

Apostle COVID-19 RNA Extraction System Applied in the Effective Detection of SARS-CoV-2

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Summary

The current coronavirus disease 2019 (COVID-19) pandemic started in late 2019. COVID-19 is the result of severe acute respiratory syndrome 2 (SARS-CoV-2) virus contraction. COVID-19 is often accompanied by a wide range of symptoms including fever, cough, and shortness of breath. The SARS-CoV-2 virus consists of a ~30 kb RNA genome encoding for 15 proteins, including the spike protein that enables the virus to enter host cells. The current gold standard qualitative detection method, qRT-PCR, reverse transcribes the viral RNA into cDNA, which is subsequently amplified and quantitated.

This application note illustrates the effective detection of SARS-CoV-2 using the Apostle COVID-19 Viral RNA Isolation Automation System and qRT-PCR in clinical lab settings. This system uses efficient magnetic nanoparticle technology for fast extraction and purification of viral nucleic acids from various types of biological samples collected in transport media. The proficient and consistent systems provide reliable test results to individuals that contribute to COVID-19 pandemic relief.

Materials & Methods

Apostle COVID-19 RNA Extraction System is composed of an Apostle MagTouch Nucleic Acids Isolation Automation System, an Apostle MiniGenomics Viral TotalNA Isolation Fast Kit, Apostle 96-Well Deep Well Plates and Tip Combs. The system is based on magnetic nanoparticle technologies designed for fast extraction and purification of viral nucleic acids from various kinds of biological samples collected in multiple transport media. To date, our clients have processed more than **8,000,000** swabs through over forty Apostle MagTouch Nucleic Acids Extraction Automation Systems deployed in various CAP/CLIA clinical labs in the United States. Samples were run with an input volume of 200 μ L and output volume (elution volume) of 80 μ L. The presence of SARS-CoV-2 viral RNA in the extracts was determined by using the qRT-PCR method.



Figure 1 | The Apostle MagTouch Nucleic Acids Extraction Automation System in the clinical setting.

Results

Viral RNA Extraction Time

Our clients have processed more than **8,000,000** samples through this system. The extraction time is 40 minutes per 96 samples to isolate the viral RNA from the samples.

Quality of the Downstream SARS-CoV-2 Detection

Based on the use of Apostle COVID-19 RNA Extraction System, the downstream test results are typically available within 24-48 hours after the clinical samples were received by the lab. These data demonstrate a high quality of the downstream SARS-CoV-2 detection based on the use of Apostle COVID-19 RNA Extraction System. The quality of the system has been confirmed by various users. For example, as commented by Harry Gao, MD, PhD, DABMG, FACMG, Lab Director and Chief Scientific Officer of Fulgent Genetics, "Apostle COVID-19 RNA Extraction System is a fast and reliable solution for SARS-CoV-2 viral RNA extraction. We look forward to continuing the collaboration with Apostle and providing high quality COVID-19 tests for our community."

Inclusion in US FDA IVD EUA – Molecular Diagnostic Tests For SARS-CoV-2

- Apostle RNA extraction method is included in a US FDA EUA authorized SARS-Cov-2 molecular diagnostic test: Fulgent COVID-19 by RT-PCR Test.
- Weblink for the US FDA EUA summary | <https://www.fda.gov/media/138150/download>
- Weblink for the US FDA EUA letter | <https://www.fda.gov/media/138147/download>

Conclusion

The use of Apostle COVID-19 Viral RNA Isolation Automation System has proven to be an effective process as a part in detecting SARS-CoV-2 from more than **8,000,000** samples carried out by our clients in clinical lab settings.

References

1. <https://www.fulgentgenetics.com/covid19/molecular>
2. <https://www.fda.gov/media/138150/download>
3. <https://www.fda.gov/media/138147/download>