

Contains Nonbinding Recommendations

Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID- 19) Public Health Emergency (Revised)

Guidance for Commercial Manufacturers, Clinical Laboratories, and Food and Drug Administration Staff

November 2021

This document supersedes “Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Commercial Manufacturers, Clinical Laboratories, and Food and Drug Administration Staff” issued July 20, 2020.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders> and the FDA webpage titled "Search for FDA Guidance Documents," *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 20038-R2 and complete title of the guidance in the request.

Questions

For questions about this document, contact CDRH-EUA-Templates@fda.hhs.gov or call 1-888-INFO-FDA.

Table of Contents

I.	Introduction.....	1
II.	Background.....	2
III.	Scope.....	3
IV.	Policy for Transport Media.....	4
A.	Overview	4
B.	Policy for Commercial Manufacturers of VTM.....	4
(1)	Validation	5
(2)	FDA Notification.....	5
(3)	Labeling	6
(4)	Alternative Approaches or Additional Transport Media Device Types.....	7
C.	Policy for Commercial Manufacturers of PBS/Saline Transport Media Devices.....	7
D.	Transport Media Developed and Used by Laboratories Certified under CLIA that Meet the Requirements to Perform High-Complexity Testing	9
V.	Additional Resources for Developing Transport Media.....	9

Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID- 19) Public Health Emergency (Revised)

Guidance for Commercial Manufacturers, Clinical Laboratories, and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to help facilitate the availability of devices for use in transporting certain clinical specimens, including transport media that can be used to transport certain clinical specimens for use with molecular Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) assays or antigen-detection diagnostic SARS-CoV-2 assays (hereinafter collectively referred to as SARS-CoV-2 assays) for the duration of the COVID-19 public health emergency.

Contains Nonbinding Recommendations

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2”, and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the U.S. Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

To respond effectively to the COVID-19 pandemic, rapid detection of cases and contacts, appropriate clinical management and infection control, and implementation of community mitigation efforts are critical. FDA has issued Emergency Use Authorizations (EUA) for numerous molecular and antigen tests for detection of SARS-CoV-2, the virus that causes COVID-19. In order to perform testing, most EUA-authorized diagnostic SARS-CoV-2 assays require a transport media to transport clinical specimens to a laboratory for testing using those EUA-authorized assays. FDA believes that the policy set forth in this guidance will help address public health concerns regarding the availability of

¹ Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued on Jan. 31, 2020, and subsequently renewed) available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>. On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID-19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic (February 24, 2021), available at <https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic>.

Contains Nonbinding Recommendations

such transport media devices and therefore help expand the availability of SARS-CoV-2 diagnostic testing. This update removes references to certain aspects of the test modification policy described in earlier versions of the “Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)”³ due to revisions in that guidance.

III. Scope

The enforcement policy described in this guidance applies to the following transport media devices that can be used to transport certain clinical specimens that are tested by molecular or antigen diagnostic assays for use during availability concerns resulting from the COVID-19 public health emergency (see Table 1). This policy applies to the transport media devices identified below in Table 1 that are intended for use: (1) to stabilize and transport clinical specimens, usually obtained on swabs, (2) with molecular or antigen assays for measuring various viral markers (e.g., nucleic acids, antigens, etc.), and (3) with molecular or antigen assays conducted on various test platforms. This policy applies to viral transport media (VTM), sterile phosphate buffered saline (PBS) (including molecular grade PBS and other similar formulations such as Dulbecco’s PBS), and sterile normal saline.

Table 1

Classification Regulation	Device Type	Product Code	Device Classification
21 CFR 866.2300*	Culture Media, Non-Selective and Non-Differential	JSG	I (Exempt)
21 CFR 866.2390*	Culture Media, Non-Propagating Transport	JSM	I (Reserved)
	Culture Media, Anaerobic Transport	JSL	I (Reserved)
	Culture Media, Propagating Transport	JSN	I (Reserved)
21 CFR 866.2900*	Device, Specimen Collection	LIO	I (Reserved)
	System, Transport, Aerobic	JTW	I (Reserved)
	Transport Systems, Anaerobic	JTX	I (Reserved)

* With regard to devices classified under 21 CFR 866.2300, 866.2390 or 866.2900, this policy applies only to those devices intended for the use as described above.

Note that because VTM devices are intended to sustain the viability of viruses/other organisms, they do not contain substances that inactivate viruses and therefore do not contain guanidinium/guanidine thiocyanate or similar chemicals intended to inactivate a virus. Devices intended for viral inactivation are classified under 21 CFR 866.2950 (assigned product code QBD) and the policy in this guidance does **NOT** apply to those devices.

³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>

IV. Policy for Transport Media

A. Overview

In light of the need to help ensure adequate testing supplies for COVID-19 are available during the public health emergency, FDA is taking steps to help expand the availability of transport media, which are critical to SARS-CoV-2 tests. FDA believes that the policies described in this guidance will help address the urgent public health concerns caused by shortages of such products and will help expand the availability of SARS-CoV-2 diagnostic testing.

This guidance describes three policies intended to help expand the availability of transport media devices used to transport certain clinical specimens for use with molecular or antigen diagnostic tests for the duration of the COVID-19 public health emergency.

In addition, this guidance includes FDA's recommendations concerning how developers may validate transport media intended for use in transporting certain clinical specimens that are known or suspected of including the SARS-CoV-2 virus. FDA encourages transport media developers to discuss any alternative approaches to validation with FDA (see subsection B.4 below).

Developers with an EUA-authorized SARS-CoV-2 molecular or antigen assay should refer to FDA's "[Policy for Coronavirus Disease-2019 Test During the Public Health Emergency](#)"⁴ for guidance on certain modifications to their assays and refer to the Conditions of Authorization section in their Letter of Authorization for instructions on how to update their labeling, including Instructions for Use, to incorporate any new transport media.⁵ Please note that if a laboratory modifies an authorized test (e.g., by using alternative transport media), the modified test may no longer be authorized under the EUA.

B. Policy for Commercial Manufacturers of VTM

The policy in this section applies to commercial manufacturers that want to develop and distribute transport media for use transporting clinical specimens for testing with molecular or antigen assays during the COVID-19 public health emergency that are class I (reserved) and subject to premarket notification requirements under section 510(k) of the FD&C Act, as identified in Table 1.

To help foster the availability of transport media that can transport specimens for testing using molecular or antigen diagnostic tests, for the duration of the public health emergency, FDA does not intend to object to the distribution and use of VTM by commercial manufacturers, without submission of a premarket notification to FDA as required by section 510(k) of the FD&C Act (21 U.S.C. 360(k)), or compliance with the Unique Device Identification (UDI) requirements in 21 CFR Part 830 and 21 CFR 801.20 where the VTM device is validated as described in subsection B.1, where notification of validation is provided to FDA as described in subsection B.2, and where the

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>

⁵ For a comprehensive list of *in vitro* diagnostic EUAs that FDA has issued during the COVID-19 public health emergency, see FDA's website at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>.

Contains Nonbinding Recommendations

manufacturer includes a statement in the labeling that the transport medium has not been reviewed by FDA and other labeling information so that the product does not create an undue risk in light of the public health emergency. (See subsection B.3 below for information on VTM labeling). Additionally, to further help increase availability of commercially manufactured VTM, FDA does not intend to enforce the Quality System Requirements under 21 CFR Part 820 when manufacturers conform to ISO 13485:2016 *Medical Devices Quality Management Systems Requirements for Regulatory Purposes*. Manufacturers should have documentation demonstrating their compliance with ISO 13485.

This policy does not apply to compliance with other requirements and manufacturers are responsible for ensuring compliance with those requirements, including Registration and Listing requirements in 21 CFR Part 807, reports of corrections and removals in 21 CFR Part 806, medical device reporting under 21 CFR Part 803, and *in vitro* diagnostics (IVD) labeling requirements under 21 CFR Parts 801 and 809.

(1) Validation

It is important that VTM are appropriately designed and validated prior to distribution to ensure that the transport medium will preserve the viral particles without meaningful degradation that could lead to inaccurate test results. To reduce the risk of inaccurate test results, only VTM devices labeled as sterile should be used in the transport of clinical specimens. FDA believes that VTM distributed by commercial manufacturers under this policy should be designed and validated consistent with the [Centers for Disease Control and Prevention's \(CDC's\) Standard Operating Procedure \(SOP\): Preparation of Viral Transport Media](#).⁶ For commercial manufacturers that wish to discuss alternative validation methods or alternative transport media device types, please see subsection B.4 Alternative Approaches or Additional Transport Media Device Types.

(2) FDA Notification

Commercial manufacturers should notify FDA by e-mail to CDRH-EUA-Templates@fda.hhs.gov after the transport medium has been validated that the manufacturer intends to distribute the VTM. This notification should include the name of the manufacturer, address, a contact person and e-mail address at which the contact person can be reached, the names of authorized importers and distributors, the name(s) under which the product is sold or distributed, a copy of the instructions for use, a statement and documentation that the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, and a statement that the device has been designed and validated consistent with [CDC's SOP: Preparation of Viral Transport Media](#).⁷ FDA will acknowledge receipt of this email via auto-reply.

It would be helpful to FDA if manufacturers additionally provide information on their expected manufacturing capacity of their transport medium in their notification discussed above. This information will help the Agency and Department monitor the landscape as we work to help ensure

⁶ For the current edition of the SOP, see CDC's website at <https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf>.

⁷ <https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf>

Contains Nonbinding Recommendations

adequate testing supplies are available across the country during the COVID-19 public health emergency.⁸

Following notification, FDA intends to update the list of transport media on its webpage with devices manufactured and distributed under the policy outlined in this section. If a problem is identified, FDA intends to work with the manufacturer to address the problem (e.g., through labeling or analytical studies). If any problems are significant and cannot be addressed in a timely manner, FDA would expect the manufacturer to suspend the distribution and conduct a recall of the transport media devices, including the collection kits and/or tests when they are distributed with the transport media, which should include a notice to customers concerning their transport media. In such circumstances, FDA intends to remove the manufacturer's transport medium from the website list of notifications.

(3) Labeling

As noted above, VTM are devices subject to the labeling requirements in 21 CFR Parts 801 and 809, including the labeling requirements under 21 CFR 809.10(a) for the immediate container of the transport medium (i.e., tube label). The following information is intended to assist manufacturers in complying with 21 CFR 809.10 for transport media devices. Manufacturers should refer to that regulation for the complete list of labeling requirements for *in vitro* diagnostic devices. The additional labeling recommendations describe circumstances intended to help ensure that the transport media under this policy does not create an undue risk in light of the public health emergency.

VTM labeling must include the following, in addition to other requirements set forth in 21 CFR 809.10:

- An intended use statement that the transport medium is for transport of clinical material and a statement that the transport medium serves as a culture media, non-propagating transport, as appropriate (21 CFR 809.10(a)(2) and 21 CFR 809.10(b)(2));
- Appropriate warnings and limitations of the transport medium (21 CFR 809.10(a)(4) and 21 CFR 809.10(b)(5)(ii));
- Shelf life and stability information (21 CFR 809.10(a)(5)) and storage instructions (21 CFR 809.10(b)(5)(iv));
- A list of all materials provided (21 CFR 809.10(b)(8)(i));
- Results and specific performance criteria (21 CFR 809.10(b)(9) and 21 CFR 809.10(b)(12));
- Specifications (21 CFR 809.10(b)(12));

⁸ In addition to this recommendation, manufacturers should be aware of their notification obligations under section 506J of the FD&C Act (21 U.S.C. 356j). Section 506J of the FD&C Act requires manufacturers to notify FDA “of a permanent discontinuance in the manufacture of the device” or of “an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States” during or in advance of a public health emergency. For more information about providing FDA notifications during the COVID-19 public health emergency, see FDA’s guidance entitled “[Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency \(Revised\)](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc),” including who must notify FDA, what information to include in the notification, and how to notify FDA. (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc>).

Contains Nonbinding Recommendations

- Instructions for handling of collected specimens, including storage instructions, and transport conditions instructions, as appropriate (21 CFR 809.10(b)(7));
- Details of kinds of quality control procedures and materials required (21 CFR 809.10(b)(8)(iv)); and
- The name and place of business of manufacturer (21 CFR 809.10(a)(8) and 21 CFR 809.10(b)(14)).

FDA also recommends developers include the following in the labeling for their VTM:

- A statement that the transport medium has not been reviewed by FDA, as appropriate;
- A statement that the transport medium serves as a culture media, non-propagating transport, as appropriate;
- Results and specific performance criteria per 21 CFR 809.10(b)(9) and 21 CFR 809.10(b)(12) should include an indication of the compatibility of the transport medium with molecular and/or antigen diagnostic assays based on internal verification data by the commercial manufacturer;
- Labeling should also include any additional technical information or instructions that might be helpful for the user;
- Any additional technical information or instructions that might be helpful for the user; and,
- A reference or point of contact for technical information or questions.

(4) Alternative Approaches or Additional Transport Media Device Types

FDA is interested in interacting with commercial manufacturers of additional transport media device types, or that may wish to discuss alternative approaches to validation of VTM that are not identified above in subsection B.1. Commercial manufacturers that wish to discuss an alternative validation approach should send the following information to CDRH-EUA-Templates@fda.hhs.gov.

- 1) A summary of any data to support that the transport medium's ability to preserve viral particles is equivalent to legally marketed VTM;
- 2) Instructions for use for the VTM that includes all the items identified in subsection B.3 above; and
- 3) Whether the device is manufactured in compliance with either 21 CFR Part 820, ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, or an alternative quality system, and the manufacturer or importer has documentation of such.

C. Policy for Commercial Manufacturers of PBS/Saline Transport Media Devices

PBS/saline transport media are generally exempt from premarket notification requirements under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) pursuant to 21 CFR 866.2300(b). To help foster the availability of transport media that may help expand the nation's capacity for COVID-19 testing

Contains Nonbinding Recommendations

during the public health emergency, for the duration of the public health emergency, FDA does not intend to object to the distribution and use of sterile PBS/saline transport media by commercial manufacturers, without compliance with the UDI requirements in 21 CFR Part 830 and 21 CFR 801.20 where the manufacturer gives notification of validation to FDA as described below.

Commercial manufacturers of PBS/Saline transport media are required to comply with the Quality System Requirements in 21 CFR Part 820. In order to help increase the availability of sterile PBS/saline transport media, FDA does not intend to enforce the Quality System Requirements under 21 CFR Part 820 when manufacturers conform to ISO 13485:2016 *Medical Devices Quality Management Systems Requirements for Regulatory Purposes*. Manufacturers should have documentation demonstrating their compliance with ISO 13485.

This policy does not apply to compliance with other medical device requirements and manufacturers are responsible for ensuring compliance with those requirements, including Registration and Listing requirements in 21 CFR Part 807, reports of corrections and removals in 21 CFR Part 806, medical device reporting under 21 CFR Part 803, and *in vitro* diagnostics (IVD) labeling requirements under 21 CFR Parts 801 and 809.

To reduce the risk of inaccurate test results, only PBS/saline devices labeled as sterile should be used in the transport of clinical specimens. Sterile PBS/saline devices should be appropriately verified and/or validated prior to distribution, and this should include process sterilization validation and validation that the device remains sterile in its packaging when maintained in accordance with the labeled storage conditions.

Following completion of sterilization validation, notification should be provided to FDA by e-mail to CDRH-EUA-Templates@fda.hhs.gov that the transport medium has been validated. This notification should include the name and address of the manufacturer, the name and e-mail address of a contact person, the name(s) under which the product is sold or distributed, names of authorized importers and distributors, a copy of the instructions for use, and a statement and documentation that the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485:2016 *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*. FDA will acknowledge receipt of this email via auto-reply.

It would be helpful to FDA if manufacturers provide information on the expected manufacturing capacity of their sterile PBS/saline devices in their notification discussed above. This information will help the Agency and Department monitor the landscape as we work to help ensure adequate testing supplies are available across the country during the COVID-19 public health emergency.⁹

⁹ In addition to this recommendation, manufacturers should be aware of their notification obligations under section 506J of the FD&C Act. Section 506J of the FD&C Act (21 U.S.C. 356j) requires manufacturers to notify FDA “of a permanent discontinuance in the manufacture of the device” or of “an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States” during or in advance of a public health emergency. For more information about providing FDA notifications during the COVID-19 public health emergency, see FDA’s guidance entitled “[Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency \(Revised\)](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc),” including who must notify FDA, what information to include in the notification, and how to notify FDA. (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc>).

Contains Nonbinding Recommendations

Following notification, FDA intends to update the list of transport media on its webpage with devices manufactured and distributed under the policy outlined in this section. If a problem is identified, FDA intends to work with the manufacturer to address the problem (e.g., through labeling or analytical studies). If any problems are significant and cannot be addressed in a timely manner, FDA would expect the manufacturer to suspend the distribution and conduct a recall of the transport media devices, including collection kits and/or tests when they are distributed with the transport media, which should include a notice to customers concerning their transport media. In such circumstances, FDA intends to remove the manufacturer's transport medium from the website list of notifications.

D. Transport Media Developed and Used by Laboratories Certified under CLIA that Meet the Requirements to Perform High-Complexity Testing

The policy described in this subsection applies to laboratories certified under the Clinical Laboratory Improvements Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high-complexity testing and that seek to develop and use transport media to transport certain clinical specimens for testing using a SARS-CoV-2 molecular or antigen diagnostic assay. Laboratories seeking to distribute transport media to entities that are not within the same corporate organization and that share common ownership by the same parent corporation should refer to Section IV.B or Section IV.C.

In light of the need to help ensure adequate testing supplies are available for increasing numbers of COVID-19 cases throughout the country, and the urgent need to expand the nation's capacity for COVID-19 testing during the public health emergency, FDA does not intend to object to the development and use of transport media, including VTM, or PBS/saline, for transport of clinical specimens by laboratories certified under CLIA that meet the requirements to perform high-complexity testing where the transport medium has been validated in-house and where use of the transport medium is limited to laboratories within the same corporate organization and having common ownership by the same parent corporation. FDA does not expect laboratories to notify FDA if they plan to develop and use a transport media within the same corporate organization and common ownership by the same parent corporation. However, if FDA becomes aware of questions or concerns about a laboratory-developed transport medium, FDA will communicate those concerns to the laboratory and provide the laboratory an opportunity to address the questions or concerns about that device. If the concerns cannot be or have not been addressed in a timely manner, FDA may take additional actions as appropriate.

All transport media should be validated prior to use. FDA recommends that laboratories seeking to develop and use their own VTM refer to [CDC's SOP: Preparation of Viral Transport Media](#).¹⁰

V. Additional Resources for Developing Transport Media

The following resources may be useful for developing and validating transport media:

- Centers for Disease Control and Prevention [SOP: Preparation of Viral Transport Media](#)

¹⁰ <https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf>

Contains Nonbinding Recommendations

(<https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf>)

- Leland, D.S., “Concepts of clinical diagnostic virology.” In *E.H. Lennette (ed.), Laboratory Diagnosis of Viral Infections*, Second Edition: p. 3-43, 1992.
- Johnson, F.B., “Transport of Viral Specimens.” *Clinical Microbiology Reviews* 3(2):120-131, 1990.
- World Health Organization. Viral Transport Media.
<https://www.who.int/ihr/publications/Annex8.pdf?ua=1>.
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), current edition.
<https://www.cdc.gov/labs/BMBL.html>.