NailPath™ Report

12076 Technology Avenue • Alachua, FL 32615, USA
Phone: 352.375.5553 Fax: 352-505-5506
CLIA# 10D2042485

NCF | Diagnostics & DNA Technologies

Patient Information

Patient Name: [redacted]
DOB: [redacted]
Gender: Male
Race: Not Provided
Ethnicity: Not Provided
Ordered By: Andrew Woods, DPM
Lab Director: Marc Zumberg, M.D.
Clinical Molecular Pathology Supervisor: Ayyamperumal Jeyaprakash Ph.D, TS (ABB), MB (ASCP)

Accession#: [redacted]
Collection Date: 3/22/2018
Received Date: 3/23/2018
Report Date: 3/23/2018
Sample Type: L1 Nail Clipping
Additional Comments: Sample arrived in good condition.

Low ($\leq 10^5$ CFU/mL) Medium ($10^5 - 10^6$ CFU/mL) High ($\geq 10^6$ CFU/mL)

BACTERIA

Pathogen	Result	Qualitative Low/Medium/High	Quantity (CFU/mL sample)	% of Total Pathogen Load
Klebsiella pneumoniae	Negative	N/A	N/A	N/A
Pseudomonas aeruginosa	Negative	N/A	N/A	N/A
Staphylococcus aureus	Negative	N/A	N/A	N/A

FUNGI

Pathogen	Result	Qualitative Low/Medium/High	Quantity (CFU/mL sample)	% of Total Pathogen Load
Acremonium recifei	**Positive**	**High**	**1 x 10^7 CFU/mL**	**50 %**
Acremonium strictum	Negative	N/A	N/A	N/A
Alternaria alternate	Negative	N/A	N/A	N/A
Asperigillus flavus	Negative	N/A	N/A	N/A
Aspergillus fumigatus	Negative	N/A	N/A	N/A
Aspergillus niger	Negative	N/A	N/A	N/A
Aspergillus terreus	Negative	N/A	N/A	N/A
Cladosporium carrionii	Negative	N/A	N/A	N/A
Cladosporium uredinicola	Negative	N/A	N/A	N/A
Epidermophyton floccosum	Negative	N/A	N/A	N/A
Fusarium oxysporum	Negative	N/A	N/A	N/A
Microsporum audouinii	Negative	N/A	N/A	N/A
Microsporum canis	Negative	N/A	N/A	N/A
Onychocola canadensis	Negative	N/A	N/A	N/A
Scopulariopsis brevicaulis	Negative	N/A	N/A	N/A
Trichophyton mentagraphophytes var.interdigitale	Negative	N/A	N/A	N/A
Trichophyton mentagraphophytes var. mentagrophytes	Negative	N/A	N/A	N/A
Trichophyton rubrum	Negative	N/A	N/A	N/A
Trichophyton schoenleinii	Negative	N/A	N/A	N/A
Trichophyton soudanense	Negative	N/A	N/A	N/A
Trichophyton tonsurans	Negative	N/A	N/A	N/A

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Trichophyton verrucosum	**Positive**	**High**	**1 x 10^7 CFU/mL**	**50 %**
Trichophyton violaceum	Negative	N/A	N/A	N/A

Methodology:
DNA/RNA Extractions followed by Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), TaqMan qPCR and Sanger Sequencing assays detect pathogens with clinical significance at analytical sensitivity and specificity >99%.

Limitations:
This assay may detect pathogens other than those listed. Pathogens of unknown clinical significance detected by the assay are considered experimental. Rare false positive and false negative results may occur.

Disclaimer: This test was developed and its performance characteristics determined by NCF Diagnostics & DNA Technologies. 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.

ResistantPath Report

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CLIA# 10D2042485

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Patient Information

Patient Name: [redacted]
DOB [redacted]
Gender: Male
Race: Not Provided
Ethnicity: Not Provided
Ordered By: Andrew Woods, DPM
Lab Director: Marc Zumberg, M.D.
Clinical Molecular Pathology Supervisor: Ayyamperumal Jeyaprakash Ph.D, TS (ABB), MB (ASCP)

Accession#: [redacted]
Collection Date: 3/22/2018
Received Date: 3/23/2018
Report Date: 3/23/2018
Sample Type: L1 Nail Clipping
Additional Comments: Sample arrived in good condition.

Antibiotic Resistance Overview

The emergence of antibiotic resistance has led to the discovery of specific associated genetic mutations within a pathogen that allows it to resist the effects of a medication. Pathogens can acquire these antibiotic resistance genes from other pathogens via mobile genetic elements. NCF Diagnostics utilizes the most advanced technology to identify the commonly associated "resistant" genes in an effort to help guide providers in choosing the most appropriate and effective therapy to eradicate the identified pathogen.

Gene	Detection	Clinical Relevance
mecA Gene	**Positive Detection**	**Increased Risk of Antibiotic Resistance to Beta-lactams**
mecC Gene	Negative Detection	Decreased Risk of Antibiotic Resistance to Beta-lactams
blaSHV-5 Gene	Negative Detection	Decreased Risk of Antibiotic Resistance to Beta-lactams
mcr-1 Gene	Negative Detection	Decreased Risk of Antibiotic Resistance to Polymixins
1546 Transposon	Negative Detection	Decreased Risk of Antibiotic Resistance to Quinolones
grlA Gene	Negative Detection	Decreased Risk of Antibiotic Resistance to Quinolones
VanA Gene	**Positive Detection**	**Increased Risk of Antibiotic Resistance to Vancomycin**
VanB Gene	Negative Detection	Decreased Risk of Antibiotic Resistance to Vancomycin
Cfr23S Gene	Negative Detection	Decreased Risk of Antibiotic Resistance to Macrolides
ampC Gene	Negative Detection	Decreased Risk of Ampicillin and Cephalosporin Resistance
ermB Gene	Negative Detection	Decreased Risk of Erythromycin Resistance
tetM Gene	Negative Detection	Decreased Risk of Tetracycline Resistance
tetS Gene	Negative Detection	Decreased Risk of Tetracycline Resistance

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A = ACTIVE LA = LESS ACTIVE R = RESISTANT
Blank = No Resistance Detected
Patient Name [redacted]

Medication	Acremonium spp.(Skin)	Trichophyton spp. (Skin)
Terbinafine/Naftifine/Butenafine (PO/Topical)	A(1)	A(1)
Nystatin/Miconazole/Clotrimazole/Econazole/Ciclopirox (Topical)	A(1)	A(1)
Clotrimazole (Troche/Intravaginal/Topical)	A(1)	A(1)
Fluconazole/Itraconazole (PO/IV)	A(1)	A(1)
Voriconazole/Posaconazole (PO)	A(1)	A(1)
Griseofulvin (PO)	A(1)	A(1)
Amphoteracin B (IV)		
Cefazolin (IM/IV)	R	R
Cefdinir (PO)	R	R
Cefepime (IM/IV)	R	R
Cefotetan (IM/IV)	R	R
Cefoxitin (IV)	R	R
Cefpodoxime (PO)	R	R
Cefotaxime (IM/IV)	R	R
Ceftaroline (IV)	R	R
Ceftazidime (IM/IV)	R	R
Ceftolozane/Tazobactam (IV)	R	R
Ceftriaxone (PO/IV)	R	R
Cephalexin (PO)	R	R
Cefuroxime (PO/IV)	R	R
Ampicillin/Sulbactam (IM/IV)	R	R
Ampicillin (IM/IV)	R	R
Amoxicillin (PO)	R	R
Amoxicillin/Clavulanate (PO)	R	R
Dicloxacillin (PO)	R	R
Oxacillin/Nafcillin (IM/IV)	R	R
Penicillin V (PO)	R	R
Penicillin G (IV)	R	R
Piperacillin/Tazobactam (IV)	R	R
Ertapenem (IM/IV)	R	R
Imipenem (IM/IV)	R	R
Meropenem (IV)	R	R
Vancomycin (PO/IV)	R	R
Daptomycin (IV)		
Clindamycin (PO/IM/IV)		
Azithromycin (PO)		
Clarithromycin (PO/IV)		
Erythromycin (PO/IV)		
Josamycin (PO)		
Aztreonam (IM/IV)	R	R
Metronidazole (PO/IV)		
Quinupristin/Dalfopristin (IV)		
Nitrofurantoin (PO/IV)		
Chloramphenicol (PO/IV/OPHTH)		
Linezolid (PO/IV)		
Fosfomycin (PO)		
Colistin (Inh/IM/IV)		
Polymyxin B (IT/IV)		
Ciprofloxacin (PO/IV)		
Levofloxacin/Moxifloxacin (PO/IV)		
Trimethoprim/Sulfamethoxazole (PO/IV)		
Amikacin (IM/IV)		
Gent/Tobra/Amikacin (IM/IV)		
Paromomycin (PO/IM) & Strepto (IM/IV) & Tobra (IV)		
Doxycycline (PO/IV)		
Tetracycline (PO/IV)		
Tigecycline (IV)		
Oritavancin (IV)		
Telavancin (IV)		

WoundPath™ Report

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Gender: Not Provided
Race: Not Provided
Ethnicity: Not Provided
Ordered By: Andrew Woods, DPM
Lab Director: Marc Zumberg, M.D.

Accession#: [redacted]
Collection Date: 3/23/2018
Received Date: 3/27/2018
Report Date: 3/27/2018
Sample Type: Swab Left Foot
Additional Comments: Sample arrived in good condition.

Ayyamperumal Jeyaprakash Ph.D

Clinical Molecular Pathology Supervisor: Ayyamperumal Jeyaprakash Ph.D, TS (ABB), MB (ASCP)

Low (< 10^5 CFU/mL) **Medium (10^5 - 10^6 CFU/mL)** **High (>10^6 CFU/mL)**

BACTERIA

Pathogen	Result	Qualitative Low/Medium/High	Quantity (CFU/mL sample)	% of Total Pathogen Load
Acinetobacter baumannii	Negative	N/A	N/A	N/A
Bacteroides spp.	Negative	N/A	N/A	N/A
Clostridium perfringens	Negative	N/A	N/A	N/A
Corynebacterium amycolatum	Negative	N/A	N/A	N/A
Corynebacterium striatum	**Positive**	**Low**	**6 x 10^3 CFU/mL**	**25 %**
Enterobacter aerogenes	Negative	N/A	N/A	N/A
Enterobacter cloacae	Negative	N/A	N/A	N/A
Enterococcus faecalis	Negative	N/A	N/A	N/A
Enterococcus faecium	Negative	N/A	N/A	N/A
Escherichia coli	**Positive**	**Low**	**6 x 10^3 CFU/mL**	**25 %**
Finegoldia magna	Negative	N/A	N/A	N/A
Klebsiella pneumoniae	Negative	N/A	N/A	N/A
Morganella morganii	Negative	N/A	N/A	N/A
Peptostreptococcus anaerobius	Negative	N/A	N/A	N/A
Proteus mirabilis	Negative	N/A	N/A	N/A
Pseudomonas aeruginosa	**Positive**	**Low**	**6 x 10^3 CFU/mL**	**25 %**
Salmonella enterica	Negative	N/A	N/A	N/A
Serratia marcescens	Negative	N/A	N/A	N/A
Staphylococcus aureus	Negative	N/A	N/A	N/A
Staphylococcus epidermidis	**Positive**	**Low**	**6 x 10^3 CFU/mL**	**25 %**
Stenotrophomonas maltophilia	Negative	N/A	N/A	N/A
Streptococcus pneumoniae	Negative	N/A	N/A	N/A
Streptococcus pyogens	Negative	N/A	N/A	N/A

FUNGI

Pathogen	Result	Qualitative Low/Medium/High	Quantity (CFU/mL sample)	% of Total Pathogen Load
Candida albicans	Negative	N/A	N/A	N/A
Candida glabrata	Negative	N/A	N/A	N/A
Candida parapsilosis	Negative	N/A	N/A	N/A

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Candida tropicalis	Negative	N/A	N/A	N/A

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ResistantPath Report

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Patient Information

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DOB: [redacted]
Gender: Not Provided
Race: Not Provided
Ethnicity: Not Provided
Ordered By: Andrew Woods, DPM
Lab Director: Marc Zumberg, M.D.

Accession#: [redacted]
Collection Date: 3/23/2018
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Report Date: 3/27/2018
Sample Type: Swab Left Foot
Additional Comments: Sample arrived in good condition.

Ayyamperumal Jeyaprakash Ph.D

Clinical Molecular Pathology Supervisor: Ayyamperumal Jeyaprakash Ph.D, TS (ABB), MB (ASCP)

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VanB Gene	Negative Detection	Decreased Risk of Antibiotic Resistance to Vancomycin
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tetS Gene	Negative Detection	Decreased Risk of Tetracycline Resistance

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A = ACTIVE LA = LESS ACTIVE R = RESISTANT
Blank = No Resistance Detected
Patient Name: [redacted]

Medication	Coryne-bacterium spp. (Skin)	E. Coli (Skin)	Pseudomonas aeruginosa (Skin)	Staphylococcus epidermidis (Skin)
Terbinafine/Naftifine/Butenafine (PO/Topical)				
Nystatin/Miconazole/Clotrimazole/Econazole/Ciclopirox (Topical)				
Clotrimazole (Troche/Intravaginal/Topical)				
Fluconazole/Itraconazole (PO/IV)				
Voriconazole/Posaconazole (PO)				
Griseofulvin (PO)				
Amphoteracin B (IV)				
Cefazolin (IM/IV)				A(1)
Cefdinir (PO)				
Cefepime (IM/IV)		A(1)	A(1)	
Cefotetan (IM/IV)				
Cefoxitin (IV)				
Cefpodoxime (PO)				
Cefotaxime (IM/IV)		A(1)		
Ceftaroline (IV)				
Ceftazidime (IM/IV)		A(1)	A(1)	
Ceftolozane/Tazobactam (IV)				
Ceftriaxone (PO/IV)		A(1)		
Cephalexin (PO)				
Cefuroxime (PO/IV)		A(1)		
Ampicillin/Sulbactam (IM/IV)				
Ampicillin (IM/IV)		A(1)		
Amoxicillin (PO)				
Amoxicillin/Clavulanate (PO)				
Dicloxacillin (PO)				
Oxacillin/Nafcillin (IM/IV)				A(1)
Penicillin V (PO)				
Penicillin G (IV)				
Piperacillin/Tazobactam (IV)		A(1)	A(1)	
Ertapenem (IM/IV)		A(1)		
Imipenem (IM/IV)		A(1)	LA(1)	
Meropenem (IV)		A(1)	LA(1)	
Vancomycin (PO/IV)	A(1)			
Daptomycin (IV)	A(1)			A(1)
Clindamycin (PO/IM/IV)				
Azithromycin (PO)				
Clarithromycin (PO/IV)				
Erythromycin (PO/IV)	R	R	R	R
Josamycin (PO)				
Aztreonam (IM/IV)			LA(1)	
Metronidazole (PO/IV)				
Quinupristin/Dalfopristin (IV)	A(1)			
Nitrofurantoin (PO/IV)				
Chloramphenicol (PO/IV/OPHTH)				
Linezolid (PO/IV)	A(1)			
Fosfomycin (PO)				
Colistin (Inh/IM/IV)			A(1)	
Polymyxin B (IT/IV)				
Ciprofloxacin (PO/IV)		A(1)	A(1)	LA(1)
Levofloxacin/Moxifloxacin (PO/IV)	LA(1)	A(1)	A(1)	LA(1)
Trimethoprim/Sulfamethoxazole (PO/IV)		A(1)		A(1)
Amikacin (IM/IV)				
Gent/Tobra/Amikacin (IM/IV)		A(1)	A(1)	
Paromomycin (PO/IM) & Strepto (IM/IV) & Tobra (IV)				
Doxycycline (PO/IV)	R	R	R	R
Tetracycline (PO/IV)	R	R	R	R
Tigecycline (IV)				
Oritavancin (IV)				
Telavancin (IV)				