

## CORONASYS INNOVATION SHEET 9

### A PROOF-AT-HOME ANTIBODY TEST

#### Background

People who have been infected with Sars-CoV-2 usually form antibodies against the virus within approximately one to two weeks<sup>1</sup>. These are to be detected by the test developed by Adversis Pharma<sup>2</sup> in collaboration with the Biotechnological Biomedical Center (BBZ) of the University of Leipzig<sup>3</sup>. According to the manufacturer the test can easily be carried out by laymen at home. The test has been heavily advertised in Germany.

#### Features

People can order the test online and will receive a set, with which they can collect a few drops of blood from the fingertip with a lancet and drip the blood onto a filter card. The blood sample must then be dried and sent to a laboratory in Leipzig<sup>4</sup>, where it is tested for antibodies using the standard ELISA method<sup>5</sup>. The result can be retrieved online with the personalized code in the testing kit within 24 to 48 hours. The manufacturer claims that the test has a sensitivity of 100% and a specificity of 99.4%<sup>6</sup>. The test costs 49 euros<sup>7</sup>.

#### Potentials

The user receives information about whether or not he has antibodies against Sars-CoV-2. Since the majority of those infected have mild or no symptoms, the knowledge of an infection acquired retrospectively could affect how individuals assess the situation and deal with the pandemic<sup>8</sup>. Moreover, the test is part of a larger research project aimed, among other things, at obtaining data on the immune status of the population (especially titers of neutralizing antibodies), which could also play a role in the long term in disease monitoring and the development of vaccines<sup>9</sup>.

#### Points to consider

The presence of antibodies is not to be equated with immunity<sup>1011</sup>. Until now, many researchers had hoped that one would be immune to the virus after infection. But at the end of August, several cases of individuals infected with Sars-CoV-2 a second time became known<sup>1213</sup>. In addition, the body usually develops better detectable IgG antibodies, for which the test is designed, not until a few weeks after infection. So if one does the test too early, one will not get a reliable test result. But if the test is conducted too late it might not produce a valid result either, as cases are known where the concentration of antibodies dropped again after a short period of time<sup>1415</sup>. Furthermore, The Federal Association of German Pharmacists' Associations (ABDA) strongly advises pharmacies against offering such tests to their customers due to legal concerns, referring to a passage in the German Medical Devices Act<sup>16</sup>. Initially, Adversis had been counting on pharmacies to sell the product in addition to the online sale.

#### Conclusion

For patients with symptoms, a PCR test is the means of choice anyway, because it shows an active infection. Antibody testing is more likely to be useful in asymptomatic patients who want to know if they have already survived the infection. The data collected could also contribute to a better understanding of the immune situation of the population.

**State of information:** 10/09/2020

**Launch:** September 2020

**Country:** Germany

**Focus area:** Testing

**Developers:**

- Adversis Pharma
- Biotechnological Biomedical Center (BBZ) of the University of Leipzig

**Beneficiaries:** General population

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- <sup>1</sup> Xiang, Fei, Xiaorong Wang, Xinliang He, Zhenghong Peng, Bohan Yang, Jianchu Zhang, Qiong Zhou, et al. "Antibody Detection and Dynamic Characteristics in Patients with COVID-19." *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, April 19, 2020. <https://doi.org/10.1093/cid/ciaa461>.
- <sup>2</sup> "Adversis Pharma." Accessed September 10, 2020. <https://adversis-pharma.de/>.
- <sup>3</sup> Universität Leipzig. "Biotechnologisch-Biomedizinisches Zentrum." Accessed September 10, 2020. <https://www.bbz.uni-leipzig.de/>.
- <sup>4</sup> Deutsches Ärzteblatt, Deutscher Ärzteverlag GmbH, Redaktion Deutsches. "Leipziger Forscher entwickeln Coronaantikörper-test für zuhause." *Deutsches Ärzteblatt*, September 1, 2020. <https://www.aerzteblatt.de/nachrichten/116099/Leipziger-Forscher-entwickeln-Coronaantikoeperptest-fuer-zuhause>.
- <sup>5</sup> Hnasko, Robert, ed. *ELISA: Methods and Protocols. Methods in Molecular Biology* 1318. New York: Humana Press, 2015.
- <sup>6</sup> Deutsches Ärzteblatt. "Leipziger Forscher entwickeln Coronaantikörper-test für zuhause." *Deutsches Ärzteblatt*, September 1, 2020. <https://www.aerzteblatt.de/nachrichten/116099/Leipziger-Forscher-entwickeln-Coronaantikoeperptest-fuer-zuhause>.
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- <sup>9</sup> Sächsische Staatskanzlei. "Sächsische Forscher Entwickeln Neuen Corona-Antikörper-test." Accessed September 10, 2020. <https://www.medien-service.sachsen.de/medien/news/240156>.
- <sup>10</sup> Eckert, Nadine. "COVID-19: Was Antikörper aussagen können." *Deutsches Ärzteblatt*, June 12, 2020. <https://www.aerzteblatt.de/archiv/214379/COVID-19-Was-Antikoerper-aussagen-koennen>.
- <sup>11</sup> Deutsches Ärzteblatt. "COVID-19: Was Antikörper aussagen können." *Deutsches Ärzteblatt*, June 12, 2020. <https://www.aerzteblatt.de/archiv/214379/COVID-19-Was-Antikoerper-aussagen-koennen>.
- <sup>12</sup> Deutsches Ärzteblatt. "Nach 4 Berichten zu Re-Infektionen: Wie lange hält eine Immunität..." *Deutsches Ärzteblatt*, August 31, 2020. <https://www.aerzteblatt.de/nachrichten/116059/Nach-4-Berichten-zu-Re-Infektionen-Wie-lange-haelt-eine-Immunitaet-gegen-SARS-CoV-2-an>.
- <sup>13</sup> To, Kelvin Kai-Wang, Ivan Fan-Ngai Hung, Jonathan Daniel Ip, Allen Wing-Ho Chu, Wan-Mui Chan, Anthony Raymond Tam, Carol Ho-Yan Fong, et al. "COVID-19 Re-Infection by a Phylogenetically Distinct SARS-Coronavirus-2 Strain Confirmed by Whole Genome Sequencing." *Clinical Infectious Diseases*. Accessed September 10, 2020. <https://doi.org/10.1093/cid/ciaa1275>.
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- <sup>16</sup> Köhler, Anja. "Neuer Antikörper-test Für Zuhause Sorgt Für Verwirrung - BMG Positioniert Sich." *DAZ.online*, September 1, 2020. <https://www.deutsche-apotheke-zeitung.de/news/artikel/2020/09/01/neuer-antikoerper-test-fuer-zuhause-sorgt-fuer-verwirrung-bmg-positioniert-sich>.

### **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
- 7 BinaxNOW antigen test
- 8 Corona traffic light

All previous CoronaSys Innovation Sheets are available online:

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

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