

There is currently not a single point-of-birth newborn testing panel available for biochemical screening, although screening for hearing disorders is performed at point of birth using automated brain stem response and pulse oximetry is performed to screen for congenital heart defects.

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SUMMARY

The present invention relates to a point-of-birth testing system, a point-of-birth instrument, and a biological cartridge. The present invention further relates to a method of newborn screening and method for using a point-of-birth newborn screening system.

10 A point-of-birth testing system for newborn screening is disclosed. The point-of-birth testing system may include a point-of-birth instrument for processing sample fluid of a newborn, a smart display communicatively coupled to the point-of-birth instrument to provide user interface and operate the point-of-birth instrument, and a biochemical cartridge for receiving sample fluid to be processed. The biochemical cartridge may
15 insert into the point-of-birth instrument for processing the sample fluid. Further, the smart display may communicate results of the processed sample fluid.

The biochemical cartridge of the point-of-birth testing system of the present invention may be portable. Further, the point-of-birth instrument of the point-of-birth testing system of the present invention may be portable. The smart display of the point-
20 of-birth system of the present invention may be a portable smart device. Alternatively, the smart display of the point-of-birth system may be a laptop computer. In yet a further alternative embodiment, the smart display is a display built into the point-of-birth instrument.

In one embodiment, the point-of-birth testing system of the present invention may
25 only support newborn biological screening. Alternatively, the point-of-birth testing system of the present invention may support both newborn biological screening and newborn physiological screening. In one embodiment of the present invention, the point-of-birth testing system may include a pulse oximetry mechanism. In another embodiment of the present invention, the point-of-birth testing system may include a hearing
30 screening mechanism. In yet a further embodiment of the present invention, the point-of-

birth testing system may include both a pulse oximetry mechanism and a hearing screening mechanism.

The point-of-birth testing system of the present invention may support multiplexed testing. Further, the point-of-birth testing system of the present invention
5 may test multiple analytes with a single sample fluid on the biochemical cartridge.

In an embodiment of the present invention, the point-of-birth testing system may perform multiple types of biochemical tests. For example, the point-of-birth testing system of the present invention may perform multiples types of biochemical testing such as enzymatic test(s), colorimetric test(s), immunoassay test(s), and/or a nucleic acid
10 test(s). In one embodiment of the point-of-birth testing system of the present invention, the system may perform screenings for biological markers. For example, the point-of-birth testing system of the present invention may screen for biological markers such as total bilirubin, ammonia, and/or medium-chain acyl-CoA dehydrogenase.

In one embodiment of the present invention, the smart display of the point-of-
15 birth testing system may include a newborn screening mobile application to interface with a user and/or operate the point-of-birth instrument.

In an embodiment of the biochemical cartridge of the point-of-birth testing system of the present invention, the biochemical cartridge may include a horizontal reservoir module for holding liquids. Further, in one embodiment, the horizontal reservoir module
20 may be angled. For example, the horizontal reservoir module may be angled 13 through 17 degrees. In one embodiment of the present invention, the biochemical cartridge includes an optics interface region. The optics interface region of the biochemical cartridge may correspond to an optics detector of the point-of-birth instrument when the biochemical cartridge is inserted into the point-of-birth instrument.

25 A point-of-birth instrument for processing sample fluid is disclosed. The point-of-birth instrument may include a housing, a loading deck for receiving a biochemical cartridge having sample fluid, a smart display that interfaces with a user, an input reader, and a biochemical testing module that includes a processor for testing assays. The smart display of the point-of-birth instrument may provide results from the testing assays, such
30 as to a user.

one embodiment of the point-of-birth instrument of the present invention, the instrument may be portable.

5 In an aspect of the present invention, a biochemical cartridge for newborn screening is disclosed. The biochemical cartridge of the present invention may include a bottom substrate, a top substrate spaced from the bottom substrate by a gap, a cover positioned adjacent the top substrate, and a sample input well having a loading port and a well cap assembly for opening and closing the loading port. The sample input well may be for collection of newborn testing fluids. Further, the biochemical cartridge may be inserted into a newborn screening instrument for testing. The sample input well is a horizontal reservoir module and the biochemical cartridge
10 further comprises a cover gasket, a horizontal reservoir module mounting plate, and mounting posts for holding the horizontal reservoir module. The well cap assembly comprises a foil strip for sealing fluid inside the horizontal reservoir module and the biochemical cartridge further comprises a take-up reel for winding the foil strip off of the horizontal reservoir module, a reel engaging feature secured to the top substrate, and a reservoir module capture feature.

15 In one embodiment of the biochemical cartridge of the present invention, the sample input well may be integrated into the cover. The cover of the biochemical cartridge may include contoured regions. In an embodiment of the biochemical cartridge of the present invention, the gap between the top and bottom substrates may be an assay chamber.

20 In an embodiment of the biochemical cartridge of the present invention, the horizontal reservoir module may include a first reservoir for holding a first sample fluid and a second reservoir for holding a second sample fluid. In one embodiment of the biochemical cartridge of the present invention, the reservoir(s) may be angled. For example, the reservoir(s) may be angled 13 through 17 degrees.

25 In one embodiment of the biochemical cartridge of the present invention, the cartridge supports digital microfluidics. Alternatively, the biochemical cartridge of the present invention does not support digital microfluidics. In an embodiment of the

biochemical cartridge of the present invention, the newborn testing fluid may be urine and/or blood. Further, in an embodiment of the biochemical cartridge of the present invention, the bottom substrate may include a printed circuit board. In an embodiment of the biochemical cartridge of the present invention, the gap between the bottom substrate and top substrate may include filler fluid.

A method for newborn screening is disclosed. In one embodiment, the method for newborn screening includes the step of providing a point-of-birth testing system having (1) a point-of-birth instrument for processing sample fluid, (2) a smart display that interfaces with the point-of-birth instrument, and (3) a biochemical cartridge having a reservoir for receiving sample fluid for processing. Further, the method for newborn screening may include the steps of providing identification information to the testing system, loading sample fluid into the reservoir of the biochemical cartridge, sealing the reservoir of the biochemical cartridge after loading with sample fluid, loading the biochemical cartridge into the point-of-birth instrument, releasing the sample fluid into an assay of the biochemical cartridge for processing, processing of the sample fluid by the point-of-birth instrument, interfacing with the smart display to obtain results of the processed sample fluid, and/or communicating the results.

In an embodiment of the method for newborn screening, the method may further include the steps of providing a foil strip for sealing the reservoir of the biochemical cartridge after loading with sample fluid, providing a foil take-up reel on the biochemical cartridge that secures a portion of the foil strip, providing a stepper motor that is engaged with the foil take-up reel, activating the stepper motor after loading the biochemical cartridge into the point-of-birth instrument, and/or unsealing the foil strip from the reservoir after the stepper motor is activated to allow for releasing of the sample fluid.

In one embodiment of the method for newborn screening, the reservoir of the biochemical cartridge may include a first reservoir and a second reservoir. Further, the method may include the steps of providing a foil strip for sealing the first and second reservoir of the biochemical cartridge after loading both reservoirs with first and second respective sample fluids, providing a foil take-up reel on the biochemical cartridge that secures a portion of the foil strip, providing a stepper motor that is engaged with the foil

take-up reel, activating the stepper motor after loading the biochemical cartridge into the point-of-birth instrument, unsealing the foil strip from the first reservoir after the stepper motor is activated to allow for releasing of the first sample fluid in the first reservoir, and/or unsealing the foil strip from the second reservoir after the first reservoir is
5 unsealed to allow for releasing of the second sample fluid in the second reservoir.

A method for using a point-of-birth newborn screening system is disclosed. In one embodiment, the method for using a point-of-birth newborn screening system includes the step of providing a smart display having a point-of-birth newborn screening software application, wherein the smart display may be in communication with a point-
10 of-birth testing system having a point-of-birth instrument for processing sample fluid and a biochemical cartridge for receiving sample fluid for processing. Further, the method for using a point-of-birth newborn screening system of the present invention may include the steps of logging into the software application of the smart display, interfacing with the smart display by selecting an open order, scanning a sample fluid identifier on the
15 biochemical cartridge, inserting the biochemical cartridge containing sample fluid into the point-of-birth testing instrument, interfacing with the smart display to initialize processing of the biochemical cartridge, verifying adequate fluid sample for processing of the biochemical cartridge, processing the sample fluid by the point-of-birth testing instrument, monitoring the smart display to determine the status of the processing of the
20 sample fluid, and/or viewing test results of the processed sample fluid.

In an embodiment of the method for using a point-of-birth newborn screening system, the step of logging into the smart display may be done by manually entering a user ID and a password and/or by using a barcode reader to scan credentials. Further, in one embodiment of the method for using a point-of-birth newborn screening system, the
25 sample fluid identifier may be a barcode reader.

In one embodiment of the method for using a point-of-birth newborn screening system, the method may further include the step of entering sample fluid identifying information to create an open order in the software application of the smart display. Further, the method for using a point-of-birth newborn screening system may include the
30 step of collecting sample fluid from a newborn using the biochemical cartridge. In one

CLAIMS

1. A biochemical cartridge for newborn screening comprising:
- 5 a bottom substrate;
- a top substrate spaced from the bottom substrate by a gap;
- a cover positioned adjacent the top substrate; and
- a sample input well having a loading port and a well cap assembly for opening
 and closing the loading port;
- wherein the sample input well is for collection of newborn testing fluids and the
 biochemical cartridge is for insertion into a newborn screening
10 instrument for testing;
- wherein the sample input well is a horizontal reservoir module and the
 biochemical cartridge further comprises a cover gasket, a horizontal
 reservoir module mounting plate, and mounting posts for holding the
 horizontal reservoir module; and
- 15 wherein the well cap assembly comprises a foil strip for sealing fluid inside the
 horizontal reservoir module and the biochemical cartridge further
 comprises a take-up reel for winding the foil strip off of the horizontal
 reservoir module, a reel engaging feature secured to the top substrate,
 and a reservoir module capture feature.
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2. The biochemical cartridge of claim 1 wherein the sample input well is integrated into the cover.
3. The biochemical cartridge of claim 1 wherein the cover comprises contoured regions.
- 25 4. The biochemical cartridge of claim 1 wherein the gap is an assay chamber.

5. The biochemical cartridge of claim 1 wherein the horizontal reservoir module comprises a first reservoir for holding a first sample fluid and a second reservoir for holding a second sample fluid.
6. The biochemical cartridge of claim 5 wherein the reservoirs are angled.
7. The biochemical cartridge of claim 6 wherein the reservoirs are angled 13 through 17 degrees.
8. The biochemical cartridge of claim 1 wherein the cartridge supports digital microfluidics.
9. The biochemical cartridge of claim 1 wherein the cartridge does not support digital microfluidics.
10. The biochemical cartridge of claim 1 wherein the newborn testing fluid is urine and/or blood.
11. The biochemical cartridge of claim 1 wherein the bottom substrate is a printed circuit board.
12. The biochemical cartridge of claim 1 wherein the gap between the bottom substrate and the top substrate comprises filler fluid.