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infection caused by an organism not detected by the panel. Test results may be affected by concurrent antibacterial or antiviral therapy or levels of bacteria or virus in the sample that are below the limit of detection for the test. A result of No Targets Detected on the ePlex RP2 Panel should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

- A result of No Targets Detected on the **cobas eplex** RP2 panel in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test or lower respiratory tract infection that is not detected by a nasopharyngeal swab sample.
- There is a risk of false positive results due to contamination of the sample with target organisms, their nucleic acids, or amplicons. Particular attention should be given to the Laboratory precautions noted under the *Warnings and Precautions* section.
- There is a risk of false positive results due to non-specific amplification and cross-reactivity with organisms found in the respiratory tract. Erroneous results due to cross-reactivity with organisms that were not specifically evaluated or new variant sequences that emerge are possible.
- If four or more organisms are detected in a sample, retesting is recommended to confirm polymicrobial result.
- The **cobas eplex** RP2 panel influenza A subtyping reagents target the influenza A hemagglutinin gene only. The **cobas eplex** RP2 panel does not detect or differentiate the influenza A neuraminidase gene.
- The performance of this test has not been established for monitoring treatment of infection with any of the panel organisms.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods when prevalence is moderate to low.
- Clinical performance was established when influenza A H3 and influenza A H1-2009 were the predominant influenza A viruses in circulation. When other influenza A viruses emerge, performance may vary.
- Due to the small number of positive samples collected for *Chlamydia pneumoniae* during the prospective and retrospective clinical studies, performance characteristics for *Chlamydia pneumoniae* were established primarily with contrived clinical specimens. Performance characteristics for Influenza A H1 were established using contrived clinical specimens only.
- Clinical evaluation indicates a lower sensitivity for the detection of coronavirus OC43. If infection with coronavirus OC43 is suspected, negative samples should be confirmed using an alternative method.
- The effect of interfering substances has only been evaluated for those listed in this package insert. Interference due to substances other than those described in the “Interfering Substances” section can lead to erroneous results.
- At concentrations greater than 1% weight/volume in the sample, tobramycin was found to inhibit assay performance.
- Minimum Essential Media (MEM) may be inhibitory and negatively impact the performance of the **cobas eplex** RP2 panel.
- Diluents from external quality controls or proficiency testing materials that include the following substances have been shown to interfere with the performance of the **cobas eplex** RP2 panel: human plasma proteins and 941 L media with methanol.
- The performance of this test has not been specifically evaluated for specimens collected from individuals who recently received influenza vaccine. Recent administration of a live intranasal influenza virus vaccine may cause false positive results for influenza A, H1, H3, H1-2009, and/or influenza B.
- The **cobas eplex** RP2 panel cannot differentiate variant viruses, such as H3N2v, from seasonal influenza A viruses. If variant virus infection is suspected, clinicians should contact their state or local health department to arrange specimen transport and request a timely diagnosis at a state public health laboratory.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the

Target	Site	Agreement with expected negative results Agreed / N	Agreement with expected negative results %	Agreement with expected negative results 95% CI
Mycoplasma pneumoniae	All	321/323	99.4	(97.8-99.8)

Samples with co-detected organisms

Co-detection of SARS-CoV-2 with other organisms

Detection of SARS-CoV-2 in the presence of another clinically relevant organism was evaluated using a natural clinical matrix (pooled, negative nasopharyngeal swab samples) spiked with SARS-CoV-2 and a second organism co-amplified in the same PCR reaction. In this study, SARS-CoV-2 was tested at a low concentration (3x LoD) in combination with the second organism at a high concentration (1×10^3 - 1×10^6 $TCID_{50}$/mL). SARS-CoV-2 was also tested at a high concentration (2.5×10^6 copies/mL) in combination with the second organism at low concentration (3x LoD). **Table 65** contains the results of co-detection testing which demonstrated that there is no competitive inhibition when SARS-CoV-2 is co-amplified at low concentrations in the presence of the indicated organisms at high concentrations or when SARS-CoV-2 at high concentration is co-amplified with the indicated organism at low concentration.

Table 65: Detection of co-detections

Organism 1	High titer	Organism 2	Multiple of LoD	% positive of organism 2
SARS-CoV-2	2.5×10^6 copies/mL	Influenza A H1-2009	3x	100%
SARS-CoV-2	2.5×10^6 copies/mL	Adenovirus	3x	100%
SARS-CoV-2	2.5×10^6 copies /mL	Influenza B	3x	100%
Influenza A H1-2009	1×10^3 $TCID_{50}$/mL	SARS-CoV-2	3x	100%
Adenovirus	1×10^6 $TCID_{50}$/mL	SARS-CoV-2	3x	100%
Influenza B	1×10^3 $TCID_{50}$/mL	SARS-CoV-2	3x	100%

Samples with co-detected organisms on the cobas eplex RP2 panel

Detection of more than one clinically relevant viral organism in a sample was evaluated with the **cobas eplex** RP panel using a natural clinical matrix (pooled, negative nasopharyngeal swab samples) spiked with two RP panel organisms: one organism at a low concentration (1-3x LoD) and the second organism at a high concentration (1×10^5 $TCID_{50}$/mL). **Table 66** contains the results of co-detection testing which demonstrated the ability of the **cobas eplex** RP panel to detect 2 organisms in a sample at both high and low concentrations as indicated in the table.

Table 66: Detection of co-detections

Organism 1	High titer	Organism 2	Low titer	Multiple of LoD
Influenza A H3	1×10^5 $TCID_{50}$/mL	Adenovirus B	2×10^0 $TCID_{50}$/mL	1x
Adenovirus	1×10^5 $TCID_{50}$/mL	Influenza A H3	5×10^1 $TCID_{50}$/mL	1x
Influenza A H3	1×10^5 $TCID_{50}$/mL	RSV A	1.5×10^0 $TCID_{50}$/mL	1x
RSV A	1×10^5 $TCID_{50}$/mL	Influenza A H3	5×10^1 $TCID_{50}$/mL	1x
Influenza A H1-2009	1×10^5 $TCID_{50}$/mL	RSV B	6×10^{-1} $TCID_{50}$/mL	3x
RSV B	1×10^5 $TCID_{50}$/mL	Influenza A H1-2009	$1x\ 10^{-1}$ $TCID_{50}$/mL	1x

Technical Support

GenMark Technical support is available 24 hours a day, 7 days a week to provide the highest level of customer support and satisfaction.

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GLOSSARY OF SYMBOLS

Symbol	Description	Symbol	Description
	Batch code		Catalog number
	Caution		Biological risks
	Contains sufficient for <n> tests		Upper limit of temperature
	Consult instructions for use		Lower limit of temperature
	Manufacturer		Temperature range
	Cartridge lot		Irritant, dermal sensitizer, acute toxicity (harmful), narcotic effects, respiratory tract irritation
	Use by date YYYY-MM-DD		Oxidizers
	Serial number		For Use Under the Emergency Use Authorization Only

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