

## PRODUCT INFORMATION

Product SKU	RPPOS
Product Name	RP Positive Run Control
Lot Number	645100070
Date of Expiration	2024-02-29
Base Matrix	Stabilizing Matrix
Preservative	ProClin® 300
Fill Volume	0.3 mL
Storage Temperature	-20°C or Below
Regulatory Status	CE-IVD
Testing Platform	BioFire FilmArray (RP2.1 <i>plus</i> )

This is an unassayed control and does not have assigned analyte values. The end user is responsible for determining the value of the control. This quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols.

TESTING DATA

Lot Number	Product Description	Analyte	Target Concentration	Testing Results (Analyte detection rate ≥ 90%)	Quantity
64510070	RP Positive Run Control	Adenovirus	500,000 cp/mL	Pass	6 Vials
		Bordetella parapertussis	5,000 cp/mL	Pass	
		Bordetella pertussis	500,000 cp/mL	Pass	
		Chlamydomphila pneumoniae	1,000 cp/mL	Pass	
		Coronavirus 229E	500,000 cp/mL	Pass	
		Coronavirus HKU	20,000,000 cp/mL	Pass	
		Coronavirus NL63	2,000,000,000 cp/mL	Pass	
		Coronavirus OC43	25,000 cp/mL	Pass	
		Human metapneumovirus	20,000,000 cp/mL	Pass	
		Influenza A H1N1-09	500,000,000 cp/mL	Pass	
		Influenza A H3N2	500,000,000 cp/mL	Pass	
		Influenza B	500,000 cp/mL	Pass	
		Mycoplasma pneumoniae	1,000 cp/mL	Pass	
		Parainfluenza 1	50,000 cp/mL	Pass	
		Parainfluenza 2	5,000 cp/mL	Pass	
		Parainfluenza 3	5,000 cp/mL	Pass	
		Parainfluenza 4a	500,000 cp/mL	Pass	
		Rhinovirus 1A	500,000 cp/mL	Pass	
		RSV A	10,000 cp/mL	Pass	
		Influenza A H1N1	100,000 cp/mL	Pass	
RSV B	10,000 cp/mL	Pass			
MERS	50,000,000 cp/mL	Pass			
Severe Acute Respiratory Syndrome Coronavirus 2	132,000 cp/mL	Pass			

Bioburden Testing Results	
Acceptance Criteria: Less than 10 CFU/mL	Pass

APPROVAL

Quality Assurance	Date
<i>Melody Hamilton</i>	29 Sep 22