NanoEnTek
220 Bear Hill Road, Suite 102
Waltham, MA 02451
888-988-0108

NanoEntek America, Inc. Receives FDA Emergency Use Authorization Approval for COVID-19 Total Antibody Test for Novel Coronavirus EUA Approval # 202530

http://nanoentek.com/?lang=en

NanoEntek America, Inc. (Waltham, MA, USA / Seoul, South Korea) has launched the FREND™ COVID-19 Total Antibody test to assist in the identification of coronavirus current or past infection. The test is intended for the qualitative detection of Total Antibodies to SARS-CoV-2 in human plasma. The test utilizes fluorescence immunoassay (FIA) analysis on the FREND™ System and provides from a single test cartridge a positive/negative result for the Total Antibodies in three minutes or less.

The FREND™ COVID-19 Total Antibody is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Currently, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. On August 3, 2020, Interim Guidelines for COVID-19 Antibody Testing | CDC stated “Currently, there is no identified advantage whether the assays test for IgG, IgM and IgG, or total antibody.”

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C §263a, to perform moderate or high complexity tests and as applicable, point-of-care (POC) testing.

“NanoEntek, Inc. is very excited to achieve the EUA authorization for the COVID-19 Total Antibody test.” said Dr. Chanil Chung, CEO of NanoEntek, Inc. “We are pleased to provide a valuable test to support the medical community’s efforts in containing the spread of the COVID-19 pandemic.”

CPT Code: 86769
Expected Reimbursement: $42.38
Product Number: COVD020
Distributor Price: $220.00 Per Box of 20 Tests
External Controls from NanoEntek. Product Number: FRCOAC-012
Distributor Price: $100