

Bioinformatic Analysis shows Fluxergy CE-IVD, POC COVID-19 PCR test can detect all major variants of concern including Delta and Omicron

As of November 29, 2021, sequence analysis of over 5.1 million sequences from 12 major variants shows Fluxergy RT-PCR COVID-19 assay detects > 99.96% of all reported variants. Fluxergy’s easy-to-use, POC assay is CE-IVD and is ideal for community level diagnostic testing as well as clinical testing for COVID-19.

One of the hallmarks of RNA viruses is their ability to adapt by mutation. The SARS-CoV-2 virus is not any different and has been mutating since the beginning of the pandemic, resulting in a number of variants of circulating strains. COVID-19 diagnostic tests are affected by these mutations differently due to the inherent design differences of each test. As genetic variants of SARS-CoV-2 arise regularly, false-negative test results may occur. PCR tests that use multiple genetic targets to determine a result are less likely to be impacted by the increased prevalence of genetic variants. Fluxergy continuously checks its assay against reported variants to ensure inclusivity of target genes.

The Fluxergy system detects conserved regions of the ORF1ab polyprotein and N genes (dual target regions). Fluxergy has performed in silico inclusivity testing against over 2 million sequences of available SARS-related coronavirus 2 genomic RNA sequences and further analyze our primer and probe design regions against upcoming variants. Due to selection pressure, mutations tend to emerge on spike gene sequences (S gene, vaccine target), in and around the receptor-binding domain. As Fluxergy’s PCR targets non-S genes, (ORF1ab and N), these mutations do not affect our assays overall sensitivity. The following 12 variants were included in this analysis, A.23.1 (Uganda), B.1.1.207, B.1.1.7 (UK), B.1.351 (South Africa), B.1.427, B.1.429, B.1.525/6 (New York), B.1.1.529 (Omicron), P.1/P.2/P3 (Brazil), B.1.617.2 (Delta variant) and B.1.621 (Mu variant).

Table 1: 12 variants were included in the analysis totaling 2247789 individual variant sequences. 43.74 percent of all available sequences were analyzed to ensure inclusivity to detect the most current, known SARS-CoV-2 variants.

Variant	Info	# of sequences	# of mutations
A.23.1	Uganda	1431	1071
B.1.1.207	Nigeria	919	743
B.1.1.7	UK	1230469	49144
B.1.1.529 (Omicron)	South Africa	80	70
B.1.351	South Africa	37130	5021
B.1.427	California	20994	5032
B.1.429	California	45029	9171
B.1.525	New York	9785	4148
B.1.526	New York	49563	9217
B.1.617.2 (Delta)	Originated in India, world-wide	768374	42203
B.1.621 (Mu)	Colombia	10235	3855
P1	Brazil	67654	14702
P2	Brazil	5500	3929
P3	Brazil	625	93
Total		2247789	
% of total		5139150	43.74

None of these variants had challenged both assay target regions together, further reducing the impact of these changes on Fluxergy's assay. A summary of distribution of mismatches/variant sequences against Fluxergy's individual assay components is presented below. **Sequence analysis confirms that is the Fluxergy COVID-19 assay detects > 99.96% of all reported variants as of November 29, 2021.**

Table 2: A distribution of mismatches toward individual assay components is shown. Each nucleotide mismatch was attributed to an individual variant. None of the variants challenged both assay targets further reducing the impact to Fluxergy's assays performance. The sequence analysis of this large set of genomic sequences confirmed that Fluxergy's CoVID-19 assay is robust and detects >99.96% of all reported variants today.

Fluxergy CoVID-19 Assay Component	Gene	# of total nucleotide mismatches from all variant sequences	%
Orf1ab Fwd Primer	Orf1ab	171	0.003
Orf1ab Probe	Orf1ab	602	0.012
Orf1ab Rvs Primer	Orf1ab	196	0.004
N-Gene Fwd Primer	N	262	0.007
N-Gene Probe	N	349	0.007
N-Gene Rvs Primer	N	249	0.005

About Fluxergy

Fluxergy is a medical device manufacturing company specializing in point-of-use detection technologies with the goals of making affordable diagnostics accessible in all settings. The Fluxergy system uses patented microfluidics and a highly integrated sensor system to produce a more flexible and cost-effective multimodal testing platform. Fluxergy is ISO 13485 and MDSAP certified for IVD manufacturing. Fluxergy's manufacturing and R&D campus spans 80,000 sqft in Irvine, CA. Fluxergy Europe GMBH is based in Aschaffenburg, Germany. Fluxergy, Inc. launched in 2013 with funding support from principal investor and Kingston Technology co-founder John Tu.

The Fluxergy Diagnostic Testing System consists of The Fluxergy Card, a single-use "lab-on-chip" consumable test cartridge; the Fluxergy Analyzer, which conducts the testing process, and Fluxergy Works software is used to review and interpret the test data. The Fluxergy Cards are multi-modal (meaning different types of diagnostic tests can be run simultaneously ie. PCR, immunochemistry, chemistry, etc.) and designed to be very cost-effective and scalable, using proprietary printed circuit board (PCB) manufacturing and microfluidics technologies. Fluxergy Works enables organizations to link together via the Cloud as many devices as a network can support. The Fluxergy Point-of-Care CoVID-19 PCR Test is only available for purchase in the European Union market and any other markets that accept the CE-marking as valid regulatory approval.