

complex binds to the analyte in the sample to form a magnetic binding complex. Optionally, the microcoil array is activated to move the magnetic binding complex to another fluidic zone. The signal analyte complex then displaces the analyte from the magnetic binding complex to form a competitive binding complex. Optionally, the microcoil array is activated to move the competitive binding complex to another fluidic zone. The detection element detects an optical or electrical signal from the signal analyte complex that did not form the competitive binding complex, thus indicating the presence of the analyte. In such an embodiment, the analyte is typically a small molecule such as, but not limited to, sugars, drugs, steroids, and vitamins.

[0168] In another embodiment, the sample zone comprises a coded magnetic affinity complex. A sample suspected of comprising an analyte is introduced a sample into the sample zone, wherein the coded magnetic affinity complex binds to the analyte to form a coded magnetic binding complex. The microcoil array is activated to move the coded magnetic binding complex from the sample zone to a first affinity surface where it is immobilized. Typically, the affinity agent of the first affinity surface binds to the analyte or to the affinity agent coupled to the magnetic particle. The code is detached from the bound coded magnetic binding complex. A magnetic signal affinity complex is provided in one of the fluidic zones, so situated that the detached code binds to the magnetic signal affinity complex to form a coded magnetic signal binding complex. Typically, the affinity agent of the magnetic signal affinity complex is a polynucleotide complementary to the code. The microcoil array is activated to move the coded magnetic signal binding complex to the detection zone which comprises a second affinity surface, where it is immobilized. Typically, an affinity agent of the second affinity surface comprises a polynucleotide complementary to the code. The coded magnetic signal binding complex is then detected by the detection element. The second affinity surface can comprise an array of probes for detecting any number of analytes.

[0169] The vibration element can be activated to agitate the fluid of one or more of the fluidic zones. In certain embodiments, the vibration element agitates the fluid in one or more fluidic zones to disperse the magnetic particles, analyte, and/or signal particles so that they can interact to form a binding complex. In other embodiments, the vibration element agitates the fluid in one or more fluidic zones to facilitate aggregation-disaggregation and removal of unbound signal particles and/or non-analyte components of the sample from the binding complex. For example, before the binding complex is moved to the detection zone, it is moved to the cleaning zone where the vibration element is activated to aggregate and de-aggregate the binding complex to remove unbound signal particles and/or other components from the sample from the binding complex. In other embodiments, a coded magnetic binding complex and/or a coded signal binding complex are moved to a cleaning zone by activating the microcoil array, wherein the vibration element is activated to aggregate and de-aggregate the complexes to thereby remove unbound coded magnetic affinity complex, detached code, and/or magnetic signal affinity complex before the binding complex is moved to the next zone.

[0170] Embodiments of the invention also comprise methods of fabricating the devices. One embodiment comprises fabricating a plurality of fluidic zones on a substrate, where at least one of the fluidic zones is a sample zone designed to hold a sample and a magnetic particle, fabricating one or more

diffusion barriers on the substrate, wherein a diffusion barrier connects each fluidic zone to the adjacent fluidic zone; and forming an integrated circuitry component for storing data on the substrate. The diffusion barrier can be fabricated as a fluidic channel or as a thermally-sensitive barrier. In further embodiments, a microcoil array is fabricated on the substrate. Alternatively, the microcoil array is fabricated separately, and is removeably coupled to the device when it is in use. A detection element can be fabricated into the substrate, or can be fabricated separately and removeably coupled to the device when in use. Preferably the detection element is an optical detection element or an electrical detection element. In further embodiments, a vibration element is fabricated into the device. Alternatively, the vibration element is fabricated separately and removeably coupled to the device when in use. **[0171]** In certain embodiments, fabricating the plurality of fluidic zones on a substrate comprises combining two or more solid supports.

[0172] Embodiments of the invention also comprise a binding complex, which is an analyte bound to a magnetic affinity complex and a signal affinity complex. Typically the analyte is a protein, an antibody or a nucleic acid. In one embodiment, the analyte comprises an anti-PSA antibody. In a further embodiment, the signal affinity complex comprises a COIN-PSA conjugate. The magnetic affinity complex can comprise a streptavidin (SA)-coated magnetic bead. The analyte can comprise an antibody, which includes an autoantibody.

[0173] As disclosed herein, compound and molecules suitable for analysis by the embodiments of the invention include proteins, peptides, and, specifically, nucleic acids (DNA and RNA), which can form double-stranded molecules by hybridization, that is, complementary base pairing. For example, in an embodiment of the invention, a molecular probe, such as a DNA probe, is associated with or attached to a fluidic zone, which is located near or on the surface of, or otherwise integrated into, the substrate. The specificity of nucleic acid hybridization from the binding of the analyte to the molecular probe is such that the detection of molecular and/or nanomaterials binding events can be done through measurements of the signals by the detection element or other external circuitry. This specificity of complementary base pairing also allows thousands of hybridization to be carried out simultaneously in the same experiment on a DNA chip (also called a DNA array).

[0174] Molecular probes are immobilized on the surface of individual or individually addressable reservoirs through surface functionalization techniques. The probe in a DNA chip is usually hybridized with a complex RNA or cDNA target (the analyte) generated by making DNA copies of a complex mixture of RNA molecules derived from a particular cell type (source). The composition of such a target reflects the level of individual RNA molecules in the source. The optical or electrical signals resulting from the binding events from the DNA spots of the DNA chip after hybridization between the probe and the target represent the relative expression levels of the genes of the source.

[0175] The DNA chip could be used for differential gene expression between samples (e.g., healthy tissue versus diseased tissue) to search for various specific genes (e.g., connected with an infectious agent) or in gene polymorphism and expression analysis. Particularly, the DNA chip could be used to investigate expression of various genes connected with various diseases in order to find causes of these diseases and to enable accurate treatments.