

identify individuals who have seroconverted to HIV infection. Viral antigen detection may be used to identify individuals in the pre-seroconversion “window phase” of HIV infection, also called the acute infection phase.

**[0072]** In another embodiment, the array may have two or more reaction sites, and each of the two or more reaction sites contains a different capture molecule selected from the group consisting of gp41, p24, gp120, and gp160 antigens of HIV-1; gp36, gp120, and p24 antigens of HIV-2; antibodies against p24 for HIV; p17, p47, p15, and TmpA of *T. pallidum*; core antigen, NS3, NS4, and NS5 of HCV and fragments thereof; antibodies against HCV antigens; antibodies against hepatitis B surface antigen (“HBsAg”); core and surface antigens of HBV; antigens of human herpes virus 8 (“HHV-8”); and combinations thereof.

**[0073]** In another embodiment, the array on the first surface contains a first reaction site and a second reaction site, wherein the first reaction site contains gp41 antigen of HIV-1, while the second reaction site contains p24 antigen of HIV-1. In another embodiment, the array further contains a third reaction site and a fourth reaction site, wherein the third reaction site contains p47 of *T. pallidum*, and the fourth reaction site contains p17 of *T. pallidum*. In yet another embodiment, the array further contains a fifth reaction site and a sixth reaction site, wherein the fifth reaction site contains HCV core antigen, and the sixth reaction site contains an HCV antigen selected from the group consisting of HCV NS3, HCV NS4, HCV NS5, and combination thereof. In another embodiment, the array may contain at least five reaction sites, wherein each of reaction sites contains a different capture molecule selected from the group consisting of p41 antigen of HIV-1, p24 antigen of HIV-1, p17 of *T. pallidum*, p47 of *T. pallidum*, HCV core antigen, and combination thereof.

**[0074]** As an alternative to visually-read RDTs, a disposable cartridge designed to be inserted into a reader instrument that provides qualitative, semi-quantitative, or fully quantitative results may be considered. Such a cartridge may have a defined channel volume through which a sample fluid can flow and, in certain embodiments, analyte presence may be determined by changes in fluorescent properties of reaction in the cartridge. The cartridge may be further configured to support identifying indicia capable of being read in the same field of view as the fluorescent analyte sites. The depth of field of the reader instrument may be such that the fluorescent sites and identifying indicia (e.g., bar codes or alphanumeric symbols) may be simultaneously read.

**[0075]** A reader instrument **100** for analyte detection is schematically illustrated in FIGS. **1** and **2**. Insertion of a cartridge **110** into reader instrument **100**, as indicated by an arrow **101** is schematically illustrated in FIG. **1**. Suitable cartridge embodiments are discussed in U.S. Patent Application Ser. No. 61/391,911 entitled “Fluidic Assay Cartridge with Controlled Passive Flow” filed 11 Oct. 2010, as well as U.S. Pat. No. 5,677,196 entitled “Apparatus and Methods for Multi-Analyte Homogeneous Fluoroimmunoassays” to Heron et al., the disclosures of which are both herein incorporated by reference. Reader instrument **100** may include, for example, a housing **102**, a screen **132**, and an aperture **150** for receiving cartridge **110**.

**[0076]** Reader instrument **100** may be used for rapid detection or quantitation of analytes in various settings including, but not limited to, medical clinics in small hospitals, centralized laboratory facilities, public health laboratories, remote and low resource settings, and mobile monitoring units in the

United States and internationally. Reader instrument **100** may be a component of a rapid analyte detection system for quickly and accurately identifying target analytes in a sample carried by a cartridge **110**. The sample may be a biological or environmentally-derived fluid, sputum, tears, urine, animal or human blood, serum, plasma, or any other sample, which potentially contains an analyte, that is suitably processed before or after placement in cartridge **110**. That is, the sample may be a fluidic sample from a human, an animal or otherwise obtained from the environment or from an industrial process. Although shown as a standalone unit, in certain embodiments, the reader instrument may be integrated with other laboratory or processing equipment, including modules for automatic sample preparation, sample storage or containment, or additional laboratory testing.

**[0077]** As may be seen in FIG. **2**, reader instrument **100** may be formed from housing **102** that contains a rigidly mounted laser illumination module **104**. Laser illumination module **104** may optionally be offset vertically (as indicated by a double-headed arrow **106**) or longitudinally (as indicated by a double-headed arrow **108**) from cartridge **110**. Cartridge **110** includes a refractive volume **120** coupled with a planar waveguide **121**. Optionally, refractive volume **120** and planar waveguide **121** may be integrally formed from one material as a single unit, such as disclosed in U.S. Provisional Pat. App. Ser. No. 61/156,586, filed Mar. 2, 2009 and entitled “Waveguide with Integrated Lens,” and U.S. patent application Ser. No. 12/617,535, filed Nov. 12, 2009 and also entitled “Waveguide with Integrated Lens,” both of which applications are incorporated by reference in their entirety herein. Laser illumination module **104** may include lenses, refractive or reflective elements, spatial or intensity patterning elements, and/or beam diffusers or homogenizers that condition and redirect light emitted from laser illumination module **104**. In certain embodiments, laser illumination module may include a rotating beam homogenizer element that reduces speckle and improves reader instrument imaging performance, as discussed in U.S. Patent Application Ser. No. 61/383,150 entitled “Uniform Illumination of a Region by Laser Light Guided in a Planar Waveguide Using a Rotating Diffuser in a Target Imaging System” and filed 15 Sep. 2010, the disclosure of which is herein incorporated by reference. In other embodiments, beam homogenizer element may be omitted, or alternately formed using piezoelectric, acoustic or other time and/or spatially varying optical elements that reduce speckle without requiring large scale rotational, oscillatory, or random motion of optical elements.

**[0078]** In the illustrated embodiment, planar waveguide **121** capable of transmitting laser light directly, or through total internal reflection, to an assay region **122**. In one embodiment, cartridge **110** incorporates a microarray of proteins, such as recombinant antigens and antibody controls, in a channel, and is capable of providing multiple parallel fluorescence assay results from a single sample. Cartridge **110** may include a channel, optionally with an inlet port and an outlet port, and may be formed as a single piece or separate pieces that cooperate to define the channel. Cartridge **110** may optionally include multiple parallel channels. For example, multiple channels on the same cartridge may be used to run replicates of the same assay on multiple samples, providing increased throughput. Alternatively, multiple channels on the same cartridge may be used to run different assays on the same sample.