



## eplex RP3 Control M530

### INTENDED USE:

The eplex RP3 Control M530 is intended for use as an external positive and negative assayed quality control to monitor the performance of the cobas® eplex respiratory pathogen (RP3) panel 3 on the cobas eplex system. The cobas eplex RP3 panel qualitatively detects the following viral and bacterial targets: adenovirus, enterovirus/rhinovirus, human bocavirus, human coronavirus (229E, HKU1, NL63, and OC43), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), human metapneumovirus, human parainfluenza virus 1, human parainfluenza virus 2, human parainfluenza virus 3, human parainfluenza virus 4, influenza A virus, influenza A virus H1, influenza A virus H1-2009, influenza A virus H3, influenza B virus, respiratory syncytial virus A (RSV A), respiratory syncytial virus B (RSV B), *Bordetella parapertussis*, *Bordetella pertussis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, and *Mycoplasma pneumoniae*. The eplex RP3 Control M530 contains synthetic DNA and RNA transcripts in stabilizing solution, buffers, and preservatives. The eplex RP3 Control M530 is designed for and intended for use with the cobas eplex RP3 panel. This product is not intended to replace manufacturer internal controls provided with the cobas eplex RP3 panel.

### PRODUCT SUMMARY and PRINCIPLE:

The eplex RP3 Control M530 is composed of 3 controls, eplex RP3 Positive A, eplex RP3 Positive B, and eplex RP3 Negative. The eplex RP3 Positive controls contain surrogate control material composed of synthetic DNA and RNA corresponding to genome segments of the pathogens listed in Table 1. The eplex RP3 Negative does not contain nucleic acid and serves as a true negative control to monitor contamination.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Quality controls that are consistent from lot to lot assist the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents, malfunctioning equipment, or environmental contamination. Early investigation can prevent failed assay runs and incorrect patient test results.

### COMPOSITION:

The eplex RP3 Control M530 is comprised of 12 single use tubes, 4 tubes of eplex RP3 Positive A, 4 tubes of eplex RP3 Positive B, and 4 tubes of eplex RP3 Negative, 200µL each. The eplex RP3 Positive controls are composed of synthetic DNA and RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Table 1 lists the pathogens that are detected in the eplex RP3 Control M530 when tested by the cobas eplex RP3 panel on the cobas eplex system. The eplex RP3 Negative control only contains buffer and preservatives.

### STORAGE and STABILITY:

The eplex RP3 Control M530 will be shipped on dry ice or cold packs depending on destination. Place at refrigerated temperature (2°C to 8°C) upon receipt. Unopened eplex RP3 Control M530 is stable through the expiration date printed on the kit label when consistently stored refrigerated (2°C to 8°C). The eplex RP3 Control M530 is for single use. Discard after use according to your local and federal regulations.

### PRECAUTIONS, WARNINGS, and LIMITATIONS:

- Use the control as provided. Do not dilute.
- This product is intended for *in vitro* analytical testing and is provided for Research Use only, not for use in diagnostic procedures.
- This product is for use solely with cobas eplex RP3 panel on the cobas eplex system. It does not contain the entire genome of pathogens listed in Table 1.
- Appearance: Positive controls are cloudy. Negative control is clear.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.
- eplex RP3 Control M530 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

### INSTRUCTIONS FOR USE:

*Note: See cobas eplex system User Assistance manual (Roche) for instructions to define the controls.*

1. Allow the control to come completely to room temperature (18°C to 25°C), approximately 15 minutes if stored at 2°C to 8°C, or 30 minutes if frozen due to dry ice shipping.
2. Use the control as provided. **DO NOT DILUTE.**
3. Immediately before use, **thoroughly mix** the control by flicking the tube several times, followed by vortexing for 3-5 seconds. Shake the tube down or tap it on the bench to remove any droplets remaining in the cap.
4. Use a calibrated pipette to aspirate 200µL of control and dispense into the sample inlet of the cobas eplex RP3 panel cartridge.
5. Continue to process and analyze the control with the cobas eplex RP3 panel on the cobas eplex system, following manufacturer's instructions for processing an external control.
6. Discard after use according to your local and federal regulations.

For complete cobas eplex RP3 panel instructions, refer to the appropriate instructions provided by Roche Diagnostics.

### EXPECTED VALUES:

The expected results when the controls are tested with the cobas eplex RP3 panel on the cobas eplex system are listed in Table 1.

**Table 1. Expected Results:**

Control Name:	eplex RP3 Positive A	eplex RP3 Positive B	eplex RP3 Negative
<b>Viral Analytes</b>			
Adenovirus	✓ Detected	Not detected	Not detected
Enterovirus/rhinovirus†	✓ Detected	✓ Detected	Not detected
Human bocavirus	✓ Detected	Not detected	Not detected
Human coronavirus 229E	Not detected	✓ Detected	Not detected
Human coronavirus HKU1	✓ Detected	Not detected	Not detected
Human coronavirus NL63	✓ Detected	Not detected	Not detected
Human coronavirus OC43	Not detected	✓ Detected	Not detected
SARS-CoV-2	Not detected	✓ Detected	Not detected
Human metapneumovirus	✓ Detected	Not detected	Not detected
Human parainfluenza virus 1	Not detected	✓ Detected	Not detected
Human parainfluenza virus 2	✓ Detected	Not detected	Not detected
Human parainfluenza virus 3	Not detected	✓ Detected	Not detected
Human parainfluenza virus 4	✓ Detected	Not detected	Not detected
Influenza A virus	✓ Detected	✓ Detected	Not detected
Influenza A virus H1	Not detected	✓ Detected	Not detected
Influenza A virus H1-2009	✓ Detected	Not detected	Not detected
Influenza A virus H3	✓ Detected	Not detected	Not detected
Influenza B virus	Not detected	✓ Detected	Not detected
RSV A	✓ Detected	Not detected	Not detected
RSV B	✓ Detected	Not detected	Not detected
<b>Bacterial Analytes</b>			
<i>Bordetella parapertussis</i>	Not detected	✓ Detected	Not detected
<i>Bordetella pertussis</i>	✓ Detected	Not detected	Not detected
<i>Chlamydia pneumoniae</i>	✓ Detected	Not detected	Not detected
<i>Legionella pneumophila</i>	✓ Detected	Not detected	Not detected
<i>Mycoplasma pneumoniae</i>	Not detected	✓ Detected	Not detected

†Enterovirus is detected in eplex RP3 Positive A, and Rhinovirus is detected in eplex RP3 Positive B.

### ORDERING INFORMATION:

eplex RP3 Control M530

**Part Number: M530-R**

Kit Contains: 12 tubes x 200 µL

4 each of eplex RP3 Positive A, Positive B, and Negative.

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