

EDX RP Negative Run Control Summary	
Catalog Number	RPNEG
Nonreactive Analytes	Adenovirus <i>Bordetella parapertussis</i> <i>Bordetella pertussis</i> <i>Chlamydia pneumoniae</i> 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 <i>Mycoplasma pneumoniae</i> 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 Negative 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 Negative 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 Negative Run Control is negative for 22 respiratory analytes. The EDX RP Negative Run Control is formulated in synthetic matrix which contains preservatives.

PROCEDURE:

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

STORAGE AND HANDLING:

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

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

Once thawed, EDX RP Negative 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 RP Negative Run Control beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX RP Negative Run Control should be considered biohazardous. Universal precautions and proper disposal should be practiced¹. 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:

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



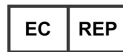
Negative Control



European Mark of Conformity



Authorized Representative



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