

S. pneumoniae + *Legionella* detection kit

CerTest
BIOTEC

Pathogen and product description

Gram positive bacteria *Streptococcus pneumoniae* is one of the most important pathogen that affects mainly children and elderly and can cause life-threatening diseases. *Streptococcus pneumoniae* infection leads to many clinical manifestations including meningitis, septicaemia, bacteraemia, pneumonia, acute otitis media and sinusitis. Pneumococcal infection annually has caused approximately 14.5 million cases of invasive pneumococcal disease (IPD) and 0.7-1 million deaths in children under five years old, mostly in developing and underdeveloped countries.

Legionnaires' Disease is caused by *Legionella pneumophila* and is characterized as an acute febrile respiratory illness ranging in severity from mild illness to fatal pneumonia. The resulting mortality rate, ranging from 25 to 40% can be lowered if the disease is diagnosed rapidly and appropriate

antimicrobial therapy is instituted early. Known risk factors include immunosuppression, cigarette smoking, alcohol consumption and concomitant pulmonary disease. *Legionella pneumophila* is responsible for 80-90% of reported cases of *Legionella* infection with serogroup 1 accounting for greater than 70% of all legionellosis.

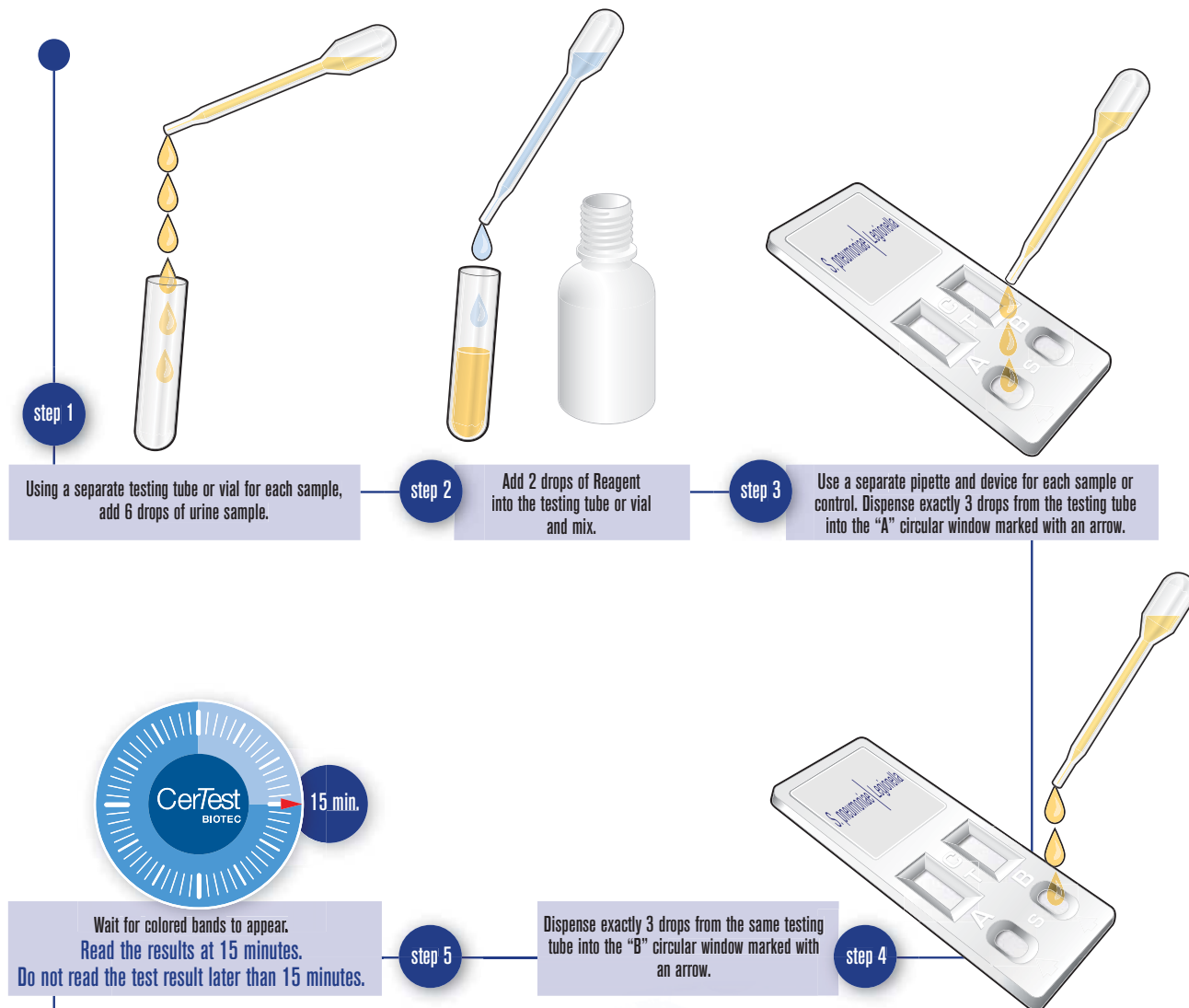
CerTest *Streptococcus pneumoniae* + *Legionella* one step card test offers a simple and highly sensitive assay to make a presumptive diagnosis of pneumoniae and/or *Legionella* caused by *Streptococcus pneumoniae* and/or *Legionella pneumophila* in infected humans from urine samples.



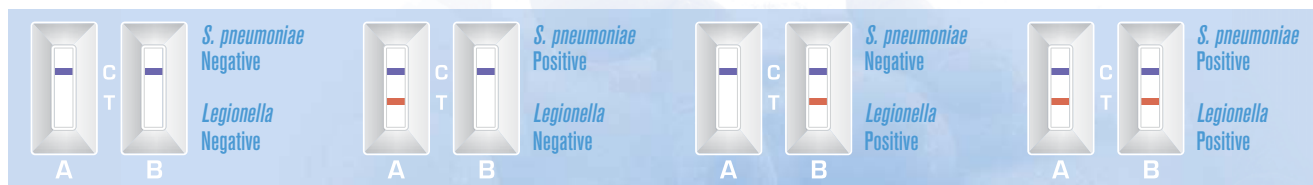
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Test procedure



Interpretation of results



ANY OTHER RESULT: INVALID

Clinical Sensitivity and Specificity

	Sensitivity	Specificity	PPV	NPV
CerTest S. pneumoniae + Legionella (S. pneumoniae strip) vs. Binax NOW® Streptococcus pneumoniae Antigen Card	89.2% (C.I. 74.6 – 97%)	98.6% (C.I. 92.7 – 100%)	97.1% (C.I. 84.7 – 99.9%)	94.8% (C.I. 87.2 – 98.6%)
CerTest S. pneumoniae + Legionella (Legionella strip) vs. Binax NOW® Legionella Urinary Antigen Card	100% (C.I. 88.8 – 100%)	99.2% (C.I. 95.4 – 100%)	96.9% (C.I. 83.8 – 99.9%)	100% (C.I. 96.9 – 100%)



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