Exact Diagnostics RP Positive Run Control

Catalog Number: RPPOS

EDX RP Positive Run Control Summary	
Catalog Number	RPPOS
Analyte	Adenovirus *Bordetella parapertussis* *Bordetella pertussis* *Chlamydia pneumoniae* Coronavirus 229E Coronavirus HKU1 (RNA IVT) Coronavirus NL63 (RNA IVT) Coronavirus OC43 Human Metapneumovirus (RNA IVT) Influenza A – H1N1 Influenza A – H1N1 2009 (RNA IVT) Influenza A – H3N2 (RNA IVT) Influenza B *Mycoplasma pneumoniae* Middle Eastern Respiratory Syndrome (RNA IVT) Parainfluenza 1 Parainfluenza 2 Parainfluenza 3 Parainfluenza 4 Rhinovirus Respiratory Syncytial Virus A Respiratory Syncytial Virus B
Matrix	Synthetic Matrix
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	0.3mL
Number of Vials Per Kit	6 Vials
Number of Uses	Single Use
Shelf Life	18 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The EDX RP Positive Run Control is an external quality control, intended to be used with respiratory assays to monitor the performance of that given assay. Routine use of EDX RP Positive Run Control allows laboratories to meet their individualized quality control plans including evaluation of reagent lot changes and new shipments, monitoring of multiple identical devices, and assessment of different personnel and locations.

PRODUCT DESCRIPTION:

The EDX RP Positive Run Control contains 22 respiratory analytes. This multiplex control is a combination of whole, intact virus and bacteria, that have been heat or chemically inactivated, and synthetic RNA transcripts. The multiplex control is intended to test the entire process of a molecular assay including extraction, detection, and amplification. EDX RP Positive Run Control is internally value assigned using digital droplet PCR. EDX RP Positive Run Control is formulated in synthetic matrix which contains preservatives.

PROCEDURE:

The EDX RP Positive Run Control requires an extraction step. The control must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique.

The EDX RP Positive Run Control is an unassayed control and does not have assigned values. The control is not a substitute for the manufacturer's kit controls provided with the assay. EDX RP Positive Run Control is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Expected results utilizing EDX RP Positive Run Control must be established by the end user for their specific assay.

STORAGE AND HANDLING:

The EDX RP Positive Run Control should be stored at -20°C or below.

Thaw EDX RP Positive Run Control at room temperature and vortex briefly prior to use.

Once thawed, EDX RP Positive Run Control must be used immediately. Any remaining materials must be disposed of after one use. Do not reuse. Do not dilute.

Do not use EDX RP Positive Run Control beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

Manufactured By: Exact Diagnostics LLC, 3400 Camp Bowie Blvd. CBH-214, Fort Worth, Texas 76107
For assistance and reordering, contact customerservice@exactdiagnostics.com or **817.989.9262**
www.exactdiagnostics.com

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WARNINGS AND PRECAUTIONS:

The EDX RP Positive Run Control contains heat inactivated virus and bacteria but should be considered biohazardous. Universal precautions and proper disposal should be practiced[1]. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution. Dispose of all materials and liquids used in the procedure as if they contained pathogenic agents.

PERFORMANCE CHARACTERISTICS:

The data provided for EDX Positive Run Control when tested on the BioFire® FilmArray® Respiratory Panel (RP), BioFire® FilmArray® Respiratory Panel 2 (RP2), and BioFire® FilmArray® Respiratory Panel 2 *plus* (RP2*plus*) is for informational use only. Expected results must be established by the end user for the assay system used. Results may vary depending on instrumentation, reagents, operators, and systematic or random errors.

BioFire® FilmArray® Respiratory Panel Results

	RP	RP2	RP2*plus*
Viruses			
Adenovirus	Detected	Detected	Detected
Coronavirus 229E	Detected	Detected	Detected
Coronavirus HKU1	Detected	Detected	Detected
Coronavirus NL63	Detected	Detected	Detected
Coronavirus OC43	Detected	Detected	Detected
Human metapneumovirus	Detected	Detected	Detected
Human Rhinovirus/Enterovirus	Detected	Detected	Detected
Influenza A – H1 2009	Detected	Detected	Detected
Influenza A – H3	Detected	Detected	Detected
Influenza B	Detected	Detected	Detected
Middle East Respiratory Syndrome Coronavirus	N/A	N/A	Detected
Parainfluenza 1	Detected	Detected	Detected
Parainfluenza 2	Detected	Detected	Detected
Parainfluenza 3	Detected	Detected	Detected
Parainfluenza 4	Detected	Detected	Detected
Respiratory Syncytial Virus	Detected	Detected	Detected
Bacteria			
Bordetella parapertussis	N/A	Detected	Detected
Bordetella pertussis	Detected	Detected	Detected
Chlamydophila pneumoniae	Detected	Detected	Detected
Mycoplasma pneumoniae	Detected	Detected	Detected

REFERENCES:

[1] Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

SYMBOL REFERENCES:

Catalog Number

Lot Number

For In Vitro Diagnostic Use


Biological Risks


Expiration Date


Upper Limit of Temperature


Manufacturer

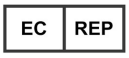

Caution


Consult Instructions for Use

Positive Control


European Mark of Conformity

Authorized Representative



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