



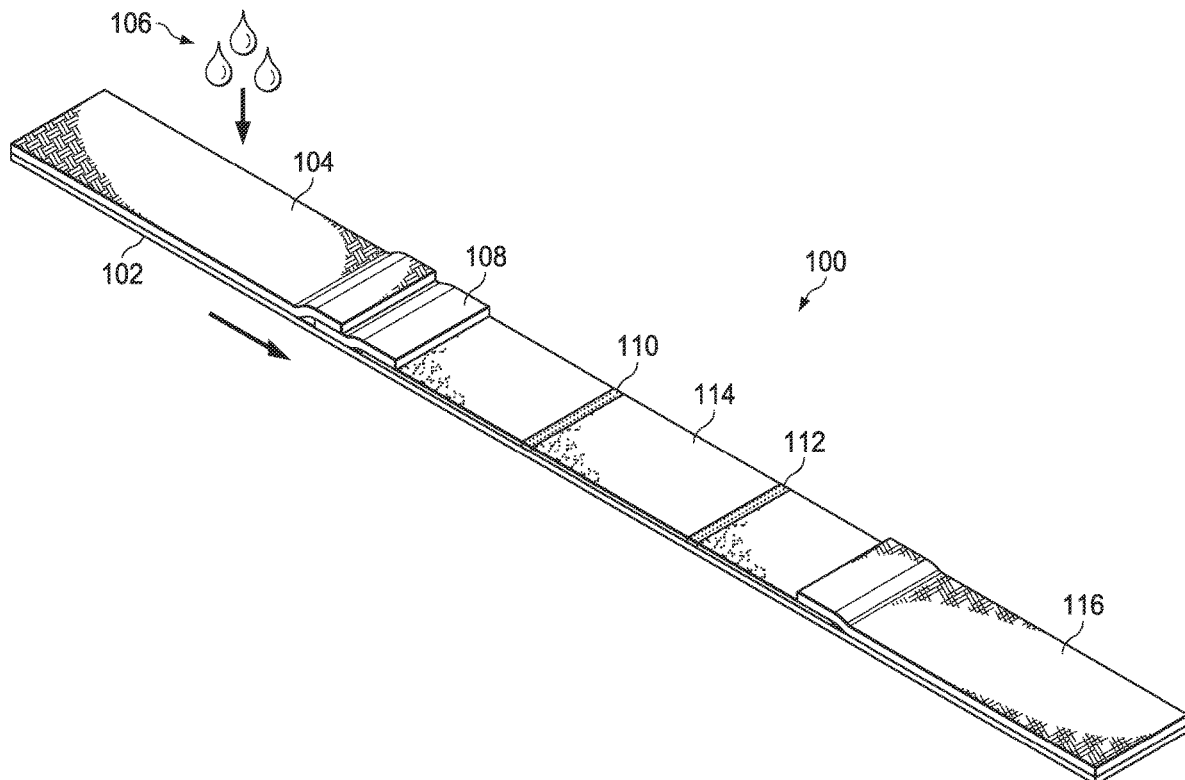
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(19) **United States**(12) **Patent Application Publication**
PULITZER et al.(10) **Pub. No.: US 2019/0384890 A1**(43) **Pub. Date: Dec. 19, 2019**(54) **SYSTEM AND METHOD FOR DIGITAL
REMOTE PRIMARY, SECONDARY, AND
TERTIARY COLOR CALIBRATION VIA
SMART DEVICE IN ANALYSIS OF MEDICAL
TEST RESULTS****G01N 33/76** (2006.01)**G01N 33/53** (2006.01)**G06T 7/90** (2006.01)(52) **U.S. CL.****CPC** **G06F 19/708** (2013.01); **G01N 33/56983**(2013.01); **G01N 33/76** (2013.01); **G06T****2207/30204** (2013.01); **G06T 7/90** (2017.01);**G01N 2333/59** (2013.01); **G01N 2333/185**(2013.01); **G01N 33/5302** (2013.01)(71) Applicant: **RELIANT IMMUNE
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(57)

ABSTRACT

A method for providing immunoassay test results includes collecting at least one biologic with a testing device, conjugating the biologic with particles on a conjugate pad of a test strip to create an immune complex, binding antigens or antibodies of the immune complex to antigens or antibodies of a test line, providing a software application to be stored on a mobile device having a camera; capturing an image of the testing device, including a color mosaic having at least one color value corresponding to a positive test result, comparing the color values of the test line image to the color values of the image of the color mosaic, determining if the color values of the image of the test line are within a predetermined range of the at least one color value of the image of the color mosaic corresponding to a positive test result; and presenting test results on the viewing screen.



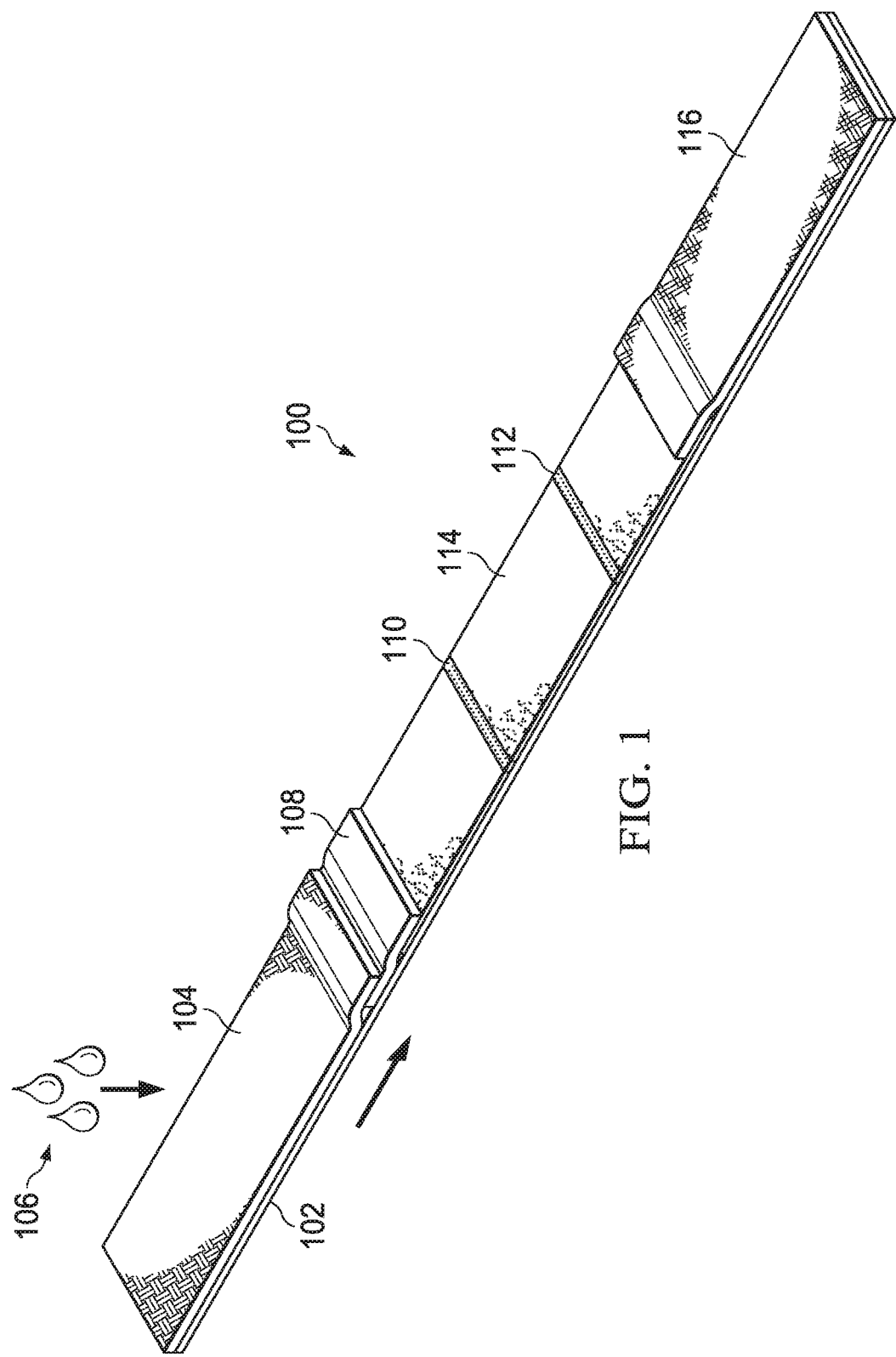


FIG. 1

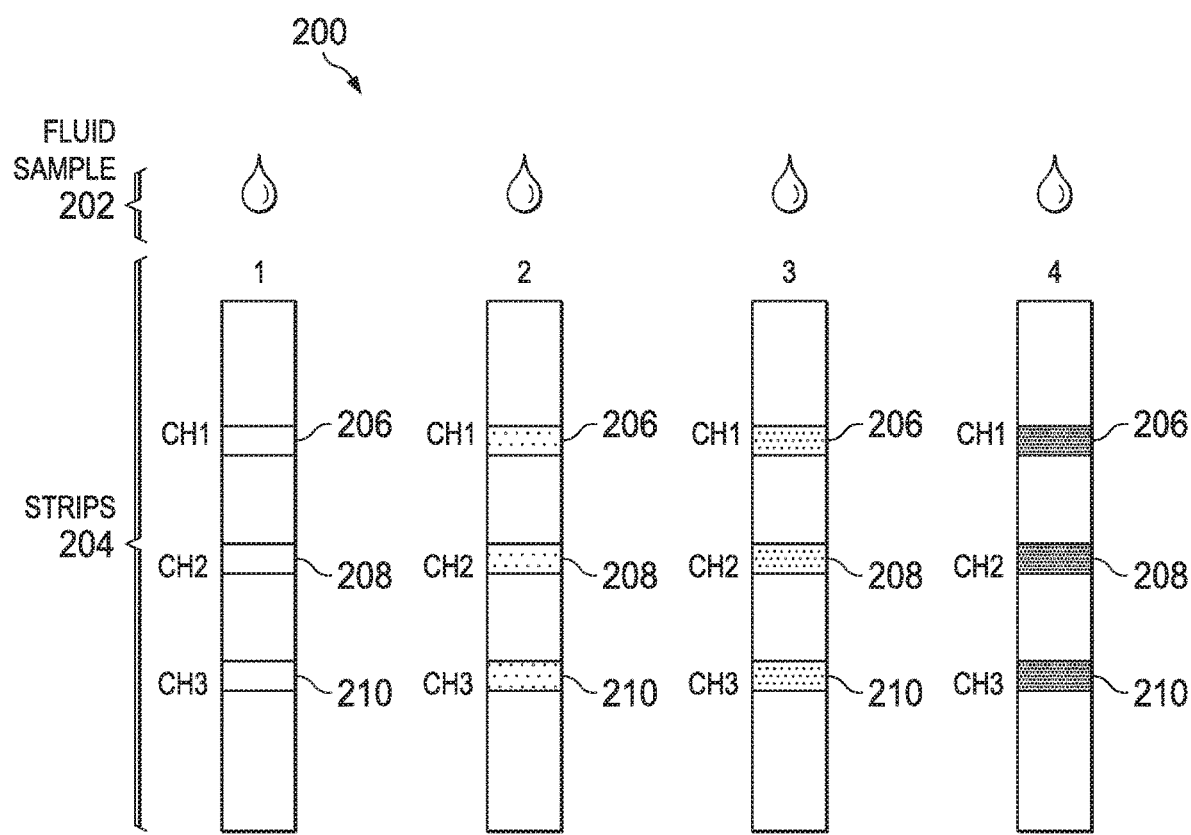


FIG. 2

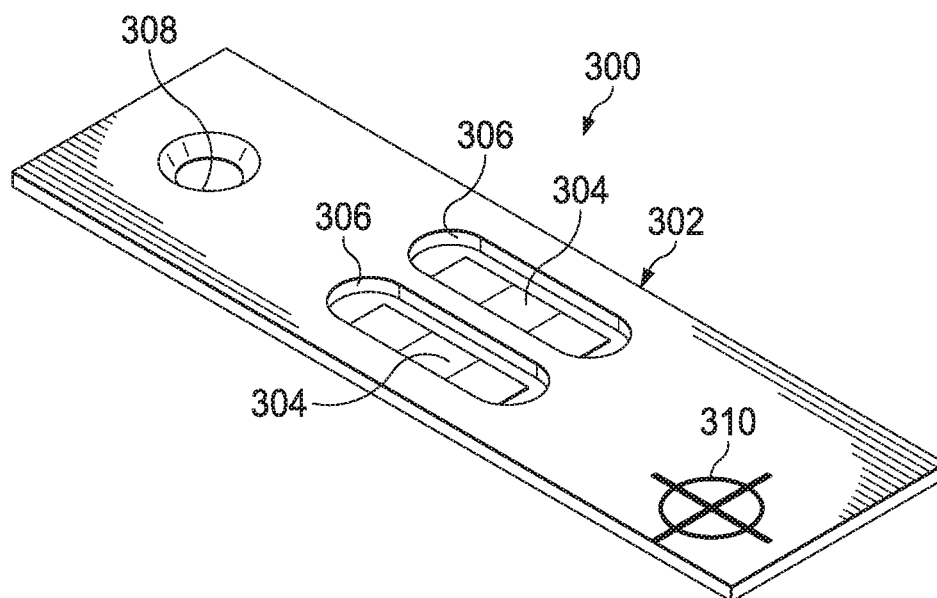


FIG. 3

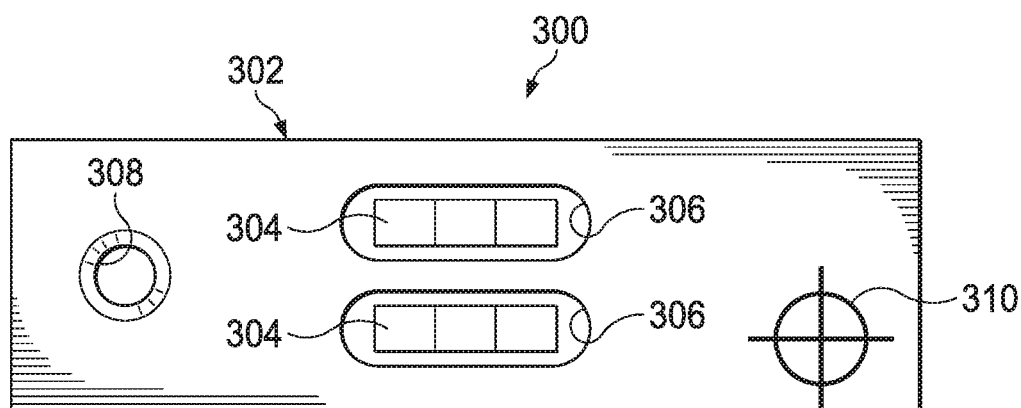


FIG. 4

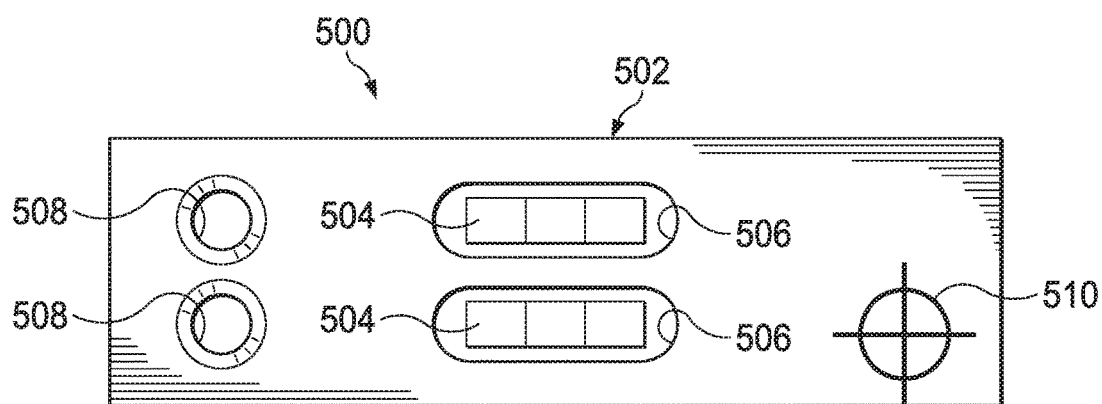


FIG. 5

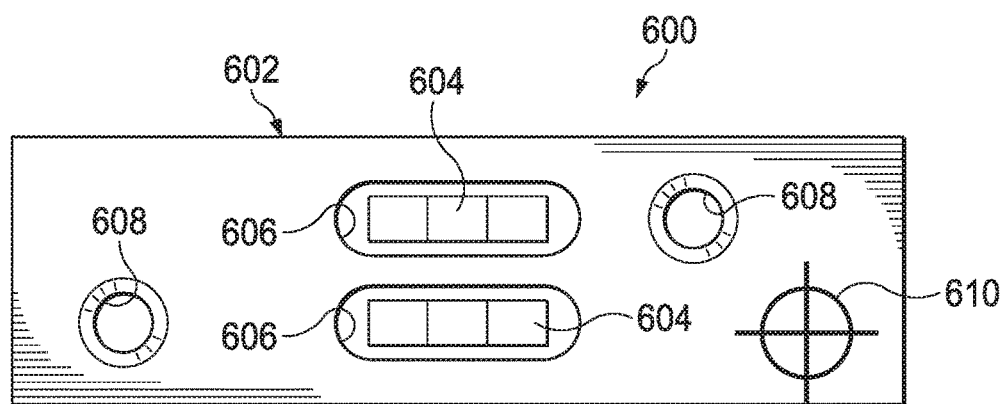


FIG. 6

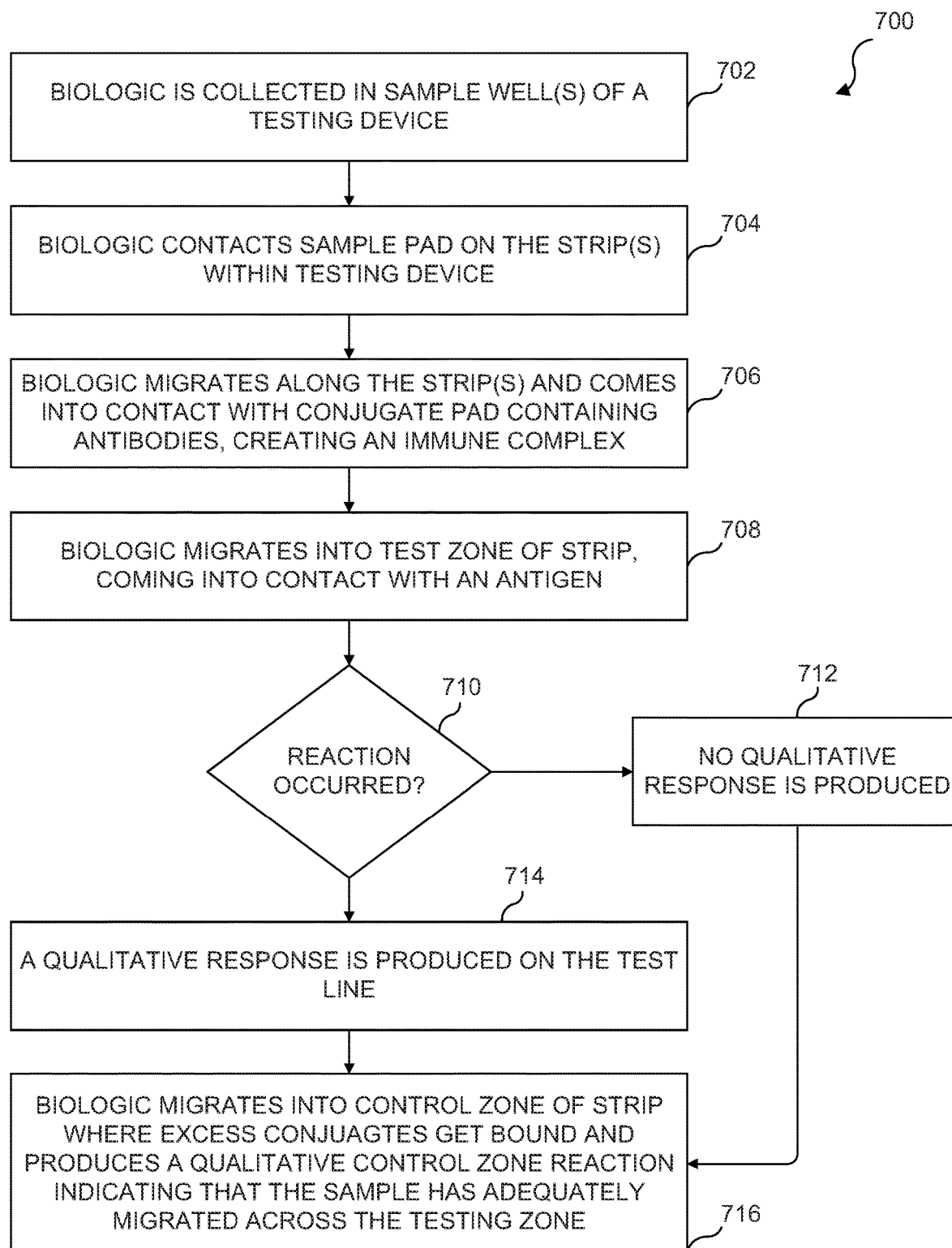


FIG. 7

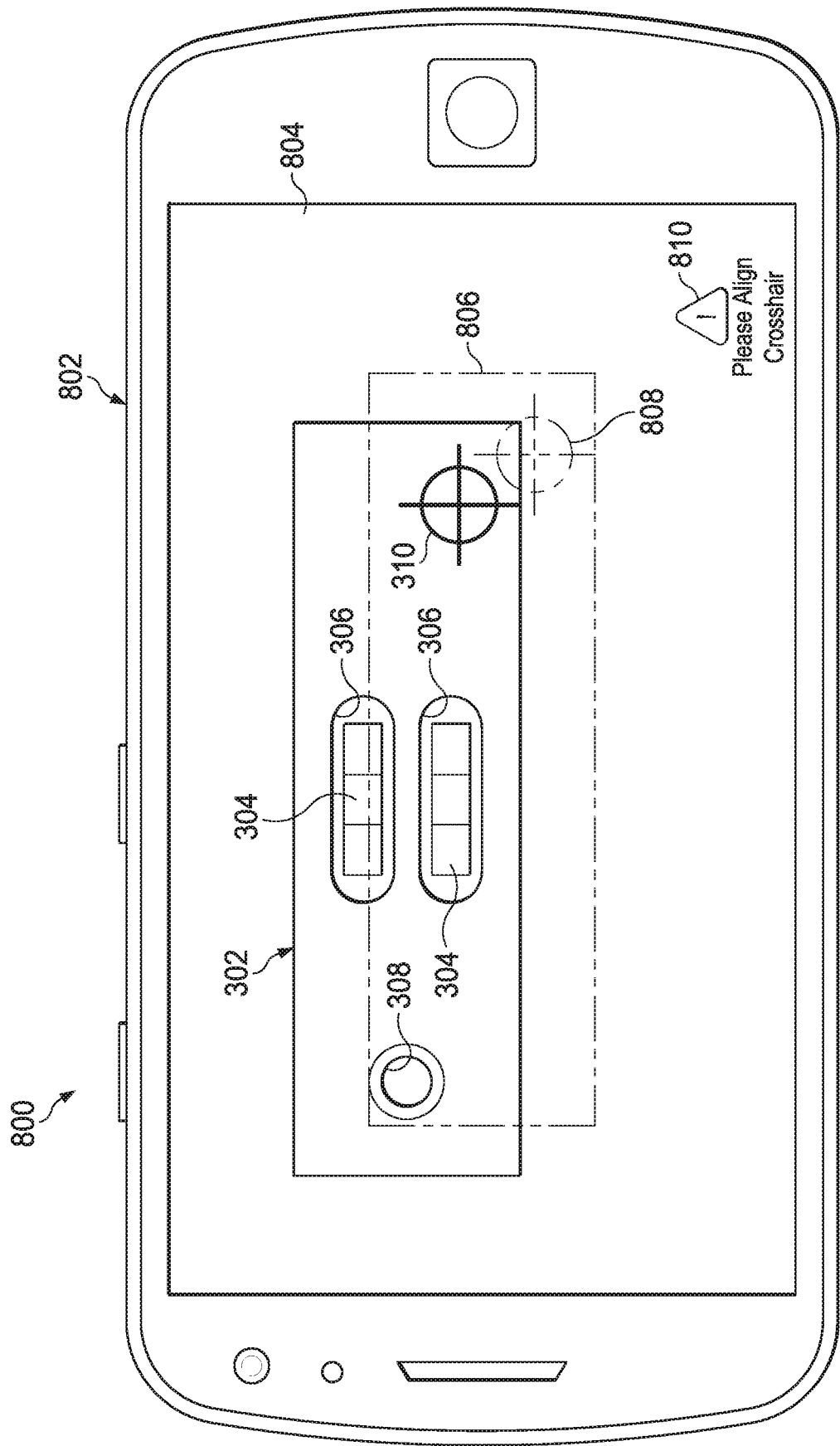


FIG. 8A

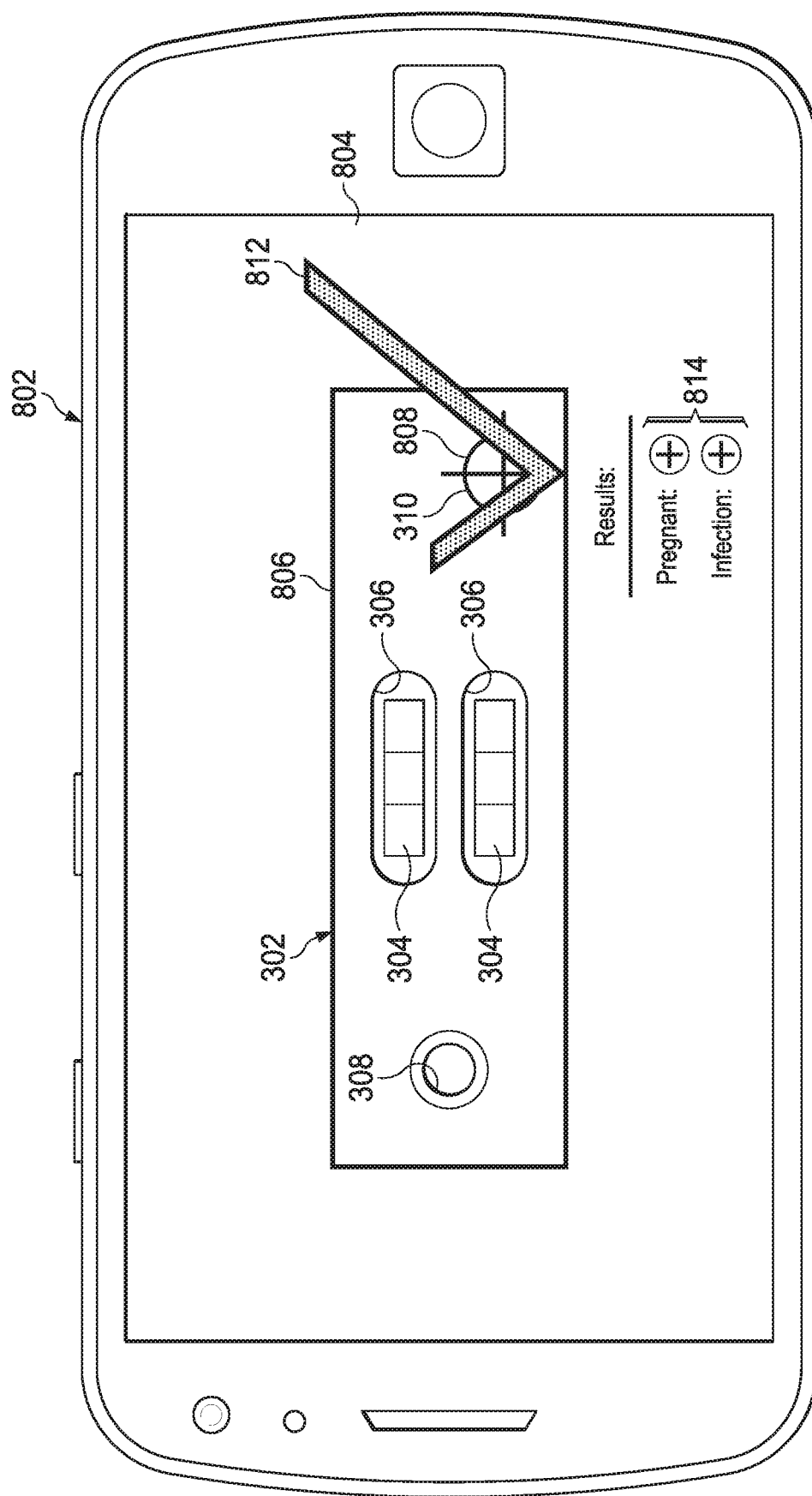


FIG. 8B

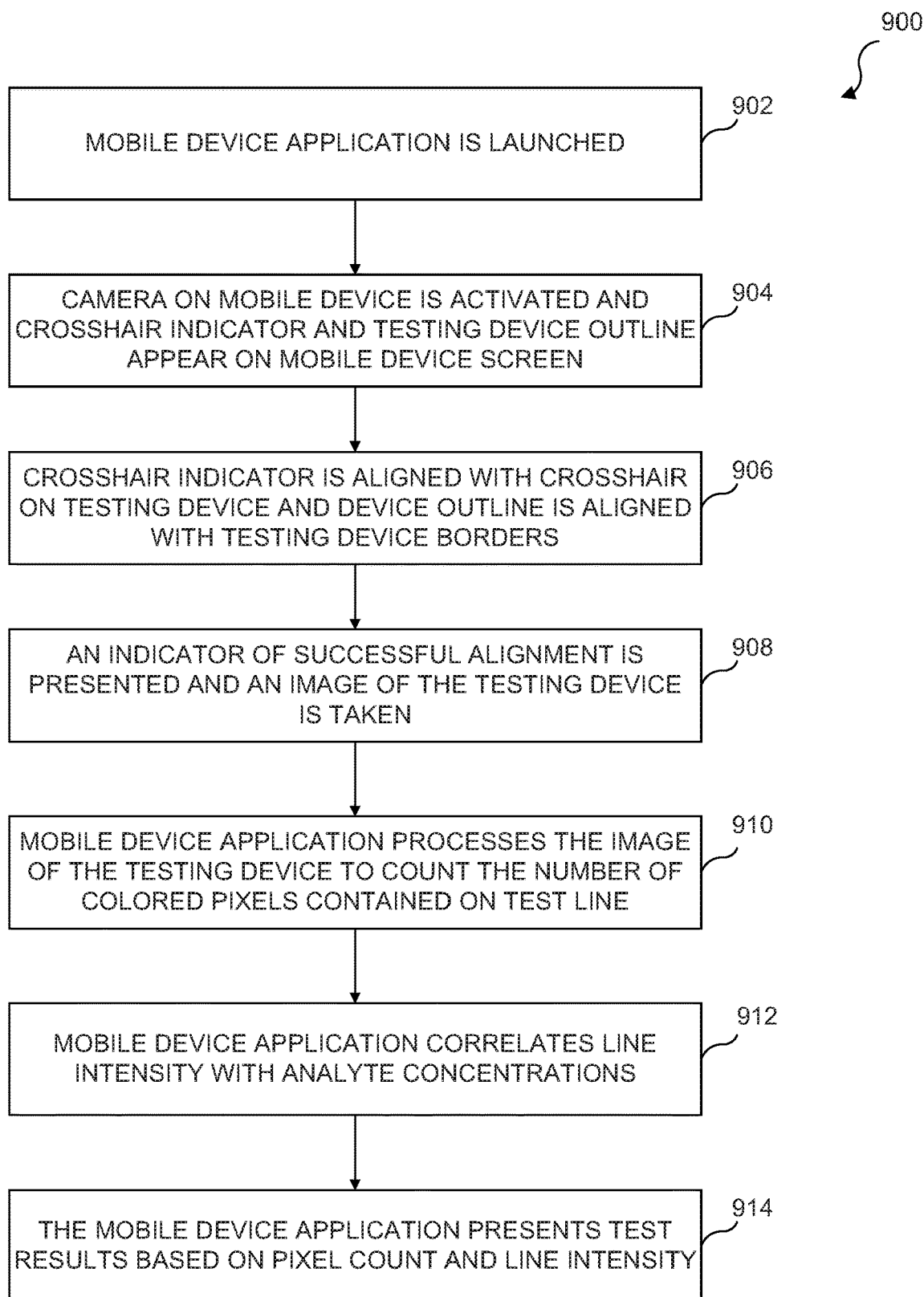


FIG. 9

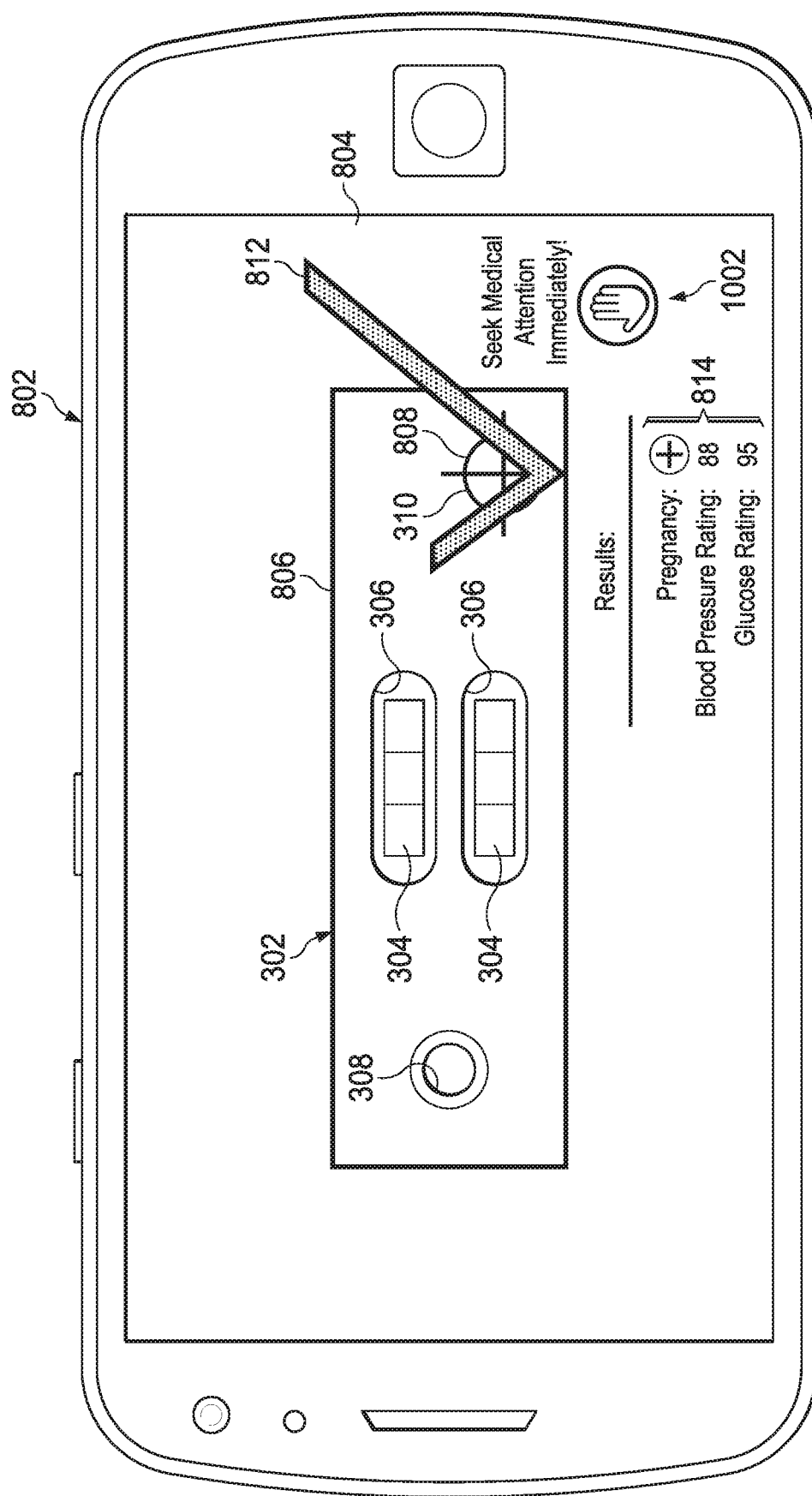


FIG. 10

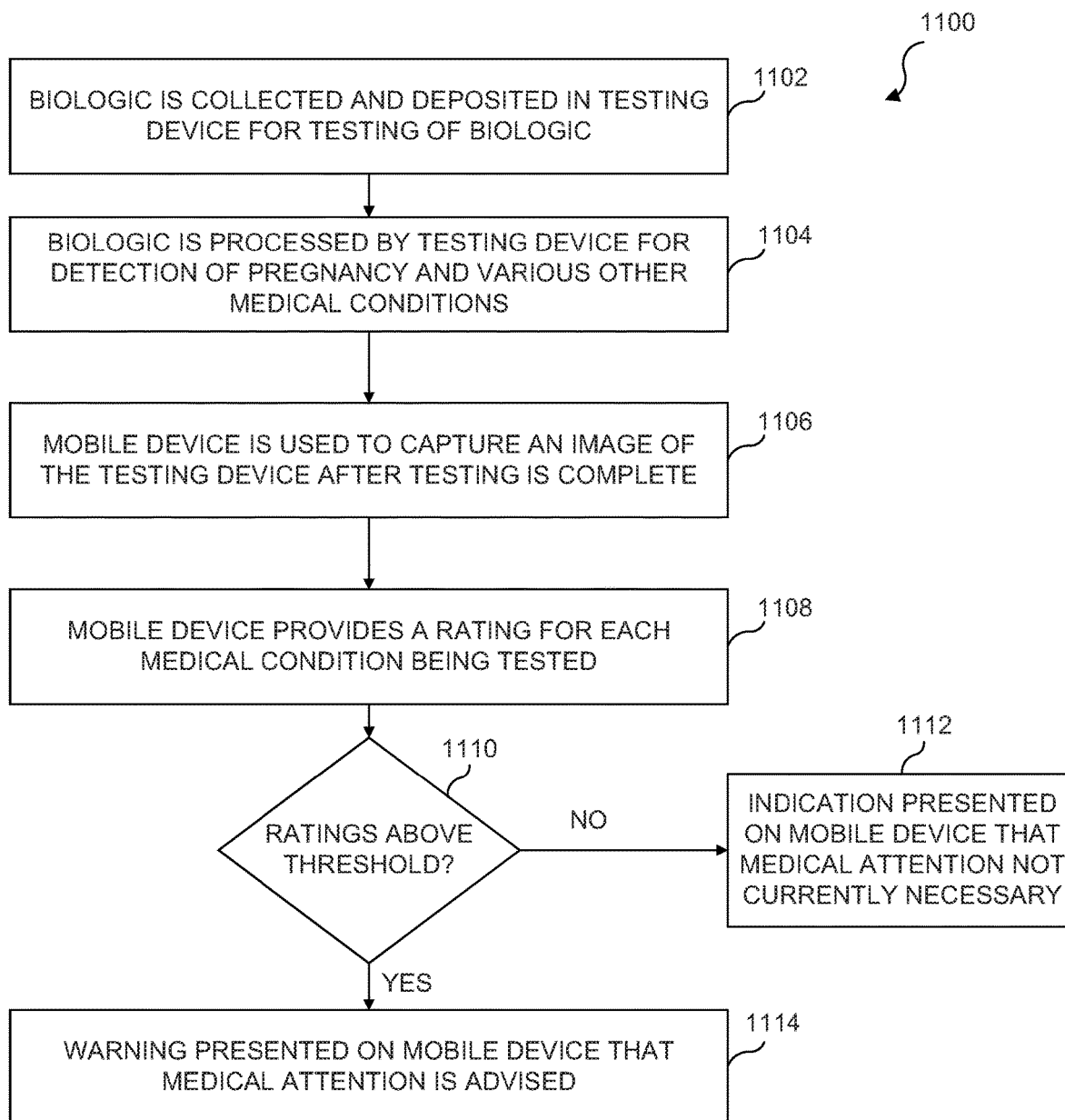


FIG. 11

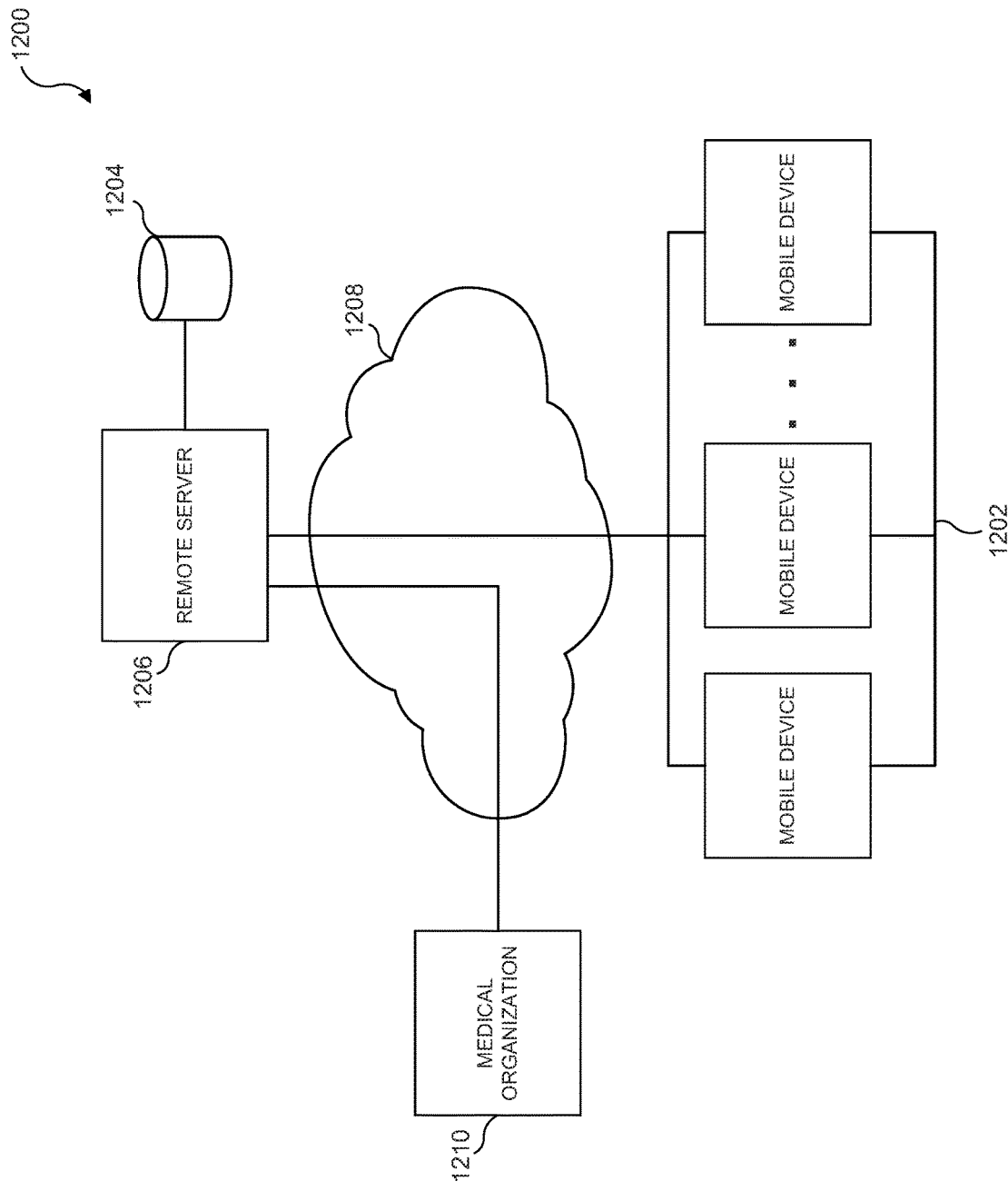


FIG. 12

1300

BIOLOGIC ID # 2402	
BIOLOGIC TYPE	BLOOD
PREGNANCY RATING	99
ZIKA INFECTION RATING	75
GLUCOSE RATING	10

1302

1304

1304

FIG. 13

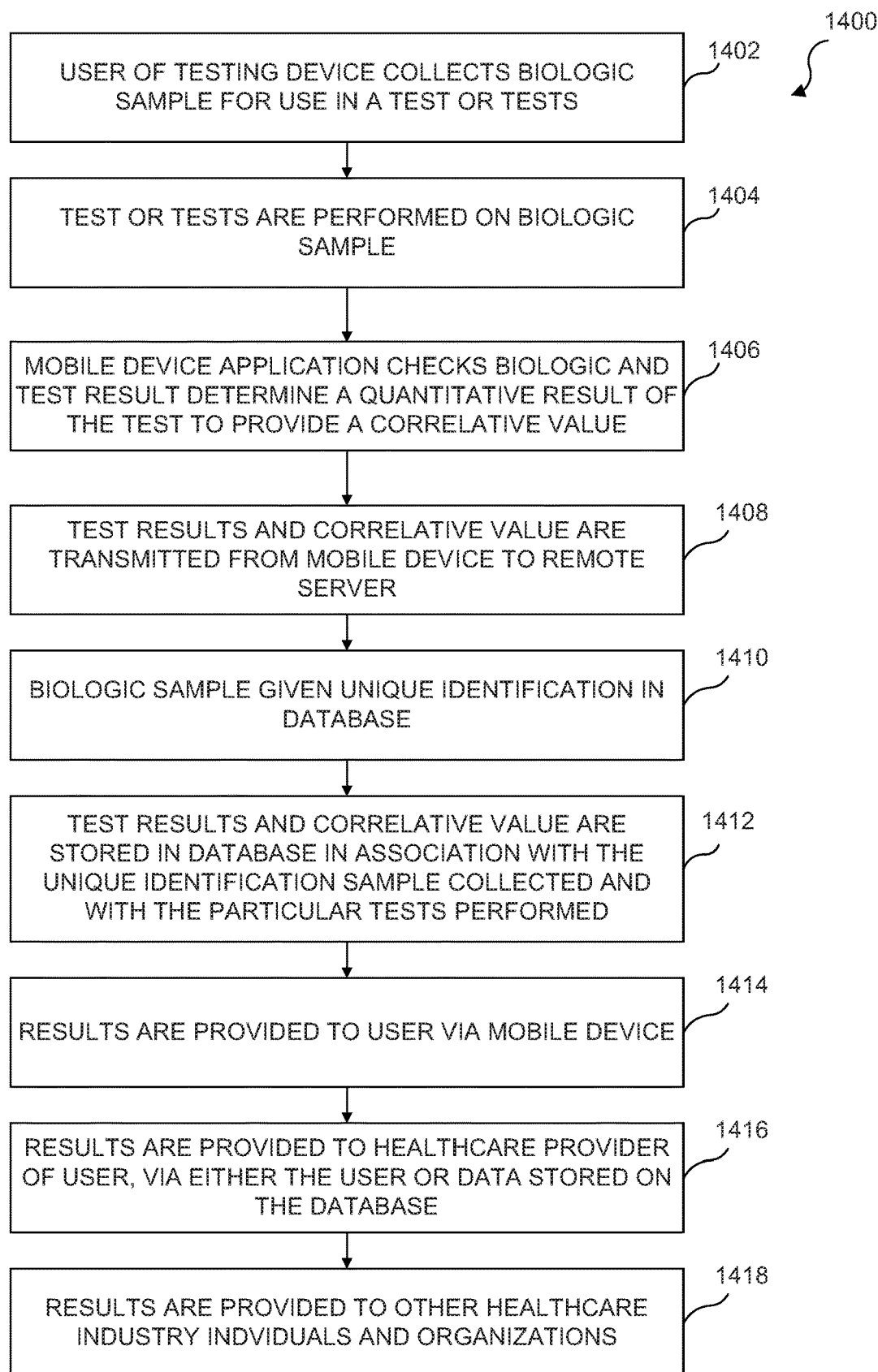
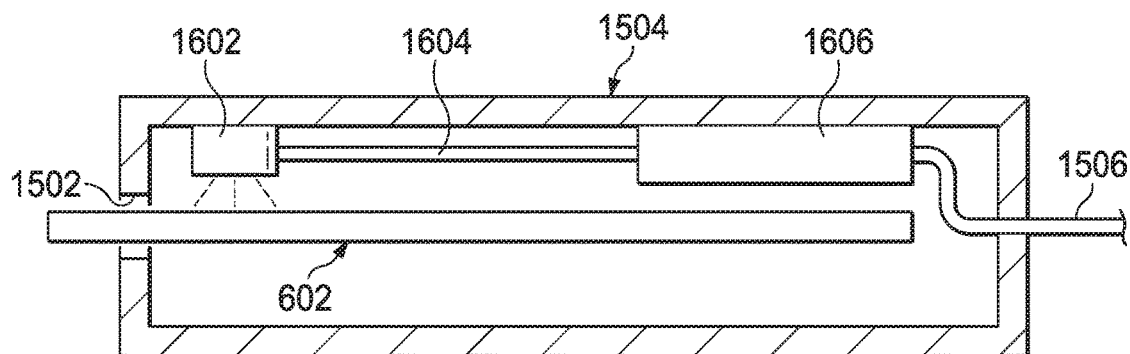
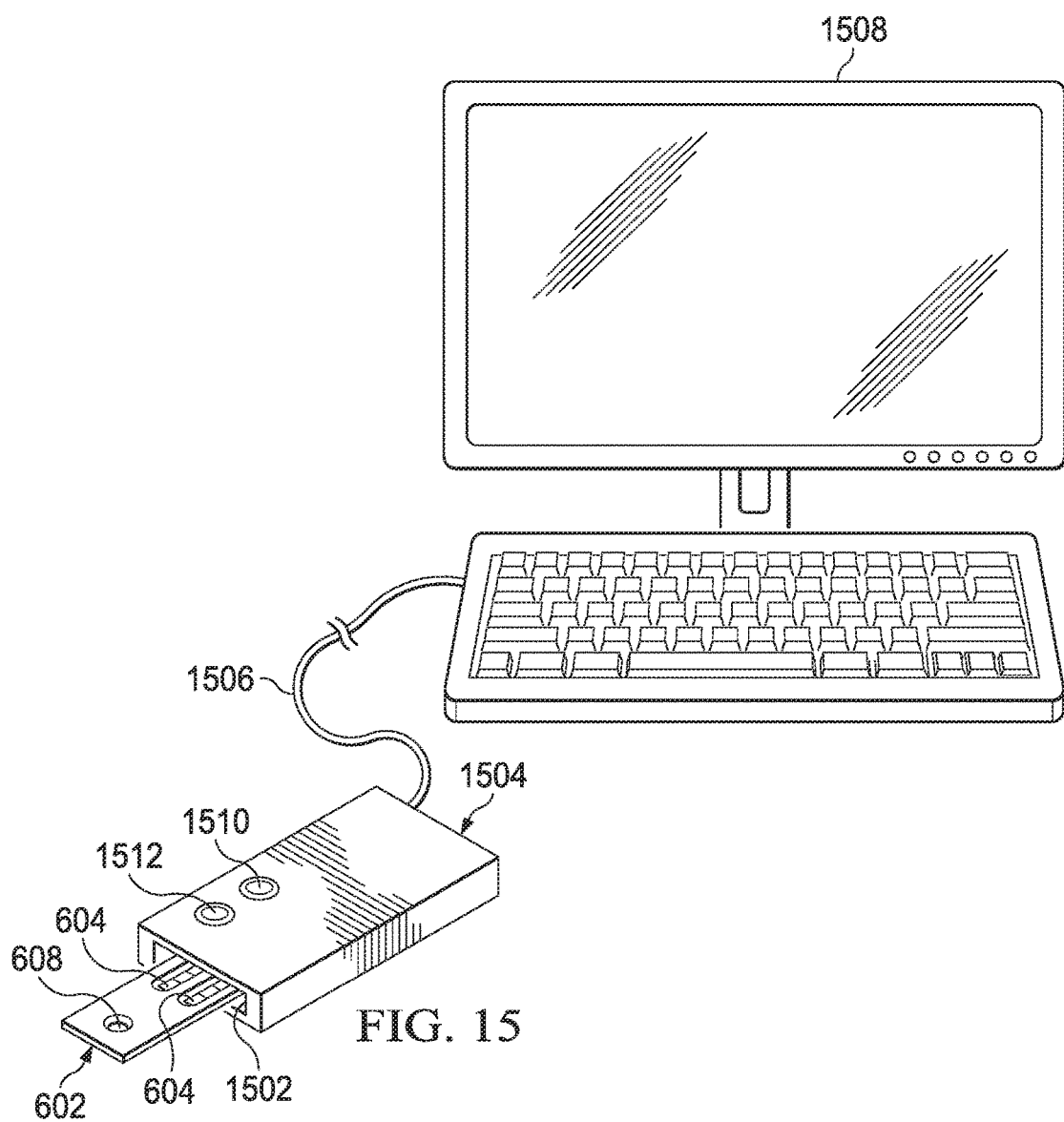


FIG. 14



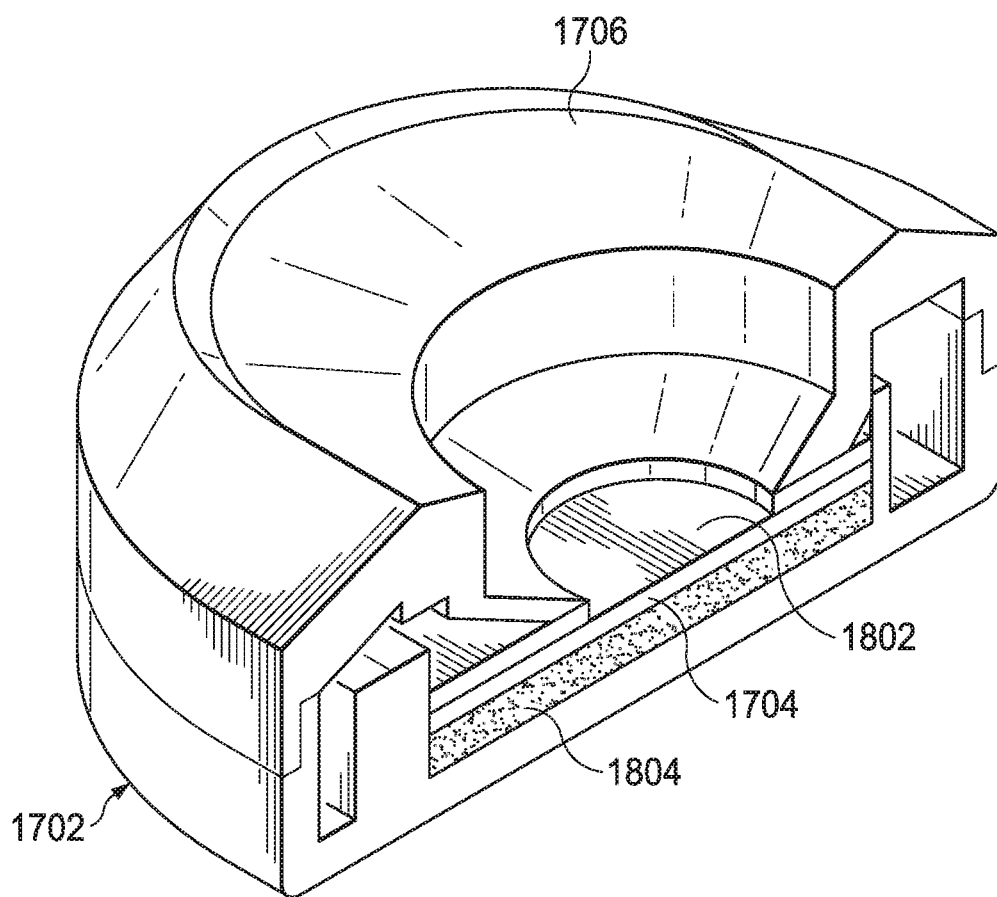
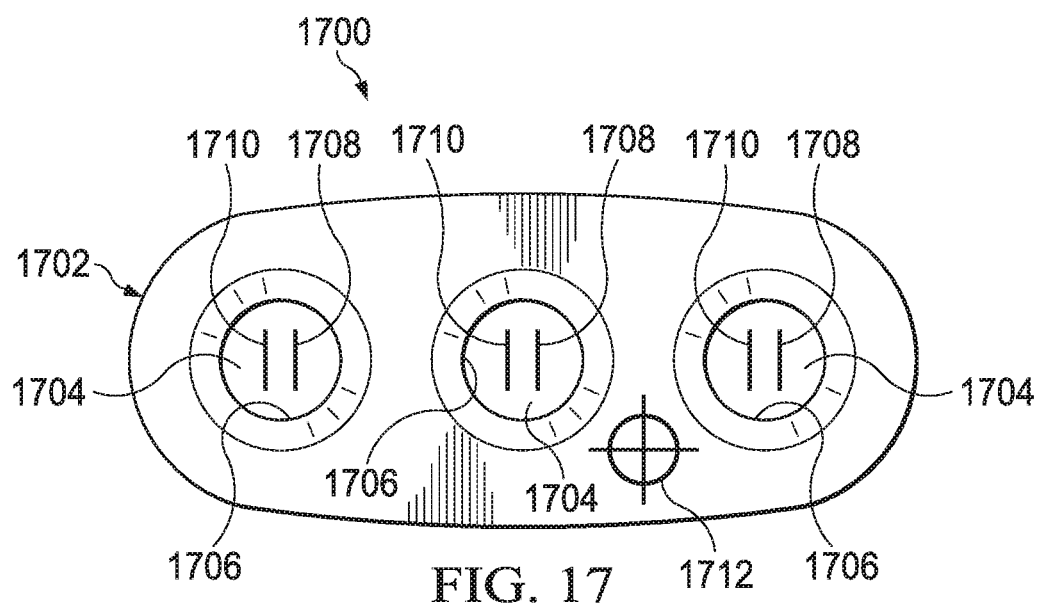


FIG. 18

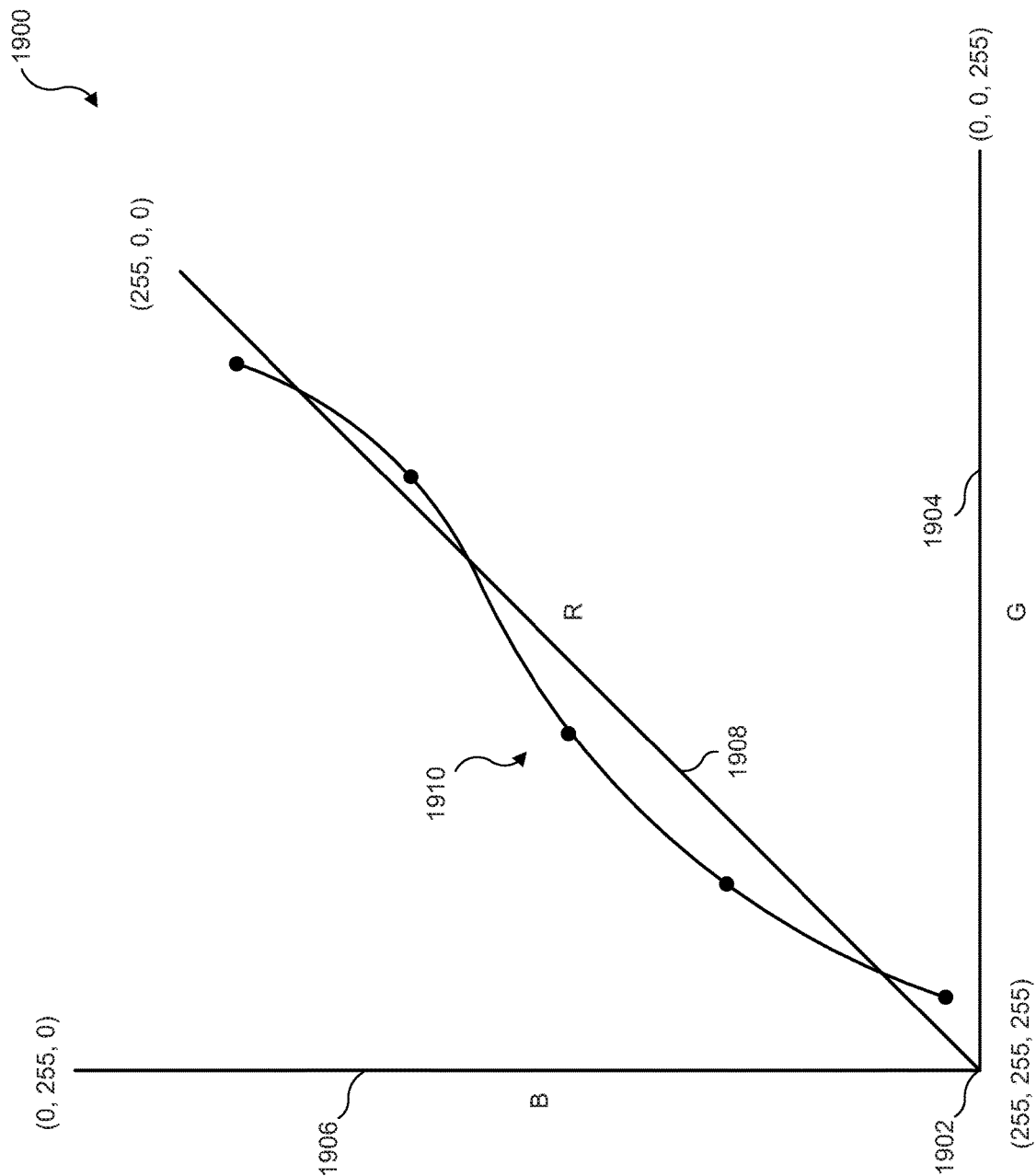


FIG. 19

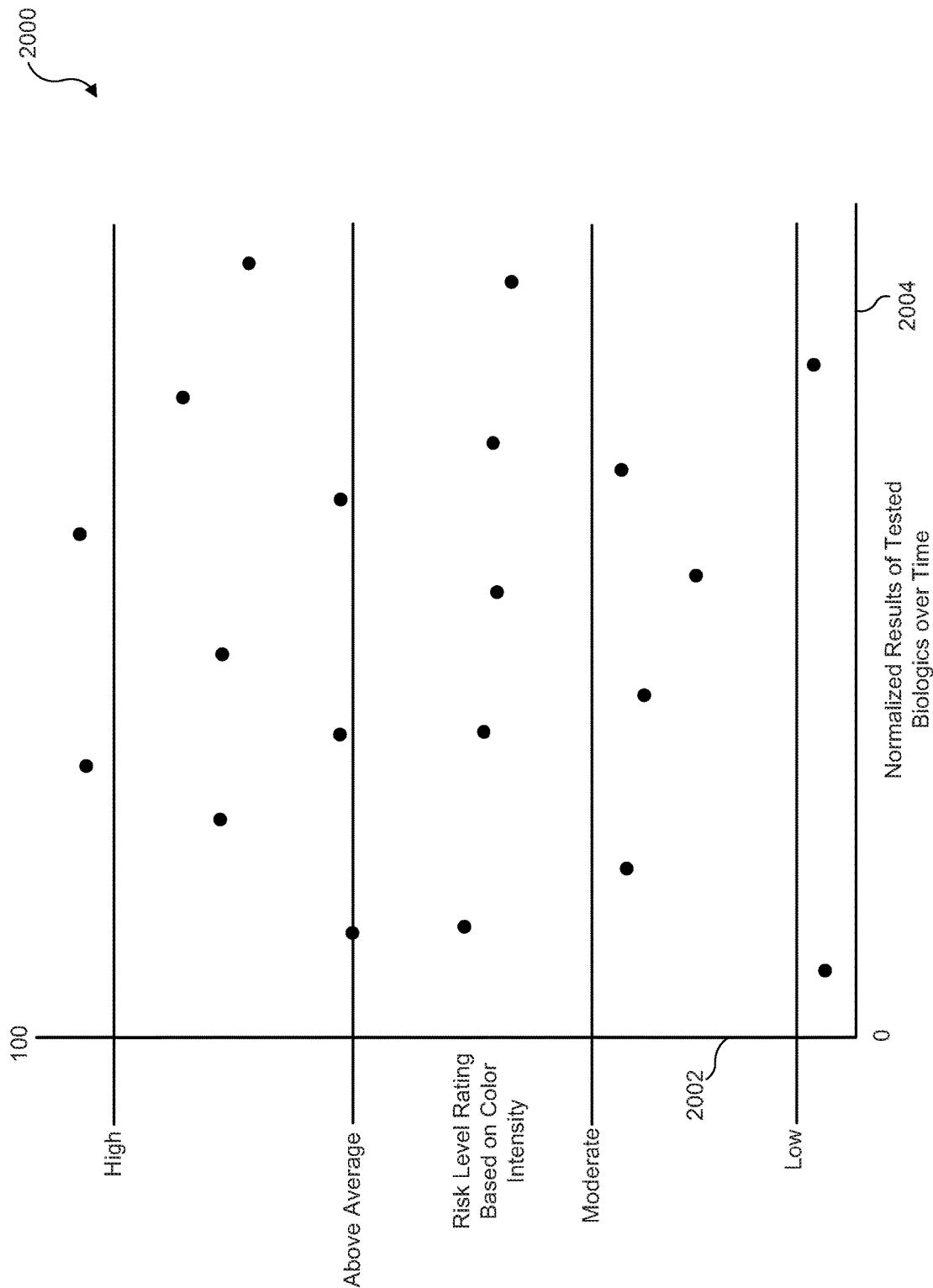


FIG. 20

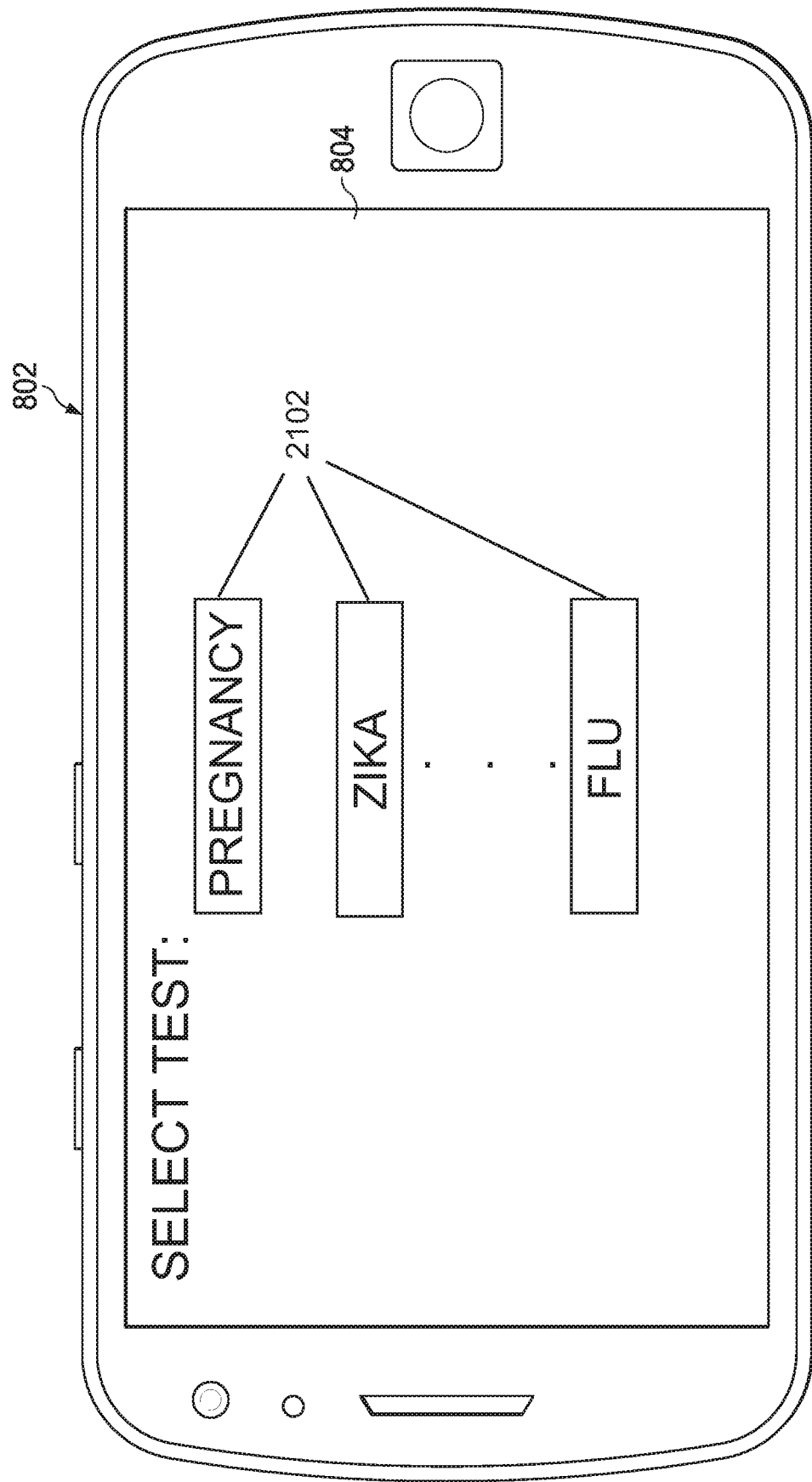


FIG. 21

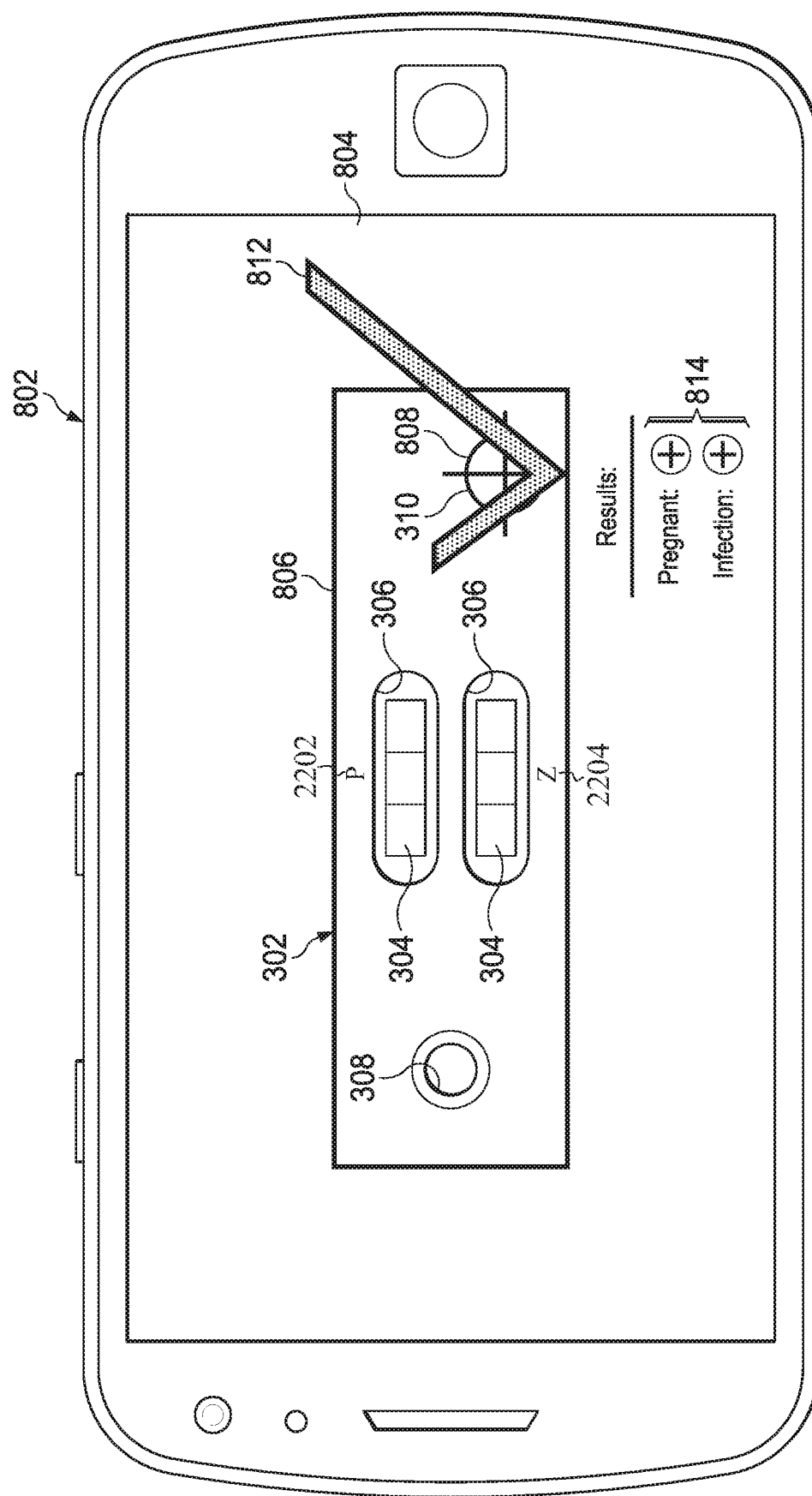


FIG. 22

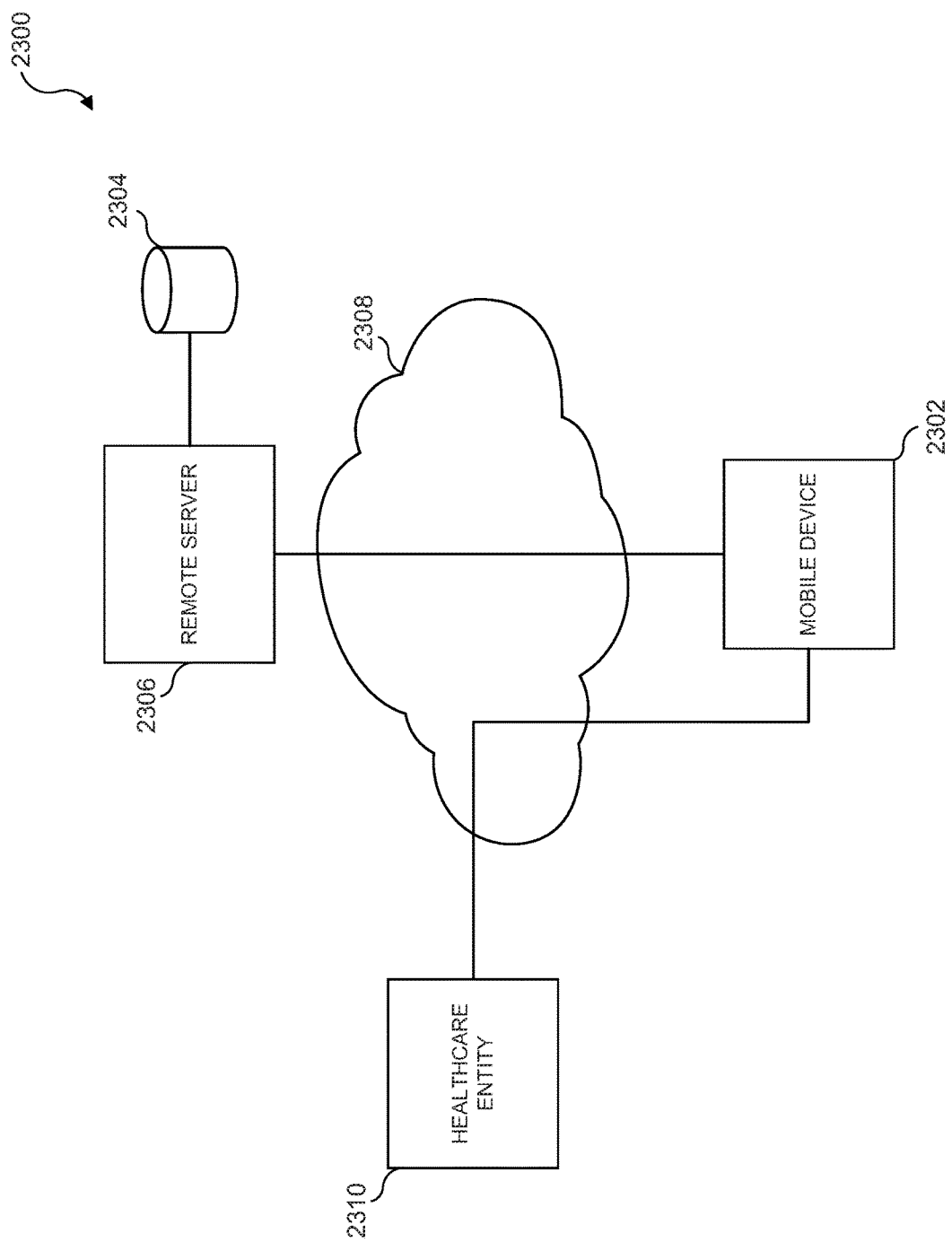

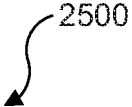


FIG. 23



STREP HOME RETAIL TEST	
DIAGNOSIS CODE	J02.0
HCPCS CODE	G0435
PHARMACY CODE	NDC 54569-5182-0

FIG. 24



PREGNANCY & ZIKA HOME RETAIL TEST		
	PREGNANCY	ZIKA
DIAGNOSIS CODE	Z33.1	A92.5
HCPCS CODE	G8802	G0435
PHARMACY CODE	NDC 42192-321-30	NDC 50580-501-30

FIG. 25

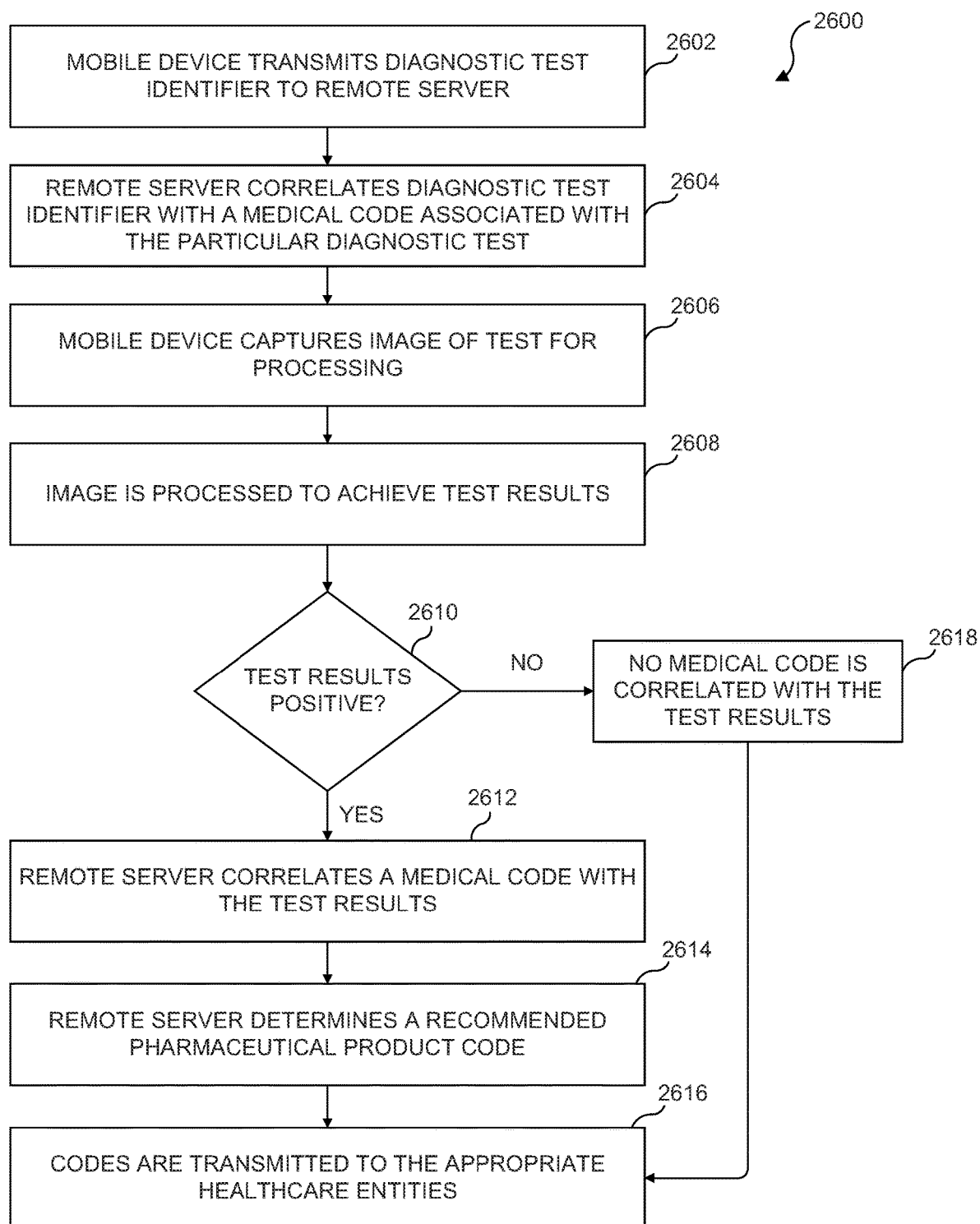


FIG. 26

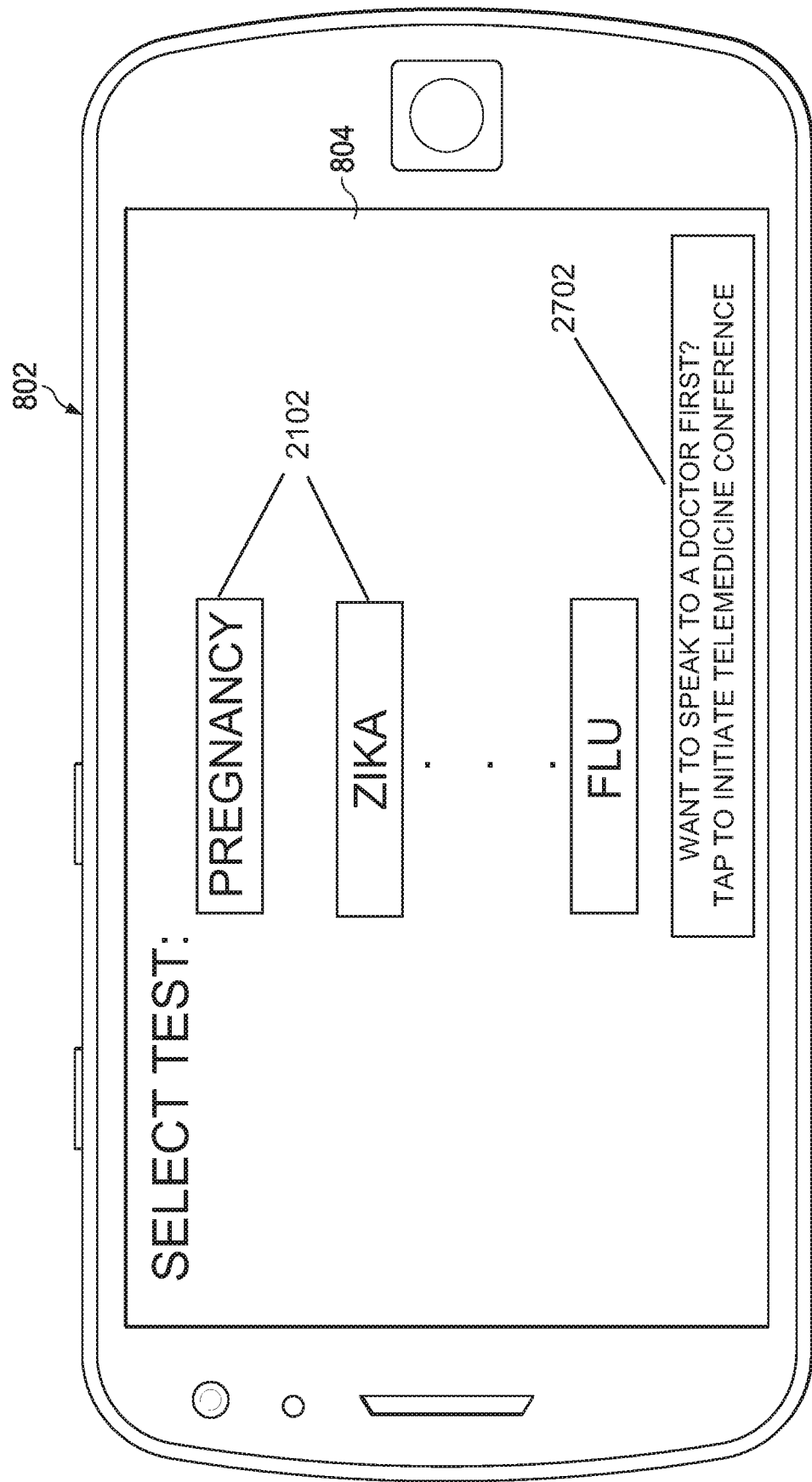


FIG. 27

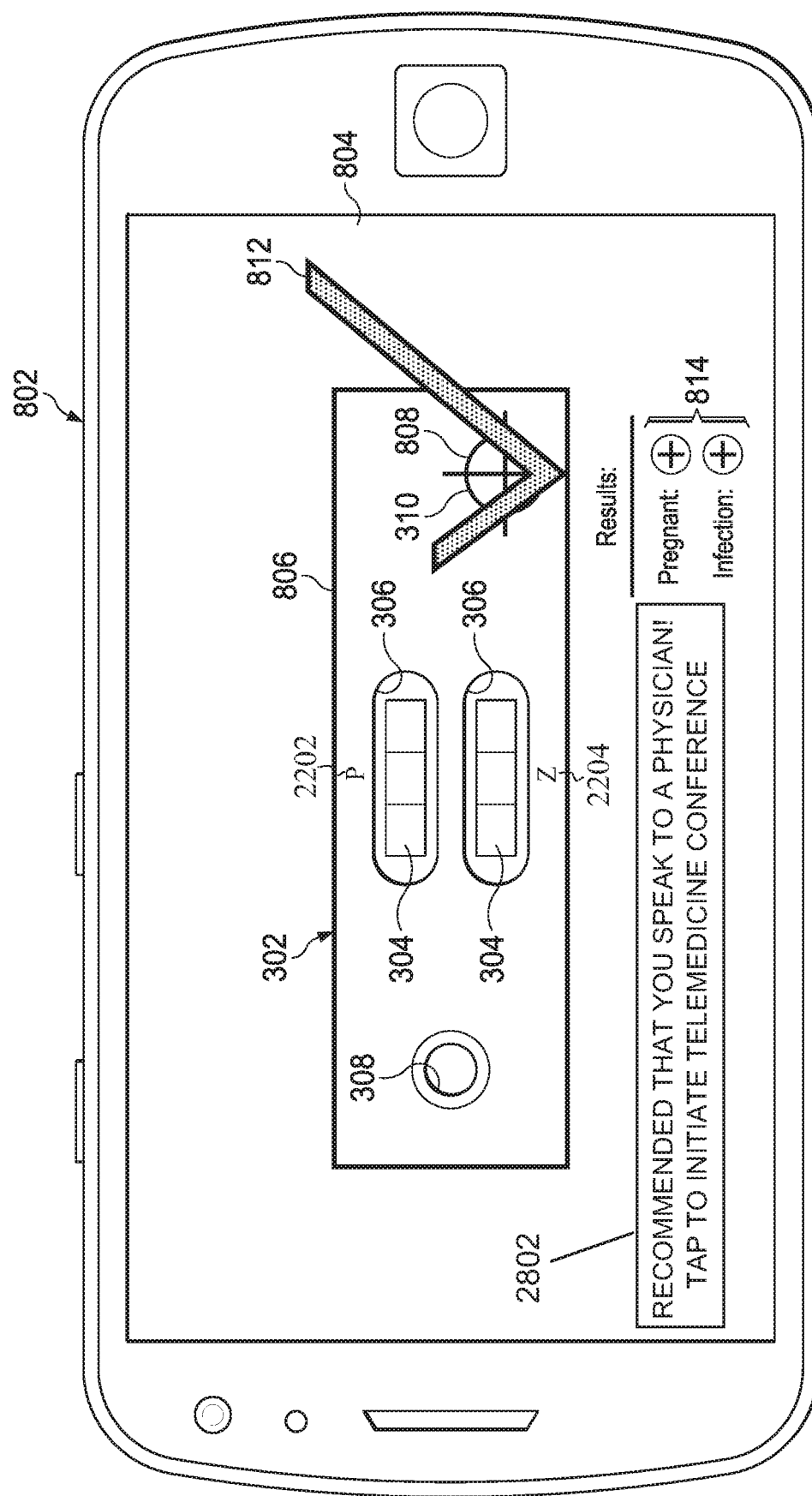


FIG. 28

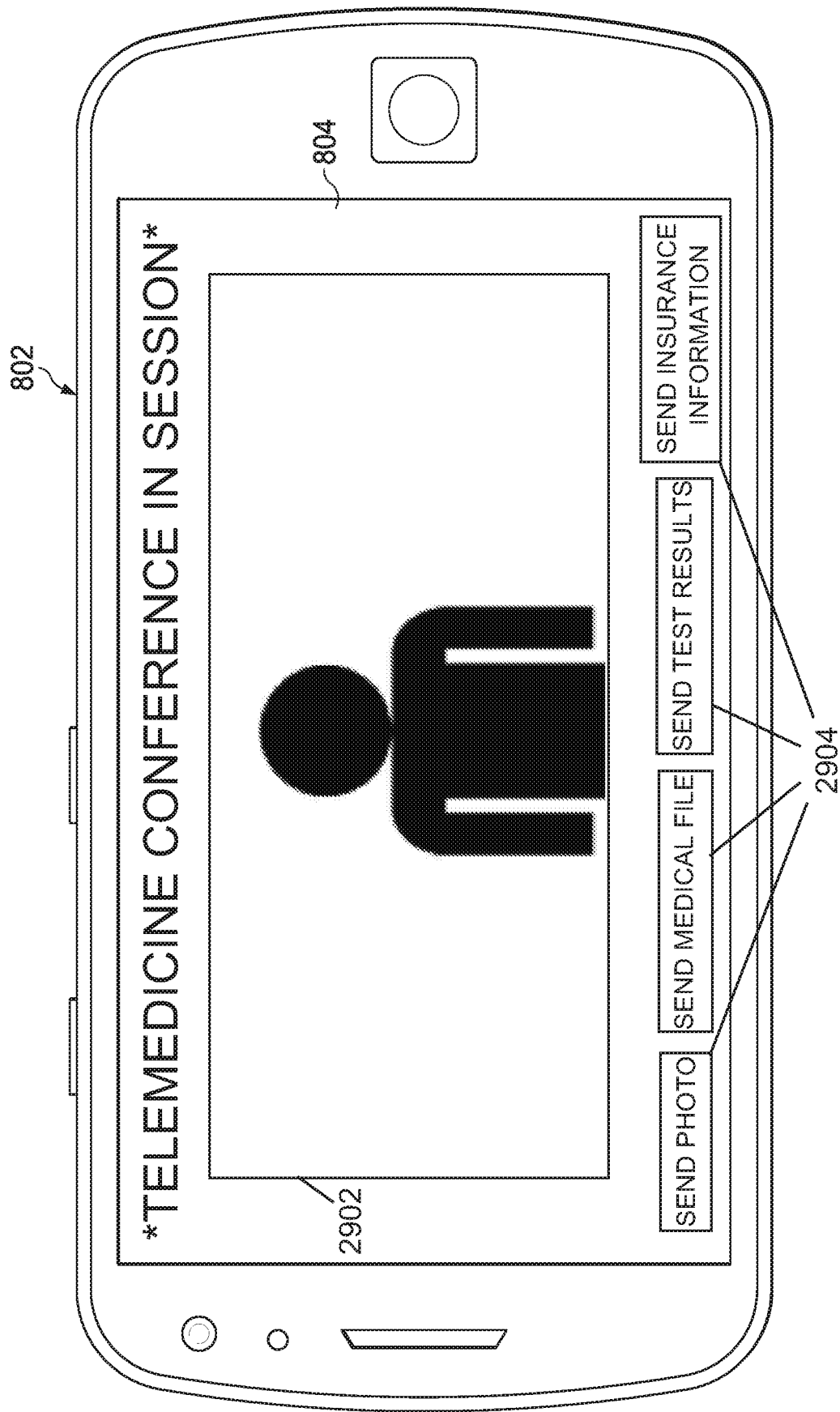


FIG. 29

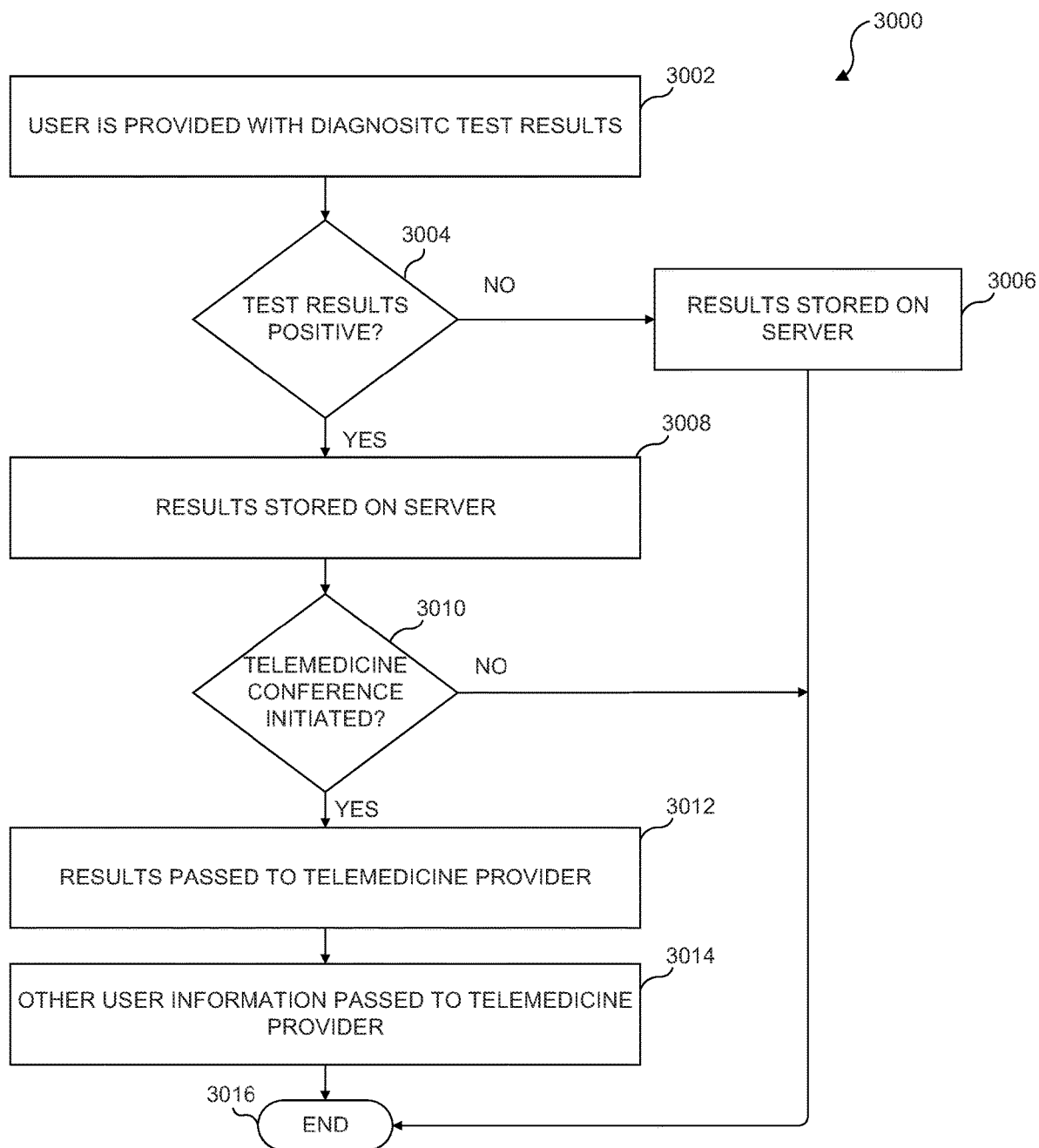


FIG. 30

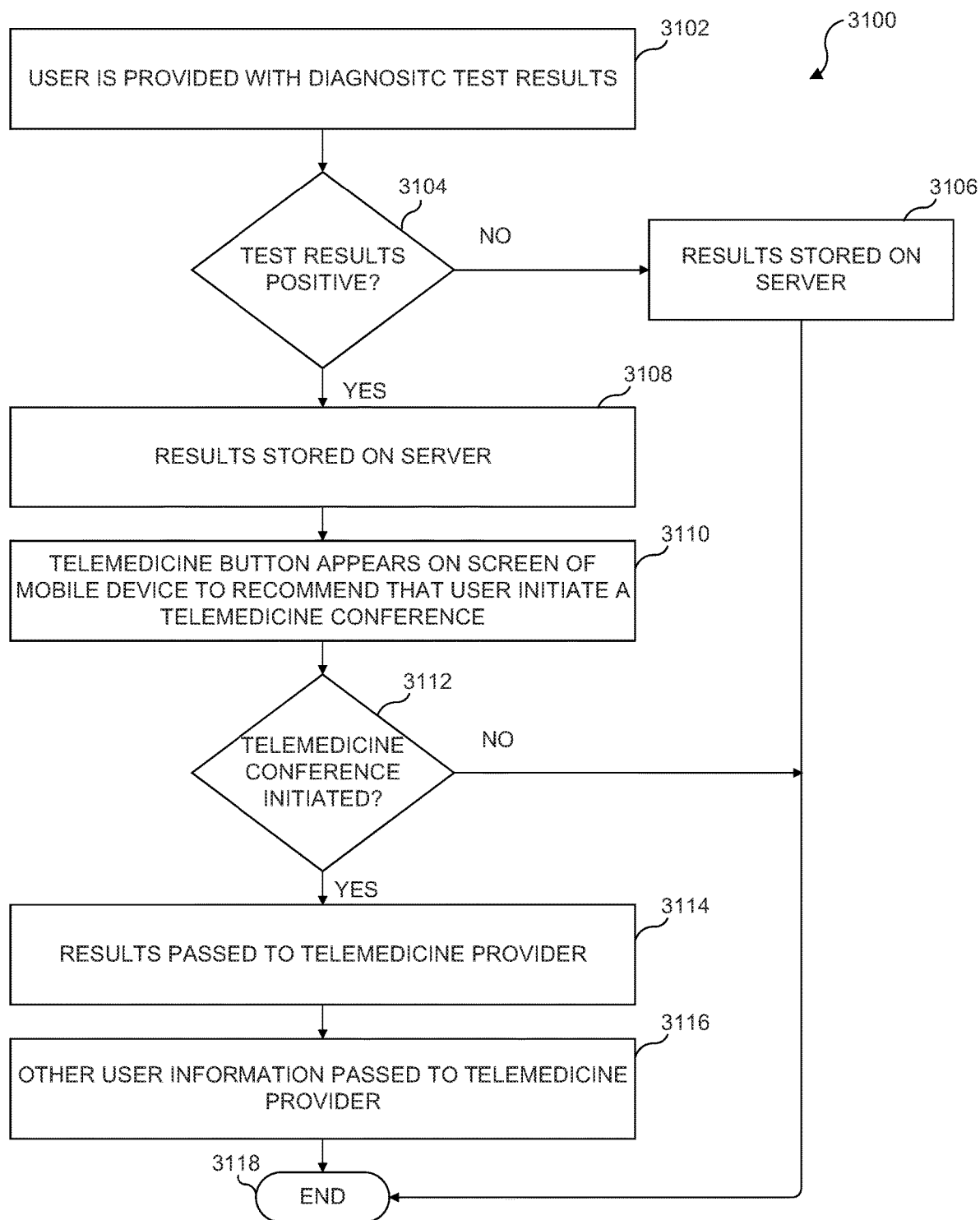
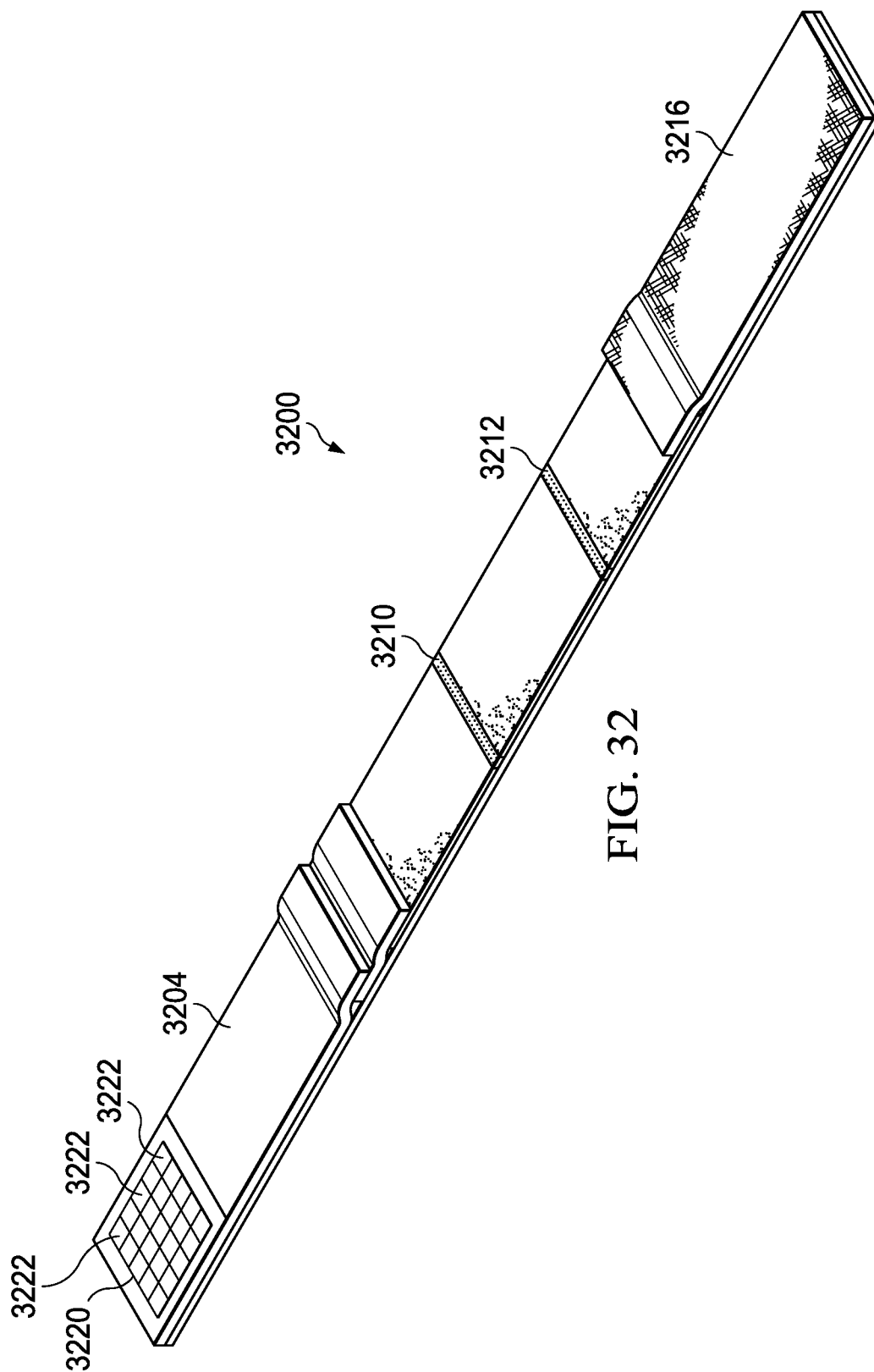


FIG. 31



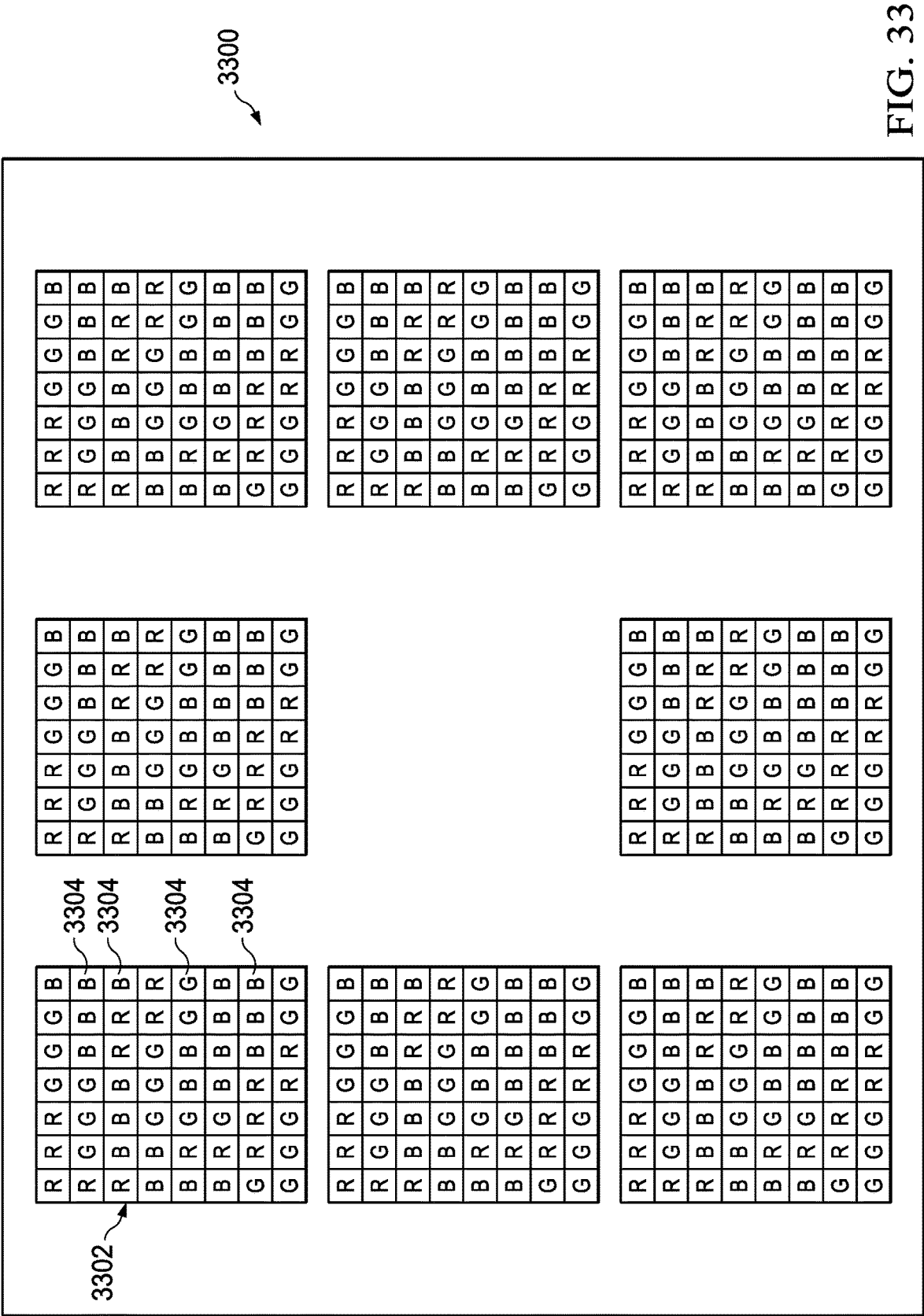


FIG. 33

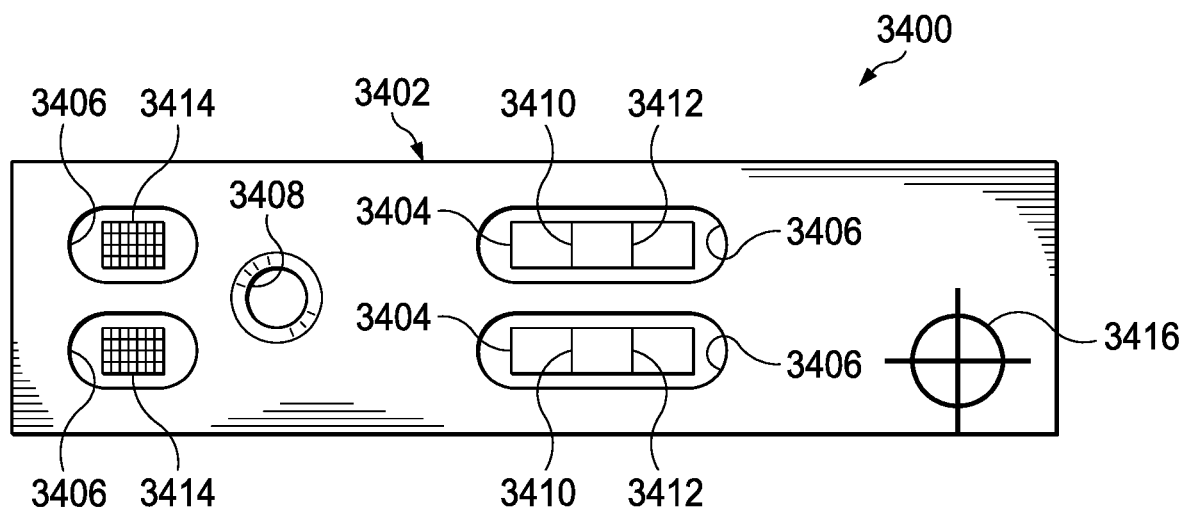


FIG. 34

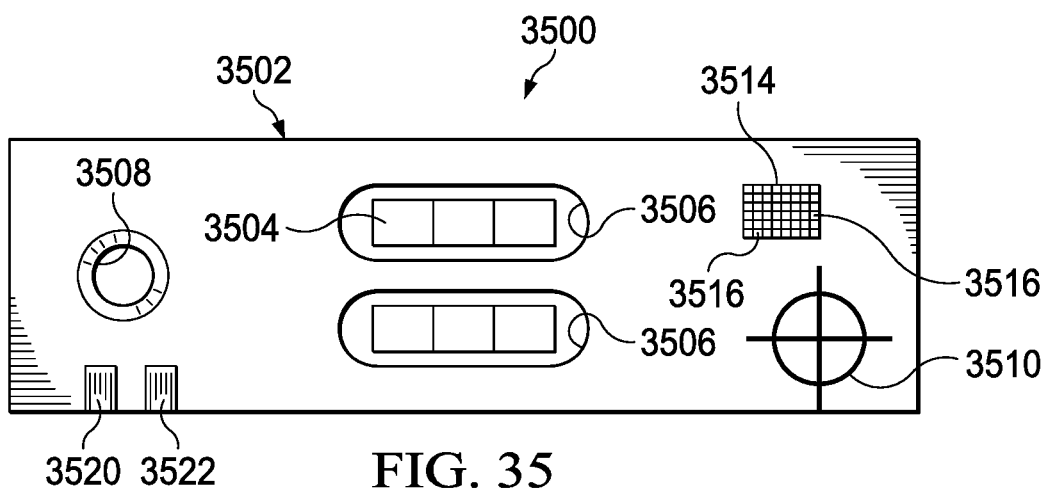


FIG. 35

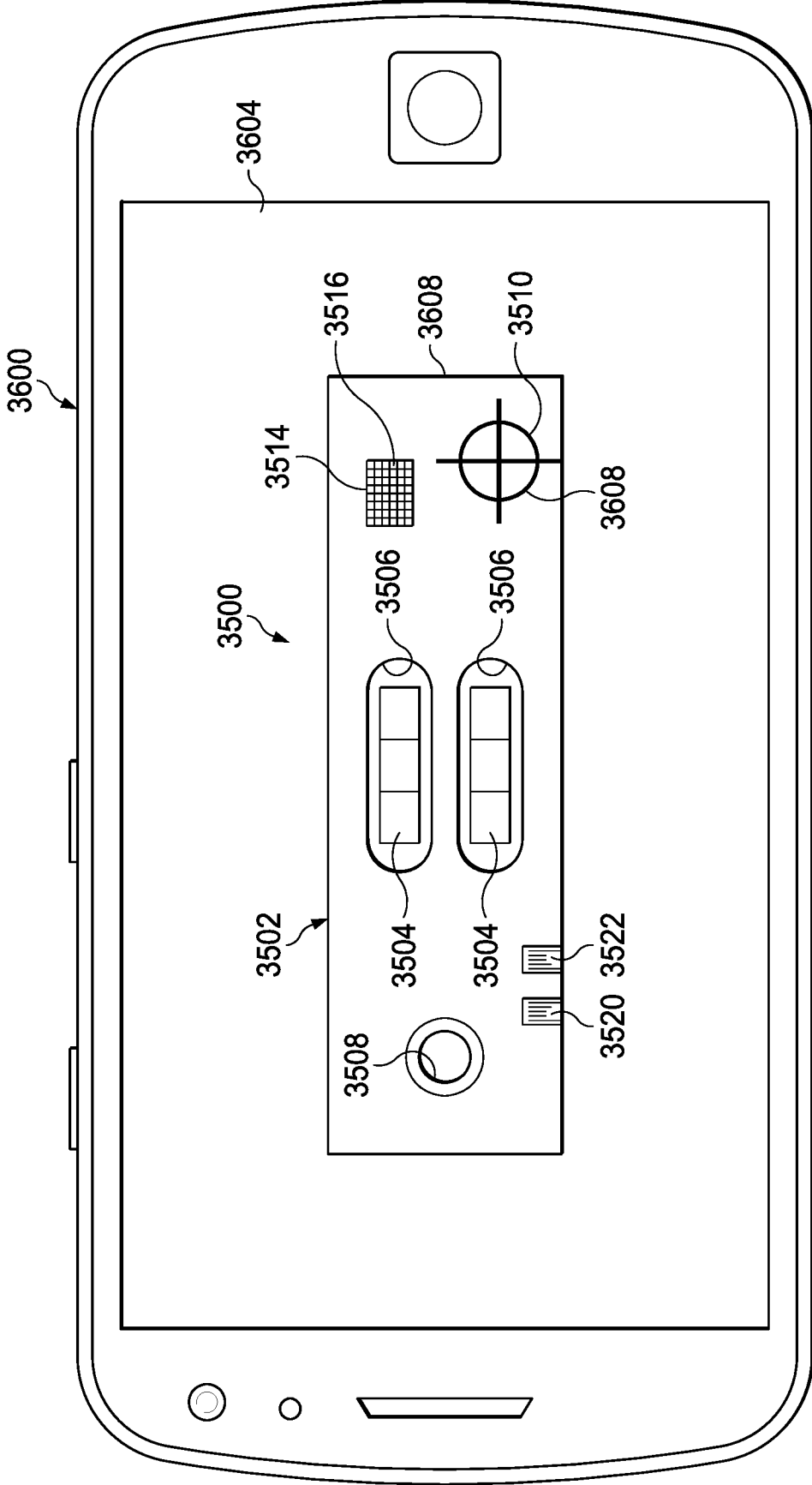


FIG. 36

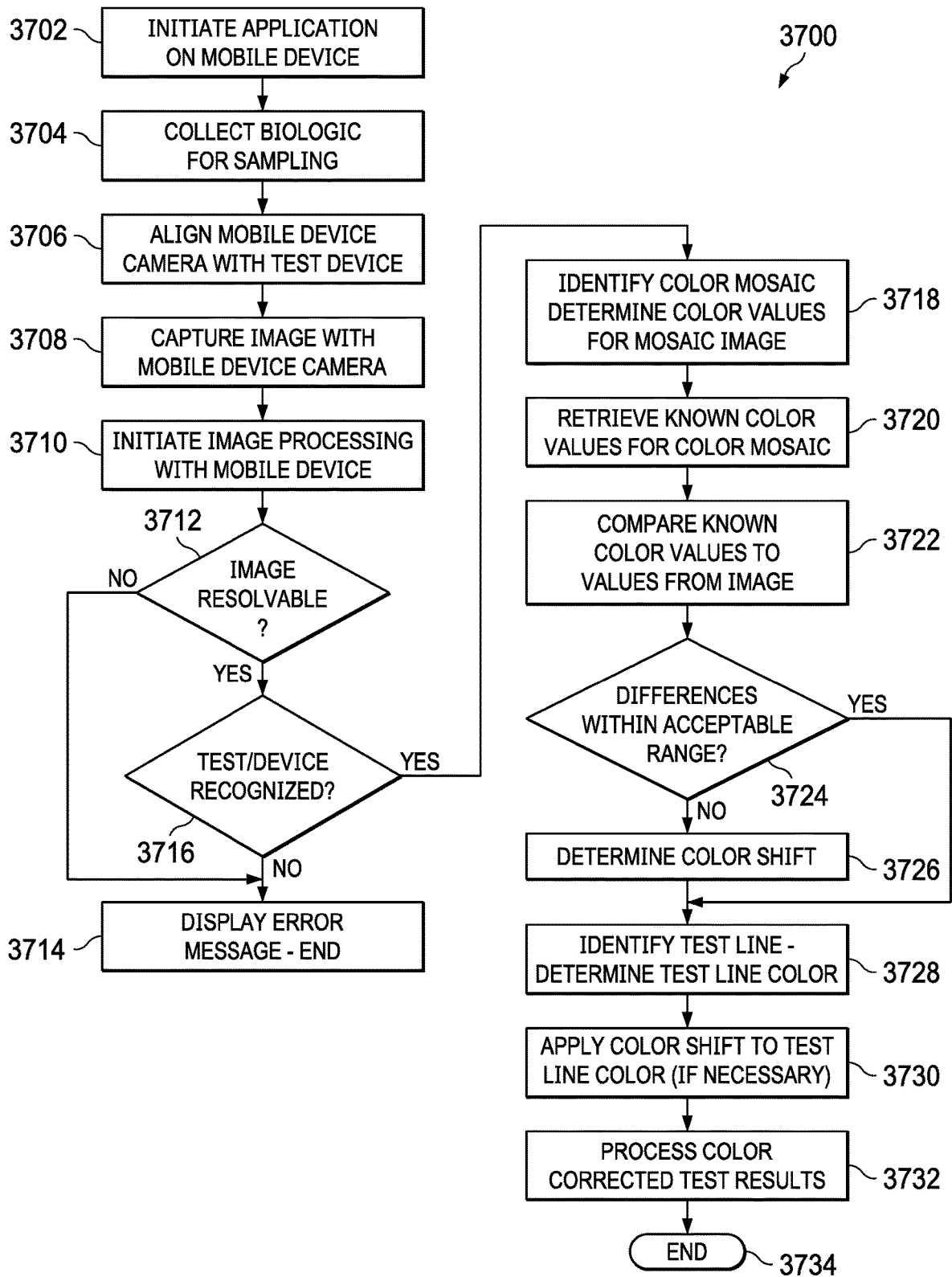


FIG. 37

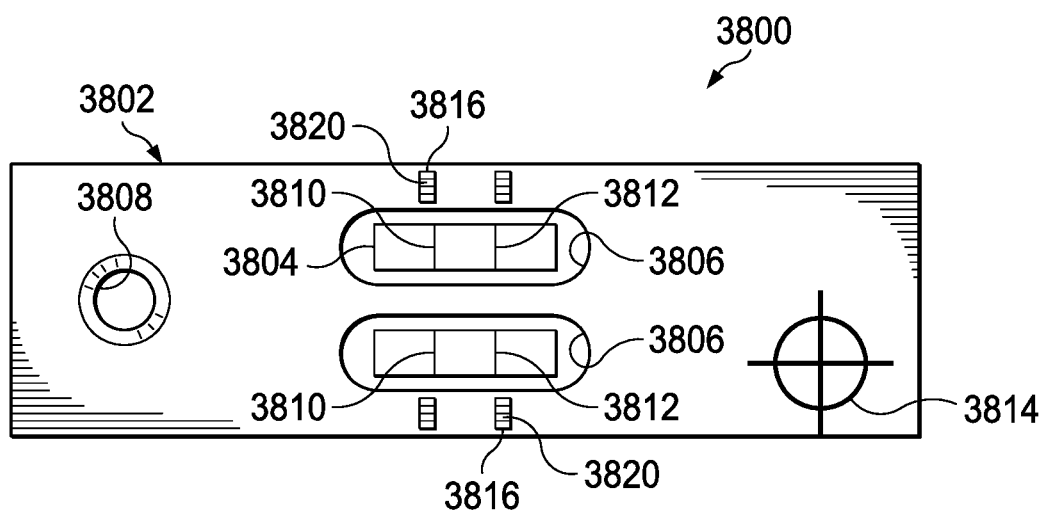


FIG. 38

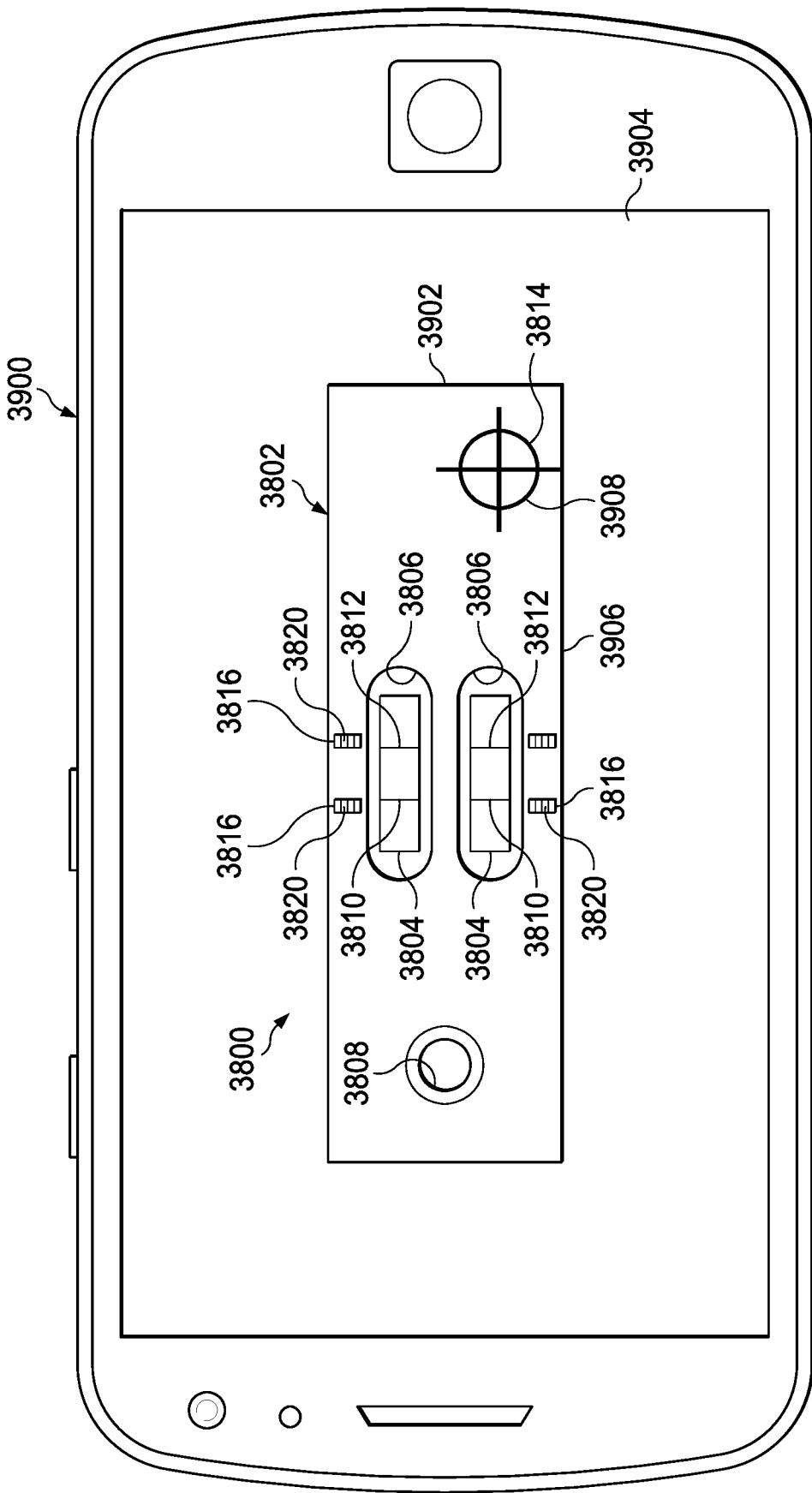


FIG. 39

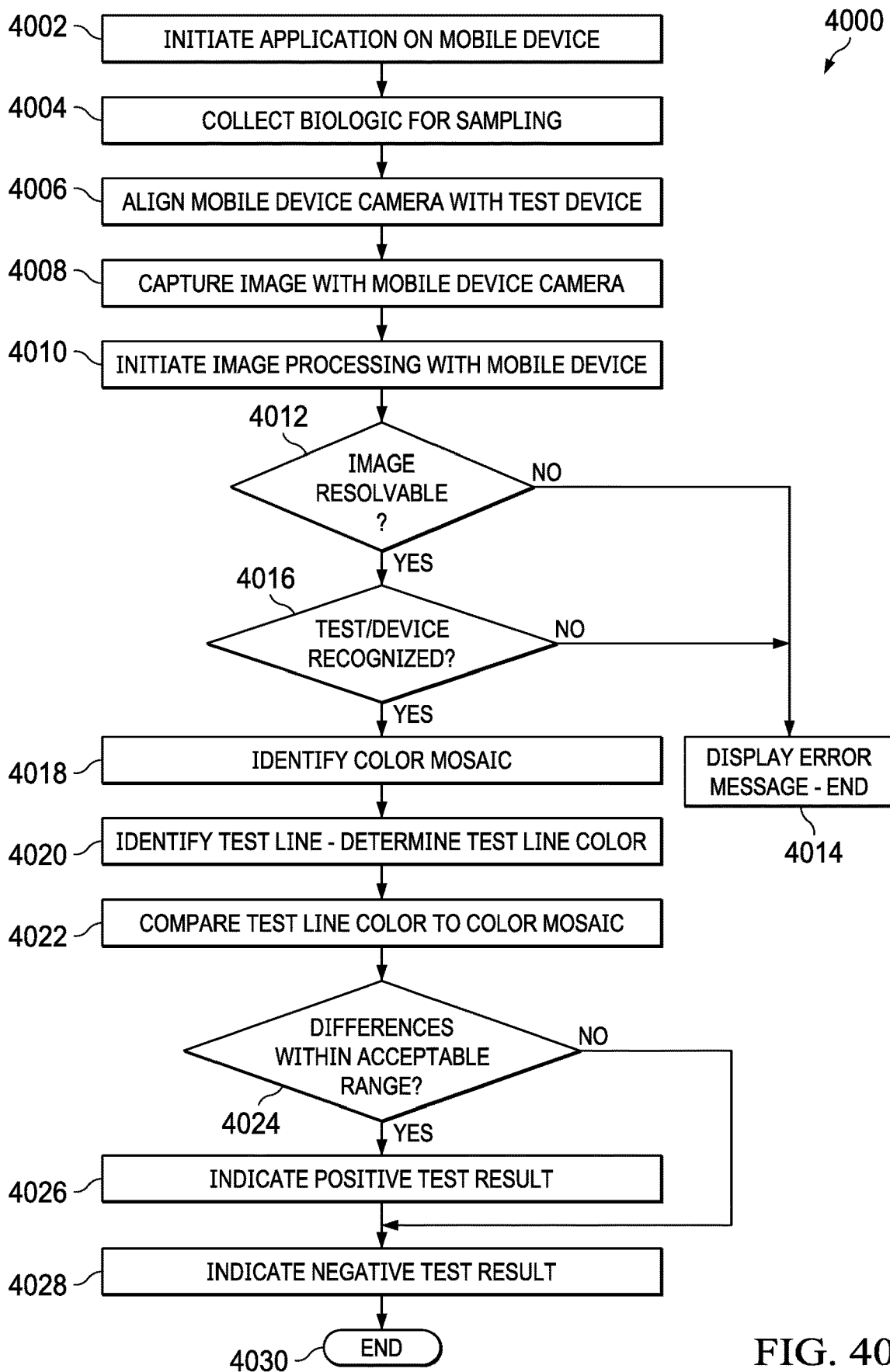


FIG. 40

SYSTEM AND METHOD FOR DIGITAL REMOTE PRIMARY, SECONDARY, AND TERTIARY COLOR CALIBRATION VIA SMART DEVICE IN ANALYSIS OF MEDICAL TEST RESULTS

TECHNICAL FIELD

[0001] The following disclosure is related to a system and method for initiating a telemedicine conference in response to diagnostic test results.

SUMMARY

[0002] A method for initiating a telemedicine conference on a mobile device is provided. The method comprises receiving diagnostic test results in response to a diagnostic test, determining if the diagnostic test results include a positive result, storing the diagnostic test results on a server disposed on a network, presenting, if the diagnostic test results are positive, a telemedicine initiation option on a screen of the mobile device, determining whether the telemedicine initiation option is selected, sending the diagnostic test results from the server to the telemedicine provider, sending additional medical history information to the telemedicine provider, and initiating a telemedicine conference with the telemedicine provider.

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] For a more complete understanding, reference is now made to the following description taken in conjunction with the accompanying Drawings in which:

[0004] FIG. 1 illustrates a diagrammatic representation of one embodiment of an immunoassay test strip;

[0005] FIG. 2 illustrates a diagrammatic representation of one embodiment of an immunoassay test wherein an analyte is tested across a plurality of test strips;

[0006] FIG. 3 illustrates a diagrammatic representation of one embodiment of a testing device;

[0007] FIG. 4 illustrates a top view of the testing device of FIG. 3;

[0008] FIG. 5 illustrates a top view of one embodiment of a testing device;

[0009] FIG. 6 illustrates a top view of another embodiment of a testing device;

[0010] FIG. 7 illustrates a flowchart of one embodiment of a testing device use method;

[0011] FIG. 8A illustrates a diagrammatic representation of one embodiment of a process for a mobile device application for testing device image capture and image processing, wherein an image alignment indicator is not aligned with the subject of the image;

[0012] FIG. 8B illustrates a diagrammatic representation of one embodiment of a process for a mobile device application for testing device image capture and image processing, wherein an image alignment indicator is aligned with the subject of the image;

[0013] FIG. 9 illustrates a flowchart of one embodiment of an image analysis process using a mobile device;

[0014] FIG. 10 illustrates a diagrammatic representation of another embodiment of a process for a mobile device application for testing device image capture and image processing, wherein an image alignment indicator is aligned with the subject of the image;

[0015] FIG. 11 illustrates one embodiment of a consumer driven biologic and disease data collection system;

[0016] FIG. 12 illustrates one embodiment of a consumer driven biologic and disease data collection system;

[0017] FIG. 13 illustrates an example of a unique biologic ID database table;

[0018] FIG. 14 illustrates a flowchart of one embodiment of a biologic data collection and dissemination process;

[0019] FIG. 15 illustrates a perspective view of a system for scanning test strips;

[0020] FIG. 16 illustrates a cross-sectional view of the system of FIG. 15;

[0021] FIG. 17 illustrates one embodiment of a vertical flow immunoassay device;

[0022] FIG. 18 illustrates a cross-sectional view of one embodiment of the vertical immunoassay device of FIG. 17;

[0023] FIG. 19 illustrates a color gradient chart;

[0024] FIG. 20 illustrates a normalized past tests results rating chart;

[0025] FIG. 21 illustrates a mobile device displaying on a screen a mobile application variable test functionality;

[0026] FIG. 22 illustrates the mobile device of FIG. 21, wherein a housing of a testing device also includes thereon test function indicators;

[0027] FIG. 23 illustrates one embodiment of a medical code correlation system;

[0028] FIG. 24 illustrates one embodiment of a strep home retail test codes table;

[0029] FIG. 25 illustrates one embodiment of a combined pregnancy and Zika home retail test codes table;

[0030] FIG. 26 illustrates a flowchart of one embodiment of a medical code correlation process;

[0031] FIG. 27 illustrates one embodiment of a telemedicine initiation option within a mobile application;

[0032] FIG. 28 illustrates another embodiment of a telemedicine initiation option within a mobile application;

[0033] FIG. 29 illustrates one embodiment of a telemedicine conference session on a mobile device;

[0034] FIG. 30 illustrates a flowchart of one embodiment of a medical file handoff process;

[0035] FIG. 31 illustrates a flowchart of one embodiment of a telemedicine conference initiation process;

[0036] FIG. 32 illustrates a diagrammatic representation of one embodiment of an immunoassay test strip incorporating a color mosaic;

[0037] FIG. 33 is a diagrammatic representation of a color mosaic;

[0038] FIG. 34 is a diagrammatic representation of one embodiment of a testing device;

[0039] FIG. 35 illustrates a diagrammatic representation of one embodiment of a testing device;

[0040] FIG. 36 illustrates a diagrammatic representation of one embodiment of a process for a mobile device application for testing device image capture and image processing;

[0041] FIG. 37 illustrates a flowchart one embodiment of an image analysis process using a mobile device with a camera;

[0042] FIG. 38 illustrates a diagrammatic representation of one embodiment of a testing device;

[0043] FIG. 39 illustrates a diagrammatic representation of one embodiment of a process for a mobile device application for testing device image capture and image processing; and

[0044] FIG. 40 illustrates a flowchart one embodiment of an image analysis process using a mobile device with a camera.

DETAILED DESCRIPTION

[0045] Referring now to the drawings, wherein like reference numbers are used herein to designate like elements throughout, the various views and embodiments of an arbovirus indicative birth defect risk test are illustrated and described, and other possible embodiments are described. The figures are not necessarily drawn to scale, and in some instances the drawings have been exaggerated and/or simplified in places for illustrative purposes only. One of ordinary skill in the art will appreciate the many possible applications and variations based on the following examples of possible embodiments.

[0046] Referring now to FIG. 1, there is illustrated one embodiment of an immunoassay test strip 100. The test strip 100 is typically housed in a testing device configured to collect a biologic analyte 106 from a user and to direct to the biologic analyte 106 onto the testing strip 100. However, it will be understood that the biologic may be applied onto a strip 100 without the strip 100 needing to be within a testing device. The test strip 100 includes a backing 102. The test strip 100 is made up of multiple sections disposed on the backing 102. A sample pad 104 is disposed on one end of the strip 100, for collecting the biologic analyte 106. The biologic analyte 106 may be any biologic needed for use in the immunoassay, such as urine, blood, saliva, stool, sweat, or other biologics to be used as an analyte. Various methods may be used to acquire the needed biologic, and such may be provided to the user packaged with the test, such as swabs, vials, containers, diluents and other solutions, or any other equipment required. In the case of a blood analyte, a few drops of blood may be obtained from a finger stick using a finger prick device. Such a blood analyte may be blood mixed with an adequate amount of buffered solution to create the sample analyte 106 or a blood sample that is not diluted or otherwise manipulated, in which case the blood only is the analyte 106.

[0047] The biologic analyte 106, after coming into contact with the sample pad 104, begins to migrate across the strip 100 by capillary action, coming into contact with other sections of the strip 100. A particle conjugate pad 108 is disposed between the sample pad 104 and a test line 110. The conjugate pad 108 may contain various reagents associated with a particular antigen, such as a virus, allergen, or bacteria, the reagents being items such as antibodies, enzymes, or other reagents needed to diagnose the particular condition. The reagent in the conjugate pad 108 may be conjugated with particles of materials such as colloid gold or colored latex beads. As the analyte 106 migrates through the conjugate pad 108, antibodies present in the sample analyte 106 complex with the reagents in the conjugate pad 108, thereby creating an immune complex that will migrate to the test zone or test line 110.

[0048] The test line 110 (T) may be precoated with the relevant antigen in question, i.e., a virus, allergen, or bacteria, for the detection of antibodies associated with the particular antigen. The immune complex created when the analyte 106 passes through the conjugate pad 108 is captured onto the antigen contained on the test line 110. This may create a qualitative response on the strip where the test line 110 is located, such as a colored response. In some

embodiments, the test line 110 may not be a line, but may be other shapes or symbols, such as a plus sign. If no antigen-antibody complexes are present in the analyte, no reaction occurs in the test line 110 and a qualitative response will not occur.

[0049] After passing through the test line 110, the analyte migrates further along the strip to reach a control line 112, where excess anti-antibody-colloidal gold or latex conjugates get bound. A qualitative response may be shown at the control line 112, indicating that the sample has adequately migrated across the testing membrane or substrate as intended. It will be understood that the control line 112 is not necessarily needed to perform the test, and may be eliminated entirely, but the control line 112 does provide a comparative example for a user reading the test. For example, the control line 112, in embodiments where a colored qualitative response is provided, may appear as an overly saturated color, such as a dark or bright saturated red, once the sample reaches the control line 112. This saturated color may be used as a comparison against the qualitative response shown on the test line 110. For example, if the qualitative response shown on the test line 110 is a much lighter red than that on the test line 110, it may be that very little reaction occurred at the test line. Of course, if no response is shown at all at the test line 110, no reaction has occurred. If the qualitative response at the test line 110 is of a similar saturation to the control line 112, a strong reaction is indicated.

[0050] The strip 100 may not be a continuous substrate. Rather, the various sections of the strip 100 may be separate from each other, but all adhered to the backing 102. As shown in FIG. 1, the sample pad 104 and the conjugate pad 108 are separate structures from each other. The test line 100 or zone and the control line 112 or zone are both disposed as part of a nitrocellulose membrane strip 114. The nitrocellulose membrane strip 114 is also adhered to the backing 102, but separate from the sample pad 104 and the conjugate pad 106. As shown in FIG. 1, the end of the sample pad 104 adjacent to the conjugate pad 106 may overlap the conjugate pad 106, with that end of the sample pad 106 lying over the adjacent end of the conjugate pad 106. Similarly, the end of the conjugate pad adjacent to the nitrocellulose membrane strip 114 may lie over the end of the nitrocellulose membrane adjacent to the conjugate pad. This allows for the analyte 106 to be more easily deposited onto each section of the strip 100 as it migrates across the strip 100. After the analyte 106 migrates across the nitrocellulose membrane strip 114, and thus across the test line 110 and the control line 112, the analyte 106 comes into contact with a wick 116 for absorption and collection of the analyte 106. The end of the wick 116 adjacent to the nitrocellulose membrane strip 114 may lie over that adjacent end of the nitrocellulose membrane strip 114, as shown in FIG. 1.

[0051] Several Flow Immune Assays have been directed toward identifying proteins, molecules of interest, and even immunoglobulins IgG, IgA, and IgM. IgE is an antibody (immunoglobulin E) that is normally present in the blood freely circulating until it moves into the tissue where it is bound to mast cells through the receptor FcERI (F-C-epsilon-R-one) otherwise known as the high affinity IgE receptor. There is a small amount of IgE bound to IgE receptors (high and low affinity receptors) on basophils, eosinophils, and other cells in the blood and tissues.

[0052] Many assay systems are geared toward the detection of infectious proteins. All of the aforementioned tests use a non-human antibody—usually IgG type—e.g., goat IgG antibody directed against a protein of interest to detect the protein of interest from the sample (blood, urine, saliva, sweat, etc.). This antibody complexes with protein of interest and forms a complex that travels across the membrane until it reaches the test zone. In the test zone there is an IgG type antibody directed against IgG from that species of animal. As further described herein, the present detecting apparatus and method use human (patient/consumer-derived) antibodies from the sample and the test zone that contains a humanized antibody directed against the protein of interest that is pre-conjugated to a detecting substance that results in a visual change.

[0053] Summary of Target Antigen:

[0054] The target antigens may be proteins, glycoproteins, lipoproteins or other molecular substances capable of eliciting an immune reaction and/or being bound by human specific IgE (sIgE).

[0055] Immune Assay to Detect Specific IgE:

[0056] In the detecting apparatus and method of using the same, the antigens are proteins conjugated to a noble metal, for example, gold, or latex conjugated to antigen in the test zone, for the purpose of detecting the presence of specific IgE (e.g., anti-peanut IgE in a blood sample from a finger prick). For example, an IgG class antibody (IgG1, IgG2, IgG3, or IgG4) or fragments of those classes of antibodies (fab fragments) whose origin may be any animal species (goat, rat, human, etc.) capable of detecting human IgE (anti-IgE IgG)—a suitable commercially available humanized antibody, such as omalizumab may be used—may be used to form immune complexes of IgG-anti-IgE-sIgE that will migrate to the test zone having selected specific IgE that can bind to the conjugated antigen.

[0057] Immune Assay to Detect Total IgE (not Concerned about Specific IgE):

[0058] Another embodiment includes using an IgG class antibody (IgG1, IgG2, IgG3, or IgG4) or fragments of those classes of antibodies (fab fragments) whose origin may be any animal species (goat, rat, human, etc.) capable of detecting human IgE (anti-IgE IgG)—a suitable commercially available humanized antibody that is pre-conjugated to a detecting molecule that results in a color change when bound to IgE as the target antigen in the test zone.

[0059] Referring now to FIG. 2, there is illustrated one embodiment of an immunoassay test **200** wherein an analyte **202** is tested across a plurality of test strips **204**. The plurality of test strips **204** may each be configured for testing for a particular antigen. For instance, one strip may be for testing for the presence of streptococcal bacteria (strep throat), one strip may be for testing for a peanut allergy, one strip may be for testing for the Zika virus, etc. Additionally, each strip may also test for multiple antigens. For example, as shown in FIG. 2, multiple testing panels or lines may be incorporated. Each line may be for a particular antigen. As shown in FIG. 2, multiple test lines **206**, **208**, and **208** may be disposed along the plurality of strips **204**. A strip testing for allergens may have a panel for testing for peanut allergies shown at test line **206** (CH1), for cat allergies shown at test line **208** (CH2), or grass allergies shown at test line **210** (CH3).

[0060] Other examples of configurations for the testing panels can be, but are not limited to: 1) Food 5: Peanut, milk, soy, wheat, egg; 2) Nut and seed panel: almond, cashew, hazelnut, peanut, pecan, walnut, sesame seed, sunflower seed; 3) seafood: crab, lobster, shrimp, salmon, tuna; 4) Pets: cat, dog; 5) Indoor allergens: dust mites, mold mix (*alternaria*, *aspergillus*, *penicillium*, *cladosporium*), cat, dog; and 6) seasonal allergens: grass (Bermuda, bahia, Johnson, rye, timothy), trees (oak, elm, cedar, mesquite, pine, etc.), weeds (pigweed, ragweed, sage, Russian thistle).

[0061] With respect to other non-allergen antigens, the panels may be for testing for strep, Zika, flu, anthrax, cold viruses, cancer, HPV, Lyme disease, mononucleosis (mono), and other illnesses, and/or other conditions such as pregnancy (hCG detection) and disease risks. Some embodiments may allow for the testing of various arboviruses (arthropod-borne viruses). Arboviruses are viruses that are transmitted by arthropods, with mosquitoes being a common vector for the virus. Vectors are organisms that transfer the virus from a host that carries the virus. Thus, in the case of mosquitoes, a mosquito that feeds on a host that is infected with a virus may infect others when that mosquito again feeds on an uninfected host. Well-known arboviruses include Dengue virus, Japanese encephalitis virus, Rift Valley fever virus, West Nile virus, yellow fever virus, chikungunya, and Zika virus. Urine, blood, and saliva and other biologics may be used for arboviruses testing.

[0062] Certain antigens or medical conditions may be logically paired together. For instance, a testing device may include both a strip for detection of pregnancy and a strip for the detection of the Zika virus, as the Zika virus has been known to cause birth defects in infants born to pregnant women that are infected with Zika. Thus, combining these two tests into a single testing device or kit would alert a woman to a potential Zika infection proximate in time to the time she also discovers she is pregnant, allowing the woman to seek medical attention immediately. This is a substantial improvement over past Zika testing, where a woman may be required to wait weeks before results are returned from a lab after having the biologic collected by her physician. In many cases, this may lead to a woman having passed a state-mandated cutoff point for abortions, such as 24 weeks in some states. Combining a Zika test with a pregnancy test and physically linking the two tests, and thus allowing for a woman to determine a Zika risk at the time of taking a pregnancy test, in which a pregnancy test may be taken as soon as six days after conception, allows for that woman to take action much sooner than the state mandated cutoff and waiting for lab results would allow.

[0063] Various testing devices that include the test strip **100** or strips may be used, such as a slide that supports the test strip **100**, a cassette based diagnostic test, a dipstick, or combinations thereof. The test results in various embodiments may be in the form of a visual qualitative reading test, a visual semiquantitative format, a reader quantitative assay format, and/or combinations thereof. Additionally, an electronic implementation may be used where the result is displayed digitally on a screen disposed within the apparatus, and visible to the user.

[0064] The apparatus and method of detection may be a “one-step” approach from sample to reading without sample dilution or other sample manipulation. The sample may be diluted or endure other sample manipulation, for example the blood sample is diluted with a buffer.

[0065] Referring now to FIG. 3, there is illustrated a diagrammatic representation of one embodiment of a testing device 300. The testing device 300 includes a housing 302 that forms the body of the testing device. The housing 302 may be made of plastic, metal, or any material durable enough for shipping and subsequent handling by a user. The housing 302 may be hollow so that a plurality of test strips 304 may be housed within and so that a biologic may be deposited within the housing 302. The testing device 300 may further have a plurality of windows 306, each window being associated with one of the plurality of test strips 304, and allowing for a user to view at least the section of the nitrocellulose membrane strip 114 where the test line 110 and control line 112 are located. The plurality of windows 306 may be open, or covered with plastic, glass, or other materials that allow for viewing the plurality of strips 304. A sample well 308 may be disposed on a surface of the housing 302 to allow a user to deposit a biologic into the housing 302. The sample well 308 would be disposed over or near the sample pad 104 of the test strip or strips 100. In the embodiment shown in FIG. 3, a single sample well 308 is included for collection of a single type of biologic for testing, with each of the plurality of strips 304 being suited for testing for antigens using that particular biologic sample type. For example, if the testing device 300 is a combined pregnancy and Zika test, having both a pregnancy strip and a Zika strip, a urine sample may be deposited into the sample well 308, causing the urine sample to come into contact with the sample pad 104 on both the pregnancy strip and the Zika strip. It will be understood that both of these tests may also be performed with a blood sample.

[0066] The testing device 300 may also have disposed on the surface of the housing a crosshair symbol 310, used as an alignment target. This symbol may be a graphic printed or adhered to the testing device 300. The crosshair symbol 310 is used to align the testing device 300 for the taking of an image of the testing device 300 using a camera on a mobile device, for use in a mobile device application described herein. In other embodiments, the crosshair symbol 310 may be other types of symbols, such as a simple shape (circle, square, etc.), other images (such as a medical cross symbol, an arrow, etc.), or any other type of image.

[0067] Referring now to FIG. 4, there is illustrated a top view of the testing device 300. There is again shown the housing 302, the plurality of test strips 304, the plurality of windows 306, the sample well 308, and the crosshair symbol 310.

[0068] Referring now to FIG. 5, there is illustrated a top view of one embodiment of a testing device 500. The testing device 500 includes a housing 502 having a plurality of test strips 504 within the housing 502 and a plurality of windows 506 for display of the plurality of strips 504. The housing 502 also includes a plurality of sample wells 508 disposed on one side of the testing device 500. Each of the plurality of sample wells 508 is associated with one of the plurality of test strips 504 and each of the plurality of sample wells 508 may be disposed over one of the sample pads 104 on the associated one of the plurality of test strips 504. This allows for a biologic to be deposited into each of the plurality of sample wells 508, with each well 508 serving to transfer the biologic to the test strip underneath the sample well. The testing device 500 further includes a crosshair 510. The crosshair symbol 510 is used to align the testing device 500

for the taking of an image of the testing device 500 using a camera on a mobile device, for use in a mobile device application described herein.

[0069] Referring now to FIG. 6, there is illustrated a top view of another embodiment of a testing device 600. The testing device 600 includes a housing 602 having a plurality of test strips 604 within the housing 602 and a plurality of windows 606 for display of the plurality of strips 604. The housing 602 also includes a plurality of sample wells 608. In this embodiment, the sample wells are located on different ends of the housing 602. In the case of a two test strip device, the sample wells 608 are disposed on opposite ends of the testing device 600. The strips 604 would be arranged within the housing in such a way as to allow the sample pad 104 on each of the strip to be disposed underneath one of the sample wells 608. This is useful for testing devices that require different biological samples. For example, if the testing device 600 required a urine sample for one strip and a blood sample for the other strip, having the wells 608 disposed on opposite sides of the testing device would reduce the likelihood that a urine sample, for instance, might be inadvertently deposited into the well designated for the blood sample. In embodiments where there are more than two strips, and more than two wells, the well positions may alternate between the two sides of the testing device. For instance, a first well for a first strip might be disposed on the left side of the testing device, a second well for a second strip might be disposed on the right side of the testing device, a third well for a third strip might be disposed on the left side of the testing device, a fourth well for a fourth strip might be disposed on the right side of the testing device, and so on. The testing device 600 further includes a crosshair 610. The crosshair symbol 610 is used to align the testing device 600 for the taking of an image of the testing device 600 using a camera on a mobile device, for use in a mobile device application described herein.

[0070] The diagnostic test can, for example, be produced in a various formats for different users, such as, but not limited to, consumer/in-home use where the test is purchased through retail channels which will allow individuals to get an immediate, cost-effective test result that can lead to specific avoidance and treatment through follow-up with a medical professional.

[0071] The diagnostic test can be provided to and used by hospitals and clinics to provide rapid, on-site test results that are required to prescribe certain medications, such as omalizumab, by their FDA labels.

[0072] This diagnostic assay can be modified to detect the presence of specific IgE in pets.

[0073] It is also noted that housing 602 is designed such that both strips 604 are disposed in physical proximity thereto and in the same actual housing. In this manner, both sets are linked physically to each other such that they cannot be separated and can be associated with a single individual and the actual test cannot be separated. As such, when a patient applies the specimens to the two areas 608 and the test results are exhibited, there is a high probability that two tests were performed at the same time associated with the same patient. Additionally, and electronic chip (not shown) can be embedded within the housing 602 such that the housing 602 can be registered to a specific patient and associated with the medical records of that patient.

[0074] Referring now to FIG. 7, there is illustrated a flowchart of one embodiment of a testing device use method

700. The method **700** begins at step **702** where a biologic is collected in a sample well or wells of a testing device. The biologic collected may be a non-diluted or non-manipulated biologic, such as blood, urine, or saliva from the user of the test. Diluted or manipulated biologics may be used instead, as required by the specific test. For example, if a viral test requires the biologic to be added to a solution, the biologic could be added to a solution that has previously been placed in a sterilized vial provided with the testing device. After the required amount of time has passed, the solution containing the biologic could be deposited into the well or wells. At step **704**, the biologic contacts a sample pad disposed on a strip or strips within the testing device. At step **706**, the biologic migrates along the strip or strips to come into contact with a conjugate pad containing antibodies. Antibodies present in the biologic will complex with the antibodies in the conjugate pad to create an immune complex. At step **708**, the biologic migrates into a test zone of the strip or strips, coming into contact with an antigen. The antibodies in the conjugate pad serve to provide a means of detection, such as a colored response, if the immune complex binds with the antigen present in the test zone of the strip. At decision block **710**, binding of the antibodies with the antigen may or may not occur depending on if antibodies associated with the antigen are present in the biologic or not. If a binding between the antibodies and the antigen does not occur the process moves to step **712** where no qualitative response is produced on the test line. If a binding does occur, at step **714** a qualitative response is produced on the test line. Whether a binding occurs or not, and whether a qualitative response is produced or not, the process moves to step **716** where the biologic migrates into a control zone of the strip or strips where excess conjugates get bound and produces a qualitative control zone reaction indicating that the sample has adequately migrated across the testing zone.

[0075] It will be understood by one skilled in the art that the antibodies and antigens applied to the testing strip may be altered depending on the type of condition being tested. For example, in the case of testing for medical conditions that do not involve an illness or infection, like pregnancy, and thus the sample biologic does not contain antibodies associated with the condition, antibodies that react to markers being tested for may be applied to the testing strip instead of an antigen. For instance, pregnancy test requires testing for the presence of hCG. Since hCG is a hormone and not an antibody produced in response to an infection, the testing strip may have antibodies that will react to the presence of hCG applied to the testing zone or line of the testing strip, as well as to the conjugate pad. Similarly, some tests might require antibodies be applied to the testing strip to detect antigens present in the sample, rather than antibodies.

[0076] Referring now to FIGS. **8A** and **8B**, there is illustrated a diagrammatic view of one embodiment of a process **800** for a mobile device application for testing device image capture and image processing. The mobile device application allows for an image of a testing device, such as testing device **300**, to be captured using a camera installed on a mobile device **802** having a screen **804**. While the mobile device **802** displays on the screen **804** the scene captured by the camera, the mobile device application also displays a graphic on the screen **804** in the form of a boxed outline **806**, the size of the outline **806** corresponding to the size of the testing device **300**. Also displayed on the screen of the mobile device **802** within or near the outline is a crosshair

graphic **808**. A user of the mobile device **802** attempts to align the outline **806** with the borders of the testing device **300** and also attempts to align the crosshair graphic **808** with the crosshair **310** on the testing device **300**. While alignment has not yet been achieved, a misalignment warning **810** may appear on the screen of the mobile device **802**, indicating to the user that alignment has not yet been achieved. Such is shown in FIG. **8A**.

[0077] In FIG. **8B**, there is shown the result of a successful alignment of the outline **806** with the testing device **300** and successful alignment of the crosshair graphic **808** with the crosshair **310** on the testing device **300**. As shown in FIG. **8B**, once aligned, a success indicator **812** may appear, such as a check mark or other positive status symbol, on the aligned image. Successful alignment causes the camera on the mobile device **802** to capture the current image of the testing device **300**. Other checks may occur, including ensuring that the image is focused before the image is saved. This image is then processed to determine a result based on the severity of the reaction occurring on the test strip. The mobile device application performs an analysis of the test line captured in the image, counting the number of colored pixels, as well as determining the intensity of the color. The mobile device may then compare this number and color intensity to that in the control line, providing a mathematical evaluation of the test line. Utilizing unique wavelengths of light for illumination in conjunction with either CMOS or CCD detection technology, a signal rich image is produced of the test lines to detect the colloid gold or latex particles. This provides an advantage because a user simply looking at the two lines may not know what the test line indicates, such as when the colored line does appear on the strip, but it is a faded line, rather than a dark line. Based on this analysis, the mobile device application may provide a results indicator **814**.

[0078] The results indicator **814** may be a qualitative result or a quantitative result. For example, and as shown in FIG. **8B**, a qualitative result for the results indicator **814** may indicate, in the case of a testing device for testing pregnancy as well as an infection, a plus sign next to a line reading "pregnant:" and a plus sign next to a line reading "infection:" to indicate that the user is both pregnant and infected with the bacteria or virus being tested, such as the Zika virus. For a quantitative result, the results might provide a numeric rating. For instance, a rating system between 1-100 may be used. If the results provide a low rating to the user, such as a rating of 10, this indicates a low risk of infection, although medical attention may be sought by the user anyway. For example, if the user is pregnant, and also receives a 10 rating for Zika, this may indicate that Zika was detected in low amounts. However, the user may still seek medical attention or further testing from her doctor because Zika has been known to cause birth defects. If the rating is a high rating, such as 95, this indicates that an infection has most likely occurred and medical attention should be sought immediately.

[0079] This same quantitative rating system may be applied to any test (viral infections, bacterial infections, pregnancy, and other health conditions), as the quantitative test can be performed using the software described herein to accurately test bound antibody concentrations on the test strip. In some embodiments, a combined qualitative and quantitative result may be presented, such as both a rating and a plus or minus sign being presented, or other types of

quantitative and qualitative indications. Additionally, various combinations of tests may be provided for in the testing device, such as pregnancy/Zika, pregnancy/flu, pregnancy/strep/Zika, etc.

[0080] Referring now to FIG. 9, there is illustrated a flowchart of one embodiment of an image analysis process 900 using a mobile device. At step 902 a mobile device application is launched. At step 904 a camera on the mobile device is activated and a crosshair indicator and a testing device outline appear on the mobile device screen. At step 906 the crosshair indicator presented on the screen of the mobile device is aligned with a crosshair icon on the testing device and the device outline presented on the screen of the mobile device is aligned with the borders of a testing device. At step 908, an indicator of successful alignment is presented on the screen and an image of the testing device is taken by the mobile device camera. At step 910, the mobile device application processes the image of the testing device to determine test line strength by counting the number of colored pixels contained in the test line. At step 912, the mobile device application correlates line intensity with analyte concentrations to further determine test line strength. At step 914, the mobile device application presents the test results based on pixel count and line intensity, providing either a qualitative or quantitative result.

[0081] In some embodiments, the number of pixels indicating bound antibodies on the strip may be measured against that in the control line to compare line intensity between the two lines, with the control line acting as an example of a strong reaction, indicating a strong infection, and determining how close the test line intensity is to the control line. This would lead to a logical quantitative result. For instance, if the test line is determined to have a pixel count and line intensity that is 25% of the pixel count and line intensity of the control line, a rating of 25 may be given. If a qualitative result is to be provided, a rating of 25 may give a qualitative result that is negative, or it could be positive depending on the type of condition being tested and known actual infection results where a rating of 25 occurred for that condition.

[0082] In some embodiments, the test line may not be compared with the control line to determine a result. Rather, the mobile device application may have access to a database having data on numerous past tests for the same condition. This data may instead be used as the control. This allows the application on the mobile device to retrieve data on past tests and compare the test line data of the current test to past tests. Overall data for past tests may be provided and compared against, such as providing an average or a curve of past tests, or individual tests rated as having accurate results may be compared against.

[0083] In addition to a status result of an infection or other medical condition being provided to the user, other indicators of health may also be tested and results thereon provided. This provides for potential early identification of pregnancy and risk of morbidity, allowing for medical attention to be sought much more quickly. Indicators of health may be detected from biologics, such as urine and blood. Urine, for example, allows for the detection of glucose levels, proteins, bacteria, and infectious markers. In the case of glucose, glucose is usually not found in urine, but, if it is, that is an indicator of extremely high levels of glucose in the body, where the kidneys release excess glucose into urine. This is often a sign of diabetes. Protein

in the urine may indicate a malfunctioning of the kidneys, which could be the result of high blood pressure. Similarly, if blood is detected in urine, it could be a sign of a problem with the kidneys or the bladder. Blood, for example, allows for the detection of glucose, inflammation, hormones, genetic defect risks, and metabolic endocrine disorders.

[0084] Referring now to FIG. 10, there is illustrated another embodiment of a successful alignment of the outline 806 with the testing device 300 and successful alignment of the crosshair graphic 808 with the crosshair 310 on the testing device 300, wherein quantitative results for health risk indicators are provided. In this embodiment, the results indicator 814 provides a qualitative result for pregnancy and quantitative results for other health risk indicators. In the embodiment shown in FIG. 10, the health risk indicators being tested are markers for blood pressure and for glucose levels. For blood pressure, this is a test for markers in the blood that can be associated with high blood pressure. These could be test for such things as low levels of vitamin D and the such. Studies have shown that patients suffering from essential hypertension will be under oxidative stress and Malondialdehyde (MDA) is the principal and most studied product of polyunsaturated fatty acid pre-oxidation. This can show an indirect correlation with anti-oxidants, particularly with superoxide dismutases (SODs) ($r=0.573$) and catalase ($r=0.633$) representative anti-oxidant are involved in reducing the stress of a patient's biological system during hypertension. Another marker for hypertension is buildup of uric acid, where in uric acid is a marker for xanthine oxidase-associated oxidants and that the latter could be driving the hypertensive response. Additional markers are cortisol, a hormone. The test strips 604 can test for the different biological markers.

[0085] The results indicator 814 provides numeric ratings, in this case, 1-100, with the blood pressure rating being 88 and the glucose rating being 95. This indicates that both blood pressure and glucose are extremely high. Due to this, an additional alert indicator 1002 is presented to the user on the screen of the mobile device, alerting the user to seek medical attention immediately. This is to ensure that the health of both the pregnant woman and the fetus can be checked as close to the time of pregnancy detection as possible and medical attention received if needed.

[0086] Referring now to FIG. 11, there is provided a flowchart of one embodiment of a pregnancy disease risk assessment process 1100. The process 1100 begins at step 1102 where a biologic is collected and deposited in a testing device for testing of the biologic. At step 1104, the biologic is processed by the testing device for detection of pregnancy and various other medical conditions. These medical conditions may be high blood pressure, diabetes, bacterial or viral infections, inflammation, an increase in hormone levels, genetic disease markers, and/or metabolic disorders. At step 1106, a mobile device is used to capture an image of the testing device after testing is complete. In some embodiments, test results may be immediate. In other embodiments, and depending on the medical conditions being tested, the test may take a certain amount of time to complete. In this case, the user of the test would be alerted to this fact in instructions provided with the testing device. Additionally, a visual indicator on the testing device may alert the user that a test is now complete. At step 1108, the mobile device provides a rating for each medical condition being tested, such as that described with respect to FIG. 10 herein.

[0087] At decision block 1110, it is determined whether the ratings for each condition exceed a certain threshold for that condition. If not, the process 1100 moves to step 1112, where an indication is presented to the user via the mobile device screen that medical attention is not currently advised or necessary. If at step 1110 it is determined that at least one of the medical conditions being tested rises above a certain threshold, the process 1100 moves to step 1114 where a warning is presented to the user via the mobile device screen that medical attention is advised. The thresholds for medical conditions may not trigger a warning even if a rating exceeds a threshold, if, in the event of multiple tests being performed, the combined test results do not warrant immediate medical attention. For example, if a user is testing for a cold virus, blood pressure, and glucose, and only the cold virus rating is above the threshold, there may not be a warning provided to the user. Additionally, ratings may be weighted or aggregated based on the medical conditions being tested. For example, if blood pressure, inflammation, and glucose are being tested for, and they all are given only moderate ratings that do not rise above the threshold for any condition individually, an warning to seek medical attention may still be provided due to the combination of conditions taken together.

[0088] Referring now to FIG. 12, there is illustrated one embodiment of a consumer driven biologic and disease data collection system 1200. Data collected from users performing the tests disclosed herein effectively can provide a wealth of information. As tests are performed data may be passed by a plurality of mobile devices 1202 being used by users performing tests to a database 1204, the database being at a remote server 1206, over a network 1208. The user is sourcing a biologic from user's own body. This is done at home, not in a lab, hospital, or clinic. Each particular test would expect a certain type of biologic to be provided. For instance, for a pregnancy test, a urine sample is provided and tested for pregnancy markers. For a stool test, the stool might be dissolved in a vial with a solution provided with the testing device/kit, and tested for various disease or infectious markers. Data and results from the tests may be stored on the database 1204 at the remote server 1206. As described herein, this data may be used as a control for testing analysis for users of the plurality of mobile devices 1202. This data may also be used to provide data sets for biologics to a medical organization 1210. The medical organization 1210 may be doctor's offices, researchers, hospitals, testing labs, and other individuals or organizations that have an interest in the health and analysis of users taking the test and of their biologic samples. In this way, data can be gathered from a variety of biologics tested for a variety of different medical conditions and characteristics.

[0089] Referring now to FIG. 13, there is illustrated an example of a unique biologic ID database table 1300. The table 1300 is illustrative of the type of data stored in association with data for a biologic transmitted by the plurality of mobile devices 1202 for storage on the database 1204. A biologic ID header 1302 is provided that shows that the biologic sample has been given a unique ID. All data concerning the biologic may be stored in association with the unique biologic ID. The table 1300 also includes a biologic type entry 1304. This designates what type of biologic that the biologic associated with the unique ID is, such as blood, urine, stool, saliva, sweat, or other biologics. The table 1300 also provides a plurality of test ratings 1304,

for various tests performed on the biologic. In the example shown in FIG. 13, a blood biologic is provided having an assigned ID of 2402, and having been testing for pregnancy markers, the Zika virus, and for glucose levels. The rating for pregnancy was a 99 rating, the rating for a Zika infection was a 75, and the rating for glucose levels was a 10. This would indicate that the test subject has an extremely high likelihood of both a pregnancy and a Zika infection, which would have resulted in a warning to seek medical attention at the conclusion of the tests. Other information may also be stored in the database in relation to the biologic, including other condition ratings, time and date each test was performed, user information such as ethnicity, gender, and age, and status indicators such as whether a test subject visited a physician as a result of the tests. The database 1204 thus provides the test subject with a growing collection of information that may be accessed by the test subject. This allows the test subject to present the test results to her physician for medical attention or additional testing, and allows for others who may access the database, such as disease researchers, to have access to data on various biologic samples and their markers.

[0090] Referring now to FIG. 14, there is illustrated a flowchart of one embodiment of a biologic data collection and dissemination process 1400. The process 1400 begins at step 1402 where a user of a testing device collects a biologic sample for use in a test or a series of tests. At step 1404, the test or series of tests are performed on the biologic sample. At step 1406, a mobile device application checks the biologic sample the testing device result to determine a quantitative result of the test to provide a correlative value for the condition being tested in the biologic sample. At step 1408, the test results and correlative values, or multiple values if multiple tests on the biologic sample were conducted, are transmitted to the remote server 1206. At step 1410, the biologic sample is given a unique identification number in the database 1204. At step 1412, the test results and correlative value or values are stored in the database 1204 in association with the unique identification number given to the biologic sample collected and in association with the particular tests performed. This way, the particular biologic sample may have various characteristics stored and retrieved in association with the biologic sample, and the test results may also be retrieved when data on a particular test is needed on a cross-section of users.

[0091] At step 1414, the results are provided to the user on the user's mobile device. At step 1416, the results are provided to the user's healthcare provider. The healthcare provider may receive the test results due to a visit from the user, the user bringing the results of the test with her on her mobile device, or the healthcare provider may receive the results from the database 1204 if the healthcare provider has permission to access the database 1204, or if access is granted in anticipation of the user's appointment with the healthcare provider. At step 1418, the test results are also provided to other healthcare industry individuals and organizations, including medical researchers, hospitals, and others.

[0092] Referring now to FIG. 15, there is illustrated a perspective view of a system for scanning test strips. The housing 604, as described hereinabove with respect to FIG. 6, is illustrated as being disposed within a slot 1502 in a test housing 1504. The test housing 1504 is connected through a line 1506 to a PC 1508. When the housing 604 containing

the test strips **604** after being subjected to the biologics is inserted within the slot **1502**, the test housing **1504** will scan the test strips **604** and analyze the results with the PC **1508**. The PC **1508** will run some type of algorithm that can analyze the results of both of the test strips **604**. There can be provided to indicators **1510** and **1512** on the surface of the test housing **1504**, one being, for example, a ready LED and one being a green LED. The PC **1508**, after analyzing results, can then provide a warning indicator such as lighting up the green LED for a positive indication of pregnancy and the red LED for indicating that there is some issue. As an example, suppose that the second test strip tested for the Zika virus. If so, a warning would be appropriate to output and activate the red LED. There could be any other type of indicator associated with the second test at **604** that, in a combination with the test results of the first test strip, i.e. for testing for the presence of a pregnancy state, testing for such things as diabetes, etc. Further, although only two test strips **604** are illustrated, there could be multiple test strips testing for many different biological issues that may be present in an individual. In this embodiment, by inserting the housing **602** into the test housing **1504** and allowing the PC **1508** to analyze the results, the indicators associated with the test strips can be analyzed with the assumption that all of the test return results were associated with an individual and in proximate time to each other. That means that the individual patient applied biological specimens, such as urine, blood, etc., to the appropriate test strips and, since these were all contained within the same test strip housing **602**, this provides an indication that they are associated with a single patient. Further, the test performed will typically be a test that will provide a very short-term response. Thus, the specimens can be applied to the test strips **604** in the test strip housing **602** and then inserted within the slot **1502** for testing by the PC **1508**.

[0093] Referring now to FIG. 16, there is illustrated a cross-section of the test housing **1504**. It can be seen that the test strip housing **1602** is passed in slot **1502** past the camera **1602**. The camera **1602** is operable to scan a small cross-section of the test strips **604** on the surface thereof as the test strip housing **602** passes thereby. Of course, there could also be a much larger camera provided for taking an entire image of the test strips **604** after being inserted within the test housing **1504**. The camera **1602** is connected via a wire **1604** to an electronics package **1606** to process the information and send it to the PC **1508**. The electronics package **1606** will also drive the indicators **1510** and **1512**.

[0094] Referring now to FIG. 17, there is illustrated one embodiment of a vertical flow immunoassay device **1700**. It will be understood that testing device **300** and other embodiments herein illustrate a lateral flow immunoassay device. However, other types of immunoassay devices may be used. For example, vertical flow immunoassay devices may be used, a two-sided flow through assay, or even a sandwich ELISA test may be run.

[0095] The testing device **1700** includes a housing **1702** that forms the body of the testing device. The housing **1702** may be made of plastic, metal, or any material durable enough for shipping and subsequent handling by a user. The housing **1702** may be hollow so that a plurality of immunoassay test pads **1704** may be housed within and so that a biologic may be deposited within the housing **1702**. The testing device **1700** may further have a plurality of sample wells **1706**, each sample well having one of the plurality of

immunoassay test pads **1704** disposed within, and allowing for a user to view at least a section of a nitrocellulose membrane of each of the immunoassay test pads **1704**, the membrane **1708** having a test line **1708** and control line **1710**. The testing device **1700** may also have disposed on the surface of the housing a crosshair symbol **1712**, used as an alignment target. This symbol may be a graphic printed or adhered to the testing device **1700**. The crosshair symbol **1712** is used to align the testing device **1700** for the taking of an image of the testing device **1700** using a camera on a mobile device, for use in a mobile device application described herein. In other embodiments, the crosshair symbol **1712** may be other types of symbols, such as a simple shape (circle, square, etc.), other images (such as a medical cross symbol, an arrow, etc.), or any other type of image. In other embodiments, the device **1700** may be configured in such a way as to allow a biologic sample to be deposited into a sample well, and to present the results of the test on the opposite side of the housing. Such a configuration would allow the biologic to flow through the testing pad within the housing, with the reaction occurring on a reactive membrane on the side of the device opposite the sample well, with the device having a window for viewing the results.

[0096] Referring now to FIG. 18, there is illustrated a cross-sectional view of one embodiment of the vertical immunoassay device **1700**. There is shown one of the plurality of immunoassay test pads **1704** residing within the housing **1702** below one of the plurality of sample wells **1706**. The one of the plurality of immunoassay test pads **1704** includes an immunoreactive membrane **1802**, such as the nitrocellulose membranes disclosed herein. The immunoreactive membrane **1802** may have particle conjugates disposed thereon that binds when a biologic sample is received onto the immunoreactive membrane **1802** via the sample well **1706**, if the biologic sample contains the antigens or antibodies, or other indicators, for which the test is configured. The one of the plurality of immunoassay test pads **1704** also includes an absorbent pad **1804** for collection of excess biologic sample. It will be understood that the cross-sectional view illustrated in FIG. 18 shows one well of the plurality of sample wells **1704**. The other wells included in the device **1700** would be configured in a similar manner as that shown in FIG. 18. There may also be included in the device **1700** an inner separating wall between each of the plurality of immunoassay test pads **1704**, to ensure that excess biologic material that is not adequately absorbed by the absorbent pad **1804** does not contaminate neighboring immunoassay test pads.

[0097] Referring now to FIG. 19, there is illustrated a color gradient chart **1900**. When the mobile application described herein captures an image of the testing device, in some embodiments each pixel that makes up the test line captured in the image is processed to place it on a color gradient scale. In some embodiments, this placement may be done by examining the RGB color values of the pixel. For any given test, there may be a visual color indicator (such as a test line) presented to the user of the test to indicate whether a reaction occurred. The color that is to be presented is known for the given test. Additionally, in some embodiments, the strength of the reaction will affect the strength of the color indicator. For example, if a test is supposed to produce a brown colored indicator, an image can be taken of the colored indicator to examine each pixel of the colored indicator to determine the strength of the color produced on

the testing device, which indicates the strength of the reaction, and thus the risk level for the user.

[0098] The embodiment illustrated in FIG. 19 uses as an example a set of pixel RGB results for a test that produces a red colored indicator on the test strip when a reaction has occurred. There can be seen an origin point **1902** on the chart **1900**, wherein the RGB color value is (255, 255, 255) or white. This may represent a no reaction state for the test strip, since the test line on the strip may only appear as a white blank space if no reaction has occurred. An x axis **1904** represents the color green, wherein the amount of green in the pixel decreases as it moves away from the origin in relation to the x axis **1904**. A y axis **1906** represents the color blue, wherein the amount of blue in the pixel decreases as it moves away from the origin in relation to the y axis **1906**. A diagonal line **1908** running in between the x axis **1904** and the y axis **1906** represents the color red, wherein the diagonal line **1908** running through the center of the chart **1900** is a maximum red color all along the diagonal line **1908**. If a pixel has less red than a 255 value, the pixel would be plotted away from the diagonal line **1908** in relation to whichever color is more predominant. For instance, if the pixel has RGB color values of (127, 50, 205), a shade of purple, the pixel would be plotted somewhere in the lower right quadrant of the chart **1900**. FIG. 19 further illustrates an example plurality of pixel plot points **1910**, connected by a curved line, wherein the example plurality of pixel plot points **1910** shows tests results that likely indicate a positive reaction, as the plot points are all located near the diagonal line **1908**, demonstrating that the colored indicator was a heavy red color for the most part.

[0099] Referring now to FIG. 20, there is illustrated a normalized past tests results chart **2000**. The captured pixels may be normalized into a single value for determining whether there is a likelihood of infection, pregnancy, or whatever else the test is designed to detect. This may be done in various ways. For example, the shade of red in all the pixels may be averaged to reach a single RGB value. Outliers may be left out so that the average is not heavily skewed, especially when there are few outliers present. This RGB value may then be given a value, such as a risk rating, ranging from 0 to 100. For example, an RGB value of (255, 255, 255) would be given a rating of 0. An RGB value of (255, 0, 0) would be given a rating of 100. An RGB value of (205, 150, 75) may be given a rating of 70, and so on. This normalized value may then be used to compare the user of the test to users of past tests to determine a risk level. In some embodiments, the control line and the test line may be captured and the results compared, as well. In addition, the real results of risk levels may also be used to adjust the stored normalized value. For instance, if a particular RGB value that seems to indicate a strong reaction repeatedly was found to not indicate an infection, this value may be adjusted to provide a lower risk rating. For instance, if a physician who saw a patient who had a (205, 150, 75) RGB value later reported to the operator of the server **1206** that further testing showed no infection was present, and if this trend continued substantially as reported by other physicians or medical organizations, subsequent test results by other test users that were near the RGB value of (205, 150, 75) may be given a lower rating.

[0100] Chart **2000** illustrates how past tests results may be collected and used to determine the risk of a current test user. A y axis **2002** represents a risk level rating, ranging from 0

at the origin to 100. An x axis **2004** represents time, wherein a plurality of normalized test results is plotted on the chart **2000**. The chart **2000** is further divided into sections across the y axis **2002**, indicating various risk level thresholds. For instance, and as illustrated in the chart **2000**, there may be at certain rating levels different thresholds of risk labeled as low, moderate, above average, and high risk levels. These thresholds may be moved over time as more data is accumulated via users conducting tests and the mobile application storing the data on the tests. When a user conducts a test, the user's normalized rating can be plotted similarly to past test results and weighed against them in order to provide a risk level for the user.

[0101] Referring now to FIG. 21, there is illustrated the mobile device **802** displaying on the screen **804** a mobile application variable test functionality. There is displayed on the screen **804** a plurality of test functions **2102**. The plurality of test functions **2102** may be buttons that can be selected by a user to switch between tests within the mobile application. This allows for all test functions to be within the same mobile application. For each test run by the mobile application, data for the particular test chosen is utilized in performing the test, pulling the data from the remote server **1206**.

[0102] Referring now to FIG. 22, there is illustrated the mobile device **802** of FIG. 8B, wherein the housing **302** of the testing device **300** also includes thereon test function indicators **2202** and **2204**. The test function indicators **2202** and **2204** are visual markers located on the housing **302** that identify to the mobile application the types of tests for which the testing device **300** is configured. These indicators may be any symbol, alphanumeric character, shape, etc. that can be added to the surface of the testing device **300**. The mobile application is programmed to recognize the indicator and perform the test function associated with the indicator. For example, the embodiment illustrated in FIG. 22 shows a "P" symbol for test function indicator **2202** and a "Z" symbol for test function indicator **2204**. In this embodiment, test function indicator **2202** indicates that one test strip in the testing device **300** is a pregnancy test, while test function indicator **2204** indicates that one test strip in the testing device **300** is a Zika test. This is used for merely illustrative purposes, and any recognizable symbol may be used for these two test functions, and any other type of test may have a symbol assigned in this way as well. Further, in some embodiments there may only be one indicator on the housing **302**, even if there are multiple tests. This single indicator would be for the combined test. For example, if the testing device **300** of FIG. 22 had a single symbol of "PZ," this would indicate that the testing device **300** is a combined pregnancy and Zika testing device, allowing for the mobile application to recognize such and perform each test with knowledge of which strip is associated with which test based on the stored data on the testing device associated with the "PZ" symbol.

[0103] Referring now to FIG. 23, there is illustrated a medical code correlation system **2300**. The system **2300** includes a mobile device **2302**, which is configured to run the mobile application described herein. The mobile device **2302** is connected to a database **2304** disposed on a server **2306**, over a network **2308**. To correlate a medical code, the mobile device first passes a diagnostic test identifier to the remote server. This identifier allows for the type of test being used by the user of the mobile device **2302** to be determined. The identifier may simply be the name of the test, may be a

number associated with the test, or any other means of identifying the test being performed by the user of the mobile device **2302**. This may be done when the phone capture the image of the testing device to process the results, or the user may enter the test to be performed before a test is conducted, at which time the mobile device **2302** may pass the identifier to the remote server. In other embodiments, the diagnostic test identifier may even be the medical code. For example, if the diagnostic test is a strep test, the identifier may be G0435, an HCPCS code for a rapid immunoassay test, or any other appropriate medical code.

[0104] Once the physical test results of the diagnostic test is captured, and once the results are processed by the mobile device **2302** or the server **2306**, the results are also received by the server. Once the server **2306** has the diagnostic test identification and the results of the test, the server **2306** may then correlate the specific test and the results with appropriate medical codes stored within the database **2304**. It will be understood that the database **2304** may be physically located with the server **2306**, or the database **2306** may be a remote database, such as a centralized database that allows entities within the healthcare industry to retrieve the latest medical codes. The medical codes assigned may then be transferred from the mobile device **2302** to a healthcare entity **2310**. In other embodiments, the medical codes may be transferred from the server **2306** to the healthcare entity **2310**. The healthcare entity **2310** may be a physician, a hospital, a pharmacy, an insurance company, or any other entity that may provide the user with further assistance.

[0105] Referring now to FIG. **24**, there is illustrated a strep home retail test codes table **2400**. The table **2400** lists the various medical codes that may be associated with a home testing device that is used to test for a streptococcal infection. The table **2400** is representative of the types of codes that may be stored in the database **2304** in relation to a particular retail strep test device. The table **2400** lists a diagnosis code of J02.0, an ICD-10-CM code for streptococcal pharyngitis. The table **2400** also lists an HCPCS code of G0435, which is a code for a rapid antibody test. The table **2400** also lists an NDC code of 54569-5182-0, which is the NDC code for an amoxicillin prescription. Thus, when the server **2306** assigns the medical codes to the testing device or the test results, various codes may be produced. The example shown in table **2400** shows that the strep home retail testing device is assigned the HCPCS code of G0435 to indicate the type of test it is, a rapid antibody test. If the test results come back as positive, the server assigns the ICD-10-CM code to this event, indicating a streptococcal throat infection. In response to these positive test results, the server **2306** provides the NDC code for amoxicillin as a recommended prescription to give to the user to treat the infection.

[0106] In some embodiments, this prescription may be passed to a pharmacy so that the pharmacy may fill the prescription for the user to pick up, or to be delivered to the user. In some embodiments, the medical codes and other information may be passed to a physician for review. This physician may be the primary care physician of the user, allowing the user to set an appointment to go over the test results and get a prescription from the physician. In other embodiments, the physician may be a telemedicine physician that either the user contacts, the physician sets up a telemedicine conference, or the system described herein automatically initiates in response to the test results. The

physician may alter the recommended prescription provided by the system, may conduct additional testing, or otherwise handle the situation as he or she sees fit as a physician. In addition, in some embodiments, the medical codes may be passed to an insurance company to seek reimbursement for the testing device, the prescription, the visit with the physician, or any other costs that arise from this testing event. To accomplish such, the user may have provided his or her insurance information when signing up to use the mobile application in conjunction with the various testing devices provided.

[0107] Referring now to FIG. **25**, there is illustrated a combined pregnancy and Zika home retail test codes table **2500**. The table **2500** lists the various medical codes that may be associated with a home testing device that is used to test for both pregnancy and a Zika infection. The table **2500** is representative of the types of codes that may be stored in the database **2304** in relation to a particular retail pregnancy/Zika testing device. The table **2500** has a pregnancy codes column and a Zika codes column. The pregnancy codes column lists a diagnosis code of Z33.1, an ICD-10-CM code for a pregnant state. The pregnancy codes column also lists an HCPCS code of G8802, which is a code for a pregnancy test. The pregnancy codes column also lists an NDC code of 42192-321-30, which is the NDC code for prenatal vitamins. The Zika codes column lists a diagnosis code of A92.5, an ICD-10-CM code for the Zika virus. The Zika codes column also lists an HCPCS code of G0435, which is a code for a rapid antibody test. The Zika codes column also lists an NDC code of 50580-501-30, which is the NDC code for prescription strength Tylenol. In some embodiments, instead of separate codes for each type of test performed, there may be a single code assigned to, for example, a combined pregnancy and Zika test, or even a single code for a pregnant with Zika infection state.

[0108] It will be understood that the codes listed in FIGS. **24-25** are examples of how the system may assign codes to a testing event. The use of the specific codes and the types of codes (ICD-10-CM, HCPCS, and NDC codes) are merely used for illustrative purposes; any type of codes may be used and the specific codes listed in FIGS. **24-25** may be other, more appropriate, codes for the particular testing device, diagnosis, etc. Different types of codes include, but are not limited to, ICD-9-CM, ICPC-2, NANDA, Read code, SNOMED, CCI, CDT, NIC, NMDS, NOC, CCAM, OPCS-4, or other codes.

[0109] Referring now to FIG. **26**, there is illustrated a flowchart of one embodiment of a medical code correlation process **2600**. The process begins at step **2602** where the mobile device **2302** running the application described herein transmits a diagnostic test identifier to the remote server **2306**. At step **2604**, the remote server **2306** correlates the diagnostic test identifier with a medical code associated with the particular diagnostic test. This identifier allows for the type of test being used by the user of the mobile device **2302** to be determined. The identifier may simply be the name of the test, may be a number associated with the test, or any other means of identifying the test being performed by the user of the mobile device **2302**. This may be done when the phone capture the image of the testing device to process the results, or the user may enter the test to be performed before a test is conducted, at which time the mobile device **2302** may pass the identifier to the remote server. In other embodiments, the diagnostic test identifier may even be the medical

code. For example, if the diagnostic test is a strep test, the identifier may be G0435, an HCPCS code for a rapid immunoassay test, or any other appropriate medical code.

[0110] The process then flows to step **2606**, where the mobile device **2302**, as part of the overall operation of the system and mobile application described herein, capture an image of the testing device for processing. At step **2608**, the image is processed to achieve the test results. Such processing may be performed on the mobile device **2302**, on the remote server **2306**, another server, or any other device that may be interfaced with the system disclosed herein. The process then flows to decision block **2610**, where it is determined whether the test results indicated a positive result (positive infection, pregnancy, or other outcomes). If the test result is positive, the process flows to step **2612**, where the remote server **2306** correlates a medical code with the test results. As described herein, components other than the remote server **2306** may correlate the test results with a medical code, such as a centralized server and database used in the healthcare industry to retrieve medical codes. The process then flows to step **2614** to assign a recommended pharmaceutical product based on the test results. This may be an NDC code for a product, and there may even be provided a prescription for such. At step **2616**, the codes are transmitted to the appropriate healthcare entities, such as a physician, a pharmacy, or other entities.

[0111] If at decision block **2610** it is determined that the test results are negative, the process instead flows to step **2618**, where no medical code is correlated with the test results. This provides that no diagnosis code is provided, since the test results indicate that the user is not positive for the condition being tested. However, a medical code for the test itself, determined at step **2604**, may still be applicable in this scenario, because the user still used the diagnostic test, and therefore may still be reimbursed for the cost of the test, if the user's insurance company chooses to do so. The user's physician may also want to see the test results, even if they are negative, and the code for the test and the negative results may still be transmitted to the physician. Therefore, after step **2618**, the process then flows to step **2616** to transmit the codes (in this case, the code for the testing device product) to the appropriate healthcare entities. The test results themselves may also be transmitted.

[0112] Referring now to FIG. 27, there is illustrated one embodiment of a telemedicine initiation option within a mobile application. The mobile application and system described herein is predominantly meant to first test a patient for a medical condition, and then recommend an action, such as seeing a physician. However, the system allows for telemedicine conferences to be initiated, and therefore functionality may exist wherein a user can request a telemedicine conference with a physician at any time while using the mobile application, in order to receive a diagnosis or simply to ask questions. Thus, FIG. 27 again shows the plurality of test functions **2102** displayed on the screen **804**. In addition to these options, an additional option is presented to the user. This option is a telemedicine conference button **2702** that allows a user to initiate a telemedicine conference with a qualified telemedicine provider. This button **2702** is shown on the screen where the user selects the type of test to be performed, but the button **2702** may be presented within the user interface on any screen of the mobile application.

[0113] Referring now to FIG. 28, there is illustrated another embodiment of a telemedicine initiation option

within a mobile application. There is shown on the screen **804** the test results as previously shown on FIG. 22, which indicate positive pregnancy and Zika test results. In such a situation where the test results indicate a possible serious medical condition, a button **2802** may appear to the user on the screen **804**. The button **2802** may have a warning message within, urging the user to seek a consultation with a physician to talk about the user's options in light of the positive test results, and inviting the user to tap the button **2802** to initiate a telemedicine conference with a physician. Tapping the button **2802** will initiate such a telemedicine conference. The physician that is connected with for the conference may be an on-call physician that has agreed to make his or her services available through the system described herein, the telemedicine conference may use an existed telemedicine conference platform and physician base, the user's primary care physician may be a user of the system and mobile application, allowing for them to be used as the default telemedicine contact for the user, or other methods of making physicians available for a conference with the users of the mobile application may be provided.

[0114] Referring now to FIG. 29, there is illustrated one embodiment of a telemedicine conference session on a mobile device. During a telemedicine conference that has been initiated as described herein, the user is presented with a video conference window **2902** on the screen **804**. The video conference window **2902** allows for user to see the physician that is providing the telemedicine services to the user. It will be understood that the physician may have a similar video window on the device being used by the physician that allows the physician to see the user. This allows the physician to make some visual observations of the user's condition. In addition to the video conference window **2902**, the user is presented with a plurality of actions **2904** on the screen **804**. The plurality of action **2904** may be buttons that allow the user to provide the physician with further information. For example, one button may allow for the user to send a photograph to the physician, such as a photograph of the user's symptoms, or of the user's test results presented on the testing device. One button may also provide an option for sending the user's medical file to the physician, so that the physician can review the user's medical history or other important information. This medical file may include all the information accumulated from all tests performed by the user under the system described herein, and may also include all other medical history information. The user may have provided a copy of his or her medical history, or such may have been retrieved from a central electronic medical records system.

[0115] Other actions that may be provided in the plurality of actions **2904** may be a button to send test results to the physician. This would allow the user to send the test results of the latest test the user took before initiating the telemedicine conference, or it may allow for the user to choose the test. The plurality of actions **2904** may also include a button for sending the user's insurance information to the physician. The user may have provided this information within the mobile application and had it stored to the server, or this information may have been pulled for the user based on the user's identification information. This option allows the user to give the physician insurance information so that the physician can use the user's insurance for reimbursement of the telemedicine services, and may even set up reimburse-

ment to the user for certain services or products, such as the testing device used for the test.

[0116] Referring now to FIG. 30, there is illustrated a flowchart of one embodiment of a medical file handoff process 3000. The process 3000 starts at step 3002 where a user is provided with diagnostic test results at the conclusion of a performance of a test. At decision block 3004, it is determined whether the test results provide a positive result. If not, at step 3006 the results are stored on the server of the system described herein and the process ends at end block 3016. If the results are positive, the process flows to step 3008 where the results are stored on the server. At step 3010, it is determined whether a telemedicine conference has been initiated. This initiation may have been selected as described with respect to FIGS. 27 and 28, may have been initiated automatically due to the results provided, or may have been initiated in some other way. If the telemedicine conference was not initiated, the process ends at end block 3016. If the telemedicine conference was initiated, the process flows to step 3012 where the test results are passed to the telemedicine provider participating in the telemedicine conference. The process then flows to step 3014, where other user information is passed to the telemedicine provider. The process then ends at end block 3016.

[0117] The passing of the results to the telemedicine provider and other information at steps 3012 and 3014 may be performed by the user's mobile device, wherein the mobile device sends the files to the telemedicine provider. The passing may also be done by the server of the system described herein, wherein the results and other information was previously stored to the server and the server then passes the results and other information to the telemedicine provider as a result of the server being notified of a telemedicine conference initiation. The other user information of step 3014 may be any information needed by the telemedicine provider, such as past medical records and history of the user, past test results, insurance information, or any other information.

[0118] Referring now to FIG. 31, there is illustrated a flowchart of one embodiment of a telemedicine conference initiation process 3100. The process 3100 starts at step 3102 where a user is provided with diagnostic test results at the conclusion of a performance of a test. At decision block 3104, it is determined whether the test results provide a positive result. If not, at step 3106 the results are stored on the server of the system described herein and the process ends at end block 3118. If the results are positive, the process flows to step 3108 where the results are stored on the server. At step 3110 a telemedicine button is presented to the user on the screen of the mobile device, similar to that shown in FIG. 28. This button recommends to the user that the user initiate a telemedicine conference, since the test results indicate a positive reaction. At step 3112, it is determined whether a telemedicine conference has been initiated. This initiation may have been selected as described with respect to FIGS. 27 and 28, may have been initiated automatically due to the results provided, or may have been initiated in some other way. If the telemedicine conference was not initiated, the process ends at end block 3118. If the telemedicine conference was initiated, the process flows to step 3114 where the test results are passed to the telemedicine provider participating in the telemedicine conference. The

process then flows to step 3116, where other user information is passed to the telemedicine provider. The process then ends at end block 3118.

[0119] The passing of the results to the telemedicine provider and other information at steps 3114 and 3116 may be performed by the user's mobile device, wherein the mobile device sends the files to the telemedicine provider. The passing may also be done by the server of the system described herein, wherein the results and other information was previously stored to the server and the server then passes the results and other information to the telemedicine provider as a result of the server being notified of a telemedicine conference initiation. The other user information of step 3116 may be any information needed by the telemedicine provider, such as past medical records and history of the user, past test results, insurance information, or any other information.

[0120] Resolution of test results as described above requires accurate color determination. However, cameras incorporated into mobile devices such as smart phones differ from phone to phone and model to model. The optical design of the cameras used in smart phones varies with different manufactures and models with varying degrees of chromatic aberration and lens-light interactions that can affect the color balance of captured images. Different hardware sensors are used in different mobile devices to detect lighting conditions and adjust image acquisition parameters. Further, image and color correction algorithms incorporated into different models of smart phones will not necessarily produce the same colors and intensity of images. Image correction algorithms incorporated into many mobile devices are designed to produce images that are pleasing to the eye of the viewer, e.g., provide acceptable contrast, color intensity and brightness. These algorithms may adjust the color and intensity of colors in captured images. Additionally, variations in manufacturing and components such as lenses can add to differences in the coloration of captured images.

[0121] Environmental factors may also introduce variations. Lighting, the angle of the camera, and other factors such as dust or other material on the camera lens may affect image capture and color reproduction. Thus, different images acquired with the same and different mobile devices such as smart phones will have differing and unique color balances. A particular color, for example a "red" in one image, will not necessarily match the "red" in another image, regardless of the color space used to represent the image, e.g. sRGB, HSV, etc. Consequently, there is a need to insure that test images captured by mobile devices as described herein provide consistent accurate color results.

[0122] Referring to FIG. 32, in one embodiment, a test strip 3200 is substantially similar to test strip 100 of FIG. 1. Test strip 3200 is made up of multiple sections disposed on the backing 3202. A sample pad 3204 is disposed near a first end of strip 3200 with a particle conjugate pad 3208 disposed between sample pad 3204 and a test line 3210. A control line 3212 provides a comparative example for a user reading the test. A wick 3216 is provided to absorb analyte applied to the strip as described in connection with FIG. 1. As illustrated, test strip 3200 includes a color mosaic 3220 at an end of the strip. Color mosaic 3220 includes a plurality of different color tiles 3222. Depending upon the particular test, e.g., the anticipated color or colors of test line 3210 and control line 3212 upon completion of the test, the number of tiles of a particular color or color range may be biased to

include more tiles of the anticipated color range and/or shades of the anticipated color or colors upon completion of the test. In other words, if the anticipated color of test line 3210 and control line 3212 is red, a relatively large number of color tiles 3222 may be colored red or different shades of red. Color mosaic 3220 may be applied to strip 3220 by imprinting the color mosaic on the strip or applied as an adhesive label or sticker.

[0123] FIG. 33 is a diagrammatic illustration of one color mosaic 3300. Color mosaic 3300 includes a plurality (6 illustrated) of color blocks 3302. In different variations a single color block or other geometries may be used. Each colored block 3302 is subdivided into color tiles 3304 of different colors and shades of colors that may be used for color correction of test results as hereinafter described. The use of multiple color blocks 3302 provides a means of cross-checking since the arrangement and color of each of tiles 3304 is the same in each of the blocks. Depending upon the anticipated results of a test, the colors of tiles 3304 may be biased to include a larger number of tiles of the anticipated color of the test result and shades of that color. For example, if the anticipated color of the test strips upon completion of the test is red, then color matrix 3212 may be biased to include more “red” tiles than “green” or “blue” tiles. Although as illustrated, color mosaic is comprised of a plurality of rectangular blocks, in different variations color mosaic could be circular, ring-shaped or a different geometry with different colors displayed in different areas of the mosaic.

[0124] Referring now to FIG. 34, a top view of one embodiment of a testing device 3400. Device 3400 is configured to receive a plurality of test strips 3404, the same as or similar to strip 3200 of FIG. 32. Device 3400 includes a housing 3402 that may be made of plastic, metal, or other suitable material. Housing 3402 is configured such that one or more test strips 3404 may be contained therein with portions of the strips visible through windows 3406. Windows 3406 may be open or covered with a suitable transparent material to allow observation of at least test and control lines 3410, 3412 and a color mosaic 3414. As illustrated, color mosaic 3414 includes a plurality of different colored tiles 3416 which may be biased toward the anticipated color or colors of the test and control lines after contact with the analyte.

[0125] Housing 3402 includes one or more sample wells 3408 disposed on a surface of the housing to receive a biologic into the housing and onto the test strip as described herein. In one embodiment, a single sample well 3408 is included for collection of a single type of biologic for testing, with each of strips 3404 selected to test for antigens using that particular biologic sample type, (i.e. blood, urine, saliva et.). In other embodiments multiple sample wells, each associated with one or more strips, may be provided to enable testing using different biologics.

[0126] Device 3400 may include an alignment target 3410 (crosshair illustrated) printed or adhered to the device. Alignment target 3410 is provided to align device 3400 with a camera of a mobile device such as a smart phone to capture an image of the device including at least test and control lines 3410, 3412 and color block 3414. Alignment target 3410 may one of any number of different symbols or insignia and may be imprinted on device 3400, applied as an adhesive label or otherwise applied to the device.

[0127] FIG. 35 is a top view of an embodiment of a testing device 3500. Device 3500 is substantially similar to device 3400 of FIG. 34 with a housing 3502, one or more sample wells 3508, an alignment target 3510 and windows 3506 to enable viewing of test strips 3504. The embodiment illustrated in FIG. 35 further includes a color mosaic 3514 applied to housing 3502. Color mosaic 3514 includes a plurality of tiles 3516 of different selected colors. Color mosaic 3514 may be imprinted on housing 3502, applied as an adhesive label or otherwise placed on the housing. In the case where device 3500 is used with multiple different test strips to perform multiple tests, different mosaics may be supplied with different test strips as adhesive labels and selectively applied to housing 3502 depending upon the particular test or tests to be performed with the device. Depending upon the anticipated results, (color or colors of the test and control lines), the colors of tiles 3504 may be biased to include a larger number of tiles of the anticipated color or colors of the test and control lines.

[0128] A medical test code 3520 or codes may also be imprinted on or applied to device 3500. Test code 3520 may be a representation of an ICD-10-CM code or similar code associated with the underlying condition that is the subject of the test. A device identification code 3522 may also be imprinted on device 3500. Device identification code 3522 may be unique to the specific device or to a group of devices. In the case where device 3500 is provided to a user with one or more selected test strips, device code 3500 may be used to insure that the device is used with the intended test or tests. In some embodiments, similar medical test codes or identification codes may be imprinted or applied to test strips, such as strip 3200 of FIG. 32.

[0129] FIG. 36 is a top view of a mobile device 3600 using an application for testing device image capture and image processing. The mobile device application allows for an image of a testing device, such as testing device 3500, to be captured using a camera installed on mobile device 3600 having a screen 3604. While the mobile device 3600 displays on the screen 3604 the scene captured by the camera, the mobile device application may also display a graphic on the screen 3604 in the form of a boxed outline 3608, similar or identical to outline 806 of FIG. 8A, the outline corresponding to the size of the testing device 3600. Also displayed on the screen of the mobile device 3600 is an alignment graphic 3608. A user of the mobile device 3600 aligns the outline with the borders of the testing device 3500 and also aligns the alignment graphic 3608 with the alignment target 3510 on the testing device 3500 until the outline and the alignment graphic 3608 are superimposed upon the test device 3500 and alignment target 3510 as illustrated. As described in connection with FIG. 8B, a success indicator may appear, such as a check mark or other positive status symbol, on the aligned image when the alignment is successful. In one embodiment, successful alignment causes the camera on the mobile device 3600 to capture the current image of the testing device 3500. Other checks may occur including ensuring that the image is focused before the image is saved.

[0130] The captured image of testing device 3500 also includes color mosaic 3515. The mobile device application recognizes color mosaic 3514 based upon its position in the captured image and/or other criteria, such as the arrangement of color tiles 3516 or a code imprinted with the color

mosaic. The inclusion of the color mosaic in the captured image provides a means of calibrating and interpreting the results of the test.

[0131] FIG. 37 is a flowchart 3700 of one embodiment of an image analysis process using mobile device 3600 and device 3500. The process begins at 3702 with initialization of the application on the mobile device 3600 (FIG. 36). The user may be required to identify the particular test or device by entering an associated code or selecting a test from a displayed menu of tests. The user collects the biologic, e.g. blood, urine, saliva, at 3704 and places the sample in the sample well 3508 (FIG. 36). The user aligns the testing device 3500 with the mobile device camera at 3706 and an image of the testing device is captured at 3708. Correct alignment of the mobile device camera with the testing device may be used by the application to trigger the mobile device to activate the camera to capture an image of the test device. In other embodiments, the application may require proper alignment or alignment within a certain range, for example plus or minus 1 mm or 0.5 mm, before a user may activate the camera to capture an image of the test device.

[0132] Processing of the captured image with the mobile device is initiated at 3710. Initial steps in the image process may include determining if the image is resolvable at 3712. If, for some reason, such as a dirty camera lens or insufficient lighting, the image cannot be resolved, an error message is displayed on the mobile device screen at 3714 and the process ended before the image is saved. The application may also check to determine if the test device is recognized, for example, if the image of the test device does not fit the expected profile or if a device identification code 3522 (FIG. 35) is not recognized, an error message may be displayed at 3714 and the process terminated.

[0133] At 3718, the color mosaic 3514 (FIG. 35) in the captured image is identified and the color values for all or selected ones of color tiles 3516 determined. For example, each pixel corresponding to a color tile in the color matrix of the captured image is assigned a RGB value. After the color values for the captured image color matrix are determined, known values for the colors in the matrix may be retrieved at 3720. The known values may be stored on a database associated with remote server, such as server 1206 of FIG. 12, and/or transmitted to mobile device 3600 for comparison with the color values of the color matrix in the captured image at 3722. For example, a RGB value may be established for each color tile 3516 in the captured image and compared to the known RGB of the color tile. This step may be performed with mobile device 3600 or with the remote server. The comparison may also be done by downloading the known values to mobile device 3600 which then conducts the comparison or, if the values for the color matrix in the captured image have been transmitted to a remote server 1206, the comparison of the color values from captured image with the known values may be done with the server. The comparison may be done on a pixel-by-pixel basis for each color tile 3516, or the color values for the pixels within each color tile in the image may be averaged and compared to a known color value for the particular color tile.

[0134] After comparison, the differences between the color values of the captured image of the color mosaic and the known color values may be checked to determine if the differences are within a predetermined acceptable range at 3724. For example, if the red, green and blue values (RGB) for the different color tiles 3516 of the color mosaic in the

captured image were all within a range of -5 to +5 of the known values, the color values of the captured image may be determined to be acceptable in which case, no color correction is necessary and the process skips to 3728.

[0135] If the color values of the color matrix of the captured image are not within an acceptable range when compared to the known values, a color shift factor or correction may be determined at 3726. The color shift factor may be determined with an algorithm that uses the differences between the color values of the color mosaic of the captured image and the known color values to determine a color shift factor or factors.

[0136] The test line is identified at 3728 and the colors of the test line pixels determined. In one variation, the color of the test line may be determined as an average color value of the pixels of the test line. If a color correction or shift has been determined at step 3726, the color shift factor or factors may then be applied to the pixels of the test line (or to the average color value) at 3730 to obtain corrected values. After the corrected values for the pixels of the test line are obtained, the results are processed at 3732, positive and negative results displayed on screen 3604 (FIG. 36) and the results processed as described herein. The process ends at 3734.

[0137] FIG. 38 is a top view of another embodiment of a testing device 3800. Device 3900 is substantially similar to device 3400 of FIG. 34 with a housing 3802, one or more sample wells 3808, an alignment target 3814 and windows 3806 to enable viewing of test strips 3804 including test lines 3810 and control lines 3812. A color mosaic 3816 is positioned on testing device 3800 adjacent each of test lines 3810 and control lines 3812. Color mosaic 3816 may include color tiles 3820 of different shades of a single color. For example, if the expected result of a positive test is red, color mosaic 3816 will include color tiles 3820 of different shades of red corresponding to a positive test result. In one variation, color mosaic 3816 may include a single color shade corresponding to a positive test result.

[0138] Color mosaic 3816 may be imprinted on housing 3802, applied as an adhesive label or otherwise placed on the housing. In the case where device 3800 is used with multiple different test strips to perform multiple tests, different mosaics 3816 are applied to housing 3802 or supplied with different test strips as adhesive labels and selectively applied to housing 3802 depending upon the particular test or tests to be performed with the device. In another variation, color mosaic 3816 may be applied to test strips 3804 similar to color mosaic 3220 of FIG. 32. In this case, the color mosaic could be exposed through a window in a test device similar to window 3406 of FIG. 34.

[0139] FIG. 39 is a top view of a mobile device 3900 using an application for testing device image capture and image processing. The mobile device application allows for an image of a testing device, such as testing device 3800, to be captured using a camera installed on mobile device 3900 having a screen 3904. While the mobile device 3600 displays on the screen 3604 the scene captured by the camera, the mobile device application may also display a graphic on the screen 3604 in the form of a boxed outline 3906, similar or identical to outline 806 of FIG. 8A, the outline corresponding to the size of the testing device 3600. An alignment graphic 3908 may be displayed on screen 3904 of the mobile device 3900.

[0140] A user of the mobile device 3900 aligns outline 3906 with the borders of testing device 3800 and may also align graphic 3908 with the alignment target 3814 on the testing device 3800 until the outline and the alignment graphic 3608 are superimposed upon the test device 3500 and alignment target 3814 as illustrated. As described in connection with FIG. 8B, a success indicator may appear, such as a check mark or other positive status symbol, on the aligned image when the alignment is successful. Successful alignment may be a trigger that causes the camera on the mobile device 3900 to capture the image of the testing device 3800. Other checks may occur including ensuring that the image is focused before the image is saved.

[0141] The captured image of testing device 3800 also includes color mosaic 3816. The mobile device application recognizes color mosaic 3816 based upon its position in the captured image and/or other criteria, such as a code imprinted with the color mosaic. Color mosaic 3816 in the captured image provides a means of interpreting the results of the test.

[0142] FIG. 40 is a flowchart 4000 of one embodiment of an image analysis process using mobile device 3900 and device 3800. The process begins at 4002 with initialization of the application on the mobile device 3900. The user may be required to identify the particular test or device by entering an associated code or selecting a test from a displayed menu of tests. The user collects the biologic, e.g. blood, urine, saliva, at 4004 and places the sample in the sample well 3808. (FIG. 38). The user aligns the mobile device camera with testing device 3900 with the mobile device camera at 4006. When the testing device 3800 is aligned with the mobile device camera an image of the testing device is captured at 4008. Correct alignment of the mobile device camera with the testing device may be used by the application to trigger the mobile device to activate the camera to capture an image of the test device. In other embodiments, the application may require proper alignment or alignment within a certain range, for example plus or minus 1 mm or 0.5 mm, before a user may activate the camera to capture an image of the test device.

[0143] Processing of the captured image with the mobile device is initiated at 4012. Image processing may include determining if the image is resolvable at 4012. If, for some reason, such as a dirty camera lens or insufficient lighting, the image cannot be resolved, an error message is displayed on the mobile device screen at 4014 and the process ended before the image is saved. The application may also check to determine if the test device is recognized, for example, if the image of the test device does not fit the expected profile or if a device identification code such as code 3522 (FIG. 35) is not recognized, an error message may be displayed at 4014 and the process terminated.

[0144] At step 4018, color mosaic(s) 3816 are identified in the captured image. The test line or lines 3810 and control lines 3812 are identified in the captured image at 4020 and the color values of the images of the pixels of the test and control lines are determined. The color values of the pixels of the test and control line images may be averaged to obtain a single value for comparison. The color values of the pixels of the image of the test line (or the average color value) are compared to the color values of the image of color mosaic at 4022. If the color values of the pixels of the test line (or the average value) fall within a predetermined range of the color or colors of the color mosaic indicating a positive test result, for example $\pm 5\%$ or within a predetermined range of

RGB color values, a positive test result is determined at 4026. If the color values of the pixels of the test line (or the average) fall outside of the predetermined range, a negative test result is determined at 4028. The positive or negative test results may be displayed on screen 3904, similar to FIG. 8B and FIG. 22, and the results processed as described herein. The process ends at 4030.

[0145] It should be understood that the drawings and detailed description herein are to be regarded in an illustrative rather than a restrictive manner, and are not intended to be limiting to the particular forms and examples disclosed. On the contrary, included are any further modifications, changes, rearrangements, substitutions, alternatives, design choices, and embodiments apparent to those of ordinary skill in the art, without departing from the spirit and scope hereof, as defined by the following claims. Thus, it is intended that the following claims be interpreted to embrace all such further modifications, changes, rearrangements, substitutions, alternatives, design choices, and embodiments.

1. A system for providing immunoassay test results for medical conditions, comprising:

a testing device configured to collect at least one biologic, the testing device including at least one immunoassay test strip, the at least one immunoassay test strip including:

a conjugate pad including particles configured to conjugate with the at least one biologic to create an immune complex, and

a membrane strip including a test line, the test line configured to receive the immune complex, wherein the test line includes particular antigens or antibodies, wherein, if the immune complex contains antigens or antibodies capable of binding with the particular antigens or antibodies included on the test line, the antigens or antibodies of the immune complex bind to the antigens or antibodies of the test line, and wherein the test line is configured to produce a qualitative response if the antigens or antibodies of the immune complex are bound to the antigens or antibodies on the test line;

a software application stored on a mobile device, the mobile device including a camera and a viewing screen, wherein the software application, when executed, causes the mobile device to:

present an outlined area on the viewing screen to be aligned with borders of the testing device;

present on the viewing screen an alignment graphic to be aligned with an alignment target of the testing device, wherein the alignment graphic is offset from a center of the outlined area;

capture an image of the testing device, the image including a color mosaic having at least one color value corresponding to a positive test result and the test line;

process the image to determine the color values of the pixels on the test line of the at least one immunoassay test strip;

compare the color values of the image of the test line to the color values of the image of the color mosaic; determine if the color values of the image of the test line is within a predetermined range of the at least one color value of the image of the color mosaic corresponding to a positive test result; and

present test results on the viewing screen.

2. The system of claim 1 wherein the software application, when executed, further causes the mobile device to:

detect when an alignment of the outlined area and the borders of the testing device has taken place, and when an alignment of the alignment graphic and the alignment target has taken place; and

capture an image of the testing device in response to the detecting step.

3. The system of claim 1 wherein the color values of the pixels of the image of the test line are averaged and an average color value of the image of the test line is compared to the color values of the image of the color mosaic.

4. The system of claim 3 wherein the test line of one of a plurality of immunoassay test strips includes Zika virus antigens and the test line of another one of the plurality of immunoassay test strips includes antibodies suitable for binding with hCG, and wherein the software application, when executed, further causes the mobile device to:

collect at least one biologic with a testing device having thereon an alignment target and contacting the test line of the one of the plurality of immunoassay test strips that includes Zika virus antigens with the biologic; and
contact the test line of the one of the plurality of immunoassay test strips that includes antibodies suitable for binding with hCG.

5. A method for providing immunoassay test results for medical conditions, comprising:

collecting at least one biologic with a testing device including at least one immunoassay test strip;

conjugating the at least one biologic with particles on a conjugate pad on the at least one immunoassay test strip to create an immune complex;

receiving the immune complex at a test line on a membrane strip on the at least one immunoassay test strip, wherein the test line includes particular antigens or antibodies;

binding, if the immune complex contains antigens or antibodies capable of binding with the particular antigens or antibodies included on the test line, the antigens or antibodies of the immune complex to the antigens or antibodies of the test line;

producing a qualitative response on the test line if the antigens or antibodies of the immune complex are bound to the antigens or antibodies on the test line;

providing a software application to be stored on a mobile device, the mobile device having a camera and a viewing screen;

presenting an outlined area on the viewing screen to be aligned with borders of the testing device;

presenting on the viewing screen an alignment graphic to be aligned with an alignment target of the testing device, wherein the alignment graphic is offset from a center of the outlined area;

capturing an image of the testing device, the image including a color mosaic having at least one color value corresponding to a positive test result and the test line;

processing the image to determine the color values of the pixels on the test line of the at least one immunoassay test strip;

comparing the color values of the image of the test line to the color values of the image of the color mosaic;

determining if the color values of the image of the test line is within a predetermined range of the at least one color value of the image of the color mosaic corresponding to a positive test result; and

presenting test results on the viewing screen.

6. The method of claim 5 further comprising:

detecting when an alignment of the outlined area and the borders of the testing device has taken place, and when an alignment of the alignment graphic and the alignment target has taken place; and

capturing an image of the testing device in response to the detecting step.

7. The method of claim 5 wherein the color values of the pixels of the image of the test line are averaged and an average color value of the image of the test line is compared to the color values of the image of the color mosaic.

8. The method of claim 7 wherein the test line of one of a plurality of immunoassay test strips includes Zika virus antigens and the test line of another one of the plurality of immunoassay test strips includes antibodies suitable for binding with hCG, the method further comprising:

collecting at least one biologic with a testing device having thereon an alignment target and contacting the test line of the one of the plurality of immunoassay test strips that includes Zika virus antigens with the biologic; and

contacting the test line of the one of the plurality of immunoassay test strips that includes antibodies suitable for binding with hCG.

9. A method for providing immunoassay test results for medical conditions, comprising:

collecting at least one biologic with a testing device;

conjugating the at least one biologic with particles on a conjugate pad on the at least one immunoassay test strip to create an immune complex;

receiving the immune complex at a test line on a membrane strip on the at least one immunoassay test strip, wherein the test line includes particular antigens or antibodies;

binding, if the immune complex contains antigens or antibodies capable of binding with the particular antigens or antibodies included on the test line, the antigens or antibodies of the immune complex to the antigens or antibodies of the test line;

producing a qualitative response on the test line if the antigens or antibodies of the immune complex are bound to the antigens or antibodies on the test line;

providing a software application to be stored on a mobile device, the mobile device having a camera and a viewing screen;

presenting an outlined area on the viewing screen to be aligned with borders of the testing device;

presenting on the viewing screen an alignment graphic to be aligned with an alignment target of the testing device, wherein the alignment graphic is offset from a center of the outlined area;

capturing an image of the testing device, the image including a color mosaic having a plurality of different colors at different locations in the mosaic;

identifying the different colors at the different locations in the captured image of the color mosaic;

comparing the different colors at the different locations in the captured image of the color mosaic to known color values for the different locations in the color mosaic;

determining at least one color correction factor based upon the difference(s) between the known color values for the different locations in the color mosaic and the colors identified in the captured image at the corresponding locations;

processing the image to determine colors of pixels on the test line and a control line of the at least one immunoassay test strip;

applying the at least one color correction factor to the pixels of the test line and control line;

comparing the corrected results of processing the image of the test line to the control line for the test line of the at least one immunoassay test strip; and

presenting test results on the viewing screen.

10. The method of claim 9 further comprising:

detecting when an alignment of the outlined area and the borders of the testing device has taken place, and when an alignment of the alignment graphic and the alignment target has taken place; and

capturing an image of the testing device in response to the detecting step.

11. The method of claim 9 wherein the test line of one of a plurality of immunoassay test strips includes Zika virus antigens and the test line of another one of the plurality of immunoassay test strips includes antibodies suitable for binding with hCG, the method further comprising:

collecting at least one biologic with a testing device having thereon an alignment target and contacting the test line of the one of the plurality of immunoassay test strips that includes Zika virus antigens with the biologic; and

contacting the test line of the one of the plurality of immunoassay test strips that includes antibodies suitable for binding with hCG.

12. The method of claim 9 further comprising transmitting the captured image of the color mosaic to a remote server and comparing, with the remote server, the different colors at the different locations in the captured image of the color mosaic to known color values for the different locations in the color mosaic.

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