vamPure Extraction

Application of BioChain's vamPure Viral Nucleic Acid Extraction Kit in the Effective Detection of COVID-19

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This application note illustrates the highly effective detection of COVID-19 using BioChain's vamPure Viral Nucleic Acid Extraction Kit in CLIA lab settings. This magnetic beads-based kit can be used in automation systems for fast extraction and purification of viral nucleic acids from various types of biological samples collected in transport media. As a result, this kit can contribute to COVID-19 pandemic assessment with its ability to provide efficient, consistent, and reliable test results to individuals.

Introduction

Introduced in late 2019, the coronavirus disease 2019 (COVID-19) pandemic has brought serious damage to the world. Millions of lives have been lost, and human life is no longer the same (ref. https://coronavirus.jhu.edu/map.html). In an effort to control the pandemic, COVID-19 tests have become very important in our public health system. This coronavirus 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 detection method, qRT-PCR, reverse transcribes the viral RNA into cDNA, which is subsequently amplified and quantitatively analyzed.

Materials & Methods

BioChain's vamPure Viral Nucleic Acid Extraction kit can be applied on various automation systems, such as Thermofisher's Kingfisher Flex, Apostile's MagTouch, and Hamilton's Presto, for high throughput extraction of viral RNA from nasal swab samples. To date, our clients have processed more than 2.5 million swabs with our kits in the United States. For each swab sample, 200 ul of input were processed and 80 ul of eluted viral RNA were obtained. The presence of COVID-19 RNA was then determined by qRT-PCR.

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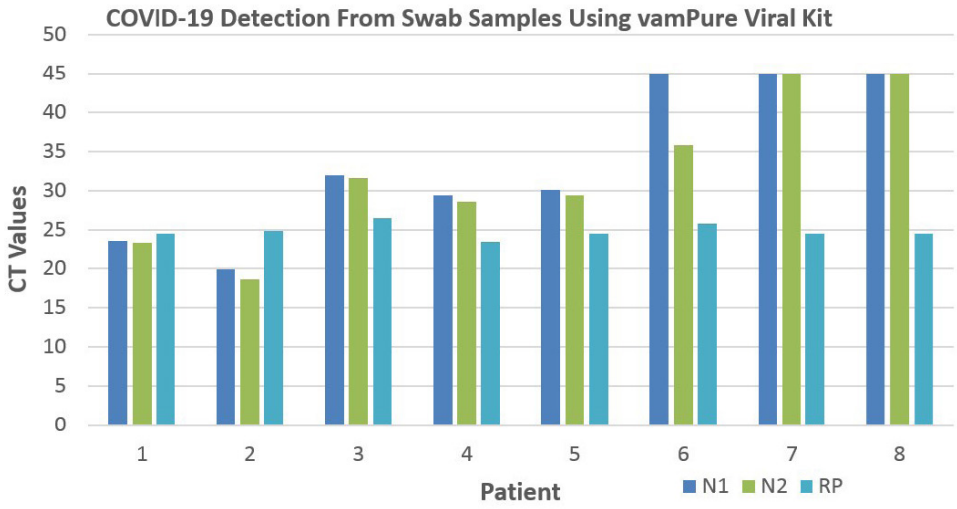

Figure 1. 200 µl of human swab sample from 8 patients were extracted using BioChain's vamPure Viral Nucleic Acid Extraction kit. RT-PCR was then performed on the elution from each subject to target either the nucleocapsid gene (N1 and N2 regions) of the novel 2019 coronavirus, or human RNase P as a control. The results show that 2 of the donors tested negative for the coronavirus, but the other 6 subjects had detectable levels of the viral nucleocapsid gene.

Patient	Estimated Viral Copies per µl
1	9.32E+03
2	1.78E+05
3	25.87
4	186.42
5	107.56
6	2.19
7	0
8	0

Table 1. BioChain's vamPure Viral Nucleic Acid Extraction kit provides high sensitivity for viral detection. The estimated viral copies shown here correlate with the results in Figure 1. As low as 2 viral copies of the novel coronavirus per µl were detected in one test subject. This sensitivity is important to distinguish between a negative test result and one where the donor has low viral loads and may not exhibit symptoms.

Results

Viral RNA Extraction Time

With the automated system, 96 samples can be processed in as little as 40 minutes. Our clients have processed more than 2.5 million samples.

Quality of the Downstream COVID-19 Detection

The downstream test results are typically available within 24-48 hours after the clinical samples are received by the lab. The downstream Limit of Detection (LoD) for the COVID-19 by qRT-PCR test was reported at 3.6 NDU/µL. The resulting sensitivity and specificity for the COVID-19 by qRT-PCR test were both reported at 99.9% at >3 copies/µL.

These data demonstrate a high quality of the downstream COVID-19 detection based on the use of vamPure Viral Nucleic Acid Extraction Kit. The quality of the kit has been confirmed by various users.

For example, as commented on by Harry Gao, MD, PhD, DABMG, FACMG, Lab Director and Chief Scientific Officer of Fulgent Genetics, "BioChain's vamPure Viral Nucleic Acid Extraction kit is cost-effective and reliable on our automation system. We look forward to continuing the collaboration with BioChain and providing high-quality COVID-19 tests for our community."

Conclusion

The use of BioChain's vamPure Viral Nucleic Acid Extraction Kit has proved to be highly effective for COVID-19 testing applications. Currently, more than 2.5 million samples have been tested through CLIA labs using this kit.

References

Center for Devices and Radiological Health. (n.d.). Sars-cov-2 reference panel comparative data. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data

"Coronavirus Testing: Fulgent Genetics." Coronavirus Testing | Fulgent Genetics, www.fulgentgenetics.com/covid19/molecular.

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