Disposable Capillary-Driven Immunoassays for COVID-19

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Abstract

The COVID-19 pandemic has had an unprecedented impact on the physical economic health of people from around the world. The pandemic has also highlighted the centrality of diagnostics in controlling the spread of infectious disease, protecting vulnerable populations, and maintaining the economic viability of many public and private institutions. Early on in the pandemic RNA assays like RT-PCR dominated the diagnostic market and remain the clinical standard for determining if an individual is infected.[1] Unfortunately, PCR and many isothermal amplification techniques require some form of heating and therefore instrumentation. An alternative approach is to detect protein antigens produced by the virus.[2] Antigens can be detected in nasal and nasopharyngeal swabs and the concentration is known to correlate closely to RNA levels in the same samples. The most common approach to detecting antigens is a laboratory-based ELISA. Alternatively, lateral flow immunoassays can also be used[3] but lack stringency relative to ELISAs due to the lack of a rinsing step. We have developed a new capillary driven immunoassay based on our fast-flow paper-based analytical devices[4] that is capable of performing all the steps of a traditional ELISA in a disposable format we call the capillary-driven immunoassay (CaDI). Figure 1A shows a photograph of a CaDI and Figure 1B shows a comparison of serology tests done with the CaDI versus a traditional well-plate ELISA using the same reagents and samples. Key for point-of-care diagnostics, the entire assay requires only two steps, addition of sample and addition of a single aliquot of buffer. Detection can be achieved using either colorimetric or electrochemical modes. During this talk, the development of this system, including the fluidic concepts will be discussed. Application to testing of patient samples will also be presented.

1. Vogels, et. al., Analytical sensitivity and efficiency comparisons of SARS-COV-2 qRT-PCR primer-probe sets. *medRxiv* **2020**, 2020.03.30.20048108.
2. Preliminary report from the Joint PHE Porton Down & University of Oxford SARS-CoV-2 test development and validation cell: Rapid evaluation of Lateral Flow Viral Antigen detection devices (LFDs) for mass community testing.
3. Grant, et al. , A SARS-CoV-2 Coronavirus Nucleocapsid Antigen-Detecting Half-Strip Lateral Flow Assay Towards the Development of Point of Care Tests Using Commercially Available Reagents. *Analytical chemistry* **2020**.
4. Channon, et al., Rapid flow in multilayer microfluidic paper-based analytical devices. *Lab Chip* **2018,** *18* (5), 793-802.

A)

B)

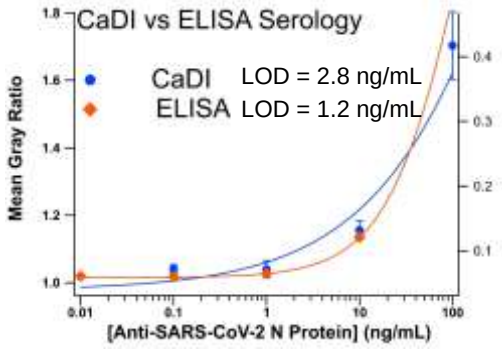

Figure 1A: Photograph of a CaDI device in its housing. Figure 1B: Comparison of data obtained in a serology assay for the CaDI versus a traditional ELISA.