ENCOMPASS DIAGNOSTICS



ONYCHOMYCOSIS (Nail Fungus)

Encompass Diagnostics offers molecular PCR testing to identify nail fungus infections.



Tomorrow's Results.

Today's Peace of Mind.

NEXT DAY RESULTS FOR ALL COMMON INFECTIONS



Onychomycosis (Nail Fungus) Panel

Bacterial

Pseudomonas aeruginosa
Staphylococcus aureus

Dermatophytes

Epidermophyton floccosum
Microsporum audouinii
Microsporum canis
Microsporum gypseum
Microsporum nanum
Trichophyton interdigitale
Trichophyton mentagrophytes
Trichophyton rubrum
Trichophyton soudanense
Trichophyton tonsurans

Dimorphic Fungi

Blastomyces dermatitidis

Molds

Acremonium strictum
Alternaria spp
Aspergillus flavus
Aspergillus fumigatus
Aspergillus niger
Aspergillus terreus
Cladosporium herbarum
Curvularia lunata
Fusarium oxysporum complex
Fusarium solani complex
Neofusicoccum mangiferae
Scopulariopsis brevicaulis
Scytalidium dimidiatum

Yeasts

Candida albicans
Candida auris
Candida dubliniensis
Candida glabrata
Candida krusei
Candida lusitaniae
Candida parapsilosis
Candida tropicalis
Malassezia spp

Resistance Genes

AmpC beta-lactamase (ACT/MIR, FOX, ACC)
Class A beta-lactamase (blaSHV)
Class A beta-lactamase (CTX-M-1, CTX-M-2, CTX-M-8/25, CTX-M-9)
Class B beta-lactamase (NDM, IMP, VIM)
Class D Oxacillinase (OXA-48, OXA-51)
Extended spectrum beta-lactamases (blaTEM)
Fluoroquinolone (qnrA1/A2, qnrB, qnrS)
Macrolide, Lincosamide, Streptogramin (ermA1/A2, ermB, ermC)
Tetracycline (tetB, tetM)
Trimethoprim and Sulfonamide (dfrA1/dfrA5, sul1/sul2)

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Accession Number: xxxxxxxx
Test Number: xxxxxxxx
Date Test Performed: xx-xx-xxxx
Date Test Released: xxxxxxxx
Lab Director: xxxx xxxxxxx, xx.xxxxx

Molecular Pathology Report

ONYCHOMYCOSIS

Patient Information	Specimen Information	Facility Information
Patient Record No: xxxxx **Name:** xxxxx xxxxxx **DOB:** xx-xx-xxxx **Gender:** x **Address:** xxxxxx xxxxxxx **Phone** (xxx) xxx-xxxx	**Reference ID:** **Collection Date:** xx-xx-xxxx **Received Date :** xx-xx-xxxx **Accession Date:** xx-xx-xxxx **Specimen Type:** xxxx **Specimen Location:**	**Facility:** xxxxx **Address:** xxxxxxxx xx xxxx **Phone:** xxx xxxx xxxx **Physician Name:** xxxxx **Physician NPI:** xxxxxxxxxx

Pathogens Detected

Bacterial

No microbes detected

Dermatophytes

Target Name	Result	Microbial Load	CFU/mL Equivalence
Trichophyton rubrum	Detected	MED	10,000 - 100,000 [17.0001 - 24.9999 Ct]
Trichophyton soudaenese	Detected	MED	10,000 - 100,000 [17.0001 - 24.9999 Ct]

Molds

No microbes detected

Yeasts

Target Name	Result	Microbial Load	CFU/mL Equivalence
Malassezia spp	Detected	LOW	100 - 10,000 [25.0001 - 30.0000 Ct]
Candida tropicalis	Detected	HIGH	>100,000 [5.0000 - 16.9999 Ct]
Candida auris	Detected	HIGH	>100,000 [5.0000 - 16.9999 Ct]

Dimorphic Fungi

No microbes detected

Resistances Detected

Target Name	Result
Macrolide, Lincosamide, Streptogramin (ermA1/A2, ermB, ermC) resistance	Detected
AmpC beta-lactamase (ACT/MIR, FOX, ACC) resistance	Detected
Class A beta-lactamase (blaSHV) resistance	Detected
Class A beta-lactamase (CTX-M-1, CTX-M-2, CTX-M-8/25, CTX-M-9) resistance	Detected
Trimethoprim and Sulfonamide (dfrA1/dfrA5, sul1/sul2) resistance	Detected

ENCOMPASS DIAGNOSTICS

Therapeutic Guidance
ONYCHOMYCOSIS

RxMDx TREATMENT NAVIGATOR

Patient: XXXX XXXXXX	Accession: XXXX	Physician: XXXX XXXXX	Provider: XXXX XXXXX

This report is provided for informational purposes only and does not constitute a medical diagnosis or prescription. The Lab results and recommendations are based on and are limited to the specimen source, organisms, resistance, allergies, and ICD-10 codes. These suggestions do not take into account the patient's full medical history, physical examination findings, or other diagnostic information. All diagnostic evaluations, clinical interpretations, and treatment decisions must be made by the treating physician. The treatment options listed in this report are generated by the RxMDx Treatment Navigator software, which synthesizes data from microbiological results and recognized clinical guidelines. These options are drawn from reputable sources such as: WHO, IDSA, NLM, NIAID, CDC, NIH, ATS, FDA

Primary Oral Option(s)

Treatment	Success	Cost	Dosage
Itraconazole (Sporanox, Itracon, Lozanoc),FDA	95%	$$	200 mg, Oral 1x/day, 84 days
Terbinafine (Lamisil, Terbisil, Terbi),FDA	85%	$	250 mg, Oral 1x/day, 84 days

Alternative Oral Option(s)

Treatment	Success	Cost	Dosage
Voriconazole (Vfend, Voritek)	90%	$$$	200 mg, Oral 2x/day, 84 days,
Fluconazole (Diflucan, Afungil, Fluco)	70%	$	150 mg, Oral 0.14x/day, 168 days

Topical Adjuncts

Treatment	Success	Cost	Dosage
Efinaconazole (Jublia)	75%	$$$	Topical 1x/day, 336 days
Ciclopirox (Penlac, Batrafen)	60%	$	Topical 1x/day, 336 days

IV / Escalation Therapy

Treatment	Success	Cost	Dosage
Voriconazole, (Vfend)	90%	$$$	200 mg, IV 2x/day, 14 days

Not Recommended (Resistance-Guided Exclusions)

Treatment	Descrption
Amoxicillin-Clavulanate	Not recommended because this is an antibacterial agent and has no clinical activity against the detected fungal pathogens including Epidermophyton and Aspergillus.
Ciprofloxacin	Not recommended because fluoroquinolone antibiotics are ineffective against fungal infections such as Onychomycosis caused by Alternaria or Acremonium.

[$] - If less than 100 [$$] - 100 to 500 [$$$] - If > 500 Allergies: Not provided

ENCOMPASS DIAGNOSTICS

SPECIMEN COLLECTION METHOD
NAIL

2 Methods: Clip & Scrape

MATERIALS PROVIDED



1 Nail Collection Bag
1 specimen bag
1 molecular transport tube
1 UPS/FedEx Lab Pak mailer

COLLECTION DO'S & DON'TS

DO - Collect nails from infected areas.

DO - Rinse nail clippers with saline prior to cutting if the nail clippers are kept in cold sterile container.

DO - Wipe nail with Alcohol before sample collection.

DO - Ship the sample as soon as possible after collection. EDx stability testing shows samples as viable at room temperature for at least 21 days after collection.

DO NOT - Use any cleansing agent other than alcohol. Biocides and other non-alcohol, agents can cause inconclusive results.

DO NOT - Touch the nail samples with hands.

DO NOT - Take antibiotics. Patient must be off all antibiotics and antifungals (topicals) for 2 days prior to collection.
This is optimal. However, if not possible, the test can still be run.

Patient Information

Step 1: MARK SAMPLE
Use a permanent marker to write patient name, date of birth and sample collection date on Nail Collection Bag



Step 2: SIGN LAB REQ
Please have the patient sign the lab requisition form accepting financial responsibility. Be sure the physician has also signed the lab requisition form confirming consent.



Step 3: INSURANCE INFORMATION
Submit patient face sheet and demographics with insurance information or both sides of a patient's insurance card. If this is a prepaid test skip this step.



Clipped Nail Method

Step 1: Clean nails with alcohol wipes.



Step 2: If nail clippers are kept in cold sterile container, rinse with saline prior to cutting. Skip this step if using autoclaved clippers.



Step 3: Clip the nail as close to the discolored area as possible.



Step 4: Putthe swab into the Nail Collection Bag and seal shut.



Scrape Nail Method

Step 1 : Clean nails with alcohol wipes.



Step 2 : Use scalpel to scrape the top nail bed to collect shavings.



Step 3: Placenail shavings into the Nail Collection Bag, then seal the bag shut.



1.Place the Swab Specimen Tube or 2mL Vial into the center/sealable pocket of Biohazard Lab Bag.
2.Place folded Lab Requisition Form into the short pocket of the Lab Bag.
3.**IMPORTANT:** Place only one Sample and one Lab Requisition in each Lab Bag.
4.Peel strip off Lab Bag to expose adhesive backing and follow instructions printed on Bag to create a continuous, airtight seal.
5.Place the sealed Lab Bag into the EDx Shipping Box (shipping label already attached to bottom of box).
6.Close the EDx Shipping Box and seal with the clear sealing sticker or a piece of tape.
7.You can add multiple completed lab bags into the EDx Shipping Box.



DO NOT DISINFECT THE WOUND PRIOR TO SAMPLING UNLESS OTHERWISE NOTED

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Revision 05.05.2026