Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Journal of Clinical Virology 141 (2021) 104901

Contents lists available at ScienceDirect

Journal of Clinical Virology

journal homepage: www.elsevier.com/locate/jcv

Detection of SARS-CoV2 variants by Mesa Accula

ARTICLE INFO

Keywords
Variants
COVID-19
SARS-CoV2
Mesa Accula
Point-of-Care Testing

Rapid and accurate point-of-care (POC) testing for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) diagnosis is a cornerstone of patient care [1,2]. In order to decentralize testing and enhance rapid diagnosis and implementation of infection control measures, the Mesa Accula SARS-CoV2 test (Mesa POC, Mesa Biotech) was adopted at the National Institute of Health Clinical Center (NIH CC) in addition to other laboratory-based PCR assays with longer turn-around times. Emergence of viral variants over time are not unexpected for SARS-CoV-2 and as a proactive response, the Food and Drug Administration (FDA) routinely monitors potential influence of viral variants on diagnostic assays [3]. In January 2021 one such variant (28,881 GGG > AAC) was reported to potentially reduce the diagnostic efficacy of Mesa POC [3,4]. However, this was based on *in silico* analysis.

In this study we attempted to determine the performance of the Mesa POC for the viral variants that can affect test sensitivity according to the FDA [4]. Previous validation of the instrument was performed using 14 positive and 10 negative SARS-CoV-2 specimens, supporting sensitivity and specificity of the assay. The genetic variant that may impact assay performance (28881 GGG > AAC) was the target of this study, but we also included emerging viral variants R.1, P.2, B.1.526, B.1.1.7 and B.1.351 [5]. A total of 16 specimens collected between July 2020 and April of 2021 were tested (Table 1) and 48 contrived specimens were generated by diluting specimens in Mesa Accula Test Buffer and then split for testing in parallel on the Mesa POC and the Panther Fusion® (Panther) SARS-CoV-2 Assay (Hologic, Inc.).

SARS-CoV-2 RNA was detected on all specimens by Mesa POC, indicating that the N gene variations tested (specifically 28881 GGG > AAC) do not affect Mesa POC detection of this viral target (Table 1). Dilution ranges generated to approximate accuracy in detection at higher Cycle threshold (Ct) values showed comparable detection rates between the Panther assay and the Mesa POC. Estimated Ct ranges showed that at values of > 35 there was variability was present in nucleic acid detection with specimens on both Panther and Mesa Accula assays. Of the 48 contrived specimens, the Panther PCR platform was unable to detect 2 that were identified by the Mesa POC (estimated Ct > 38). In contrast, the Mesa POC was unable to detect 1 specimen that the Panther assay detected at a Ct value of 38.4.

In summary, we investigated the accuracy and specificity of the Mesa POC test for variants of SARS-CoV-2 in a limited specimen set. The FDA release suggested 28881 GGG > AAC mutation may impact assay performance [4]. Our findings do not support *in silico* predictions that SARS-CoV-2 detection is impaired for clinically relevant variants that were targeted within this study [4,5]. Our study had a limited number of variants tested, and contrived specimens may not adequately represent viral heterogeneity within different populations. Further analysis and examination of emerging variants will continue at the NIH CC to ensure detectability of SARS-CoV-2 as the virus continues to evolve. This underscores the need for *in vitro* studies to validate predictions generated by *in silico* analysis.

Ethics approval

None required.

Declaration of Competing Interest

We declare that we have no conflicts of interest.

Acknowledgments

We would like to thank the following individuals from NIH Clinical Center COVID team for aid in specimen processing / analysis: Gloria Osei, Chelsea Scudder, Pravesh Regmi, Wiam Makki, and Rachel Mercado.

This work was supported in part by the Intramural Research Program of the National Institutes of Health Clinical Center and the National Institute of Allergy and Infectious Diseases. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jcv.2021.104901.

https://doi.org/10.1016/j.jcv.2021.104901
Received 5 March 2021; Received in revised form 8 June 2021; Accepted 13 June 2021
Available online 19 June 2021
1386-6532/Published by Elsevier B.V.

Table 1
Specimen data of SARS-CoV strains detected between Hologic Panther and Mesa Accula assays.

Specimen ID	Specimen type	Initial Panther Result (Ct value*)	Panther Results (Ct value of serial dilutions)	Accula Results	Nextstrain clade (Pango lineage)	N gene mutation‡
MD-NIH-00009	NP Swab	Positive (15.94)	23.2	Positive	20B (B.1.1)	28881–28883 GGG>AAC
			33.2	Positive		
			37.5	Positive		
MD-NIH-00013	NP Swab	Positive (17.4)	24	Positive	20B (B.1.1)	28881–28883 GGG>AAC
			30.5	Positive		
			Negative	Positive		
MD-NIH-b1157	MT Swab	Positive (19.6)	22.8	Positive	20B (B.1.1.186)	28881–28883 GGG>AAC
			29.7	Positive		
			32.7	Positive		
MD-NIH-b0378	MT Swab	Positive (29.4)	30.2	Positive	20B (B.1.1.306)	28881–28883 GGG>AAC
			33.9	Positive		
			37	Positive		
MD-NIH-b0198	MT Swab	Positive (18.6)	33.2	Positive	20B (B.1.1.207)	28881–28883 GGG>AAC
			37.3	Positive		
			Negative	Negative		
MD-NIH-b0563	MT Swab	Positive (23.5)	26.3	Positive	20B (B.1.1.207)	28881–28883 GGG>AAC
			33	Positive		
			36.1	Positive		
MD-NIH-b0232	MT Swab	Positive (27.5)	27	Positive	20C (B.1.2)	28472, 28869
			33.7	Positive		
			Negative	Negative		*C>T, C>T*
MD-NIH-00031	NP Swab	Positive (20.2)	24.2	Positive	20B (B.1.298)	28843
			34.2	Positive		
			36.4	Positive		*T>G*
MD-NIH-00051	MT Swab	Positive (26.4)	31	Positive	20C (B.1.2)	28472, 28869
			32.5	Positive		
			38.4	Negative		*C>T, C>T*
MD-NIH-00052	NP Swab	Positive (ND)	23.6	Positive	20B (B.1.1.207)	28881–28883 GGG>AAC
			31.8	Positive		
			Negative	Negative		
MD-NIH-00244	NP Swab	Positive (18.3)	33	Positive	20I/501Y.V1 (B.1.1.7)	28280–28282 GAT>CTA
			Negative	Positive		28881–28883 GGG>AAC
			Negative	Negative		28977 *C>T*
						29440 *G>T*
MD-NIH-00158	NP Swab	Positive (29.7)	21.8	Positive	20H/501Y.V2 (B.1.351)	28887 *C>T*
			25	Positive		
			28.4	Positive		
MD-NIH-00315	MT Swab	Positive (20)	24.1	Positive	(P.2)	28881–28883 GGG>AAC
			27.5	Positive		
			30.8	Positive		28628 *G > T*
						28975 *G > T*
MD-NIH-00335	MT Swab	Positive (18.5)	22	Positive	(P.2)	28881–28883 GGG>AAC
			26	Positive		
			27.7	Positive		28628 *G > T*
						28975 *G > T*
MD-NIH-00355	MT Swab	Positive (20.1)	24.7	Positive	(R.1)	28881–28883 GGG>AAC
			27.9	Positive		
			31.1	Positive		28833 *C > T*
						29527 *G > T*
MD-NIH-00615	MT Swab	Positive (19.8)	24.2	Positive	(B.1.526)	28887 *C>T*
			27.4	Positive		
			30	Positive		

NP = Nasopharyngeal.
MT = Midturbinate.
* All Ct values based on original Ct of diagnostic testing prior to validation.
ND = Not determined. Sample was from outside hospital and original Ct value was not available.
‡ Sequence variations in comparison to Wuhan-Hu-1 reference genome (NC_045512).

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