A Probe-Based Real-Time qPCR Assay for Detection of Pneumocystis Pneumonia and sulfanilamide resistance gene mutations

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Backgroud

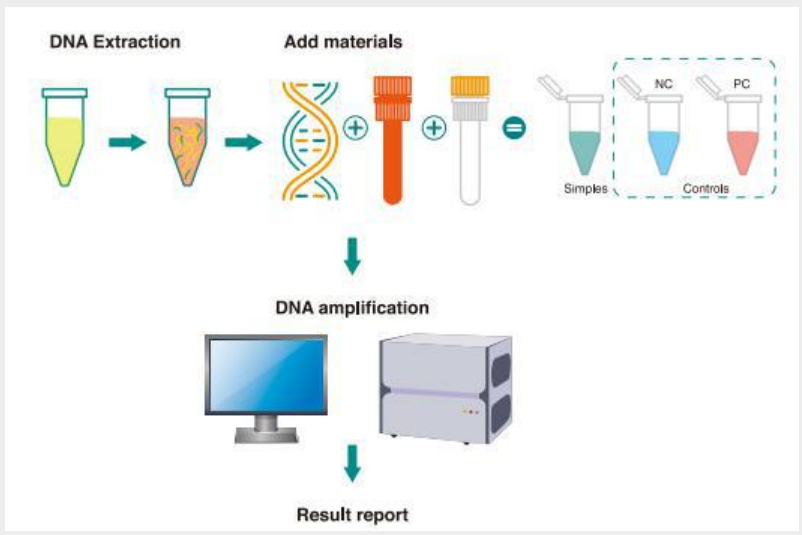
- ***Pneumocystis jirovecii*** **is an atypical opportunistic fungus with lung tropism and worldwide distribution that continues to be one of the major opportunistic pathogens causing severe Pneumocystis pneumonia (PcP) in individuals with acquired immune deficiency syndrome (AIDS) and patients with immunosuppression due to other causes.**

- **Widespread prophylaxis and treatment for *P. jirovecii* with sulfa drugs have decreased the incidence of PcP, but concerns have been raised about the possible emergence of *P. jirovecii* isolates resistant to these drugs. Point mutations in this gene have been associated with prior exposure to sulfa drugs in other microorganisms, the polymorphic positions 165 and 171, which lead to an amino acid change at positions 55 (Thr55Ala) and 57 (Pro57Ser) of the polypeptide chain, respectively.**

- **Fluorescent PCR technology can detect the nucleic acid fragments of *P. jirovecii* in patients' serum, bronchoalveolar lavage fluid (BALF) and tissue samples, and further identify drug-resistant mutations, which is of great significance for early clinical and accurate initiation of antifungal therapy. MycoMDx *Pneumocystis Jirovecii* PCR Assay is the use of PCR-fluorescence probe method, combined with other methods to achieve the auxiliary diagnosis of P. jirovecii infection and resistance to sulfonamides.**

Methods

- **In this study, we did a performance evaluation of the MycoMDx *Pneumocystis Jirovecii* PCR Assay (CE-approved), including diagnostic sensitivity and specificity, the limit of detection (LoD), precision and stability. The above PCR assay reagents were developed and produced by Dynamiker Biotechnology (Tianjin) Co., Ltd.**



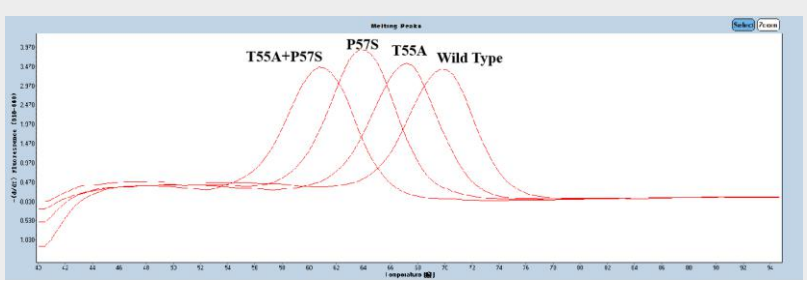


Figure 1 The product photo of MycoMDx *Pneumocystis Jiroveci* PCR Assay

Results

- **The sensitivity and specificity of the PCR assay reagents for detection *P. Jirovecii* were above 90%, the LoD was 1000 copies/mL, and the precision and stability were in accordance with the requirements (CV≤5%). The mutation sites of sulfonamides resistance genes could be accurately identified.**

Table 1 Test Results of serum Samples

Assessment reagent kit results	Clinical diagnosis results		Total
	Positive	Negative	
Positive	15（A）	7（B）	22（A+B）
Negative	0（C）	81（D）	81（C+D）
Total	15（A+C）	88（B+D）	103（A+B+C+D）

Sensitivity =A/(A+C)×100%＝100%

Specificity =D/(B+D)×100%＝92.1%

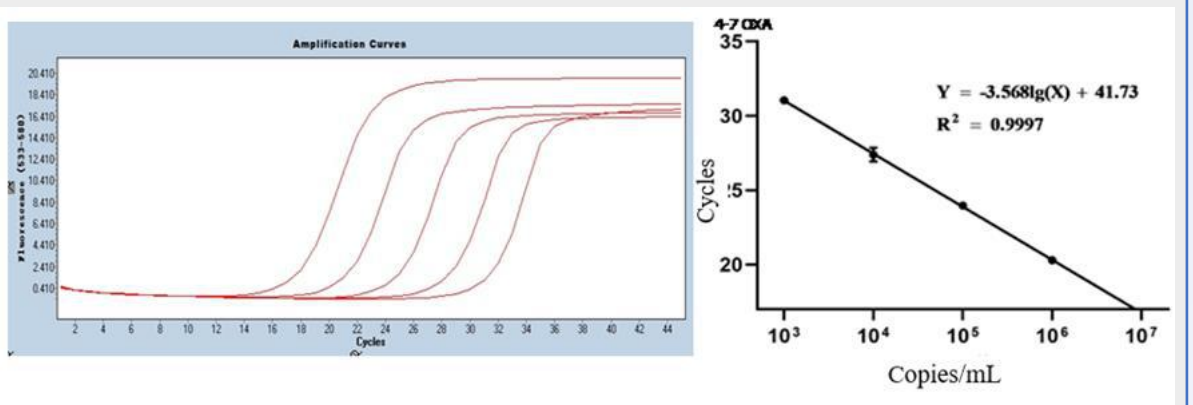


Figure 2 Amplification efficiency of the kit

Conclusions

- **The MycoMDx *Pneumocystis Jirovecii* PCR Assay has great clinical value by providing a rapid and reliable test to aid in early diagnosis.**

Reduce death due to Fungal Infection