

Pilot Clinical Evaluation of the BioFire® Emerging Coronavirus Panel

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Background

BioFire Defense has developed the BioFire Emerging Coronavirus (ECoV) panel as an in vitro diagnostic test for the simultaneous detection and differentiation of seasonal and emerging coronaviruses from nasopharyngeal swab (NPS) specimens collected from patients suspected of a novel or emerging coronavirus infection using the BIOFIRE® FILMARRAY® TORCH system. Specifically, the panel contains assays for the four genera from the *Orthocoronavirinae* subfamily: *Alphacoronavirus*, *Betacoronavirus*, *Gammacoronavirus*, and *Deltacoronavirus*, as well as species-specific assays for known human coronaviruses: HCoV-229E, HCoV-NL63, HCoV-HKU1, HCoV-OC43, SARS-CoV-1, SARS-CoV-2, and MERS-CoV. Health care providers would be able to diagnose patients infected with an emerging coronavirus and differentiate between other known human respiratory coronaviruses. If stockpiled, the panel could be used immediately on the broad commercial TORCH System install base during an outbreak until more targeted tests become available.

Methods

BioFire Defense performed a pilot prospective clinical evaluation at three clinical sites in the United States to test a prototype version of the panel in the intended use setting. A total of 421 prospective NPS specimens were tested between June and October 2025. Enrollment consisted of residual, coded NPS specimens, leftover from Standard of Care (SOC) testing for a suspected respiratory infection as determined by a health care provider. Coded specimens were tested at the study site using the prototype ECoV Panel and the comparator, BIOFIRE® Respiratory Panel 2.1 (RP2.1 Panel) to evaluate preliminary performance – positive percent agreement (PPA) and negative percent agreement (NPA) were assessed.

The BioFire Emerging Coronavirus (ECoV) Panel

	<i>Alphacoronavirus</i> spp. HCoV-229E HCoV-NL63 <i>Betacoronavirus</i> spp. HCoV-HKU1 HCoV-OC43 SARS-CoV-1 SARS-CoV-2 MERS-CoV	<i>Gammacoronavirus</i> spp. <i>Deltacoronavirus</i> spp.
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Conclusions

In total, 421 specimens were tested using the prototype ECoV Panel.

Based on the results from this study, the ECoV Panel was determined to be highly specific with the NPA for all targets between 97.6-100%. There were no unexpected detections for targets that were expected to be negative.

Sensitivity could only be evaluated with enough confidence for one target, SARS-CoV-2. The sensitivity for SARS-CoV-2 met the desired performance goal of ≥ 95% PPA.

Overall, these data support that the ECoV Panel design meets the performance expectations for the assays that could be evaluated in this study. Pending regulatory clearance, the ECoV Panel may be a valuable diagnostic tool to aid in national pandemic preparedness.

Study Sites

- Between June 2025 and October 2025, three (3) study sites enrolled 424 specimens

Site	Study Site Location Principle Investigator	Enrolled Population	Enrollment Dates Started-Completed	Total Subjects Enrolled (Excluded)	Total Valid Specimens (Excluded)
01	The George Washington University – Medical Faculty Associates Washington D.C. Aileen Chang, MD MSPH FACP	Pediatric and Adult	June 2025-October 2025	141 (1) ^a	140
02	Children’s Hospital Los Angeles Los Angeles, CA Jenn Dien Bard, PhD D(ABMM) F(CCM)	Pediatric	June 2025-August 2025	140	140
03	Emory University Hospital Atlanta, GA Colleen Kraft, MD MSc	Pediatric and Adult	June 2025-September 2025	142 (1) ^b	141 (1) ^c

^a Insufficient volume for testing
^b SCN input incorrectly
^c Unable to obtain valid result

Subject Demographics and Specimen Information

		Overall	Site 01	Site 02	Site 03
Sex	Male	192 (45.6%)	61 (43.6%)	81 (57.9%)	50 (35.5%)
	Female	229 (54.4%)	79 (56.4%)	59 (42.1%)	91 (64.5%)
Age	≤ 5 years	69 (16.4%)	1 (0.7%)	68 (48.6%)	0 (0.0%)
	6-18 years	70 (16.6%)	2 (1.4%)	67 (47.9%)	1 (0.7%)
	19-40 years	72 (17.1%)	35 (25.0%)	5 (3.6%)	32 (22.7%)
	41-60 years	101 (24.0%)	53 (37.9%)	0 (0.0%)	48 (34.0%)
	61+ years	109 (25.9%)	49 (35.0%)	0 (0.0%)	60 (42.6%)
Health Setting	Emergency Department	215 (51.1%)	104 (74.3%)	61 (43.6%)	50 (35.5%)
	Inpatient	107 (25.4%)	36 (25.7%)	71 (50.7%)	0 (0.0%)
	Outpatient	99 (23.5%)	0 (0.0%)	8 (5.7%)	91 (64.5%)
Transport Media	VTM	140 (33.3%)	140 (100%)	0 (%)	0 (0.0%)
	UTM	281 (66.7%)	0 (0.0%)	140 (100%)	141 (100%)
SOC Test	BIOFIRE RP2.1 Panel	150 (35.6%)	30 (21.4%)	115 (82.1%)	5 (3.5%)
	Cepheid Xpert Xpress COV-2 Plus	2 (0.5%)	0 (0.0%)	2 (1.4%)	0 (0.0%)
	Cepheid Xpert Xpress COV-2/Flu/RSV Plus	269 (63.9%)	110 (78.6%)	23 (16.4%)	136 (96.5%)
Total		421	140	140	141

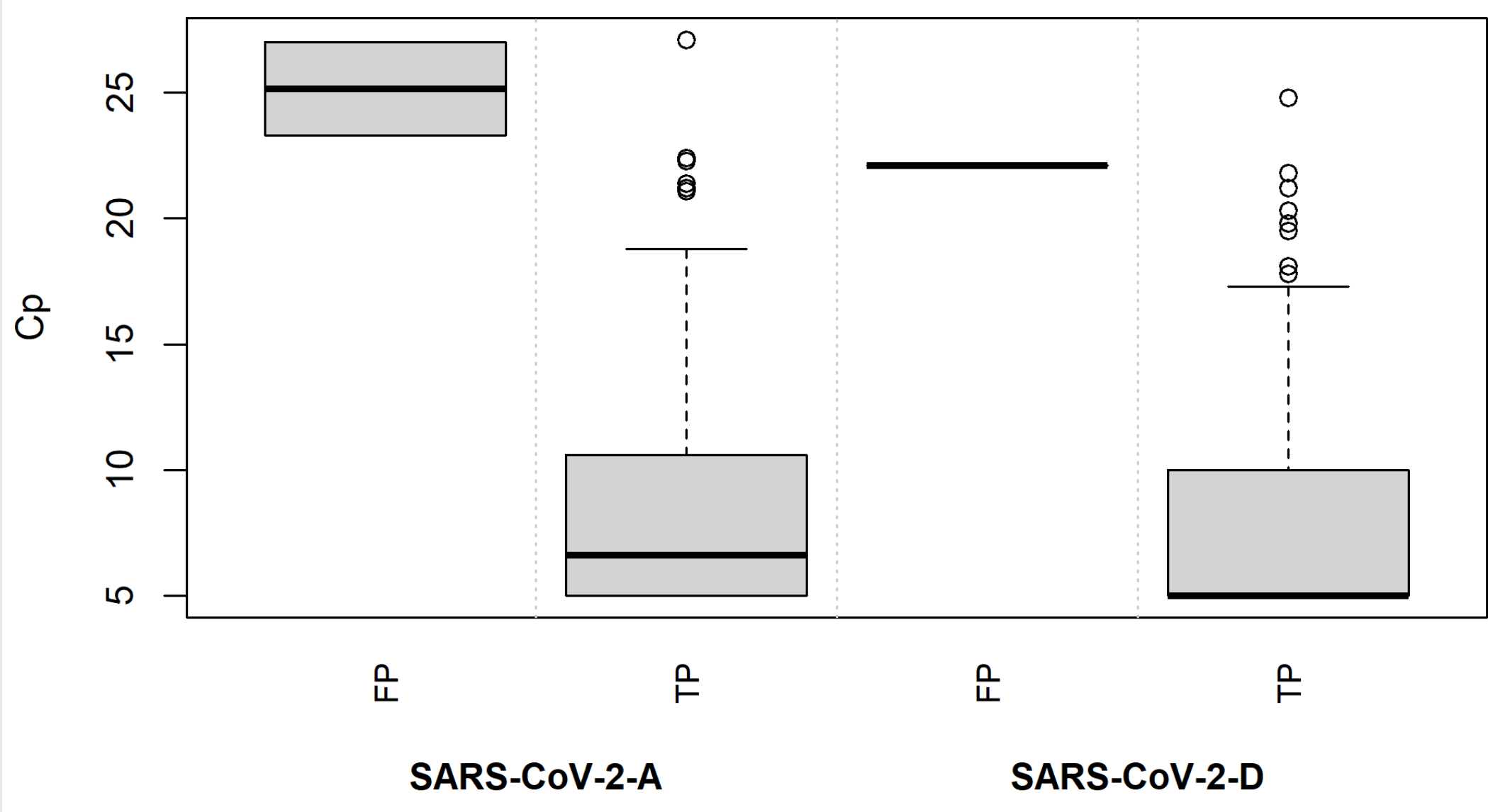
- 421 subjects were included in the final data analysis
- Site 02 enrolled the majority of the under 18 years of age specimens based on the site exclusively serving pediatric patients
- NPS specimens were stored in both UTM and VTM
- Three (3) different standard of care tests were used at sites

Performance of the Prototype BioFire Emerging Coronavirus (ECoV) Panel

ECoV Panel Target Result	PPA			NPA		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
<i>Alphacoronavirus</i> spp.	2/2	100%	34.2% – 100%	419/419	100%	99.1% - 100%
HCoV-229E	1/1	100%	20.6% - 100%	420/420	100%	99.1% - 100%
HCoV-NL63	1/1	100%	20.6% - 100%	420/420	100%	99.1% - 100%
<i>Betacoronavirus</i> spp.	123/123	100%	97.0% - 100%	196/198	99.3%	97.6% - 100%
HCoV-HKU1	0/0	-	-	421/421	100%	99.1% - 100%
HCoV-OC43	2/2	100%	34.2% - 100%	419/419	100%	99.1% - 100%
SARS-CoV-2	122/122	100%	97% - 100%	297/299	99.3%	97.6% - 99.8%
MERS-CoV	-	-	-	421/421	100%	99.1% - 100%
SARS-CoV-1	-	-	-	421/421	100%	99.1% - 100%
<i>Deltacoronavirus</i> spp.	-	-	-	421/421	100%	99.1% - 100%
<i>Gammacoronavirus</i> spp.	-	-	-	421/421	100%	99.1% - 100%

- ECoV Panel demonstrated high sensitivity for SARS-CoV-2
 - PPA of 100% across 122 comparator-positive specimens
- HCoV-229E, HCoV-NL63, and HCoV-OC43 also had an observed PPA of 100%
 - The number of comparator-positive specimens was insufficient to support a definitive performance assessment
- No comparator-positive specimens for HCoV-HKU1 were identified during this study
- ECoV Panel demonstrated high specificity with NPA ranging from 99.3-100.0%
 - Two False Positive (FP) results: SARS-CoV-2 and *Betacoronavirus* spp.
 - Both FP specimens were positive for SARS-CoV-2 by standard of care testing

Cp Values for the ECoV Panel SARS-CoV-2A and SARS-CoV-2-D Assays for Specimens Identified as Positive



- SARS-CoV-2 target consists of two assays, SARS-CoV-2A and SARS-CoV-2-D, and positivity of either assay results in a SARS-CoV-2 panel detection
- Distribution of Cp values for the ECoV Panel for each of the SARS-CoV-2 assays in the FPs were significantly later cycles than the mean Cp values for TP specimens
- Cp values suggest that the samples were likely near or below the assays' LoD

Prevalence of Analytes in Co-Detections as Determined by the BioFire Emerging Coronavirus (ECoV) Panel

Organism		Prevalence in Co-Detections
SARS-CoV-2	2/3	66.7%
HCoV-OC43	2/3	66.7%
HCoV-NL63	1/3	33.3%
HCoV-229E	1/3	33.3%

- ECoV Panel is a multiplex test that can identify multiple analytes in a single specimen
- There were three (3) specimens with reported co-detections
- The co-detection combinations were as follows: HCoV-229E and SARS-CoV-2, HCoV-OC43 and SARS-CoV-2, and HCoV-OC43 and HCoV-NL63

Acknowledgements

This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50122C00073.

The authors thank Principal Investigators, Dr. Aileen Chang, Dr. Jenn Dien Bard, and Dr. Colleen Kraft and their respective study teams for their involvement in this study.



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