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(54) Title: METHODS AND COMPOSITIONS FOR DETECTION OF A PATHOGEN, DISEASE, MEDICAL CONDITION, OR BIOMARKER THEREOF

(57) Abstract: Provided are methods for detecting the presence or absence of a pathogen, disease, or medical condition, or biomarker thereof, using an enzymatic activity assay. In one embodiment, the method provided utilizes competitive inhibition of an enzyme for detecting a pathogen, disease, or medical condition, or biomarker thereof, in a subject. The method comprises providing a biological sample from the subject that may or may not contain an endogenous substrate. A test reaction is provided by contacting the biological sample with an enzyme indicative of the biomarker of a pathogen, disease, or medical condition and a substrate comprising a signaling moiety. The enzyme modifies the endogenous substrate and the substrate comprising the signaling moiety. Modification of the substrate comprising the signaling moiety by the enzyme produces a signal from the signaling moiety. Data from a control reaction comprising the enzyme and the substrate comprising the signaling moiety is further provided. The signal produced by the signaling moiety in the test reaction is detected. The presence of the biomarker of the pathogen, disease, or medical condition is indicated by a difference caused by the presence of the endogenous substrate in the biological sample between the signal produced in the test reaction and the data from the control reaction. In another embodiment, there is provided a method of detecting the presence or absence of enzymatic activity in a biological sample indicative of a pathogen, disease, or medical condition, or biomarker thereof, in a subject. The method comprises contacting a biological sample obtained from a subject that may or may not contain an enzyme with a substrate of the enzyme to be detected. The substrate comprises a signaling molecule such that when the enzyme is present in the biological sample, the enzyme modifies the substrate and the signaling moiety emits a signal, indicating the presence of a pathogen, disease, or a medical condition, or a biomarker thereof, in the subject.



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