

## KAYA17 Inc.

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### **Kaya17 completes its second clinical validation of a rapid COVID-19 antigen test with PCR-level accuracy on nasal swab samples**

Kaya17 Inc., the developer of an innovative Point of Care test for COVID-19 and other medical diagnostics applications, completed its first clinical validation study in collaboration with paradigm labs, Tucson, Arizona.

Paradigm labs is one of the leading testing entities for COVID-19 in the state of Arizona and routinely performs thousands of nasal swab-based RT-PCR test of COVID-19 tests per day. Kaya17 is the first company to have developed a rapid (15min) saliva test with PCR level accuracy. It offers a complete system with test kit, reader, and software.

Two hundred samples were run in this test using two readers supplied by Kaya17 and samples procured from patients by Paradigm Labs. The tests were run at the Tucson facility by Paradigm personnel. Since Kaya17's system is easy-to-use, Kaya17 was able to train the paradigm personnel to operate its reader and software in less than 30 min. Techicians trained on Kaya17's test found that it was so much simpler to operate, unlike many other commercial PCR tests that require elaborate training.

This study was a retrospective clinical study with nasal swab samples collected in viral transport media (VTM) for the Kaya17 test and stored in refrigerator form. The validation was done against the RT-PCR test of Paradigm labs that is already FDA approved.

The test on 200 samples was completed using the Kaya17 system in less than 8 hours ( ~25 samples/hr). Two readers were used to validate repeatability of results. Kaya17 test to RT-PCR matched in 97% of the cases. The sample set contained approximately an equal set of positive and negative results.

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Kaya17's CSO, Dr. Camille Troup, said, "Proving that our tests work with both saliva and nasal swab samples gives us an added level of confidence. However, saliva samples are much easier to procure and are much more "patient friendly". The 97% agreement with RT-PCR is very encouraging."