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Pneumocystis jirovecii Real Time PCR Detection Kit

Pathogen and product description

Pneumocystis jirovecii pneumonia (PCP) is an acute and life-threatening lung disease caused by the fungus *Pneumocystis jirovecii*. PCP is an important disease of immunocompromised humans, particularly patients with HIV, but also patients with an immune system that is severely suppressed for other reasons. In humans with a normal immune system, it is an extremely common silent infection. In developing regions of the world, the prevalence of PCP was once thought to be much lower, but studies have shown that the lower reported incidence is likely a failure to accurately diagnose.

The symptoms of PCP are nonspecific, in patients with HIV tends to present much later, often after several weeks of symptoms, compared with PCP associated with other immunocompromising conditions. Symptoms of PCP include the following: progressive exertional dyspnea, fever, non-productive cough, chest discomfort, weight loss, chills and hemoptysis (rare).

PCP is difficult to diagnose as a result of the associated nonspecific signs and symptoms. Because *P. jirovecii* cannot be propagated in culture, microscopic visualization of cysts or trophic forms in pulmonary specimens with cytochemical or immunofluorescent staining with monoclonal antibodies and/or DNA amplification are the standard procedures to detect this microorganism.

VIASURE *Pneumocystis jirovecii* Real Time PCR Detection Kit is designed for the diagnosis of *Pneumocystis jirovecii* in respiratory samples. After DNA isolation, the identification of *Pneumocystis jirovecii* is performed by the amplification of a conserved region of the large-subunit (mt LSU) rRNA gene using specific primers and a fluorescent-labelled probe.

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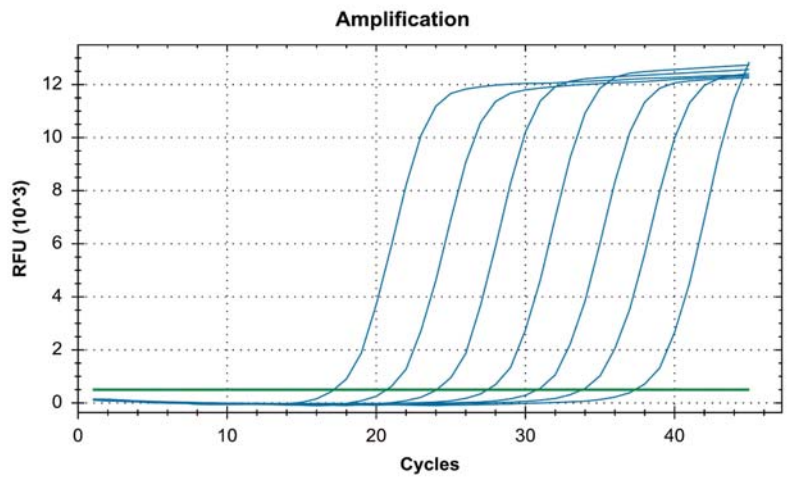
Analytical sensitivity

VIASURE *Pneumocystis jirovecii* Real Time PCR Detection Kit has a detection limit of ≥ 10 DNA copies per reaction.



Dilution series of Pneumocystis jirovecii (10^7-10^1 copies/rxn) template run on the Bio-Rad CFX96 Touch™ Real-Time PCR Detection System.

Components

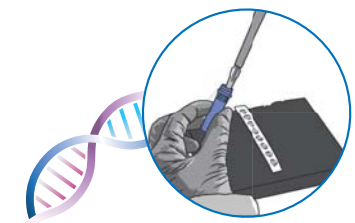
Reagent/Material	Description	Quantity
Pneumocystis jirovecii 8-well strips	A mix of enzymes, primers-probes, buffer, dNTPs, stabilizers and Internal control in stabilized format	6/12 x 8-well strip
Pneumocystis jirovecii 96-well plate	A mix of enzymes, primers-probes, buffer, dNTPs, stabilizers and Internal control in stabilized format	1 plate
Rehydration Buffer	Solution to reconstitute the stabilized product	1 vial x 1,8 mL
Pneumocystis jirovecii Positive Control	Non-infectious synthetic lyophilized cDNA	1 vial
Negative Control	Non template control	1 vial x 1 mL
Water RNAse/DNAse free	Water RNAse/DNAse free	1 vial x 1 mL
Tear-off 8-cap strips	Optical caps for sealing Wells during thermal cycling	6/12 x 8-cap strip
Shell Frame Grid	Shell Frame Grid	1 or 2

Kit References

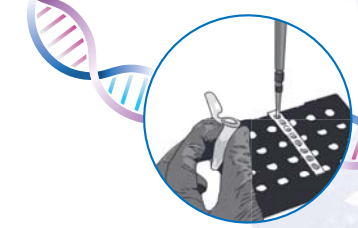
Reference	Description
VS-JIR106L	Viasure *Pneumocystis jirovecii* Real Time PCR Detection Kit 6 x 8-well strips, low profile
VS-JIR106H	Viasure *Pneumocystis jirovecii* Real Time PCR Detection Kit 6 x 8-well strips, high profile
VS-JIR112L	Viasure *Pneumocystis jirovecii* Real Time PCR Detection Kit 12 x 8-well strips, low profile
VS-JIR112H	Viasure *Pneumocystis jirovecii* Real Time PCR Detection Kit 12 x 8-well strips, high profile
VS-JIR113L	Viasure *Pneumocystis jirovecii* Real Time PCR Detection Kit 96-well plate, low profile
VS-JIR113H	Viasure *Pneumocystis jirovecii* Real Time PCR Detection Kit 96-well plate, high profile

Work Flow

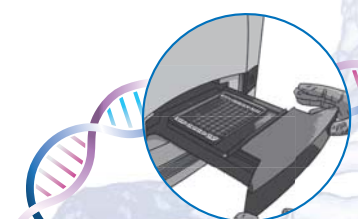
One-step rehydration of wells and add your extracted DNA



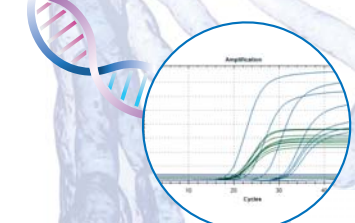
STEP 1
Add 15 µl of rehydration buffer into each well



STEP 2
Add 5 µl of DNA sample / positive control / negative control



STEP 3
Load the strips into the thermocycler and run the specified protocol



STEP 4
Interpretate results

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CSQ MED ISO 13485