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Frequently Asked Questions Smart *Detect*[™] SARS-CoV-2 rRT-PCR Kit

Regulatory Status:

InBios received an EUA for for the Smart *Detect*[™] 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*[™] 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)
- CFX384 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*[™] 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)
- MagMAX Viral/Pathogen II (MVP II) Nucleic Acid Isolation Kit (Applied Biosystems, catalog #A48383)

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



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What is the Limit of Detection (LOD) of the InBios Kit?

The limit of detection may vary based on PCR instrument, RNA extraction method, and Master Mix used.

Below is a selected summary of LODs of the Smart *Detect*[™] SARS-CoV-2 rRT-PCR Kit.

All below LODs were determined using the TaqPath[™] 1-Step RT-qPCR Master Mix.

	7500 Fast Dx Real-Time PCR Instrument*	CFX96 Touch Real-Time PCR*	CFX384 Touch Real-Time PCR**
Per reaction	12.5 GE	10 GE	10 GE
Per ml specimen	1100 GE	860 GE	250GE

*LOD was determined using QIAamp Viral RNA Mini Kit with 140µL specimen input volume

**LOD was determined using Hamilton MagEx Star with MagMAX[™] Viral/Pathogen II Nucleic Acid Isolation Kit and 400µL specimen input volume

GE ~ viral copies