News release

Apostle RNA Extraction Method is Included in a US FDA EUA Authorized SARS-CoV-2 Molecular Diagnostic Test: Fulgent COVID-19 by RT-PCT Test

For immediate release

San Jose, CA, Apirl 12, 2021 – Apostle Inc is pleased to announce that the company's Apostle RNA Extraction Method is included in the recent US FDA EUA authorization of a SARS-CoV-2 Molecular Diagnostic Test: Fulgent COVID-19 by RT-PCT Test, as reagent and system used with the FDA EUA authorized test.

Final LoD Study (Apostle)

	N1 (Ct)				N2 (Ct)			
	9 copies/µL	8 copies/µL	7 copies/µL	5.4 copies/µL	9 copies/µL	8 copies/µL	7 copies/µL	5.4 copies/µL
Replicate 1	35.44	33.26	34.60	35.12	36.01	34.26	34.66	35.73
Replicate 2	33.62	36.58	34.17	34.58	35.42	38.90	35.00	35.62
Replicate 3	33.66	35.32	34.10	N/A	37.29	37.99	N/A	35.76
Replicate 4	34.13	34.43	35.63	32.95	35.73	35.52	N/A	33.77
Replicate 5	33.89	33.50	32.46	34.42	34.25	35.66	32.46	N/A
Replicate 6	32.96	33.62	34.25	35.38	34.82	34.93	35.30	38.18
Replicate 7	34.74	34.14	34.20	35.31	37.05	36.69	34.67	36.40
Replicate 8	32.78	34.41	35.46	36.40	34.44	34.94	35.05	N/A
Replicate 9	32.37	33.76	34.78	33.39	32.81	34.48	35.28	33.61
Replicate 10	32.86	32.99	33.96	33.44	33.35	34.38	36.44	35.39
Replicate 11	34.39	34.97	34.80	34.83	37.57	36.49	36.27	35.73
Replicate 12	34.20	34.46	33.98	33.75	34.11	36.01	33.86	35.18
Replicate 13	33.83	34.75	35.24	31.90	35.04	37.07	34.93	33.68
Replicate 14	32.60	34.95	33.64	33.25	33.87	36.63	34.94	34.25
Replicate 15	34.83	34.03	36.36	34.15	35.92	35.85	37.99	35.47
Replicate 16	34.44	31.14	34.60	35.35	36.11	31.73	34.09	36.30
Replicate 17	34.15	34.78	33.04	35.11	34.96	35.92	33.21	38.34
Replicate 18	33.53	35.46	36.36	35.32	34.86	35.49	38.95	36.53
Replicate 19	34.10	34.10	34.83	34.86	35.90	35.66	35.56	33.81
Replicate 20	34.98	34.85	34.78	35.44	35.12	36.51	35.64	35.95

Confirmation of the final LoD was determined using serial dilutions of inactivated virus (9 copies/µL, 8 copies/µL, 7 copies/µL, 5.4 copies/µL) in 20 extracted replicates (Final LoD Study (Apostle)). The final LoD of each test was determined to be the lowest concentration resulting in positive detection in 100% of the replicates (20/20) for both targets (N1 and N2). As shown in the summary table below (Summary Final LoD Study (Apostle)), the final LoD determined for this test was 8 copies/µL.

Source: https://www.fda.gov/media/138150/download

"We are very glad to see more and more clinical tests are made available with the integration of the Apostle technology. We stand with our community to fight COVID-19 together." Said Dr. David Ge, CEO of Apostle Bio.

More information:

- **Weblink for the US FDA EUA summary of Fulgent COVID-19 by RT-PCT Test : https://www.fda.gov/media/138150/download**
- **Weblink for the US FDA EUA letter of Fulgent COVID-19 by RT-PCT Test : https://www.fda.gov/media/138147/download**

About Apostle Inc

Apostle Inc is a biotechnology company in San Jose, CA, a provider of innovative technologies and services for public health and life sciences. Apostle aims to develop innovative technologies in the space of liquid biopsy - the sampling and analysis of non-solid biological tissue, primarily blood, often utilizing circulating free DNA (cfDNA) as a biomarker. Apostle's innovations include Apostle MiniMax, a new scalable and automatable method to efficiently capture cfDNA from a standard blood draw; Apostle MagTouch, a nucleic acids isolation automation system, and Apostle MiniEnrich, a high-resolution DNA size enrichment technology using a magnetic nano-platform.

In 2020, the company responded to the COVID-19 pandemic to help our community fight together with a high quality, low cost, fast, automated, Apostle COVID-19 Viral RNA Isolation System.

More information can be found at www.apostle.bio .
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