

What is claimed is:

1. A molecular diagnostic test device, comprising:

a housing;

a sample preparation module within the housing, the sample preparation module including a heater and a sample preparation housing, the sample preparation housing defining a sample input volume that receives an unprocessed biological sample and a flow channel in fluid communication with the sample input volume, the heater configured to heat the unprocessed biological sample as it flows through the flow channel to A) extract RNA from a target virus within the unprocessed biological sample and B) produce a reverse transcription solution containing cDNA;

an amplification module within the housing, the amplification module configured to receive the reverse transcription solution from the sample preparation module, the amplification module configured to heat the reverse transcription solution to amplify the cDNA within the reverse transcription solution to produce a detection solution containing a target amplicon;

a reagent module within the housing, the reagent module including a reagent container containing a detection reagent formulated to facilitate production of a signal that indicates a presence of the target amplicon; and

a detection module including a detection surface configured to capture the target amplicon from the detection solution, the detection module in fluid communication with the amplification module and the reagent module such that the signal is produced in response to the detection reagent being conveyed into the detection module while the target amplicon is captured on the detection surface.

2. The molecular diagnostic test device of claim 1, wherein the sample input volume contains a solid form reverse transcriptase that is formulated to dissolve into the unprocessed biological sample within the sample input volume.

3. The molecular diagnostic test device of claim 2, wherein the sample input volume is devoid of a ribonuclease inhibitor.

4. The molecular diagnostic test device of claim 1, wherein:

the flow channel is a serpentine flow channel; and
the heater is configured to heat the reverse transcription solution to a reverse transcription temperature range within 30 seconds to limit degradation of the extracted RNA.

5. The molecular diagnostic test device of claim 1, wherein:
the flow channel is a serpentine flow channel; and
the heater is configured to heat the serpentine flow channel while not heating the sample input volume.

6. The molecular diagnostic test device of claim 5, wherein the heater is constructed on a printed circuit board, the printed circuit board defining a slot that thermally isolates the sample input volume from the serpentine flow channel.

7. The molecular diagnostic test device of claim 2, wherein:
the flow channel is a serpentine flow channel; and
the heater includes a plurality of independently controlled heating elements,
a first heating element from the plurality of independently controlled heating elements configured to heat the unprocessed biological sample as it flows through the flow channel to a first temperature to A) extract RNA from the target virus within the unprocessed biological sample and B) produce the reverse transcription solution containing cDNA,
a second heating element from the plurality of independently controlled heating elements configured to heat the reverse transcription solution to a second temperature to inactivate the reverse transcriptase within the reverse transcription solution.

8. The molecular diagnostic test device of claim 7, wherein the heater is constructed on a printed circuit board, the printed circuit board defining a slot that thermally isolates the first heating element from the second heating element.

9. The molecular diagnostic test device of claim 1, wherein the sample preparation module is devoid of any of a filter or a capture mechanism for purifying the extracted RNA.

10. The molecular diagnostic test device of claim 1, wherein the sample preparation housing defines an input opening through which the sample input volume can be accessed, the molecular diagnostic test device further comprising:

a lid movably coupled to the housing, the lid including a seal portion, a switch portion, and a reagent actuator, the lid configured to move relative to the housing between a first lid position and a second lid position, the input opening being exposed when the lid is in the first lid position, the seal portion of the lid covering the input opening when the lid is in the second lid position, the switch portion configured to actuate a switch to provide power to the heater when the lid is moved from the first lid position to the second lid position, the reagent actuator configured to cause the detection reagent to be released from the reagent container when the lid is moved from the first lid position to the second lid position.

11. The molecular diagnostic test device of claim 10, further comprising:

a fluid pump disposed within the housing, the fluid pump configured to produce an input flow of the reverse transcription solution within the amplification module; and

a control module within the housing, the control module including the switch and a processor, the switch providing power to the processor when the lid is moved from the first lid position to the second lid position, the processor configured to regulate a power input to the fluid pump to control a rate of the input flow of the reverse transcription solution within the amplification module.

12. The molecular diagnostic test device of claim 10, further comprising:

a control module within the housing, the control module including the switch and a processor, the processor configured to control transmission of power to the heater, the switch portion of the lid including a switch protrusion configured to engage the switch when the lid is in the second lid position.

13. A method of detecting a nucleic acid performed by the molecular diagnostic test device of claim 1, comprising:

loading an unprocessed biological sample into the sample input volume defined by the sample preparation module within the molecular diagnostic test device;

mixing, within the sample input volume, a reverse transcriptase with the unprocessed biological sample;

heating the unprocessed biological sample as it flows within the flow channel defined by the sample preparation module to A) release ribonucleic acid (RNA) molecules from a target virus within the unprocessed biological sample and B) produce a reverse transcription solution containing complementary deoxyribonucleic acid (cDNA);

heating the reverse transcription solution to an inactivation temperature to cause inactivation of the reverse transcriptase;

heating the reverse transcription solution within the amplification module within the molecular diagnostic test device to amplify the cDNA within the reverse transcription solution to produce a detection solution containing a target amplicon; and

reacting within the detection module within the molecular diagnostic test device each of the detection solution and a reagent formulated to produce a signal that indicates a presence of the target amplicon within the detection solution, the detection module including the detection surface configured to capture the target amplicon to produce the signal.

14. The method of claim 13, wherein each of the sample input volume and the unprocessed biological sample is devoid of a ribonuclease inhibitor.

15. The method of claim 13, wherein:

the heating the unprocessed biological sample as it flows within the flow channel is performed to produce the cDNA within between 5 seconds and 5 minutes.

16. The method of claim 13, wherein:

the heating the unprocessed biological sample as it flows within the flow channel is performed to produce the cDNA within less than 30 seconds.

17. The method of claim 16, wherein:

the heating the unprocessed biological sample as it flows within the flow channel is performed to heat the reverse transcription solution to a temperature of between about 30°C and about 80°C.

18. The method of claim 17, wherein:

the heating the unprocessed biological sample as it flows within the flow channel is performed to heat the reverse transcription solution to a temperature of between about 50°C and about 60°C.

19. The method of claim 17, wherein:

the heating the unprocessed biological sample as it flows within the flow channel lyses the target virus within the unprocessed biological sample to release the RNA.

20. The method of claim 17, wherein the sample preparation module is devoid of any of a filter or a capture mechanism for purifying the extracted RNA.

21. The method of claim 13, further comprising:

actuating the molecular diagnostic test device, after the unprocessed biological sample is loaded into the sample input volume and before the mixing, by only a single action of closing a lid of the molecular diagnostic test device to cover the sample input volume.

22. The method of claim 21, wherein the molecular diagnostic test device is a single-use device, the method further comprising:

discarding the molecular diagnostic test device after the method of detecting the nucleic acid is performed.

23. The method of claim 21, wherein the single action of closing the lid to cover the sample input volume includes A) moving a seal portion of the lid over an input opening that provides access to the sample input volume, B) actuating a switch to provide power to a heater of the sample preparation module, and C) releasing the reagent from a sealed reagent container within the molecular diagnostic test device by the single action.

24. The method of claim 21, wherein after the lid covers the sample input volume, a lock portion of the lid is irreversibly engaged with the molecular diagnostic test device to prevent uncovering the sample input volume.
25. The method of claim 13, wherein the target virus is an enveloped virus.
26. The method of claim 25, wherein the target virus is a coronavirus.
27. The method of claim 13, further comprising:
mixing a sample buffer with the unprocessed biological sample, the sample buffer comprising a detergent.
28. An apparatus, comprising:
a housing;
a sample preparation module within the housing, the sample preparation module including a heater and a sample preparation housing, the sample preparation housing defining a sample input volume that receives an unprocessed biological sample via a input opening, the sample preparation housing defining a flow channel in fluid communication with the sample input volume, the heater configured to heat the unprocessed biological sample as it flows through the flow channel to A) extract RNA from a target virus within the unprocessed biological sample and B) produce a reverse transcription solution containing cDNA;
an amplification module within the housing, the amplification module configured to receive the reverse transcription solution from the sample preparation module, the amplification module configured to heat the reverse transcription solution to amplify the cDNA within the reverse transcription solution to produce a detection solution containing a target amplicon;
a reagent module within the housing, the reagent module including a reagent container containing a detection reagent formulated to facilitate production of a signal that indicates a presence of the target amplicon;
a detection module including a detection surface configured to capture the target amplicon from the detection solution, the detection module in fluid communication with the reagent module

such that the signal is produced in response to the detection reagent being conveyed into the detection module; and

a lid movably coupled to the housing, the lid including a cover portion, a switch portion, and a reagent actuator, the lid configured to move relative to the housing between a first lid position and a second lid position, the input opening being exposed when the lid is in the first lid position, the cover portion of the lid covering the input opening when the lid is in the second lid position, the switch portion configured to cause actuation of a switch to provide power to the heater in response to the lid being moved from the first lid position to the second lid position, the reagent actuator configured to cause the detection reagent to be released from the reagent container in response to the lid being moved from the first lid position to the second lid position.

29. The apparatus of claim 28, wherein the sample input volume contains a solid form reverse transcriptase that is formulated to dissolve into the unprocessed biological sample within the sample input volume.

30. The apparatus of claim 29, wherein the sample input volume is devoid of a ribonuclease inhibitor.

31. The apparatus of claim 28, further comprising:

a fluid pump disposed within the housing, the fluid pump configured to produce an input flow of the reverse transcription solution within the amplification module; and

a control module within the housing, the control module including the switch and a processor, the switch providing power to the processor in response to the lid being moved from the first lid position to the second lid position, the processor configured to regulate a power input to the fluid pump to control a rate of the input flow of the reverse transcription solution within the amplification module.

32. The apparatus of claim 28, further comprising:

a control module within the housing, the control module including the switch and a processor, the processor configured to control transmission of power to the heater, the switch portion of the lid including a switch protrusion.

33. The apparatus of claim 29, wherein the solid form reverse transcriptase includes a lyophilized reverse transcriptase.

34. An apparatus, comprising:

a housing;

a sample preparation module within the housing, the sample preparation module including a heater and a sample preparation housing, the sample preparation housing defining an input opening, a sample input volume that receives an unprocessed biological sample via the input opening, and a flow channel in fluid communication with the sample input volume, the heater configured to heat the unprocessed biological sample as it flows through the flow channel to A) extract RNA from a target virus within the unprocessed biological sample and B) produce a reverse transcription solution containing cDNA;

an amplification module within the housing, the amplification module configured to receive the reverse transcription solution from the sample preparation module, the amplification module configured to heat the reverse transcription solution to amplify the cDNA within the reverse transcription solution to produce a detection solution containing a target amplicon;

a detection module within the housing, the detection module defining a detection channel configured to receive the detection solution from the amplification module and react the target amplicon within the detection solution with a detection reagent to produce a signal that indicates a presence of the target amplicon; and

a lid movably coupled to the housing, the lid including a cover portion and a switch portion, the lid configured to move relative to the housing between a first lid position and a second lid position, the input opening being exposed when the lid is in the first lid position, the cover portion of the lid covering the input opening when the lid is in the second lid position, the switch portion configured to cause actuation of a switch to provide power to the heater in response to the lid being moved from the first lid position to the second lid position.

35. The apparatus of claim 34, wherein a lock portion of the lid is configured to be irreversibly engaged with the housing to prevent the lid from moving from the second lid position back towards the first lid position.

36. The apparatus of claim 35, further comprising:
a fluid pump disposed within the housing, the fluid pump configured to produce an input flow of the reverse transcription solution within the amplification module; and
a control module within the housing, the control module including the switch and a processor, the switch providing power to the processor in response to the lid being moved from the first lid position to the second lid position, the processor configured to regulate a power input to the fluid pump to control a rate of the input flow of the reverse transcription solution within the amplification module.
37. The apparatus of claim 34, wherein the sample input volume contains a solid form reverse transcriptase that is formulated to dissolve into the unprocessed biological sample within the sample input volume.
38. The apparatus of claim 37, wherein the sample input volume is devoid of a ribonuclease inhibitor.
39. The apparatus of claim 37, wherein the solid form reverse transcriptase includes a lyophilized reverse transcriptase.
40. The apparatus of claim 34, wherein:
the lid includes a reagent actuator configured to cause the detection reagent to be released from the reagent module in response to the lid being moved from the first lid position to the second lid position.
41. The apparatus of claim 34, further comprising:
a control module within the housing, the control module including the switch and a processor, the processor configured to control transmission of power to the heater, the switch portion of the lid including a switch protrusion.