

## **Biomimicry control for COVID diagnostics**

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Containing the scourge of COVID-19 requires testing of individuals, and isolating those who test positive, together with recent contacts, so as to prevent further spread. It is therefore critical to ensure that testing is independently verified so as to assure its accuracy.



Given the urgent need to ramp up testing, a team from Wits University's Center for Biomedical Tuberculosis Research (CBTBR) has developed a unique "control standard," which does exactly this for certain diagnostic testing platforms. What makes it unique is that it uses biomimicry, a safer alternative to incorporating the actual SARS-COV-2 virus.

The Wits team, headed up by Professor Bavesh Kana, used this biomimicry technique to engineer a control organism that mimics the genetic material of the virus, when used in diagnostic tests kits. If the tests work correctly, the genetically modified organism is identified as being SARS-CoV-2. This control is a safe, non-pathogenic (non-disease causing), and stable. It can be rapidly deployed in a range of settings—from central laboratories to clinics across the country. In contrast, viral based controls require specialist shipping and handling procedures, and the need for highly skilled staff and infrastructure.

Kana says that accuracy testing controls are central to the deployment of any successful diagnostic <u>test</u>. "The virus continues to spread viciously across countries, with infections again rising rapidly across Europe and North America. In order for governments to halt its spread, reliable tools with verifiable results are of utmost importance. Without appropriate controls to report whether tests are delivering the correct result, diagnosing and effectively managing COVID-19 will be very difficult, if not impossible," says Kana.

The pandemic has put healthcare systems across the globe under immense pressure, particularly on the issue of rapid diagnostic test development and implementation. Specific sections of the DNA is typically the targeted molecule for diagnosing bacteria and viruses. With certain viruses like HIV and SARS-CoV-2, the genetic material is contained in the RNA, and consequently diagnosis relies on the detection of the SARS-CoV-2 RNA.



Recognizing the gap in the verification of COVID-19 tests obtained via molecular diagnosis tools, and understanding the risks and complications of using the live virus, Kana and his team: Dr. Edith Machowski, Dr. Bhavna Gordhan and Dr. Christopher Ealand, heeded the call to support the fight against the pandemic, by developing control standards for diagnostics tools used in the testing of the COVID-19 virus.

Having previously contributed to the development of biomimicry based control standards for diagnostics for drug resistant tuberculosis (TB), which are now deployed in more than 20 countries internationally, the team embarked on a fast tracked research program to develop the SARS-CoV-2 diagnostic control as early as February 2020.

"As SARS-CoV-2 is an RNA virus, the biomimicry process was not straight forward as compared to TB. This is due to the inherent instability of RNA. However, we have been able to include elements to produce a control that mimics the diagnostic profile of SARS-CoV-2, which is stable, effective and a safer alternative to using the live <u>virus</u>," says Machowski.

Previous controls developed by Wits have been commercialized through a Wits spin-out company, SmartSpot Quality (Pty) Ltd. Dean Sher, Managing Director of SmartSpot, says that "Through our development and rollout of packaged controls for diagnostics for TB, SmartSpot is well geared to package the bulk stock of COVID-19 controls in its Wits developed control cards. Under license to WITS, we will drive the roll out of the controls, and the ongoing external quality assessment program."

As result of the outstanding efforts of Kana and his team, as well as the long standing relationship between Wits and SmartSpot, the new controls are now deployed in the National Health Laboratories' testing program.



Kana says "We are grateful for the opportunity to contribute to the COVID-19 testing efforts within the country, and internationally, enabled by the support provided by Wits, funders including the National Research Foundation, Department of Science and Innovation, Technology Innovation Agency, South African Medical Research Council, and the Innovation Support Unit at Wits Enterprise."

## Provided by Wits University

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