SARS-CoV-2 (N gene detection)
Test Information for Laboratory Manuals (United States)

Test name:	SARS-CoV-2 (N gene detection)
Test Description:	Qualitative real-time reverse transcription polymerase chain reaction
Specimen Collection / Specimen Type:	Nasopharyngeal (NP) specimen is preferred. When collection of a nasopharyngeal swab is not possible, the following are acceptable alternatives: • An oropharyngeal (OP) specimen collected by a healthcare professional, or • A nasal mid-turbinate (NMT) swab collected by a healthcare professional or by onsite self-collection (using a flocked tapered swab), or • An anterior nares specimen (NS) collected by a healthcare professional or by onsite self-collection (using a round foam swab). • For NS, a single polyester swab with a plastic shaft should be used to sample both nares. Specimens should be collected into viral or universal transport media, Amies, or RNase free Normal saline.
Acceptable Volume:	1mL (0.8mL minimum)
Days/Times of Analysis:	Sunday – Saturday, variable times
Specimen TAT:	72 hours from receipt of specimen at Exact Sciences Laboratories (ES Labs) • For positive results, ES Labs will place a call to the ordering provider at the phone number indicated on the test requisition form (as applicable). • ES Labs will report results to state health departments in accordance with communicable disease reporting requirements.
Transport:	Refrigerate specimens after collection and during transport to ES Labs
Stability:	Specimens are stable at refrigerated temperatures for up to 72 hours after collection. Specimens can be stabilized at -70C for up to one month for clinical testing. Specimens should be shipped frozen on dry ice if they are anticipated to arrive at the lab beyond 72 hours from collection.
CPT Code:	U0003
LOINC Code:	94533-7 SARS coronavirus 2 N gene [Presence] in Respiratory specimen by NAA with probe detection
McKesson Z-Code Identifier	None
Reference Value:	The normal value for this test is “Negative”

Test Results:	**Positive** – SARS-CoV-2 (COVID-19) RNA detected. **Negative** –SARS-CoV-2 (COVID-19) RNA NOT detected. Negative results do not preclude SARS-CoV-2 (COVID-19) infection and should not be used as the sole basis for treatment or other patient management decisions **Invalid** – This specimen exhibited inhibition in the PCR assay or the specimen contained an inadequate amount of clinical material. Repeat testing is suggested if clinically indicated. **Inconclusive**- This specimen did not meet the full criteria established for the detection of SARS-CoV-2 (COVID-19) RNA. The sample will be evaluated using an alternative test method
Methodology:	Real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens. Two primary steps: • Extraction of viral RNA from patient specimens • One-step reverse transcription and PCR amplification with SARS-CoV-2 specific primers & real-time detection SARS-CoV-2 specific probes for the N gene of the SARS-CoV-2 viral RNA and the human RNase P (RP) gene.
Analytical Sensitivity:	2.6 copies per µl specimen
Disclaimer Statement:	The SARS-CoV-2 (N gene detection) Test is a real-time RT-PCR assay intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasal, nasopharyngeal, and oropharyngeal swab specimens, from individuals suspected of COVID-19 by a healthcare professional. Testing is limited to Exact Sciences Laboratories, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. 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 Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. This assay is intended for use under the Food and Drug Administration's Emergency Use Authorization.
Aliases	COVID-19, nCoV-2019