CoronaSys Innovation sheet 28

Lucira™ COVID-19 All-In-One Test Kit

Background

While testing remains a major challenge around the globe[1], the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization[2] to the first molecular at-home test developed by Lucira Health[3].

Features

The test is based on RT-LAMP-Technology (reverse transcription loop-mediated isothermal amplification). As in the polymerase chain reaction (PCR) used in conventional testing, individual genes are reproduced until they are detectable with a chemical reaction. However, unlike PCR, the reaction can be carried out at a constant temperature. This eliminates the need for a laboratory facility to perform the test. The subsequent chemical reaction is also quite simple. It consists of a change in the pH.

State of information: 11/20/2020

Emergency Use Authorization: November 2020

Country: USA

Focus area: Testing

Developers: Lucira Health

Beneficiaries: General Population

The test´s results were compared with an FDA- approved PCR smear assay, the current gold standard, in a "Community Testing" Study. According to the manufacturer, the test achieved a positive percent agreement, i.e. sensitivity, of 94% and a negative percent agreement, i.e. specificity, of 98%. If samples with low viral load (at or below 37.5 Ct) were excluded the test even achieved a 100% positive percent agreement[45].

With the supplied swab, the user takes a sample from the nose, opens the test tube of the detection device, tunes the swab into the reagent and stirs. After the test tube is closed again a slight pressure on the test tube starts the detection reaction. The user waits about 30 minutes for a lamp to signal the end of the reaction. Two more lights indicate whether the test was positive or negative[6].

Potentials

The Lucira™COVID-19 All-In-One Test Kit is the first prescription molecular test for COVID-19. The testing device could help to upscale testing capacities, provide opportunities for at-home testing, and help to ease the pressure on laboratories and primary care physicians.

Points to consider

The product is a single-use device and with a price of $50 quite expensive[7]. But the FDA Emergency Use Authorization might help to accelerate the development of similar but less costly testing devices. Currently, the test is available in the United States only[8] and requires a prescription from a health care provider[9].

Conclusion

The test might be a nice addition in an effort to upgrade testing capacities in the United States. Hopefully, there will soon be similar products at a lower price range in order to make the technology accessible and useful for larger scales of the population.

[1] Statista.com. “COVID-19 Testing Rate by Country as of November 19, 2020.” Statista, November 19, 2020. https://www.statista.com/statistics/1104645/covid19-testing-rate-select-countries-worldwide/.

[2] FDA. “Coronavirus (COVID-19) Update: FDA Authorizes First COVID-19 Test for Self-Testing at Home.” FDA. FDA, November 18, 2020. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-test-self-testing-home.

[3] Lucira Health. “Lucira™ Is Developing a Single Use, Disposable COVID-19 Test That Provides Results in Just 30 Minutes.” Lucira Health. Accessed November 19, 2020. https://www.lucirahealth.com/.

[4] Deutsches Ärzteblatt. “SARS-CoV-2: FDA genehmigt ersten Schnelltest für zuhause.” Deutsches Ärzteblatt, November 18, 2020. https://www.aerzteblatt.de/nachrichten/118496/SARS-CoV-2-FDA-genehmigt-ersten-Schnelltest-fuer-zuhause.

[5] Lucira Health. “Lucira Health News Release: FDA-Authorizes-First-Prescription-At-Home-Molecular-Test-for-COVID-19-Released-20201118.Pdf,” November 18, 2020. https://2nyvwd1bf4ct4f787m3leist-wpengine.netdna-ssl.com/wp-content/uploads/2020/11/FDA-Authorizes-First-Prescription-At-Home-Molecular-Test-for-COVID-19-released-20201118.pdf.

[6] Lucira Health. “Lucira-HCP-Instructions-For-Use-IFU.Pdf.” Accessed November 19, 2020. https://2nyvwd1bf4ct4f787m3leist-wpengine.netdna-ssl.com/wp-content/uploads/2020/11/Lucira-HCP-Instructions-For-Use-IFU.pdf.

[7] Deutsches Ärzteblatt. “SARS-CoV-2: FDA genehmigt ersten Schnelltest für zuhause.” Deutsches Ärzteblatt, November 18, 2020. https://www.aerzteblatt.de/nachrichten/118496/SARS-CoV-2-FDA-genehmigt-ersten-Schnelltest-fuer-zuhause.

[8] Armus, Teo, and Meryl Kornfield. “A Rapid At-Home Covid-19 Test — for under $50 — Just Got FDA Approval.” Washington Post, November 18, 2020. https://www.washingtonpost.com/nation/2020/11/18/home-test-coronavirus-covid-fda/.

[9] Wu, Catherine J. “The F.D.A. Authorizes the First at-Home Coronavirus Test.” The New York Times, November 18, 2020, sec. World. https://www.nytimes.com/live/2020/11/18/world/covid-19-coronavirus.

Background on Innovation Sheet Series

As part of a real-time evaluation of the SARS CoV 2 pandemic (with focus on epidemiological, medical, economical, societal, technical, and cultural developments in Germany and Armenia) the CoronaSys research team, under the leadership of Prof. Dr. Martin Voss, is conducting a continuous monitoring of developments and medical, technical, and social innovations concerning Covid-19.

Multiple national and international media outlets, research platforms, and scientific and organizational guidelines, briefs, and updates are screened to feed into this outlet. The rationale behind this is to support the projects' network partners in Armenia and Germany with short summaries of key developments and promising innovations that are shaping the global, German, and Armenian outbreak response and recovery.

The aim of these short briefs is to give condensed and structured information on selected innovations emerging out of the conducted horizon scanning. This could be mainstream big-ticket items or fringe subjects that are easily overlooked in the global flood of information. Some innovations will be followed through their evolution in time while others may only appear once. While subjectively selected, the briefs are descriptive in nature and leave analysis and critical interpretation to the reader. Network partners in both countries are invited to provide feedback on their interest areas and suggest particularly relevant topics for the CoronaSys Workshop series.

The CoronaSys Innovation Sheet Series is published by the Academy of the Disaster Research Unit, which is, as a non-profit limited liability company, a spin-off of the Disaster Research Unit at the Free University of Berlin. The series is part of the research project "CoronaSys: Addressing the corona pandemic in Armenia through systemic risk management", sponsored by the German Federal Ministry of Education and Research.

If you have any questions, suggestions, or if you wish to be taken on (or off) the project mailing list for CoronaSys updates, innovation sheets, and workshop invitations, please send a message to Janina Schäfer (schaefer@a-kfs.de). For general project inquiries, you may contact the team lead Sara Merkes (merkes@a-kfs.de) or the project lead Martin Voss (voss@a-kfs.de).

Previous CoronaSys Innovation Sheets

1 “New” Antiviral Face Masks
2 “Dyphox” Surface Coating
3 MOVES SLC Portable ICU
4 Portable TRI- KLEEN 500UV
5 Convalescent Plasma Therapy
6 ASIC-App
7 BinaxNOW Antigen Test
8 Corona Traffic Light
9 Aproof at Home Antibody Test
10 IVAT Hygiene Tower
11 LY-CoV555 Antibody Treatment
12 4C Mortality Score
13 Regional Corona Prediction Model
14 Computer-designed Mini- Proteins
15 Covid-19 Simulator
16 Trimodulin
17 BNT162b2-Vaccine
18 SARS-COV-2 Rapidplex
19 European Corona- Map
20 FELUDA Paper Strip Test
21 Humanitarian Action Mapping Tool
22 IKKA Score
23 WHO Digital Implementation Investment Guide
24 RCCE Toolkit
25 Cough-Analyzing App
26 Follow Up on LY-CoV555 Antibody Treatment
27 Follow-up on BNT162b2-Vaccine

All previous CoronaSys Innovation Sheets are available online:
http://coronasys.a-kfs.de/category/innovation-stream/

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