

Evaluation of a Rapid Multiplex PCR Diagnostic Device for the Detection of Microorganisms from Nasopharyngeal Swab Specimens in the Near-Patient Setting



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BACKGROUND

Limited availability of multiplex molecular tests in the near-patient setting can impact the rapid diagnosis and treatment of patients experiencing symptoms of respiratory tract infections. The BIOFIRE® SPOTFIRE® Respiratory (R) Panel (bioMérieux, Salt Lake City, UT), designed for use with the BIOFIRE® SPOTFIRE® System, is a PCR-based sample-to-answer diagnostic test that identifies four bacteria and 11 viruses (including SARS-CoV-2) from nasopharyngeal swab (NPS) in about 15 minutes. This study evaluated the performance of an Investigational Use Only (IUO) version of the SPOTFIRE R Panel in the near-patient setting.

NPS specimens were prospectively enrolled from symptomatic consented/assented volunteers of all ages or obtained as residual leftover specimens. Enrollment was conducted between December 2020 and September 2021 at five study sites in the US and UK (general and pediatric emergency departments or urgent care clinics) with testing performed by personnel representative of the intended users (non-laboratory professionals). Several organisms that were not circulating during the COVID-19 pandemic were supplemented with archived specimens of known organism composition and tested by the intended users at the clinical study sites. Performance was determined by comparison to FDA cleared multiplex PCR tests.

SUMMARY

98.4% PPA and 99.1% NPA (prospective)
overall when compared to FDA cleared multiplex PCR

98.9% PPA and 99.3% NPA (archived)
overall when compared to FDA cleared multiplex PCR

Identification of at least one organism in **60.7%** of prospectively collected nasopharyngeal swab specimens

Ability to detect multiple organisms in a single specimen

Success rate of **97.3%** for obtaining valid results on initial specimen test

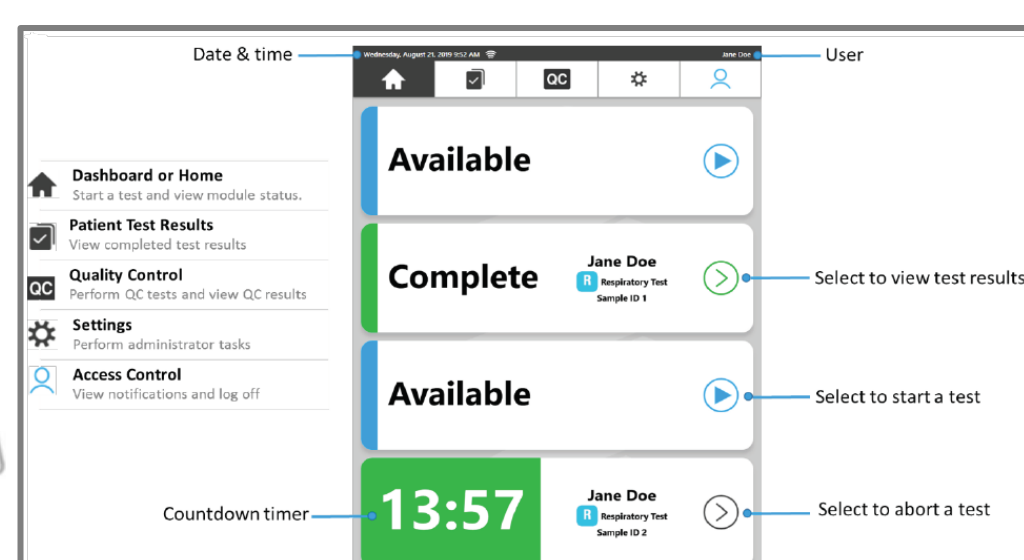
This poster contains data regarding an IUO version of the SPOTFIRE R Panel that has not been reviewed or approved by regulatory agencies for in vitro diagnostic use.

THE SYSTEM

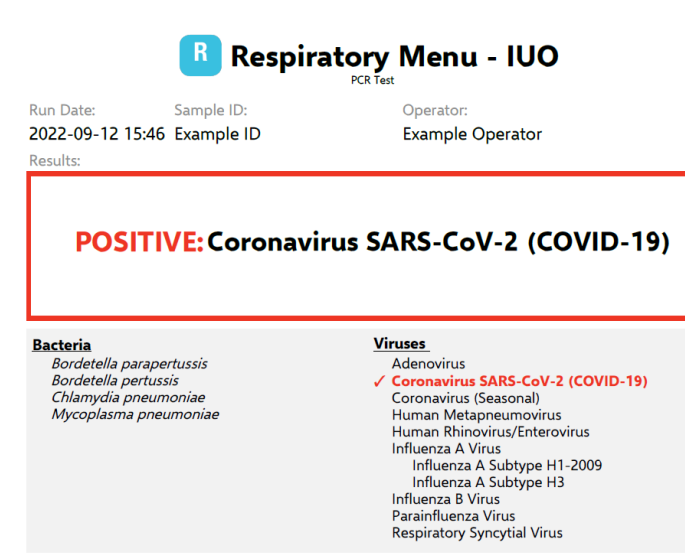
Instrument



Graphical User Interface



Customer Report



Note: Seasonal Coronavirus is composed of 229E, HKU1, OC43, and NL63, and Parainfluenza Virus is composed of Parainfluenza viruses 1-4

Table 1. Participating Study Sites

Site (Abbreviation)	Study Site Clinical Setting Location	Predominantly Enrolled Population	Valid NPS Specimens
1 (IU)	IU Health University Hospital Adult Emergency Department Indianapolis, IN	General	361
2 (TMCKC)	Truman Medical Center Adult Emergency Department Kansas City, MO	General	36
3 (CMH)	Children's Mercy Hospital Pediatric Urgent Care & Emergency Department Kansas City, MO	Pediatric	511
4 (NCH)	Nationwide Children's Hospital Pediatric Emergency Department Columbus, OH	Pediatric	154
5 (UCLH)	University College London Hospital Adult Emergency Department London, England	General	69

Table 2. Overall and Per Site Demographics

	NPS	Overall	Site 1	Site 2	Site 3	Site 4	Site 5
Sex	Male	588 (52.0%)	177 (49.0%)	22 (61.1%)	270 (52.8%)	83 (53.9%)	36 (52.2%)
	Female	543 (48.0%)	184 (51.0%)	14 (38.9%)	241 (47.2%)	71 (46.1%)	33 (47.8%)
Age	≤5 years	462 (40.8%)	34 (9.4%)	0 (0%)	315 (61.6%)	113 (73.4%)	0 (0%)
	6-18 years	258 (22.8%)	27 (7.5%)	0 (0%)	193 (37.8%)	38 (24.7%)	0 (0%)
	19-40 years	165 (14.6%)	113 (31.3%)	20 (55.6%)	3 (0.6%)	3 (1.9%)	26 (37.7%)
	41-60 years	147 (13.0%)	108 (29.9%)	15 (41.7%)	0 (0%)	0 (0%)	24 (34.8%)
	61+ years	99 (8.8%)	79 (21.9%)	1 (2.8%)	0 (0%)	0 (0%)	19 (27.5%)
Total	1131	361	36	511	154	69	

Figure 1. Organism Prevalence

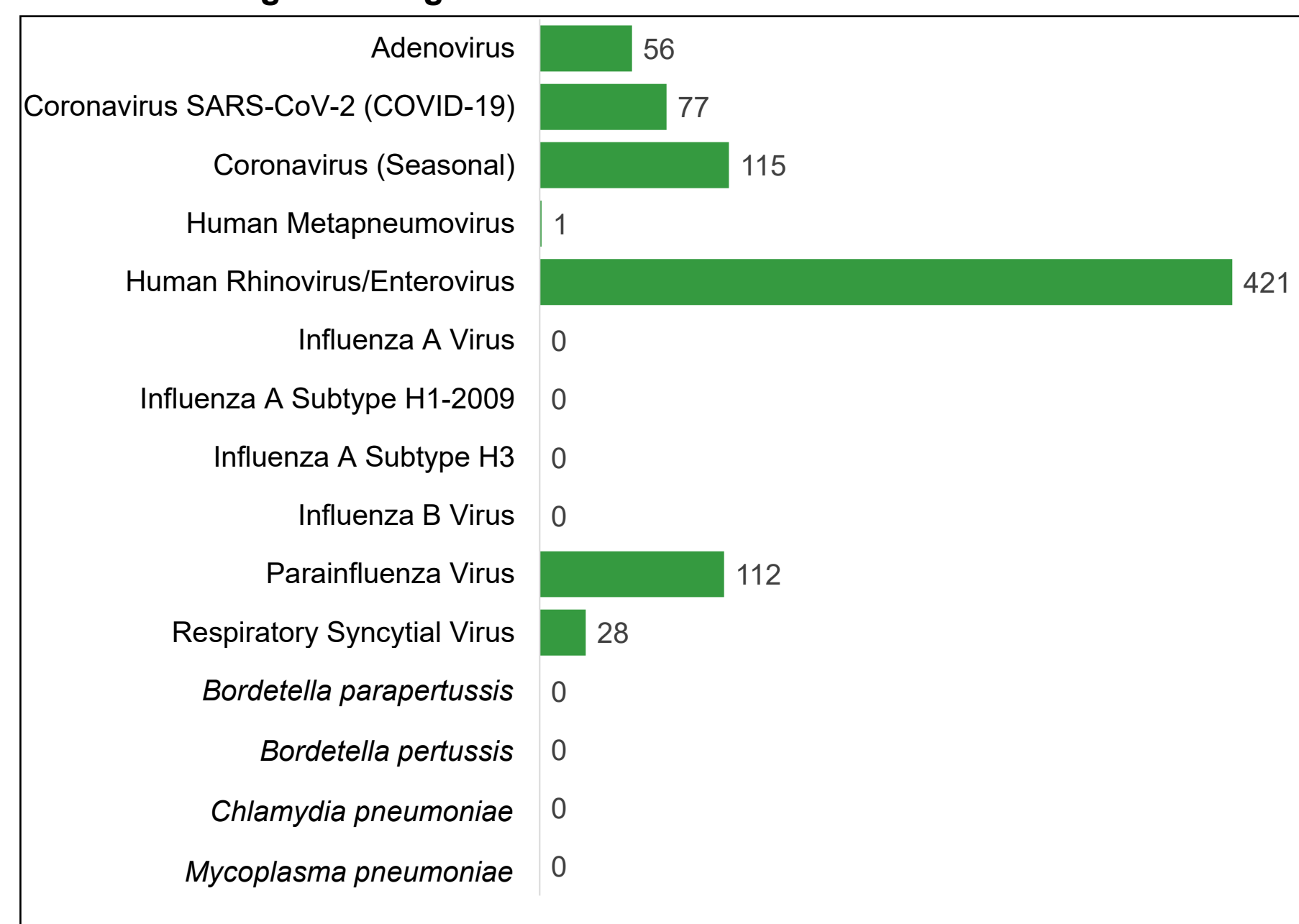


Figure 2. SPOTFIRE R Panel Detections

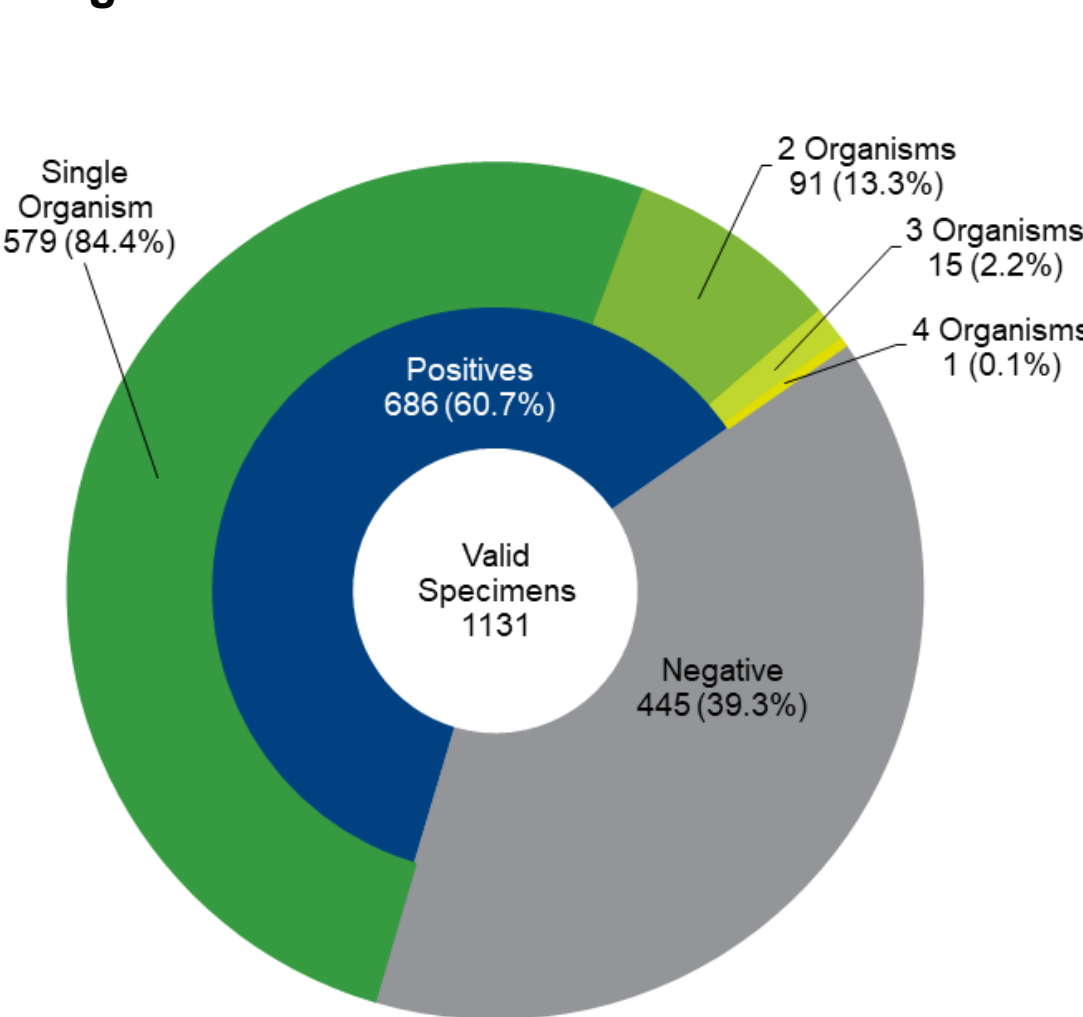


Table 4. Prevalence of Organisms in Co-Detections as Determined by the SPOTFIRE R Panel

Organism	Prevalence in Co-Detections (107 NPS specimens)	
Viruses		
Adenovirus	39	36.4%
Coronavirus SARS-CoV-2 (COVID-19)	11	10.3%
Coronavirus (Seasonal)	37	34.6%
Human Metapneumovirus	1	0.9%
Human Rhinovirus/Enterovirus	83	77.6%
Influenza A Virus	0	0%
Influenza A Subtype H1-2009	0	0%
Influenza A Subtype H3	0	0%
Influenza B Virus	0	0%
Parainfluenza Virus	44	41.1%
Respiratory Syncytial Virus	16	15.0%
Bacteria		
<i>Bordetella parapertussis</i>	0	0%
<i>Bordetella pertussis</i>	0	0%
<i>Chlamydia pneumoniae</i>	0	0%
<i>Mycoplasma pneumoniae</i>	0	0%

Table 5. SPOTFIRE R Panel Performance

SpotFire R Panel Organism	Prospective				Archived			
	TP/ (TP + FN)	%	TN/ (TN + FP)	%	TP/ (TP + FN)	%	TN/ (TN + FP)	%
Viruses								
Adenovirus	32/34	94.1	1068/1092	97.8	29/29	100	439/452	97.1
Coronavirus SARS-CoV-2 (COVID-19)	71/73	97.3	1042/1048	99.4	0/0	-	0/0	-
Coronavirus (Seasonal)	102/103	99.0	1010/1023	98.7	89/89	100	380/387	98.2
Human Metapneumovirus	1/1	100	1125/1125	100	29/30	96.7	448/448	100
Human Rhinovirus/Enterovirus	348/351	99.1	703/775	90.7	0/0	-	0/0	-
Influenza A Virus	0/0	-	1126/1126	100	58/59	98.3	421/421	100
Influenza A Subtype H1-2009	0/0	-	1126/1126	100	31/32	96.9	450/450	100
Influenza A Subtype H3	0/0	-	1126/1126	100	27/27	100	453/453	100
Influenza B Virus	0/0	-	1121/1121	100	30/30	100	28/28	100
Parainfluenza Virus	100/102	98.0	1013/1024	98.9	113/114	99.1	358/359	99.7
Respiratory Syncytial Virus	26/27	96.3	1097/1099	99.8	29/29	100	439/446	98.4
Bacteria								
<i>Bordetella parapertussis</i>	0/0	-	1121/1121	100	24/25	96.0	31/31	100
<i>Bordetella pertussis</i>	0/0	-	1126/1126	100	27/28	96.4	437/438	99.8
<i>Chlamydia pneumoniae</i>	0/0	-	1126/1126	100	30/30	100	452/452	100
<i>Mycoplasma pneumoniae</i>	0/0	-	1126/1126	100	29/29	100	445/446	99.8
Overall	680/691	98.4	14930/15058	99.1	545/551	98.9	4781/4811	99.3

Figure 3. Discrepancy Investigation Results

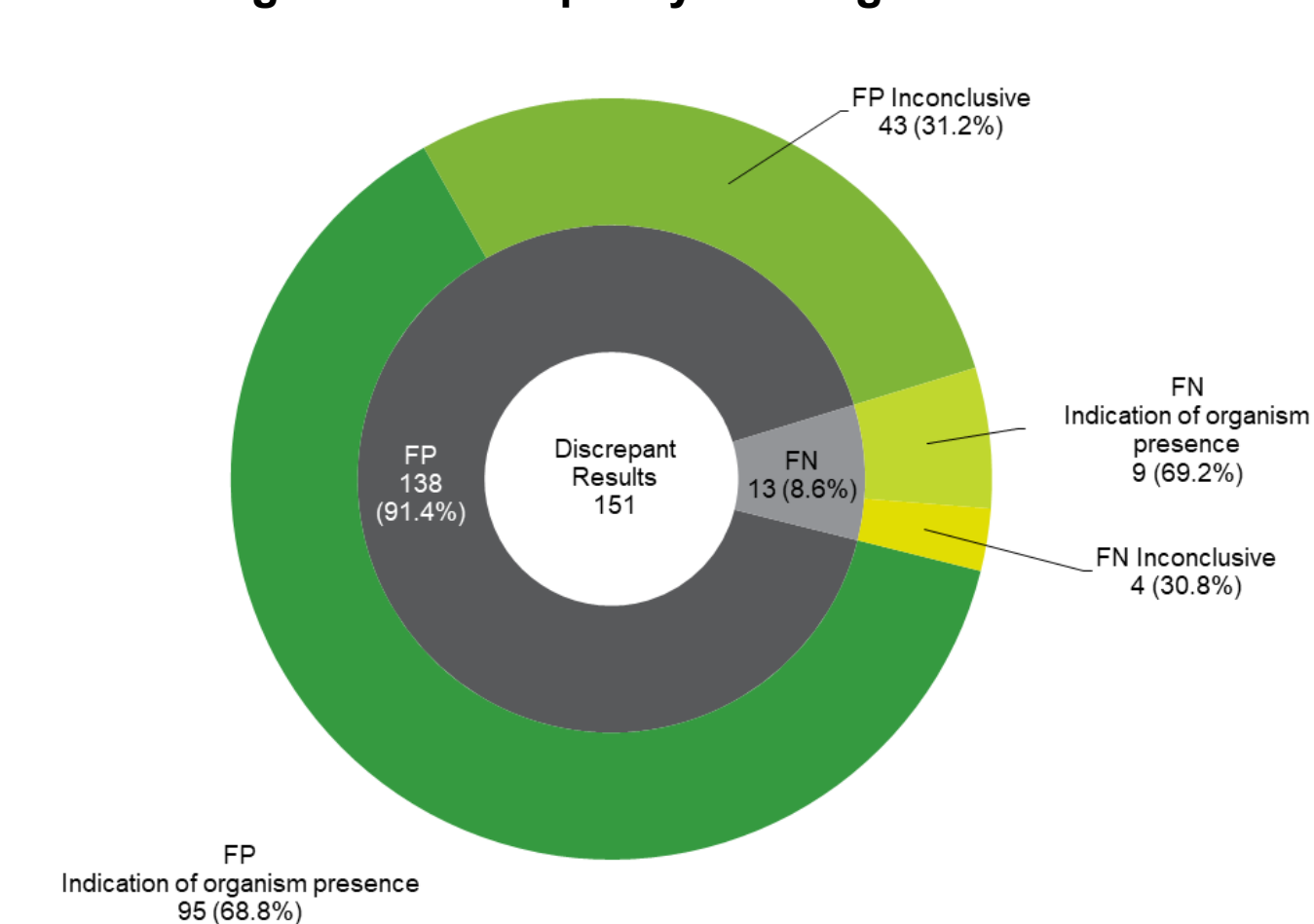


Table 6. SPOTFIRE R Panel Internal Pouch Control Performance

Total Completed Initial Tests	Total Tests with Pouch Controls Passed	Total Tests with Pouch Controls Failed	Both PCR2 and RNA Process Controls Failed	Only PCR2 Control Failed	Only RNA Process Control Failed
1201	1169	32	9	0	23
	97.3%	2.7%	0.7%	0%	1.9%