## RESPIRATORY VIRUS MULTIPLEX FORMULATIONS DESICCATED ON COPAN'S FLOQSWAB® FOR USE AS CROSS-PLATFORM COMPATIBLE EQA SAMPLES AND LABORATORY QUALITY CONTROLS

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### INTRODUCTION



## **RESULTS CONTINUED**

#### B. Product: VP-S-15-M1

Manufacturer Assay	Λεεργ	Target Analytes			
	Adv	hMPV	PIV2	PIV3	
BIO FIRE BY BIOMÉRIEUX	BioFire® Respiratory Panel 2.1	+	+	+	+
Seegene	Allplex <sup>™</sup> Respiratory Panel 2	+	+	+	+

Molecular syndromic assays that simultaneously detect and differentiate common respiratory viruses are becoming widely used diagnostic tools during the COVID-19 pandemic. To support the growing use of syndromic assays, external respiratory virus multiplex panels are needed for reliable assay verification/validation, personnel training, laboratory quality control, and External Quality Assessment (EQA) programs. Small multiplex formulations with 3 to 4 mixed analytes provide laboratories with economical solutions for evaluating assay cross-reactivity and performance; therefore, the objective of this study was to assess the performance of Microbix Biosystems Inc.'s novel respiratory virus multiplex panel using common assays in the IVD industry.

## **MATERIALS & METHODS**

Microbix Biosystems Inc. formulated whole-genome respiratory virus multiplex samples that are desiccated on Copan's FLOQSwab® (Table 1). These products are inactivated, whole-workflow samples that are analogous to human patient specimens. Sample performance was evaluated in Original Equipment Manufacturer (OEM) and clinical laboratories in order to demonstrate product usability in: (1) verifying the performance of respiratory viral syndromic molecular assays, and (2) evaluating laboratory workflows, from swab elution in transport medium to reporting test results.

Table 3: Sample performance using a variety of molecular assays Adv= Adenovirus; hMPV= Human Metapneumovirus; PIV2= Parainfluenza Virus 2; PIV3= Parainfluenza Virus 3

### C. Product: VP-S-20-M1

Manufacturer	Assay	Target Analytes			
		S-CoV	HEV	HRV	
BIO FIRE BY BIOMÉRIEUX	BioFire® Respiratory Panel 2.1	+	-	F	
Seegene	Allplex <sup>™</sup> Respiratory Panel 2 & Allplex <sup>™</sup> Respiratory Panel 3	+	+	+	

Table 4: Sample performance using a variety of molecular assays S-CoV= Seasonal Coronavirus; HEV= Human Enterovirus; HRV= Human Rhinovirus

### 2. Clinical Laboratory Testing – RED-S-19-M1

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**Methodology:** Elute SARS-CoV-2 /FluA&B/RSV Positive Swab in 2mL of Bioer molecular transport media. Subsequently, 10ul and 250ul of this solution were used to prepare the contrived specimens used for testing (Bioer molecular transport media, 2mL per tube).



FluA/B, RSV cut-off

SARS-CoV-2 cut-off

M2S

RŠV

M2S cut-off

• 10ul

250ul

Target pathogens	<b>RED FLOQ</b> ®	<b>PROCEED</b> FLOQ
SARS-CoV-2/Influenza A&B/Respiratory Syncytial Virus Positive	RED-S-19-M1	VP-S-19-M1
Adenovirus/Human Metapneumovirus/ Parainfluenza Virus 2&3 Positive		VP-S-15-M1
Seasonal Coronavirus OC43/ Enterovirus/Rhinovirus Positive		VP-S-20-M1

Table 1: Respiratory Virus Multiplex Samples used in the Study

### RESULTS

**1. Respiratory Syndromic Assays Performance** 

A. Products: RED-S-19-M1 and VP-S-19-M1

Manufacturer	Assay	Target Analytes			
		SARS	FluA	FluB	RSV
BIO FIRE <sup>®</sup> BY BIOMÉRIEUX	BioFire® Respiratory Panel 2.1	+	+	+	+
Seegene	Allplex™ SARS-CoV-2/FluA/FluB/RSV	+	+	+	+
<b>QUIDE</b> L	Savanna™ RVP4	+	+	+	+
Cepheid.	Xpert® Xpress CoV-2/Flu/RSV plus	+	+	+	+
ThermoFisher SCIENTIFIC	TaqMan™ SARS-CoV2 FluA/B RSV Assay	+	+		+
	TaqPath™ COVID-19, FluA, FluB Combo Kit	+	+	+	NA
OSANG HEALTHCARE	GeneFinder™ COVID-19/Flu A&B RealAmp Kit	+	+	+	NA



Figure 1: Clinical Laboratory Testing of RED-S-19-M1 Using 3 Molecular Assays

### CONCLUSION

Microbix Biosystems Inc. successfully designed whole-workflow respiratory virus multiplex samples that are formulated on Copan's FLOQSwab®. The samples performed on multiple OEM platforms and clinical laboratory set ups, demonstrating their potential use as cross-platform compatible quality controls, verification panels, and EQA samples.

Table 2: Sample performance using a variety of molecular assays SARS= Severe acute respiratory syndrome coronavirus 2; FluA= Influenza A; FluB = Influenza B; RSV= Respiratory Syncytial Virus

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