotech plc (Nasdaq: TRIB) has achieved CE Mark approval and registration for its Covid-19 IgG ELISA antibody test, the Captia™ SARS-CoV-2 IgG ELISA.

Trinity Biotech has launched the test in countries throughout the European Union as well as other countries that recognise the CE Mark designation. This is in addition to our launch of the product in the US following submission under the FDAs Emergency Use Authorisation pathway.

Test Overview

The test uses a recombinant form of coronavirus spike protein to detect IgG antibodies which are the focus for SARS-CoV-2 vaccine development. The detection of IgG antibodies indicates either past exposure to the virus or the desired immune response following vaccination.

Trinity Biotech expects that the antibody test will have a number of uses, including:

- Assessing if an individual has previously had a SARS-CoV-2 infection and may now be assumed immune.
- Monitoring individuals in the weeks and months following vaccination, to assess the degree to which their immune system builds an antibody response to the virus.
- Assisting governments manage the prevalence of Covid-19 immunity in the population.
- Screening people prior to vaccination to avoid vaccinating individuals who already have a circulating antibody response, particularly in an environment where vaccine supply is constrained.

The instrumentation platforms that perform this type of ELISA test are available in virtually all clinical testing laboratories. Trinity Biotech have significant capacity for ELISA manufacture within their current operations and intend to leverage their existing distribution network to optimise the commercialisation of the test kit.

Performance Evaluation

A study of healthcare workers using the Trinity Biotech ELISA took place between June and October 2020. In addition to extensive internal testing, eighty-eight participants provided appropriate samples for calculation of the Sensitivity and Specificity at 14 days post Day 0 (date of oro/nasopharyngeal swab). Participants were tested with a PCR test and the Trinity Biotech ELISA.

Sensitivity	*95.9%*
Specificity	*100.0%*

A high Specificity value indicates the potential risk of a false positive result as low – this is a critical parameter when determining immune status and minimising the risk of an individual being incorrectly determined as having immunity.

Other Details

For sales enquiries, please contact customerservicesgroup@trinitybiotech.com

Forward Looking Statements

Certain statements made in this release that are not historical are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words “estimate”, “project”, “intend”, “expect”, “believe” and similar expressions are intended to identify forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties. Many factors could cause the actual results, performance or achievements of Trinity Biotech to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements, including, but not limited to, the results of research and development efforts, risks associated with the outbreak and global spread of the coronavirus (COVID-19), the effect of regulation by the U.S. Food and Drug Administration and other agencies, the impact of competitive products, product development commercialization and technological difficulties. For additional information regarding these and other risks and uncertainties associated with Trinity Biotech’s business, reference is made to our reports filed from time to time with the U.S. Securities and Exchange Commission. We undertake no obligation to update or revise any forward-looking statements for any reason.

About Trinity Biotech

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.

Contact: **Trinity Biotech plc**
Terence Dunne
(353)-1-2769800
E-mail: terence.dunne@trinitybiotech.com