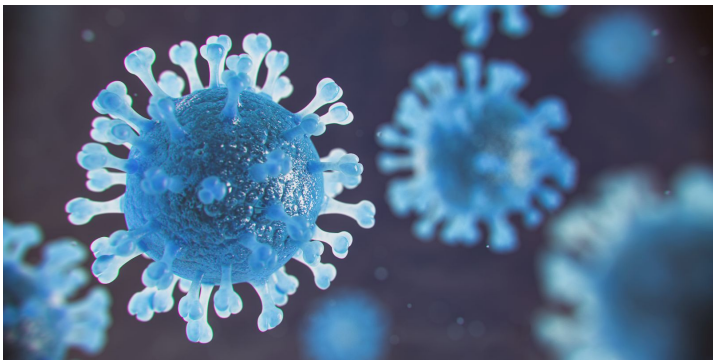
iCubate®

iC-COVID19 Assay™



The *iC-COVID19 Assay* is a multiplexed, *in vitro* diagnostic test for the qualitative detection of RNA from the SARS-CoV-2 virus.

Regulatory status and history

iCubate has submitted the *iC-COVID19 Assay* to the FDA for Emergency Use Authorization for the detection of the virus that causes COVID19. iCubate's submission (FDA Reference no. EUA200687) is currently pending with the FDA.

The iC-System™ has previously earned two 510k FDA clearances for the iC-GPC Assay™ (FDA Reference no. K163390) and the iC-GN Assay™ (FDA Reference no. K190341). These assays rapidly detect and identify potentially pathogenic gram positive bacteria and gram negative bacteria, respectively, for the detection of bacteria associated with blood stream infection associated with sepsis. Additionally, the FDA has designated iCubate's iC-Myco Assay™ (FDA Reference no. Q191070) a "Breakthrough Device" for the detection and identification of potentially pathogenic non-tuberculosis Mycobacterium, a major cause of pulmonary infections.

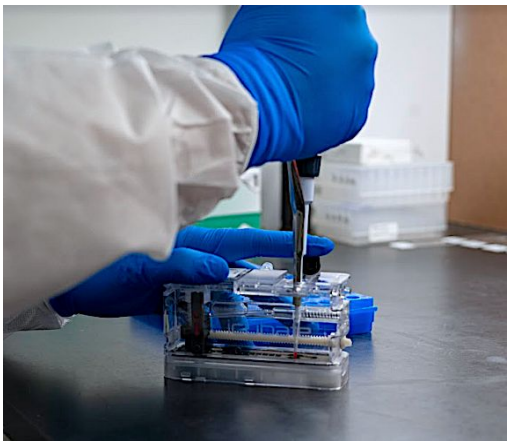
Intended use

The *iC-COVID19 Assay's* intended use is for the qualitative detection of RNA from SARS-CoV-2 in nasopharyngeal, nasal or mid-turbinate nasal swabs from patients with signs and symptoms of infection who are suspected to have COVID19. The *iC-COVID19 Assay* targets two conserved SARS-CoV-2 genes: S (spike protein) gene, and ORF1ab (open reading frame) gene.

With less than 5 minutes of hands-on time, the *iC-COVID19 Assay* minimizes the potential of hazardous exposure of laboratory personnel to SARS-CoV-2 or other microorganisms. The *iC-COVID19 Assay* is for use by clinical laboratory personnel instructed and trained in the techniques of biological sample handling and iCubate procedures. The *iC-COVID19 Assay* is currently for prescription use only. Testing must be performed in laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) regulations to perform high or moderate complexity tests. Positive results should also be reported in accordance with local, state, and federal regulations. Laboratories within the U.S. are required to report all positive results to the appropriate public health authorities.

Overview of *iC-COVID19 Assay*™ and Testing Process

Each *iC-COVID19 Assay* is performed in a single-use, closed, disposable cassette that is pre-loaded with the reagents necessary to isolate, amplify, and detect target nucleic acids from a single patient sample.



A nasopharyngeal, nasal, or mid-turbinate nasal swab should be collected according to standard procedures into transport media. Using routine laboratory procedures, the patient sample is prepared and loaded into the *iC-COVID19 Assay* cassette. The cassette is then closed and linked to the iC-System™ using a handheld barcode scanner.

After the *iC-COVID19 Assay* cassette is linked, it is inserted into the iC-Processor®, which automates nucleic acid extraction; reverse transcription polymerase chain reaction (RT-PCR); proprietary amplicon rescued multiplex polymerase chain reaction (ARM-PCR); and hybridization onto the microarray. These processes are defined by a processing script, identified by a barcode label on the top of each *iC-COVID19 Assay* cassette.

After processing is complete, the *iC-COVID19 Assay* cassette automatically ejects from the iC-Processor and is loaded into the iC-Reader™ for fluorescence-based detection and data analysis. To maximize efficiency for laboratory personnel, the *iC-COVID19 Assay* cassettes can be read up to 12 hours after processing is complete.

The data collected by the iC-Reader is automatically transferred to the iC-System software on the iC-System computer. A final report is generated providing a qualitative result clearly indicating if COVID19 is "Detected" or "Not Detected." The results are analyzed and interpreted using iCubate's proprietary software and a Final Report is generated in ~5 minutes. Using the *iC-COVID19 Assay*, a result can be generated in less than 6 hours from the time of sample collection.

The modular design of the iCubate system accommodates laboratories of various size and throughput requirements. Each iC-Processor can run up to four tests simultaneously with random access. Up to eight iC-Processors can be connected to a single iC-Reader to allow up to 32 tests to be run on a single iC-System.

Performance data

Limit of Detection (LoD)-Analytical Sensitivity

Validation studies were performed to determine the limit of detection of the *iC-COVID19 Assay*™, defined as the lowest concentration of analyte that can be detected 95% of the time. The final *iC-COVID19 Assay* LoD was determined to be 180 copies/mL.

Commitment to quality

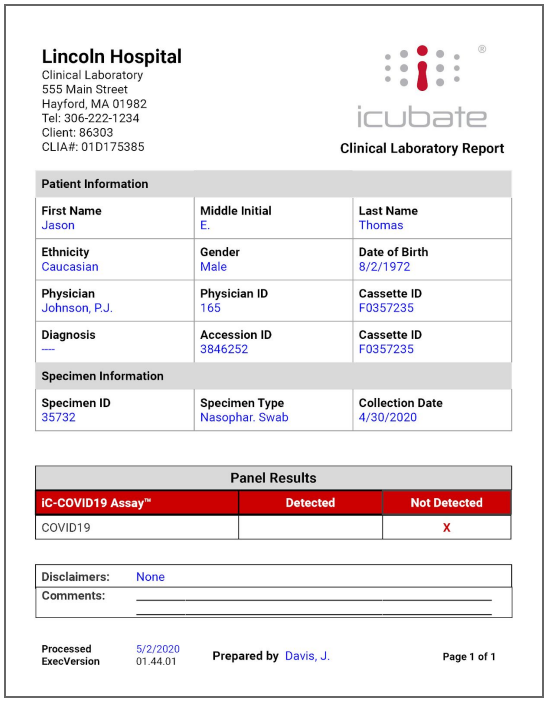
iCubate has taken every measure to ensure the quality of the *iC-COVID19 Assay*. An internal positive control is included in all steps of *iC-COVID19 Assay* processing. Failure of the positive control may indicate the presence of PCR inhibitors, degradation of reagents or processing failures.

Manufacturing

iCubate's portfolio of products, including *the iC-COVID19 Assay,* is manufactured at iCubate's main operational site (FDA Registration#: 3009506385) by iCubate personnel consistent with practices for the production of *in vitro* diagnostic devices based on 21 CFR 820 Quality System Regulation requirements. The *iC-COVID19 Assay* cassette manufacturing process is similar to the validated processes for the manufacture of the iC-GPC Assay™ (K166390) and iC-GN Assay™ (K190341).

Clearly-defined results

The image to the right is an *iC-COVID19 Assay*™ sample report.



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Clinical Laboratory
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Hayford, MA 01982
Tel: 306-222-1234
Client: 86303
CLIA#: 01D175385

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Clinical Laboratory Report

Patient Information		
First Name Jason	**Middle Initial** E.	**Last Name** Thomas
Ethnicity Caucasian	**Gender** Male	**Date of Birth** 8/2/1972
Physician Johnson, P.J.	**Physician ID** 165	**Cassette ID** F0357235
Diagnosis ---	**Accession ID** 3846252	**Cassette ID** F0357235
Specimen Information		
Specimen ID 35732	**Specimen Type** Nasophar. Swab	**Collection Date** 4/30/2020

Panel Results		
iC-COVID19 Assay™	**Detected**	**Not Detected**
COVID19		X

Disclaimers:	None
Comments:	

Processed 5/2/2020
ExecVersion 01.44.01

Prepared by Davis, J.

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For more information on the *iC-COVID19 Assay* or other iCubate products, visit iCubate.com or call 855-256-3330.

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