

jugate complex. The third domain of the lateral-flow chromatographic immunoassay cassette is a solid-phase with immobilized capture antibody. The capture antibody can bind the antigen of the antigen-color conjugate complex and forms capture antibody-antigen-color conjugate complex sandwich. The fourth domain is for solution absorption. It draws sample solution towards it continuously.

[0038] During the testing, sample added to the first domain flows to the second domain. If the antigen is present in the sample, it will bind the color conjugate to form antigen-color conjugate complex. This complex then migrates to the third domain to bind the capture antibody and forms the capture antibody-antigen-color conjugate complex sandwich. Since the capture antibody is immobilized in the third domain, the sandwich shows as a visible color signal or a fluorescent signal, depending on the dye type, on the site of the capture antibody. If there is no antigen in the sample, no sandwich can be formed and hence no visible color signal can be seen in the third domain. This is a so-called non-competitive immunoassay or a sandwich assay where the amount of signal is directly proportional to the concentration of the analyte of interest in the sample.

[0039] Lateral-flow chromatographic immunoassay cassettes can also be adapted for competitive immunoassays. In a competitive immunoassay, the analyte of interest in the unknown sample competes for binding to an antibody with a labeled analyte. In a competitive assay, the labeled analyte is able to provide a known signal. In the assay, the amount of labeled analyte bound to the antibody is measured and any reduction in the known signal is attributed to the presence of the analyte in the sample. That is, in this method, the response will be inversely related to the concentration of analyte in the unknown. This is because the greater the response, the less antigen in the unknown was available to compete with the labeled antigen.

[0040] Lateral-flow chromatographic immunoassay cassettes may be adapted for assaying a number of different analyte types. For example, immunoassay cassettes have been adapted or may in the future be adapted for blood glucose testing, metabolic testing (e.g., thyroid stimulating hormone), blood gas and electrolytes analysis, rapid coagulation testing, rapid cardiac markers diagnostics, drugs of abuse screening, urine testing, pregnancy testing, fecal occult blood analysis, food pathogen screening, complete blood count ("CBC"), hemoglobin diagnostics, infectious disease testing (e.g., a multi-analyte rapid diagnostic test for detecting malaria infection), cholesterol screening, hormone testing, cardiac pulmonary, gastroenterology, urology, renal, dermatology, neurology, pediatrics, surgical, public health, and veterinary and plant pathology testing, combinations thereof, and the like.

[0041] In addition to the foregoing, another embodiment of a lateral flow immunoassay cassette is described. Examples of such lateral flow immunoassay cassettes are shown at **200** in FIGS. 2A and 2B and at **300** in FIGS. 3A and 3B. In the lateral flow immunoassay cassettes **200** and **300**, a test sample (i.e., a sample containing an unknown concentration of an analyte of interest) may be run in parallel with a calibration standard (i.e., a sample containing a known concentration of the analyte of interest). The response to the known concentration of the analyte of interest in the calibration standard on the lateral flow immunoassay device may be used to generate a calibration curve that can be used to quantify the amount of the analyte of interest in the test sample.

[0042] Such an arrangement may provide superior results. For example, the test and calibration strips of such cassettes may be manufactured side-by-side under substantially equal temperature and humidity conditions. As a result, it is generally the case that the test and calibration strips each have the same amount on antibody immobilized thereon and that the antibody on each will react substantially the same. Also, because the test and calibration assays are run in parallel, the test and calibration results are generally unaffected by factors like temperature and humidity. This is generally not the case if the test and calibration assays are run at separate times on strips that may have been manufactured at different times. Likewise, because the test and calibration assays are run in parallel, the cassettes and a reader device, if used, are calibrated for each assay run on each cassette, which is believed to provide more reliable quantitative results.

[0043] The lateral flow immunoassay cassette **200** illustrated in FIGS. 2A and 2B includes a base **214** that includes a test strip **201a** and a calibration strip **201b**. The test strip **201a** includes a sample application zone **202a** with a sample collection pad **216a**, a conjugate pad **204a**, a test assay strip **206a** (e.g., a nitrocellulose ("NC") membrane), and an absorbent pad **212**. Likewise, the calibration strip **201b** includes a sample application zone **202b** with a sample collection pad **216b**, a conjugate pad **204b**, a calibration strip **206b**, and the absorbent pad **212**. Each of the test assay strip **206a** and the calibration strip **206b** include at least one capture binding moiety **208a** and **208b** (e.g., an antibody, a nucleic acid, or the like) that can specifically interact with and capture the analyte of interest for detection. In one embodiment, the sample pad **212** may include flow indicator lines **210a** and **210b** (e.g., a water soluble dye) that indicate whether or not sample has successfully diffused through the test strip **201a** and the calibration strip **201b**.

[0044] In the illustrated embodiment, the test **201a** and calibration strips **201b** are run in opposite directions (i.e., both the test sample and calibration standard flow toward absorbent pad at the center of the cassette). In other embodiments, the test and calibration strips may be arranged such that the test sample and calibration standard flow parallel to one another. Such an embodiment may, for example, include a divider arranged between the test assay strip and the calibration assay strip.

[0045] The lateral flow immunoassay cassette **300** illustrated in FIGS. 3A and 3B is similar to the cassette **200** of FIGS. 2A and 2B. The lateral flow immunoassay cassette **300** includes a base **314** that includes a test strip **301a** and a calibration strip **301b**. The test strip **301a** includes a sample application zone **302a** with a sample collection pad **316**, a conjugate pad **304a**, a test assay strip **306a** (e.g., a nitrocellulose ("NC") membrane), and an absorbent pad **312**. In addition, the test strip **301a** includes includes a sachet **320** (e.g., a blister pack) of buffer that can be used to chase (i.e., wash) a test sample through the conjugate pad **304a** and the assay strip **306a** toward the absorbent pad **312**.

[0046] In contrast to the cassette **200** of FIGS. 2A and 2B, the cassette **300** omits a calibration standard application zone and instead includes a standard solution sachet **318** that contains a known volume of a solution that contains a known amount of at least one analyte of interest. When the standard solution sachet **318** is pierced at the time of use, the solution wicks through the conjugate pad **304b** and the calibration strip **306b** toward the absorbent pad **312**. Each of the test assay strip **306a** and the calibration strip **306b** include at least