

REVOLUTIONARY DIAGNOSTICS – NONTRADITIONAL APPROACHES FOR DEVELOPING BREAKTHROUGH CAPABILITIES AGAINST EMERGING THREATS

The Smart Detect Poc Pcr Platform Is A Multi-use, Portable Device For The Detection Of Infectious Agents

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There is a vital need to deliver a rapid nucleic acid-based diagnostics to the point-of-care. The ideal detection platform is one that is used near the individual seeking testing and provides results comparable the tests generated in centralized clinical laboratories. The “gold-standard” technology is the polymerase chain reaction (PCR). PCR is well established as a sensitive and specific method to detect viruses and bacteria, distinguishing emerging pathogen strains by exploiting regions of genomic variation. In general, PCR is limited to centralized clinical laboratories, where tests are performed by trained individuals, using expensive machinery and refrigerated reagents. The entire process includes sample collection, transport, and processing prior to PCR amplification, all of which impacts the total time to diagnosis. Any delays in the process potentially contributes to spread of disease. To speed diagnosis, we have developed a portable PCR platform for rapid pathogen detection at the point-of-care (POC).

Advances in battery technology, dry reagent storage, and sample lysis simplify the entire process so that untrained users can set up diagnostic PCR tests. A key component is reducing the PCR thermal cycling machine to a low-cost, reusable, user-friendly device. Our Smart Detect POC PCR Platform rapidly detects infectious pathogens, such as SARS-CoV-2 (SCoV2) or monkeypox virus (MPXV) in real-time using fluorescent probes to target pathogen. The platform’s compact design is portable and operates via battery or power outlet. The speed of PCR cycling is comparable to “Fast-PCR” technology with test results in less than 30 minutes. The operator interface is streamlined to reduce user error and facilitate clear delivery of test results. Similar platforms are commercially available, but rely on isothermal amplification, which has a higher false positive rate than PCR due to spurious amplification from non-specific primer interaction. Additionally, the available isothermal amplification platforms are single-use devices, resulting in an accumulation of electronic-waste. Our Smart Detect POC PCR Platform is reusable by inserting a new amplification tube.

To use the Smart Detect POC PCR platform, the user collects a nasal (SCoV2) or skin lesion (MPXV) swab and places the swab in lysis buffer similar to a rapid antigen test. The lysed sample is then added to an amplification tube and placed in the PCR platform for amplification to detect SCoV2 or MPXV on-demand. The MPXV assay detects the emerging MPXV strain, as well as a non-specific “pan” assay to detect orthopox virus strains including. Both assays are expected to be positive if an individual is infected with MPXV. However, if the pan-orthopox assay is positive, but the MPXV assay is negative, this suggests a new strain may have emerged during an outbreak. Including a pan-orthopox virus assay is a fail-safe approach, leading to faster detection than if targeting MPXV alone.

Impact to DTRA Mission: the platform is agnostic to the PCR assay that is used for amplification, thus is responsive to quick changes to the oligonucleotides used to detect emerging pathogens. Moreover, many strains can be detected by direct amplification of non-invasive sample types (skin, saliva, nasal) in remote environments.