

Final Report

LAB INFORMATION

Name: Precision Health Solutions

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Medical Director: Fatemeh Mousavi, MD

CLIA: 10D2181177

PATIENT INFORMATION

Patient: Mickey Mouse **DOB:** 07/08/1963 Age: 60 Years Gender: Male

Patient Address: 123 Lake

City: Orlando State: FL **Zipcode:** 33655

SPECIMEN INFORMATION

Acc #: D23355555

Facility: ENTAAF - South Tampa ENT

Provider: John Smith

Collection Date: 11/22/2023 08:00 A.M

Received in Lab: 11/22/2023

Resulted Date: 11/22/2023 15:02 P.M

Specimen Type: Ear

Sinus, Throat and Ear

Result Summary			
Organism(s)	Patient Result	Qualitative	Reference Range
Aspergillus species (A. fumigatius, terreus, niger)	Detected	Low	Not Detected

No Resistance Gene Markers Detected

Lab Comment:

Limitations

Negative results do not preclude a Sinus, Throat and Ear infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Positive results do not rule out infection, or co-infection with other pathogens not on our panel. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence and radiography) and clinical presentation must be taken into consideration in the final diagnosis of a Sinus, Throat and Ear. Detection of a marker of antibiotic resistance does not preclude other antibiotic resistance mechanisms not tested for in the panel. Positive detection of an antibiotic resistance marker only indicates that marker is present in the flora in the sample tested and may not indicate potential for use in Sinus, Throat and Ear. Conversion estimates determined by a correlation study, for additional details go to our website: www.precision-healthsolutions.com.



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The following organisms and resistance genes were tested using this Sinus, Throat and Ear panel test and are **NOT DETECTED**

Organism(s)	Patient Result	Reference Range
Gram Po	sitive Bacteria	
Staphylococcus aureus	Not Detected	Not Detected
Streptococcus pyogenes	Not Detected	Not Detected
Streptococcus pneumoniae	Not Detected	Not Detected
Gram Ne	gative Bacteria	
Klebsiella pneumoniae	Not Detected	Not Detected
Haemophilus influenzae	Not Detected	Not Detected
Moraxella catarrhalis	Not Detected	Not Detected
Pseudomonas aeruginosa	Not Detected	Not Detected
Gram Vai	riable Bacteria	
Mycoplasma pneumoniae	Not Detected	Not Detected
F	ungus	
Candida species (C.albicans, glabrata, tropicalis, parapsilosis)	Not Detected	Not Detected
P	arasite	
Resist	ance Genes	
erm(A) and erm(B): 23S rRNA (adenine(2058)-N(6))- methyltransferase ErmA and ErmB	Not Detected	Not Detected
blaKPC: carbapenem-hydrolyzing class A beta-lactamase KPC (blaKPC)	Not Detected	Not Detected
blaGES: class A beta-lactamase GES(blaGES)	Not Detected	Not Detected
CTXM1 group: Class A beta-lactamase ESBLCTX-M GROUP	Not Detected	Not Detected
mecA: PBP2a family beta-lactam-resistant peptidoglycan transpeptidase mecA	Not Detected	Not Detected
blaOXA OXA-48: OXA-48 family class D beta-lactamase OXA (blaOXA)	Not Detected	Not Detected
qnrA and qnrS: quinolone resistance pentapeptide repeat protein QnrA2 and quinolone resistance pentapeptide repeat protein QnrS9	Not Detected	Not Detected
$\label{eq:tet} \textbf{tet}(\textbf{M}) \\ \vdots \\ \textbf{tetracycline resistance ribosomal protection protein Tet} \\ \textbf{(M)}$	Not Detected	Not Detected
1/114 P4 P 4 1 1/114	Not Detected	Not Detected
VIM: B1 Beta lactamse VIM	Not Detected	Not Detected

Methodology and Intended Use

Real-Time PCR was performed on genomic DNA extractions using the King Fisher and analyzed on a QuantStudio 7 and 12 Platform. Data was obtained for each assay to detect species specific sequences within a sample, During amplification, se-quence specific oligonucleotides probes (dually labeled with a fluorophore and quencher) hybridize to a specific DNA template. The 5'-3' exonuclease activity of DNA polymerase during elongation cleaves the fluorophore from being quenched on the oligonucleotide probe, causing the fluorophore to be excited; emitting fluorescence. The accumulation of fluorescence for each sample, in each well is measured by the instrument software during each cycle of amplification, directly corresponding to amplification of target sequence. The Applied Biosystems™ QuantStudio 7 and 12 software analyzes the data generated, producing quality scores and confidence values for each assay in each well, for each sample. The Applied Biosystems™ QuantStudio 7 and 12 software provides a qualitative and quantitative result, the presence or absence of the pathogens or drug resistance markers contained in the panel, along with the internal controls, based upon whether the amplification is above or below the threshold of detection, in conjunction with the quality and confidence values. This test aids in the treatment of infections and should be used in conjunction with other clinical and epidemiological information. This test is a Laboratory Derived (LDT) qualitative nucleic acid multiplex diagnostic test intended for use on an Applied Biosystems™ QuantStudio 7 and 12 Real-Time PCR System for the simultaneous detection and identification of multiple pathogen nucleic acids in samples obtained from individuals