

Onychodystrophy Laboratory Testing

Accurate Diagnosis is the Standard of Care



Actionable Results from the Leading Diagnostic Company



Onychodystrophy Testing Designed for Improved Outcomes

Laboratory testing delivers the objective information necessary to support a complete patient treatment algorithm.



HISTOPATHOLOGY

Microscopic evaluation of a specimen to determine infectious or non-infectious pathologies including traumatic, inflammatory or neoplastic processes.

Periodic Acid–Schiff (PAS)

Identifies non-degenerated fungal elements

Grocott Methenamine Silver (GMS)

Identifies degenerated fungal elements

Fontana-Masson (FM)

Identifies pigmented saprophytes and melanin pigment which may be associated with a melanocytic neoplasm



PCR

Molecular analysis of a specimen to determine if DNA of an infectious organism is present.

Onychodystrophy PCR Test

Identifies genus and species of most common fungi (dermatophytes, saprophytes, and yeasts) as well as the bacteria, *pseudomonas aeruginosa*, that cause nail dystrophy

PCR with Terbinafine Resistance Reflex

When positive for *T. rubrum* or *T. mentagrophytes*, detects mutations associated with terbinafine resistance



“Don't guess! Evidence-based decisions on treating patients with nail disease begin with the correct identification of the underlying cause of onychodystrophy. Lab confirmation of the clinical diagnosis is my standard of care.”

-Jeffrey D. Lehrman, DPM, FASPS, MAPWCA, CPC

The Clinical Need for Diagnostic Confirmation

Various nail disorders appear identical and clinical examination alone may not be adequate.

Only 50% of suspected cases of onychodystrophy are onychomycosis.¹



Laboratory testing provides definitive diagnosis for precise patient treatment.

- ✓ Comprehensive evaluation for definitive diagnosis
- ✓ Targeted therapy for effective outcomes
- ✓ Prevention of complications and disease progression
- ✓ Improved treatment time and cost
- ✓ Higher patient satisfaction

Don't prescribe oral antifungal therapy for suspected nail fungus without confirmation.

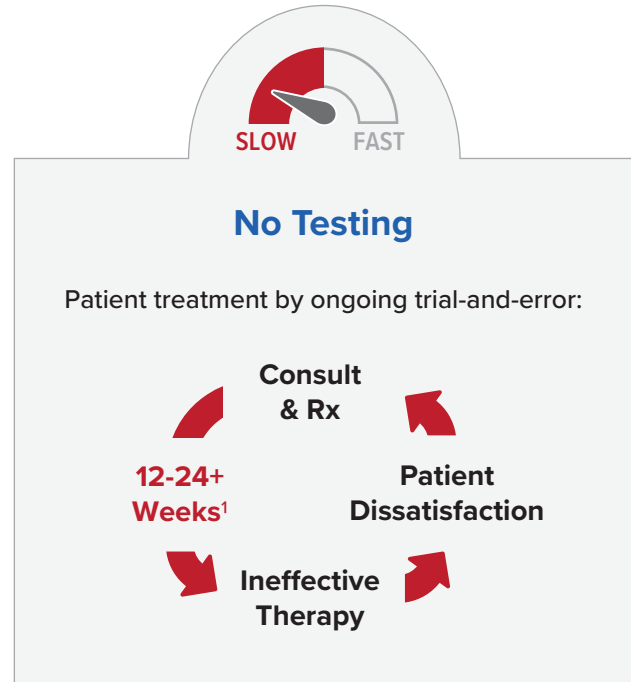
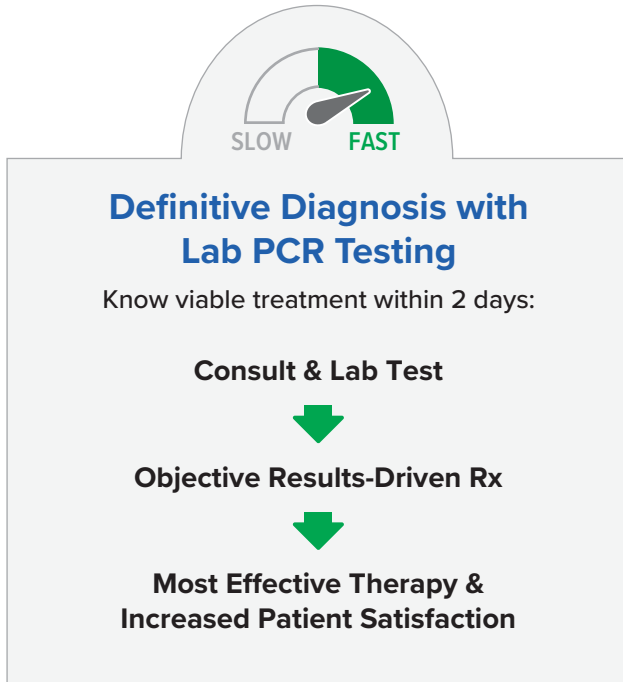
*It is important to ensure accurate diagnosis of nail disease before beginning treatment. By confirming a fungal infection, patients are not inappropriately at risk for the side effects of antifungal therapy.**

- The American Academy of Dermatology (AAD)

*<https://www.choosingwisely.org/clinician-lists/american-academy-dermatology-oral-antifungal-therapy>

¹Ghannoum, M.A., et al., "A large-scale North American study of fungal isolates from nails: The frequency of onychomycosis, fungal distribution, and antifungal susceptibility patterns", J Am Acad Dermatol 2000;43:641-8

How does BakoDx lab testing impact therapy outcomes, especially if a patient's fungus is terbinafine-resistant?



¹Sigurgeirsson B, Olafsson JH, Steinsson JB, Paul C, Billstein S, Evans EG. Long-term Effectiveness of Treatment With Terbinafine vs Itraconazole in Onychomycosis: a 5-year blinded prospective follow-up study. Arch Dermatology 2002; 138:353–357.

Save Patients Time & Rx Costs

Predict treatment efficacy like never before by using our Onychodystrophy PCR Test with Terbinafine Resistance



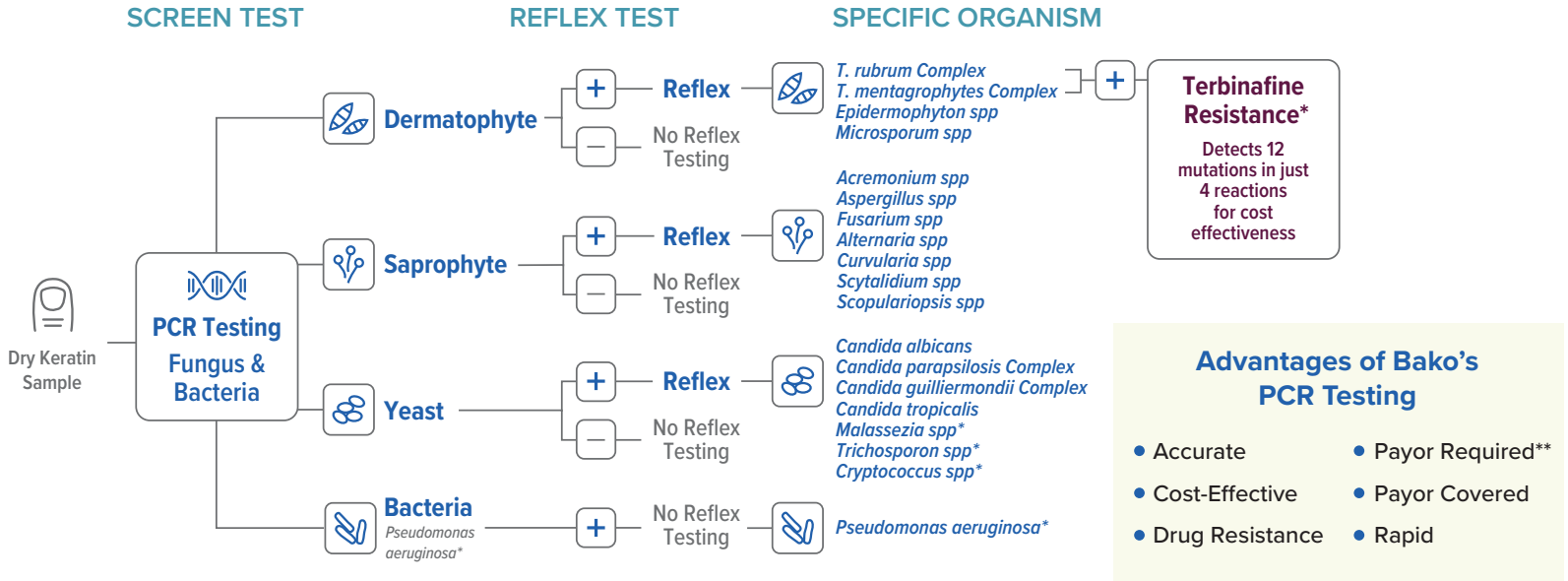
Know *before* you treat

Physicians who order the BakoDx terbinafine resistance assay understand the chances of terbinafine treatment effectiveness in 1-2 days, instead of months.

- ✓ Eliminate terbinafine “watchful waiting” period
- ✓ Avoid unnecessary medications & potential side effects
- ✓ Increase treatment efficacy & patient satisfaction

BakoDx Onychodystrophy Testing plus Terbinafine Resistance

With a proprietary algorithm, BakoDx eliminates extraneous testing and ineffective treatment







*Pending in New York.

**Many payors require precise identification of fungal species for pre-authorization of antifungal Rx.

PCR Testing: 99.9% Analytical Specificity, 86% Clinical Sensitivity¹, Clinical Sensitivity correlates with histopathology results.

¹Internal validation.

The Complete Picture with Histopathology + PCR Testing with Terbinafine Resistance

	 Fungal Culture	 Histopathology (PAS/GMS/FM)	 PCR Testing	 Histopathology + PCR Testing
GENUS & SPECIES	?	×	✓	✓
TERBINAFINE RESISTANCE	✓ LOW SENSITIVITY	×	✓ HIGH SENSITIVITY	✓
NON-INFECTIOUS NAIL DYSTROPHY	×	✓	×	✓
HIGH SENSITIVITY	×	✓	✓	✓ HIGHEST
RAPID RESULTS	×	✓	✓	✓ 1-2 DAYS

Comprehensive Nail Analysis

- Speciation for Targeted Treatment
- Terbinafine Resistance for Treatment Efficacy
- Identification of Non-Infectious and Infectious Causes
- Highest Sensitivity and Specificity Testing Available*
- Rapid Results

*When used in combination;

Bako Nail PCR Testing: 99.9% Analytical Specificity, 86% Clinical Sensitivity¹. Bako's PCR testing highly correlates with histopathology. Histopathology: 93% Clinical Sensitivity, 96% Clinical Specificity². Fungal culture: 42% False Negative Rates³, up to a 30-45 day turnaround time.

¹BakoDx internal validation.

²Velasquez-Agudelo, V., Cardona-Arias, J., "Meta-analysis of the utility of culture, biopsy, and direct KOH examination for the diagnosis of onychomycosis", BMC Infect Dis, 2017 Feb 22;17(1):166.

³Chandran, N. S., J. Y. Pan, Z. A. Pramono, H. H. Tan and C. S. Seow (2013). "Complementary role of a polymerase chain reaction test in the diagnosis of onychomycosis." Australas J Dermatol 54(2): 105-108

BakoDx is Your Trusted Lab Partner for Diagnosis and Management of Onychodystrophy

We have the knowledge and expertise to support your diagnostic needs.



Anatomic Pathology



Molecular



Microbiology

- ✓ Advanced proprietary testing for superior analytical and clinical sensitivity
- ✓ Access to board-certified dermatopathologists and podiatric advisors
- ✓ Patient and physician educational resources
- ✓ Contracted with all national and over 200 local insurance providers



Bako Diagnostics | 855-422-5628 | [BakoDx.com](https://www.BakoDx.com)

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