ADRU
Academy of the Disaster Research Unit

CoronaSys

CoronaSys Innovation sheet 37

Ellume Test

Background

Although vaccination campaigns have started in many countries testing will remain an issue for the foreseeable future. The US Food and Drug Administration (FDA) has now authorized the first over the counter COVID-19 test[12] produced by the Australian manufacturer Ellume[3].

Features

The test uses a patented detection method that combines several known procedures for antigen detection. Contrary to other at-home tests, the swabs do not have to be sent to a laboratory per mail but can be analysed on-site. The test can be used for adults and children older than 24 months with and without symptoms of COVID-19. It costs about 30 US$[45]. The manufacturers reported a specificity of 97% and a sensitivity of 95% compared to an emergency use-authorized RT-PCR laboratory test. The Ellume test delivers results within 15 minutes[6].

State of information: 22/12/2020

FDA Authorization: 12/15/2020

Country: Australia

Focus area: Detection and Diagnostics

Developers: Ellume

Beneficiaries: General population

Potentials

The test could help to scale up testing capacities. It saves the user a trip to a clinic or testing site and therefore helps to minimize contacts. One major advantage is that the test requires the user to download an app that transmits the result to a cloud where local health officials can access the data which means that the test result can be included in the official epidemiological statistics.[7]

Points to consider

Like other antigen tests, there is a probability of false-negative results, since these tests perform best in cases with high viral load[89]. Some experts also argue that a negative test result might lead to a false sense of security and more reckless behaviour in people who do not realize that the test can be negative the one day and they can acquire the virus the next day. Another issue is that the manufacturer will need some time to produce a sufficient quantity of the assays although production capacities have already been scaled up. Additionally, the test has to be authorized by each country separately to give people access to this form of testing[10].

Conclusion

The test might be a valuable addition to existing tests as soon as it is available and accessible for the respective population.

[1] FDA. "Coronavirus (COVID-19) Update: FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19." FDA, December 17, 2020. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-antigen-test-first-over-counter-fully-home-diagnostic.

[2] NS Healthcare.com. "FDA Authorises Ellume Covid-19 Home Test as OTC Product," December 16, 2020. https://www.ns-healthcare.com/news/ellume-covid-19-at-home-test/.

[3] Ellume. "Ellume | Home." Ellume, December 2020. https://www.ellumehealth.com/.

[4] NS Healthcare.com. "FDA Authorises Ellume Covid-19 Home Test as OTC Product," December 16, 2020. https://www.ns-healthcare.com/news/ellume-covid-19-at-home-test/.

[5] Stieg, Cory. "The FDA Just Approved a $30 At-Home Covid Test — Here's What You Need to Know." CNBC, December 16, 2020. https://www.cnbc.com/2020/12/16/fda-approves-ellume-home-covid-test-how-it-works-and-antigen-accuracy.html.

[6] Ellume. "FDA Authorizes Ellume COVID-19 Home Test as First Over-the-Counter Fully At-Home Diagnostic Test." Ellume (blog), December 15, 2020. https://www.ellumehealth.com/2020/12/15/fda-authorizes-ellume-covid-19-home-test-as-first-over-the-counter-fully-at-home-diagnostic-test/.

[7] Wan, William. "FDA Authorizes First Rapid, over-the-Counter Home Coronavirus Test." Washington Post, December 16, 2020. https://www.washingtonpost.com/health/2020/12/15/covid-home-rapid-test/.

[8] Stieg, Cory. "The FDA Just Approved a $30 At-Home Covid Test — Here's What You Need to Know." CNBC, December 16, 2020. https://www.cnbc.com/2020/12/16/fda-approves-ellume-home-covid-test-how-it-works-and-antigen-accuracy.html.

[9] European Centre for Disease Prevention and Control. "Options for the Use of Rapid Antigen Tests for COVID-19 in the EU/EEA and the UK." European Centre for Disease Prevention and Control, November 19, 2020. https://www.ecdc.europa.eu/en/publications-data/options-use-rapid-antigen-tests-covid-19-eueea-and-uk.

[10] Wan, William. "FDA Authorizes First Rapid, over-the-Counter Home Coronavirus Test." Washington Post, December 16, 2020. https://www.washingtonpost.com/health/2020/12/15/covid-home-rapid-test/.

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).

ADRU
Academy of the Disaster Research Unit

CoronaSys

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
28 Lucira™COVID-19 All-In-One Test Kit
29 COVID-19 Humanitarian
30 AI-Epidemiology-Model
31 Solar- Powered Steam Generator
32 Gradian CCV
33 Rapid Hospital Readiness Checklist
34 School Reopening Checklist
35 CURIAL AI Screening Test
36 Prioritization Roadmap

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

Project lead:
Prof. Dr. Martin Voss
Email: voss@a-kfs.de
Phone: +49 30 838 72613
Website: http://coronasys.a-kfs.de

CoronaSys

SPONSORED BY THE
Federal Ministry of Education and Research

Citation: Academy of the Disaster Research Unit (2020): Ellume Test. CoronaSys Innovation Sheet 37. Berlin: ADRU.

Akademie der Katastrophenforschungsstelle (AKFS) gGmbH
c/o Katastrophenforschungsstelle
Carl-Heinrich-Becker-Weg 6-10
12165 Berlin