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A Platform for Rapid Diagnosis of Infections and Antibiotics Susceptibility Test

The prevalence of multi-drug resistant organisms (MDROs) is poised to be one of the greatest threats to global public health as new MDROs emerge over time. The current standard of care for the diagnosis and treatment of infectious diseases is based on bacteria culture, which consists of three basic steps: (1) detection/confirmation of infection by sample-culture (24-48 hours), (2) identification (ID) of bacteria in the culture (2 hours) and (3) antibiotic susceptibility testing (AST) (16-24 hours). If a culture indicates the presence of bacteria, the bacteria will be identified and AST will be performed to determine the antibiotics that are most effective against the bacteria. Generally, the amount of bacteria in the original sample is too low [<10 colony forming unit (CFU)/mL for blood samples] to be detected directly by visual inspection. Culturing allows the bacteria in the sample to multiply to a visually observable amount. Currently, clinicians are frustrated with the long time-to-result for culture-based assays. The need for rapid administration of antibiotics to prevent death or severe disability requires them to prescribe empiric broad-spectrum antibiotics while waiting for the results of culture and AST. However, overuse of broad-spectrum antibiotics leads to the prevalence of MDROs. The proposed platform is based on quantum tunneling in biological systems, a technique invented by the PI, and will provide a culture-free approach for the diagnosis and treatment of infectious diseases. The platform consists of a set of disposable detection electrodes operated by a hand-held device. It will allow a typical pathogenic bacterium present together with other typical bacteria in a complex sample such as blood or urine to be detected directly (without culture) with a detection limit of <10 CFU/mL and identified in 72 minutes. Using the platform, AST of the bacterium will be completed in 132 minutes, which include bacterial growth response to antibiotics (60 minutes) plus detection (72 minutes). With further research and development (R&D), the complete process time is anticipated to be even shorter. Multiple typical pathogenic bacteria in the same sample can be detected and identified using electrodes specific to those bacteria. The disposable detecting electrodes will be operated using a hand-held device, allowing point-of-care (POC) use for both the inpatient and outpatient setting. The estimated cost for a detecting electrode is less than $4. The antibody-antigen immune reaction employed in the detection mechanism will allow a wide range of bacteria to be detected. The operation of the platform will require minimal training.