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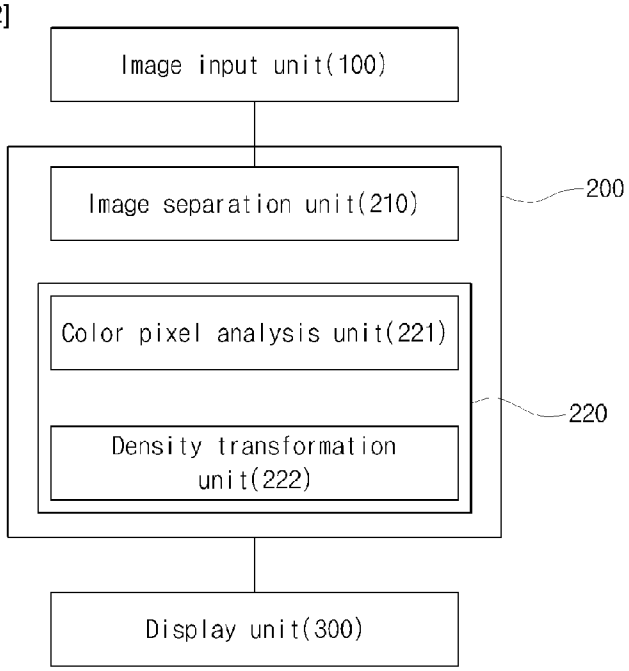
(54) **Title**: OPTICAL IN-VITRO DIAGNOSTIC APPARATUS AND A DIAGNOSIS METHOD USING THE SAME

[Fig. 2]



(57) **Abstract**: Provided is a high-efficiency optical in-vitro diagnostic apparatus, including: an image input unit inputting a color image of a target to be detected; an image controller forming the image at a density of a target to be detected by analyzing pixel intensity of an image input from the image input unit; and a display unit displaying result values of the transformed target density. The exemplary embodiment of the present invention can analyze the color images of the targets to be detected for each pixel and select and measure the color channel implementing the high-density pixel to obtain the image in the specific wavelength band capable of increasing the measured sensitivity using the color information of the color image, thereby increasing the measurement efficiency.

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Description

Title of Invention: OPTICAL IN-VITRO DIAGNOSTIC APPARATUS AND A DIAGNOSIS METHOD USING THE SAME

Technical Field

[1] The present invention relates to an optical in-vitro diagnostic apparatus capable of improving measurement efficiency.

Background Art

[2] Generally, an in-vitro diagnostic apparatus is medical equipment that performs a diagnosis by analyzing an assay under an environment composed in vitro for a predetermined purpose. Generally, the in-vitro diagnostic apparatus measures sugar, liver enzyme, calcium, salt, potassium, drug, or the like.

[3] FIG. 1 shows a strip structure used for immunochromatography frequently used in the in-vitro diagnostic apparatus. As shown in FIG. 1, a general immunochromatography strip 10 used for immunochromatography analysis is configured to include a elongated rectangular support 11 made of an adhesive plastic material, and a sample pad 21, a conjugate pad 22, a signal detection pad 23, and an absorbing pad 24 that are sequentially disposed on the support from one side of the support to the other side thereof. The sample pad 21 absorbs a liquid sample (or analysis sample) to be analyzed and ensures a uniform flow of the liquid sample. The conjugate pad 22 disposed to partially overlap the other end of the sample pad includes a flowable conjugate uniquely bound with an analysis material contained in the liquid sample. Therefore, the unique binding between the analysis material and the flowable conjugate is generated while the liquid sample introduced through the sample pad 21 passes through the conjugate pad 22. The signal detection pad 23 disposed at a position next to the sample pad 21 and the conjugate pad 22 is generally configured to include a detection zone 23a and a control zone 23b that are spaced apart from each other at a predetermined distance. In this case, the detection region 23a is a region for confirming whether the analysis material is present in the liquid sample and the control region 23b is a region to confirm whether the liquid sample normally passes through the detection regions 23a. The absorbing pad 24 is disposed at a position next to the signal detection pad 23, that is, at a position adjacent to the other end of the support 11. The absorbing pad 24 absorbs the liquid sample passing through the signal detection pad 23 and assists a capillary flow of the liquid sample on the immunochromatography strip 10.

[4] In particular, a measurement factor bound with a tagging particle in the detection region 23a is bound with an antibody and in the case of a colormetric in-vitro diagnosis apparatus, a density of a target to be measured is proportional to a color density of the

detection region by the tagging particle (for example, Au particle). The color density of the detection region is detected by using an image sensor such as CCD and CMOS, in particular, by using most monochrome devices in the case of the optical in-vitro diagnostic apparatus using the image sensor.

[5] Until now, it is difficult to apply the color image sensor in the case of the diagnostic apparatus performing quantitative analysis. The reason is that the image sensor serves to intentionally distort information on a wavelength input from a subject in order to replicate a human eye more sensitive to green than other color elements. Actually, in a bayer filter used for most color CCDs and CMOSs, a ratio of a pixel number to R, G, and B is 1 : 2 : 1.

[6] However, the diagnostic apparatus using the monochrome CCD and CMOS cannot acquire color information and cannot satisfy the measured sensitivity that may be implemented through differentiation color as well as cannot implement improvement in performance such as expansion of a linear period, or the like.

[7] Further, when the small in-vitro diagnostic medical equipment uses the monochrome image sensor, there is a problem in that the small in-vitro diagnostic medical equipment inevitably uses a physical optical filter when intending to improve the performance thereof by extracting only the signal in a specific wavelength band and is therefore inefficient in costs and manufacturing.

Disclosure of Invention

Technical Problem

[8] An object of the present invention is to provide in-vitro diagnostic apparatus and method analyzing color images of targets to be detected for each pixel and selecting and measuring a color channel implementing a high-density pixel to obtain an image in a specific wavelength band capable of increasing measured sensitivity using color information of a color image, thereby increasing measurement efficiency.

Solution to Problem

[9] To solve the above-mentioned problem, the exemplary embodiment of the present invention can improve the performance of the in-vitro diagnostic apparatus as compared with the use of the monochrome apparatus by separating R, G, B images from the color image of the assay captured from the color image device and using only the specific channel having the highest sensitivity for diagnostic measurement.

[10] According to an embodiment of the present invention, there is provided a high-efficiency optical in-vitro diagnostic apparatus, including: an image input unit inputting a color image of a target to be detected; an image controller forming the image at a density of a target to be detected by analyzing pixel intensity of an image input from the image input unit; and a display unit displaying result values of the

transformed target density.

[11] The image controller may be configured to include an image separation unit separating the input color image into red (R), green (G), and blue (B) channels and an image processor transforming the average intensity of any one of the separated channels into the density to be detected.

Advantageous Effects of Invention

[12] As set forth above, the exemplary embodiment of the present invention can analyze the color images of the targets to be detected for each pixel and select and measure the color channel implementing the high-density pixel to obtain the image in the specific wavelength band capable of increasing the measured sensitivity using the color information of the color image, thereby increasing the measurement efficiency.

[13] In addition, the exemplary embodiment of the present invention can implement the simplification of the structure and the high sensitivity of the detection performance by removing the configuration of the optical filter so as to obtain the specific wavelength band in the monochrome detection equipment according to the related art.

Brief Description of Drawings

[14] The above and other aspects, features and advantages of certain exemplary embodiments of the present invention will be more apparent from the following description taken in conjunction with the accompanying drawings, in which:

[15] FIG. 1 shows a strip structure used for immunochromatography frequently used in the in-vitro diagnostic apparatus;

[16] FIG. 2 is a configuration diagram showing a high-efficiency optical in-vitro diagnostic apparatus (hereinafter, referred to as the present apparatus) according to an exemplary embodiment of the present invention;

[17] FIGS. 3 and 4 are diagrams showing an exemplary embodiment actually implementing the above-mentioned apparatus;

[18] FIG. 5 is a flow chart of image analysis showing a process of transforming a color image acquired at the above-mentioned process into a final target density; and

[19] FIG. 6 is a diagram showing results obtained by comparing a measurement method according to the exemplary embodiment of the present invention with a monochrome image analysis method according to the related art.

Best Mode for Carrying out the Invention

[20] Exemplary embodiments of the present invention will be described below in detail with reference to the accompanying drawings. Wherever possible, the same reference numerals will be used to refer to the same elements throughout the specification, and a duplicated description thereof will be omitted. It will be understood that although the terms first, second , etc. are used herein to describe various elements, these elements

should not be limited by these terms. These terms are only used to distinguish one element from another element.

Mode for the Invention

[21] The gist of the present invention is to provide a diagnostic measurement apparatus implementing remarkable sensitivity and performance improvement as compared with a monochrome use by separating R, G, and B images from a color image of an assay captured from a color image device and using a specific channel having the highest sensitivity for analysis measurement.

[22] FIG. 2 is a configuration diagram showing a high-efficiency optical in-vitro diagnostic apparatus (hereinafter, referred to as the present apparatus) according to an exemplary embodiment of the present invention.

[23] Referring to the shown drawings, the present apparatus according to the exemplary embodiment of the present invention may include an image input unit 100 inputting a color image of a target to be detected, an image controller 200 forming the image at a density of a target to be detected by analyzing pixel intensity of an image input from the image input unit, and a display unit 300 displaying result values of the transformed target density.

[24] In particular, the image input unit 100 may be implemented by an imaging module that may input the color image of the target to be detected. In particular, as the exemplary embodiment according to the present invention, the image input unit 100 may be configured by the imaging module using the image sensor configured by a color CCD or a color CMOS.

[25] The image controller 200 performs a function of analyzing the image input from the image input unit 100, analyzing the pixel intensity, selecting the specific channel capable of implementing the highest sensitivity, obtaining an average intensity of the channel, and transforming the obtained average intensity into the density of the target to be measured. In detail, the image controller 200 may be configured to include an image separation unit 210 separating the input color image into red (R), green (G), and blue (B) channels and an image processor 220 transforming the average intensity of any one of the separated channels into the density to be detected. In particular, the image processor 220 may be configured to include a color filter analyzer 221 analyzing a distribution of the number of pixels for each intensity of the separated channel and a density transformer 222 transforming the average intensity of the channel in which the distribution of the pixel analyzed in the color pixel analyzer is the highest into the density of the target to be detected.

[26] FIGS. 3 and 4 are diagrams showing an exemplary embodiment actually implementing the above-mentioned apparatus.

[27] Referring to FIG. 3, the present apparatus may include a receiving module 400 receiving a target fixing unit receiving the target to be detected. The target fixing unit means an assay receiving a structure which fixes the target to be detected to a predetermined support. An example of the diagnostic kit may include the above-mentioned immunochromatography strip or a diagnostic kit including the same, or the like.

[28] In addition, the present apparatus may further include a lighting module 500 disposed on a top of the receiving module 400 to irradiate a predetermined amount of light and a lens module 600 disposed on a top of the lighting module to control a multiplication of the image and transfer the image to the image input unit 100.

[29] Further, the top of the lens module 600 may be provided with the image input unit 100 configured of the above-mentioned imaging module and the color image captured in the imaging module may be analyzed by being subjected to the image processing in the image controller including the image separator and the image processor software formed therein. The analyzed results may be represented on the display unit 300 and the display unit 300 may be implemented to control the operation of the entire equipment through GUI. In addition, the outside of the present apparatus may be provided a housing H as shown in FIG. 3B.

[30] The method of measuring the target to be detected using the above-mentioned apparatus may be made through the following processes.

[31] In detail, a process of applying light to the detection region in which the target to be detected is present and inputting the color image of the detection region through the imaging module using the image sensor configured by the color CCD or the color CMOS may be performed.

[32] Thereafter, a process of separating the color image into red (R), green (G), and blue (B) channels may be performed and a process of transforming the average intensity of any one of the separated channel into the density of the target to be detected may be performed. In detail, the average intensity having the channel in which the distribution of the pixel is highest by analyzing the distribution of the number of pixels for each intensity of the separated channel may be transformed into the target density using the inverse proportional relationship with the target to be detected.

[33] Of course, it is possible to mix one or more channel, that is, the plurality of channels rather than one channel and transform the mixed channels into the target density. In this case, at least one channel may perform the analysis of each channel with the same or different weights, which means, for example, the case in which it is possible to analyze the detection region of the wavelength band capable of maximizing the sensitivity by a combination of two channels by processing the pixel intensity used for the analysis by using a combination of a G channel having a weight of 0.7 and a B channel having a weight of 0.3 such as 0.7 x G + 0.3 x B.

[34] Thereafter, the measured results may be displayed based on the target density.

[35] FIG. 5 is a flow chart of image analysis showing a process of transforming a color image acquired at the above-mentioned process into a final target density.

[36] As the shown image, the detection target is first considered as the lateral flow assay and the color image of the lateral flow assay acquired through the imaging module is separated into red (R), green (G), and blue (B) channels as shown in FIG. 5 (S1).

[37] The shown region of interest (ROI) shows a portion (test line portion) of the entire image in which the actual image analysis is performed and acquired. The histogram of each channel intensity of the ROI portion shows a distribution S2 to S4 of the number of pixels for each intensity of each color and the obtained average intensity is transformed into the target density to be obtained.

[38] In the case of the particle color used in the present test, the measured sensitivity for each target density at the B channel is best. Therefore, the average intensity of the B channel is obtained and is transformed into the target density to be measured, which is used for measurement.

[39] However, in the configuration of the present apparatus, as described above, the selection of the color channel having the excellent sensitivity may be taken differently according to the colors. The plurality of color channels may be mixed in some cases.

[40] FIG. 6 is a diagram showing results obtained by comparing a measurement method according to the exemplary embodiment of the present invention with a monochrome image analysis method according to the related art.

[41] The configuration of the measurement using the monochrome CCD according to the related art is the same by disposing the monochrome CCD in the image input unit according to the exemplary embodiment of the present invention for accurate comparison results. The color (with bayer mask) camera and the monochrome (without bayer mask) camera having the same specifications are compared so as to exclude the difference in performance according to the camera specifications. In addition, the same ROI is used in the case of the color analysis in processing the monochrome image. That is, the average pixel intensity within the obtained ROI is obtained through the monochrome histogram. In drawings shown, an x axis represents a density of an indicator (particle) that may be considered to be equal to the target material and a y axis represents the intensity when no particles are present (intensity at the time of normalization based on I (0) value). As shown in the drawings, the measured sensitivity when performing the analysis using the color CCD according to the exemplary embodiment of the present invention and the blue (B) channel of the captured image.

[42] While the invention has been shown and described with reference to exemplary embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of

the invention as defined by the appended claims. Therefore, the scope of the invention is defined not by the detailed description of the invention but by the appended claims, and all differences within the scope will be construed as being included in the present invention.

Claims

[Claim 1] A high-efficiency optical in-vitro diagnostic apparatus, comprising:
an image input unit inputting a color image of a target to be detected;
an image controller forming the image at a density of a target to be detected by analyzing pixel intensity of an image input from the image input unit; and
a display unit displaying result values of the transformed target density.

[Claim 2] The apparatus of claim 1, wherein the image input unit includes an imaging module using an image sensor configured by a color CCD or a color CMOS.

[Claim 3] The apparatus of claim 1, wherein the image controller includes an image separation unit separating the input color image into red (R), green (G), and blue (B) channels; and
an image processor transforming the average intensity of any one of the separated channels into the target density using an inverse proportional relationship with the target to be detected.

[Claim 4] The apparatus of claim 3, wherein the image processor includes:
a color filter analyzer analyzing a distribution of the number of pixels for each intensity of the separated channel; and
a density transformer transforming the average intensity of at least one channel into the target concentration to be detected based on a distribution for each target of pixels analyzed in the color pixel analyzer.

[Claim 5] The apparatus of claim 4, wherein the density transformer mixes at least one channel separated in the image separator and transforms the average intensity into the target concentration to be detected by combining the at least one channel to which the same or different weights are applied.

[Claim 6] The apparatus of claim 3, further comprising a receiving module receiving a target fixing unit receiving the target to be detected.

[Claim 7] The apparatus of claim 6, wherein the target fixing unit is an immunochromatography strip or a diagnostic kit including the immunochromatography strip.

[Claim 8] The apparatus of claim 6, wherein the target to be detected is a lateral flow assay.

[Claim 9] The apparatus of claim 6, further comprising a lighting module disposed on a top of the receiving module to irradiate a predetermined amount of light.

[Claim 10] The apparatus of claim 9, further comprising a lens module disposed on a top of the lighting module to control a multiplication of the image and transfer the multiplied image to the image input unit.

[Claim 11] The apparatus of claim 10, wherein the lens module further includes an optical filer that selects and transmits a specific wavelength.

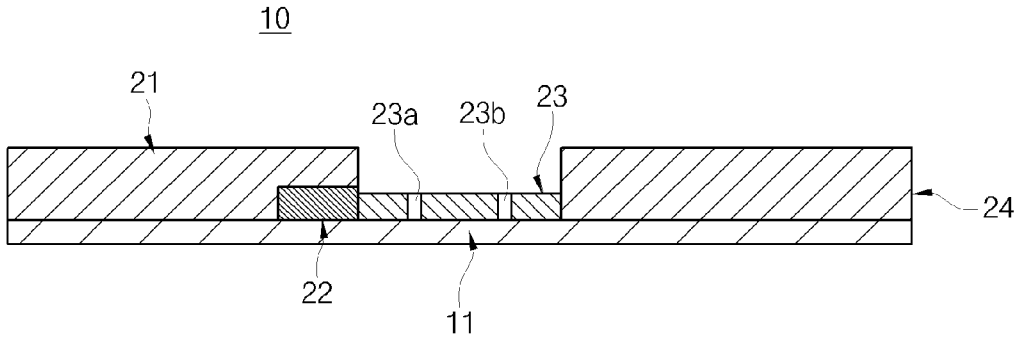
[Claim 12] A high-efficiency optical in-vitro diagnostic method, comprising:
applying light to a detection region in which a target to be detected is present and inputting a color image of the detection region;
separating the color image into red (R), green (G), and blue (B); and
transforming an average intensity of any one of the separated channels into a target density.

[Claim 13] The method of claim 12, wherein the inputting inputs a color image to the detection region through an imaging module using an image sensor configured by a color CCD or a color CMOS.

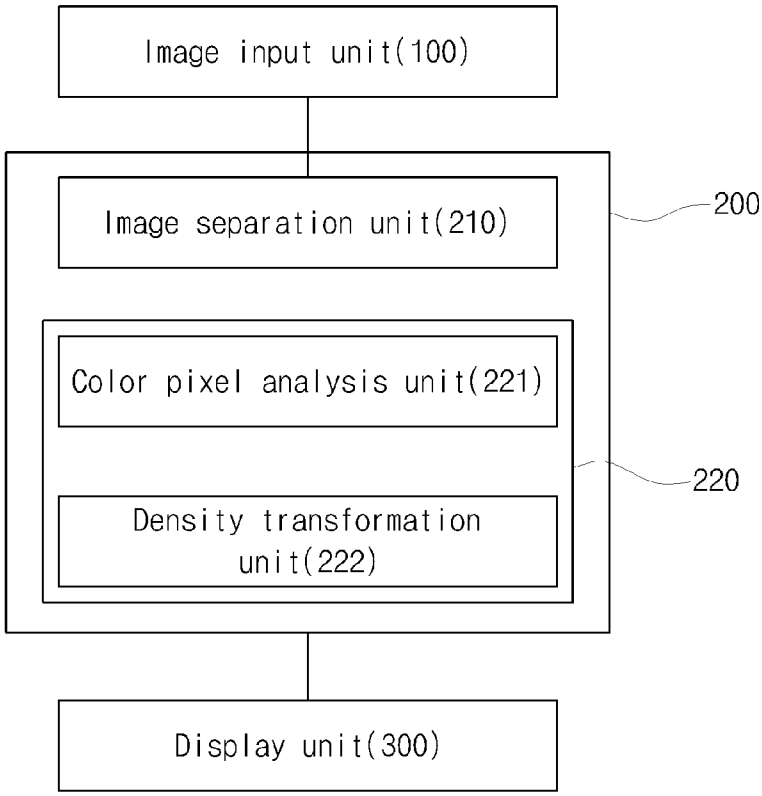
[Claim 14] The method of claim 7, wherein the transforming transforms an the average intensity of the channel having the highest sensitivity (change) of a change in pixel by analyzing a distribution of the number of pixels for each intensity and a relationship for each target density of the separated channels into the target density by using an inverse proportional relationship with the target to be detected.

[Claim 15] The method of claim 7, wherein the transforming analyzes the distributions of the number of pixels for each intensity of the separated channels and the relationship for each target density and transforms the average intensity by combining at least one channel to which the same or different weights are applied into the target density of the target to be detected.

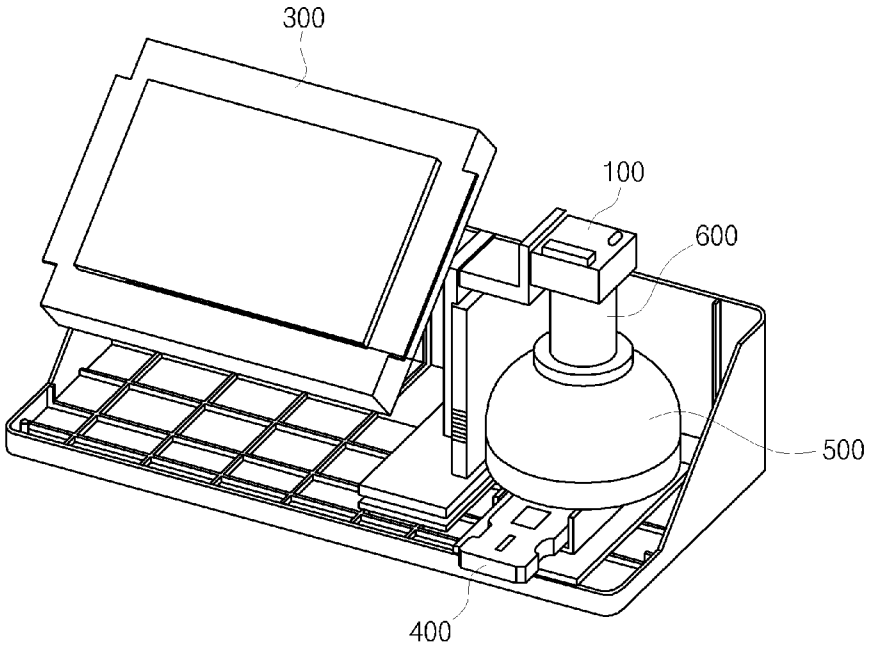
[Fig. 1]



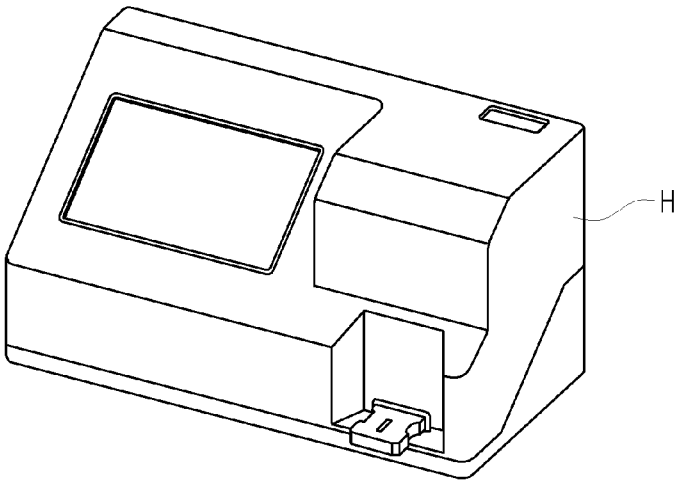
[Fig. 2]



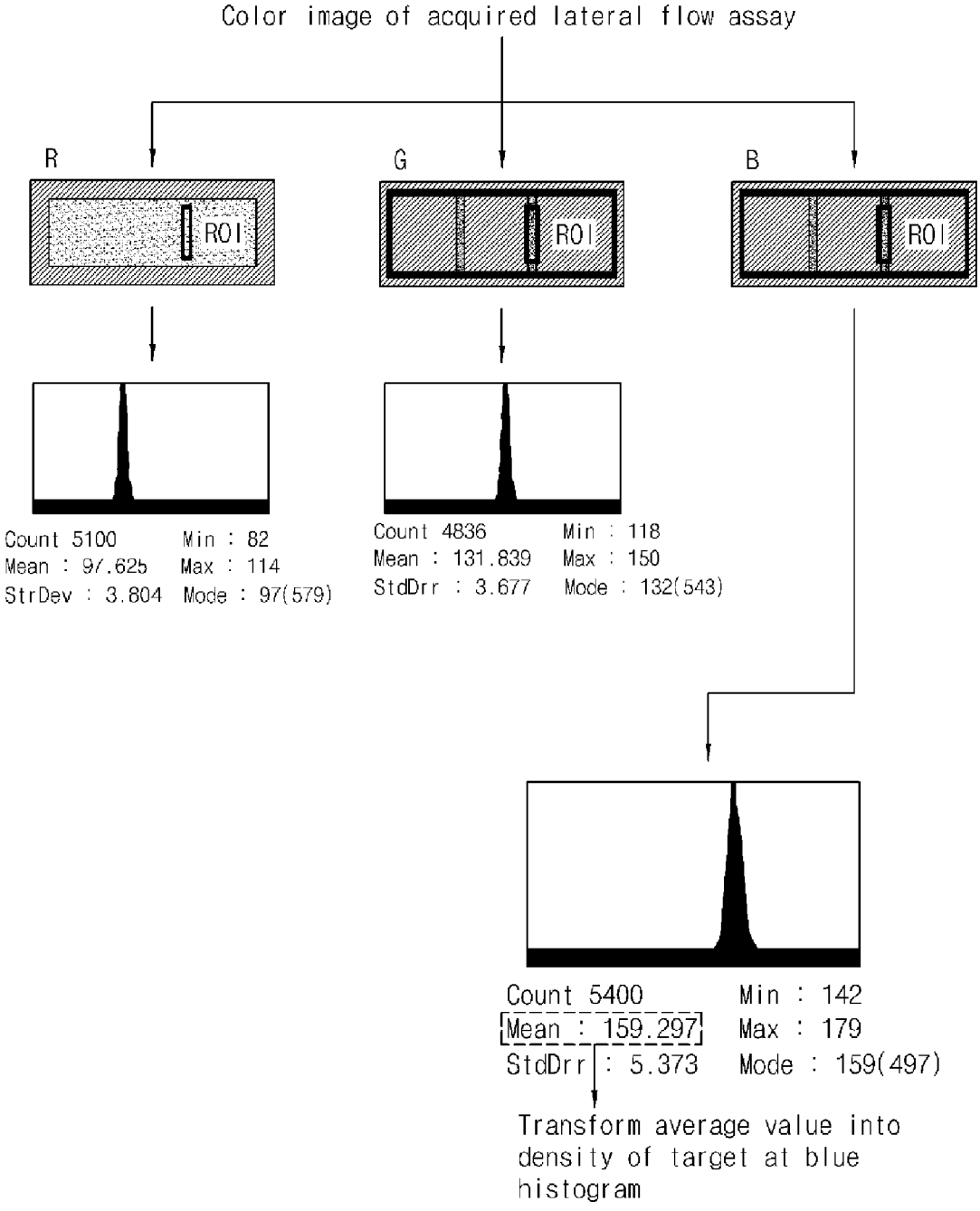
[Fig. 3]



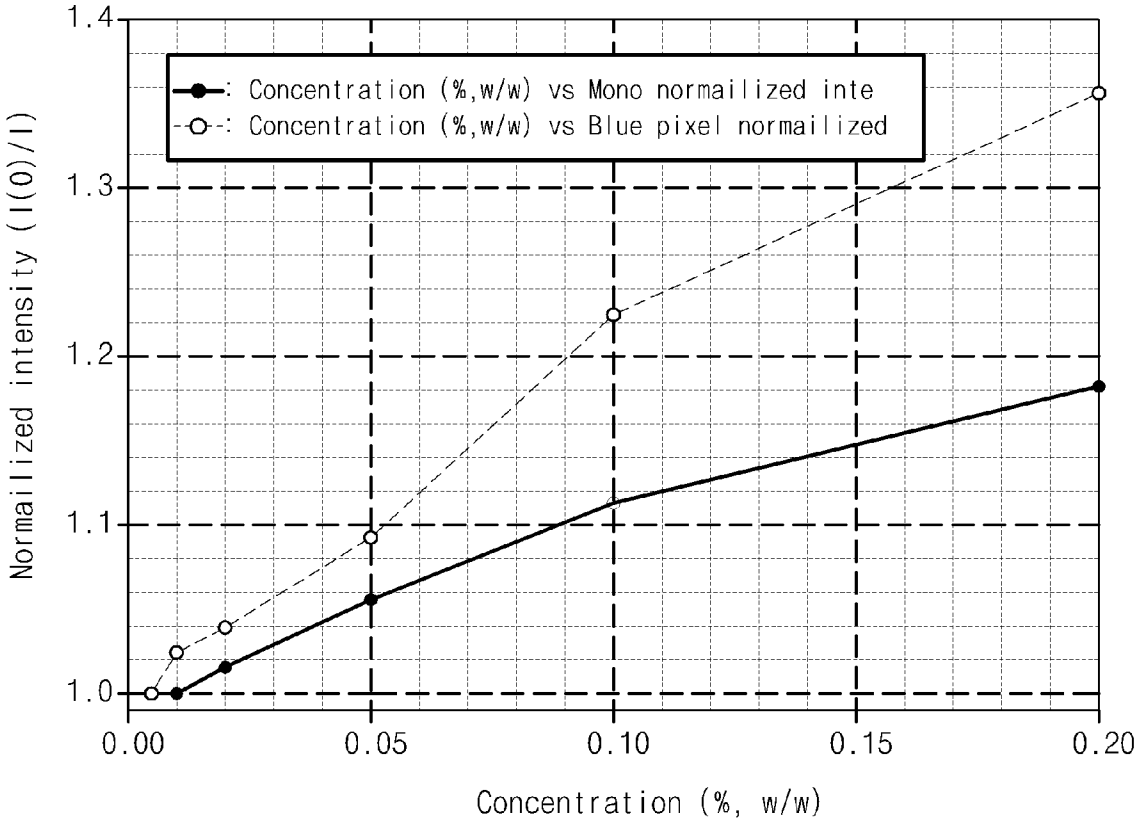
[Fig. 4]


H

[Fig. 5]


Color image of acquired lateral flow assay
R
G
B
ROI
ROI
ROI
Count 5100
Mean : 97.625
StrDev : 3.804
Min : 82
Max : 114
Mode : 97(579)
Count 4836
Mean : 131.839
StdDrr : 3.677
Min : 118
Max : 150
Mode : 132(543)
Count 5400
Mean : 159.297
StdDrr : 5.373
Min : 142
Max : 179
Mode : 159(497)
Transform average value into density of target at blue histogram

[Fig. 6]


Concentration (%,w/w) vs Mono normailized inte
Concentration (%,w/w) vs Blue pixel normailized
Normailized intensity (I(0)/I)
1.4
1.3
1.2
1.1
1.0
0.00
0.05
0.10
0.15
0.20
Concentration (%, w/w)