1. Title:

Development of IoT enabled rapid screening device for COVID-19 specific antigen and antibody in point of care application

2. Expected outcome

- Here we propose a human monoclonal anti-SARS-CoV2 antibody/ antigen-coated strip-sensor for a novel, point of care noninvasive device to detect the COVID-19 specific biomarker antigens (spike proteins S1 and S2) in patient sample.
- The final prototype will be the suitable one-time usable, low-cost electrode strip, containing three electrodes, developed with suitable electrode materials, configuration and a microcontroller-based sensing and digital display system that can be used repeatedly.
- The cross reactivity validation by the device would make it possible to detect the variety of B beta-coronavirus lineage respiratory diseases.
- The proposed sensor will be accurate enough to under wide varieties of environmental conditions, such as variations in analyte concentration, temperature, and humidity etc.
- The novel point-of-care diagnostic tool will be designed in the context of Indian scenario and under the National Health Mission India to combat the current pandemic situation.
- Final deliverables are patent, publications, technology transfer and prototype for commercialization.

3. Scope of application indicating anticipated product and processes

Novel corona virus-induced pneumonia, which was named as corona virus disease 2019 (COVID-19) by the WHO on the February11, 2020, has rapidly increased in epidemic scale since it first appeared in Wuhan, China, in December2019. Corona viruses have caused three epidemic diseases, namely, COVID-19, severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). At present, the cases of COVID-19 have been found in many countries around the world. According to the latest data, upto the March30th, 2020, the number of confirmed cases in India reached 942, of which 29 were dead, and 100 were cured. As the viral gene is novel to infect human being severely, contact basis no specific diagnostic tool is available. Recently rt-PCR based diagnosis is being introduced, but it requires skilled setup and no indigenous serum antibody detection tool is evolved. The **proposed sensor device offers a biomarker-based low cost, quicker and simpler** immunoassays,which leads to further development in **point-of-care testing** of COVID-19 antibody as well as antigen in bio-specimens.

4. Summary:

Corona virus disease2019 (COVID-19) caused by SARS-CoV-2 virus, is a kind of viral pneumonia originated from Wuhan, China, and then spread alarmingly to different countries across the world. It infects approximately 7.2 lakhs peoples with more than 33 thousands total death worldwide. The most affected nations are China, United States, South Korea, Italy and Iran. The COVID-19 out break with four stages of progression (namely stages I-IV) has been declared as a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO). In India, as per the latest reports on 30th March, 2020, the out break of COVID-19 infection is in stage-II. The total number of infection has risen to 1,071 with a mortality count of 29. In this critical situation, the primary concern is to easy and rapid detection of the infected individuals in order to minimize the outbreak of the disease. However, the current existing analytical techniques forCOVID-19 detection including, ELISA, nucleic acid based detection, blood culture and CT scan are laboratory based, time consuming and costly processes. Moreover, there is a certain risk of infection among lab technicians and health professionals.The present study is proposed to develop a portable and affordable device for screening test for detection of in vitro developed anti-COVID-19 antibody and antigen, using surface modified paper-based/thin-film disposable electrodes, with little or no involvement of a medical professional. As potential biomarkers, were proposing the (i) Spike Protein S1,S2 and S2' (ii) Envelop protein (iii) Membrane glycoprotein and (iv) Nucleo-capsid phosphor protein coat proteins, as they are highly immunogenic and reported to be thee efficient biomarkers of SARS-CoV-2virus. The proposed microfluidic device could offers a biomarker-based low cost,quicker and simpler substitute to existing time consuming, laborious etection tools, which leads to further development in point-of-care testing of COVID-19detection.

5. Aim:

The main objective is to develop a portable and affordable device for screening test for detection of in vitro developed anti-COVID-19 antibody and antigen, using surface modified paper-based/thin-film disposable electrodes, with little or no involvement of a medical professional.

6. Objectives:

I. Surface modification and functionalization of electrodes for the detection of sample human recombinant COVID-19 antigen and antibody presence and investigation through conventional voltammetry and impedance spectroscopy for specific monitoring of the rate of reaction.

II. Investigation and monitoring of the rate of electrochemical reaction by impedance spectroscopy.

II. Development of a digital system prototype, capable of measuring viral antigen level through the monitoring of the rate of reaction and validating the proposed device by commercial recombinant antigen sample.

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