LUCIRA

“The Lucira COVID-19 All-In-One Test Kit utilizes RT-LAMP technology to detect RNA of the N gene for SARS-CoV-2” (IFU 4). This method can produce test results in under 30 min. The kit includes:

* Nasal swab
* Disposable vial
* Disposable test unit
* Batteries
* Bag to dispose of the kit

Results are obtained quickly because of the RT-LAMP technology so no thermocycling.

There seems to be no contamination control or negative control, but there is a positive and lysis internal control.

“Your product requires the following control materials, or other authorized control materials (as may be requested under Condition K below), that are processed along with the patient specimen in the Test Unit. The Positive Internal Control (PIC) and Lysis Internal Control (LIC) contained within the Test Unit must generate expected signal/results in order for a test to be considered valid, as outlined in the Quick Reference Instructions.” (FDA EUA 3)

External positive and negative controls can be bought separately.

It seems that the test unit is a “single-use” design.