Press release

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German COVAG Study proves significant inaccuracy of rapid antigen tests in detecting SARS-CoV-2 variants and when applied to medium to low viral loads

- The COVID-19 Antigen Study (COVAG Study), conducted by SYNLAB, the Universities of Heidelberg and Graz, and a large COVID-19 test centre in Stuttgart, is one of the most comprehensive systematic evaluations of rapid antigen testing in a real-life setting
- The COVAG Study confirms a significantly lower accuracy of rapid antigen tests compared to PCR tests, determining the actual sensitivity of rapid antigen tests at about 60 percent
- Study results imply that rapid antigen tests have a lower sensitivity when testing for new virus variants
- Effectiveness of rapid antigen tests as a tool to control the pandemic is limited

SYNLAB, Europe's leading medical diagnostic services provider, collaborated with researchers from the Universities of Heidelberg and Graz, and a large COVID-19 test centre in Stuttgart to conduct the COVID-19 Antigen Study (COVAG Study). The COVAG Study is one of the most comprehensive field research studies to systemically assess the actual sensitivity and specificity of rapid antigen tests.

The results indicate that the actual sensitivity of two commonly used rapid antigen tests considered reliable, are only at 60.4 and 56.8 percent, respectively, compared to PCR tests. In addition, for the first time the COVAG Study identified a variant-dependency of rapid antigen tests: the sensitivity of the tests is significantly lower when detecting the alpha variant compared to their sensitivity when detecting the SARS-CoV-2 wild-type.

338 out of 2,215 individuals participating in the study tested positive for SARS-CoV-2 using the PCR testing method. Of these 338 positive cases, however, the two rapid antigen tests only identified 204 and 192 participants, respectively, as virus carriers. In other words, rapid antigen tests missed four out of ten individuals who tested positive for SARS-CoV-2 with PCR tests. Here, the viral load was the most decisive factor for the detection of the virus. Only individuals with a very high viral load (CT value ≤ 20) were reliably detected as virus carriers by rapid antigen tests. The virus, however, already spreads at a medium to low viral load.

In addition, the COVAG Study was the first to investigate variant dependence of rapid antigen tests in samples with moderate to high viral loads (CT value ≤ 30). For the SARS-CoV-2 wild-type, the two rapid antigen tests' sensitivity was determined with 87.7 and 84.0 percent, respectively. Yet, for the alpha

variant the same tests' sensitivity was only at 77.1 and 72.3 percent, respectively. Compared to other circulating variants, however, the alpha variant has the lowest structural deviation from the SARS-CoV-2 wild-type. Accordingly, it can be assumed that the sensitivity of rapid antigen tests is also significantly lower for other virus variants than for the original wild-type. Meanwhile, however, the latter has been completely displaced by the spread of new variants.

Univ.-Prof. Dr. Winfried März, co-author of the COVAG Study and project lead at SYNLAB, emphasises: "The COVAG Study provides valuable scientific findings regarding the properties of rapid antigen tests. Only with targeted and reliable testing, we can detect infections at an early stage and interrupt chains of infections early on. Given the potentially decreasing sensitivity of rapid antigen tests with virus variants, it is crucial to carefully consider in which cases the speed of rapid antigen tests remains preferable to the significantly higher accuracy of PCR tests. We need to minimise the risk of false certainty from false test results."

The COVAG Study was conducted from February 1st to March 31st, 2021, at the Cannstatter Wasen Test Center in Stuttgart, Germany.

The full COVAG Study can be read here.

For more information:

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About SYNLAB

- SYNLAB, (ISIN: DE000A2TSL71, SYMBOL: SYAB) is the largest European clinical laboratory and medical diagnostic services company and offers a full range of innovative and reliable medical diagnostics for patients, practising doctors, clinics and the pharmaceutical industry.
- Providing the leading level of service within the industry, SYNLAB is the partner of choice for diagnostics in human and veterinary medicine. The Group continuously innovates medical diagnostic services for the benefit of patients and customers.
- SYNLAB operates in 36 countries across four continents and holds leading positions in most markets. More than 20,000 employees, including over 1,200 medical experts, as well as a large number of other specialists such as biologists, chemists and laboratory technicians, contribute every day to the Group's worldwide success. SYNLAB carries out ~500 million laboratory tests per year and achieved revenues of EUR 2.6 billion in 2020.
- More information can be found on www.synlab.com