

Testing Supply Substitution Strategies

This resource is intended for labs performing COVID-19 tests that are authorized. This resource includes validated supply alternatives that labs can use to continue performing testing when there is a supply issue with some components of a test.

The information in this resource is not intended to alter any already issued EUA for a COVID-19 diagnostic test nor is it intended to speak to any specific FDA regulatory requirement. Rather, the information is being provided to help address availability concerns regarding certain critical components of COVID-19 diagnostic tests during this pandemic.



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Real-time RT Polymerase Chain Reaction (PCR) Component Substitution Strategies



Select a button to learn more about a topic



Learn about RT-PCR: what it is and what it's used for

Compare use of Open Mix and Match Systems vs. Closed Systems, including instruments, supplies, and reagents

PCR Testing Process

Intro to PCR

System Types

Learn about the steps in the PCR testing process

Substitution Options

Learn about substitution options for the Open Mix and Match style CDC test



Additional Resources

Specimen Collection

Specimen collection is the process of obtaining a sample from a patient, usually by swabbing the nose or mouth, then placing the swab in a tube that is commonly filled with liquid (media) which maintains the sample for transport to the lab.

Originally, specimen collection for SARS-CoV-2 testing required a specialized Nasopharyngeal (NP) swab and Viral Transport Media (VTM)/ Universal Transport Media (UTM).

Options for swabs and media are below.



Explore acceptable choices for swabs

Explore acceptable choices for media

For more information please see the <u>FDA FAQ on this topic</u> under, "What if I Do Not Have...?" It is important that the swab type be appropriate for the anatomic site on which it is used, i.e. only a Nasopharyngeal swab should be used to obtain a Nasopharyngeal specimen."



Additional Resources

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Specimen Collection: Swabs



Choices for Swabs*				
N aso P haryngeal (NP) Swab	O ro P haryngeal (OP) Swab	 Mid-Turbinate (MT) Swab Flocked, tapered swab 	Anterior Nares ("Nasal") Swab • Round Foam • Spun Polyester	



Return to Specimen Collection

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* For more information please see the <u>FDA FAQ on this topic</u> under, "What if I Do Not Have...?" It is important that the swab be appropriate for the anatomic site on which it is used, and that the swab type (e.g. polyester vs rayon) is compatible with that platform. Rayon swabs may not be compatible with all molecular testing platforms. Analytical testing should be performed to confirm compatibility with individual platforms.

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Specimen Collection: Media

Choices for Media					
VTM/UTM	Liquid Amies- based Media • e.g., Eswab	Nucleic Acid Transport Media • e.g., Primestore MTM*	 Saline Solution Normal saline Phosphate- buffered saline (PBS) 		

Some transport media may contain guanidine thiocyanate, which produces a dangerous chemical reaction releasing cyanide gas when exposed to bleach (sodium hypochlorite). These media may not be compatible with in vitro diagnostic products that do not utilize guanidine thiocyanate during sample processing.

*WARNING: Do not use PrimeStore MTM with the Hologic Panther or Panther Fusion Systems due to a disinfecting step involving bleach that is specific to the platform. When the bleach interacts with the guanidine thiocyanate in the transport media, it produces dangerous cyanide gas.

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What Is RT PCR?



RT-PCR stands for "Reverse-transcriptase polymerase chain reaction" (commonly referred to as "PCR")

RT-PCR is a method used to detect RNA nucleic acids (a type of genetic material)

- PCR is used to detect the presence of SARS-CoV-2, the virus that causes COVID-19 disease
- Finding SARS-CoV-2 genetic material in a specimen indicates that a person has been infected with the virus





Overview of System Types

Select a system type for more information

Closed System



Extraction and Amplification

Open Mix and Match





Extraction



Amplification

Additional Resources

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Closed System



Instruments

A single dedicated instrument performs extraction and amplification



Extraction and PCR System

Supplies and Reagents

Some materials may be specific to the instrument platform



Proprietary Reagent Kit



Collection and Media



Proprietary Reagent Cartridge



General Reagents

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Open Mix and Match (CDC Design)

Instruments

Extraction and amplification performed separately



Extraction System



Supplies and Reagents

Some materials may be usable on more than one system



Primers and Probes



Collection and Media



Master Mix



General Reagents

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PCR Testing Process



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2. RNA Nucleic Acid Extraction



4. Results Reporting



INPUT FOR THIS STEP? A sample from the patient to test for the presence of SARS-CoV-2

WHAT SUPPLIES ARE NEEDED?

A <u>swab</u> to collect the sample.

Transport Media in a collection tube to transport the sample without degradation. The swab carrying the sample is placed in a collection tube filled with transport media.

WHAT IS THE OUTCOME? A sample for PCR analysis

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4. Results Reporting



INPUT FOR THIS STEP? A sample for PCR analysis

WHAT SUPPLIES ARE NEEDED?

Extraction System

Extraction Reagents

- Lysis Buffer
- RNA Extraction Control
- Human Specimen Control
- Positive Control specific to SARS-CoV-2

WHAT IS THE OUTCOME? Extracted nucleic acids

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1. Collect Specimen from Patient



3. RT-PCR Amplification

4. Results Reporting



INPUT FOR THIS STEP? Extracted nucleic acid

WHAT SUPPLIES ARE NEEDED?

PCR REAGENTS

- PCR buffer
- dNTPs (building blocks of nucleic acids)
- Reverse Transcriptase (RT)
- No Template Control
- Polymerase (Enzyme)
- Positive Control (specific to SARS-CoV-2)
- Primers and Probe (SARS-CoV-2 specific)

WHAT IS THE OUTCOME? Fluorescence output signal indicating presence of SARS-CoV-2 RNA

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1. Collect Specimen from Patient



3. RT-PCR Amplification

4. Results Reporting



INPUT FOR THIS STEP?

Fluorescence output signal

WHAT IS THE OUTCOME? Report of output indicating presence of SARS-CoV-2 virus





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Substitution Options*

* Substitution Options are illustrated with the CDC test for this tool. Labs can identify and validate alternative options to other authorized assays.

Select a Test Component on the left to explore possible substitutions for the Open Mix and Match style CDC molecular test

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The Extraction system is the instrument performing extraction. The Extraction kit contains the reagents for the Extraction process.

Extraction Systems/kits listed in the CDC EUA

- QIAGEN/QIAmp DSP Viral RNA Mini Kit
- QIAGEN/QIAamp Viral RNA Mini Kit
- QIAGEN EZ1 Advanced XL/EZ1 DSP Virus Kit, Buffer AVL
- QIAGEN EZ1 Advanced XL/EZ1 Virus Mini Kit v2.0, Buffer AVL

Acceptable Alternatives (per FDA FAQ*)

- ✓ QIAGEN QIAcube/QIAmp DSP Viral RNA Mini Kit
- ✓ QIAGEN QIAcube/ QIAamp Viral RNA Mini Kit
- ✓ Roche MagNA Pure LC/Total Nucleic Acid Kit
- ✓ Roche MagNA Pure Compact/Nucleic Acid Isolation Kit I
- ✓ Roche MagNA Pure 96/DNA and Viral RNA Small
- ✓ bioMérieux NucliSENS easyMAG/EasyMAG Extraction
- ✓ Beckman RNAdvance Viral XP extraction kit

- ✓ bioMérieux EMAG/EasyMAG Extraction Reagents, EMAG 1000µL Tips
- ✓ KingFisher Flex/Omega Bio-Tek Mag-Bind Viral DNA/RNA 96 Kit
- ✓ Applied Biosciences MagMAX Express/Viral/Pathogen Ultra Nucleic Acid Isolation Kit
- ✓ Promega Maxwell RSC 48/Maxwell RSC Viral Total Nucleic Acid Purification Kit

* Check FDA FAQ for updates after 6/3/2020

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Additional Resources

- FDA Frequently Asked Questions on Diagnostic Testing for SARS-CoV-2
- <u>CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR</u> <u>Diagnostic Panel</u>

