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Nail-ID Case Review

- **Patient History:**
  - Female patient
  - 59yr old
  - Prior nail infections, Chronic
  - No Family history

- **Disease State:**
  - Patient scheduled her third appointment with her provider, first round of therapy failed
  - Chief complaint was reoccurring nail infection

- **Why This Test was Ordered:**
  - New Approach was warranted, this Patient was a viable candidate due to Two failure cultures
  - C/S culture was taken twice before, both came back either A.) no significant findings or B.) took to long
  - Physician ordered Nail-ID for the first time

- **Outcome:**
  - Nail-ID report detected Two pathogens: A.) *Peptostreptococcus spp.***(Bacteria)** *10^3* & B.) *Microsporum spp.***(Fungus)** *10^2*
  - Notes from pharmacist: peptostrepococcus is considered “normal flora” at low copies/ml’ if clinical judgment determines antibiotic treatment is appropriate for skin surrounding nail – recommended options are listed (show on report)
  - Therapy recommendations listed in First Line and Second Line target detected fungal organisms
  - Physician treated with First Line recommendation from Pharmacy Guidance: ***terbinafine*** 250mg qd X6 weeks for fingernail w/ Considerations (show Provider on report)
  - Physician was surprised that first round of treatment recommendations seemed to be working best for patient, patient will continue to finish out treatment, overall physician is Highly pleased with a Positive patient outcome and since has started to do more Nail-ID’s now that a quick and accurate method can now be offered to their valuable patients the First Time.

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Nail-ID™
Molecular Pathogen Report

3110 Cherry Palm Drive; Suite #340
Tampa, FL 33619
Phone: 813.932.0374
Email: info@korpath.com

Clinical Laboratory Improvement Amendments
#10D0699501

Patient Name	Date of Birth	Gender	Race

Facility Information	Specimen Information	
Ordering Provider:	**ACC**:	
Facility:	**Collection Date**: 06-25-2021	**Report Date**: 06-30-2021
Facility Phone:	**Received Date**: 06-30-2021	**Sample Type**: Nail Shavings
Facility Fax:	**Notes**:	

Laboratory Results

PATHOGENS DETECTED

Peptostreptococcus prevotii, anaerobius, asaccharolyticus, magnus	1 x 10^3 copies/uL	90.909%
Microsporum audouinii, canis, gypseum, nanum	1 x 10^2 copies/uL	9.091%

RESISTANCE GENES DETECTED & POTENTIAL MED CLASS AFFECTED

No resistance genes detected

ABXAssist™

Pharmacy Guidance Provided by: Advance Therapeutic Assist

Electronically approved on 07-01-2021 by: Robin Ritter
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MEDICATION REVIEW

Drug Allergies:	SULFA
Notes from Ordering Physician:	
Notes from Pharmacist:	The treatment guidance listed is based on infectious disease treatment references, the organisms detected, and genes known to contribute to medication resistance. Important clinical information such as comorbidities, renal function, etc. may influence the overall appropriateness of therapy. The provided guidance only takes drug allergies into account when they are provided. The provider should take the entire clinical presentation into account when making treatment decisions. Not all detected microbes will require antimicrobial therapy as some are part of the normal flora or can be non-pathogenic colonizers. Peptostreptococcus is considered normal flora at low copies/ml. If clinical judgment determines antibiotic treatment is appropriate for skin surrounding nail, recommended options are Augmentin, cephalexin, doxycycline, clindamycin, or levofloxacin. Microsporum audouinii, canis, gypseum: SKIN: aka ringworm SCALP: Tinea capitis; systemic therapy is generally required for cure. Topical therapy alone is ineffective because the fungi are located within the hair. Topical shampoos can be effective adjunctive therapy with oral therapy during early phases of therapy to prevent spread. eg. ketoconazole 2% or selenium sulfide 2.5% shampoo NAILS: tinea unguium Therapy recommendations listed below target detected fungal organisms.

FIRST LINE

Medication	Route	Dose
terbinafine	oral	250mg qd x4 weeks for hair/skin or x6 weeks for fingernail or 12 weeks for toenail Considerations: Contraindicated in chronic or active hepatic disease, need baseline LFT's and post 30 days, CrCl<50 use with caution, May cause taste and/or smell disturbances, May cause photosensitivity with prolonged use, Potential drug-drug interactions, Drug persists in nails 6 months

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SECOND LINE	itraconazole	oral	200-300mg qd x2-4 weeks for hair/skin or 200mg qd x8 weeks for fingernail or 12 weeks for toenail Considerations: Caution with renal or hepatic dysfunction, Need baseline LFT's, Black box warning: can cause or exacerbate CHF, Check drug interactions, Avoid grapefruit juice -decreases bioavailability of drug, avoid use with PPI or H2 blockers, Drug persists in nails 9 months

Methodology	The infectious disease and antibiotic resistance detection panels are tested utilizing Real-time PCR technology to detect the presence of genes associated with pathogens and antibiotic resistance via amplification of genomic DNA. Amplification and detection are performed using the Applied Biosystems™ QuantStudio™ 12K Flex Real-time PCR system, which includes the QuantStudio™ 12k Software v1.3 and Thermo Fisher Scientific TaqMan™ assays. The assays are preloaded onto TaqMan™ OpenArray plates.
Limitations	This test only detects microorganisms and antibiotic resistance (ABR) genes specified in the panel. ABR genes are detected in the specimen and are not specific to a detected pathogen. ABR genes may be detected in bacterial strains not tested for in the panel. The resistance genes for Ampicillin, selected Extended-Spectrum-Betalactamases, Vancomycin, Carbapenems, Sulfonamide, Trimethoprim, Aminoglycosides and the Quinolone gyrase groupings are assays customized by pooling the individual genes listed in the associated group. If listed as positive, this indicates that at least one of the genes in the group was detected and the class of medication could have potential resistance.
Disclaimer	This test was developed and its performance characteristics determined by Korpath™. It has not been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. Pharmacy guidance and recommendations therein are not under the purview of the laboratory or agencies which accredit the laboratory. The treatment guidance listed in the report is based on infectious disease treatment references, the organisms detected, and genes known to contribute to medication resistance. Important clinical information such as comorbidities, renal function, patient weight, platelet count, microbiology results, etc. may influence the overall appropriateness of therapy. The provided guidance only takes drug allergies into account when they are provided and available to the pharmacist making the recommendation. The overall appropriateness of therapy must be determined by the physician treating the patient. The provider has all the patient information necessary to make that determination and should take the entire clinical presentation into account when making treatment decisions. Should the treating physician wish to discuss the provided guidance, the pharmacist is available for consult at the email and phone number provided.

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NEGATIVE PATHOGENS
Acremonium strictum
Alternaria spp
Blastomyces dermatitidis
Candida albicans, glabrata, tropicalis, parapsilosis
Candida dubliniensis, lusitaniae, krusei, auris
Cladosporium herbarum
Curvularia lunata
Enterobacter spp.
Enterococcus faecalis, faecium
Epidermophyton floccosum
Fusarium solani, oxysporum
HSV 1 and 2
Herpes zoster virus (Varicella zoster virus)
Klebsiella oxytoca, pneumoniae
Pseudomonas aeruginosa
Sarcoptes scabiei
Scopulariopsis brevicaulis
Scytalidinum dimidiatum (Neoscytalidium)
Staphylococcus aureus
Streptococcus agalactiae
Streptococcus pyogenes
Trichophyton rubrum
Trichophyton soudanense, violaceum
Trichophyton tonsurans, interdigitale

NEGATIVE RESISTANCE GENES	ANTIBIOTIC CLASS
aac6-1b/aacA4, ant(3), aph(A6), aac6-1b-cr	Aminoglycosides
ampC, ACC, DHA, ACT/MIR	Ampicillin
SULL, DFRA	Bactrim
CTX-M group 1, group 2, group 9, group 8/25, PER-1, PER-2, VEB, blaNDM-1, OXA-1, GES, SHV	Beta-lactams
OXA-23, OXA-72, OXA-40, OXA-58, IMP-16, NDM, blaOXA-48, OXA-48, KPC, VIM, IMP-7	Carbapenems
TEM, TEM E102K, TEM R162S, TEM G238S	Extended - Spectrum - Betalactamases
ErmC, ErmB, ErmA	Macrolides
*mecA	Methicillin
mcr-1	Polymyxins
QnrB, Gyrase A D87N_GTT, Gyrase A S83L_TGG, QnrA	Quinolones
tetM	Tetracycline
VanB, VanA1, VanA2	Vancomycin

This report, associated with order #, has been approved by the following reviewers:

Pharmacist:

Electronically signed and dated on 06-30-2021 23:29
Robin Ritter

Report Reviewer:

Electronically signed and dated on 07-01-2021 09:55
Lawrence Rushdi
