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Fluxergy Announces Improved Clinical Performance of Its CE-IVD COVID-19 PCR Test



IRVINE, CA. (ots) -

Fluxergy, Inc., a U.S. medical diagnostic point-of-care platform company with a detection technology solution capable of multiplexity and multimodality, is further announcing improved clinical performance of its CE-IVD COVID-19 RT-PCR test. The CE marking for its one-hour COVID-19 Test Kit allows healthcare professionals to use its *in vitro* diagnostics (IVD) assay for the detection of SARS-CoV-2. Fluxergy's innovative testing platform is approved for IVD use in the European Union market and any other markets that accept CE marking as valid regulatory approval.

The simple workflow of the Fluxergy platform allows for a NP swab sample collected in a VTM or UTM vial and mixed with the Fluxergy Reaction Mixture within three minutes. This can then be immediately loaded onto the Fluxergy Card and inserted into the Fluxergy Analyzer for qualitative real-time PCR results within one hour. The platform is ideal for rapid testing applications such as emergency testing and delivery ward testing, as well as community reopening testing where expedited turnaround times are critical.

In the most recent clinical performance comparison study conducted by Fluxergy using ninety-five U.S. clinical specimens collected from November 2020 to March 2021, the COVID-19 Fluxergy Test Kit was 100% concordant with Cepheid's Xpert Xpress SARS-CoV-2 (the gold standard for COVID-19 RT-PCR at the Point-of-Care, approved for CE-IVD and other regions).

About Fluxergy

Fluxergy, Inc. launched in 2013 with funding support from principal investor and Kingston Technology co-founder John Tu. The Fluxergy system uses patented microfluidics and highly integrated sensor systems to produce a more flexible and cost-effective multimodal testing platform. Fluxergy is ISO 13485 and MDSAP certified for IVD manufacturing. Fluxergy's manufacturing facility is 30,000 m2 with the potential infrastructure to produce up to 3,000,000 test cards per month.

Contact:

Richard Laermer (+1-212-741-5106 X216; fluxergy@RLMpr.com)

Medieninhalte



The Fluxergy Diagnostic System: The Fluxergy Analyzer, which conducts the testing; the Fluxergy Card, a single-use test cartridge and its reagents; and the FluxergyWorks software, to manage the test data. The Fluxergy Test Kit COVID-19 is only available for purchase in the European Union market and any other markets that accept the CE-marking as valid regulatory approval. COURTESY: FLUXERGY, INC. / Editorial use of this picture is free of charge. Please quote the source: "obs/Fluxergy"

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