Exact Diagnostics Respiratory Run Control

Catalog Number: RPRC

EDX Respiratory Run Control Summary	
Catalog Number	RPRC
Analyte	Inactivated Adenovirus Inactivated *Bordetella pertussis* Inactivated *Bordetella parapertussis* Inactivated *Chlamydophila pneumoniae* Inactivated Coronavirus 229E Coronavirus OC43 (RNA IVT) Inactivated Enterovirus Inactivated Influenza A – H1 Inactivated Influenza A – H1 2009 Influenza A – H3N2 (RNA IVT) 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	Synthetic CSF Matrix
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	0.3mL
Number of Vials Per Kit	Mix 1: 2 Vials Mix 2: 2 Vials Mix 3: 2 Vials Mix 4: 2 Vials
Number of Uses	Single Use
Shelf Life	12 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The EDX Respiratory 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 Respiratory Run Control allows laboratories to evaluate the day-to-day and lot-to-lot variation of their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX Respiratory Run Control contains whole, intact virus and bacteria that has been heat inactivated and synthetic RNA transcripts. The control is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX Respiratory Run Control is value assigned using digital droplet PCR. EDX Respiratory Run Control is formulated in Stabilizing Matrix, which contains preservatives.

PROCEDURE:

The EDX Respiratory 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 Respiratory 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 Respiratory Run Control has been designed to produce reactive results on respiratory commercial test kits for the manufacturers' assays listed in Tables 1-4. EDX Respiratory Run Control is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Expected results utilizing EDX Respiratory Run Control must be established by the end user for their specific assay.

STORAGE AND HANDLING:

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

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

Once thawed, EDX Respiratory Run Control is stable for 24 hours when stored at 2-8°C. Any remaining materials must be disposed of after one use. Do not reuse. Do not dilute.

Do not use EDX Respiratory 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 Respiratory Run Control contains heat inactivated virus and bacteria but should be considered biohazardous. Universal precautions and proper disposal should be practiced[2]. 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.

REFERENCES:

[2] 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

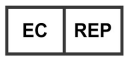

Manufacturer


Caution

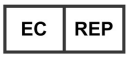

Consult Instructions for Use

Positive Control


European Mark of Conformity



Authorized Representative



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United States

TABLE 1: Respiratory Mix 1

Analyte	Luminex VERIGENE® Respiratory Pathogens Flex Test
Influenza A-H1	Detected
Influenza A-H3	Detected
Influenza B	Detected
RSV A	Detected
Coronavirus 229E	N/A

TABLE 2: Respiratory Mix 2

Analyte	Luminex VERIGENE® Respiratory Pathogens Flex Test
Rhinovirus	Detected
Adenovirus	Detected
Enterovirus	N/A
Bordetella parapertussis	Detected

TABLE 3: Respiratory Mix 3

Analyte	Luminex VERIGENE® Respiratory Pathogens Flex Test
Parainfluenza 1	Detected
Parainfluenza 2	Detected
Parainfluenza 3	Detected
Parainfluenza 4	Detected
Coronavirus OC43	N/A

TABLE 4: Respiratory Mix 4

Analyte	Luminex VERIGENE® Respiratory Pathogens Flex Test
Bordetella pertussis	Detected
Chlamydophila pneumoniae	N/A
Mycoplasma pneumoniae	N/A
Influenza A H1-2009	Influenza A H1 Detected
RSV B	Detected