

## CORONASYS INNOVATION SHEET 7

### BINAXNOW ANTIGEN TEST

#### Background

Testing has posed a major challenge to health systems tackling the novel Coronavirus. Shortages of certain items like swabs and reagents added to the supply chain problems. Overburdening of laboratories and delays in delivering the test results to the patients have been huge problems in the US and elsewhere<sup>1</sup>. The company Abbott claims to have a solution for those difficulties with their BinaxNOW antigen test.

#### Features

Rapid Antigen tests have been used in the detection of other respiratory infectious diseases before<sup>2</sup>. The BinaxNOW test looks for a specific protein on the virus surface which implies an infection with SARS CoV-2<sup>3</sup>. Antigen tests do not necessarily require specialized labs, certain machines, or highly trained staff.<sup>4</sup> The test result can be read directly from the card. The manufacturer claims that the test can deliver results in 10-15 minutes and will cost around 5 US- Dollars.

#### Potentials

The Food and Drug Administration (FDA) issued an emergency use authorization for the test on August 26, 2020<sup>56</sup>. This could massively scale up testing capacities in the United States<sup>7</sup>. The manufacturer plans to produce and distribute 50 million tests per month<sup>8</sup>. The tests might be especially useful in screening asymptomatic people if they get approved for this usage.

#### Points to consider

The speed of the test comes with trade-offs. Antigen tests are very specific but are not as sensitive as molecular tests. The tests are more likely to produce false-negative results, meaning there is a higher risk to miss an active coronavirus infection compared to molecular tests. The full FDA Approval process is still ongoing and the test is currently only authorized for people with COVID-19 symptoms within the first 7 days, which is problematic because Covid-19 is asymptomatic in many cases.<sup>9</sup>

#### Conclusion

The test may rapidly scale up testing capacity. But it remains to be seen whether it can provide accurate and reliable results in large numbers of tests and in asymptomatic patients. A similar test has been developed by the Suisse pharma company Roche and is to be launched on the European Market in September 2020<sup>1011</sup>.

**State of information:** 02/09/2020

**Launch:** August 2020

**Country:** USA

**Focus area:** Testing

**Developers:** Abbott

**Beneficiaries:** General population

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- <sup>2</sup> Green, Daniel A., und Kirsten StGeorge. „Rapid Antigen Tests for Influenza: Rationale and Significance of the FDA Reclassification“. Journal of Clinical Microbiology 56, Nr. 10 (25. September 2018). <https://doi.org/10.1128/JCM.00711-18>. [08/31/2020]
- <sup>3</sup> CDC. „Information for Laboratories about Coronavirus (COVID-19)“. CDC, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html> [09/02/2020]
- <sup>4</sup> Kane, Andrea. „Are these fast, cheap coronavirus tests the game-changer everyone is waiting for? - CNN“, 29. August 2020. <https://edition.cnn.com/2020/08/28/health/antigen-test-coronavirus/index.html>. [09/02/2020]
- <sup>5</sup> FDA, „COVID-19 Update“. FDA, 2020. <https://www.fda.gov/news-events/press-announcements/covid-19-update-fda-authorizes-first-diagnostic-test-where-results-can-be-read-directly-testing-card> [09/02/2020]
- <sup>6</sup> CNBC. com. „Abbott Wins U.S. Authorization for \$5 Rapid Covid-19 Antigen Test“. CNBC, 27. August 2020. <https://www.cnbc.com/2020/08/26/abbott-wins-us-authorization-for-5-rapid-covid-19-antigen.html>. [09/02/2020]
- <sup>7</sup> McLaren, „Will the New 15-Minute COVID-19 Test Solve US Testing Problems?“ Online: <https://theconversation.com/will-the-new-15-minute-covid-19-test-solve-us-testing-problems-145285> [09/02/2020]
- <sup>8</sup> Abbott. Com: „Abbott’s Fast, \$5, 15-Minute, Easy-to-Use COVID-19 Antigen Test Receives FDA Emergency Use Authorization; Mobile App Displays Test Results to Help Our Return to Daily Life; Ramping Production to 50 Million Tests a Month“. Online: <https://abbott.mediaroom.com/2020-08-26-Abbotts-Fast-5-15-Minute-Easy-to-Use-COVID-19-Antigen-Test-Receives-FDA-Emergency-Use-Authorization-Mobile-App-Displays-Test-Results-to-Help-Our-Return-to-Daily-Life-Ramping-Production-to-50-Million-Tests-a-Month> [09/02/2020]
- <sup>9</sup> McLaren, „Will the New 15-Minute COVID-19 Test Solve US Testing Problems?“ Online: <https://theconversation.com/will-the-new-15-minute-covid-19-test-solve-us-testing-problems-145285> [09/02/2020]
- <sup>10</sup> Doepke, Michel. „Roche mit Frontalangriff auf Abbott: Corona-Schnelltest im Anmarsch“. Der Aktionär, 2. September 2020. <https://www.deraktionaer.de/artikel/pharma-biotech/roche-mit-frontalangriff-auf-abbott-corona-schnelltest-im-anmarsch-20206345.html>. [09/02/2020]
- <sup>11</sup> Deutsches Ärzteblatt. „SARS-CoV-2: Roche bringt im September Schnelltest auf Antikörper auf...“ Deutsches Ärzteblatt, 2. September 2020. <https://www.aerzteblatt.de/nachrichten/116159/SARS-CoV-2-Roche-bringt-im-September-Schnelltest-auf-Antikoerper-auf-den-Markt>. [09/02/2020]

### **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](mailto:schaefer@a-kfs.de)). For general project inquiries, you may contact the team lead Sara Merkes ([merkes@a-kfs.de](mailto:merkes@a-kfs.de)) or the project lead Martin Voss ([voss@a-kfs.de](mailto: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

All previous CoronaSys Innovation Sheets are available online:

<http://coronasys.a-kfs.de/category/innovation-stream/>

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