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(54) **READHEAD FOR OPTICAL INSPECTION APPARATUS**

MESSKOPF FÜR OPTISCHES INSPEKTIONSGERÄT

TETE DE LECTURE POUR APPAREIL D'INSPECTION OPTIQUE

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Description

Field of the Disclosure

[0001] The present disclosure relates to an apparatus and method for optically inspecting a sample of body fluid and, more particularly, to a readhead for use with the apparatus. Even more particularly, the present disclosure relates to a readhead including components for conducting both fluorescence and reflectance spectroscopy.

Background of the Disclosure

[0002] It is useful for various medical diagnostic purposes to utilize a reflectance spectroscope to analyze samples of body fluid, for example, to determine the color of a person's urine or blood. As is known, spectroscopy uses the linear relationship between absorbance and concentration of an absorbing species (Beer's law), to determine the contents of a sample. An unknown concentration of an analyte can be determined by measuring the amount of light that a sample absorbs and applying Beer's law. If the absorptivity coefficient of the analyte is not known, the unknown concentration can be determined using a working curve of absorbance versus concentration derived from standards.

[0003] For example, immunoassay is a technology for identifying and quantifying organic and inorganic compounds. Immunoassay uses antibodies that have been developed to bind with a target compound or class of compounds. The technology has been used widely because the antibodies can be highly specific to the target compound or group of compounds and because immunoassay kits are relatively quick and simple to use. Concentrations of analytes are identified through the use of a sensitive colorimetric reaction. The determination of the target analyte's presence is made by comparing the color developed by a sample of unknown concentration with the color formed by the standard containing the analyte at a known concentration. The concentration of the analyte is determined by the intensity of color in the sample. The concentration can be estimated roughly by the naked eye or can be determined more accurately with a reflectance spectroscope.

[0004] Reflectance spectroscopy is the study of light as a function of wavelength that has been reflected or scattered from a solid, liquid, or gas. A conventional reflectance spectroscope may determine the color of a liquid sample, such as urine or blood, disposed on a white, non-reactive pad by illuminating the pad and taking a number of reflectance readings from the pad, each having a magnitude relating to a different wavelength of visible light. The color of the sample on the pad may then be determined based upon the relative magnitudes of red, green, blue and infrared reflectance signals. Reagent pads can be provided with different reagents which cause a color change in response to the presence of a certain type of constituent in urine, such as leukocytes (white blood cells) or red blood cells. A reagent strip may have ten or more different types of reagent pads, for example. Immunoassay strips or cassettes may also be used with other types of liquid samples, such as blood.

[0005] U.S. Patent No. 5,654,803, which is assigned to the assignee of the present disclosure, discloses an apparatus and method for determination of non-hemolyzed levels of occult blood in urine using reflectance spectroscopy. The apparatus is provided with a light source for successively illuminating a plurality of different portions of a reagent pad on which a urine sample is disposed, and a detector array for detecting light received from the reagent pad and generating a plurality of reflectance signals in response to light received from a corresponding one of the different portions of the reagent pad. The apparatus is also provided with means for determining whether the magnitude of one of the reflectance signals is substantially different than the magnitude of another of the reflectance signals. Where the body-fluid sample is urine, this capability allows the apparatus to detect the presence of non-hemolyzed levels of occult blood in the urine sample.

[0006] U.S. Patent No. 5,877,863, which is also assigned to the assignee of the present disclosure, shows an optical inspection apparatus for inspecting a liquid sample, such as urine, using reflectance spectroscopy. The apparatus includes a readhead for illuminating a target area substantially uniformly via only a single light-emitting diode for each wavelength of interest arid receiving light from the target area so that reagent tests may be performed. The readhead is provided with a housing, first and second light sources mounted in a fixed position relative to the housing, a light guide mounted to receive light from each of the light sources which conveys, when only one of the light sources is illuminated, substantially all of the light from the light source to illuminate a target area substantially uniformly, and a light detector coupled to receive light from the target area. Each of the first and second light sources is composed of only a single light-emitting diode for emitting substantially monochromatic light of a different wavelength.

[0007] Fluorescence spectroscopy is the study of light that has been absorbed at one wavelength and re-emitted at a different wavelength (e.g., fluorescent light is re-emitted by a sample of body fluid in response to a light having a specific wavelength, such as ultraviolet light, being directed at the sample). It is useful for various medical diagnostic purposes to use fluorescence detection to analyze samples of body fluid, for example, to determine a level of glucose in a patient's blood or urine, or to determine a pH level of the patient's blood or urine. U.S. Patent No. 6,232,609 to Snyder et al., for example, shows an apparatus for glucose monitoring. The glucose monitor illuminates a sample with water with ultraviolet excitation light that induces the water and any glucose present in the sample to emit return light that includes Raman scattered light and glucose emission or fluorescence light. The return light is monitored and processed using a predictive regression model to determine the concentration of glucose in the sample. The predictive regression model accounts for nonlinearities between the glucose concentration and intensity of return light within different wavelength bands at a predetermined excitation light energy or the intensity of return light within a predetermined wavelength band at different excitation energy levels. A fiber-optic waveguide is used to guide the excitation light from a laser excitation source to the sample and the return light from the sample to a sensor.

[0008] What is still desired is a new and improved apparatus and method for performing tests on a sample of body fluid and, more particularly, to a readhead for use with the apparatus. Preferably the readhead will include components for conducting both fluorescence spectropy and reflectance spectroscopy.

Summary of the Disclosure

[0009] The disclosure is directed to exemplary embodiments of a new and improved readhead for a diagnostic instrument for illuminating a sample carrier (e.g., a strip or cassette having a liquid sample) and receiving light from the sample carrier, and that allows both fluorescence spectroscopy and reflectance spectroscopy to be conducted in a simple and convenient manner.

[0010] One exemplary embodiment of the readhead includes a housing adapted to be incorporated in the diagnostic instrument and including an illumination chamber for receiving a sample carrier, an array of light sources mounted within the housing in a fixed position relative to the illumination chamber, and including a first light-emitting diode for emitting substantially monochromatic light of a first wavelength and a second light-emitting diode for emitting substantially monochromatic light of a second wavelength substantially different from the first wavelength, a light guide mounted in the housing to receive light from each of the light-emitting diodes, for conveying, when only one of the light-emitting diodes is illuminated, substantially all of the light from the one light-emitting diode to the illumination chamber so that the illumination chamber is illuminated substantially uniformly, and a light detector coupled to receive light from the illumination chamber. These components of the readhead allow reflectance spectroscopy to be conducted on a fluid sample.

[0011] The readhead also includes a fluorescence excitation light source for directing excitation light of a predetermined wavelength to the illumination chamber, and a light filter positioned between the illumination chamber and the light detector and adapted to prevent passage therethrough of the excitation light from the fluorescence excitation light source but allow passage of emissive light from a sample carrier in the illumination chamber having a wavelength different from the predetermined wavelength of the excitation light. These components of the readhead allow fluorescence spectroscopy to be conducted on a fluid sample.

[0012] The present invention relates to a readhead for a diagnostic instrument according to claims 1, 2 or 3.

[0013] Additional aspects and advantages of the present disclosure will become readily apparent to those skilled in this art from the following detailed description, wherein only exemplary embodiments of the present disclosure are shown and described, simply by way of illustration of the best mode contemplated for carrying out the present disclosure. As will be realized, the present disclosure is capable of other and different embodiments, and its several details are capable of modifications in various obvious respects, all without departing from the disclosure. Accordingly, the drawings and description are to be regarded as illustrative in nature, and not as restrictive.

Brief Description of the Drawings

[0014] Reference is made to the attached drawings, wherein elements having the same reference character designations represent like elements throughout, and wherein:

> **FIG. 1** is a side sectional view of a portion of an exemplary embodiment of a readhead constructed in accordance with the present invention for use as part of a medical diagnostic optical inspection apparatus and which is adapted to perform both fluorescence spectroscopy and reflectance spectroscopy on a body fluid sample;
>
> **FIG. 2** is a perspective view of an exemplary embodiment, not being part of the present invention, of an optical inspection apparatus, which may be used to perform various tests of a body fluid sample;
>
> **FIG. 3** is a perspective view of an exemplary embodiment, not being part of the present invention, of a reagent strip for use with the apparatus of **FIG. 2;**
>
> **FIG. 4** is a top sectional view of an exemplary embodiment, not being part of the present invention, of a readhead for use as part of the optical inspection apparatus of **FIG. 2,** and which is adapted to allow the apparatus of **FIG. 2** to perform reflectance spectroscopy on a body fluid sample;
>
> **FIG. 5** is a side sectional view of the readhead of **FIG. 4;** and
>
> **FIG. 6** is a cross-sectional side view of a light-emitting diode array of the readhead of **FIG. 4.**

Detailed Description of Exemplary Embodiments

[0015] **FIG. 1** shows an exemplary embodiment of a new and improved readhead **200** constructed in accordance with the present disclosure for use as part of an apparatus for optically inspecting samples of body fluid for medical diagnostic purposes. The read head of **FIG. 1** is adapted to perform both fluorescence spectroscopy and reflectance spectroscopy on a body fluid sample.

[0016] The new and improved readhead **200** of **FIG. 1**

can be incorporated into a optical inspection apparatus. Prior to discussing the new and improved readhead **200** of **FIG. 1,** the apparatus shown in **FIGS. 2** through **6** will first be discussed to provide background information on an exemplary embodiment of an optical inspection apparatus. **FIG. 2** illustrates a reflectance spectroscope **100,** for optically inspecting liquid samples such as body fluid samples. The particular apparatus **100** shown in **FIG. 2** is a CLINITEK® 50 Urine Chemistry Analyzer available from Bayer Corporation, Diagnostics Division, of Tarrytown, NY. The apparatus **100** is described in greater detail in U.S. Patent Nos. 5,654,803; 5,877,863; and 5,945,341.

[0017] It should be understood, however, that a new and improved readhead according to the present disclosure can be incorporated in optical inspection machines other than a CLINITEK® 50 Urine Chemistry Analyzer. For example, it is anticipated that a new and improved readhead according to the present disclosure will be incorporated into a CLINITEK STATUS® Chemistry Analyzer available from Bayer Corporation. Aspects of the CLINITEK STATUS® Chemistry Analyzer are disclosed in co-owned and co-pending U.S. Patent Application Serial No. 10/821,441, filed on April 9, 2004 (Attorney Docket Reference BYRK-23) and which also claim priority to provisional patent application Serial No. 60/475,288 (BYRK-27PR), filed June 3, 2003.

[0018] The exemplary inspection apparatus **100** shown in **FIG. 2** has an integral keyboard **102** for user input, and a visual display **106** for displaying various messages to a user relating to the operation of the inspection apparatus **100.** The inspection apparatus **100** also has a housing **107** with an opening **108** formed therein into which a support tray **120** may be retracted. As shown in **FIG. 2,** the support tray **120** is adapted to receive a first type of liquid sample carrier or removable insert, which may be in the form of a reagent cassette **122.**

[0019] The reagent cassette **122** may be a disposable, single-use cassette for doing a pregnancy test, for example, in a conventional manner. The reagent cassette **122** has an opening or well **124** into which a body fluid sample, such as urine, is placed. The interior of the reagent cassette **122** has a reagent strip (not shown) which may react with the body fluid sample placed in the well **124.** Depending on the results of the test, the reagent strip may change color (e.g., a colored stripe may appear), which is determinable from viewing the reagent strip through a window **128** of the reagent cassette **122.** Although not shown, the support tray **120** may have a calibration chip of a certain color, such as white, disposed in its upper surface to facilitate calibration. A new and improved readhead according to the present disclosure can also be used with a lateral flow immunoassay using a fluorescent particle as a label.

[0020] When turned over, the support tray **120** is adapted to receive sample carrier comprising a reagent strip. Referring to **FIG. 3,** a reagent strip **40** may have a thin, non-reactive substrate **41** on which a number of reagent pads **50** are fixed. Each reagent pad **50** may be composed of a relatively absorbent material impregnated with a respective reagent, each reagent and reagent pad **50** being associated with a particular test to be performed. When urinalysis tests are performed, they may include, for example, a test for leukocytes in the urine, a test of the pH of the urine, a test for blood in the urine, etc. When each reagent pad **50** comes into contact with a urine sample, the pad changes color over a time period, depending on the reagent used and the characteristics of the urine sample. The reagent strip **40** may be, for example, a MULTISTIX® reagent strip commercially available from Bayer Corporation, Diagnostics Division, of Tarrytown, NY.

[0021] Referring back to **FIG. 2,** during an inspection procedure the support tray **120** is moved between an outwardly extended position as shown in **FIG. 2** and an optical inspection position in which the tray **120** is retracted inwardly into the housing **107** of the inspection apparatus **100** and into a readhead contained in the housing.

[0022] **FIGS. 4** and **5** show an exemplary embodiment of a readhead **10** of the inspection apparatus **100.** In the exemplary embodiment shown, the readhead **10** has a housing formed from an upper housing portion **12,** a middle housing portion **14,** and a lower housing portion **16** which maybe connected together in any conventional manner. The housing portions **12, 14, 16** may be injection-molded parts comprising black plastic to substantially absorb any errant light rays that are incident upon the housing.

[0023] Light sources in the form of light-emitting diodes (LEDs) **20** are supported on a ledge **22** formed in the lower housing portion **16.** Each of the LEDs **20** is designed to emit monochromatic radiation of a different wavelength, corresponding to red light, green light, blue light and infrared. The wavelength of the light emitted may vary from about 400 nanometers (for blue light) to about 1,000 nanometers (for infrared). Each of the LEDs **20** may be selectively turned on and off via a plurality of wires **24** connected between the LEDs **20** and an activation circuit (not shown). The readhead **10** may be provided with additional LEDs providing additional wavelengths. The CLINITEK STATUS® Urine Chemistry Analyzer includes six LEDs, while the CLINITEK® 50 Urine Chemistry Analyzer includes four LEDs.

[0024] The LEDs **20** are disposed directly adjacent and in very close proximity with an inlet end **26a** of a light guide **26** into which light from the LEDs **20** is radiated. As shown in **FIG. 5,** the light guide **26** has a relatively long, substantially planar portion **26b** and a portion **26c** that curves downwardly towards an outlet end **26d** of the light guide **26.** As shown in **FIG. 4,** which is a top cross-sectional view of a portion of the readhead **10,** the light guide **26** has a pair of curved sides **26e, 26f** that diverge outwardly from the inlet end **26a** to the outlet end **26d** of the light guide **26.**

[0025] The light guide **26,** which may be an injection-molded part composed of clear plastic such as acrylic or polycarbonate, conducts substantially all light that enters its inlet end **26a** to its outlet end **26d** via total internal reflection. To prevent any internally reflected light from exiting the light guide **26** between its inlet **26a** and outlet **26d,** the exterior of the light guide **26** could optionally be coated with a highly reflective coating, such as silver.

[0026] The light guide **26** is supported within the lower housing portion **16** by a pair of supports **28** disposed beneath the light guide **26** at a point near its inlet end **26a** and a plurality of supports **30** disposed beneath the light guide **26** at a point near its outlet end **26d.** The supports **28, 30** may be integrally formed with the lower housing portion **16.** As shown in **FIG. 4,** the light guide **26** is positioned between a pair of angled guide walls **32, 34.**

[0027] As shown in **FIG. 5,** light is emitted from the outlet end **26d** of the light guide **26** towards the reagent strip **40** disposed on a support **42** in an illumination chamber **44,** as indicated by an arrow **46.** The support **42** is nonmovable relative to the housing portions **12, 14, 16.** Light from the reagent strip **40** passes through a rectangular opening **54** formed in the lower housing portion **16,** in a direction indicated by an arrow **56,** towards a mirror element **58** fixed in the upper left corner of the upper housing portion **12.** The mirror element **58** is composed of a cylindrical mirror **60** and a pair of mounting tabs **62** connected to the mirror **60.** The mirror element **58,** which may be a plastic injection molded part having the curved portion **60** being coated with a highly reflective material, extends approximately the length of the aperture **54** shown in **FIG. 5** (the CLINITEK STATUS® Urine Chemistry Analyzer includes a flat mirror). The mirror **60** reflects light that is incident upon it from the reagent strip **40** through a square aperture **64** formed in the middle housing portion **14** and to a lens **66** supported by the middle housing portion **14,** as indicated by an arrow **68.** One side of the lens **66** has a planar surface and the other side of the lens **66** has a convexly curved (aspheric) surface. Light passing through the lens **66** is transmitted to a light detector array **70,** as indicated by an arrow **72.**

[0028] The detector array **70,** which is fixed to a side wall **74** of the upper housing portion **12,** may comprise a conventional detector array, such as a TSL 1402 commercially available from Texas Instruments, which is composed of 256 individual light detectors aligned in a single horizontal row, or a Sony ILX511, a 2048 detector array, which is used in the CLINITEK STATUS® Urine Chemistry Analyzer includes.

[0029] In operation, only one of the LEDs **20** is illuminated at a time, and the illumination provided by that single LED **20** is sufficient to uniformly illuminate the reagent strip **40** to an extent that allows the detector array **70** to detect enough light from the reagent strip **40** to have the reagent tests described above satisfactorily performed. Each individual light detector in the array **70** senses light from a particular point along the length of the reagent strip **40.** For example, to detect light from the lowermost reagent pad **50,** a number of the light detectors on the corresponding end of the detector array **70** would be activated. Light from all of the reagent pads **50** could be simultaneously detected by activating all of the detectors in the array **70.**

[0030] The cross-sectional shape of the mirror **60** is curved so that each light detector in the detector array **70** detects light from a wider portion of the reagent strip **40** than if a mirror having a straight cross-sectional shape were used. However, depending on the particular design of the readhead **10,** a straight mirror could be used instead of the cylindrically curved mirror **60.** In an alternative design, the mirror element **58** could be omitted, and the detectors **70** could be placed directly above the aperture **54.**

[0031] Referring to **FIG. 4,** the light guide **26** is diverging, having a relatively small width at its inlet end **26a** and a relatively large width at its outlet end **26d.** The fact that the light guide **26** is diverging acts to 1) spread the light from a single one of the LEDs **20** along a relatively large length, corresponding to the length of the outlet end **26d,** and 2) cause the light rays emitted by one of the LEDs **20** to be randomized, thus providing more uniform illumination at the target area in which the reagent strip **40** is located, by causing some of the light rays to be internally reflected within the light guide **26** at different angles. With respect to feature 2), it should be understood that in a light guide having diverging side walls, a single light ray may be reflected from the walls at different angles (i.e. at successively shallower angles of incidence with respect to the side walls as the light ray passes from the inlet to the outlet), thus increasing the randomness of the light rays and the uniformity of the illumination.

[0032] In the exemplary embodiment shown, the LEDs **20** comprise lensless LEDs, such as surface-mount LEDs. Conventional LEDs are typically provided with a lens which covers the light-emitting component of the LED, however, a lensless LED acts more of a Lambertian source by exhibiting a much lower degree of directionality. **FIG. 6** illustrates the structure of the conventional lensless LEDs **20.** Referring to **FIG. 6,** each LED **20** is shown to generally comprise a substrate **80** having a cavity **82** formed therein, with the light-emitting structure **84** being disposed within the cavity **82** and with no lens covering the cavity **82** or the light-emitting structure **84.**

[0033] Referring back to **FIG. 1,** the present invention provides a new and improved readhead **200** for use as part of an apparatus (such as the apparatus **100** of **FIG. 2**) for optically inspecting samples of body fluid for medical diagnostic purposes. The read head **200** of **FIG. 1** is similar to the readhead **10** of **FIGS. 4** and **5** such that similar elements have the same reference numeral preceded by a **"2".** The read head **200** of **FIG. 1** however is adapted to perform fluorescence spectroscopy, in addition to reflectance spectroscopy, on a body fluid sample.

[0034] In **FIG. 1** only an end portion of the readhead **200** is shown. Although not shown in **FIG. 1,** the readhead **200** also includes LEDs, a lens and a detector array, similar to the readhead **10** of **FIGS. 4** and **5.** In addition to the LEDs, however, the readhead **200** of **FIG. 1** further includes an ultraviolet light source chamber **300** containing an ultraviolet light source **302** and having an opening **304** for directing light from the ultraviolet light source **302** into the illumination chamber **244** of the readhead **200.** As shown, the interior of the chamber **300** may be lined with metal foil **306** to protect the plastic walls of the chamber from ultraviolet light degradation. The readhead **200** also includes an ultraviolet filter **308** in the light path **256** to prevent an excitation wavelength of the light source **302** from being detected by the detector array, so that the detector array will only detect an emission wavelength produced by the pads **50** of the reagent strip **40.**

[0035] Many substances will fluoresce (re-emit energy at a higher wavelength) when exposed to ultraviolet light. During use of the readhead **200** of the present disclosure, ultraviolet excitation light from the light source **302** is directed against the pads **50** of the reagent strip **40,** as illustrated by arrow **310.** Emission light from the pads **50** of the reagent strip **40** then travels through the ultraviolet filter **308** in the light path **256,** is reflected off the mirror **260** and directed along the light path **268** to the detector array. Determining the wavelength and intensity of emissive light received by the detector array can be used to determine properties of the sample being excited with the light source **302.** For instance, the wavelength and intensity of emissive light can be used to determine the amount of glucose in a blood sample. U.S. Patent No. 6,232,609 to Snyder et al., for example, shows an apparatus for glucose monitoring that uses ultraviolet excitation and monitors the wavelength and intensity of emissive light to monitor glucose levels.

[0036] According to one exemplary embodiment of the present disclosure, the detector array monitors the return light and generates electrical signals indicative of the intensity of return light associated with glucose concentration distinguishing characteristics of the emission light. A processor connected to the detector array processes the electrical signals, using a predictive model, to determine the concentration of glucose in the sample. Suitable examples of predictive models are shown in U.S. Patent No. 6,232,609 to Snyder et al.

[0037] According to another exemplary embodiment of the disclosure, the light source **302** comprises a black fluorescent lamp having a line output at 364 nanometers, 405 nanometers, and 436 nanometers, and a broadband output from 330-385 nanometers. Alternatively, the light source may comprise an ultraviolet LED positioned in the ultraviolet light source chamber **300** or adjacent to the other LEDs **20** at the input end of the light guide **26.** The ultraviolet LED may have an output of 370 nanometers or 400 nanometers, for example. The light guide **26** for an ultraviolet LED is made of glass or quartz. In addition, a high intensity green LED can be used to trigger fluorescence, and can be used with suitable filters. It should be anticipated that future LEDs will cover a wider range of UV wavelengths and that more fluorescent dyes or markers will also be developed.

Claims

1. A readhead (200) for a diagnostic instrument (100) for illuminating a sample carrier (40) and receiving light from the sample carrier (40), the readhead (200) comprising: a housing adapted to be incorporated in the diagnostic instrument (100) and including an illumination chamber (244) for receiving a sample carrier (40); an array of reflectance light sources mounted within the housing in a fixed position relative to the illumination chamber (244), and including a first light-emitting diode (20) for emitting substantially monochromatic light of a first wavelength and a second light- emitting diode (20) for emitting substantially monochromatic light of a second wavelength substantially different from the first wavelength; a light guide (226) mounted in the housing to receive light from each of the light-emitting diodes (20), for conveying, when only one of the light-emitting diodes (20) is illuminated, substantially all of the light from the one light-emitting diode (20) to the illumination chamber (244) so that the illumination chamber (244) is illuminated substantially uniformly; a light detector (70) coupled to receive light from the illumination chamber (244); a fluorescence excitation light source positioned in the housing and positioned to direct excitation light (310) of a predetermined wavelength to the illumination chamber (244); and a light filter (308) positioned between the illumination chamber (244) and the light detector (70) and adapted to prevent passage therethrough of the excitation light (310) from the fluorescence excitation light source but allow passage of emissive light (256) from a sample carrier (40) in the illumination chamber(244) having a wavelength different from the predetermined wavelength of the excitation light (310), wherein the fluorescence excitation light source comprises an ultraviolet light source (302) positioned in an ultraviolet light source chamber (300) within the housing, the ultraviolet light source chamber having an opening (304) for directing light from the ultraviolet light source (302) into the illumination chamber (244), wherein the interior of the ultraviolet light source chamber (300) is lined with metal foil.

2. A readhead (200) for a diagnostic instrument (100) for illuminating a sample carrier (40) and receiving light from the sample carrier (40), the readhead (200) comprising: a housing adapted to be incorporated in the diagnostic instrument (100) and adapted to receive and support a sample carrier (40); a reflectance light source comprising a light-emitting diode (20) mounted within the housing in a fixed position relative to the sample carrier (40); a diverging light guide (226), mounted in the housing to receive light from the light-emitting diode (20) and adapted to convey substantially all of the light from the light- emitting diode (20) to the sample carrier (40) so that the sample carrier (40) is illuminated substantially uniformly, the diverging light guide (226) having a relatively small width at a point adjacent an inlet (226a) of the diverging light guide (226) and a relatively large width at a point adjacent an outlet (226d) of the diverging light guide (226); a light detector (70) coupled to receive light from the sample carrier (40); a fluorescence excitation light source for directing excitation light (310) of a predetermined wavelength to the sample carrier (40); and a light filter (308) positioned between the sample carrier (40) and the light detector (70) and adapted to prevent passage therethrough of the excitation light (310) from the fluorescence excitation light source but allow passage of emissive light (256) from the sample carrier (40) having a wavelength different from the predetermined wavelength of the excitation light (310), wherein the fluorescence excitation light source comprises an ultraviolet light source (302) positioned in an ultraviolet light source chamber (300) within the housing, the ultraviolet light source chamber having an opening (304) for directing light from the ultraviolet light source (302) into the illumination chamber (244), wherein the interior of the ultraviolet light source chamber (300) is lined with metal foil.

3. A readhead (200) for a diagnostic instrument (100) for illuminating a sample carrier (40) and receiving light from the sample carrier (40), the readhead (200) comprising: a housing adapted to be incorporated in the diagnostic instrument (100) and including an illumination chamber (244) for receiving a sample carrier (40); a reflectance light source comprising a lensless light-emitting diode (20) mounted within the housing in a fixed position relative to the illumination chamber (244); a light guide (226), mounted in a fixed position relative to the lensless light- emitting diode (20), for conveying light from the lensless light-emitting diode (20) to a sample carrier (40) in the illumination chamber (244); a light detector (70) coupled to receive light from the sample carrier (40); a fluorescence excitation light source positioned in the housing for directing excitation light of a predetermined wavelength to the illumination chamber (244); and a light filter (308) positioned between the illumination chamber (244) and the light detector (70) and adapted to prevent passage therethrough of the excitation light (310) from the fluorescence excitation light source but allow passage of emissive light (256) from a sample carrier (40) in the illumination chamber (244) having a wavelength different from the predetermined wavelength of the excitation light (310), wherein the fluorescence excitation light source comprises an ultraviolet light source (302) positioned in an ultraviolet light source chamber (300) within the housing, the ultraviolet light source chamber having an opening (304) for directing light from the ultraviolet light source (302) into the illumination chamber (244), wherein the interior of the ultraviolet light source chamber (300) is lined with metal foil.

4. A readhead (200) as defined in any of claims 1, 2 or 3 wherein the ultraviolet light source comprises a black fluorescent lamp having a line output at 364 nanometers, 405 nanometers, and 436 nanometers, and a broadband output from 330-385 nanometers.

5. A readhead (200) as defined in claim 1, 2 or 3 wherein a mirror is positioned between the light detector (70) and the light filter (308).

6. A readhead (200) as defined in claim 1, 2 or 3 wherein a lens is positioned between the light detector (70) and the light filter (308) and adapted to focus light on the light detector (70).

7. A diagnostic instrument (100) including a readhead (200) as defined in claim 1, 2 or 3 and further comprising a processor connected to the light detector (70) and programmed to process electrical signals from the light detector (70) to determine a physical property of a sample on a sample carrier (40) received in the illumination chamber (244) of the readhead (200).

8. A diagnostic instrument (100) as defined in claim 7 wherein the processor is programmed to use a predictive model to determine the physical property.

9. A readhead (200) as defined in claim 1 or 3 wherein the light guide (226) comprises a diverging light guide (226) having a relatively small width at a point adjacent an inlet (226a) of the diverging light guide (226) and a relatively large width at a point adjacent an outlet (226d) of the diverging light guide (226).

10. A diagnostic instrument (100) as defined in claim 7 wherein the physical property comprises a glucose concentration.

11. A readhead (200) as defined in any of claims 1, 2 or 3 wherein the ultraviolet light source comprises a light-emitting diode.

12. A readhead (200) as defined in claim 11 wherein the light-emitting diode comprises a high intensity green light-emitting diode.

13. A readhead (200) as defined in claim 11 wherein the ultraviolet light-emitting diode is positioned next to the reflectance light source and the light guide (226) comprises glass or quartz.

Patentansprüche

1. Lesekopf (200) für ein Diagnoseinstrument (100) zum Beleuchten eines Probenträgers (40) und zum Empfangen von Licht von dem Probenträger (40), wobei der Lesekopf (200) Folgendes umfasst: ein Gehäuse, das dafür eingerichtet ist, in das Diagnoseinstrument (100) eingebunden zu werden, und eine Beleuchtungskammer (244) zum Aufnehmen eines Probenträgers (40) beinhaltet, eine Anordnung aus Reflexionslichtquellen, die an einer festen Position im Verhältnis zur Beleuchtungskammer (244) in das Gehäuse montiert sind, und eine erste Leuchtdiode (20) zum Emittieren von im Wesentlichen monochromem Licht einer ersten Wellenlänge und eine zweite Leuchtdiode (20) zum Emittieren von im Wesentlichen monochromem Licht einer zweiten Wellenlänge, die sich von der ersten Wellenlänge unterscheidet, beinhalten, einen Lichtleiter (226), der in das Gehäuse montiert ist, um Licht von jeder der Leuchtdioden (20) zu empfangen, um, wenn nur eine der Leuchtdioden (20) leuchtet, im Wesentlichen das gesamte Licht von der einen Leuchtdiode (20) zu der Beleuchtungskammer (244) zu befördern, sodass die Beleuchtungskammer (244) im Wesentlichen gleichmäßig erleuchtet ist, eine Lichterkennung (70), die dafür gekoppelt ist, Licht von der Beleuchtungskammer (244) zu empfangen, eine Fluoreszenzanregungs-Lichtquelle, die in dem Gehäuse positioniert ist und dafür positioniert ist, Anregungslicht (310) einer festgelegten Wellenlänge zur Beleuchtungskammer (244) zu lenken, und einen Lichtfilter (308), der zwischen der Beleuchtungskammer (244) und der Lichterkennung (70) positioniert und dafür eingerichtet ist, ein Hindurchtreten des Anregungslichts (310) von der Fluoreszenzanregungs-Lichtquelle zu verhindern, jedoch ein Hindurchtreten von emittiertem Licht (256) von einem Probenträger (40) in die Beleuchtungskammer (244) mit einer Wellenlänge zu ermöglichen, die sich von der festgelegten Wellenlänge des Anregungslichts (310) unterscheidet, wobei die Fluoreszenzanregungs-Lichtquelle eine Ultraviolett-Lichtquelle (302) umfasst, die in einer Ultraviolett-Lichtquellenkammer (300) in dem Gehäuse positioniert ist, wobei die Ultraviolett-Lichtquellenkammer eine Öffnung (304) aufweist, um Licht von der Ultraviolett-Lichtquelle (302) in die Beleuchtungskammer (244) zu lenken, wobei der Innenraum der Ultraviolett-Lichtquellenkammer (300) mit Metallfolie ausgekleidet ist.

2. Lesekopf (200) für ein Diagnoseinstrument (100) zum Beleuchten eines Probenträgers (40) und zum Empfangen von Licht von dem Probenträger (40), wobei der Lesekopf (200) Folgendes umfasst: ein Gehäuse, das dafür eingerichtet ist, in das Diagnoseinstrument (100) eingebunden zu werden, und dafür eingerichtet ist, einen Probenträger (40) aufzunehmen und zu tragen, eine Reflexionslichtquelle, die eine Leuchtdiode (20) umfasst, die an festen Position einer im Verhältnis zu dem Probenträger (40) in das Gehäuse montiert ist, einen divergierenden Lichtleiter (226), der in das Gehäuse montiert ist, um Licht von der Leuchtdiode (20) zu empfangen, und der dafür eingerichtet ist, im Wesentlichen das gesamte Licht von der Leuchtdiode (20) zu dem Probenträger (40) zu befördern, sodass der Probenträger (40) im Wesentlichen gleichmäßig beleuchtet ist, wobei der divergierende Lichtleiter (226) an einem Punkt angrenzend an einen Einlass (226a) des divergierenden Lichtleiters (226) eine relativ geringe Weite aufweist und an einem Punkt angrenzend an einen Auslass (226d) des divergierenden Lichtleiters (226) eine relativ große Weite aufweist, eine Lichterkennung (70), die dafür gekoppelt ist, Licht von dem Probenträger (40) zu empfangen, eine Fluoreszenzanregungs-Lichtquelle, um Anregungslicht (310) einer festgelegten Wellenlänge zum Probenträger (40) zu lenken, und einen Lichtfilter (308), der zwischen dem Probenträger (40) und der Lichterkennung (70) positioniert und dafür eingerichtet ist, ein Hindurchtreten des Anregungslichts (310) von der Fluoreszenzanregungs-Lichtquelle zu verhindern, jedoch ein Hindurchtreten von emittiertem Licht (256) von dem Probenträger (40) mit einer Wellenlänge zu ermöglichen, die sich von der festgelegten Wellenlänge des Anregungslichts (310) unterscheidet, wobei die Fluoreszenzanregungs-Lichtquelle eine Ultraviolett-Lichtquelle (302) umfasst, die in einer Ultraviolett-Lichtquellenkammer (300) in dem Gehäuse positioniert ist, wobei die Ultraviolett-Lichtquellenkammer eine Öffnung (304) aufweist, um Licht von der Ultraviolett-Lichtquelle (302) in die Beleuchtungskammer (244) zu lenken, wobei der Innenraum der Ultraviolett-Lichtquellenkammer (300) mit Metallfolie ausgekleidet ist.

3. Lesekopf (200) für ein Diagnoseinstrument (100) zum Beleuchten eines Probenträgers (40) und zum Empfangen von Licht von dem Probenträger (40), wobei der Lesekopf (200) Folgendes umfasst: ein Gehäuse, das dafür eingerichtet ist, in das Diagnoseinstrument (100) eingebunden zu werden, und eine Beleuchtungskammer (244) zum Aufnehmen eines Probenträgers (40) beinhaltet, eine Reflexionslichtquelle, die eine linsenlose Leuchtdiode (20) umfasst, die an einer festen Position im Verhältnis zur Beleuchtungskammer (244) in das Gehäuse montiert ist, einen Lichtleiter (226), der an einer festen Position im Verhältnis zur linsenlosen Leuchtdiode (20) montiert ist, um Licht von der linsenlosen Leuchtdiode (20) zu einem Probenträger (40) in der Beleuchtungskammer (244) zu befördern, eine Lichterkennung (70), die dafür gekoppelt ist, Licht von dem Probenträger (40) zu empfangen, eine Fluoreszenzanregungs-Lichtquelle, die in dem Gehäuse po-

sitioniert ist, um Anregungslicht einer festgelegten Wellenlänge zur Beleuchtungskammer (244) zu lenken, und einen Lichtfilter (308), der zwischen der Beleuchtungskammer (244) und der Lichterkennung (70) positioniert und dafür eingerichtet ist, ein Hindurchtreten des Anregungslichts (310) von der Fluoreszenzanregungs-Lichtquelle zu verhindern, jedoch ein Hindurchtreten von emittiertem Licht (256) von einem Probenträger (40) in die Beleuchtungskammer (244) mit einer Wellenlänge zu ermöglichen, die sich von der festgelegten Wellenlänge des Anregungslichts (310) unterscheidet, wobei die Fluoreszenzanregungs-Lichtquelle eine Ultraviolett-Lichtquelle (302) umfasst, die in einer Ultraviolett-Lichtquellenkammer (300) in dem Gehäuse positioniert ist, wobei die Ultraviolett-Lichtquellenkammer eine Öffnung (304) aufweist, um Licht von der Ultraviolett-Lichtquelle (302) in die Beleuchtungskammer (244) zu lenken, wobei der Innenraum der Ultraviolett-Lichtquellenkammer (300) mit Metallfolie ausgekleidet ist.

4. Lesekopf (200) nach einem der Ansprüche 1, 2 und 3, wobei die Ultraviolett-Lichtquelle eine Schwarzlicht-Fluoreszenzlampe mit einem Leitungsausgang bei 364 Nanometern, 405 Nanometern und 436 Nanometern und einem Breitbandausgang von 330 bis 385 Nanometern umfasst.

5. Lesekopf (200) nach einem der Ansprüche 1, 2 und 3, wobei zwischen der Lichterkennung (70) und dem Lichtfilter (308) ein Spiegel positioniert ist.

6. Lesekopf (200) nach einem der Ansprüche 1, 2 und 3, wobei zwischen der Lichterkennung (70) und dem Lichtfilter (308) eine Linse positioniert und dafür eingerichtet ist, Licht auf die Lichterkennung (70) zu fokussieren.

7. Diagnoseinstrument (100), einen Lesekopf (200) nach einem der Ansprüche 1, 2 und 3 beinhaltend und ferner einen Prozessor umfassend, der mit der Lichterkennung (70) verbunden und dafür programmiert ist, elektrische Signale von der Lichterkennung (70) zu verarbeiten, um eine physikalische Eigenschaft einer Probe auf dem Probenträger (40) zu bestimmen, der in der Beleuchtungskammer (244) des Lesekopfes (200) aufgenommen ist.

8. Diagnoseinstrument (100) nach Anspruch 7, wobei der Prozessor dafür programmiert ist, ein Vorhersagemodell zu verwenden, um die physikalische Eigenschaft zu bestimmen

9. Lesekopf (200) nach Anspruch 1 oder 3, wobei der Lichtleiter (226) einen divergierenden Lichtleiter (226) umfasst, der an einem Punkt angrenzend an einen Einlass (226a) des divergierenden Lichtleiters (226) eine relativ geringe Weite aufweist und an einem Punkt angrenzend an einen Auslass (226d) des divergierenden Lichtleiters (226) eine relativ große Weite aufweist.

10. Diagnoseinstrument (100) nach Anspruch 7, wobei die physikalische Eigenschaft eine Glukosekonzentration umfasst.

11. Lesekopf (200) nach einem der Ansprüche 1, 2 oder 3, wobei die Ultraviolett-Lichtquelle eine Leuchtdiode umfasst.

12. Lesekopf (200) nach Anspruch 11, wobei die Leuchtdiode eine grüne Hochintensitäts-Leuchtdiode umfasst.

13. Lesekopf (200) nach Anspruch 11, wobei die Ultraviolett-Leuchtdiode neben der Reflexionslichtquelle positioniert ist und der Lichtleiter (226) Glas oder Quarz umfasst.

Revendications

1. Tête de lecture (200) pour un instrument de diagnostic (100) destiné à illuminer un porte-échantillon (40) et à recevoir la lumière provenant du porte-échantillon (40), la tête de lecture (200) comprenant : un boîtier adapté pour être incorporé dans l'instrument de diagnostic (100) et comprenant une chambre d'illumination (244) pour recevoir un porte-échantillon (40) : un réseau de sources lumineuses à réflectance montées à l'intérieur du boîtier dans une position fixe par rapport à la chambre d'illumination (244), et comprenant une première diode électroluminescente (20) pour émettre une lumière sensiblement monochromatique d'une première longueur d'onde et une seconde diode électroluminescente (20) pour émettre une lumière sensiblement monochromatique d'une seconde longueur d'onde sensiblement différente de la première longueur d'onde ; un guide de lumière (226) monté dans le boîtier pour recevoir la lumière de chacune des diodes électroluminescentes (20), pour transporter, lorsqu'une seule des diodes électroluminescentes (20) est illuminée, sensiblement toute la lumière de ladite diode électroluminescente (20) vers la chambre d'illumination (244), de sorte que la chambre d'illumination (244) soit illuminée sensiblement de manière uniforme; un détecteur de lumière (70) couplé pour recevoir la lumière provenant de la chambre d'illumination (244) ; une source lumineuse d'excitation à fluorescence positionnée dans le boîtier et positionnée pour diriger une lumière d'excitation (310) d'une longueur d'onde prédéterminée vers la chambre d'illumination (244) ; et un filtre de lumière (308) positionné entre la chambre d'illumination (244) et le détecteur de lumière

(70) et adapté pour empêcher le passage à travers celui-ci de la lumière d'excitation (310) de la source lumineuse d'excitation à fluorescence mais permettre le passage de lumière émissive (256) provenant d'un porte-échantillon (40) dans la chambre d'illumination (244) présentant une longueur d'onde différente de la longueur d'onde prédéterminée de la lumière d'excitation (310), dans laquelle la source lumineuse d'excitation à fluorescence comprend une source lumineuse ultraviolette (302) positionnée dans une chambre de source lumineuse ultraviolette (300) à l'intérieur du boîtier, la chambre de source lumineuse ultraviolette présentant une ouverture (304) pour diriger la lumière de la source lumineuse ultraviolette (302) dans la chambre d'illumination (244), dans lequel l'intérieur de la chambre de source lumineuse ultraviolette (300) est revêtu avec un film métallique.

2. Tête de lecture (200) pour un instrument de diagnostic (100) destiné à illuminer un porte-échantillon (40) et à recevoir de la lumière provenant du porte-échantillon (40), la tête de lecture (200) comprenant : un boîtier adapté pour être incorporé dans l'instrument de diagnostic (100) et adapté pour recevoir et supporter un porte-échantillon (40) ; une source lumineuse à réflectance comprenant une diode électroluminescente (20) montée à l'intérieur du boîtier dans une position fixe par rapport au porte-échantillon (40) ; un guide de lumière divergent (226), monté dans le boîtier pour recevoir de la lumière provenant de la diode électroluminescente (20) et adapté pour transporter pratiquement toute la lumière de la diode électroluminescente (20) vers le porte-échantillon (40) de sorte que le porte-échantillon (40) est illuminé sensiblement uniformément, le guide de lumière divergent (226) présentant une largeur relativement petite à un point adjacent à une entrée (226a) du guide de lumière divergent (226) et une largeur relativement grande à un point adjacent à une sortie (226d) du guide de lumière divergent (226) ; un détecteur de lumière (70) couplé pour recevoir de la lumière provenant du porte-échantillon (40); une source lumineuse d'excitation à fluorescence pour diriger une lumière d'excitation (310) d'une longueur d'onde prédéterminée vers le porte-échantillon (40) ; et un filtre de lumière (308) positionné entre le porte-échantillon (40) et le détecteur de lumière (70) et adapté pour empêcher le passage à travers celui-ci de la lumière d'excitation (310) de la source lumineuse d'excitation à fluorescence mais permettre le passage de lumière émissive (256) provenant du porte-échantillon (40) présentant une longueur d'onde différente de la longueur d'onde prédéterminée de la lumière d'excitation (310), où la source lumineuse d'excitation à fluorescence comprend une source lumineuse ultraviolette (302) positionnée dans une chambre de source lumineuse ultraviolette (300) à l'intérieur du boîtier, la chambre de source lumineuse ultraviolette présentant une ouverture (304) pour diriger de la lumière de la source lumineuse ultraviolette (302) dans la chambre d'illumination (244), où l'intérieur de la chambre de source lumineuse ultraviolette (300) est revêtu d'un film métallique.

3. Tête de lecture (200) pour un instrument de diagnostic (100) destiné à illuminer un porte-échantillon (40) et à recevoir la lumière provenant du porte-échantillon (40), la tête de lecture (200) comprenant : un boîtier adapté pour être incorporé dans l'instrument de diagnostic (100) et comprenant une chambre d'illumination (244) pour recevoir un porte-échantillon (40) ; une source lumineuse à réflectance comprenant une diode électroluminescente (20) sans lentille montée à l'intérieur du boîtier dans une position fixe par rapport à la chambre d'illumination (244) ; un guide de lumière (226), monté dans une position fixe par rapport à la diode électroluminescente (20) sans lentille, pour transporter la lumière de la diode électroluminescente (20) sans lentille vers un porte-échantillon (40) dans la chambre d'illumination (244) ; un détecteur de lumière (70) couplé pour recevoir la lumière provenant du porte-échantillon (40) ; une source lumineuse d'excitation à fluorescence positionnée dans le boîtier pour diriger la lumière d'excitation d'une longueur d'onde prédéterminée vers la chambre d'illumination (244) ; et un filtre de lumière (308) positionné entre la chambre d'illumination (244) et le détecteur de lumière (70) et adapté pour empêcher le passage à travers de celui-ci de la lumière d'excitation (310) de la source lumineuse d'excitation à fluorescence mais permettre le passage de lumière émissive (256) provenant d'un porte-échantillon (40) dans la chambre d'illumination (244) présentant une longueur d'onde différente de la longueur d'onde prédéterminée de la lumière d'excitation (310), où la source lumineuse d'excitation à fluorescence comprend une source lumineuse ultraviolette (302) positionnée dans une chambre de source lumineuse ultraviolette (300) à l'intérieur du boîtier, la chambre de source lumineuse ultraviolette présentant une ouverture (304) pour diriger la lumière de la source lumineuse ultraviolette (302) dans la chambre d'illumination (244), où l'intérieur de la chambre de source lumineuse ultraviolette (300) est revêtu d'un film métallique.

4. Tête de lecture (200) telle que définie dans l'une quelconque des revendications 1, 2 ou 3, dans laquelle la source lumineuse ultraviolette comprend une lampe fluorescente noire présentant une sortie de ligne à 364 nanomètres, 405 nanomètres et 436 nanomètres, et une sortie large bande à 330-385 nanomètres.

5. Tête de lecture (200) telle que définie dans la revendication 1, 2 ou 3, dans laquelle un miroir est positionné entre le détecteur de lumière (70) et le filtre de lumière (308).

6. Tête de lecture (200) telle que définie dans la revendication 1, 2 ou 3, dans laquelle une lentille est positionnée entre le détecteur de lumière (70) et le filtre de lumière (308) et adaptée pour concentrer la lumière sur le détecteur de lumière (70).

7. Instrument de diagnostic (100) comprenant une tête de lecture (200) telle que définie dans la revendication 1, 2 ou 3 et comprenant en outre un processeur connecté au détecteur de lumière (70) et programmé pour traiter des signaux électriques provenant du détecteur de lumière (70) pour déterminer une propriété physique d'un échantillon sur un porte-échantillon (40) reçu dans la chambre d'illumination (244) de la tête de lecture (200).

8. Instrument de diagnostic (100) tel que défini dans la revendication 7, dans lequel le processeur est programmé pour utiliser un modèle prédictif pour déterminer la propriété physique.

9. Tête de lecture (200) telle que définie dans la revendication 1 ou 3, dans laquelle le guide de lumière (226) comprend un guide de lumière divergent (226) présentant une largeur relativement petite à un point adjacent à une entrée (226a) du guide de lumière divergent (226) et une largeur relativement grande à un point adjacent à une sortie (226d) du guide de lumière (226).

10. Instrument de diagnostic (100) tel que défini dans la revendication 7, dans lequel la propriété physique comprend une concentration en glucose.

11. Tête de lecture (200) telle que définie dans l'une quelconque des revendications 1, 2 ou 3, dans laquelle la source lumineuse ultraviolette comprend une diode électroluminescente.

12. Tête de lecture (200) telle que définie dans la revendication 11, dans laquelle la diode électroluminescente comprend une diode électroluminescente verte à haute intensité.

13. Tête de lecture (200) telle que définie dans la revendication 11, dans laquelle la diode électroluminescente ultraviolette est positionnée à côté de la source lumineuse à réflectance et le guide de lumière (226) comprend du verre ou du quartz.

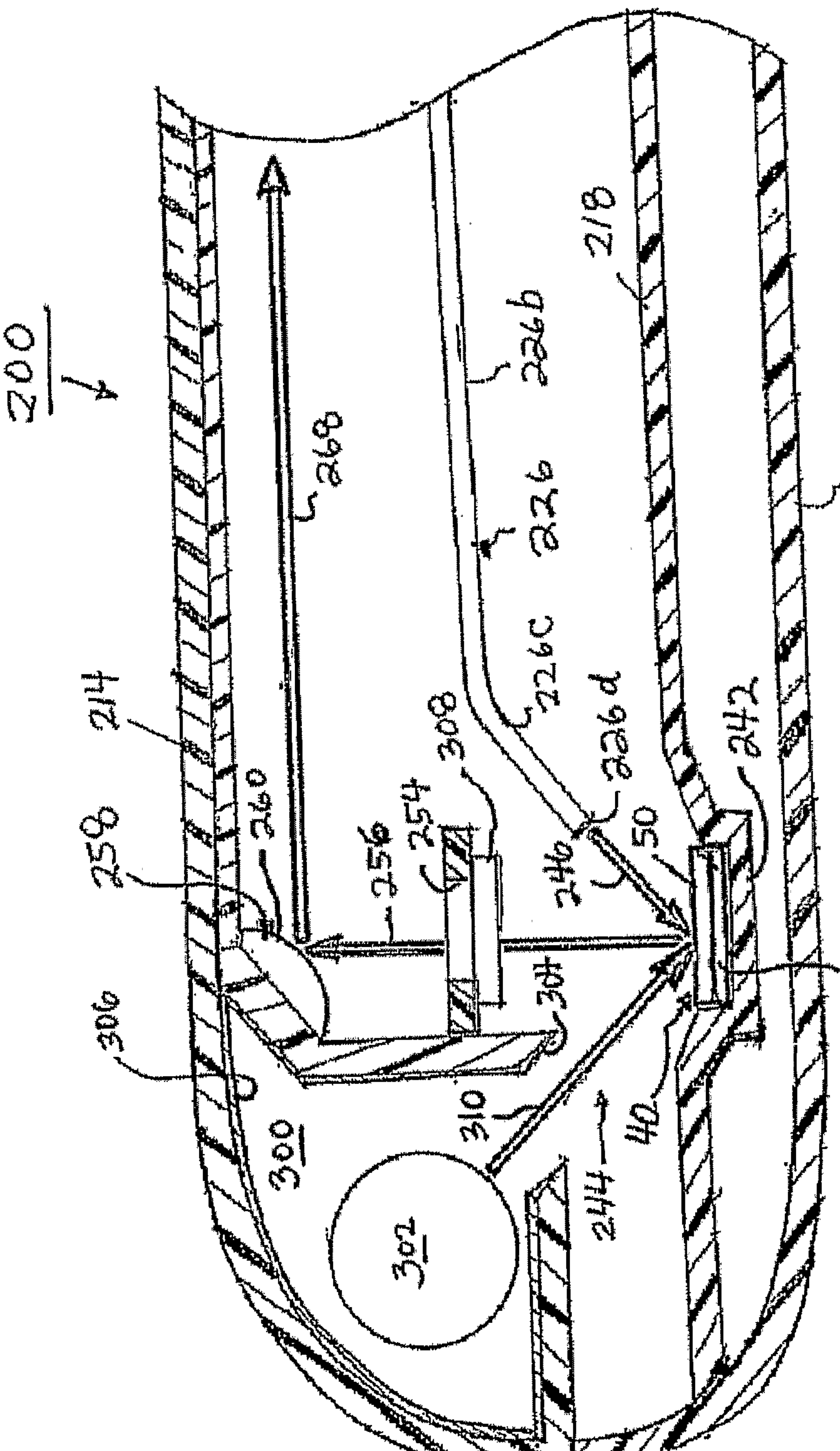
200
214
258
260
256
254
308
268
226b
226
226c
226d
240
50
242
41
40
244
310
304
306
300
302
218
216

FIG. 1

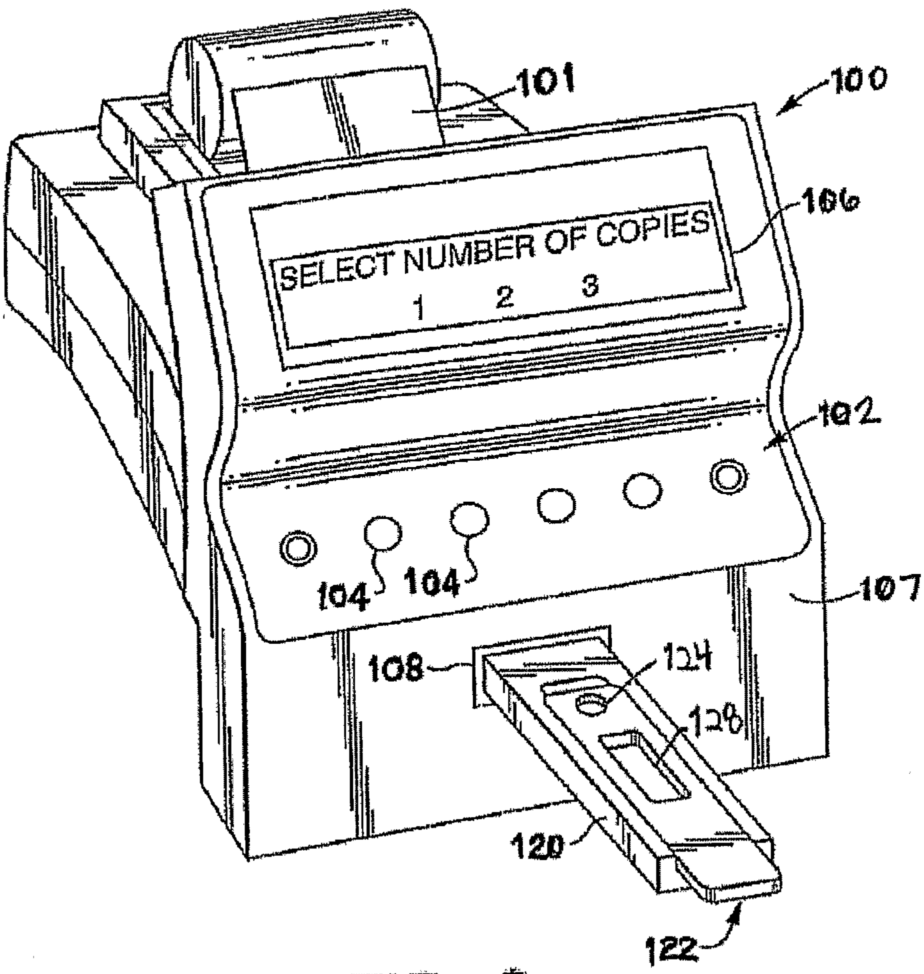

FIG. 2

(PRIOR ART)

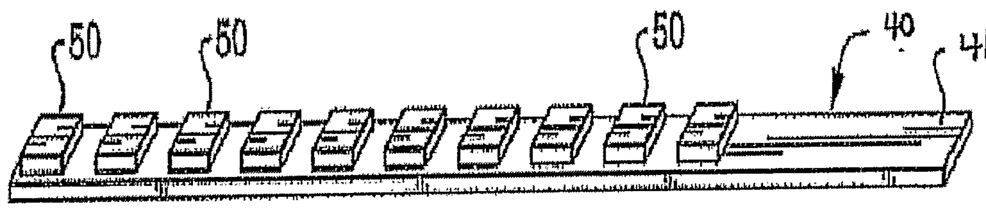

FIG. 3

(PRIOR ART)

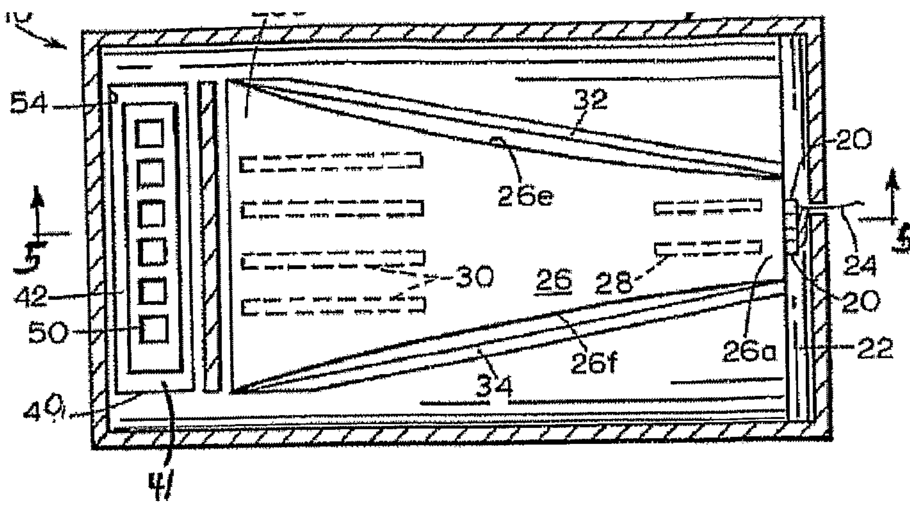

FIG. 4

(PRIOR ART)

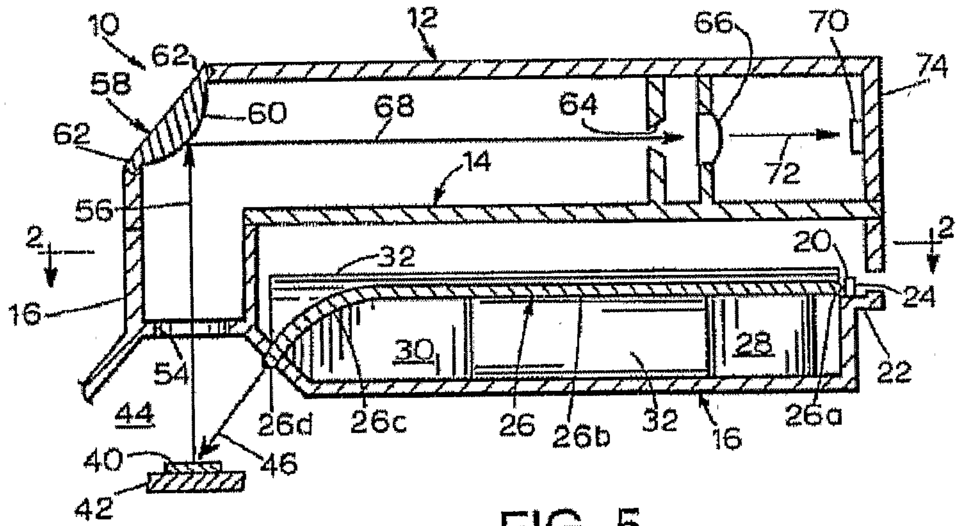

FIG. 5

(PRIOR ART)

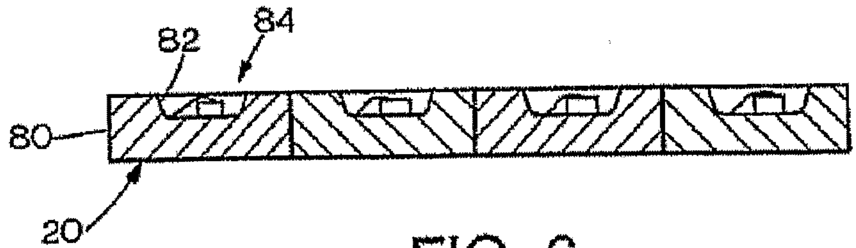

FIG. 6

(PRIOR ART)

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	光学检查仪器的红发		
公开(公告)号	EP1634062B1	公开(公告)日	2019-10-23
申请号	EP2004754753	申请日	2004-06-03
[标]申请(专利权)人(译)	拜尔健康护理有限责任公司		
申请(专利权)人(译)	拜耳医药保健有限责任公司		
当前申请(专利权)人(译)	西门子医疗诊断INC.		
[标]发明人	LEDDEN DAVID J		
发明人	STOCK, N. T., COED-Y-TWYN ROSS, G. D., ORCHARD OAK LEDDEN, DAVID, J.		
IPC分类号	G01N21/47 A61B5/00 G01N21/25 G01N21/84 G01N21/64 G01N21/86		
代理机构(译)	施韦泽KLAUS		
优先权	60/475288 2003-06-03 US		
其他公开文献	EP1634062A1		
外部链接	Espacenet		

摘要(译)

识别具有测试区域的测试产品包括在测试区域上以已知的测试波长照射一组测试信号。根据反射信号生成测试区域的图像。该图像由一组反射率值组成，将这些反射率值与测试信号波长处的参考反射率值进行比较，以确定测试产品的类型。

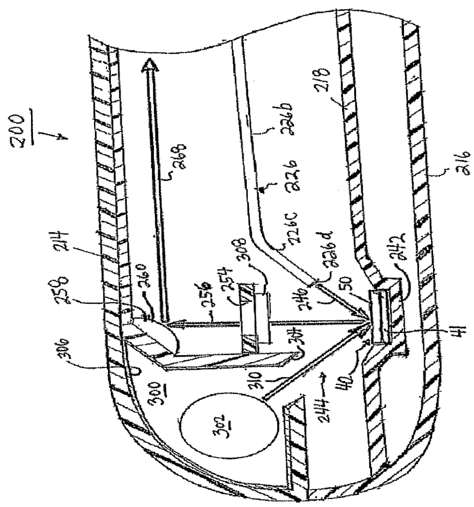

FIG. 1