

# **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:** 04/03/2016 Age: 7 Years

Gender: Male Patient Address: 1234 Hola **City:** Celebration

State: AL **Zipcode:** 34736

## **SPECIMEN INFORMATION**

Acc #: D2327805555

Facility: SQA/TruemdIT facility

Provider: Abdul Hanan

Collection Date: 10/04/2023 19:30 **Received in Lab:** 10/04/2023

Resulted Date: 10/05/2023 12:27 P.M Specimen Type: Nasopharyngeal

## **RESPIRATORY COVID Test**

Result Summary		
Organism(s)	Patient Result	Reference Range
SARS-CoV2 (Covid)	Detected	Not Detected
SARS-CoV2 (Covid)	Detected	Not Detected

#### **Lab Comment:**

#### Limitations:

Negative results do not preclude a RESPIRATORY COVID Test 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 RESPIRATORY COVID Test. 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 RESPIRATORY COVID Test. .

# **Calling Notes:**

## 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 Respiratory 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 Respiratory samples obtained from individuals