Saliva as a sample matrix for rapid, quantitative diagnostics in resource limited settings.

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The use of saliva as a sample matrix in limited resource settings has many advantages over blood based sampling. It is a simple to acquire sample, doesn't require skilled personnel for collection and preparation and has diagnostic significance for disease testing. Saliva however, poses a challenge for use in rapid diagnostic settings due to the matrix effect a neat sample has, interfering with diagnostic results and reducing the sensitivity of the assay. To reduce matrix effects, saliva samples go through mechanical processes to help remove mucins and other proteins that diminish assay performance. Mechanical processing is commonly centrifugation or freezing. These processing requirements do not allow for point of care testing with a quantitative diagnostic tool to readily take place, as mechanical processes required for sample preparation are not easily deployable in resource limited settings.

AgPlus have developed fully quantitative assays on their platform using saliva. The key goal of the assay development has been to remove these mains powered mechanical processing steps prior to assay running, which would deliver a true point of care test where the analytical sensitivity of the assay is not compromised. The work has resulted in an assay that can be used with a saliva sample which only requires a single step dilution for immediate analysis easily utilised in resource limited settings for POC diagnostics.

Saliva is collected from a swab held under the tongue for approximately 5 minutes. After collection, the swab is placed in a syringe filter with a .2µm filter attached and 200µl is filtered into a dilution buffer. The dilution buffer contains the buffers that allow the saliva to be used with the assay without further mechanical preparation. A 65µl aliquot is added to the assay chip. The assay uses silver nanoparticles as an electrochemical label and magnetic particles as the solid phase, with the assay run on a fluidic chip. The chip contains all required assay reagents. The silver and magnetic conjugates are dried down on the fluidic chip reaction chamber, and the wash buffer and silver reading solution held in fluid filled blisters, deployed by the actuation system contained in the handheld device during the assay sequence. Assay run time to result is 8minutes and doesn't require user intervention once the sample is added to the assay chip. The assay demonstrated for salivary analysis is Testosterone which has a working range of 15pg/ml-500pg/ml with CV <20%.

A saliva based assay that does not require mains powered mechanical sample preparation step has overcome a significant barrier to delivering a fully quantitative assay system that can be used in resource limited settings. The electrochemical detection system has low per test power consumption which has allowed for the development of a fully portable, battery powered, hand held device for the running of the assay that utilises a simple touchscreen interface and is communication enabled. The system has been developed as a platform technology and can be customised to applications where rapid, accurate diagnostics can allow for quicker clinical decision to be made in resource limited environments.