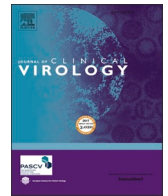




Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



Performance characteristics of the Abbott Alinity m SARS-CoV-2 assay

Garrett A. Perchetti^{a,1}, Gregory Pepper^{a,1}, Lasata Shrestha^a, Katrina LaTurner^a, Da Yae Kim^a, Meei-Li Huang^a, Keith R. Jerome^{a,b}, Alexander L. Greninger^{a,b,*}

^a Department of Laboratory Medicine and Pathology, Virology Division, University of Washington, Seattle, WA, United States

^b Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Research Center, Seattle, WA, United States

ARTICLE INFO

Keywords:

Alinity m
Abbott
SARS-CoV-2
Limit of Detection
Coronavirus
COVID-19

ABSTRACT

Mass molecular diagnostic testing for the SARS-CoV-2 pandemic has drawn on laboratory developed tests, commercial assays, and fully-automated platforms to accommodate widespread demand. The Alinity m instrument by Abbott is capable of detecting several clinically relevant pathogens and has recently received FDA emergency use authorization for SARS-CoV-2 molecular testing. The Alinity m performs automatic sample preparation, RT-PCR assembly, amplification, detection, and result calculation in under two hours. Here, we validate the performance characteristics of the Alinity m SARS-CoV-2 assay in comparison with the Roche cobas 6800 and Hologic Panther Fusion platforms. Across 178 positive and 195 negative nasopharyngeal swab specimens (C_T range 14.30–38.84), the Alinity m detected one additional positive specimen that was found to be negative on the Roche cobas 6800 (PPA 100%, NPA 99.5%). Across a separate set of 30 positive and 174 negative nasopharyngeal swab specimens (C_T range 14.1–38.5), the Alinity m had 100% positive and negative agreement with the Hologic Panther Fusion. Using SeraCare SARS-CoV-2 RNA standards, the assay limit of detection was verified to be two-fold more sensitive than the parameters stated by the SARS-CoV-2 AMP kit package insert, at 50 virus copies/mL. Assay specificity was 100% over 20 specimens positive for other respiratory viruses and intraday precision was 100% concordant with <2% CV. These data illustrate the Abbott Alinity m system's high concordance with reference assays and analytical high analytical for SARS-CoV-2 molecular detection.

1. Introduction

As SARS-CoV-2 continues to spread, multiple automated molecular diagnostic platforms have received emergency use authorization (EUA) from the US Food and Drug Administration (FDA) in 2020. The benefits of assay automation and standardization are many, such as improved reproducibility, efficiency, and safety [1–7]. However, automated platforms can take considerable time and resources to implement into clinical workflows [8–10].

The Alinity m SARS-CoV-2 assay is intended for the qualitative detection of nucleic acid from nasal swabs, nasopharyngeal (NP) and oropharyngeal (OP) swabs, or bronchoalveolar lavage fluid (BAL). The assay detects two targets, located in the RdRp and N genes of SARS-CoV-2. A sequence unrelated to SARS-CoV-2 (RNA from the hydroxypyruvate reductase gene of *Cucurbita pepo*, a pumpkin plant) is introduced into each specimen at the beginning of sample preparation. This unrelated RNA sequence is simultaneously amplified by RT-PCR and serves as an

internal control (IC) to demonstrate that the process has proceeded correctly for each sample.

Here, we evaluate the clinical performance of the Alinity m SARS-CoV-2 assay (Abbott Laboratories, Chicago, IL, USA) using clinical NP specimens in comparison with reference assays on the cobas 6800 (Roche, Basel, Switzerland) and Panther Fusion SARS-CoV-2 (Hologic, Marlborough, MA) real-time RT-PCR assays [11–13]. To determine the analytical sensitivity for this assay, we ran initial and confirmatory dilutions of previously quantified SARS-CoV-2 RNA standards. To evaluate specificity, a panel of non-SARS-CoV-2 laboratory-confirmed respiratory infections was run on the Alinity m. Assay precision was evaluated utilizing RNA standards in triplicate with appropriate controls over 72 h for each target concentration. Although the Alinity m SARS-CoV-2 assay is qualitative, here we also assess the linearity and PCR efficiency by serial tenfold dilutions of a remnant clinical NP specimen. Finally, we compare two Alinity m instruments side-by-side using positive clinical specimens over a range of SARS-CoV-2 viral loads.

* Corresponding author at: Department of Laboratory Medicine and Pathology, Virology Division, University of Washington, Seattle, WA, United States.

E-mail address: agrening@uw.edu (A.L. Greninger).

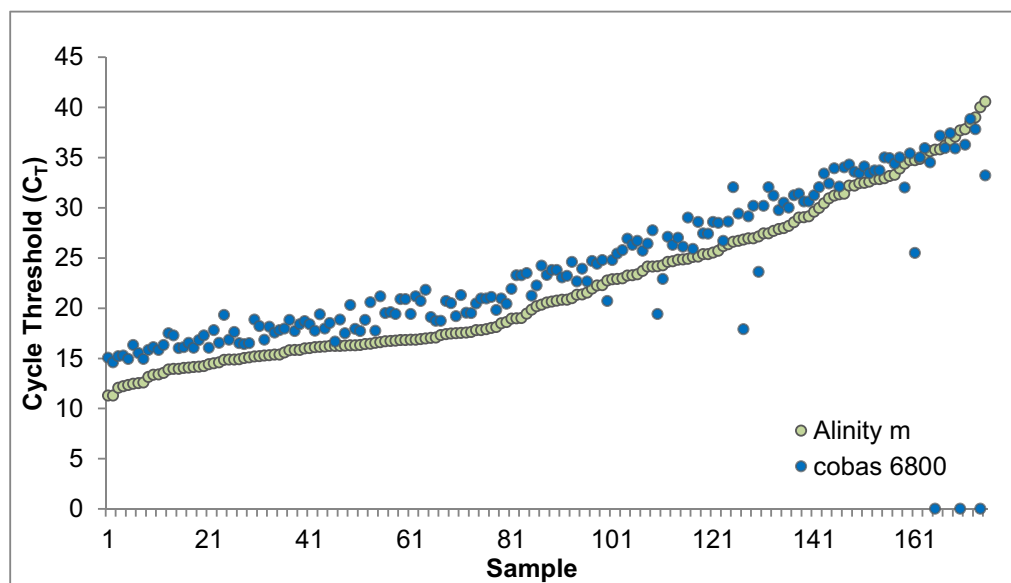
¹ These authors contributed equally to this work.

Table 1

Abbott Alinity m Clinical Concordance with Roche cobas 6800 and Hologic Panther Fusion SARS-CoV-2 Assay.

	Roche cobas 6800			Hologic Panther Fusion			
	Positive	Negative	Total	Positive	Negative	Total	
Positive	83	0	83	30	0	30	Abbott Alinity m #1
Negative	0	106	106	0	90	90	
Total	83	106	189	30	90	120	
	Positive	Negative	Total	Positive	Negative	Total	Abbott Alinity m #2
Positive	94	1	95	30	0	30	
Negative	0	89	89	0	84	84	
Total	94	90	184	30	84	114	

The positive percent agreement (PPA) and for both Alinity m instruments was reported at 100% compared to the cobas 6800 SARS-CoV-2 assay. The negative percent agreement (NPA) was determined at 100% and 98.9% for instrument #1 and #2, respectively. In comparison to the Panther Fusion SARS-CoV-2 assay, both PPA and NPA were calculated at 100%. Line-item CN values for all samples on each platform are included in Supplemental Data 1.

**Fig. 1.** Alinity m and cobas 6800 SARS-CoV-2 Cycle Threshold Comparison of Positive Samples

Alinity m positive cycle threshold (C_T) values compared to cobas 6800 positive sample C_T s. 178 positive samples were assayed with one discordant sample not detected on the cobas 6800 but was detected on the Alinity m with a C_T of 40.02. Two other samples are inconclusive and would be resulted as a positive by the cobas 6800, however they are displayed not detected here as these C_T values are plotted from the E-gene target.

2. Materials and methods

2.1. Specimen collection and panel selection

NP specimens in viral transport media (VTM) were sent to the University of Washington (UW) Clinical Virology Laboratory for SARS-CoV-2 RT-PCR testing, and de-identified excess sample was used to evaluate platform clinical concordance [14,15]. This work was approved under a consent waiver by the University of Washington institutional review board. 577 remnant clinical NP specimens (208 positives, 369 negatives) were compared to reference SARS-CoV-2 assays on the Roche cobas 6800 and Panther Fusion real-time RT-PCR platforms. Positive cycle thresholds (C_T s) from the cobas 6800 ranged from 14.30 to 38.84 while Panther Fusion panel C_T s ranged from 14.1 to 38.5.

For analytical sensitivity, recombinant virus containing SARS-CoV-2 RNA (SeraCare Life Sciences, Milford, MA, USA) was used as a positive control at a stock concentration of 1000 copies/mL. Assay calibrators at 1000 copies/mL, 200 copies/mL, 100 copies/mL, 50 copies/mL, and 25 copies/mL were prepared based on dilutions of the positive control in dH₂O and tested in triplicate for initial analytical sensitivity. Confirmatory limit of detection experiments were performed using 20 replicates at concentrations of 100 copies/mL, 50 copies/mL, and 25 copies/mL. Twenty non-SARS-CoV-2 respiratory NP specimens with C_T s ranging 17.5–37.6 from an in-house respiratory panel were used to evaluate assay specificity.

For precision, triplicates of the SeraCare RNA standards were run at 1000 copies/mL and 200 copies/mL with He-La cells serving as a

negative control. Mean cycle number (CN), standard deviation (SD), and percent coefficient of variation (%CV) were recorded over 3 days at each target concentration. Of note, the Alinity platform's CN is analogous to a standard PCR's C_T . Linearity and PCR efficiency was evaluated with a remnant clinical NP specimen serially diluted 10-fold. For instrument comparisons, two separate Alinity m platforms were tested with a panel of remnant clinical NP samples ($n = 32$) with a C_T range of (12.34–37.70). C_T shifts at 40 cycles were calculated based on Passing-Bablok linear regression analyses.

3. Results

3.1. Clinical concordance and platform comparison

Using 373 remnant clinical NP specimens (178 positive and 195 negative) assayed on the Roche cobas 6800 platform, the clinical performance of the Alinity m SARS-CoV-2 assay was evaluated (Table 1, Supp. Data 1). The accuracy and percent agreement between the candidate (Alinity m) and reference method (cobas 6800) were calculated as follows: overall percent agreement = 99.7%, PPV = 99%, NPV = 100%, PPA = 100%, and NPA = 99.5%. Individual C_T s for all 178 positive specimens run on the cobas 6800 were plotted against mean C_T s from the two Alinity m instruments (Fig. 1).

The clinical performance of the Alinity m SARS-CoV-2 assay was also compared to the Hologic Panther Fusion SARS-CoV-2 assay. 204 remnant clinical NP specimens (30 positive and 174 negative) were assayed (Table 1). Overall percent agreement, PPV, NPV, PPA, and NPA

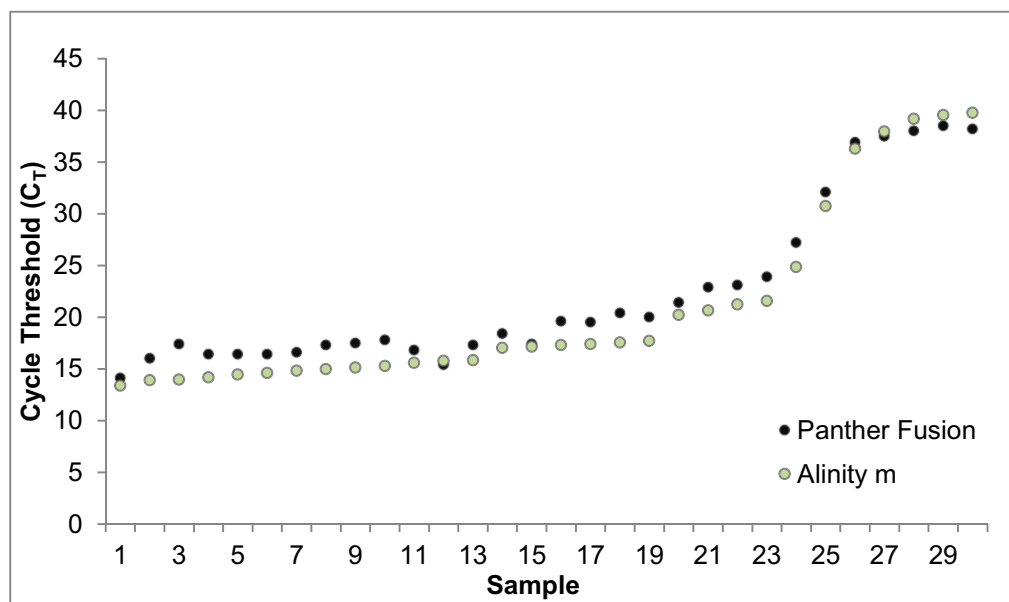


Fig. 2. Alinity m and Panther Fusion SARS-CoV-2 Cycle Threshold Comparison of Positive Samples

Alinity m positive cycle threshold (C_T) values compared to Panther Fusion positive sample C_T s. Across 30 positive nasopharyngeal specimens with a range of viral titers assayed on the Panther Fusion, 100% were detected on the Alinity m SARS-CoV-2 assay.

Table 2

Abbott Alinity m SARS-CoV-2 Assay Analytical Sensitivity.

Analytical Sensitivity	Virus Copies/mL	Replicates	% Positive	Mean CN	Instrument
Initial	1000	3	100%	32.11	Alinity m #1
	200	3	100%	34.77	
	100	3	100%	35.36	
	50	3	100%	37.11	
	25	3	100%	38.71	
Confirmatory	100	20	100%	35.80	Alinity m #2
	50	20	100%	36.91	
Initial	1000	3	100%	33.08	Alinity m #2
	200	3	100%	35.40	
	100	3	100%	35.82	
	50	3	100%	37.11	
	25	3	67%	38.17	
Confirmatory	100	20	100%	36.38	Alinity m #2
	50	20	100%	37.12	
	25*	20	60%	39.18	

Abbreviations: CN, cycle number.

*The twenty replicates for confirmatory sensitivity at 25 virus copies/mL was run only on a single Alinity m instrument due to reagent/consumable constrictions. Notably, the congruency between both instruments is adequate. The limit of detection for both Alinity m instruments with an observed positivity rate >95% was confirmed at 50 virus copies/mL using SeraCare RNA standards. Confirmatory line-item CN data is described in Supplemental Data 2.

were all calculated at 100% accuracy for the candidate method. Individual C_T s from the 30 positive specimens assayed on the Panther Fusion were plotted against mean C_T s from both Alinity m platforms (Fig. 2).

3.2. Analytical sensitivity

The initial estimation of LoD was performed in triplicate at 1000 copies/mL, 200 copies/mL, 100 copies/mL, 50 copies/mL, and 25 copies/mL using SeraCare RNA standards of recombinant virus containing SARS-CoV-2 (Table 2, Supp. Data 2). Confirmation of the LoD was performed at 100 copies/mL and 50 copies/mL with 20 replicates

for each instrument. A total of 110 contrived samples ranging from 50 to 1000 virus copies/mL were run to evaluate the analytical sensitivity of the assay on two separate Alinity m instruments.

Further assay sensitivity was interrogated after the Alinity platform detected all contrived samples below the manufacturer's claimed LoD at 100 virus copies/mL. Twenty-three additional samples, at 25 virus copies/mL, were assayed to confirm an empirical limit of detection on a single Alinity m due to reagent and consumable constrictions. The mean CN for the manufacturer declared 100 copies/mL concentration was determined at 36.09. However, the Alinity m was able to detect >95% of samples below this threshold, with a confirmed empirical limit of detection of 50 virus copies/mL, with a mean CN of 37.02.

3.3. Assay specificity

Non-SARS-CoV-2 infections from patient NP swabs ($n = 20$), laboratory-confirmed by UW Virology's laboratory-developed respiratory panel test, were evaluated for assay specificity [16–18]. Specimens included infection with adenovirus ($n = 2$), bocavirus ($n = 2$), non-SARS-CoV-2 coronavirus ($n = 5$), influenza ($n = 3$), human metapneumovirus ($n = 1$), parainfluenza ($n = 3$), respiratory syncytial virus ($n = 2$), and rhinovirus ($n = 2$). Respiratory panel C_T ranges for laboratory-confirmed respiratory infections spanned from 17.5 to 37.6. All respiratory infection samples were negative for SARS-CoV-2 when tested on the Alinity m.

3.4. Assay precision

RNA standards were run daily at 1000 copies/mL, 200 copies/mL, and with a negative control - He-La cells - over the course of 3 days. The mean CN, SD, and %CV were calculated at each target concentration (Table 3A). All positive dilutions were detected with <2% CV and 100% concordance based on qualitative interpretation for both Alinity m instruments. All negative controls did not amplify.

The Abbott Alinity m SARS-CoV-2 assay precision was then compared to UW Virology's Laboratory Developed Test (LDT which received EUA authorization from the Washington State Department of Health on March 18, 2020). The same RNA standards were diluted to 1000 virus copies/mL and 200 virus copies/mL, run over 3 days on two

Table 3**A. Abbott Alinity m SARS-CoV-2 Assay Precision.**

Concentration	Day	CN	Mean CN	SD	%CV	Instrument
1000 virus copies/mL	1	33.48	33.0	0.5	1.50%	Alinity m #1
	2	33.10				
	3	32.48				
200 virus copies/mL	1	35.18	35.4	0.2	0.60%	
	2	35.48				
	3	35.55				
Negative	1	NDET	N/a	N/a	N/a	
	2	NDET				
	3	NDET				
1000 virus copies/mL	1	33.41	33.1	0.3	0.80%	Alinity m #2
	2	33.07				
	3	32.92				
200 virus copies/mL	1	36.22	35.5	0.7	1.90%	
	2	34.99				
	3	35.16				
Negative	1	NDET	N/a	N/a	N/a	
	2	NDET				
	3	NDET				

Table 3B. UW LDT SARS-CoV-2 Assay Precision Comparison

Concentration	Day	N1 CN	N2 CN	N1 Mean FCN	N2 Mean FCN	N1 SD	N2 SD	N1%CV	N2%CV	Extraction Instrument
1000 virus copies/mL	1	34.19	35.28	34.65	35.16	0.40	0.17	1.16	0.48	MagNA Pure 96 #1
	2	34.95	34.97							
	3	34.80	35.23							
200 virus copies/mL	1	36.81	38.02	36.36	37.34	1.82	0.96	5.00	2.57	
	2	34.36	36.66							
	3	37.91	NDET							
Negative	1	NDET	NDET	N/a	N/a	N/a	N/a	N/a	N/a	
	2	NDET	NDET							
	3	NDET	NDET							
1000 virus copies/mL	1	33.76	35.79	33.89	35.44	0.32	0.51	0.95	1.44	MagNA Pure 96 #2
	2	33.66	35.67							
	3	34.26	34.86							
200 virus copies/mL	1	36.42	36.70	37.07	37.41	0.63	0.97	1.70	2.59	
	2	37.11	37.02							
	3	37.68	38.51							
Negative	1	NDET	NDET	N/a	N/a	N/a	N/a	N/a	N/a	
	2	NDET	NDET							
	3	NDET	NDET							

Abbreviations: CN, cycle number; SD, standard deviation, %CV, percent coefficient of variance, NDET, not detected; N/a, not applicable.

Different sample concentrations and a negative control (He-La cells) were run in triplicate over 72 h to evaluate SARS-CoV-2 assay precision between two separate Alinity m instruments.

Abbreviations: UW, University of Washington; LDT, laboratory developed test; CN, cycle number; SD, standard deviation, %CV, percent coefficient of variance, NDET, not detected; N/a, not applicable.

Different sample concentrations and a negative control (He-La cells) were run in triplicate over 72 h to evaluate the Alinity m SARS-CoV-2 assay precision in comparison to UW's LDT.

separate MagNA Pure 96 extraction instruments (Roche, Basel, Switzerland), and amplified on 7500 PCR systems (Applied Biosystems, Foster City, CA, USA) as previously described [14,15]. All positive dilutions of the SeraCare standards were detected by the MagNA Pure 96 extractions except one sample at 200 copies/mL on day 3 for MagNA Pure 96 instrument #1. The N1 target amplified with a C_T of 37.91, and the N2 target was not detected, resulting in an inconclusive that would be reported as a positive (Table 3B). All other positive dilutions were detected with <3% CV.

3.5. Linearity and PCR efficiency

Remnant clinical NP swabs were serially diluted 10-fold to evaluate assay linearity and PCR efficiency (Supp. Data 3). The most diluted samples ($1:10 \times 10^5$) were omitted from the PCR efficiency calculation. The assay is linear from a CN/ C_T of approximately 23 - 37 with an R^2 value > 0.99. PCR efficiency was calculated at 87.4%, respectively. Notably, the Alinity m assay is qualitative so does not require a quantitative calculation of linearity and PCR efficiency.

3.6. Instrument comparison

To compare the Alinity m instruments #1 and #2, a panel of 32 remnant clinical NP swabs with a range of C_T s (12.34–37.70) was tested on each instrument. The C_T shift was calculated based on Passing-Bablok Linear Regression analyses where the X-axis comprised C_T values from Instrument #1, and the Y-axis corresponds with C_T values from Instrument #2 (Supp. Data 4). A Two-tailed test for linearity was performed, and as the computed p-value is greater than the significance level of $\alpha = 0.05$, the relationship between the two variables can be considered linear. Using the regression analysis equation of $Y = A + BX$, a comparative C_T value [X;40] was calculated as $40 = A + BX$. For 32 observations, $Y = -0.184 + 0.995B$ comparative C_T values for instrument #1 and #2 are [40.4;40], respectively. *In Silico* performance analysis determined a 0.4 C_T difference between the two instruments at 40 cycles.

4. Discussion

Here, we validate the Abbott Alinity m SARS-CoV-2 assay and find

performance characteristics superior to the parameters stated in the AMP kit package insert. Previous work has evaluated the Alinity m for viral assays such as HCV, HIV, and HPV, though, no research to our knowledge has characterized and validated the Alinity m SARS-CoV-2 assay performance [19–23]. The PPA and NPA for both comparator groups (cobas 6800 and Panther Fusion assays) were calculated at >95% expected correlation as outlined by the FDA EUA minimum requirement for assay validation. Moreover, the PPA compared with both reference assays was calculated at 100%, indicating the Alinity m SARS-CoV-2 assay has equivalent clinical performance to verified and established assays.

Importantly, the Alinity m instruments were able to detect all inconclusive samples from the cobas 6800 platform ($n = 7$). Inconclusive samples typically correspond with very low viral loads (i.e. late C_T s); the mean and median C_T s from the seven inconclusive samples were calculated at 36.82 and 37.7, respectively, when detected on the Alinity m (Supp. Data 1). Notably, one sample that was indicated negative for both targets by cobas 6800 was detected by the Alinity m SARS-CoV-2 assay with a C_T of 40.02.

According to work done by Zhen et al., the Panther Fusion assay has an LoD of C_T 35.6, corresponding with 86 copies/mL (Panther Fusion - <https://www.fda.gov/media/136156/download>) [24]. The cobas 6800 SARS-CoV-2 assay has an LoD of C_T 32.7 and 36.4 for ORF1a and E-gene, or 46 copies/mL for both targets (Cobas 6800 - <https://www.fda.gov/media/136049/download>). In comparison, Abbott reports the Alinity m SARS-CoV-2 AMP Kit's limit of detection at 100 virus copies/mL according to their package insert (<https://www.fda.gov/media/137979/download>). However, when quantified with RNA standards, both Alinity m instruments were confirmed to detect >95% of positive specimens at 50 virus copies/mL (with a mean C_T 37.02), comparable to other FDA EUA reference assays. At 25 virus copies/mL, 60% of the 20 replicates were detected. It is also worth noting that all samples tested were transported in VTM as phosphate buffered saline is not currently an approved specimen type on the instrument.

Here, the Alinity m SARS-CoV-2 assay by Abbott has been validated to be accurate, specific, and more sensitive than the AMP kit package insert declared, with an empirical limit of detection determined at 50 virus copies/mL. The instrument's sensitivity permits detection of very low viral load specimens that may be missed by other platforms. The clinical concordance to reference assays was greater than 95% NPA and PPA when compared to the cobas 6800 and Panther Fusion. In summary, the Abbott Alinity m SARS-CoV-2 assay performance was superior to the parameters stated in the SARS-CoV-2 AMP kit package insert and equivalent to other FDA EUA molecular assays.

Declaration of Competing Interest

ALG reports contract funding from Abbott and Gilead for testing, research funding from Merck, all outside of the submitted work. Abbott had no role in the design or execution of the study.

Acknowledgments

We would like to thank Jared Castor and Aria Bovell for thoughtful discussion and assistance with clinical data. This research was funded from departmental funds from the Department of Laboratory Medicine and Pathology.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.jcv.2021.104869](https://doi.org/10.1016/j.jcv.2021.104869).

References

- [1] G. Lippi, G. Da Rin, Advantages and limitations of total laboratory automation: a personal overview, *Clin. Chem. Lab. Med.* 57 (2019) 802–811 (CCLM).
- [2] C. Ialongo, O. Porzio, I. Giambini, S. Bernardini, Total automation for the core laboratory: improving the turnaround time helps to reduce the volume of ordered STAT tests, *J. Lab. Autom.* 21 (2016) 451–458.
- [3] A. Dolci, D. Giavarina, S. Pasqualetti, D. Szóke, M. Panteghini, Total laboratory automation: do stat tests still matter? *Clin. Biochem.* 50 (2017) 605–611.
- [4] M. Zaninotto, M. Plebani, The “hospital central laboratory”: automation, integration and clinical usefulness, *Clin. Chem. Lab. Med.* 48 (2010).
- [5] B. Dharavath, N. Yadav, S. Desai, R. Sunder, R. Mishra, M. Ketkar, P. Bhanse, A. Gupta, A.K. Redhu, N. Patkar, S. Dutt, S. Gupta, A. Dutt, A one-step, one-tube real-time RT-PCR based assay with an automated analysis for detection of SARS-CoV-2, *Heliyon* 6 (2020) e04405.
- [6] S. Zimmermann, Lab automation in the microbiology lab: an ongoing journey, not a tale? *J. Clin. Microbiol.* (2020). JCM02592-20, jcm/JCM.02592-20v1.
- [7] K. Culbreath, H. Piwonka, J. Korver, M. Noorbash, Benefits derived from full laboratory automation in microbiology: a tale of four laboratories, *J. Clin. Microbiol.* (2020). JCM.01969-20, jcm/JCM.01969-20v1.
- [8] S.L. Mitchell, St. George K, D.D. Rhoads, S.M. Butler-Wu, V. Dharmarha, P. McNult, M.B. Miller, Understanding, verifying, and implementing emergency use authorization molecular diagnostics for the detection of SARS-CoV-2 RNA, *J. Clin. Microbiol.* 58 (2020) e00796-20 jcm/58/8/JCM.00796-20.atom.
- [9] W. Feng, A.M. Newbigging, C. Le, B. Pang, H. Peng, Y. Cao, J. Wu, G. Abbas, J. Song, D.B. Wang, M. Cui, J. Tao, D.L. Tyrrell, X.E. Zhang, H. Zhang, X.C. Le, Molecular diagnosis of COVID-19: challenges and research needs, *Anal. Chem.* 92 (2020) 10196–10209.
- [10] C. Archetti, A. Montanelli, D. Finazzi, L. Caimi, E. Garrafa, Clinical laboratory automation: a case study, *J. Public Health Res.* 6 (1) (2017) 881.
- [11] S. Pfeifferle, S. Reucher, D. Nörz, M. Lütgehetmann, Evaluation of a quantitative RT-PCR assay for the detection of the emerging coronavirus SARS-CoV-2 using a high throughput system, *Euro. Surveill.* 25 (9) (2020), 2000152.
- [12] J.A. Lieberman, G. Pepper, S.N. Naccache, M.L. Huang, Jerome KR, A.L. Greninger, Comparison of commercially available and laboratory-developed assays for *in vitro* detection of SARS-CoV-2 in clinical laboratories, *J. Clin. Microbiol.* 58 (2020) e00821-20jcm/58/8/JCM.00821-20.atom.
- [13] A. Moran, K.G. Beavis, S.M. Matushek, C. Ciaglia, N. Francois, V. Tesic, N. Love, Detection of SARS-CoV-2 by use of the cepheid xpert xpress SARS-CoV-2 and Roche cobas SARS-CoV-2 assays, *J. Clin. Microbiol.* 58 (2020) e00772-20, jcm/58/8/JCM.00772-20.atom.
- [14] A.K. Nalla, A.M. Casto, M.L.W. Huang, G.A. Perchetti, R. Sampoleo, L. Shrestha, Y. Wei, H. Zhu, Jerome KR, A.L. Greninger, Comparative performance of SARS-CoV-2 detection assays using seven different primer/probe sets and one assay kit, *J. Clin. Microbiol.* (2020). JCM00557-20, jcm/JCM.00557-20v1.
- [15] G.A. Perchetti, A.K. Nalla, M.L. Huang, H. Zhu, Y. Wei, L. Stensland, M.A. Loprieno, K.R. Jerome, A.L. Greninger, Validation of SARS-CoV-2 detection across multiple specimen types, *J. Clin. Virol.* 128 (2020), 104438.
- [16] J. Kuypers, N. Wright, L. Corey, R. Morrow, Detection and quantification of human metapneumovirus in pediatric specimens by real-time RT-PCR, *J. Clin. Virol.* 33 (2005) 299–305.
- [17] J. Kuypers, N. Wright, J. Ferrenberg, M.L. Huang, A. Cent, L. Corey, R. Morrow, Comparison of real-time PCR assays with fluorescent-antibody assays for diagnosis of respiratory virus infections in children, *J. Clin. Microbiol.* 44 (2006) 2382–2388.
- [18] J. Kuypers, E.T. Martin, J. Heugel, N. Wright, R. Morrow, J.A. Englund, Clinical disease in children associated with newly described coronavirus subtypes, *Pediatrics* 119 (2007) e70–e76.
- [19] L. Maree, M. Krügel, B. Reinhardt, A.J. Glass, Evaluation of the Alinity m HIV-1 assay for the quantification of HIV-1 RNA plasma viral load in a high-throughput molecular laboratory in South Africa, *J. Clin. Virol.* 132 (2020), 104644.
- [20] P. Braun, A. Glass, L. Maree, M. Krügel, M. Pacenti, F. Onelia, R. Gunson, E. Goldstein, L. Martínez-García, J.C. Galán, A. Vilas, J. D'costa, R. Sameer, R. Ehret, H. Knechten, G. Naeth, M. Bouvier-Alias, N. Marlowe, M.J. Palm, A. M. Joseph, J. Dhein, B. Reinhardt, K. Pfeifer, D. Lucic, M. Obermeier, Multicenter clinical comparative evaluation of Alinity m HIV-1 assay performance, *J. Clin. Virol.* 129 (2020), 104530.
- [21] S. Chevaliez, F. Onelia, M. Pacenti, E. Goldstein, J.C. Galán, L. Martínez-García, A. Vilas, A. Glass, L. Maree, M. Krügel, R. Ehret, H. Knechten, P. Braun, G. Naeth, S. Bonanzinga, K. Jackson, K. Abravaya, J. Dhein, S. Huang, A.M. Joseph, D. Lucic, N. Marlowe, M.J. Palm, K. Pfeifer, D. Toolsie, B. Reinhardt, M. Obermeier, R. Gunson, Multicenter clinical evaluation of Alinity m HCV assay performance, *J. Clin. Virol.* 129 (2020), 104531.
- [22] A. Oštrbenk Valenčak, A. Šterbenc, K. Seme, M. Poljak, Alinity m HR HPV assay fulfills criteria for human papillomavirus test requirements in cervical cancer screening settings, *J. Clin. Microbiol.* 58 (2019) e01120-19, jcm/58/1/JCM.01120-19.atom.
- [23] L. Mouna, C. Pallier, S. Proust, C. Prégermain, A.M. Roque-Afonso, Comparison of the Abbott Alinity m and m2000 assays for the quantification of HIV-1, HCV and HBV in clinical samples, *J. Clin. Virol.* 126 (2020), 104331.
- [24] W. Zhen, R. Manji, E. Smith, G.J. Berry, Comparison of four molecular *in vitro* diagnostic assays for the detection of SARS-CoV-2 in nasopharyngeal specimens, *J. Clin. Microbiol.* 58 (2020) e00743-20, jcm/58/8/JCM.00743-20.atom.