# DevLab bio

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Dir: Aaron LeFebvre, PhD

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| **Patient/Specimen Information** |
| *Name:* | Doe, John D | *Specimen Type:* | Nasopharyngeal Swab |
| *DOB:* |  01/01/1980 | *Collection Date/Time:* | 10/01/2020 12:00 PM |
| *Gender:* | M | *Received Date:* | 10/01/2020 |
| *Accession #:* | 20-00123 | *Ordering Physician:* | N/A; Direct Access Testing |
| *Passport ID:* | 123456789 |  |  |

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| ***Test Name*** | ***Reference Range*** | ***Result*** |
| COVID-19 Real-Time PCR (COV-P) | Not Detected | Not Detected |

***Disclaimers/Notes***:

1. The laboratory utilizes the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel that has been authorized by the FDA under an Emergency Use Authorization (EUA) on instrumentation that is not covered by the EUA and is therefore classified as a Laboratory Developed Test (LDT); performance characteristics for this test have been verified according to federal guidelines for performance verification of high complexity tests (42 CFR § 493.1253(b)(2)).
2. Detection of viral RNA may not indicate the presence of infectious virus or that SARS-CoV-2 is the causative agent for clinical symptoms.
3. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions.

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| ***Issued By: Dr. Name*** | Dr Signature |