

BakoDx Launches Terbinafine Resistance PCR Test for Onychomycosis

As terbinafine resistance incidents rise, new reflex detects 12 mutations.

By Aldo Nahed

While onychomycosis caused by dermatophytic fungi are most often treated with terbinafine, an increasing incidence of cases with terbinafine resistance mutations may be impeding treatment success.

A new terbinafine resistance assay, available only with the **BakoDx Onychodystrophy PCR Test**, can quickly detect these resistance-associated mutations, so prescribing physicians can limit ineffective medications and increase treatment efficacy. BakoDx, a diagnostic leader in dermatopathology and molecular analysis (PCR), has developed a real-time PCR assay that de-

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etects these 12 fungal mutations, and identifies terbinafine resistance in *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

Dermatophytic fungi, primarily *T. rubrum* and *T. mentagrophytes*, are the leading cause of mycotic nail infections. However, there is a global public health concern that the most common antifungal treatment, terbinafine, may become less effective due to genetic mutations found in members of the *Trichophyton* genera, which have been shown to confer resistance to this agent.

This newly-developed assay is offered as a reflex test, meaning that only specimens confirmed as *T. rubrum* or *T. mentagrophytes* by the BakoDx proprietary onychodystrophy assay will be screened for the mutations associated with terbinafine resistance.

“As all physicians involved in the treatment of patients with onychomycosis know all too well, the therapeutic difficulties and patient frustrations encountered with managing this problem are real,” said Dr. Wayne L. Bakotic, Chief Medical Officer and co-founder of BakoDx. “The emergence of terbinafine resistance has complicated the issue all the more.”

“The potential impacts of this decreased treatment efficacy include psychosocial issues such as low self-es-

teem and depression, issues secondary to ill-fitting shoe gear and with ambulation due to nail deformity. But the greatest potential impact is in those high-risk patients where complications, including secondary bacterial infections, may lead to the most adverse outcomes,” Bakotic said.

An increased incidence of onychomycosis is noted in specific populations, including immunocompromised individuals, those with diabetes, nail injuries and/or co-existing tinea pedis. The elderly population not only has a higher incidence of onychomycosis, but this incidence increases with advancing age with 50 percent of those over 70 years affected. Physicians could speculate that any group with an increased incidence of onychomycosis will also show an increase in clinical isolates demonstrating terbinafine resistance.

The emergence of terbinafine resistance is likely multifactorial. Certainly, the broad empiric use of antifungal medications without laboratory confirmation of onychomycosis, as well as the widespread use of over-the-counter antifungal agents, primarily in international markets, have resulted in this emergence. In addition, the use of combination antifungal/steroid medications have likely also played a role.

Based on the current treatment strategies employed, antifungal sensitivity testing is rarely performed and when it is, the inherent difficulties associated with routine mycologic culture makes identification of terbinafine resistant isolates exceedingly difficult. Given the fact that there is a lack of routine antifungal sensitivity testing in general, the current level of antifungal resistance is likely an underestimate. Therefore, with the increasing incidence of antifungal resistance, the current treatment algorithm standard may be insufficient in the present and evolving world.

It is recommended that cases of clinically suspected onychomycosis have laboratory confirmation prior to the initiation of treatment therapy. Due to the relatively limited options available for antifungal agents, the importance of correctly identifying the pathology as onychomycosis, as well as accurate speciation of the infectious agent, are more important than ever. In addition, when the infectious organism is confirmed to be *T. rubrum* and/or *T. mentagrophytes* complex, molecular identification of resistance associated gene mutations empowers physicians to utilize the most efficacious antifungal agent and improve treatment success, as well as patient outcomes.

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