

Legionella pneumophila detection kit

CerTest
BIOTEC



Pathology and product description

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 disease occurs in both epidemic and endemic forms. 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. The young and the elderly are particularly susceptible.

Legionella pneumophila is responsible for 80-90% of reported cases of *Legionella* infection with serogroup 1 accounting for greater than 70% of all legionellosis.

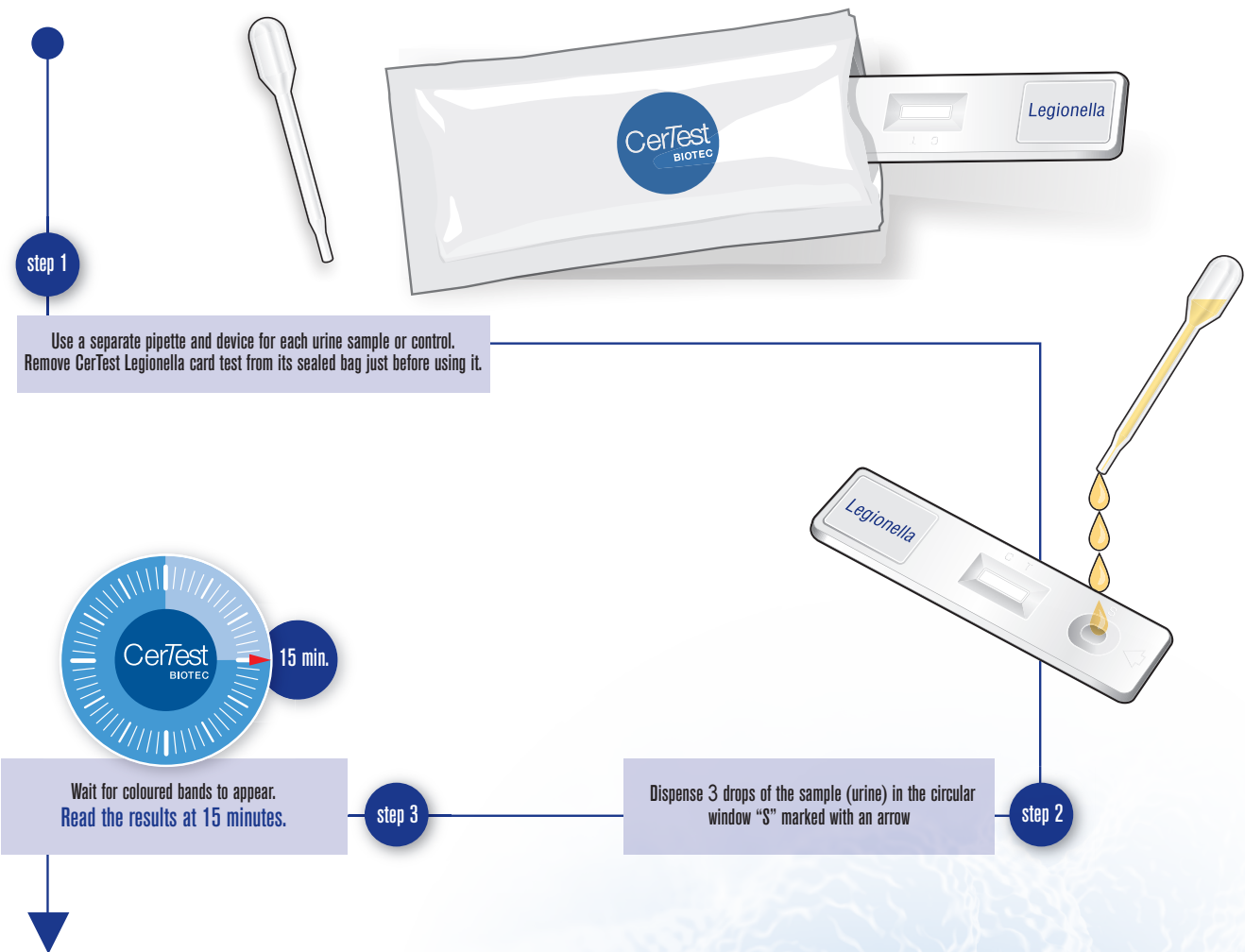
The CerTest *Legionella* allows for early diagnosis of *Legionella pneumophila* serogroup 1 infection through detection of a specific soluble antigen present in the urine of patients with Legionnaires' Disease.



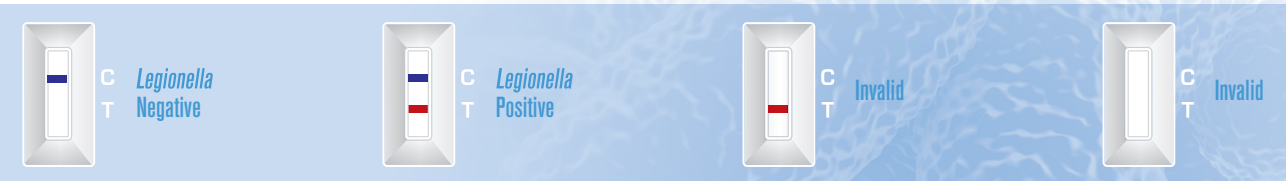
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Test procedure



Interpretation of the results



External Positive and Negative Controls are included in the kit

The use of positive and negative controls is recommended to assure functionality of reagents and proper performance of assay procedure.

Clinical Sensitivity and Specificity

	Sensitivity	Specificity	PPV	NPV
CerTest Legionella vs. Binax NOW® Legionella Urinary Antigen	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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