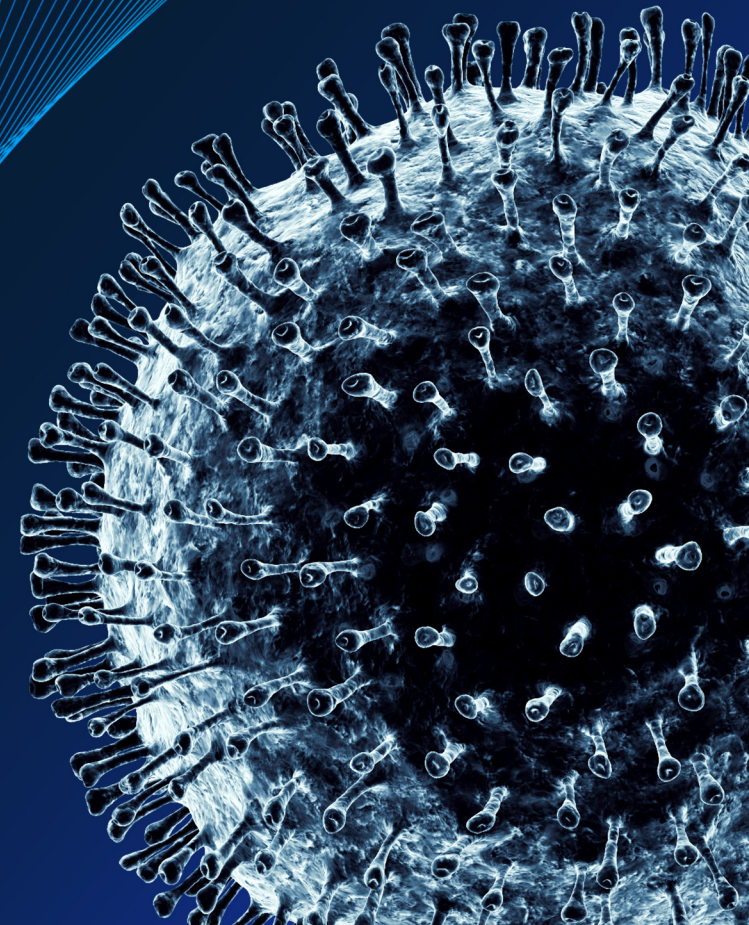


# COVID-19 Diagnostic Technology Fact Pack

May 15, 2020

DOCUMENT INTENDED TO PROVIDE INSIGHT BASED ON CURRENTLY  
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## **COVID-19 is, first and foremost, a humanitarian challenge**

Thousands of health professionals are heroically battling the virus, putting their own lives at risk. Governments and industry are working together to understand and address the challenge, support victims and their families and communities, and search for treatments and a vaccine.

## **Solving the humanitarian challenge is the top priority**

Globally, much remains to be done to prepare, respond, and recover, from protecting at-risk populations to supporting affected communities to developing a vaccine. To address this crisis, responses must be informed by evidence and based on partnership among various stakeholders and sectors, including but not limited to the medical product industry and regulatory and compliance agencies.

# Disclaimer

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CURRENT AS OF MAY 15, 2020

These materials are preliminary, non-exhaustive, and are being made available on a non-exclusive basis solely for information purposes in response to the urgent need for measures to address the COVID-19 crisis. They reflect general insight and may present potential options for consideration based on currently available information, which is inherently uncertain and subject to change, but do not contain all of the information needed to determine a future course of action. The insights and concepts included in these materials have not been validated or independently verified. References to specific products or organizations are solely for illustration and do not constitute any endorsement or recommendation.

These materials do not constitute, and should not be interpreted as, policy, accounting, legal, medical, tax or other regulated advice, or a recommendation for any specific course of action. These materials are not a guarantee of results and cannot be relied upon. Future results may differ materially from any statements of expectation, forecasts, or projections. Particularly in light of rapidly evolving conditions, these materials are provided “as is” without any representation or warranty, and all liability is expressly disclaimed for any loss or damage of any kind. The recipient is solely responsible for all of its decisions, use of these materials, and compliance with applicable laws, rules and regulations. Consider seeking advice of legal and other relevant certified/licensed experts prior to taking any specific steps.

# Scope of this document

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CURRENT AS OF MAY 15, 2020



Fact pack on the current supply  
landscape of COVID-19 tests

High-level summary of the various  
technologies currently being  
deployed for COVID-19 testing

Summary of high-level levers  
to consider to increase supply  
of testing materials



Comprehensive list of all  
COVID-19 testing options

Recommendations on how  
to expand COVID-19 testing

Comprehensive supplier list

Endorsement of testing  
technologies or suppliers

# Broadly, COVID-19 can be screened or diagnosed via 3 techniques

CURRENT AS OF MAY 15, 2020

■ Focus of this document

Techniques	Molecular assays		Immunoassays	Clinical diagnosis
Testing for...	Viral RNA	Viral protein (antigen)	IgG/IgM (antibodies) from immune response	Mix of symptom, CT scan, and blood test
Detection window	Can be as soon as infection starts, but viral load decreases after 20 days		Concentration peaks a few days after infection for IgM, a few weeks for IgG	Typically, two weeks after infection
Common sample type	Nose or throat swab Sputum specimen	Nose or throat swab Sputum specimen	Blood/plasma	Blood
Key considerations	Gold standard for diagnostic testing	Rapid screening for recent or active infection given fast turnaround and low cost		63% of patients with COVID-19 also saw lymphopenia and 55% with dyspnea <sup>1</sup>

1. Huang C, et al. Lancet (2020)



# There are multiple types of COVID-19 tests commercialized or under development

CURRENT AS OF MAY 15, 2020

Commercialized, with deep dives to follow Under development

Test type	Technology	Test location <sup>1</sup>	Description	Typical sample collection method	Typical turnaround time
<b>Molecular assay tests</b> Detection of viral genetic materials, ie, RNA	<b>1 RT-PCR:</b> reverse transcription polymerase chain reaction	<b>1a</b> Lab-based	Typically consists of three steps: Sample preparation and extraction of virus RNA Synthesis of complementary DNA (cDNA) via reverse transcription	Nasopharyngeal (NP) and Oropharyngeal (OP) swab specimens  Sputum collection cups	Hours to days
		<b>1b</b> Near POC / POC	Amplification of cDNA and attachment of probe, causing fluorescence if virus is detected		< 1h
	<b>2 Isothermal amplification</b>	Near POC / POC	Viral RNA is amplified isothermally and identified visually via enhanced fluorescence; the reaction can be performed with a relatively fast turnaround		~15 mins
	<b>CRISPR</b>	Near POC / POC	Uses CRISPR protein to detect viral RNA presence after isothermal amplification		< 1h
<b>Immunoassay tests</b> Detection of antigens or antibodies	<b>3 Labeled immunoassays</b>	<b>3a</b> Lab-based	Uses antigen-antibody interaction to capture and visualize the substance of interest (antibody or antigen)  Labels can then either be fluorescent (ELISA, enzyme-linked immunosorbent assay) or chemiluminescent (chemiluminescence immunoassay)	Blood sample (antibody) NP/OP swab (antigen) <sup>2</sup>	Hours
		<b>3b</b> POC	Some tests may use lateral flow strips for visualization in addition to other equipment	Blood (antibody) NP/OP swab (antigen)	<1 hr
	<b>4 Lateral flow immuno-chromatographic assays</b>	POC / self-administered	Antibody: antigen coated on a membrane within a test stick/paper is used to detect the COVID-19 antibody. Nanoparticles then bind to antibodies to provide a positive or negative indication  Antigen: similar principle, targeting viral proteins from COVID-19	Blood Serum/plasma sample  NP/OP swab	~15 mins

1.Lab-based: conducted in a specialized lab that requires skilled technician; POC: point of care, can be done in a convenient location with less-trained personnel, sometimes by using portable, specialized equipment; self-administered: no need for special instrument and can be run anywhere

2.Some antigen tests could use blood samples

Source: <https://www.finddx.org/covid-19/pipeline/>, FDA EUAs in diagnostics

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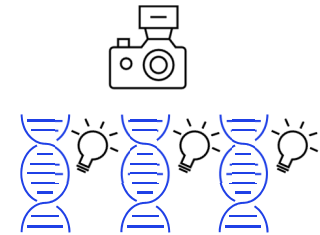
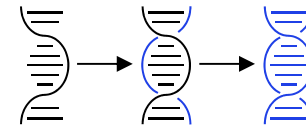
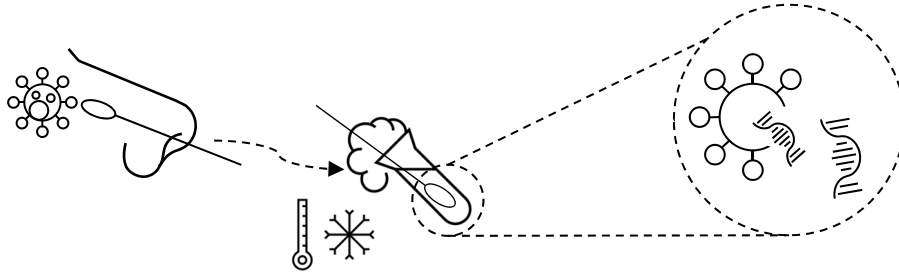
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# 1a: Lab-based RT-PCR testing:

## The testing process consists of 4 key steps

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### Illustration of the process



Typical steps	Sample collection and transportation	Sample preparation and RNA extraction	RNA reverse transcription	cDNA amplification and readout
<b>Description</b>	<p>Upper respiratory tract specimens are collected as nasopharyngeal and/or oropharyngeal swabs, stored in collection tubes with viral transport medium and sealed in biohazardous bags to be safely transported under refrigerated condition for further analysis</p> <p>In some cases, other sample collection methods such as sputum specimens are also used</p>	<p>Upon arrival at the lab, sample preparation is performed on the collected specimen by lysing the virus and extracting/purifying RNA within</p>	<p>Purified RNA is then reverse transcribed into cDNA with the help of reverse transcriptase; this step can sometimes be combined with amplification as a one-step reaction</p>	<p>cDNA is then amplified through PCR (requiring thermal cycling), using primers designed to target sequences specific to SARS-COV-2</p> <p>Probes tagged with fluorescent labels will illuminate upon embedding into the amplified cDNA region and will signify the presence of viral RNA</p>
<b>Common performance questions (not exhaustive)</b>	<p>Was the sample collection technique or procedure properly followed to avoid false negatives?</p>	<p>Were the laboratory hygiene best practices followed so as to avoid false positives from contamination?</p>	<p>Were the procedures adhered to maintain test accuracy and avoid potential cross-contamination (especially for the open systems)?</p>	

# 1a: Lab-based RT-PCR testing: Related supplies for each step

## Journey, Supplies, Manufacturers

CURRENT AS OF MAY 15, 2020

Used to illustrate supplies shared across steps

Non-exhaustive—for more detailed lists, please contact us by filling out [this online request form](#)



Steps	Sample collection and transportation	Sample preparation and RNA extraction	RNA reverse transcription	cDNA amplification and readout
Equipment (automated)		RNA extraction system Integrated lab automation system, combining both nucleic acid purification and RT-PCR	Real-time PCR system	
Equipment (manual)		Micro-pipettors Vortex mixer	Microplate shaker Incubator	Microcentrifuge
Key consumables / materials / reagents	Swab kits, or as the following individual components: Swabs Viral transport medium Collection tubes Biohazardous bag	RNA isolation kit (Proteinase K, buffer, either with beads or spin column)  Multi-well plates (ie, 96 wells) and adhesive film Nuclease-free water Surface decontaminants	Primer and probe kit RT-PCR reagent kit or master mix (buffer, dNTPs, passive reference dye, DNA polymerase, reverse transcriptase, etc) Human specimen control (HSC) (obtained from IRR1) EUA positive control (obtained from IRR)  RNase-free microfuge tubes Reagent reservoirs	Ethanol Filtered pipette tips

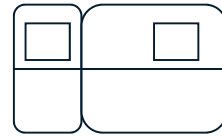
1. IRR: International Reagent Resource <https://www.internationalreagentresource.org/About/IRR.aspx>



# 1a: Lab-based RT-PCR testing: Broadly, there are two categories of testing supplies

CURRENT AS OF MAY 15, 2020

Deep dive to follow

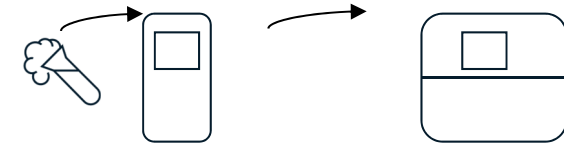


## Type of supplies

## Description

### A Test kits

Integrated systems provide end-to-end solutions covering all steps in RT-PCR tests, with specialized consumables



### B Primers and probes that can be matched with enzymes

Primers/probes and enzymes can be sourced separately and then used together for testing

Examples of primers and probes:

Biosearch Technologies (2019-nCoV CDC Probe and Primer Kit for SARS-CoV-2)

IDT (2019-nCoV Kit)

Examples of enzymes:

Thermo Fisher (TaqPath 1-Step RT-qPCR Master Mix, CG)

# 1a: Lab-based RT-PCR testing: Examples of COVID-19 test kits currently available

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists, please contact us by filling out [this online request form](#)

Examples of manufacturers	Test	Reactivity	Cross-reactivity	Limit of detection
<b>Roche</b>	Cobas® SARS-CoV-2 (for use on Cobas 6800/8800 Systems)	100% match	None for 43 microorganisms	0.009 TCID <sub>50</sub> /mL
<b>Thermo Fisher</b>	TaqPath COVID-19 Combo Kit (USA FDA-EUA)	100% match	None for 43 microorganisms	10 GCE/reaction
<b>Qiagen</b>	QIAstat-Dx® Respiratory SARS-CoV-2	No info	None for any clinically relevant pathogens	500 copies/mL
<b>bioMérieux</b>	SARS-COV-2 R-GENE® (manual & automated lab-based)	No info	No info	No info
<b>Abbott</b>	Abbott RealTime SARS-CoV-2 EUA test	100% match	None for 31 microorganisms	100 copies/mL
<b>Hologic</b>	Panther Fusion SARS-CoV-2 assay	100% match	No info	0.01 TCID <sub>50</sub> /mL

Some of these tests may be compatible with open systems as well

References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

Source: Manufacturers' websites: [Roche](#), [Thermo Fisher](#), [Qiagen](#), [bioMérieux](#), [Abbott](#), [Hologic](#); [FDA EUAs in diagnostics](#)

Document intended to provide insight based on currently available information for consideration and not specific advice

# 1a: Lab-based RT-PCR testing: COVID-19 test kits have different degrees of compatibility across RT-PCR platforms

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists, please contact us by filling out [this online request form](#)

Examples of manufacturers	RT-PCR instrument/system	Companies with compatible tests
Thermo Fisher	Applied Biosystems 7500/7900	Thermo Fisher, AB Analytica, BGI, CerTest Biotec, Perkin Elmer, Primer Design, Quidel, Life River, SD Biosensor, Ingenetix
	Applied Biosystems QuantStudio	Thermo Fisher, Genetic Signatures, Ingenetix
Roche	cobas 6800/8800	Roche
	LightCycler 480	Thermo Fisher, AB Analytica, CerTest Biotec, Primer Design, Quidel, SD Biosensor, Ingenetix
Bio-Rad	CFX	Thermo Fisher, AB Analytica, Gene First, Genetic Signatures, CerTest Biotec, Primer Design, Life River, SD Biosensor, Ingenetix
Agilent	AriaDx/Mx	Thermo Fisher, AB Analytica, CerTest Biotec, Primer Design, Ingenetix
Sansure	Slan 96P	Thermo Fisher, Gene First, Life River
Abbott	Abbott m2000rt	Abbott
Qiagen	Rotor-Gene Q	Qiagen, CerTest Biotec, Life River, Ingenetix

## Specific considerations for US:

Most EUAs (Emergency Use Authorization) given by the FDA apply to a specific combination of a test kit and a platform

While it might be possible to use test kits with a variety of equipment, different combinations may be considered LDT (laboratory developed test) and may require additional validation steps.

These restrictions may or may not apply in other countries

Source: Manufacturers' website or specification sheets filed with the FDA: [AB analytica](#), [Thermo Fisher](#), [Roche](#), [Sansure](#), [Qiagen](#), [Perkin-Elmer](#), [Quidel](#), [Primer Design](#), [Gene First](#), [LifeRiver](#), [BGI](#), [Ingenetix](#), [CerTest Biotec](#), [SD Biosensor](#), [Genetic Signatures](#), [Abbott](#), [Bio-Rad](#), [Qiagen](#), [Rotor Gene Q \(Qiagen\)](#), [Agilent](#), [FDA EUAs in diagnostics](#)

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# 1a: RT-PCR / traditional lab-based: Examples of manufacturers for generic components used for COVID-19 testing (1/2)

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists, please contact us by filling out [this online request form](#)

Steps	Supplies	Examples of manufacturers (product name)
Sample collection and transportation	NP/OP <sup>1</sup> swabs	Copan (FLOQSwabs) Puritan Medical Products (HydraFlock)
	Universal/viral transport mediums <sup>2</sup>	Copan, BD
Sample preparation	RNA isolation kits	Qiagen (QIAmp DSP Viral RNA Mini Kit, EZ1 Advanced XL with EZ1 DSP Virus Kit, QIAcube with QIAmp DSP Viral RNA Mini Kit) Roche (MagNA Pure LC with Total Nucleic Acid Kit, MagNA Pure Compact with Nucleic Acid Isolation Kit I, MagNA Pure 96 with DNA and Viral NA Small Volume Kit)
Reverse transcription, amplification, and readout	RT-PCR reagent kits	Thermo Fisher (TaqPath 1-Step RT-qPCR Master Mix, CG)

Local companies are starting to produce swabs to meet demand, but there could be potential IP challenges

References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

1. NP/OP: nasopharyngeal/oropharyngeal 2. Can be manufactured by laboratories using approved methods

Source: [FDA website](#), Manufacturer websites: [Puritan](#), [Copan](#), [BD](#), [Qiagen](#), [Roche](#), [Thermo Fisher](#)

Document intended to provide insight based on currently available information for consideration and not specific advice

# 1a: RT-PCR / traditional lab-based: Examples of manufacturers for generic components used for COVID-19 testing (2/2)

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists , please contact us by filling out [this online request form](#)

Steps	Supplies	Examples of manufacturers (product name)
<b>Specific lab equipment</b>	RNA extraction	Thermo Fisher Scientific (KingFisher Flex) Abbott (Abbott m2000sp) Qiagen (QIAcube Connect)
<b>Common lab equipment</b>	Micro-pipettors Vortex mixer Microplate shaker Incubator	Avantor <sup>1</sup> Thermo Fisher Scientific <sup>1</sup>
<b>Common lab consumables</b>	Multi well plates and adhesive film Nuclease-free water RNase-free microfuge tubes Reagent reservoirs Ethanol, 100% Pipette tips Surface decontaminants	Avantor <sup>1</sup> Thermo Fisher Scientific <sup>1</sup>

References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

1. Generic equipment and consumables with code numbers depending on manufacturer

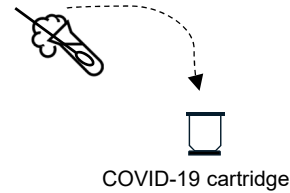
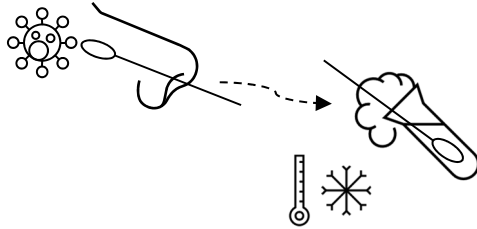
Source: FDA EUAs in diagnostics, Manufacturers' websites: [Thermo Fisher](#), [Abbott](#), [Qiagen](#), [Avantor](#)

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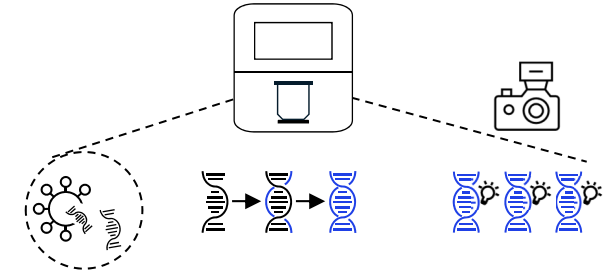
# 1b: Point of care (POC) RT-PCR testing: The testing process consists of 3 key steps

CURRENT AS OF MAY 15, 2020

## Illustration of the process



COVID-19 cartridge



Typical steps	Sample collection and transportation	Sample is directly pipetted into test cartridge	Cartridge is placed inside POC system, test result is directly obtained in < 1 hr
<b>Description</b>	<p>Upper respiratory tract specimens are collected as nasopharyngeal and/or oropharyngeal swabs, stored in collection tubes with viral transport medium and sealed in biohazardous bags to be safely transported under refrigerated condition for further analysis</p> <p>In some cases, other sample-collection methods, such as sputum specimens, are also used</p>	<p>Sample is directly pipetted into proprietary test cartridge. Cartridge contains all needed reagents<sup>1</sup></p>	<p>Cartridge is placed inside near POC or true POC testing system: all required steps take place within cartridge</p> <ul style="list-style-type: none"> <li>sample preparation and RNA extraction</li> <li>RNA reverse transcription</li> <li>cDNA amplification with PCR (requiring thermal cycling) and readout</li> </ul> <p>POC system can run several cartridges at the same time, depending on size of base. Results in &lt;1h</p>
<b>Common performance questions (not exhaustive)</b>	<p>Was the sample collection technique or procedure properly followed to avoid false negatives?</p>	<p>Were the laboratory hygiene best-practices followed so as to avoid false positives from contamination? (Risk is typically lower than in lab-based tests)</p>	

1. Link to YouTube video of 3D animation of a GeneXpert cartridge: <https://www.youtube.com/watch?v=j-y3xi1K7JE>



# 1b: POC RT-PCR testing: Typical supplies required for each step

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists, please contact us by filling out [this online request form](#)

Used to illustrate supplies shared across steps



## Typical steps

Sample collection  
and transportation

One integrated step including sample preparation, RNA extraction, RNA reverse transcription, and cDNA amplification and readout

## Equipment (automated)

Integrated lab automation system, combining both nucleic acid purification and RT-PCR, all taking place in one cartridge

## Equipment (manual)

Typically, no need for specific laboratory equipment

## Key consumables/ materials/reagents

Swab kits, or as the following  
individual components:

Swabs

Viral transport medium

Collection tubes

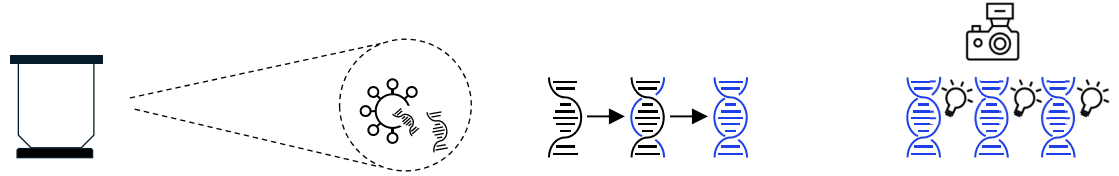
Biohazardous bag

Cartridge test kit

# 1b: POC RT-PCR testing: Examples of manufacturers for integrated systems and cartridges addressing COVID-19 testing<sup>1</sup>

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists , please contact us by filling out [this online request form](#)



All steps completed in one cartridge: RNA extraction + cDNA amplification + detection

Examples of manufacturers	Equipment	Test
<b>Cepheid</b>	GeneXpert Omni (True POC) GeneXpert Infinity 90, Infinity 48, XVI, IV,II (near POC)	Xpert® Xpress SARS-CoV-2
<b>BioFire</b>	BioFire FilmArray EZ Configuration (True POC) BioFire FilmArray Torch	BioFire COVID-19 Test BioFire Respiratory 2.1 (RP2.1) Panel (in development)
<b>GenMark</b>	ePlex system	ePlex SARS-CoV-2
<b>Mesa Biotech</b>	Accula Dock	Accula™ SARS-Cov-2 Test

References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

1. Received EUA (Emergency Use Authorization) by FDA

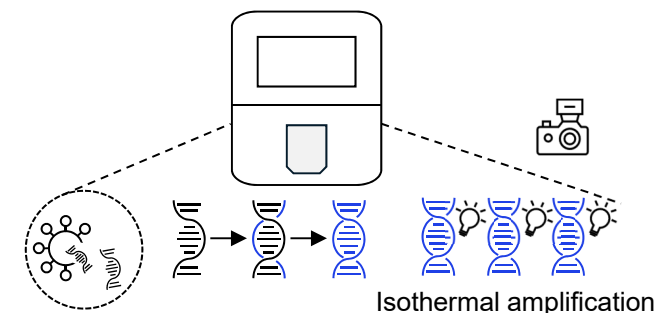
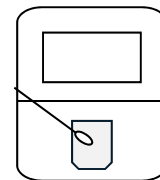
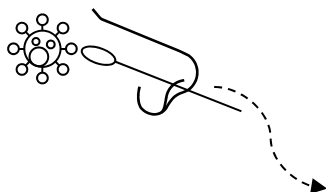
Source: FDA EUAs in diagnostics , Manufacturers' websites: [Cepheid](#), [BioFire](#), [Gen Mark](#), [Mesa Biotech](#)

Document intended to provide insight based on currently available information for consideration and not specific advice

## 2: POC isothermal amplification testing: Three key steps

CURRENT AS OF MAY 15, 2020

### Illustration of the process







Typical steps	Sample collection	Swab is directly placed in cartridge containing lysing solution	Cartridge is placed inside isothermal system containing DNA polymerase and nicking enzymes required for an isothermal amplification of cDNA
<b>Description</b>	Upper respiratory tract specimens are collected as nasopharyngeal and/or oropharyngeal swabs and directly placed in cartridge	Swab is placed directly into proprietary test cartridge. Cartridge contains all needed reagents	Cartridge is placed inside POC system where all steps take place, such as the following: sample preparation and RNA extraction RNA reverse transcription isothermal cDNA amplification using enzyme nicking and readout Results in <15min
<b>Common performance questions (not exhaustive)</b>	Was the sample collection technique or procedure properly followed to avoid false negatives?	Were the laboratory hygiene best-practices followed so as to avoid false positives from contamination? (Risk is typically lower than in lab-based tests)	--

# 2: POC Isothermal testing: Supplies required for each step

CURRENT AS OF MAY 15, 2020

Used to illustrate supplies shared across steps

Non-exhaustive—for more detailed lists , please contact us by filling out [this online request form](#)

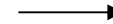
				
Steps	Sample collection	One integrated step that includes sample preparation, RNA extraction, RNA reverse transcription, and cDNA amplification and readout		
Equipment (automated)	Integrated lab automation system, combining both nucleic acid purification and isothermal DNA amplification, all taking place in one cartridge			
Equipment (manual)	Typically, no need for specific laboratory equipment			
Key consumables / materials / reagents	Swab (included in most kits)	Cartridge test kit		

References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

## 2: POC isothermal testing: Examples of manufacturers for integrated systems and cartridges addressing COVID-19 testing

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists, please contact us by filling out [this online request form](#)



**All steps completed in one cartridge: RNA extraction, RNA transcription, and isothermal cDNA amplification**

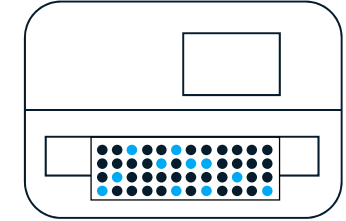
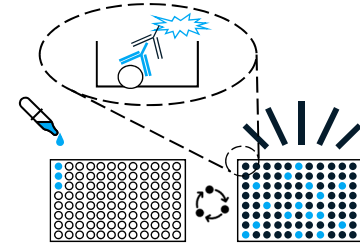
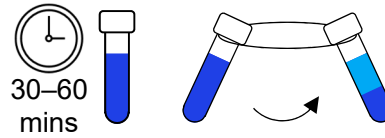
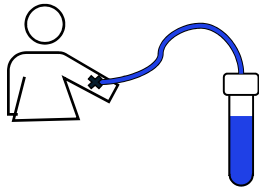
Examples of manufacturers	Equipment	Test	Typical turnaround time
<b>Abbott</b>	Abbott ID NOW	Abbott ID NOW COVID-19 test	5–13 mins
<b>BioTech</b>	(No need for equipment, result can be read by naked eye)	Colorimetric and isothermal detection kit for COVID-19 coronavirus	20 mins
<b>CapitalBio</b>	Rtisochip-W	Respiratory Virus Nucleic Acid Detection Kit	90 mins (for 16 samples against 6 respiratory viruses)
<b>USTAR</b>	EasyNAT	Nucleic Acid Reagent Test Kits for the Novel Coronavirus	30 mins

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# 3a: Lab-based labeled immunoassay: Testing process consists of 4 key steps

CURRENT AS OF MAY 15, 2020

## Illustration of the process



## Typical steps

### Sample collection

### Sample preparation and serum extraction

### Antibody/antigen capturing and labeling

### Read and determine next steps

## Description

Collect patient's whole blood from a peripheral vein and store in serum separator tube (SST)

In some cases, central spinal fluid (CSF) can also be used

For antigen test, other sample types (eg, NP swab sample) can be used

Leave blood to clot by letting it sit for 30–60 minutes and then centrifuge to extract the upper serum

Can freeze at -20 °C if immediate testing is not available; may require cold-chain transport. In most cases sample is analyzed on location (eg, hospital)

Add diluted sample to the COVID-19 antigen-coated plates. Through repetitive steps of adding reagents, incubation and wash, antibody of interest is captured by antigens. The antibodies are then bound to labels to allow for later read out

This step can be done either manually or automated in an integrated system

Measure concentration of the label-antibody complex by using microplate reader, either via colorimetric change (ELISA) or chemiluminescence (CLIA)

## Common performance questions (not exhaustive)


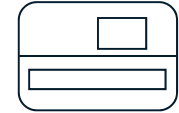
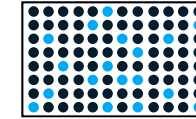
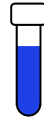
Was the sample collection technique or procedure properly followed to avoid false negatives and cross-contamination?

Were the samples handled properly to avoid false positives due to cross-contamination?



# 3a: Lab-based labeled immunoassays: Typical supplies required for each step

CURRENT AS OF MAY 15, 2020

 Used to illustrate supplies shared across steps


Typical steps	Sample collection	Sample preparation and serum extraction	Antibody capturing and labeling	Read and determine next steps
Equipment (automated)			Automated immunoassay analyzer	
Equipment (manual)		Centrifuge	Repeating dispenser Microplate washing system	Microplate reader
		Pipettes		
Key consumables / materials / reagents	Blood collection kit (butterfly needle, blood collection assembly with male luer lock, arm bank, alcohol pad)  Vacutainer serum separator tubes with self-clotting agent  NP/OP swab, collection tubes, Viral Transport Medium	Plastic freezing vial with a leak-proof screw-cap        Filtered pipette tips	Immunoassay kit (incl. COVID-19 antigen-coated microplate, sample diluent, labeled anti-human antibody, buffer, positive control and negative control)  Reagent reservoirs  Washing buffer	

# 3a: Lab-based labeled immunoassays: Examples of manufacturers for COVID-19 assay kits

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists , please contact us by filling out [this online request form](#)

Examples of manufacturers	Product	Antibody of interest	Test method	Sensitivity	Specificity
<b>Abbott</b>	SARS-CoV-2 IgG (for use on ARCHITECT)	IgG	High throughput ELISA	100%	99.6%
<b>Bio-Rad</b>	Platelia SARS-CoV-2 Total Ab assay	Pan-Ig	High throughput ELISA	92.2%	99.6%
<b>DiaSorin</b>	DiaSorin LIAISON SARS-CoV-2 S1/S2 IgG	IgG	High throughput ELISA	97.6%	99.3%
<b>Roche</b>	Roche Elecsys Anti-SARS-CoV-2	Pan-Ig	High throughput ELISA	100%	99.8%
<b>Bioscience (Chongqing) Biotech Co., Ltd.</b>	COVID-19 IgG antibody diagnostic kit	IgG	CLIA	89.6%	99.2%
	COVID-19 IgM antibody diagnostic kit	IgM	CLIA	93.7%	99.4%
<b>Shenzhen Yhlo Biotech Co. Ltd</b>	iFlash-SARS-CoV-2 IgG	IgG	CLIA	96.3%	97.4%
	iFlash-SARS-CoV-2 IgM	IgM	CLIA	86.6%	98.3%
	EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit	IgG	ELISA	100%	100%
<b>Epitope Diagnostics, Inc.</b>	EDI™ Novel Coronavirus COVID-19 IgM ELISA Kit	IgM	ELISA	45%	97.7%

References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

Source: [FindDx immunoassay test list](#); [FDA EUAs in diagnostics](#), [CFDA](#); Product specifications: [Abbott](#), [Bio-Rad](#), [DiaSorin](#), [Roche](#), [Bioscience](#), [Shenzhen Yhlo Biotech](#), [Epitope](#)

Document intended to provide insight based on currently available information for consideration and not specific advice

# 3a: Lab-based labeled immunoassays: Examples of manufacturers for other generic components required for COVID-19 assays

CURRENT AS OF MAY 15, 2020

Consumables Equipment
Non-exhaustive—for more detailed lists, please contact us by filling out [this online request form](#)

Steps	Supplies	Examples of manufacturers (product name <sup>1</sup> )
Sample collection	Blood collection kit	BD (Vacutainer)
	Butterfly needle	McKesson (Prevent)
	Blood collection assembly with mail luer lock	Wego
	Arm bank	
	Alcohol pad	
	Vacutainer serum separator tubes with self-clotting agent	BD (Vacutainer) Greiner Bio-One (Vacuette)
Sample preparation	NP/OP swab, VTM, collection tubes	Copan Puritan
	Centrifuge	Thermo Fisher (Sorvall, Heraeus), Beckman Coulter (Allegra), Eppendorf (5000 series), BD (Triac)
	Pipettes	Thermo Fisher, Beckman Coulter
	Filtered pipette tips	Eppendorf, BD
	Plastic freezing vial with a leak-proof screw-cap	Sarstedt Inc, MTCBiotech, Labcon
Antibody capturing and labeling	Automated immunoassay analyzer	Grifols (SQII ELISA Analyzer), HUMAN (Elisys), Hamilton (ELISA Nimbus)
	Repeating dispenser	Thermo Fisher, Hamilton, Dymax
	Microplate washing system	Thermo Fisher, Molecular Devices, Biotek
	Reagent reservoirs	Thermo Fisher, VistaLab, Integra Biosciences
Readout results	Microplate reader	Thermo Fisher, Biotek, BMG Labtech

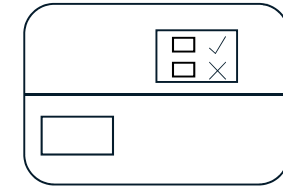
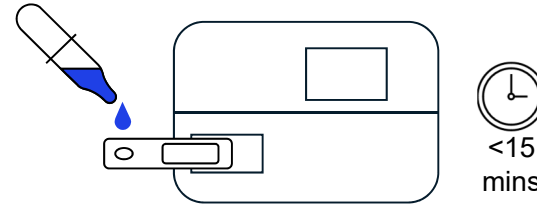
References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

Source: Company websites (eg, [Puritan](#), [Copan](#), [BD](#), [McKesson](#), [Thermo Fisher](#), [Beckman Coulter](#), [Grifols](#), [Hamilton](#), [HUMAN](#), [Sarstedt](#), [MTCBiotech](#), [Labcon](#), [Biotek](#), [BMG Labtech](#), [Integra Biosciences](#), [VistaLab](#), [Molecular Devices](#), [Eppendorf](#), [Wego](#), [Dymax](#), [Greiner Bio-One](#))<sup>1</sup> Product / brand names listed for non-generic equipment.

## 3b: POC immunoassays: Testing process consists of three key steps

CURRENT AS OF MAY 15, 2020

### Illustration of the process



### Typical steps

#### Sample collection

#### Run the assay

#### Read and determine next steps

### Description

Collect patient's blood by pricking fingers (illustrated) or other means  
Can also work with serum and plasma  
For antigen test, can use NP/OP swab sample

Directly supply the sample collected from patient into the system, insert cartridges and other necessary reagents, and then follow the instrument's instructions  
Instrument might need periodic maintenance, including calibration and quality control

Read results from the instrument and determine appropriate next steps based on antigen/antibody presence, which might include a confirmatory molecular assay

### Common performance pitfalls (not exhaustive)

Insufficient blood drawn might lead to false negatives

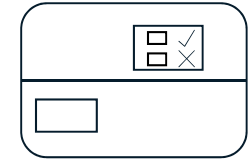
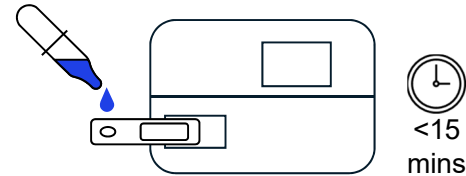
Cross-reactions can produce false positives

# 3b: POC immunoassays: Typical supplies required for each step

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists , please contact us by filling out [this online request form](#)

Used to illustrate supplies shared across steps



Typical steps

Sample collection

Run the assay

Read and determine next steps

Equipment  
(automated)

POC immunoassay analyzer

Key consumables /  
materials / reagents

Lancet  
Sterile collection tubes  
Skin antiseptic solution  
Gauze pads and adhesive bandages  
NP/OP swab

COVID-19 test kit (including  
cartridge, chip, buffer, and other  
necessary components)  
COVID-19 positive and negative  
controls

## 3b: POC immunoassays: Examples of manufacturers for POC systems and kits for COVID-19

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists , please contact us by filling out [this online request form](#)

Examples of manufacturers	COVID-19 kits	POC systems	Typical turnaround time	Sensitivity	Specificity
<b>Mokobio Biotechnology R&amp;D Center</b>	Mokobio SARS-CoV-2 IgM & IgG Quantum Dot immunoassay	Mokosensor-A300	10 mins	89.5%	99.4%
<b>Boditech Med Inc.</b>	AFIAS COVID-19 Ab (IgG/IgM)	AFIAS-1 AFIAS-6	10 mins	100.0%	96.7%
	Ichroma COVID-19 Ab (IgG/IgM)	Ichroma ii	10 mins	Not available	Not available
<b>BluSense Diagnostics</b>	ViroTrack COVID IgA+IgM/IgG/Total Ig Ab	BluBox	10 mins	Not available	Not available
<b>Quidel</b>	Sofia 2 SARS Antigen Fluorescent Immunoassay (FIA)	Sofia 2 analyzer	15 min	80%	100%

References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

Source: [FindDx immunoassay test list](#); [FDA EUAs in diagnostics](#), [CFDA](#); Specifications lists for products: [Quidel](#), [Mokobio](#), [Boditech](#), [BluSense Diagnostics](#)

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## 3b: POC immunoassays: Examples of manufacturers for other generic components required for COVID-19 assays

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists , please contact us by filling out [this online request form](#)

Steps	Supplies	Examples of manufacturers (product name)
Sample collection and transportation	Lancet (finger stick)	BD (Microtainer) Terumo (Finetouch) Smiths Medical (Safe-T-Lance)
	NP/OP swabs	Copan (FLOQSwabs) Puritan Medical Products (HydraFlock)
	Universal/viral transport mediums	Copan, BD

Local companies are starting to produce swabs to meet demand, but there could be potential IP challenges

References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

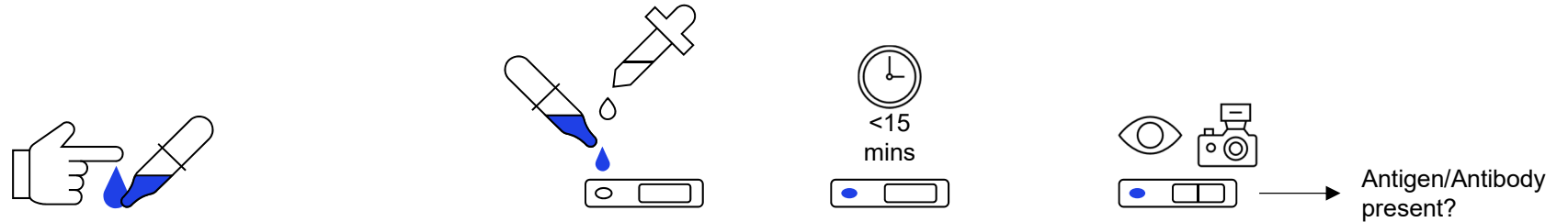
Source: Regulator websites (eg, [FDA](#) ), Published product specifications: [BD](#), [Terumo](#), [Puritan](#), [Copan](#), [Smiths Medical](#)

Document intended to provide insight based on currently available information for consideration and not specific advice

## 4: Lateral flow assays: Testing process consists of 3 key steps

CURRENT AS OF MAY 15, 2020

### Illustration of the process

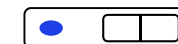
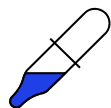


Typical steps	Sample collection	Dilute sample and place on test strip	Read and determine next steps
<b>Description</b>	<p>Collect patient's blood by pricking fingers (illustrated) or other means</p> <p>Can also work with serum</p> <p>For antigen test, other sample types (eg, NP swabs) can be used</p>	<p>Immediately after collecting patient's blood, dilute it on the test strip with supplied buffer and wait for 5–15 mins. Analysis time is dependent on nature of sample, eg, viscosity</p>	<p>Read the lines that will appear on the strips, and determine appropriate next steps based on antigen/antibody presence, which might include a confirmatory molecular assay</p>
<b>Common performance pitfalls (not exhaustive)</b>	<p>Inaccurate sample volume may reduce precision</p>		<p>Improper handling might confound the results</p>

## 4: Lateral flow assays: Typical supplies required for each step

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists , please contact us by filling out [this online request form](#)



Steps	Sample collection and transportation	Dilute sample on test strip	Read and determine next steps
Equipment (automated)			Scanner / camera with controlled lighting
Equipment (manual)	Finger-prick system For antigen test, NP/OP swab	Droppers / pipettors	Gradient score cards (for semi-quantitative scoring)
Key consumables / materials / reagents	Sterile collection tubes Skin antiseptic solution Gauze pads and adhesive bandages	Rapid test kit (test cassettes, buffer, disposable pipettes)	

# 4: Lateral flow assays: Examples of manufacturers for COVID-19 immunoassays (antibody tests)<sup>1</sup>

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists , please contact us by filling out [this online request form](#)

Examples of manufacturers	Typical turnaround time <sup>2</sup>	Sensitivity <sup>3</sup>	Specificity
Wondfo	15 mins	86%	100%
20/20 Bioresponse	15 mins	97%	92%
SD Biosensor	15 mins	98%+ after 14 days post symptom onset	96%
BioMedomics/ BD	10 mins	89%	91%
Cellex	20 mins	94%	96%
Autobio/ Hardy Diagnostics	20 mins	99%	99%
RayBiotech	10 mins	90%	98%

1. Development of antibody in response to infection is host-dependent. Early studies of SARS-COV-2 suggest that majority of patients seroconvert between 7–11 days

2. Approximate testing time as specified by manufacturer, exact testing times may vary

3. Sensitivity is highly dependent on when in the disease progression lifecycle the test is performed

Source: [FindDx immunoassay test list](#); [FDA EUAs in diagnostics CFDA](#) specifications of each product from press releases, company websites, or FDA EUAs:

[Wondfo](#), [20/20 Bioresponse](#), [SD Biosensor](#), [BioMedomics](#), [Cellex](#), [Autobio/Hardy Diagnostics](#), [RayBiotech](#)

References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

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# 4: Lateral flow assays: Examples of manufacturers for generic components that are required for COVID-19 testing

CURRENT AS OF MAY 15, 2020

Non-exhaustive—for more detailed lists , please contact us by filling out [this online request form](#)

Steps	Supplies	Examples of manufacturers (product name)
Sample collection and transportation	Blood collection systems (finger-stick)	BD (Microtainer) Terumo (Finetouch)
	Sterile collection tubes	BD (Microtainer) Terumo (Capiject)
	NP/OP swabs, collection tubes, VTM	Puritan Copan
Sample analysis	Automated readers	Lumos <sup>1</sup> (Leelu) Qiagen <sup>1</sup> (ESEQuant)

References to specific products, companies, or organizations are solely for information purposes and do not constitute any endorsement or recommendation.

1. Off-the-shelf readers that can be customized for COVID-19

Source: Product lists and specifications: [BD](#), [Terumo](#), [Puritan](#), [Copan](#), [Lumos](#), [Qiagen](#)

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