ELITE CLINICAL LABORATORY

Elite Clinical Laboratory
6776 Southwest Freeway,
Suite 620 Houston,TX,77074 USA,
Phone: 281.378.2116, Fax : 281.466.2483,
CLIA #45D1061571,
Lab Director : Dr. Albert Chen MD.

RPP qPCR REPORT

Patient		Test Details		Specimen	
First Name:	John	**Indication For:**	RP Detection	**Collection Date:**	01-17-2022
Last name:	**Doe**	**Analysis ID:**	8944	**Received Date:**	01-18-2022
Patient ID:	E9901180157	**Specimen type:**	Nasopharyngeal	**Reported Date:**	01-19-2022
DOB:	09-14-1989	**Ref. Physician:**	**Test Provider**		
Gender:	Male	**Facility Name:**	Test Facility		

Summary of Results: No Pathogenic Variants Detected

Pathogens Not Deteced

VIRUS

Respiratory Syncytial Virus A (RSV A)	Not Detected
Influenza A virus (Flu A)	Not Detected
Respiratory Syncytial Virus B (RSV B)	Not Detected
Influenza B virus (Flu B)	Not Detected
Flu A-H1pdm09	Not Detected
Flu A-H1	Not Detected
Flu A-H3	Not Detected
Parainfluenza Virus 4 (PIV 4)	Not Detected
Metapneumovirus (MPV)	Not Detected
Parainfluenza Virus 2 (PIV 2)	Not Detected
Parainfluenza Virus 1 (PIV 1)	Not Detected
Adenovirus (AdV)	Not Detected
Enterovirus (HEV)	Not Detected
Parainfluenza Virus 3 (PIV 3)	Not Detected
Coronavirus OC43 (CoV OC43)	Not Detected
Bocavirus (HBoV)	Not Detected
Coronavirus 229E (CoV 229E)	Not Detected
Coronavirus NL63 (CoV NL63)	Not Detected
Rhinovirus (HRV)	Not Detected

BACTERIA

Streptococcus Pneumoniae	Not Detected
Legionella Pneumophila	Not Detected
Haemophilus Influenzae	Not Detected
Bordetella Parapertussis	Not Detected
Mycoplasma Pneumoniae	Not Detected
Bordetella Pertussis	Not Detected
Chlamydophila Pneumoniae	Not Detected

AR GENES

NDM, KPC, OXA48, VIM, IMP	Carbapenemase Genes	Not Detected
Extended Spectrum CTX-M	Extended Specturmn Beta-Lactamase (ESBL)	Not Detected
VanA, VanB	Macrolides	Not Detected

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RPP qPCR REPORT

Patient Name	Date of Birth	Gender
John Doe	09-14-1989	Male

Methodology:

Elite Clinical Laboratory RPP (Respiratory Pathogen Panel) test is a laboratory developed test. It is a real time RT-PCR which specifically detects pathogens listed on the report in patients' specimens. Patient's nasopharyngeal or oropharyngeal swab is treated to extract RNA/DNA and processed to detect the presence of various respiratory pathogens listed on the panel using specific primers on a real time PCR machine. The results are compared to contrive positive controls, Internal controls, and Negative Template Controls (Quality Control Samples) run alongside the patient's samples for the diagnosis of respiratory infections.

Limitation:

All molecular tests have limitations. If a patient is found 'NOT DETECTED or NEGATIVE' implies that he/she is not infected with the list of pathogens mentioned in the report at the sample collection time. On the other hand, this does not discount the fact that the patient having symptoms before this test may be due to the pathogens beyond the scope of Elite Clinical Laboratory RP Panel.

Laboratory Statement:

This test was validated, and performance characteristics have been determined by Elite Clinical Laboratory, 6776 Southwest Freeway Suite 620,Houston,TX 77074, CLIA(#45D1061571), Laboratory Director- Dr. Albert Chen MD. This test is used for clinical purposes (see Eligibility for testing). Its use should not be regarded as investigational or for research and tests only the listed pathogens on the report. Hence, we strongly recommend undergoing this test when the patient experiences symptoms consistent with infectious respiratory disease etiology with the clinician's advice and prescription. This laboratory is certified under Clinical Laboratory Improvements and Amendments of 1988 (CLIA 88) as qualified to perform high complexity clinical laboratory testing. This test has not been cleared or approved by the FDA. The FDA has determined that such approval is not necessary, provided that the laboratory both (1) maintains its good standing as a clinical testing laboratory with all mandatory accrediting bodies, and (2) continually demonstrates that its testing protocols and procedures achieve a high degree of analytical accuracy. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes and should not be regarded as investigational or for research.

Eligibility for Testing:

This test is prescription use only and is limited to patients suspected of respiratory infections by their healthcare provider. The eligibility determination ultimately rests on the clinician's judgment.

Conduct of the Test:

This test is performed under strict compliance and guidelines of Elite Clinical Laboratory R&D team, including the instruments, reagents, and other recommended procedures. This includes the safety protocols where all laboratory personnel are appropriately trained in RT- qPCR techniques and use appropriate laboratory and personal protective equipment when handling this kit/test and use this test in accordance with the authorized labeling.

Result Reports for Healthcare Providers and Patients:

We have a process for reporting test results to healthcare providers as appropriate. Result reports will be provided to healthcare providers and patients.

Performance Data and Reporting:

We collect information on the performance of the test and report any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which we become aware to concerned authorities.

Recordkeeping:

As an authorized laboratory we ensure all records associated with this test are maintained until otherwise notified. Such records are available to regulatory bodies for inspection upon request at any time.