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For Immediate Release:

November 8, 2021

UserWise Facilitates FDA Emergency Use Authorization for Detect™ Over-the-Counter COVID-19 Test

San Jose, CA— UserWise, Inc., a San Jose, California-based Human Factors consultancy for medical products, conducted an expedited 100-participant FDA-compliant human factors study within a 3-week span to facilitate an Emergency Use Authorization (EUA) for the Detect™ Covid-19 Test for over-the-counter home use.

The Detect™ Covid-19 Test is a PCR-quality molecular nucleic acid amplification test (NAAT) that detects the genetic material of the SARS-CoV-2 virus. It uses a molecular amplification reaction that is a similar, alternative amplification method to polymerase chain reaction (PCR). This test can detect genetic material from the SARS-CoV-2 virus found in the nostril when a person has COVID-19.

"Detect's proprietary technology puts the complex nucleic acid amplification process into an easy-to-use and affordable format, bringing the gold standard of Covid-19 testing into the home," says Eric Kauderer-Abrams, Chief Technology Officer of Detect, Inc. "Detect is helping to create a future in which home testing can bring peace of mind to everyone, without compromising quality and accuracy."

"UserWise has been working tirelessly since March 2020 to bring COVID-19 test solutions into the homes of users," says Shannon Clark, CEO of UserWise, Inc. "We want to empower lay people to test themselves for the SARS-CoV-2 virus without having to leave their house or visit a physician. Running a swift human factors program is a major regulatory component of bringing highly-accurate COVID-19 home test solutions, like the Detect™ product, to market in a timely manner. The UserWise team is proud to play an integral role in these critical efforts."

Detect's journey with UserWise started in November of 2020 with our consultants providing early-stage human factors support, collaborating on communications with the FDA, and executing human factors validation testing for their product, which ultimately culminated in a historic EUA approval for this pioneering healthcare technology company. UserWise's experienced human factors moderators and observers met one-on-one with 100 laypersons or lay person teams to evaluate the Detect™ Covid-19 Test. In each session, a lay person used the product without training or assistance, to demonstrate that actual real-life users can successfully obtain accurate results while using the Detect™ Covid-19 Test independently at home.

Detect partnered with UserWise for its extensive human factors expertise and nearly a decade of experience successfully designing human factors studies and programs to support regulatory submissions. UserWise consultant's unwavering determination in bringing the best usability practices to the medical product industry coupled with Detect's people-first mission formed the impetus for bringing this partnership to fruition.

About UserWise, Inc.: At UserWise, we are passionate about co-creating safe and usable medical products. From injectables to robotic surgery systems, our team has worked on a variety of medical devices and combination products across numerous medical disciplines, use environments, and user groups, and recently has also been focusing on COVID-19 in-vitro diagnostic products.

UserWise offers a wide range of human factors services spanning the product development cycle. Our consultants assist in performing user research, constructing use-related risk analyses, conducting formative evaluations, executing summative usability validation testing, refining user manuals, compiling Usability Engineering Files, crafting FDA Human Factors Engineering Submission Reports and so much more. Our team has successfully prepared compliance documentation for IEC 62366-1, IEC 60601-1-6, and applicable FDA Human Factors Guidances and can offer unparalleled expertise in integrating the Usability Engineering Processes and Procedures into an individual company's Quality System.

For more about UserWise, Inc visit: UserWiseConsulting.com

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