TruGenX
Precision Medicine

136 Ridge Road, Suite 1B, Lyndhurst, NJ 07071
P: 888-413-0428 | F: 561-898-1096
CLIA: 31D2115446

**Name: Tony Stark**

**Date of Birth:** 05/29/1970| **Sex:** M| **Age:** 49
**Accession Number:** RPP18-00000
**Collection Date:** 02/17/2018
**Received Date:** 02/17/2018
**Reported Date:** 02/26/2018
**Specimen Type:** Nasopharyngeal Swab

## Physician Information

**Physician Name:** Peter Pretend
**Practice Name:** ABC Practice 2
**Address:** 123 Main 2|Suite 1| SomePlace, VA 23412

**Phone:** 804-302-2655
**Fax:** 804-302-1111

## Summary

Positive for: Influenza A, Influenza A H3, Streptococcus pyogenes (group A)

## Results

| Viral Target | Results | Bacterial Target | Results |
|---|---|---|---|
| **Influenza A** | **Positive** | *Chlamydia pneumoniae* | Target Not Detected |
| Influenza A H1 | Target Not Detected | *Mycoplasma pneumoniae* | Target Not Detected |
| **Influenza A H3** | **Positive** | *Bordetella* | Target Not Detected |
| Influenza A 2009 H1N1 | Target Not Detected | *Bordetella holmesii* | Target Not Detected |
| Influenza B | Target Not Detected | *Bordetella pertussis* | Target Not Detected |
| Respiratory Syncytial Virus RSV A | Target Not Detected | *Legionella pneumophila* | Target Not Detected |
| Respiratory Syncytial Virus RSV B | Target Not Detected | *Moraxella catarrhalis* | Target Not Detected |
| Parainfluenza Virus PIV 1 | Target Not Detected | *Streptococcus pneumoniae* | Target Not Detected |
| Parainfluenza Virus PIV 2 | Target Not Detected | ***Streptococcus pyogenes (group A)*** | **Positive** |
| Parainfluenza Virus PIV 3 | Target Not Detected | *Adenovirus* | Target Not Detected |
| Human Metapneumovirus (hMPV) | Target Not Detected | | |
| Human Rhinovirus HRV | Target Not Detected | | |
| Coronovirus | Target Not Detected | | |
| Coronovirus NL63 | Target Not Detected | | |
| Coronovirus OC43 | Target Not Detected | | |
| Coronovirus HKU-1 | Target Not Detected | | |
| Coronovirus 229E | Target Not Detected | | |
| Internal Control | test | | |

## Interpretive Comments on Test

Dai J. Li, M.D., Ph.D

Suggest treatment with antiviral drugs. There are three FDA-approved influenza antiviral drugs recommended by CDC. The brand names for these are Tamiflu® (generic name oseltamivir), Relenza® (generic name zanamivir), and Rapivab® (generic name peramivir). Tamiflu® is available as a pill or liquid, and Relenza® is a powder that is inhaled (Relenza® is not for people with breathing problems like asthma or COPD, for example.) Rapivab® is administered intravenously by a health care provider. To treat flu, Tamiflu® and Relenza® are usually taken for 5 days, although people hospitalized with the flu may need the medicine for longer than 5 days. Rapivab® is given intravenously for 15 minutes to 30 minutes.

For Streptococcus pyogenes (Group A): Use first line antibiotics; penicillin. If resistance- erythromycin, azithromycin cephalosporin, clindamycin.

## Intended Use

The detection and identification of specific nucleic acids from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral and/or bacterial infection, if used in conjunction with other clinical and epidemiological information. The RPP test is a LDT test and is not FDA approved. The RPP test is a qualitative nucleic acid multiplex diagnostic test intended for use on an Applied Biosystems™ QuantStudio™ 12K system for One-Step RT-qPCR. This assay can simultaneously detect and identify nucleic acids from multiple respiratory pathogens present from nasopharyngeal swabs (NPS), obtained from individuals exhibiting signs and symptoms of respiratory infection. The following bacteria and viruses/subtypes are identified using the RPP test: Influenza A (Influenza A H1, Influenza A H3, Influenza A 2009 H1N1), Influenza B, Respiratory Syncytial Virus (RSV) (subtypes A and B), Parainfluenza Virus (PIV) (subtypes 1, 2, and 3), Human Metapneumovirus (hMPV), Human Rhinovirus (HRV), Adenovirus, Coronavirus, (strains NL63, OC43, HKU-1, and 229E), *Chlamydia pneumoniae, Mycoplasma pneumoniae, Bordetella holmesii, Bordetella pertussis, Legionella pneumophila, Moraxella catarrhalis, Streptococcus pneumoniae, Streptococcus pyogenes* (group A).

## Methodology

The Purified RNA/DNA is isolated from the nasopharyngeal patient specimen and loaded onto Respiratory TaqMan® Array Cards. The Respiratory TaqMan® Array Card assay can detect and identify a broad range of respiratory pathogens, simultaneously, within a sample extract. The TaqMan® Array Card is a 384-well microfluidic card designed to perform 384 simultaneous reverse transcription real-time PCR (RT-qPCR) reactions. This format allows for 1-8 samples to be run in parallel against 48 specific and efficient respiratory and internal control TaqMan® Assay targets that are pre-loaded into each of the wells on the card. The cards are loaded onto the Applied Biosystems™ QuantStudio™ 12K system for One-step RT-qPCR. One-step RT-qPCR combines reverse transcription, PCR amplification, and detection into a single step. Any RNA present in the sample is first transcribed to cDNA by reverse transcriptase present in the master mix. This is immediately followed by cycles of amplification using the cDNA and/or any DNA specific to the singleplex assay targets present in the array card wells, as template. During amplification, sequence specific oligonucleotides probes (dually labeled with a fluorophore and quencher) are allowed to 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 of the array card, is measured by the instrument software during each cycle of amplification, directly corresponding to amplification of target sequence. The Applied Biosystems™ QuantStudio™ 12K system software analyzes the data generated, producing quality scores and confidence values for each assay in each well, for each sample. The Applied Biosystems™ QuantStudio™ 12K system software provides a qualitative result, the presence (CT < 40) or absence (Undetermined) of the pathogens contained in the panel, along with the Human RNA/DNA and 18s internal controls, based upon whether the amplification is above or below the threshold of detection, in conjunction with the quality and confidence values.

## Limitations

Negative results do not preclude respiratory viral infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Positive results do not rule out bacterial infection, or co-infection with other viruses. 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 respiratory viral infection.
Performance characteristics for Influenza A were established during the 2010/2011 influenza season when Influenza A 2009 H1N1 and H3N2 were the predominant Influenza A viruses in circulation. When other Influenza A viruses emerge, performance characteristics may vary.

**Assay performed at NEXT Molecular Analytics, 11601 Ironbridge Road, Suite 101, Chester, Virginia 23831. 804-977-6600, CLIA 49D2104154.**
**Laboratory Director: Dai J. Li, M.D., Ph.D**

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