scattering signal from the immunoassay apparatus while minimizing the non-specific light from the apparatus.

[0008] In one embodiment, a single immunoassay device may contain multiple types of different antibodies each conjugated with different dyes (e.g., quantum dots) and multiple capture bands each immobilized with different antibodies. A single light source (e.g., ultraviolet light) illuminates all dyes (e.g., quantum dots) simultaneously, and the detector device (e.g., a miniature spectrophotometer) captures the emitted signals from multiple bands simultaneously.

[0009] In one embodiment, the detector device further includes or can remotely access an interpretive algorithm that is adapted for interpreting and/or aiding interpretation of the results of the immunoassay. The interpretive algorithm may include one or more computer storage media having stored thereon computer executable instructions that, when executed by one or more processors, implement a method for interpreting a numerical value related to the visual signal output produced by the immunoassay apparatus in response to the presence or amount of the at least one analyte present in the sample. In one embodiment, the computer implemented method includes (1) receiving a user initiated request to convert the visual signal readout of the immunoassay apparatus to a numerical value, (2) in response to the request, an act of identifying at least one elastic light scattering signal of the immunoassay apparatus, (3) capturing at least one elastic light scattering signal from the immunoassay apparatus, (4) converting the one elastic light scattering signal to at least one numerical value proportional at least one of an intensity or density of the elastic light scattering signal, and (5) using the at least one numerical value to determine an amount or concentration of at least one analyte present in the sample. This numerical value can then be displayed on a screen located on the detector device and/or stored, interpreted, or sent to a database.

[0010] In another embodiment, a method for detecting at least one analyte of interest in a sample is disclosed. The method includes (1) providing a lateral-flow chromatographic immunoassay cassette that includes at least one ligand immobilized thereon, wherein the at least one ligand is capable of capturing an analyte of interest on the lateral-flow chromatographic immunoassay cassette (2) applying a liquid sample to the lateral-flow chromatographic immunoassay cassette, wherein the sample includes at least one analyte of interest, (3) coupling the lateral-flow chromatographic assay cassette to a sample holder configured to angle the lateral-flow chromatographic assay cassette in relation to a detector device, and (4) observing the presence of the at least one analyte of interest by elastic light scattering. In one embodiment, the device includes an illumination source, a miniature spectrophotometer, at least one optical fiber capable of transmitting an illuminating light from the illumination source to the lateral-flow chromatographic assay cassette, a collimating lens capable of transmitting a signal from the lateral-flow chromatographic assay cassette to the miniature spectrophotometer, and an adjustable variable angle stage configured for holding the lateral-flow chromatographic assay cassette at an angle greater than or less than zero degrees in relation to the illuminating light and the miniature spectrophotometer, wherein the illuminating light and the and the miniature spectrophotometer are positioned to illuminate at least a portion of the lateral-flow chromatographic assay cassette and optimize an elastic light scattering signal from the lateral-flow chromatographic assay cassette.

[0011] These and other objects and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It is appreciated that these drawings depict only illustrated embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0013] FIG. **1** illustrates a top view of a lateral-flow chromatographic immunoassay cassette;

[0014] FIG. **2** illustrates the principles of multiplex detection in a single immunoassay cassette using multiple capture antibodies and multiple detection dyes (e.g., quantum dots);

[0015] FIG. **3**A illustrates a prototype testing device having an illumination source, a miniature spectrophotometer, a pair of optical fibers, and an adjustable variable angle stage holding a lateral-flow chromatographic immunoassay cassette;

[0016] FIG. **3**B illustrates a detailed side view of the angle between a lateral-flow chromatographic immunoassay cassette, an illuminating light, and a detector;

[0017] FIG. **4** illustrates a sample holder with an adjustable variable angle stage;

[0018] FIG. **5** is a graph illustrating the relationship between the illumination angle on a lateral-flow chromatographic immunoassay cassette and a an elastic light scattering signal obtained from the lateral-flow chromatographic immunoassay cassette at a variety of angles and a variety of loading concentrations using the prototype testing device shown in FIG. **3**A; and

[0019] FIG. **6** shows elastic light scattering data for assaying thyroid stimulating hormone dissolved in phosphate buffered saline using the prototype testing device shown in FIG. **3**A.

DETAILED DESCRIPTION

[0020] A device and method for performing a point of care diagnostic test for detecting and quantifying at least one analyte in a biological sample (e.g., a body fluid). In one embodiment, the device disclosed herein may include an immunoassay apparatus (i.e., a lateral flow immunochromatographic assay cassette) and a holder with an adjustable variable angle stage for positioning the immunoassay apparatus relative to a light source and a detector device to optimize elastic light scattering. In another embodiment, the device includes an interface for a light source (e.g., an optical fiber or light pipe), an interface (e.g., a collimating lens) for a external digital imager (e.g CCD or CMOS chip), and an adjustable variable angle stage that positions a lateral flow immunochromatographic assay cassette so as to optimize the angle of incidence and angle of radiation to optimize an elastic light scattering signal from the a lateral flow immunochromatographic assay cassette. The device is based upon elastic light scattering, so the variation in the angle of incidence and angle of reflection are optimized to maximize signal generation due to elastic light scattering.