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Journal of Clinical Virology 138 (2021) 104792

Contents lists available at ScienceDirect

Journal of Clinical Virology

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

Combined SARS-CoV-2 nucleic acid amplification testing and respiratory virus panel RT-PCR on the Hologic Panther Fusion system

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ARTICLE INFO

Keywords:
SARS-CoV-2
Panther Fusion

ABSTRACT

Background: Significant overlap exists between the symptoms of SARS-CoV-2 and other respiratory viruses. This poses a serious challenge to clinical diagnosis, laboratory testing, and infection control programs.
Objectives: To evaluate the performance of the Hologic Panther Fusion Respiratory Assays (RA) compared to the GenMark ePlex Respiratory Pathogen Panel (RPP) and to assess the ability of the Panther Fusion to perform parallel testing of SARS-CoV-2 and other respiratory viruses from a single sample.
Study design: A diagnostic comparison study was carried out using 375 clinical nasopharyngeal specimens. Assay performance was assessed by overall, positive, and negative percent agreement and Cohen's kappa coefficient.
Results: Overall agreement between the Fusion RA and ePlex RPP was 97.3 % (95 % CI 96.3−98.0), positive percent agreement was 97.2 % (95 % CI 93.0−99.2), negative percent agreement was 97.3 % (95 % CI 96.3−98.0), and the kappa coefficient was 0.85 (95 % CI 0.81−0.89). Forty additional viruses in 30 specimens were detected by Fusion that were not detected by ePlex. The maximum specimen throughput for parallel testing of the Fusion Respiratory Assays with SARS-CoV-2 was 275 samples in 20.7 h for Fusion SARS-CoV-2 and 350 samples in 20.0 h for Aptima Transcription Mediated Amplification SARS-CoV-2.
Conclusion: Fusion RA demonstrated substantial agreement compared to the ePlex RPP. However, the Fusion detected respiratory viruses not identified by ePlex, consistent with higher clinical sensitivity. Workflows for parallel testing of respiratory pathogens and SARS-CoV-2 demonstrate that the Panther Fusion instrument provides a flexible, moderate to high throughput testing option for pandemic and seasonal respiratory viruses.

1. Background

Nucleic acid amplification testing for Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), the causative agent of Coronavirus Disease 2019 (COVID-19), is essential for diagnosis, clinical management, and implementation of appropriate infection control measures. The clinical presentation of COVID-19 ranges from mild upper respiratory illness to severe respiratory failure, and overlaps significantly with influenza and other common respiratory viruses [1]. In the Northern Hemisphere, the onset of the pandemic occurred during the conventional respiratory virus season, emphasizing the challenge of differentiating between viral etiologies of acute respiratory infections based on signs, symptoms, and epidemiologic data.

Diagnostic testing for non-SARS-CoV-2 respiratory viruses is critical, particularly for high-risk groups such as the immunocompromised, those with underlying heart and/or lung disease, and individuals over 65 years of age. Distinguishing COVID-19 from the clinical presentation of other respiratory virus infections, and identifying individuals with SARS-CoV-2 co-infections [2–4], will help inform hospital admissions, isolation and quarantine policies, and therapeutic options.

The SARS-CoV-2 pandemic has revealed significant deficiencies in the supply chain for critical assay reagents and consumables [5,6]. Clinical laboratories have therefore been required to validate and implement multiple platforms and workflows to ensure that SARS-CoV-2

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https://doi.org/10.1016/j.jcv.2021.104792
Received 1 November 2020; Received in revised form 7 February 2021; Accepted 4 March 2021
Available online 10 March 2021
1386-6532/© 2021 Published by Elsevier B.V.

diagnostic testing proceeds uninterrupted. In anticipation of similar challenges for all respiratory virus reagents, we performed a diagnostic comparison study of the Hologic Panther Fusion RT-PCR Respiratory assays (Fusion RA) with the GenMark ePlex Respiratory Pathogen Panel (ePlex RPP). In addition, we evaluated and optimized combined testing of all three Fusion Respiratory assays with SARS-CoV-2 nucleic acid amplification testing, using both RT-PCR and Aptima reagents, on the Panther Fusion instrument.

2. Methods

The retrospective analysis of Fusion RA (Hologic Inc. Marlborough, MA) utilized nasopharyngeal (NP) swab samples submitted for routine clinical testing of respiratory pathogens on the ePlex RPP (GenMark Diagnostics, Carlsbad, CA) collected between May 2019 and May 2020. Analysis of the capability of the Panther Fusion instrument to run both Fusion RA and either the Fusion SARS-CoV-2 RT-PCR or Aptima transcription mediated amplification (TMA) assays was evaluated using NP samples submitted for clinical testing between March 1st and 31st, 2020. Selected samples had been previously tested via the Stanford Health Care emergency use authorized laboratory-developed RT-PCR (LDT EUA) [7]. Specimens in the combined workflow evaluation had respiratory viral testing via the ePlex RPP on either the same swab (n = 3), a separate NP swab collected within 1 h of the SARS-CoV-2 sample (n = 124), or a separate NP swab collected 1–24 h after the SARS-CoV-2 collection (n = 19). The approximate sample throughput was calculated based on the following formula: ((timeframe interval [in min] – median time to complete results for first set of 5 samples) / (median time for complete results per subsequent set of 5 samples) + 1) * (5 samples per set).

Further details on the Fusion RA, ePlex RPP and SARS-CoV-2 tests, as well as discrepancy analysis using the GenMark XT-8 Respiratory Virus Panel (RVP) can be found in the Supplementary Materials.

3. Results

3.1. Comparison of fusion RA and ePlex RPP

A total of 229 nasopharyngeal samples originally tested by ePlex RPP were selected for testing on the Fusion RA, representing 142 samples positive for at least one respiratory virus and 87 negative samples. Overall percent agreement between the two assays was 97.3 % (95 % CI 96.3−98.0). The PPA was 97.2 % (95 % CI 93.0−99.2), and the NPA was 97.3 % (95 % CI 96.3−98.0). The kappa coefficient was 0.85 (95 % CI 0.81−0.89), indicating near perfect agreement.

Of the samples positive by ePlex RPP, the Fusion RA detected 21/21 (100 %) influenza A (13/13 H1−2009, 8/8 H3), 23/23 (100 %) influenza B, 19/19 (100 %) RSV, 18/21 (86 %) AdV, 21/21 (100 %) hMPV, 18/19 (95 %) RV, and 20/20 (100 %) PIV (8/8 PIV-1, 2/2 PIV-2, 3/3 PIV-3, 7/7 PIV-4) (Table 1). Of the 4 samples in which ePlex RPP detected virus nucleic acids that were not detected by Fusion RA, all were negative by confirmatory testing on the XT-8 RVP. In these ePlex positive samples, Fusion RA detected an additional 14 viral targets in 10 samples not detected by the ePlex RPP, including 3 influenza A, 2 influenza B, 4 RSV, 1 AdV, 2 hMPV, 1 RV, and 1 PIV-1 (Supplementary Table 1). The median cycle threshold (C_T) value for these additional targets was 37.2 (interquartile range (IQR): 36.3–40.2). XT8 RVP confirmed 12/14 (85.7 %) targets; 3/3 influenza A, 1/2 influenza B, 4/4 RSV, 1/1 AdV, 2/2 hMPV, 1/1 RV, and 0/1 PIV. XT8 RVP detected 2 targets (2 RSV) not found by either Fusion RA nor ePlex RPP, but missed 2 targets (1 hMPV and 1 RV) detected by both Fusion RA and ePlex RPP.

NPA by virus ranged from 93.3 % (95 % CI 89.1−96.3) for RSV to 99.5 % (95 % CI 97.4−100) for AdV (Table 1). Fusion RA detected an additional 26 viral targets in 20 NP samples in which the ePlex RPP was negative for all targets, including 6 influenza B, 10 RSV, 4 hMPV, 3 RV, and 3 PIV (Supplementary Table 1). The median C_T of the additional targets was 37.5 (IQR: 35.9–39.3). XT8 RVP confirmed 22/26 (84.6 %) additional viral targets detected by Fusion RA; 6/6 influenza B, 10/10 RSV, 2/4 hMPV, 1/3 RV, and 3/3 PIV. In addition, XT8 RVP detected 5 additional targets, 2 RSV and 2 RV, not detected by either Fusion RA or ePlex RPP.

Table 1
Positive and Negative Percent Agreement of the Fusion Respiratory Assays with the ePlex Respiratory Pathogen Panel.

Viral Targets	Fusion positive/ ePlex positive	PPA (95 % CI)	Fusion negative/ ePlex negative	NPA (95 % CI)
influenza A	21/21	100 % (83.9−100)	205/208	98.6% (95.8−99.7)
influenza B	23/23	100 % (85.2−100)	198/206	96.1% (92.5−98.3)
RSV	19/19	100 % (82.3−100)	196/210	93.3 % (89.1−96.3)
AdV	18/21	85.7 % (63.7−97.0)	207/208	99.5 % (97.4−100)
hMPV	21/21	100 % (83.9−100)	202/208	97.1% (93.8−98.9)
RV	18/19	94.7% (74.0−99.9)	206/210	98.1% (95.2−99.5)
PIV	20/20	100 % (86.1−100)	205/209	98.1% (95.2−99.5)
Total	140/144	97.2 % (93.0−99.2)	1419/1459	97.3 % (96.3−98.0)

95 % CI: 95 % confidence interval; PPA, positive percent agreement; NPA, negative percent agreement; RSV, respiratory syncytial virus; AdV, adenovirus; hMPV, human metapneumovirus; RV, rhinovirus; PIV, parainfluenza virus.

3.2. Evaluation of concurrent testing of SARS-CoV-2 and respiratory assays on the panther fusion instrument

A total of 146 NP samples, comprised of 54 SARS-CoV-2 positive and 92 SARS-CoV-2 negative samples with concurrent ePlex RPP testing, were tested in parallel for both SARS-CoV-2 and Fusion RA on a single Panther instrument. The median C_T value for SARS-CoV-2 positive samples was 31.5 (IQR: 21.4–36.5). Of the SARS-CoV-2 positive NP swabs, another respiratory virus was detected in 11/54 (20.4 %), including 1 influenza A H3, 2 RSV, 1 hMPV, 2 RV/EV, 1 PIV-3, and 4 seasonal coronaviruses. Of the SARS-CoV-2 negative NP swabs, additional respiratory viruses were detected in 29/92 (31.5 %), including 5 influenza A (2009-H1), 1 RSV, 9 hMPV, 8 RV/EV, and 3 seasonal coronavirus, as well as 1 influenza B/RV/EV, 1 CoV/RV/EV, and 1 hMPV/PIV-1.

Overall percent agreement between the LDT EUA and the Panther Fusion and Panther TMA assays was 95.9 % (95 % CI 91.3−98.5) and 94.5 % (95 % CI 89.4−97.6), respectively, in specimens concurrently tested by Fusion RA. PPA, NPA, and Cohen's kappa for these SARS-CoV-2 assays are described in Table 2. For the 11 samples discrepant by either one or both methods, the original median C_T value was 38.5 (IQR: 37.1–39.3). Two of the 4 samples negative for SARS-CoV-2 RNA by both Fusion and TMA were positive when retested by the LDT EUA with C_T values of 35.4 and 35.8.

When run in parallel with Fusion SARS-CoV-2, Fusion RA detected 30/34 (88.2 %) viruses positive by ePlex (Table 3). The Fusion RA does not detect seasonal coronaviruses, so these viruses (n = 7) were not included in the analysis. Of the four ePlex positive/Fusion RA negative discrepancies, three were XT-8 RVP negative (influenza A, influenza B, PIV-1) and the other had insufficient specimen for additional testing (RSV). Fusion RA detected an additional 16 viral targets in 15 samples, including 3 influenza A, 1 influenza B, 4 RSV, 2 AdV, 3 hMPV, and 3 RV (Supplementary Table 2). The median C_T for new viral targets detected by Fusion RA was 36.0 (IQR: 30.6–38.9). XT-8 RVP confirmed 2/3 influenza A, 0/1 influenza B, 4/4 RSV, 2/2 AdV, 0/2 hMPV, and 2/3 RV. One Fusion RA hMPV positive had insufficient volume for confirmatory

Table 2
Comparison of SARS-CoV-2 detection in specimens tested in parallel with the Panther Fusion Respiratory Virus Assays.

Comparison	Overall Agreement (95 % CI)	PPA (95 % CI)	NPA (95 % CI)	Kappa Statistic
LDT EUA v. Panther Fusion	95.9 % (91.3–98.5)	88.9 % (77.4–95.8)	100 % (96.8–100)	0.91 (0.84–0.98)
LDT EUA v. Panther TMA*	94.5 % (89.4–97.6)	84.9 % (72.4–93.3)	100 % (96.8–100)	0.88 (0.80–0.96)
Panther Fusion v. Panther TMA*	95.9 % (91.2–98.5)	91.5 % (79.6–97.6)	98.0 % (92.8–99.8)	0.91 (0.83–0.98)

95 % CI: 95 % confidence interval; PPA, positive percent agreement; NPA, negative percent agreement; LDT, laboratory developed test; EUA, emergency use authorization; TMA, transcription-mediated amplification.
* One specimen was invalid via TMA and was excluded from the analysis.

Table 3
Agreement of the Fusion Respiratory Assays with the ePlex Respiratory Pathogen Panel tested in parallel with Fusion SARS-CoV-2.

Viral Targets	Fusion positive/ ePlex positive	PPA (95 % CI)	Fusion negative/ ePlex negative	NPA (95 % CI)
influenza A	5/6	83.3% (35.9–99.6)	137/140	97.9% (93.9–99.6)
influenza B	0/1	0% (0.0–95.0)	144/145	99.3% (96.2–100)
RSV	2/3	66.7% (9.4–99.2)	139/143	97.2 % (93.0–99.2)
AdV	0/0	NA	144/146	98.6% (95.1–99.8)
hMPV	11/11	100 % (71.5–100)	132/135	97.8% (93.6–99.5)
RV	12/12	100 % (77.9–100)	131/134	97.8% (93.6–99.5)
PIV	1/2	50.0% (1.3–98.7)	144/144	100 % (97.9–100)
Total	31/35	88.6% (73.3–96.8)	971/987	98.4% (97.4–99.1)

95 % CI: 95 % confidence interval; PPA, positive percent agreement; NPA, negative percent agreement; RSV, respiratory syncytial virus; AdV, adenovirus; hMPV, human metapneumovirus; RV, rhinovirus; PIV, parainfluenza virus.

testing. Similar performance was obtained when the Fusion RA was run in parallel with TMA SARS-CoV-2 (Supplementary Table 3).

Parallel testing of SARS-CoV-2 and other respiratory pathogens was evaluated using a single Panther Fusion instrument to test the following workflows: 1) Fusion SARS-CoV-2 and Fusion RA, 2) TMA SARS-CoV-2 and Fusion RA, 3) Fusion SARS-CoV-2 and Fusion Flu A/B/RSV Assay, and 4) TMA SARS-CoV-2 and Fusion Flu A/B/RSV Assay (Fig. 1). 120 samples in Specimen Lysis Tubes can be loaded on the Panther Fusion. The instrument also holds a maximum of 224 Fusion tubes; 56 tubes per tray in 4 trays. One Fusion tube is used for each Fusion assay. In addition, the Panther Fusion holds a maximum of 28 reagent cartridges, which provides enough reagents for 336 Fusion assays. At this stage, the instrument is at max capacity and can process 56 samples for Fusion SARS-CoV-2 and Fusion RA, a total of 224 assays, without loading additional tubes and reagents. While total number of assays remains static, as the number Fusion assays being performed on each sample decreases, the number of samples that can be tested without loading additional reagents and consumables increases (Fig. 2 and Table 4).

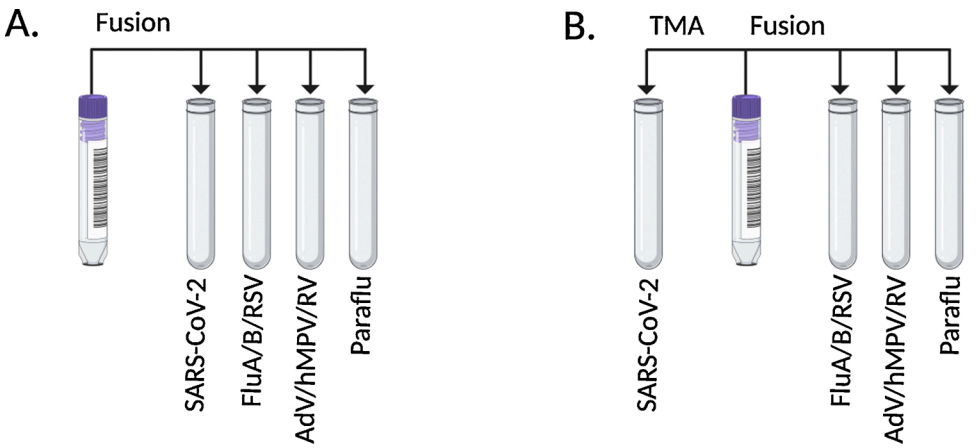
Additional samples beyond those supported by the maximum number of tubes and reagents are flagged as "pending." In order to move the pending samples forward, additional Fusion tubes and/or reagent cartridges must be loaded to queue the samples for extraction. For Panther Fusion assays, time to the first reported set of 5 samples varied across the evaluated workflows, with a range of 143–161 min. For TMA SARS-CoV-2, the first set of SARS-CoV-2 results was reported at 191 min when tested concurrently with Fusion RA, and 223 min with Fusion Flu A/B/RSV. Note that separate extractions are performed for Panther Fusion and Aptima TMA assays, both of which occur in sets of 5 samples.

The rate at which all results are reported for each subsequent set of 5 samples on the Fusion was dependent on the number of assays being performed on each sample. When running the Fusion SARS-CoV-2 and Fusion RA workflow (4 assays per sample), the median time to final results was 20 min. Each reduction in the number of Fusion assays performed per sample reduced the median time to result by 5 min per 5 sample set. While a number of consumables and reagents can be loaded on demand, the Panther instrument is required to be in the Setup or Ready state to perform key functions such as waste removal, instrument priming, and accessing the Fusion Universal Fluids Drawer. In order for the Panther instrument to move to the Ready state all instrument tasks including sample extraction, amplification, and reporting must be completed. This represents a hard limit in the sample throughput as the instrument must taken offline and is unavailable for testing. Fusion SARS-CoV-2 and Fusion RA is limited by the maximum capacity of Fusion Waste (1100 tests) to approximately 275 samples in 20.7 h (Table 4). TMA SARS-CoV-2 and Fusion RA is limited by the combination of the maximum capacity of Panther Waste and instrument priming (700 tests) to approximately 350 samples in 20.0 h. Fusion SARS-CoV-2 and Fusion Flu A/B/RSV Assay is limited by the maximum capacity of SARS-CoV-2 Assay PPR Solution. The Fusion Universal Fluids Drawer has 4 available slots to load Reconstitution Buffer packs, allowing one slot for Reconsitution Buffer for the Flu A/B/RSV assay (960 tests) and three slots for three sets of four SARS-CoV-2 Assay PPR Solutions tubes (480 tests). Fusion SARS-CoV-2 and Fusion Flu A/B/RSV Assay can test approximately 480 samples in 18.3 h. Finally, the TMA SARS-CoV-2 and Fusion Flu A/B/RSV Assay is limited by the maximum capacity of Panther Waste and instrument priming, capable of testing approximately 700 samples in 15.3 h.

4. Discussion

Combined diagnostic testing for SARS-CoV-2, influenza, and other respiratory viruses may be a critical component of the pandemic response during conventional influenza season, given the overlapping presentation of COVID-19 with other respiratory virus infections and the observation that respiratory virus co-circulation and co-infection were relatively common during the onset of the pandemic in the Northern Hemisphere. To address the need for SARS-CoV-2 and other respiratory virus testing options, we evaluated the performance of the Fusion RA compared to the ePlex RPP, and determined the characteristics and workflow of the Fusion RA combined with both Fusion SARS-CoV-2 and TMA SARS-CoV-2 testing.

The Fusion RA and ePlex RPP are currently widely used in clinical laboratories, though these tests had not previously been directly compared. In other diagnostic comparison studies, the Fusion RA demonstrated PPAs >96 % and NPAs > 98 % when compared with other respiratory virus tests, including the BioFire FilmArray Respiratory Panel (v. 1.7 and 2.0), XT-8 RVP, and Seegene Allplex Respiratory Panels [8–11]. The GenMark ePlex also exhibited similar performance when compared to a laboratory-developed RT-PCR panel and BioFire Film Array (v. 1.7), respectively [12,13]. In this study, we observed substantial agreement between Fusion RA and ePlex RPP for targets common to both tests. Importantly, Fusion RA does not detect seasonal coronaviruses and therefore, these viruses were not included in the analysis. Nevertheless, the Fusion RA detected respiratory viruses in specimens negative by ePlex RPP as well as co-infections in specimens positive for one or more ePlex RPP targets. Furthermore, Fusion RA detected other respiratory viruses not detected by ePlex RPP in specimens positive for SARS-CoV-2. These Fusion RA positive/ePlex RPP



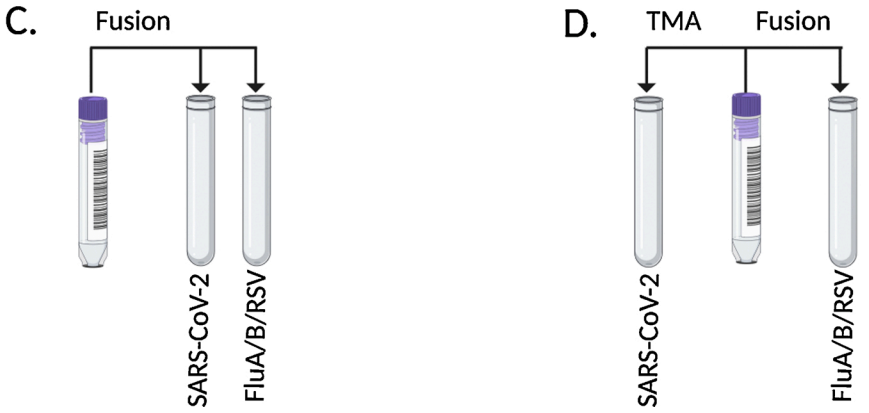


Fig. 1. Workflow options for SARS-CoV-2 and other respiratory assays on the Panther Fusion. **A.** Fusion SARS-CoV-2 and Fusion Respiratory Assays (RA). The Fusion RA are a set of three separate multiplex, real-time reverse transcription PCR (RT-PCR) reactions comprised of an assay that detects influenza A, influenza B, and Respiratory Syncytial Virus (FluA/B/RSV), an assay that detects adenovirus, human metapneumovirus, and rhinovirus (AdV/hMPV/RV), and an assay that detects parainfluenza virus (PIV) types 1, 2, 3, and 4 (Paraflu). **B.** Transcription Mediated Amplification (TMA) SARS-CoV-2 and Fusion RA. **C.** Fusion SARS-CoV-2 and Fusion FluA/B/RSV. **D.** TMA SARS-CoV-2 and Fusion FluA/B/RSV.

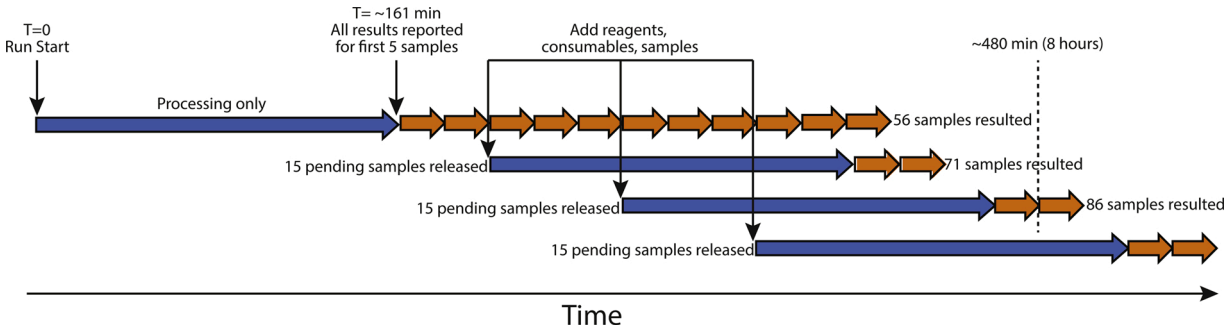


Fig. 2. Schematic of the Fusion-only workflow for SARS-CoV-2 and other respiratory assays. The first blue arrow represents the median time from assay start to the time all results from the first set of 5 samples are reported (161 min). The orange arrows represent the median time for all results from the next set of 5 samples to be reported (20 min). After 15 samples have been reported, Fusion tubes, reagent cartridges, and additional samples are loaded on the instrument. 15 of the samples in the pending queue then begin processing (second blue arrow). This workflow may be continued iteratively until testing is complete (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

negative targets were detected at high C_T values, consistent with low virus load. Taken together, this data suggests that the Fusion RA may be more clinically sensitive than ePlex RPP, and laboratories performing both assays should be prepared for a modest level of discrepant results when the same patient is tested on both platforms.

In preparation for the seasonal co-circulation of influenza and other respiratory viruses concurrent with the ongoing COVID-19 pandemic, we evaluated the ability of the Panther Fusion to perform both Fusion RA and SARS-CoV-2 testing from a single sample. First, consistent with previous work, substantial agreement was observed between Fusion SARS-CoV-2, TMA SARS-CoV-2, and the in-house LDT EUA [7,14–17]. Second, the performance characteristics of Fusion RA were not impacted by the addition of either Fusion or TMA SARS-CoV-2 testing. Finally, we detailed the workflow and sample throughput of combined testing. While the number of Fusion assays that can be performed remains static over time, the sample throughput of the instrument is diminished by a factor equivalent to the number of Fusion assays performed per sample. For example, in one 8 -h shift the Panther Fusion instrument can test ~330 samples via Fusion SARS-CoV-2. However, if a Fusion-only SARS-CoV-2 respiratory panel workflow is implemented (Fusion SARS-CoV-2 plus the three Fusion RA reactions), then the total number of samples that can be run per shift decreases by a factor of 4; or ~83 samples. Furthermore, the total number of samples that can be tested is limited by necessary maintenance which requires the Panther instrument to be unavailable for sample testing, such as waste disposal. Throughput, however, can be improved by reducing the number of

Table 4
Testing dynamics of four potential Panther Fusion workflows to test for SARS-CoV-2 and other respiratory viruses.

SARS-CoV-2 Method	Fusion Respiratory Assays v. influenza A/B/RSV only	Samples per Fusion tube tray	Sample disposition at assay start with maximum reagents and consumables loaded*		Median time to complete results for first set of 5 samples (minutes)		Median time for complete results per subsequent set of 5 samples (minutes)		Approximate maximum throughput	
			Processing	Pending	Fusion	TMA	Fusion	TMA	Samples	Time (hr)
Fusion	RA	14	56	64	162	NA	20	NA	275	20.7
TMA	RA	18	74	46	162	191	15	5	350	20.0
Fusion	A/B/RSV	28	112	8	150	NA	10	NA	480	18.3
TMA	A/B/RSV	56	120	0	143	223	5	5	700	15.3

TMA, Transcription Mediated Amplification; RA, Panther Fusion Respiratory Assay; A/B/RSV, Panther Fusion Flu A/B/RSV assay; NA, not applicable.
* Samples indicated as processing are available and queued by the instrument for extraction. Samples indicated as pending are unavailable for extraction until requisite pending tasks for that sample are completed.

assays per sample performed on the Fusion, as shown in this study with the substitution of TMA SARS-CoV-2 for the Fusion SARS-CoV-2 test. However, the combination of TMA and RT-PCR methods requires more reagents and consumables compared to the Fusion-only workflow, a significant consideration given ongoing supply chain challenges. Throughput could also be increased by limiting non-SARS-CoV-2 respiratory virus testing to influenza A, influenza B, and RSV. The Panther Fusion has sufficient flexibility to allow the respiratory panel to be tailored in real-time to the testing needs of varied patient populations, though the moderate turnaround time is best suited for patients for whom rapid results are not required for clinical decision-making.

Limitations include the retrospective study design and use of historical ePlex RPP results for reference. Nevertheless, this is unlikely to have impacted our conclusions, as all ePlex RPP positive/Fusion RA negative samples with sufficient residual archived sample were negative by XT-8 RVP confirmatory testing. Note also that most of the ePlex RPP results from the SARS-CoV-2 sample set were obtained via separate, concurrently collected NP swabs. Discrepancies in this cohort may therefore have been the result of differences in sampling, though we did observe substantial overall agreement.

In summary, this study demonstrated that the Panther Fusion can be leveraged for parallel testing of Fusion RA with either Fusion SARS-CoV-2 or TMA SARS-CoV-2, requiring only a single sample for pathogen workup. These assays performed with substantial agreement with the ePlex RPP and LDT EUA SARS-CoV-2 RT-PCR, respectively. Furthermore, Fusion RA was shown to detect respiratory pathogens of interest in low viral burden samples which were previously negative by ePlex RPP. The benefits gained from increasing respiratory panel size and consolidating testing onto a single instrument must be balanced against decreased sample throughput and increased turnaround time. Thus, optimal use of instruments such as the Panther Fusion will be a critical consideration for laboratories while successfully navigating demand for combined testing of SARS-CoV-2 and other respiratory viruses.

Funding source

None.

Ethical approval

This study was approved by the Stanford Institutional Review Board (protocol #48973). Individual patient consent was waived.

Declaration of Competing Interest

B.A.P is a member of the scientific advisory board for GenMark Diagnostics and has previously received funding from Hologic, Inc.for HIV and Hepatitis virus studies.

Acknowledgments

The authors would like to thank the hard-working clinical laboratory scientists and laboratory assistants of the Stanford Healthcare Clinical Virology Laboratory, who continually demonstrate professional excellence and are the backbone of the COVID-19 laboratory response.

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