

Ezplex® Bacterial Pneumonia Real-time PCR Kit

MFDS* approved for *in vitro* diagnostic use.

Comprehensive Panel

Identifies 6 pneumonia-causing bacteria in a single kit.

Sensitivity

Detection of all targeted bacteria with high sensitivity.

Specificity

Specific for targeted bacteria without the risk of cross reactivity with other potentially cross reactive microorganisms.

Reproducibility

CVs of less than 5%.

Convenience

Genetree Viewer analysis software available for users to conveniently produce test results.

Stability

Shelf life of up to 12 months.

The Ezplex® Bacteria Pneumonia Real-time PCR Kit is an *in vitro* diagnostic test intended for the qualitative detection of nucleic acids from 6 types of bacteria isolated and extracted from nasopharyngeal swabs.

Pneumonia-causing bacteria
<i>Bordetella pertussis, Mycoplasma pneumoniae</i>
<i>Haemophilus Influenzae, Legionella pneumophila</i>
<i>Chlamydomphila pneumoniae, Streptococcus pneumoniae</i>

Workflow



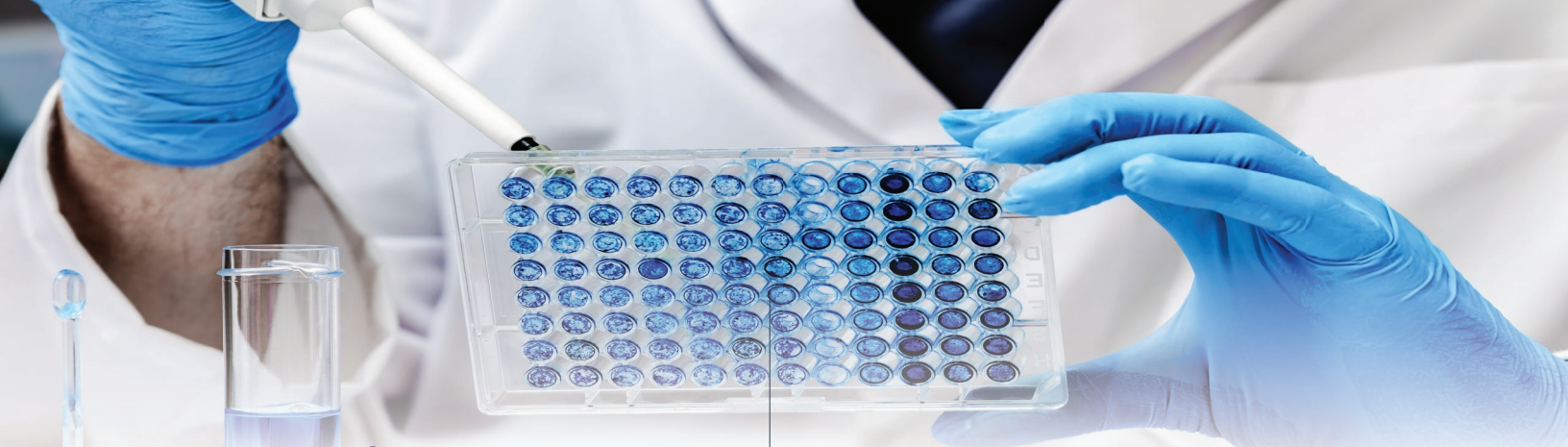
Compatible Devices and Extraction Methods

CFX96 Dx Real-time PCR Instrument
QIAamp® DSP Virus Spin Kit

Analytical Sensitivity

Repeated tests with serial dilutions of reference material showed high analytical sensitivity for the Ezplex® Bacterial Pneumonia Real-time PCR Kit.

Target	Limit of Detection(copies/uL)
Pneumonia-causing bacteria	0.925 - 92.847



Analytical Specificity

Testing of 31 species of microorganisms with the Ezplex® Bacterial Pneumonia Real-time PCR Kit showed no cross reactivity.

Microorganisms
<i>Candida glabrata</i> , <i>Candida tropicalis</i> , <i>Clostridium difficile</i> , <i>Corynebacterium amycolatum</i> , <i>Corynebacterium diphtheriae</i> , <i>Corynebacterium glutamicum</i> , <i>Enterococcus faecalis</i> , <i>Enterococcus faecium</i> , <i>Escherichia coli</i> , <i>Klebsiella oxytoca</i> , <i>Klebsiella pneumoniae subsp pneumoniae</i> , <i>Lactobacillus crispatus</i> , <i>Lactobacillus gallinarum</i> , <i>Lactobacillus vaginalis</i> , <i>Nocardia sp.</i> , <i>Peptostreptococcus anaerobius</i> , <i>Prevotella bivia</i> , <i>Prevotella disiens</i> , <i>Proteus mirabilis</i> , <i>Proteus vulgaris</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Streptococcus anginosus subsp anginosus</i> , <i>Streptococcus constellatus subsp constellatus</i> , <i>Streptococcus gordonii</i> , <i>Streptococcus mutans</i> , <i>Streptococcus oralis</i> , <i>Streptococcus parasanguinis</i> , <i>Streptococcus salivarius</i> , <i>Streptococcus sanguinis</i> , <i>Veillonella parvula</i>

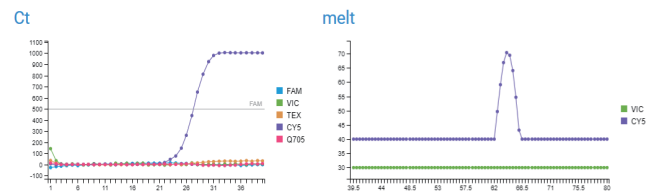
Clinical Performance

Results from testing left-over, archived nasopharyngeal swab specimens that had been previously tested with another approved product showed that positive agreement was 93.1 to 100% and negative agreement was 100%.

Genetree Viewer Analysis Software

Test results can be analyzed easily using the dedicated software.

1) Example amplification curves



2) Example Software Analysis Result

Well	Row	Col	Content	MP	SP	HI	BP	CP	LP	Q795 (Ct)	MP	SP	HI	BP	CP	LP	Q795 (Ct)	CYS	
B01	A	01	Unkn	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Invalid
B01	B	01	Unkn	N/A	N/A	N/A	N/A	N/A	N/A	81.56	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Valid
C01	C	01	Unkn	N/A	N/A	21.56	N/A	N/A	N/A	39.62	N/A	N/A	Pos	N/A	N/A	N/A	N/A	N/A	Valid
D01	D	01	Unkn	N/A	N/A	22.16	N/A	N/A	N/A	N/A	N/A	N/A	Pos	N/A	N/A	N/A	N/A	N/A	Valid
E01	E	01	Unkn	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Invalid
F01	F	01	Unkn	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Invalid
G01	G	01	Unkn	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Invalid
H01	H	01	Unkn	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Invalid
A02	A	02	Unkn	N/A	N/A	24.26	N/A	N/A	N/A	N/A	N/A	N/A	Pos	N/A	N/A	N/A	N/A	N/A	Valid
B02	B	02	Unkn	22.39	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Pos	N/A	N/A	N/A	N/A	N/A	N/A	Valid
C02	C	02	Unkn	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Invalid
D02	D	02	Unkn	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Invalid
E02	E	02	Unkn	N/A	N/A	24.24	N/A	N/A	N/A	N/A	N/A	N/A	Pos	N/A	N/A	N/A	N/A	N/A	Valid
F02	F	02	Unkn	N/A	N/A	32.99	N/A	N/A	N/A	N/A	N/A	N/A	MP	N/A	N/A	N/A	N/A	N/A	HI(w)
G02	G	02	Unkn	N/A	N/A	30.22	N/A	N/A	N/A	N/A	N/A	N/A	Pos	N/A	N/A	N/A	N/A	N/A	Valid
H02	H	02	Unkn	N/A	N/A	21.60	N/A	N/A	N/A	N/A	N/A	N/A	Pos	N/A	N/A	N/A	N/A	N/A	Valid
A03	A	03	Unkn	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Invalid
B03	B	03	Unkn	N/A	N/A	N/A	N/A	N/A	N/A	33.21	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Valid

Stability

Shelf life of 12 months at -20°C (-4°F) unopened and 6 months after opening.

Ordering information

100 Tests. Catalog Number: GNT-2008-1

Genetree Viewer Software. Catalog Number: GNT-2008-3

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