

other modifications and embodiments can be devised by those skilled in the art, which fall within the scope and spirit of the principles of the invention.

#### DETAILED DESCRIPTION

**[0022]** The present invention is a substantially self-contained apparatus for running an assay to detect an analyte, such as *staphylococcus aureus*, in a sample of material. An embodiment of the apparatus includes a plurality of housing segments. Disposed within the housing segments are the necessary buffer solutions, a testing device, and other components that are necessary for running the assay. This will be described in further detail below. The apparatus also includes a valve, which may be actuated to adjust a flow path of fluid through the apparatus. The valve may be used to both open up selective flow paths (or “pathways”) as well as control the flow rate through the flow path by opening up the flow path partially or fully. In the exemplary embodiment, four housing segments are disposed about the central housing segment. By actuating a valve, a flow path through the central housing is modified, and as a result, different housing segments are fluidically connected with one another. In this way, each housing segment is in selective fluidic communication with at least one another housing segment.

**[0023]** The apparatus is substantially self-contained because generally all the chemistry for detecting the analyte is contained in the housing. This decreases the chance that an apparatus operator will be exposed to the analyte and/or fluids that are used in the testing process, such as by an accidental spill or otherwise. The inventive apparatus assembly is a relatively simple device that allows a sample of material to be tested for an analyte at or near the sample source. Rather than transferring the sample of material to an off-site laboratory, the present invention allows an operator to obtain a sample of material from a sample source and then test the sample for the presence of an analyte at or near the sample source. This helps to decrease the waiting time for a test result. Furthermore, the apparatus assembly may be disposable, which helps to provide a clean, if not sterile, apparatus assembly for each use.

**[0024]** Of course, the inventive apparatus may also be used in a laboratory or other off-site setting. Rather than an operator manually actuating the apparatus valve in order to adjust the flow path through the central housing segment, the valve may be coupled with an automated machine, whereby the automated machine actuates the valve after a preset amount of time. The automated machine may be as simple as an egg timer or a similar spring-loaded device. The option of using an automated valve actuator allows multiple assays to be run at once.

**[0025]** The present invention is described in reference to an exemplary embodiment, which uses an indirect assay to detect an analyte in a sample of material. A general understanding of the assay process that is used with the exemplary embodiment will help aid in the description of the inventive apparatus. However, the following description of the assay process is not intended to limit the present invention in any way. Rather, the inventive apparatus and method of detecting an analyte in a sample of material may be applied to many different types of assays, direct or indirect.

**[0026]** In accordance with the exemplary embodiment, a sample of material is obtained with a device. Prior to running the assay, the sample of material is prepared. In the sample preparation stage, the sample of material is eluted (or “released”) from the sample collection device with a first

buffer solution, rendering an eluted sample. At least some of the analyte is then isolated from the eluted sample. This is done with a capture medium. The sample of material is typically a heterogeneous mixture of material. It may be necessary to isolate and, in some sense, concentrate the analyte because some analytes are only detected in large quantities. The isolation/concentration may increase the chance of an accurate detection.

**[0027]** Therefore, in order to help increase the possibility that the organism will be detected by a testing device, the organism (i.e., the analyte) is isolated from the remaining debris in the sample of material. The testing device may be any suitable device, such as a calorimetric sensor.

**[0028]** An exemplary analyte of interest to detect is *Staphylococcus aureus* (“*S. aureus*”). This is a pathogen causing a wide spectrum of infections including: superficial lesions such as small skin abscesses and wound infections; systemic and life threatening conditions such as endocarditis, pneumonia and septicemia; as well as toxinoses such as food poisoning and toxic shock syndrome. Some strains (e.g., Methicillin-Resistant *S. aureus* or MRSA) are resistant to all but a few select antibiotics.

**[0029]** At least some of the analyte captured by the capture medium is then released (or lysed) therefrom with a second buffer solution. The second buffer solution may contain a lysing agent, such as those described in U.S. Patent Application Publication No. 2005/0153370 A1, entitled “Method of Enhancing Signal Detection of Cell-Wall Components of Cells.”

**[0030]** The released analyte and second buffer solution is then put in contact with a reagent that is adapted to react with the released analyte. If a direct assay is used, a reagent may not be necessary. After the analyte and reagent react, and after a sufficient “reaction time”, the analyte and reagent, along with the second buffer solution, contact the testing device. In an indirect assay, a testing device detects the presence of a reagent adapted to react with the analyte rather than the analyte itself. Specifically, the reagent and analyte react, and then any remaining reagent (i.e., the reagent that has not reacted with the analyte to form a separate product) reacts with the testing device. Thereafter, the testing device provides a visual indicium of the presence and/or quantity of reagent. It is preferred that the analyte and reagent are given sufficient time to react prior to contacting the testing device.

**[0031]** In one embodiment, the reagent reacts with a surface of the testing device (e.g., a red color), and the testing device changes color as the reagent reacts with the testing device. If a large quantity of reagent reacts with the testing device, the testing device may change color, for example, from red to blue. If a small quantity of reagent reacts with the testing device, the testing device may not change color and remain red. The testing device may also be configured to provide an indicium of the quantity of reagent present (which typically represents the quantity of analyte present in the sample of material). For example, the testing device may change color, where the intensity or hue of the color changes depending upon the amount of reagent present. In alternate embodiments, the testing device measures the amount of reagent in another suitable way.

**[0032]** The quantity of reagent present indicates the quantity of analyte present because typically, a large quantity of reagent present after the reaction with the analyte indicates that there was not a large quantity of analyte present in the sample of material. Similarly, a small quantity of reagent