



# Perceived Ease-of-Use and Operator Performance of a Rapid Multiplex PCR Diagnostic System in a Near-Patient Setting

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## BACKGROUND

Access to multiplex molecular diagnostic tests for the rapid and accurate diagnosis of respiratory tract infections is limited in the near-patient setting, but has potential to improve patient outcomes and antibiotic stewardship. The BIOFIRE® SPOTFIRE® Respiratory (R) Panel (bioMérieux, Salt Lake City, UT), designed for use with the BIOFIRE® SPOTFIRE® System, is an Investigational Use Only (IUO) PCR-based sample-to-answer diagnostic test that identifies four bacteria and 11 viruses from nasopharyngeal swabs (NPS) in ~15 minutes. This study evaluated the ease-of-use and operator performance of the IUO SPOTFIRE® R Panel in the near-patient setting.

## METHODS

A total of 35 test operators representative of the intended users in the near-patient setting (i.e., non-laboratory professionals) participated in three studies: archived, precision (reproducibility) and prospective. Upon study completion, anonymous questionnaires were administered to assess operators' perceived ease-of-use of the BIOFIRE® SPOTFIRE® System, SPOTFIRE® R Panel testing, and training materials; the accuracy of results interpretations were also evaluated. Further, results obtained by operators in the near-patient setting and trained laboratory personnel were evaluated for reproducibility.

Figure 1. SPOTFIRE® R Panel Study Overview

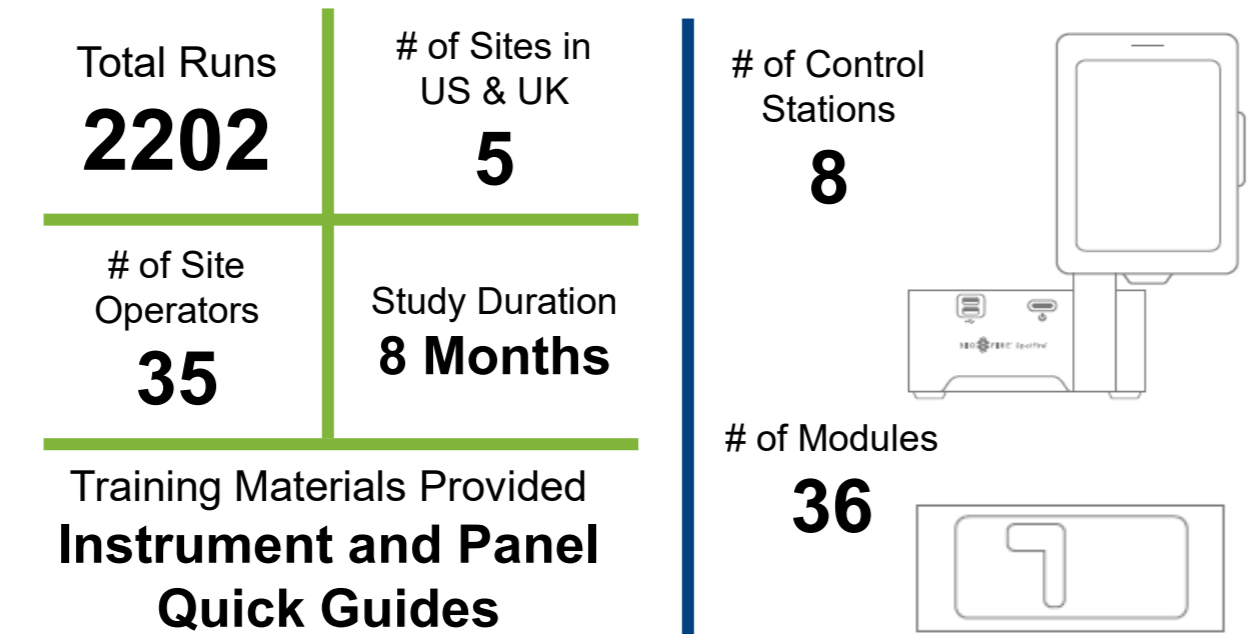
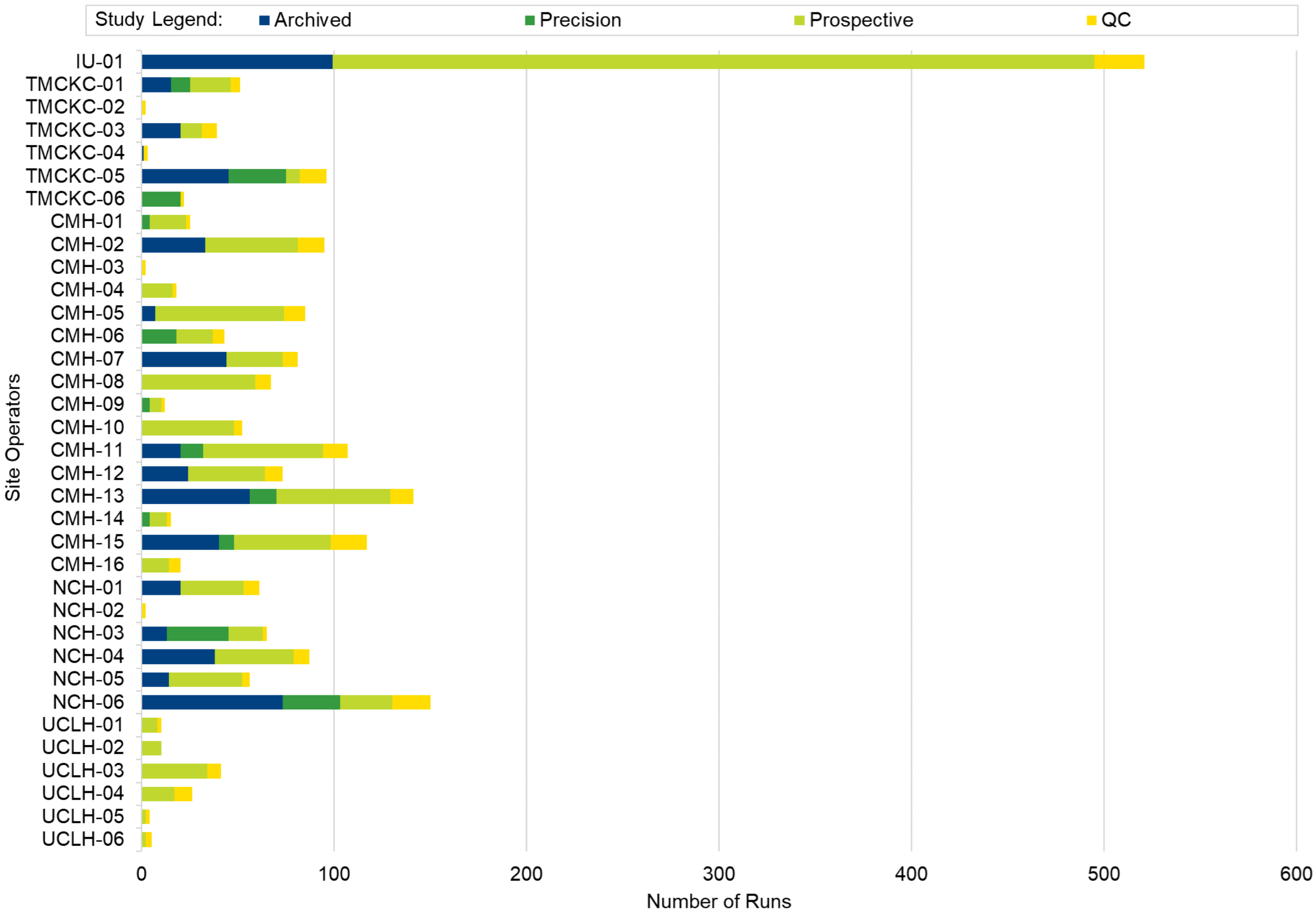


Figure 2. Operator Analysis of run by each study



## RESULTS AND DISCUSSION

Table 1. Summary of Archived and Prospective initial runs attempted by operators in near-patient setting

Number of Tests Attempted	Number of Valid Tests on Initial Attempt	Number of Invalid Tests on Initial Attempt <sup>a</sup>	Incomplete Tests / Instrument Errors	Internal Process Control Failures
1771	1719 97.1% <sup>b</sup>	52 2.9%	14 0.8%	38 2.1%

<sup>a</sup> Retests were not possible due to insufficient specimen volume  
<sup>b</sup> Trained Operators in the precision studies (data not shown) had similar success rates

Table 2. Performance Summary by Study for NPS Specimens across all near-patient setting

Site	# of Operators	Study	# of Valid Runs	Sensitivity/PPA		Specificity/NPA	
				TP/(TP + FN)	%	TN/(TN + FP)	%
Site 01 (IU)	1	Prospective	361	118/120	98.3%	6716/6739	99.7%
		Archived	97	83/83	100.0%	1311/1318	99.5%
		<b>Overall</b>	<b>458</b>	<b>201/203</b>	<b>99.0%</b>	<b>8027/8057</b>	<b>99.6%</b>
Site 02 (TMCKC)	6	Prospective	36	17/17	100.0%	663/667	99.4%
		Archived	80	73/74	98.6%	930/931	99.9%
		Precision	60	240/240	100.0%	900/900	100.0%
<b>Overall</b>	<b>176</b>	<b>330/331</b>	<b>99.7%</b>	<b>2493/2498</b>	<b>99.8%</b>		
Site 03 (CMH)	16	Prospective	511	395/403	98.0%	9157/9231	99.2%
		Archived	210	191/192	99.5%	2710/2725	99.4%
		Precision	60	237/240	98.8%	900/900	100.0%
<b>Overall</b>	<b>781</b>	<b>823/835</b>	<b>98.6%</b>	<b>12767/12856</b>	<b>99.3%</b>		
Site 04 (NCH)	6	Prospective	154	124/126	98.4%	2775/2800	99.1%
		Archived	155	138/141	97.9%	1820/1830	99.5%
		Precision	60	237/240	98.8%	900/900	100.0%
<b>Overall</b>	<b>369</b>	<b>499/507</b>	<b>98.4%</b>	<b>5495/5530</b>	<b>99.4%</b>		
Site 05 (UCLH)	6	Prospective	69	27/27	100.0%	1246/1249	99.8%
		Archived	69	27/27	100.0%	1246/1249	99.8%
		<b>Overall</b>	<b>69</b>	<b>27/27</b>	<b>100.0%</b>	<b>1246/1249</b>	<b>99.8%</b>
<b>Trained Operators<sup>a</sup></b>	<b>9</b>	<b>Precision</b>	<b>272</b>	<b>1080/1092</b>	<b>98.9%</b>	<b>4076/4076</b>	<b>100.0%</b>

<sup>a</sup> Operators were located at bioMérieux in Salt Lake City, UT and only contributed to the precision study

Table 3. Evaluation of Scope and Utility of Training Materials reported via the Post-Study Questionnaire

Question	Response Percentage (N=26)	
	Yes	No
Read Panel Quick Guide prior to running first test	26 (100%)	0 (0%)
Referred back to Panel Quick Guide during preparation of first test	26 (100%)	0 (0%)
Referred back to Panel Quick Guide at any time during the study	18 (69.2%)	8 (30.8%)
Panel Quick Guide answered their question(s)	18/18 (100%)	0/18 (0%)
Important information missing from Quick Guides <sup>a</sup>	0 (0%)	25 (100%)
Required help first time using SpotFire System (after reviewing Quick Guides) <sup>b</sup>	8 (32.0%) <sup>b</sup>	17 (68.0%)

<sup>a</sup> One respondent skipped these questions (N=25)  
<sup>b</sup> Only two operators (2/25, 8.0%) stated they did not understand the instructions/process; the remaining six indicated they had referred back to the R/ST Panel Quick Guide to answer their questions

Figure 3. Ease-of-use of the SPOTFIRE® R Panel using BIOFIRE® SPOTFIRE® System reported via the Post-Study Questionnaire (n=25)

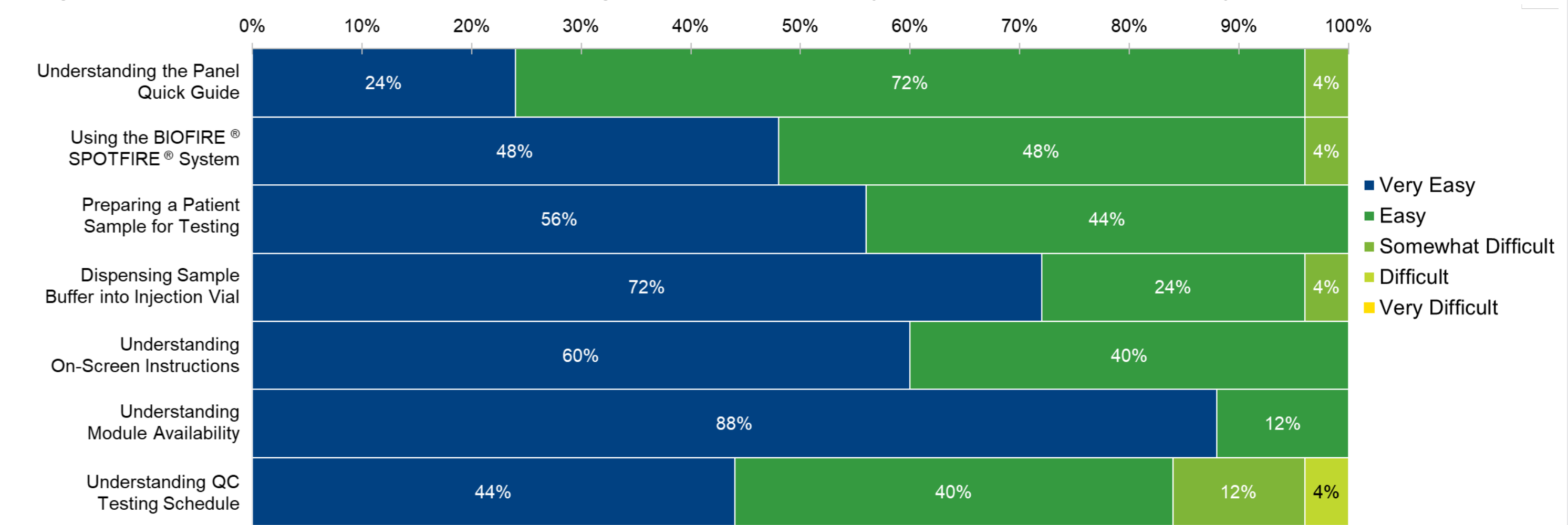
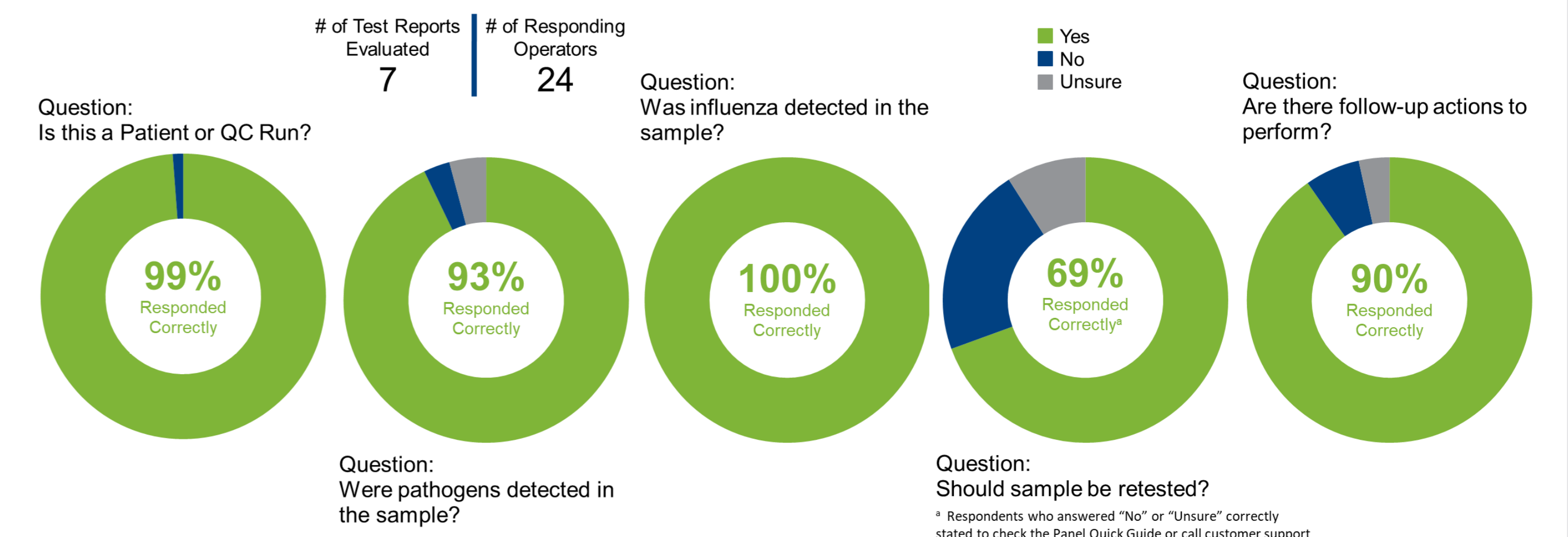


Figure 4. Evaluation of ease-of-use of the SPOTFIRE® R Panel Reports as reported via the Post-Study Questionnaire



## CONCLUSIONS

- About **97%** of operators reported the **system and panel** were **easy to use** and the provided **training materials** were **sufficient** to allow the user to perform the testing.
- The success rate of obtaining **valid** results on the initial test was **97%**, similar to the rates observed for **trained** laboratory personnel.
- **Reproducibility** between **site operators** and **trained laboratory personnel** demonstrated an overall **positive percent agreement of 99%**.
- The ability of operators to obtain accurate results indicates the BIOFIRE® SPOTFIRE® System is an **easy to use system** that can be installed and operated in a near-patient setting with **minimal training**.
- Operator questionnaires indicate the SPOTFIRE® R Panel is easy to use with **minimal risk** for operator / user error.
- Implementation of this new system may aid in **timely diagnosis** and **appropriate management** of respiratory infections.

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.