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Reagentless Capability of a Comprehensive Bioelectronic Platform developed for POC diagnostics

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Background

A novel application is described that demonstrates newly developed reagentless capability for a previously presented comprehensive bioelectronic platform using mediator technology. The platform, currently reagentless to the user, is designed for multiple Point-of-Care (POC) diagnostic applications, including ultra-sensitive protein, DNA and small molecule diagnostics. The alpha system is now automated for Lactate detection in acute settings, with an initial indication for diagnosis of lactic acidosis or Sepsis. This is developed currently in conjunction with a reagentless approach for a single test for C-Reactive Protein (CRP) and hs-CRP levels. An adaptable self-assembled monolayer (SAM) technology is presented that demonstrates quantitative, ultra-sensitive, precise and accurate measurement of numerous clinical analytes in various sample matrices (e.g. whole blood, urine, semen, prostatic fluid, saliva etc). Cyclic voltammetry techniques produce a self calibrating signal allowing for a rapid, fully quantitative dose response over a broad, 1000-fold range of analyte concentration.

Methods

Assays have been developed based on standard bioassay procedures (immunoassays, hybridization or enzymatic reactions) where a tagged probe / antibody, or a mediator specifically react with nanolayers on separate gold micro-electrodes. The tagged antibody of a standard immunoassay for hs-CRP, for example reacts specifically with a nanolayer on a gold microelectrode. The mediator produced during the enzymatic reaction of lactate oxidase also specifically reacts with a different nanolayer on a separate gold microelectrode. The alpha breadboard is fully developed as a programmable automated system for sample to results for all assays presented.

Results

Using commercially available calibrators, all assays developed to date demonstrate a dose response that spans the analytes' clinical relevant range. Results for the automated lactate test for sepsis detection and CRP test for sepsis and cardiovascular risk stratification are presented. An automated lactate test is presented with a TAT of 3 minutes. TAT for hs-CRP is 7 minutes. The Ohmx test LOD for lactate is 0.2 mM and hsCRP is 1 pM.

Conclusions

An alpha system, utilizing a versatile bioelectronic platform, is presented with validated tests for various clinical targets including proteins, DNA and small molecules and is amenable to a reagentless approach developed for a single test that measures both CRP and hs-CRP levels.