# SARS-CoV-2 Virus Detection Test Report

| PATIENT | | PHYSICIAN | | SAMPLE | |
|---|---|---|---|---|---|
| Name: | Roberto Camacho | Name: | Ali Khazaeizadeh | Pangea Sample ID: | C19P425344 |
| Date of Birth: | 9/25/1988 | Address: | 2507 Eastbluff Drive | Collection Date: | 12/28/2022 |
| Sex: | Male | City, State: | Newport Beach, CA, 92660 | Received Date: | 12/29/2022 |
| MRN/Specimen ID: | N/A / PL200339332 | Acct#: | C19D0028 | Report Date: | 12/29/2022 |
| Race: | other-race | Tel: | +1 (949) 619-6134 | | |
| Ethnicity: | hispanic | | | | |

## Results Summary

**Result**

☐ Negative ✓ Positive ☐ Invalid

**Comment:**

**Sample Type**

*Upper Respiratory (Swab)*: ✓ OP (i.e. Throat) ☐ NP ☐ Nasal ☐ Mid-Turbinate

*Lower Respiratory*: ☐ Sputum ☐ Tracheal Aspirates ☐ Bronchoalveolar Lavage (BAL)

### Assay Description:

*Quick* SARS-CoV-2 rRT-PCR Kit is real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in upper respiratory specimens (such as nasal, nasopharyngeal, mid-turbinate or oropharyngeal swabs), and lower respiratory specimens (such as sputum, tracheal aspirates, and bronchoalveolar lavage) from patients suspected of COVID-19 by their healthcare provider.

### Test Information:

The Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the *Quick* SARS-CoV-2 rRT-PCR Kit developed by Zymo Research Corp. The kit has not been FDA cleared or approved. This test has been validated in accordance with the FDA's Guidance Document "Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA during the Public Health Emergency" issued on February 29th, 2020. FDA independent review of this validation is pending. This test is only authorized for the duration of time the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb3(b)(1), unless the authorization is terminated or revoked sooner. For all test results, Pangea Laboratory will be reporting to the local health officer for the jurisdiction where the patient resides.

### Interpretation of Results:

***Negative Result***: SARS-CoV-2 virus was *not* present in the provided patient specimen above the limit of detection; however, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.

***Positive Result***: SARS-CoV-2 virus was detected in the provided patient specimen.

***Invalid Result***: Unable to obtain a valid result for the specimen submitted. It is recommended that another specimen be submitted for testing.

**Report Date:**

12/29/2022

**Jess Savala, Jr., M.D.**
**Laboratory Director**

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Clinical Laboratory Improvement Amendments

*Pangea Laboratory, LLC. is accredited and regulated (CLIA) by the Centers for Medicare and Medicaid (CMS) and the College of American Pathologists to perform high-complexity clinical testing.*