



**INTERNATIONAL, INC.**  
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## Frequently Asked Questions Smart *Detect*<sup>™</sup> SARS-CoV-2 rRT-PCR Kit

### **Regulatory Status:**

InBios received an EUA for for the Smart *Detect*<sup>™</sup> SARS-CoV-2 rRT-PCR Kit on April 7, 2020

**What is the EUA number for this kit?** EUA 200180.

**What is the GMDN code for this kit?** 64747

### **How does the assay work?**

The Smart *Detect*<sup>™</sup> SARS-CoV-2 rRT-PCR Kit is a real-time reverse transcription polymerase chain reaction (rRT-PCR) assay designed to qualitatively detect RNA from SARS-CoV-2 in respiratory specimens from individuals with signs and symptoms of infection who are suspected of COVID-19

### **What type of sample collection kit is needed to use with this kit?**

Any sample collection kit capable of collecting human nasopharyngeal swab, anterior nasal swab and mid-turbinate nasal swab specimens in universal transport medium is acceptable.

### **Does InBios supply sample collection kits?**

No.

**What is the quantity per kit?** 48 reactions that yield 45 unknown specimen tests.

**What is the storage of the kit?** -20°C or below.

**What is the shelf life of the kit?** 12 months.

### **Where can the test be performed?**

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

### **Where is the test manufactured?**

The test is manufactured in the InBios facility located at 307 Westlake Ave. N., #300, Seattle, WA 98109 USA

### **How long does the test take to run including sample preparation, extraction, and data analysis?**

Approximately 4 hours

### **What instruments are validated with the kit?**

- 7500 Fast Dx Real-Time PCR Instrument (Applied Biosystems) with Sequence Detection System (SDS) Software, version 1.4 (Applied Biosystems)
- CFX96 Touch Real-Time PCR Detection System (Bio-Rad) with CFX Maestro Software (Bio-Rad)



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**Can other PCR instruments be used with the kit?**

Yes, under proper validation. We are currently exploring and continuing to validate the Smart *Detect*<sup>™</sup> SARS-CoV-2 rRT-PCR Kit on other instruments and will update this list as completed.

Note: The Smart *Detect* SARS-CoV-2 rRT-PCR Kit is a multiplex assay with 4 targets. Any PCR instrument being considered for use, other than the currently validated instruments, should be equipped with at least 4 separate fluorescent detection channels capable of detecting the following 4 reporter dyes:

Assay target	Reporter dye	Absorbance peak (nm)	Emission peak (nm)
Orf1b	FAM	495	520
E	TEX 615	596	613
N	Cy 5	648	668
RNaseP	HEX	538	555

**What extraction kits are compatible?**

- QIAamp Viral RNA Mini Kit (QIAGEN, catalog # 52904 or 52906)

**Can you supply the master mix reagent?**

Yes. If you are unable to source the master mix, InBios can supply an InBios Master Mix kit.

**What other master mix brands can be used with your kit?**

Currently there are three choices for master mix:

rRT-PCR Master Mix	
Item	Vendor, catalog #
<b>InBios Master Mix Kit:</b> Master Mix Component A, 201011 Master Mix Component B, 201012 Master Mix Component C, 201013	MMK-1
Luna <sup>®</sup> Probe One-Step Reaction Mix (No ROX) (2X)	New England BioLabs, E3007E
Luna <sup>®</sup> WarmStart <sup>®</sup> RT Enzyme Mix (20X)	
TaqPath <sup>™</sup> 1-Step RT-qPCR Master Mix, CG	Life Technologies, A15299 and/or A15300



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### What is the LOD of the InBios Kit?

	<b>7500 Fast Dx Real-Time PCR Instrument</b>	<b>CFX96 Touch Real-Time PCR</b>
<b>Per reaction</b>	12.5 GE	10 GE
<b>Per ml specimen</b>	1100 GE	860 GE

Note: GE = Genomic Equivalents

Genome Equivalents (GE) = viral copies