

12.04.2021 – 09:00 Uhr

## Fluxergy, Inc. Receives CE-IVD Marking for a One-Hour COVID-19 RT-PCR Test and Positions for European Market Entry



Irvine, CA. (ots) -

Fluxergy, Inc., a medical diagnostic testing platform company with a detection technology solution capable of multimodality, announced today that it has obtained CE marking for its one-hour COVID-19 RT-PCR test, to use by healthcare professionals as an *in vitro* diagnostic (IVD) for the detection of SARS-CoV-2. The CE-mark will allow Fluxergy's innovative testing platform to enter the European Union market and any other markets that accept CE-marking as valid regulatory approval.

Fluxergy's platform is an automated, sample-to-answer testing platform with multimodal capability allowing for a variety of assay types, such as molecular, immunochemistry, chemistry, and cytometry assays, to be run simultaneously on the same cartridge. This will give users the ability to run unique Point-of-Care (PoC) panels with the potential ability to do built-in reflex testing, among other capabilities. Potential environments for rapid testing applications include emergency rooms, outpatient procedures, urgent care, workplace screening, mobile and community level testing settings.

Fluxergy has made its platform available as Research Use Only (RUO) system for its partners, including University of California San Diego (San Diego, CA, USA) and Mass General Brigham (Boston, MA, USA), during the public health emergency. In December 2020, Fluxergy received dual ISO-13485:2016 and MDSAP certifications.

Last year, Fluxergy received a \$30 million investment from John Tu, principal investor and Kingston Technology co-founder, to rapidly expand its capability to scale production of the Fluxergy Analyzer diagnostic testing system in response to the COVID-19 pandemic. Fluxergy has now expanded manufacturing capabilities for its testing system to up to one million per month.

"Fluxergy is seeking commercial partnerships with healthcare providers and international go-to-market partners in Europe, Asia, and Australia", states Fluxergy's Chief Commercial Officer, Dr. Ali Tinazli, responsible for global sales.

Fluxergy's potential for multimodality of its platform raises important questions: How will decentralized testing at the point-of-need become a key enabler for telemedicine? What platforms, technologies, and workflows do we need to be better prepared for the next pandemic? To what extent does telemedicine with the diagnostic data unlock new healthcare opportunities such as in preventive medicine?

### Disclaimer

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.

Contact:

For more information, contact Richard Laermer (+1-212-741-5106 X216; [fluxergy@RLMpr.com](mailto:fluxergy@RLMpr.com)) and visit [www.fluxergy.com](http://www.fluxergy.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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