

FINAL REPORT

**Doe, Jane**

Date of Birth: 09/20/1980 (39 yrs)  
 Gender: Female  
 Patient Id: 123-AB-12  
 Patient Location: COVID Test Client

**Ordering Provider**

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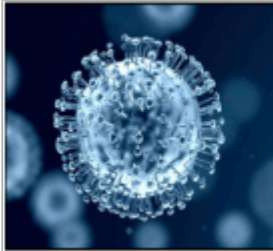
**Sample Information**

Specimen#: 5115335221  
 Accession#: 202004-14412  
 Specimen: Swab, VTM/UTM  
 Collected: 04/05/2020  
 Received: 04/06/2020 08:52  
 Reported: 04/07/2020 10:51

**Reason for Testing:** Asymptomatic  
**Related info:** Not Provided

**MOLECULAR DETECTION OF SARS-COV-2**

Test Results	
<b>SARS-CoV-2</b>	Not Detected



**Signs and Symptoms**

- Fatigue
- Sore throat
- Dry cough
- Shortness of breath
- Fever
- Nausea
- Diarrhea

**Interpretation:**

The submitted sample is negative (absence of the RNA) from SARS-CoV-2, the virus that causes the disease called COVID-19. See comments.

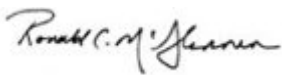
**Comments:**

- **Significance:** A respiratory disease called COVID-19 is caused by a novel coronavirus called SARS-CoV-2. Symptoms of this disease include fatigue, sore throat, dry cough, shortness of breath, fever, and occasionally nausea and diarrhea. Some persons report no symptoms.
- **Consider:** The results of this tested sample are negative. This means that SARS-Cov-2 is not likely a cause of your symptoms. This result does not eliminate another cause of your symptoms, which may include the influenza viruses, various bacterial infections, cold viruses or another coronavirus and possibly allergic conditions.
- **Recommendations:** If your symptoms persist or worsen it is important that you discuss with a healthcare professional. Your healthcare professional can evaluate your symptoms and physical condition and may request additional tests to determine the cause of your illness. Importantly, you may be contagious, and you should take precautions to protect others by staying at least 6 feet from nearby people, covering your mouth and secretions and disinfecting things that you touch.

**Methodology:** Viral RNA is extracted from 1 mL of the combined swab/rinse sample using the Chemagic Viral 300 360 HP 96 (ABI Perkin Elmer). Following this viral sequence cDNA and amplification of the SAR-Cov-2 genome (ORF1a, RdRp, E and N genes) is performed using the Logix Smart 2019 Novel Coronavirus kit (Co-Diagnostics, Salt Lake City, UT). The results of this test are based on extracted RNA and the presence of amplified DNA with an internal control gene marker. The results are reported as Detected, Not Detected or Inconclusive. The performance characteristics of this assay was determined by Access Genetics and is assigned as a laboratory developed test. These tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories and have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act 21, U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

**References:**

- CDC. (2020, Feb 13). Coronavirus Disease 2019 (COVID-19): Evaluating and Reporting Persons Under Investigation (PUI). Retrieved Feb 19, 2020, from Centers for Disease Prevention and Control: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>
- WHO. (2020, Jan 17). Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases > Interim guidance 17 Jan 2020. Retrieved Feb 19, 2020, from World Health Organization: <https://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117>



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