

DISPOSABLE CARTRIDGE AND SAMPLE ANALYZER

FIELD OF THE INVENTION

[0001] The present invention relates to a disposable cartridge for insertion into a sample analyzer, the disposable cartridge comprising a housing including a sample analysis unit for engaging with the sample analyzer and a sample extraction unit for extracting a sample from a sample collection unit and transferring said sample to the sample analysis unit.

[0002] The present invention further relates to a sample analyzer for analyzing the sample in the sample analysis unit of such a disposable cartridge.

BACKGROUND OF THE INVENTION

[0003] In the field of medical diagnostics, part-disposable sensor devices such as assay-based sensor devices are rapidly gaining popularity because of the prospect of being able to accurately determine the presence and concentration of a wide variety of analytes of interest in various samples such as bodily fluid samples including saliva, blood, blood serum, blood plasma, urine and so on.

[0004] To this end, a moiety comprising a detectable label such as a fluorescent or chemoluminescent probe, an enzyme for converting a calorimetric substrate or a magnetic particle is provided, which may specifically bind to a binding surface on a measuring apparatus, e.g. a sensor. The amount of moiety that binds to this binding surface is indicative of the amount of analyte of interest or target molecule present in the sample, for instance because the moiety can only bind to the binding surface via the analyte (i.e. a sandwich assay), because the moiety competes with the analyte to bind to the limited number of spaces on the binding surface (i.e. a competitive assay) or because the analyte also specifically binds to the same epitope of the moiety, thus inhibiting the binding of the moiety to the binding surface (i.e. an inhibitive assay). Further examples of known assays can for instance be found in WO 2007/060601, and other examples will be apparent to the skilled person.

[0005] Many suitable specific binding pair candidates are known per se, which are typically based on a lock-and-key type interaction between a receptor molecule and a molecule, e.g. a drug. This makes an assay-based apparatus particularly suitable to determine the presence or absence of specific proteins and other biological compounds such as DNA, RNA, hormones, metabolites, drugs and so on, or to determine the activity and function of active and catalytic biomolecules such as proteins, peptides, prions, enzymes, aptamers, ribozymes and deoxyribozymes. For instance, immunoassays are already used to determine the specific amount of specific proteins in body fluids to aid further diagnosis and treatment.

[0006] The use of such an assay-based apparatus provides promising new opportunities in the field of medical diagnostics, such as the provision of a handheld biosensor system for use in rapid medical diagnosis outside of laboratory environments such as the physician's office, hospital bedside, ambulance and patient's home. An example of such a diagnostic test of interest is the detection of cardiac troponin I (cTnI), which is a diagnostic marker for myocardial infarct.

[0007] A particularly promising apparatus for performing such a diagnostic test utilizes moieties labeled with a magnetic label for specifically binding to the binding surface (the sensor area) because the magnetic field can accelerate (attract) the magnetic labels towards the binding surface, thus

accelerating the binding reaction rate between the moiety and the binding surface. After the removal of the unbound moieties, e.g. by washing or rinsing, the amount of moieties bound to the binding surface can be determined by the amount of the magnetic labels present in the vicinity of the surface of the binding surface, for instance by means of light reflection techniques.

[0008] For testing outside laboratory environments it is required that the diagnostic test is compact, robust and has as few user-aided steps as possible. Ideally the user only needs to add the sample to a disposable cartridge such as disclosed in European patent application EP 0 520 408 A2 and all reagents necessary for the diagnostic test are already present in the cartridge. Such a disposable cartridge may also comprise a sample collection unit, e.g. a saliva swab coupled to a sample analysis unit via a sample extraction unit. The sample extraction unit typically is arranged to transfer the sample from the sample collection unit to the sample analysis unit where the binding reaction involving the analyte of interest takes place.

[0009] The user subsequently inserts the disposable cartridge into a sample analyzer arranged to measure the binding reaction involving the analyte of interest. In case of a magnetic particle-based assay, such a sample analyzer may comprise a magnetic field generator to attract the magnetic beads to the reaction surface of the sample analysis unit and an optical measurement unit, which may for instance be arranged to utilize the principle of frustrated total internal reflection in the sample analysis unit for the analysis of the sample in the sample analysis unit.

[0010] The sample analysis unit and sample extraction unit may already be inserted into the sample analyzer before the sample collection unit is inserted into the sample extraction unit. In this way the analyzer is able to verify and validate the sample analysis unit. Furthermore, the transfer of sample from the sample collection unit into the sample analysis unit can be monitored and the immunoassay can be started automatically upon wetting of the reaction surface. This allows accurate control on the timing of the assay.

[0011] It will be appreciated that for an accurate analyte measurement, the orientation of the sample analysis unit in the sample analyzer must be precisely maintained during the measurement to avoid measurement artifacts caused by the unintentional displacement of the sample analysis unit with respect to the analytic measurement elements of the sample analyzer such as an optical measurement unit. This is not trivial because only a small part of the disposable cartridge is inserted into the sample analyzer such that the remaining part of the disposable cartridge outside the sample analyzer acts as a lever. This causes the forces exerted upon the connection between the portion of the disposable cartridge inserted into the sample analyzer and the sample analyzer itself to be large enough to cause the inadvertent displacement of the disposable cartridge inside the sample analyzer. Such a displacement has a detrimental effect on the accuracy of the measurement. It has been found that it is not (commercially) feasible to improve the rigidity of the connection between the sample analyzer and the inserted portion of the disposable cartridge to avoid such displacements.

SUMMARY OF THE INVENTION

[0012] The present invention seeks to provide a disposable cartridge that when inserted into a sample analyzer, is less prone to such inadvertent displacements.

[0013] The present invention further seeks to provide a sample analyzer that upon receiving such a disposable cartridge suffers less from such inadvertent displacements.