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Kaya17 Complete First clinical validation study at Arizona State University Biodesign Institute

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 Arizona State University, Biodesign Institute, Phoenix, AZ.

In response to the pandemic crisis, the Biodesign institute has converted its state-of-the-art research infrastructure into an FDA-approved and clinically certified diagnostics lab capable of performing thousands of COVID-19 tests per day. The Biodesign institute is one of the early developers of saliva-based PCR tests. 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.

Ninety-six samples were run in this test using two readers supplied by Kaya17, with samples procured from patients by the Biodesign Institute. The tests were run at the Biodesign institute by Biodesign institute personnel who went through a 20-minute training.

This was a retrospective study with neat saliva samples collected for the Kaya17 test. The validation was done against the FDA-approved RT-PCR test for saliva, developed by the Biodesign Institute. The same person's samples were tested by Kaya17 and RT-PCR.

The test on 96 samples was completed using the Kaya17 system in less than 3 hours (30 samples/hour). Two readers were used to validate repeatability of results. Kaya17 test matched to RT-PCR results in 98% of the cases. The sample set contained an equal set of positive and negative results and were all from asymptomatic subjects.

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Kaya17 CEO, Dr. Sulatha Dwarakanath, one of the co-founders of the company said, “I am excited to see the high sensitivity of our test and 98% correlation to RT-PCR. The fact that our test is rapid and can be used at the point of use will make it possible for the economy to get back into gear.”