Exact Diagnostics Respiratory Run Control

Catalog Number: RPRC

EDX Respiratory Run Control	
Catalog Number	RPRC
Analyte	Inactivated Adenovirus Inactivated *Bordetella pertussis* Inactivated *Bordetella parapertussis* Inactivated *Chlamydophila pneumoniae* Inactivated Coronavirus 229E Inactivated Coronavirus OC43 Inactivated Enterovirus Inactivated Influenza A – H1 Inactivated Influenza A – H1 2009 Inactivated Influenza A – H3 Inactivated Influenza B Inactivated *Mycoplasma pneumoniae* Inactivated Parainfluenza 1 Inactivated Parainfluenza 2 Inactivated Parainfluenza 3 Inactivated Parainfluenza 4 Inactivated RSV A Inactivated RSV B Inactivated Rhinovirus
Matrix	Stabilizing Matrix
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	0.3mL
Configuration	Mix 1: 2 vials Mix 2: 2 vials Mix 3: 2 vials Mix 4: 2 vials
Number of Uses	Single Use
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

EDX Respiratory Run Controls are external quality controls, intended to be used with respiratory assays to monitor the performance of that given assay. The control materials are whole, intact viruses and bacteria allowing operators to test the entire process of a molecular assay, train operators and test for proficiency.

PRODUCT DESCRIPTION:

EDX Respiratory Run Controls are whole, intact viruses and bacteria that have been heat inactivated. The control is intended to test the entire process of a variety of molecular assays including extraction, detection, and amplification.

EDX Respiratory Run Control is value assigned using digital droplet PCR.

PROCEDURE:

EDX Respiratory Run Controls are whole, intact viruses and bacteria and should be treated similarly as all other samples going through an extraction step, allowing the operator to assess their extraction technique. EDX Respiratory Run Controls are unassayed controls. These controls must not be used as a substitute for the manufacturer's kit controls provided with the assay. Operators should test the EDX Respiratory Run Controls according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

EDX Respiratory Run Controls should be stored at -20°C or below.

Thaw material at room temperature and vortex briefly prior to use. Any remaining materials must be disposed of. Do not refreeze. Do not dilute.

LIMITATIONS:

For In Vitro Diagnostic Use.

EXPECTED RESULTS:

EDX Respiratory Run Controls are unassayed controls. EDX Respiratory Run Controls have been designed to produce reactive results on respiratory commercial test kits for the manufacturers' assays listed in Table 1-4. The expected results utilizing EDX Respiratory Run Control must be established by the end user for the specific assay.

WARNINGS AND PRECAUTIONS:

EDX Respiratory Run Controls contain heat inactivated viruses and bacteria, but should be considered biohazardous and 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.

Manufactured By: Exact Diagnostics LLC, 3400 Camp Bowie Blvd. CBH-214, Fort Worth, Texas 76107
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TABLE 1: Respiratory Mix 1

Analyte	Luminex VERIGENE® Respiratory Pathogens Flex Test	BioFire FILMARRAY® Respiratory Panel	Roche cobas® Influenza A/B and RSV Assay
Influenza A-H1	Detected	Detected	Influenza A Detected
Influenza A-H3	Detected	Detected	Influenza A Detected
Influenza B	Detected	Detected	Influenza B Detected
RSV A	Detected	RSV Detected	RSV Detected
Coronavirus 229E	N/A	Detected	N/A

TABLE 2: Respiratory Mix 2

Analyte	Luminex VERIGENE® Respiratory Pathogens Flex Test	BioFire FILMARRAY® Respiratory Panel	Roche cobas® Influenza A/B and RSV Assay
Rhinovirus	Detected	Rhinovirus/ Enterovirus Detected	N/A
Adenovirus	Detected	Detected	N/A
Enterovirus	N/A	Rhinovirus/ Enterovirus Detected	N/A
Bordetella parapertussis	Detected	N/A	N/A

TABLE 3: Respiratory Mix 3

Analyte	Luminex VERIGENE® Respiratory Pathogens Flex Test	BioFire FILMARRAY® Respiratory Panel	Roche cobas® Influenza A/B and RSV Assay
Parainfluenza 1	Detected	Detected	N/A
Parainfluenza 2	Detected	Detected	N/A
Parainfluenza 3	Detected	Detected	N/A
Parainfluenza 4	Detected	Detected	N/A
Coronavirus OC43	N/A	Detected	N/A

TABLE 4: Respiratory Mix 4

Analyte	Luminex VERIGENE® Respiratory Pathogens Flex Test	BioFire FILMARRAY® Respiratory Panel	Roche cobas® Influenza A/B and RSV Assay
Bordetella pertussis	Detected	Detected	N/A
Chlamydophila pneumoniae	N/A	Detected	N/A
Mycoplasma pneumoniae	N/A	Detected	N/A
Influenza A H1-2009	Influenza A H1 Detected	Detected	Influenza A Detected
RSV B	Detected	RSV Detected	RSV 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

Positive Control

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