

COVID-19 Specimen Collection Guidelines

Authorized Alternate Collection Options Due to Critical Shortages of Transport Media and Swabs



GENERAL COLLECTION COMMENTS

As of March 24, 2020, the FDA and CDC recommend collecting and testing an upper respiratory specimen with a nasopharyngeal collection (NP), as the preferred choice for swab-based SARS-CoV-2 testing. If a NP specimen cannot be collected, alternate collection sites are acceptable and detailed below. Refrigerate specimen at 2-8° C. Label with patient name. Place in specimen bag and label with "COVID-19" and submit to laboratory.

Flocked plastic NP swabs in universal or viral transport media (UTM/VTM) at 3 mL volume are preferred. The FDA has made alternative recommendations in the context of limited quantities of testing supplies during this public health crisis, based on the best available evidence and in consultation with outside experts. When considering alternate swab types, use only synthetic fiber swabs with plastic shafts, and transport in 3 mL of media. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.

Please refer to the most current CDC guidelines for Evaluating and Reporting Persons Under Investigation for further information. www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html and the FDA FAQs on Diagnostic Testing for SARS-CoV-2 "What If I Do Not Have...?" www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

SUMMARY OF INFORMATION FROM FDA EMERGENCY USE AUTHORIZATION FAQ (REVIEWED ON MARCH 24, 2020)

Specimen collection supplies continue to be difficult to obtain. If NP swabs and UTM/VTM transport media supplies run critically short, we are able to accept the following collection types, based on updated FDA guidance for COVID-19 testing.

ALTERNATE MEDIA

Volumes lower than 3 mL increase the risk of Invalid results or Quantity Not Sufficient (QNS). For vials that contain less than 3mL of media, client MUST add saline to bring the media volume to 3 mL in the vial before sending in for testing.

- CDC VTM Formula
 - Media can be prepared following procedures using the CDC formula: www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf
- Liquid Amies-based media
 - Liquid Amies media may be used for viral transport when UTM is not available.
- Sterile Saline
 - Using a sterile glass or plastic vial containing 3 mL of phosphate buffered saline is preferred

ALTERNATE SWABS


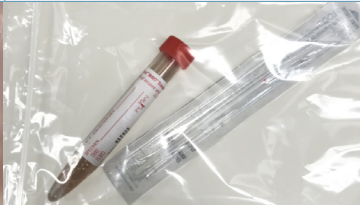


- Oropharyngeal (OP) swabs are acceptable in the absence of Nasopharyngeal (NP) swabs.
- Mid-turbinate (flocked tapered swab) or anterior nares (round foam swab) specimens are acceptable in the absence of NP
 - May be collected by a health care professional or self-collected onsite.
 - For symptomatic patients, and both nares should be swabbed. There is currently not enough evidence for mid-turbinate or nasal swabs in asymptomatic patients.
 - Multiple specimens may be taken with a single swab.
- If separate swabs are used in the same patient at different sites, both swabs may be placed in the same vial.
- Flocked swabs are preferred, when available. Avoid swabs with calcium alginate and wooden shafts, which may inhibit testing.
- Buccal swabs and saliva do not currently have sufficient evidence for use.

PRODUCTS LISTED BY THE FDA FOR USE DURING THE COVID-19 EMERGENCY

NOTE: This is not an all-inclusive list.

BIOREFERENCE PREFERRED SPECIMEN TYPE






















Nasopharyngeal flocked plastic swabs with Universal or Viral Transport Media at 3 mL volume.

PREFERRED			ALTERNATE
M6 MicroTip Flock Swab <i>(BioReference Speedy Number 510)</i>	M4 MicroTip Flock Swab <i>(BioReference Speedy Number 510)</i>	Star Swab <i>(BioReference Speedy Number 510)</i>	Swab Viral Culturette <i>(BioReference Speedy Number 509)</i>
			

OTHER UNIVERSAL TRANSPORT MEDIA FOR VIRUSES AND MOLECULAR TRANSPORT MEDIA

All of the products listed below include a NP flocked swab unless noted otherwise.










For those vials that contain less than 3mL of UTM, client MUST add saline to bring the media volume to 3 mL in the vial before sending in for testing. Volume requirements for COVID-19 testing are 3 mL.

DISTRIBUTOR/ MANUFACTURER	PART NUMBER: NAME				
Copan	305C: Flexible Minitip Nylon Flocked Swab with 3 mL UTM® Medium 	307C: Minitip Nylon Flocked Swab with 3 mL UTM® Medium 	360C: Flexible Minitip Nylon Flocked Swab with 1 mL UTM® Medium 	519CS01*: Regular Nylon Flocked Swab with 100mm Breakpoint 	
Puritan	UT-367: Puritan UniTranz-RT 3ml Filled Vial w/ Elongated & Ultrafine Flock Swabs 	UT-317: Puritan UniTranz-RT 3ml Filled Vial and 6" Sterile Ultrafine Flock Swab 	UT-302*: Puritan UniTranz-RT 3ml Filled Vial w/ Sterile Minitip & Standard Polyester Swabs 	UT-366**: Puritan UniTranz-RT 3ml Filled Vial w/ Sterile Minitip & Standard Polyester Swabs 	UT-300***: Puritan UniTranz-RT 3ml Universal Transport Solution - Vial Only 
BD	220526: 1mL Vial, one sterile Nylon flocked flexible flocked tip swab, scored Plastic shaft (Regular Flocked Tip) 	220258*: 3mL Vial, one sterile Nylon flocked tip swab, scored Plastic shaft (Regular Flocked Tip) 	220529: 3mL Vial, one sterile Nylon flocked tip swab, scored Plastic shaft (Mini Flocked Tip) 	220531: 3mL Vial, one sterile mini-tip swab, scored Plastic shaft (Mini Flocked Tip) 	
DHI/Quidel	330CHL: 3 mL UTM in 10 mL size screw cap with internal-shaped conical bottom. Each tube contains 3 3-mm glass beads. 503CS01: Flexible minitip plastic applicator, nylon fiber tip, sterile in peel pouch, 100 mm breakpoint. 				
Fisher Healthcare (Products by Copan)	23001718: Copan UTM-RT, 16x100mm Conical Tube with beads, 3ml fill, without swabs; Product also distributed by: Hardy/Healthlink: #330CHL 	23600952: Copan Nylon Flocked Dry Swabs in Peel Pouches Flexible minitip flocked 4" 	23600956: Copan Nylon Flocked Dry Swabs in Peel Pouches Minitip flocked 4" 	23600950: Copan Nylon Flocked Dry Swabs in Peel Pouches Minitip flocked 3.14" 	23600957*: Copan Nylon Flocked Dry Swabs in Peel Pouches Regular flocked 4" 
PrimeStore MTM	LH-1-02: PrimeStore MTM® 2 mL Tubes 		LH-1-03***: PrimeStore MTM® 3 mL Tubes 		

LIQUID AMIES MEDIA

May be used for viral transport when universal transport media is not available. All of the products listed below include a nasopharyngeal (NP) flocked swab unless noted otherwise.

Client MUST add saline to bring the volume to 3 mL in the vial before sending in for testing. E-swabs generally only contain only 1mL of fluid, and volume requirements for COVID-19 testing are 3 mL.

DISTRIBUTOR/ MANUFACTURER	PART NUMBER: NAME			
Copan	<p>481C: ESwab Single Minitip Size Nylon® Flocked Swab with 80mm Breakpoint packaged with 1 mL Liquid Amies Medium in Skirted Tube with Plastic Green Non-Capture Cap (BioReference Speedy #513) Product also distributed by: Hardy/Healthlink: #481C VWR: #89136-656 Fisher Healthcare: #23600901</p> 	<p>482C: ESwab Single Flexible Minitip Size Nylon® Flocked Swab with 100mm Breakpoint packaged with 1 mL Liquid Amies Medium in Skirted Tube with Plastic Blue Non-Capture Cap (BioReference Speedy #514) Product also distributed by: Hardy/Healthlink: #482C VWR: #89136-658 Fisher Healthcare: #23600902</p> 	<p>480C*: ESwab Single Regular Size Nylon® Flocked Swab with 80mm Breakpoint packaged with 1 mL Liquid Amies Medium in Skirted Tube with Plastic White Capture Cap (BioReference Speedy #502) Product also distributed by: Hardy/Healthlink: #480C* VWR: #89136-654* Fisher Healthcare: #23600900*</p> 	<p>480CFA*: Single Regular Size Nylon® Flocked Swab with 80mm Breakpoint packaged with 1 mL Liquid Amies Medium in Skirted Tube with Plastic Purple Non-Capture Cap Product also distributed by: Hardy/Healthlink: #480CFA* VWR: #76181-494* Fisher Healthcare: #23600905*</p> 
Puritan	<p>LA-117: Blue Opti-Swab 1ml Liquid Amies Transport Medium w/ 6" Ultrafine Flock Swab 1ml Liquid Amies Medium Filled Vial & Sterile Ultrafine HydraFlock® Applicator</p> 	<p>LA-116-H: Green Opti-Swab 1ml Liquid Amies Transport Medium w/ 6" Mini-tip Flock Swab 1ml Liquid Amies Medium Filled Vial & Mini-tip HydraFlock® Applicator</p> 	<p>LA-100***: White Opti-Swab 1ml Sterile Liquid Amies Transport Medium - Vial Only 1ml Liquid Amies Transport Medium</p> 	
BD	<p>220246: Includes Polypropylene screw-cap tube with 1mL of liquid Amies medium with a Green cap, one minitip swab with flocked Nylon Fiber tip</p>	<p>220245*: Includes Polypropylene screw-cap tube with 1mL of liquid Amies medium with a White cap, one regular swab with flocked Nylon Fiber tip</p>	<p>220532: Includes Polypropylene screw cap tube with 1mL of liquid Amies medium with a Blue cap, one flexible minitip swab with flocked Nylon Fiber tip</p> 	
ThermoFisher	<p>R723481: ESwab Green Minitip Flocked Collection Kit</p>	<p>R723482: ESwab Blue NPG Flocked Collection Kit</p>	<p>R723480*: ESwab White Regular Flocked Collection Kit</p> 	

* flocked oropharyngeal swab






** Polyester swab

*** no swab

f Foam swab

STERILE SALINE

Can be used if no alternate transport media is available. All the products listed below do not include a swab. Tubes should contain 1-3 mL of saline. **Client MUST add additional saline to bring the volume to 3 mL in the vial before sending in for testing. Saline vials generally only contain only 1-2 mL of fluid, and volume requirements for COVID-19 testing are 3 mL.**

DISTRIBUTOR/ MANUFACTURER	PART NUMBER: NAME				
ThermoFisher	R064430: Thermo Scientific™ Saline 0.85% Solution Tubes	R064432: Thermo Scientific™ Saline 0.85% Solution Tubes	R064434: Thermo Scientific™ Saline 0.85% Solution Tubes	R064436: Thermo Scientific™ Saline 0.85% Solution Tubes	R064438: Thermo Scientific™ Saline 0.85% Solution Tubes
					
Hardy/ Healthlink	D185: Saline, 0.85%, 1.8ml, 12x75mm tube, order by the package of 100, Black Top 	K248: Saline, 0.85%, 1ml, 15x103mm tube, optically clear, shatter resistant, polycarbonate tube, order by the package of 20, Blue top 	R45: Saline, 0.85%, 2ml, 13x100mm tube, optically clear, shatter resistant, polycarbonate tube, order by the package of 20, Blue top 	R55: Saline, 0.85%, 2ml, 13x100mm EP glass tube, order by the package of 20, Black top 	
	Edge Biologicals		No Photo Available		
	T-0625: Sterile Saline .85% 0.9mL		T-0110: Sterile Saline .85% 1mL		

* flocked oropharyngeal swab













** Polyester swab

*** no swab

f Foam swab

INDIVIDUALLY WRAPPED SWABS
























All swabs are flocked unless noted otherwise.

DISTRIBUTOR/ MANUFACTURER	PART NUMBER: NAME					
Puritan – Nasopharyngeal Swabs	25-3317-H: HydraFlock 6" Sterile Ultrafine Flock Swab w/ Polystyrene Handle, 100mm Breakpoint 	25-1406 1PF 50: Puritan 6" Sterile Thin Foam Swab w/ Tapered Acetal Handle 	25-800 1PD 50**: Puritan 6" Sterile Mini-tip Polyester Swab w/ Ultra-Fine Polystyrene Handle 	25-3320-U: PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/ Polystyrene Handle, 100mm Breakpoint 	25-3320-H EMB 80: HydraFlock 6" Sterile Revised Ultrafine Flock Swab w/ Polystyrene Handle, 80mm Breakpoint 	25-3320-U EMB 100: PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/ Polystyrene Handle, 100mm Breakpoint 
	Copan – Nasopharyngeal Swabs	503CS01: Flexible Minitip Nylon Flocked Swab with 100mm Breakpoint Product also distributed by: Fisher Healthcare #23600952 	518CS01: Minitip Nylon Flocked Swab with 100mm Breakpoint Product also distributed by: Fisher Healthcare #23600956 	501CS01: Minitip Nylon Flocked Swab with 80mm Breakpoint Product also distributed by: Fisher Healthcare #23600950 	502CS01: Regular Nylon Flocked Swab with 80mm Breakpoint 	
BD – Nasopharyngeal Swabs		220252: Regular flocked swab 			220251: Minitip flocked swab 	

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INDIVIDUALLY WRAPPED SWABS (CONTINUED)

All swabs are flocked unless noted otherwise.

DISTRIBUTOR/ MANUFACTURER	PART NUMBER: NAME								
DHI/Quidel – Nasopharyngeal Swabs	503CS01.DHI: Flexible Minitip Floq Swabs 								
Puritan – Oropharyngeal Swabs	25-1506 1PF SOLID : Puritan 6" Sterile Standard Foam Swab w/ Plastic Handle & Dry Transport Tube 	25-1506 1PF 100 ^f : Puritan 6" Sterile Standard Foam Swab w/Polystyrene Handle 	25-3206-H: HydraFlock 6" Sterile Elongated Flock Swab w/Polystyrene Handle, 20mm Breakpoint 	25-3206-U: PurFlock Ultra 6" Sterile Elongated Flock Swab w/ Polystyrene Handle 20mm Breakpoint 	25-3706-H: HydraFlock 6" Sterile Elongated Flock Swab w/Polystyrene Handle, 100mm Breakpoint 	25-806 1PD**: Puritan 6" Sterile Standard Polyester Swab w/Solid Polystyrene Handle 	25-806 1PD BT**: Puritan 6" Sterile Standard Polyester Plastic Handle Swab & Tube 		
	502CS01: Regular Nylon Flocked Swab with 80mm Breakpoint Product also distributed by: Fisher Healthcare #23600950 	519CS01: Regular Nylon Flocked Swab with 100mm Breakpoint Product also distributed by: Fisher Healthcare #23600957 	164KS01**: Regular Polyester Swab w/ Plastic Applicator Product also distributed by: Fisher Healthcare #1490641** 	167KS01**: Regular Rayon Swab w/ Plastic Applicator 	170KS01**: Regular Rayon Swab w/ Aluminium Applicator Product also distributed by: Fisher Healthcare #1490640** 	175KS01**: Regular Polyester Swab w/ Aluminium Applicator Product also distributed by: Fisher Healthcare #1490650** 			
	Copan - Oropharyngeal Swabs	220250: Regular flocked swab 							
	BD Oropharyngeal swabs:	25-3316-U: PurFlock Ultra 6" Sterile Mini-tip Flock Swab w/ Polystyrene Handle, Cust. Breakpoint 	25-3316-H: HydraFlock 6" Sterile Mini-tip Flock Swab w/ Polystyrene Handle, Cust. Breakpoint 	25-3317-U: PurFlock Ultra 6" Sterile Ultrafine Flock Swab w/ Polystyrene Handle, 100mm Breakpoint 	25-3318-U: PurFlock Ultra 6" Sterile Micro Ultrafine Flock Swab w/ Polystyrene Handle, 100mm Breakpoint 	25-3318-H: HydraFlock 6" Sterile Ultrafine Flock Swab w/ Polystyrene Handle, 100mm Breakpoint 	25-3320-U: PurFlock Ultra 6" Sterile Revised Ultrafine Flock Swab w/ Polystyrene Handle 	25-3320-H: HydraFlock 6" Sterile Revised Ultrafine Flock Swab w/ Polystyrene Handle 	25-3319-H: HydraFlock 6" Sterile Ultrafine Flock Swab w/ Polystyrene Handle, Cust. Breakpoint 
	Additional sterile flocked swabs from Puritan that may be used:								

* flocked oropharyngeal swab

** Polyester swab

*** no swab

f Foam swab

Note: All product names and images obtained from individual manufactures' websites.