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Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-21-10-CLIA

DATE: **January 8, 2021**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories Surveyor Guidance for New and Modified CLIA Requirements Related to SARS-CoV-2 Test Result Reporting

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities continue to be prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On September 2, 2020, an interim final rule with comment period (CMS-3401-IFC) was published in the Federal Register (85 FR 54820).
- CLIA regulations have been updated to require all laboratories to report SARS-CoV-2 test results in a standardized format and at a frequency specified by the Secretary.
- CMS is providing surveyor guidance for State Agency and CMS Branch Location surveyors related to the CMS-3401-IFC CLIA SARS-CoV-2 test reporting requirements.

Background

On March 13, 2020, the President declared a national emergency in response to the unprecedented public health emergency (PHE) caused by the SARS-CoV-2 virus, which causes the disease known as COVID-19. Section 18115 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act[1] requires that "[e]very laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 shall report the results from each such test, to the Secretary of Health and Human Services in such form and manner, and at such timing and frequency, as the Secretary may prescribe until the end of the Secretary's Public Health Emergency declaration with respect to COVID-19 or any extension of such declaration." As a result, CMS has made modifications to the CLIA regulations. CMS-3401-IFC requires laboratories to report SARS-CoV-2 test results in a manner and frequency specified by the Secretary. These regulatory changes are intended to update the CLIA laboratory

[1] Available at https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf.

requirements to meet the SARS-CoV-2 test result reporting provisions related to the Secretary's Public Health Emergency declaration with respect to COVID–19.

Surveyor Guidance

The detailed surveyor guidance will provide information necessary for CLIA surveyors to consistently survey laboratories for implementation of the CLIA SARS-CoV-2 reporting requirements in CMS-3401-IFC. This guidance will expand on the guidance provided by QSO-20-37-CLIA, NH which was published on August 26, 2020. The guidance contains the following sections:

- General Guidance
- Surveying
- Reporting SARS-CoV-2 Test Results
- Certificate of Waiver (CoW) and Certificate for Provider-Performed Microscopy (PPM)
- Certificate of Compliance (CoC) and Certificate of Registration (CoR)

Contact: Questions may be submitted to: LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State Agency/CMS Branch Location training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: CLIA Branch Managers
CLIA Location Staff

Attachments: CLIA Surveyor Guidance
Frequently Asked Questions (FAQs), Reporting SARS-CoV-2 Test Results

CLIA Surveyor Guidance

General Guidance

1. Following Manufacturer's Instructions (MI)/Instructions for Use (IFU)

Probe question: Is the laboratory following manufacturer's instructions/instructions for use?

A. "Must" versus "Recommend"

Words like 'always', 'shall', 'must', and 'required' mean the instruction is mandatory and must be performed. 'Should' or 'recommend' mean the action is not mandatory and is optional, but it is good laboratory practice to perform those actions.

B. Antigen assay enforcement discretion

See "**Surveying**" section below for more information.

C. Quality Control (QC)/Performance Specifications:

- CMS has found that IFU QC requirements vary across test systems, especially when an Emergency Use Authorization (EUA) is involved (e.g., should versus must), particularly for the serology antibody tests. For certain tests with EUAs the CLIA requirements at 42 CFR § 493.1256(d)(3) apply based on language within the IFU. However, because IFU language varies, CMS will need to determine if the CLIA minimum QC requirements apply for each EUA test. **Surveyors will need to forward the specific EUA or provide a copy of, or link to, the IFU so that CMS can evaluate what QC requirements apply, should the surveyor have questions related to QC.** This information should be sent to the applicable CMS Branch Location Office.
- Until such time as the FDA authorizes a revised IFU for an EUA, under the terms of the EUA, the laboratory must follow the currently authorized IFU.
- CLIA surveyors evaluate the laboratory's compliance with CLIA requirements, including following manufacturer's instructions and verification/establishment of performance specifications. The manufacturer's instructions for all tests that have an EUA must be followed, to include QC.
- *Individualized Quality Control Plan (IQCP)*: During the COVID-19 public health emergency CMS has determined that IQCP is an option for EUA tests classified as non-waived (authorized for use in moderate or high complexity settings) when manufacturers' QC is less stringent than the CLIA quality control requirements at 42 C.F.R. § 493.1256. The laboratory director may determine, based on risk assessment, that additional QC is necessary above what is otherwise required in the EUA Instructions for Use (IFU).

  The manufacturer's QC instructions for all tests that have an EUA need to be followed. However, if the Instructions for Use (IFU) indicate laboratories should perform external "QC in accordance with applicable local, state, and/or federal regulations," then for purposes of CLIA, the laboratory needs to follow the non-waived CLIA quality control

requirements found at § 493.1256 or develop an IQCP, as well as any other QC instructions provided by the manufacturer. If the laboratory opts to implement an IQCP, refer to the State Operations Manual, Appendix C (Interpretive Guidelines) page 198. The Quality Control Plan must include the **number, type, frequency of testing, and criteria for acceptable result(s) of the quality control(s)**, and must be approved by the laboratory director.

D. Specimen Type

- Specimen types listed in the intended use section of the IFU are acceptable for use with the assay under the EUA.
- To be covered by the EUA, specimens need to be collected according to the EUA's testing requirements and in accordance with the manufacturer's instructions and CDC guidelines.
- Any laboratory intending to modify a previously EUA-authorized COVID-19 assay, including the intended use or specimen type, must be CLIA-certified for high complexity testing, establish performance specifications, and be in compliance with the high complexity requirements. Please forward to the CMS Branch Location Office if this is found on survey.

E. Personnel

Staff performing COVID-19 testing need to meet the CLIA personnel requirements applicable to the assay the laboratory is performing and as designated in the EUA and by the manufacturer. Non-waived (moderate and high complexity testing) personnel requirements can be found in subpart M of the CLIA regulations (CLIA Regulations – subpart M). Waived testing does not have any CLIA personnel requirements.

2. Test Categorization (i.e., complexity) versus "Authorized Setting"

A. What is an Emergency Use Authorization (EUA)?

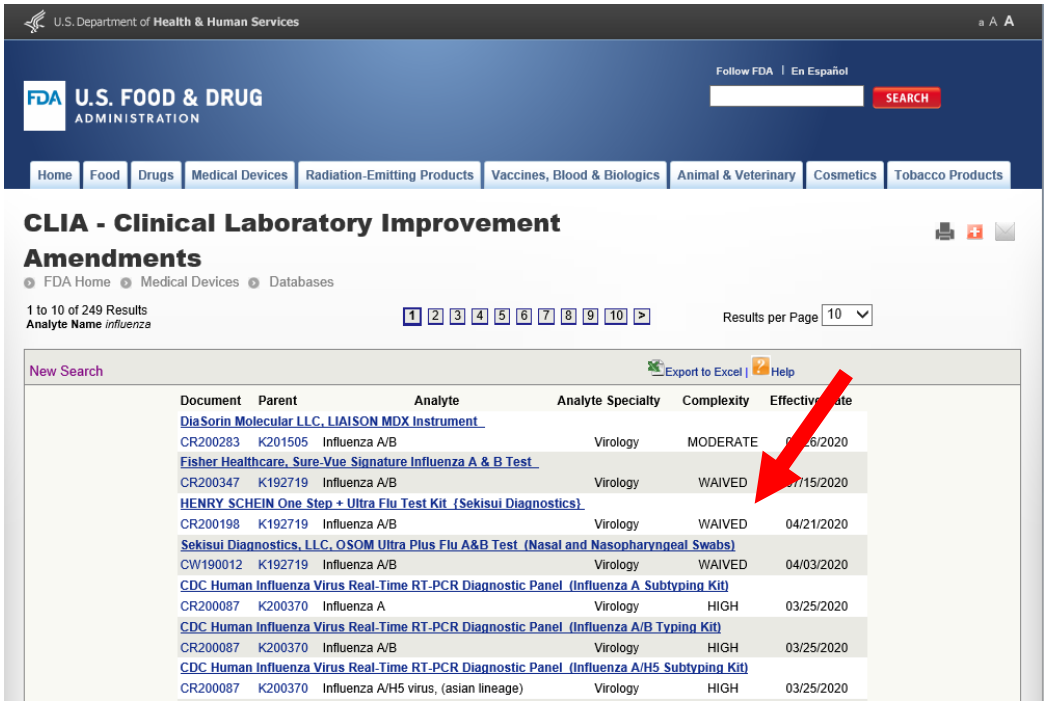
Under section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act,[1] the FDA may authorize the use of unapproved medical products, or unapproved uses of approved medical products, in certain emergency circumstances, after the HHS Secretary has made a declaration of emergency or threat justifying authorization of emergency use, to diagnose, treat, or prevent serious or life-threatening disease or conditions caused by CBRN (chemical, biological, radiological, or nuclear)[2] threat agents when certain criteria are met. The EUA is only for emergency circumstances that justify the authorization for such use, and is for the duration of the existence of those circumstances unless the declaration is terminated or the EUA is revoked sooner. In the case of SARS-CoV-2, there is a declaration for *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under section 564(b)(1) of the FD&C Act, 21 U.S.C. 360bbb-3(b)(1).

B. FDA-approved or cleared tests

[1] 21 U.S.C. 301 *et seq*.
[2] See https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/what-are-medical-countermeasures

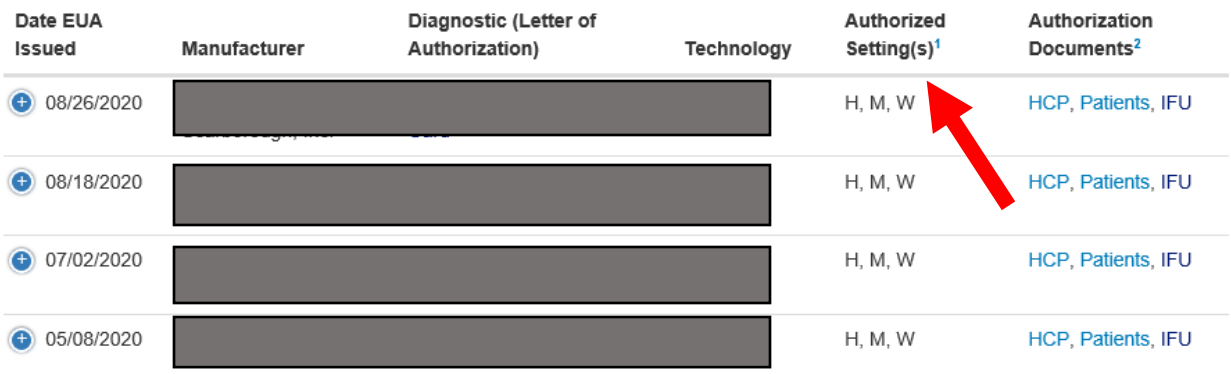
An FDA-cleared or approved test system as defined by 42 C.F.R §493.2, means that the test system has been cleared or approved by the FDA through either the pre-market notification process (section 510(k) of the FD&C Act, 21 U.S.C. 360(k)) or through the pre-market approval (PMA) process for *in vitro* diagnostic use. Test systems exempt from pre-market clearance or approval, unless otherwise stated, are included in this definition. Test categorization for test systems or assays is the responsibility of the FDA, and is determined after the FDA has cleared or approved a marketing submission or upon request for a legally marketed test.

To determine the complexity of a test system or an assay categorized by the FDA, the FDA's CLIA test categorization database at FDA CLIA Categorization can be utilized, performing a search for the test system or assay as follows in the example screenshot:



C. Authorized Settings

To date, there have been no SARS-CoV-2 assays that have been cleared or approved by the FDA. Assays which are authorized for use by the FDA are listed on the FDA's In Vitro Diagnostics EUAs website. See example of Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2 below.



Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]	Authorization Documents[2]
08/26/2020	[redacted]			H, M, W	HCP, Patients, IFU
08/18/2020	[redacted]			H, M, W	HCP, Patients, IFU
07/02/2020	[redacted]			H, M, W	HCP, Patients, IFU
05/08/2020	[redacted]			H, M, W	HCP, Patients, IFU

Under the FD&C Act, when issuing an EUA, FDA may determine that a test shall be deemed to be in a particular category. The FDA website, FDA's In Vitro Diagnostics EUAs, describes the setting in which a test is authorized to be performed, i.e., a waived, moderate complexity or high complexity setting. The site is updated as more tests receive EUAs. ADMIN 20-06-CLIA also refers to testing requirements for COVID-19.

Probe: Does the laboratory hold the correct CLIA certificate appropriate to the assigned authorized setting for the test/test system it is performing/using?

Laboratories may be offering tests for COVID-19 that have not been given an EUA, as outlined in the FDA's Policy for Coronavirus Disease-2019 Tests.

Probe: Is the laboratory offering SARS-CoV-2 testing under one of the FDA policies (see FDA FAQs on Testing for SARS-CoV-2), and is the laboratory a CLIA certified laboratory that meets regulatory requirements to perform high complexity testing under the CLIA regulations at 42 CFR §§ 493.1441 through 493.1495?

Probe: Has the laboratory established performance specifications per 42 CFR § 493.1253(b)(2) as required when the FDA has not granted an EUA for a SARS-CoV-2 test, and can the laboratory provide documentation that the performance specifications were reviewed and approved by the Laboratory Director?

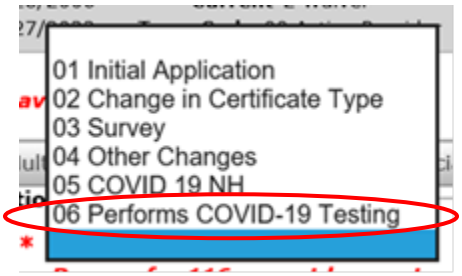
See QSO Memo, Performance Specification Verification of Assays Authorized Under Emergency Use (EUA): CMS QSO-18-19-CLIA.

3. ASPEN Data System Information

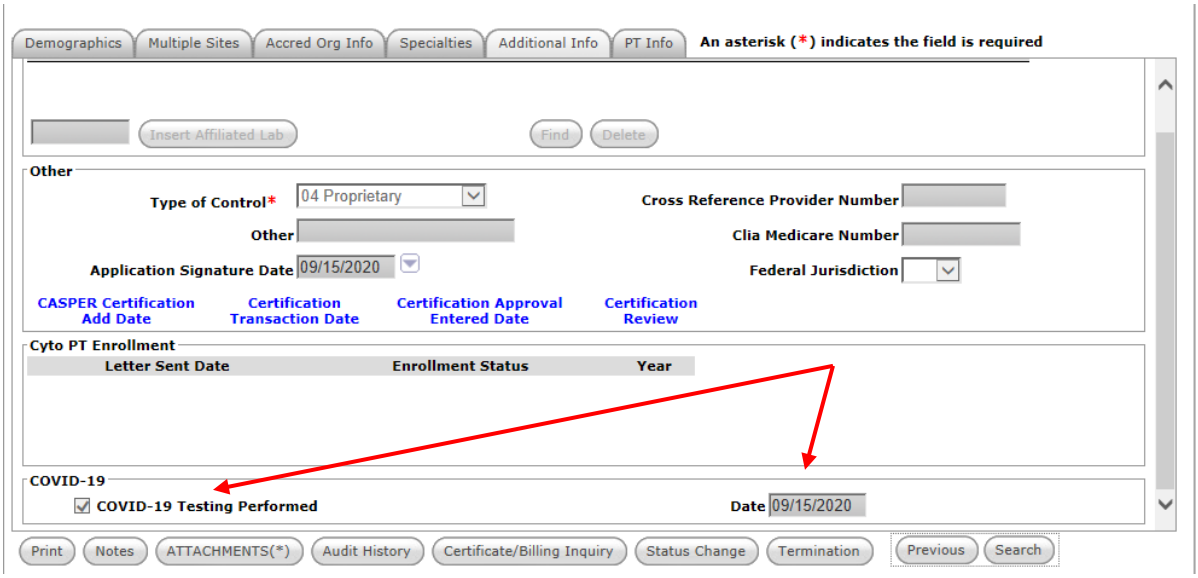
A. "05" and "06" "Reason for 116" Codes

The "05" code was inactivated as of November 2, 2020, and should no longer be. The "05" code was used to temporarily identify those long-term care facilities (also known as "nursing homes" (NHs)) that did not have Certificates of Waiver (CoWs) as required for the NH Point of Care (POC) Initiative distribution list.

In order to identify laboratories that are performing SARS-CoV-2 testing, when applications or notifications are received from laboratories, “06”, “Performs COVID-19 Testing”, should be selected in the “Reason for 116” box on the Demographics tab.



The first time the “06” code is selected and saved, the Performs COVID-19 Testing Indicator and date are set and will not be changed on subsequent updates even though “06” will be an option each time a change is made to the CMS-116 in ASPEN. The indicator and date are display on the “Additional Info” tab.

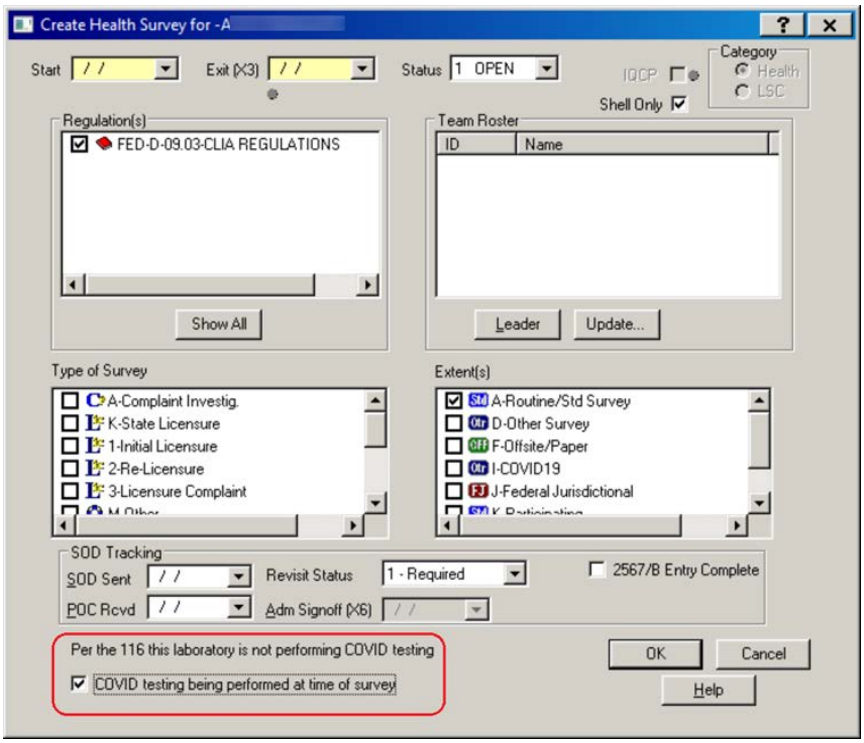


In addition, CMS plans to provide a list to the State Agencies and CMS Branch Location Offices of laboratories that have been identified with the “06” Reason for 116” code on a monthly basis.

B. <u>System Flags for Designating COVID-19 Testing when Citing Deficiencies</u>

<u>On the Survey Properties screen</u>:

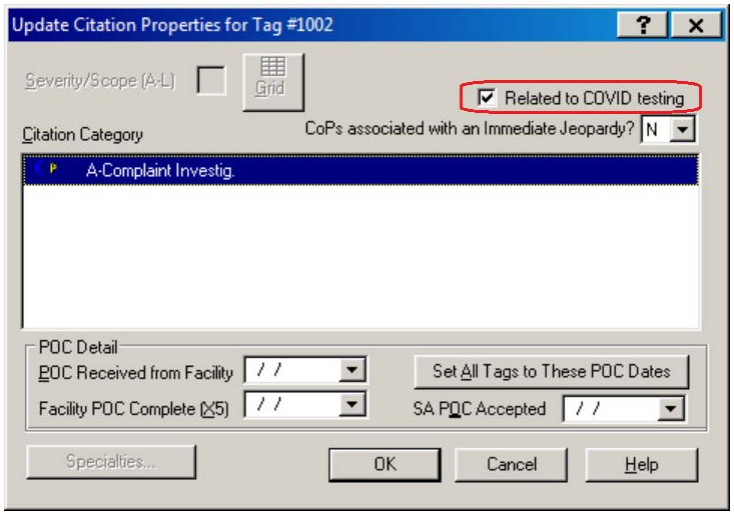
- COVID testing information from the CMS-116 will be displayed.
- Note: This information is not available in ASE-Q and will not be displayed.
- A flag can be set to indicate that COVID testing was being performed at the time of the survey.



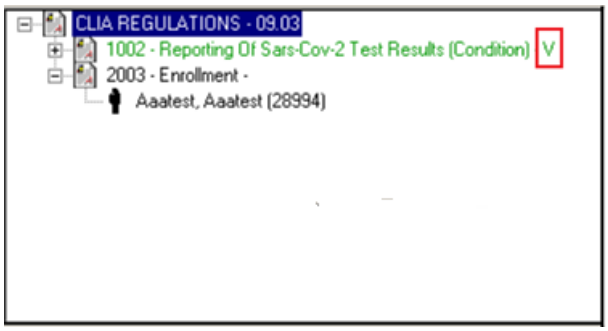
- The survey-level COVID testing flag can be set regardless of COVID testing status in the CMS-116.
- The CMS-116 will be updated if the survey determined COVID testing is being performed.

<u>Indicator to capture if a tag cited on a survey is related to COVID testing</u>

- When deficiencies are cited for laboratories that perform COVID testing as indicated on Survey Properties, surveyors can mark an indicator in the Citation Properties dialog (for any non-documentation tag) when a deficiency is related to COVID testing.



- If a tag is cited based on the laboratory's COVID testing, it will be identified with a V where it is displayed in ASPEN applications to differentiate it from citations not related to COVID testing.

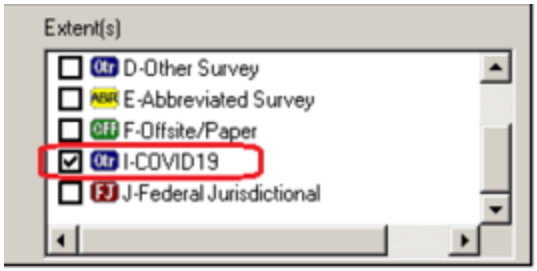


- On the CMS-2567, a tag cited based on the laboratory's COVID testing is identified by the word COVID.

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D1002 COVID	REPORTING OF SARS-CoV-2 TEST RESULTS CFR(s): 493.41 During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: sdggsgsd	D1002		
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with §493.1236(c)(1) This STANDARD is not met as evidenced by: adgsdf	D2003		

C. "I-COVID19" Extent(s) Designation

The "I-COVID19" Extent(s) should NOT be used by CLIA surveyors. This designation is used by other facility types for stand-alone surveys focusing on infection control. It allows for tracking of surveys focusing on infection control practices relating to the COVID-19 outbreak.



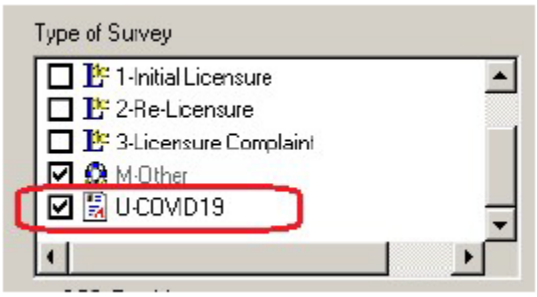
D. Creating a Special Survey for SARS-CoV-2 Test Reporting Requirements

The system allows a special survey with the same date as a certification kit or a complaint survey. Please note that only one type of special survey per day is permitted for a provider. So, there cannot be a Proficiency Testing (PT) desk review and a COVID-19 special survey with the same date.

Certificate of Compliance/Certificate of Registration/Certificate of Accreditation

When creating a special survey for citing condition-level deficiencies related to SARS-CoV-2 test reporting requirements, select "U-COVID-19" under "Type of Survey" on the "Survey Properties" window.

Please note: If a surveyor finds that a laboratory is in compliance with SARS-CoV-2 test results reporting requirements, a special survey does not need to be created.



Certificate of Waiver/Certificate for Provider Performed Microscopy (PPM)

For these two type of surveys, please continue to use the special CoW or PPM survey designations.

Please note: For all certificate types, surveyors should mark the indicator in the Citation Properties dialog to indicate that the D-Tag is related to COVID-19 testing. In addition, the flag can be set to indicate that COVID-19 testing was being performed at the time of the survey on the Survey Properties screen. (see examples above)

The ASPEN Central Office (ACO) User Guide can be accessed at:
https://qtso.cms.gov/system/files/qtso/ACO_PG_11.9.3_FINAL.pdf

- Use Google CHROME → paste and go to…

- Pages 143-146 describe the special surveys, and specifically the COVID special survey.

4. Authorized Person

For nonwaived testing, the CLIA regulations at 42 CFR § 493.1241 require the laboratory to have a written or electronic request for patient testing from an authorized individual. An authorized person is defined in the regulations as an individual authorized under State law to order tests or receive test results, or both. Laboratories will need to contact the applicable State Agency for further guidance regarding any state requirements.

5. Electronic Signatures

Secure or digital electronic signatures are acceptable (e.g., Form CMS-116, PT attestation). The electronic signature should have an electronic date/time stamp. If electronic signatures are being used, the laboratory should show evidence that only the authorized person can utilize the electronic signature.

Probes:

- Is the laboratory using a secure and traceable system (e.g., Laboratory Information System (LIS), facility network, electronic record) with date and time indications for each activity/access?

- How does the laboratory's traceable system ensure only the authorized person can use the electronic signature? For example, personal authentication card signature stamp, specific account/password.

Surveying

This guidance applies to surveying for SARS-CoV-2 test result reporting during the public health emergency as defined in 42 CFR § 400.200.

A. Complaints

Complaints should be investigated in accordance with QSO-20-35-ALL, following normal procedures in State Operations Manual (SOM) Chapter 5. Complaints that represent situations in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition-level requirements, including reporting test results, has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public (including, but not limited to injury or harm related to COVID-19) continue to be prioritized.

Reference: QSO Memo, Enforcement Cases Held during the Prioritization Period and Revised Survey Prioritization CMS QSO-20-35-ALL

B. Refused Entry

A laboratory's administrative policy may require an individual to adhere to a facility's criteria in order to grant entry, e.g., short training video, health status checklist. In the case of viewing a short (e.g., 20 minute) training video or completing a health status checklist, the surveyor can comply with the administrative policy and does not need approval from the CMS Branch Location. For other situations, e.g., requiring a negative COVID-19 test or refusal to allow a survey, the surveyor should contact State Agency Management, and if needed, CMS Branch Location, for guidance. CMS's recommends that the surveyor have a copy of the CLIA model letter 01 SA - Notice of Inspection readily available to provide to the laboratory should the laboratory continue to fail to permit the survey after consultation with State Agency Management or CMS Branch Location. The letter outlines CLIA's authority for onsite inspection and enforcement action for failure to comply. If the laboratory continues to refuse entry, gather the information as outlined in the 01 SA letter, the surveyor should generate a CMS-2567 (Refer to: 42 CFR § 493.1771 Inspection requirements **applicable to all CLIA-certified and CLIA-exempt laboratories**).

For surveyor questions related to this section, please contact State Agency Management or CMS Branch Location Office.

C. Multiple Sites

Generally, laboratories need to file a separate application for each laboratory location. However, there are three exceptions in which a laboratory may file one application for multiple locations. CMS has permitted a laboratory to extend its existing CLIA Certificate to operate a COVID-19 temporary testing site in a "designated overflow location" that is off-site. Examples of off-site locations permitted include a school, a church, or another community parking lot (with approval of the local and state authorities). The temporary site would only be permitted to perform tests consistent with the existing certificate, and would be under the direction of the primary site/home base existing lab director. As long as the temporary site provides testing consistent with the laboratory's CLIA certificate under the direction of the primary site laboratory director, the laboratory is permitted to temporarily perform testing in an alternate location.
Survey and Certification (S & C) Policy Memo S&C-12-09 provides several examples of scenarios meeting the multiple site exceptions.

Guidance related to surveying laboratories that have multiple testing locations covered under a single CLIA certificate can be found in State Operations Manual Chapter 6 §§ 6114 and 6140.2. When laboratory testing locations exist outside the state in which the primary site or home base is located, coordination among state survey agencies will be necessary in order to ensure a representative sample of the testing performed under the single CLIA certificate is surveyed. State Agencies may contact the applicable CMS Branch Location Office for assistance with coordination.

D. Issuing Form CMS-2567, Statement of Deficiencies

When a surveyor performs a complaint, initial, or recertification survey**, two** distinct surveys should be performed on Certificate of Compliance (CoC) laboratories. In addition to the routine or complaint survey, a focused survey for compliance with SARS-CoV-2 test result reporting requirements will be performed at the same time. Complaint, initial, and recertification surveys should be performed following the SOM. A separate CMS-2567 with the same date will be issued for each survey. That is, one CMS-2567 would be issued for noncompliance with SARS-CoV-2 test results reporting requirements ("U-COVID19") and a separate CMS-2567 would be issued for the complaint, recertification, or initial survey. This allows CMS to proceed to with enforcement, if applicable, on each survey and impose sanctions separately, each with its own appeal rights.

See General Guidance, Section 3, above for instructions to create a special survey for SARS-CoV-2 test reporting requirements.

E. Citations, D1002/D3000

Failure of a CLIA-certified laboratory to report SARS-CoV-2 test results as required by the new requirements at 42 CFR §§ 493.41 and 493.1100(a) will result in a **mandatory citation**. This applies to all CLIA certificate types. A laboratory must have documentation that it has reported all SARS-CoV-2 test results. ***Please note*** that a citation is not required if the laboratory attempted to report all of the SARS-CoV-2 test results but such results were not accepted due to factors outside of the laboratory's control—for example, if local or state health departments are not accepting negative results or are not equipped for the volume of reporting required under the IFC.

Compliance with the test reporting requirements will be assessed through the following process:

1. Surveyors will ask for, and review, the laboratory's policy/procedure related to SARS-CoV-2 test reporting. ***Please note*** that the laboratory may have a specific policy/procedure related to SARS-CoV-2 test reporting or it may be embedded in a more general policy/procedure. Either is acceptable.
2. Surveyors will also review SARS-CoV-2 testing records. A sampling of testing records may be selected if deemed appropriate by the surveyor.
3. Surveyors will review, and verify, the laboratory's documentation that SARS-CoV-2 test results were reported and that the laboratory's policy/procedure was followed. ***Please note*** that a citation is not required if the laboratory attempted to report all of the SARS-CoV-2 test results but such results were not accepted due to factors outside of the laboratory's control—for example, if local or state health departments are not accepting negative results or are not equipped for the volume of reporting required under the IFC.
4. It is very important that the total number of days (i.e., extent, universe) that the laboratory failed to report SARS-CoV-2 test results is clear in the Form CMS-2567 (see example of a citations in Appendix A). For citations at D1002 and D3000 (related to SARS-CoV-2 test result reporting), a laboratory director citation is not required.

CMS will issue a warning letter if the surveyor finds that the laboratory did not report, or attempt to report as described above, test results at the time of the initial, recertification or complaint survey. CMS will only assess an initial civil money penalty (CMP) of $1000 if the laboratory has not reported, or attempted to report as described above, test results at the time of the revisit from the initial, recertification, or complaint survey. However, if CMS determines that the laboratory continues to not report, or attempt to report as described above, SARS-CoV-2 test results, the laboratory will then be assessed a CMP of $500. CLIA is not assessing if all of the data elements in the Secretary's June 4th Guidance are not reported nor is CMS assessing the total number of test results not reported.

Certificate of Waiver laboratories that do not comply with the test reporting requirements at § 493.41 will be cited for noncompliance at **D1002**. All other certificate types, including PPMs, that do not comply with the test reporting requirements at § 493.1100(a) will be cited for noncompliance at **D3000**. If a laboratory is performing a SARS-CoV-2 test that is authorized for a waived setting, but is being performed under any certificate type except a CoW, **D3000** should be used.

If a laboratory is reporting its results to the state or local health department, as required, but is not following its policy or procedures, D1002/D3000 should not be cited. However, the laboratory should be cited for not following its own procedures (D1001 for CoWs and D5403 for other certificate types). Most of the EUA IFU's have a statement that the laboratory must have a process for reporting.

5. Reporting Non-Compliance with SARS-CoV-2 Test Reporting Requirements to CMS

   Once the surveyor has identified noncompliance with either D1002 or D3000, the information should be forwarded to the applicable Branch Location Office along with an electronic copy of the CMS-2567. The Branch Location Office will forward all of the information to CMS Baltimore so that the appropriate letter (i.e., warning, sanction) can be sent to the laboratory. CMS Baltimore will ensure that both the Branch Location and State Agency are cc'd on any notices.

6. **Important Note:** SARS-CoV-2 Molecular and Antigen Point of Care Test Enforcement Discretion

   CMS requires facilities with a CLIA Certificate of Waiver to follow the manufacturer's instructions (Instructions for Use) when performing laboratory testing. In addition, CMS requires facilities that perform non-waived testing ("non-waived facilities") that modify an FDA–authorized, cleared or approved test system to establish performance specifications before reporting patient test results. The FDA has granted EUAs to certain molecular and antigen POC tests for particular indications, including antigen tests that are intended to test specimens from individuals who are suspected of COVID-19 by their healthcare provider within a certain number of days after the onset of symptoms, as specified in each test's EUA and Instructions for Use. The FDA has provided recommendations and information for health care providers who are ordering authorized tests outside the test's authorization (e.g., antigen tests for asymptomatic individuals) – see FDA's FAQ on Testing for SARS-CoV-2 ("Q: Does the FDA have

recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19?") for further information.

CMS will temporarily exercise enforcement discretion under CLIA for the duration of the COVID-19 public health emergency for the use of authorized SARS-CoV-2 molecular and antigen POC tests on asymptomatic individuals outside of the test's authorization. Specifically, **CMS will not cite facilities with a CLIA Certificate of Waiver** when authorized SARS-CoV-2 molecular or antigen POC tests are performed on asymptomatic individuals outside of the test's authorization, when done so considering the information in FDA's FAQ. In addition, **CMS will not cite nonwaived facilities** when modified authorized, cleared or approved SARS-CoV-2 molecular or antigen POC tests are performed in such manner without establishing performance specifications.

7. The State Agencies may also receive concerns related to CLIA certificates or laboratory reporting requirements from Long Term Care (LTC) facility (also known as "nursing home") surveyors. These surveyors have been instructed to send this information to the LabExcellence@cms.hhs.gov mailbox. When reporting concerns, LTC surveyors should provide the CLIA number, name and address of laboratory (facility), number of days that results were not reported, if known, and number of results not reported, if known.

   Please see QSO-20-37-CLIA, NH for additional information.

F. Pre-Survey Notification Letters and Survey Tools

The State Agency should continue to use the pre-survey notification letters that are currently being used when scheduling surveys. CMS recommends that the SA add information related to SARS-CoV-2 test result reporting. For CoW/PPMs, please see section below related to CoWs/PPMs.

Due to the current PHE, CMS suggests using the following probes as part of the pre-survey process when scheduling an onsite survey:

- Can or does the laboratory provide a separate review area/room with limited access, e.g., as few as 1 – 2 staff interaction during the onsite survey?

- Has the laboratory ceased any testing since March 2020? If so, when and what?

- Has the laboratory performed any COVID-19 testing since March 2020? If so, please provide the name/manufacturer of the test.

- Does the laboratory have a mechanism in place to ensure all COVID-19 results are being reported to appropriate agencies? If yes, ensure documentation is available to assess for compliance at the survey.

- Have there been any staff/visitors that tested positive for COVID-19 in the laboratory during the past 14 days? (If the laboratory answers yes, discuss with State Agency Management, and if needed, CMS Branch Location Office for guidance.)

Reporting SARS-CoV-2 Test Results

A. Grace Period

Per the CMS Press Release dated August 25, 2020, laboratories will have a one-time, three-week grace period to begin reporting required test data. This began with the publication of the IFC, CMS-3401-IFC, in the Federal Register on September 2, 2020. Laboratories do not need to retroactively report SARS-CoV-2 test results.

B. General Guidance

- CLIA surveyors will only be assessing if laboratories have, or have not, reported, or attempted to report as described above, SARS-CoV-2 test results. CLIA surveyors will not be assessing if the data elements found in the Secretary's June 4, 2020 Guidance were reported or if the timeline in the Secretary's guidance was met. In addition, CLIA surveyors will not be citing to data elements or timelines found in the Secretary's guidance. See QSO-20-37-CLIA, NH.
- The requirements for the test report under 42 CFR § 493.1291 have not changed. The data elements outlined in the Secretary's guidance are not required on the test report unless already required under § 493.1291. Information required under §493.1291 is separate and apart from the data elements required by the Secretary's June 4th guidance.
- All CLIA Laboratories performing SARS CoV-2 testing must report all (including **positive and negative)** test results for all testing completed. This includes molecular, antigen and serology testing. This is true even if the IFU only references reporting of positive results.
- The laboratory that performs the SARS-CoV-2 test is responsible for reporting the test result.
- **See Surveying, Section D** above. for process to assess compliance with test reporting requirements. The laboratory must have documented evidence that SARS-CoV-2 test results were reported. If there are state licensure requirements for reporting that are more stringent than CLIA, the noncompliance with state licensure requirements must be cited under State requirements on a separate "Statement of Deficiencies".
- Examples of reporting mechanism that may be used by the laboratories:
  - LIS system/electronic reporting: date, time, and the person that reported the results are indicated in the LIS.
  - Fax machine: date, time, and the person that reported results are indicated on the fax cover sheet or fax "report" sheet.
  - Manual record: date, time, and the person that reported results are indicated in the communication log book.

C. CMS Medicare-certified Long-Term Care facilities (LTCFs)("Nursing Homes")

LTC facilities may submit POC SARS-Co V-2 testing data for residents and staff, including antigen testing data, to CDC's National Healthcare Safety Network (NHSN). This pathway applies only to Medicare and Medicaid-certified LTC facilities. The CLIA-waived POC test data submitted to NHSN will be reported to appropriate state and local health departments

using standard electronic laboratory messages. The new pathway will enable certified LTCFs, commonly known as nursing homes, to meet HHS' requirement to report data for SARS-CoV-2 POC antigen testing and other on-site COVID-19 laboratory testing. All other test results (e.g., for visitors) should be reported to the state or local health department.

D. Probes

- Do the laboratory's policies and procedures include how to report test results?

  CoW and PPMP Laboratories must follow the FDA EUA Manufacturer IFU when reporting the patients' test results. This requires laboratories using such test methods to have a process in place for reporting test results to healthcare providers and relevant public health authorities. All CLIA Laboratories performing SARS CoV-2 testing must report all (including positive and negative) test results for all testing completed. This is true even if the IFU only references reporting of positive results. Laboratories that do not have reporting processes in place, should be cited under 42 CFR § 493.15(e)(1)/D1001

  Certificate of Registration (COR), Certificate of Compliance (COC), and Certificate of Accreditation (COA) laboratories are required to document their existing system in place for reporting patient results in its written procedure manual as specified in 42 CFR § 493.1251(b)(13)/D5403.

  Laboratories are required under CLIA to report all (including positive and negative) results for the testing the laboratory completes to state or local health department. Failure to report any of the data elements (demographic) required in the June 4th HHS guidance is not under CLIA oversight.

- How does the laboratory track SARS-CoV-2 test results that are reported? (Cite D1002 or D3000)

- How does the laboratory document that it has reported SARS-CoV-2 test results?

  CLIA is not prescriptive as to how laboratories report SARS-CoV-2 test results. However, the laboratory must have documented evidence that test results were reported, or an attempt was made to report the test results as described above, and must have reported those results as outlined in its policies/procedures. CMS would also expect the laboratory to have verification that the test results were received by the reporting entity.

  Regardless of the means used to transmit laboratory results, routine checks should be conducted to verify that transmissions are being accurately and reliably conveyed to the final report destination. (Cite D1001 for CoW, D5801 for other certificate types)

- Does the laboratory report results to its state or local health department, or as required by the state?

  CMS is enforcing the new CLIA SARS-CoV-2 test reporting requirements in the IFC. If a laboratory or facility is reporting to state or local health department through existing public health reporting methods, then it is in compliance with CLIA and meeting this

reporting requirement. Surveyors are not expected to determine in which state a tested individual resides.

Certificate of Waiver (CoW) and Certificate for Provider-Performed Microscopy (PPM)

A. General Information for CoW and PPM Surveys

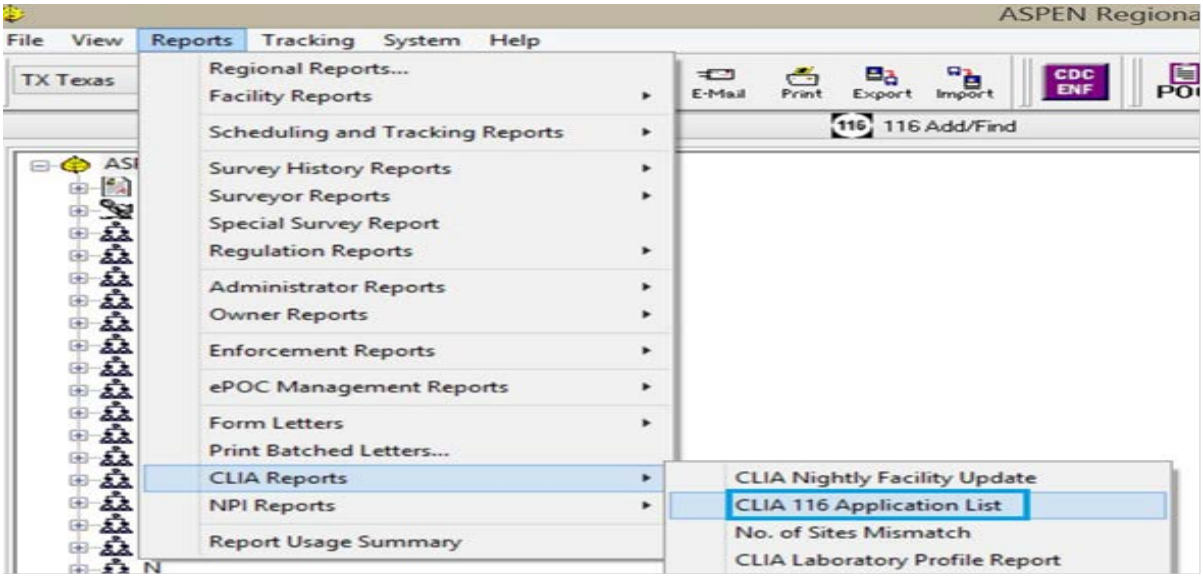
For the duration of the PHE, CMS-3401-IFC requires the survey of 5% (approximately 1.6% performed each fiscal year) of a combination of CLIA CoW and PPM laboratories. Surveyors will conduct special focused SARS-CoV-2 Reporting Requirement surveys either on-site or remote for the purpose of determining compliance with the new CLIA Condition-level regulations pertaining to SARS-CoV-2 test reporting requirements.

If the State is not allowing onsite surveys because of COVID, a remote survey is permissible. Please keep in close contact with the CMS Branch Location Office so that CMS is aware of the current State situation.

B. Laboratory Selection

CMS recommends identifying new CoW/PPM laboratories added to the CLIA Data System since February, 2020 as these laboratories are likely to have obtained CLIA certification to perform SARS-CoV-2 testing.

To facilitate identifying these laboratories, there is a report in ASPEN Central Office (ACO)/ ASPEN Regional Office (ARO) that can be used (See screenshot below). Set the date range and choose the certificate type and Lab type (if needed)



State agencies should make efforts to identify CoW and PPM laboratories performing SARS-CoV-2 testing during the survey selection and scheduling process because **only laboratories performing SARS-CoV-2 testing will be surveyed**. Laboratories should

be selected to ensure efficient use of resources and be representative of all facility types (physician office laboratories (POLs), nursing homes, pharmacies, and schools). If possible, cluster laboratories that are nearby CoCs for efficiency.

CMS-3401-IFC CoW and PPM Pre-survey Announcement Letter: The State Agency should continue to use the pre-survey notification timeframes that it currently uses when scheduling surveys. Pre-survey notification letters specifically for the Cow and PPM laboratories are provided below.

See Appendix C: CMS-3401-IFC CoW Survey Announcement Letter
See Appendix D: CMS-3401-IFC PPM Survey Announcement Letter

C. Surveys

If a surveyor observes or finds evidence during the special focused survey that the laboratory is testing outside of its certificate or finds that the laboratory is not following regulatory requirements, a complaint survey may be initiated after consultation with the applicable Branch Location Office.

On-site Surveys

Refer to **Surveying**, Section D, above.

Remote Surveys

In some cases, it may be necessary to perform the special focused SARS-CoV-2 Reporting Requirement survey remotely. In order to perform this survey remotely, we recommend the following:

- Contacting the laboratory to verify the laboratory is performing SARS-CoV-testing.
- Sending the pre-survey announcement letter (see Appendix C or D)
- Requesting the laboratory's policy/procedure for reporting, documentation of SARS-CoV-2 testing performed and evidence which demonstrates the reporting of all (including negative and positive) SARS CoV-2 test results to the appropriate authorities.

  Random sampling may be appropriate (e.g., date ranges). These documents are requested in the pre-survey announcement letter and made available to the surveyor at the date and time of the entrance conference.

Compliance with the test reporting requirements will be assessed following the process outlined in **Surveying**, Section D above.

D. Probes

Refer to **Reporting SARS-CoV-2 Test Results** for additional probes.

E. Post Survey

See Appendix A for examples of citing D1002.

F. Data Entry

To create the CMS-2567 select the stand alone survey option in ACO/ARO either Y-CoW or Z-PPM.

Certificate of Compliance (CoC) and Certificate of Registration (CoR)

A. See **Surveying**, Section D, above.

B. See Appendix A for examples of citing D3000.

C. Probes

- Does the laboratory have a (SARS-CoV-2) reporting policy/procedure, (e.g., via Quality Assessment (QA) manual)? (Cite D3000; if the laboratory does not have a policy/procedure, cite D5401; if the laboratory is not following its own written policy/procedure, cite D5401).

- Does the laboratory's SARS-CoV-2 reporting policy/procedure include reporting all (including positive and negative) SARS-CoV-2 patient results? (D5403) How does the laboratory document this reporting activity is being performed? (Cite D3031)

- How does the laboratory ensure/verify all patient samples that were tested were reported to the correct entity/agency?

- Does the policy/procedure indicate the method of reporting used by the laboratory (e.g. facsimile transmission, postal mail, electronic mail reporting, state electronic reporting system or local electronic system linked to the state electronic reporting system), entity reported to (e.g., state public health agency), and frequency of reporting?

- If a third party contractor is used to help with SARS-CoV-2 reporting, how does the laboratory ensure/verify the contractor is following the lab's reporting policy/procedure?

APPENDIX A: Examples of Citing Laboratories for Not Reporting SARS-CoV-2 Test Results

D1002 42 CFR § 493.41 Condition: Reporting of SARS-CoV-2 test results.
D3000 42 CFR § 493.1100(a) Condition: Facility administration.

> *During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.*

Please note: This example applies to both D1002 and D3000, as applicable to the certificate type (see note in "Surveying" Section, D above).

Citation Examples:

- If a surveyor goes into the laboratory for an initial, recertification or complaint survey, and the laboratory has never reported, or attempted to report as described above, results, or if the laboratory has not reported all of the test results for all days that testing was performed, it is a **mandatory citation**. *This will result in a warning letter to the laboratory.*
- If a surveyor performs an onsite or virtual revisit, and the laboratory has not reported, or attempted to report all test results as described above, it is a **mandatory citation**. Determine on which days tests were performed, but some/all test results were not reported. Count the number of days that include non-reporting even if some test results were reported on those days. For example: 10/23 – testing performed → no test results reported; 10/24 all tests performed were reported; 10/25 - 10 of 20 tests performed were not reported → 2 days of noncompliance *This will result in a $1000 CMP being assessed on the laboratory.*
- If every result has been reported, regardless of time frame, the laboratory is in compliance with the SARS-CoV-2 test result reporting requirement unless otherwise specified in the laboratory's policy/procedures or IFU. *(No mandatory citation under D1002/D3000, but would be a citation for not following policy/procedures D1001/D5401)*

See example citations below.

Example #1, Laboratory Did Not Report Results

This CONDITION is not met as evidenced by;

Based on record review and interview the laboratory failed to report SARS-Co-V-2 test results as required for 15 of 45 days reviewed from October 2020 through December 2020. Findings include:

1. SARS-CoV-2 testing documentation *(identify specific documentation reviewed)* was reviewed from October 1, 2020 through December 15, 2020.
2. SARS-CoV-2 test result reporting documentation was reviewed from October 1, 2020 through December 15, 2020.
3. Documentation revealed that SARS-CoV-2 test results were not reported as required for 6 days in October 2020, 7 days in November 2020, and 2 days in December 2020.
4. 223 test results were not reported as required during the period of review.
5. The laboratory performed 2000 SARS-CoV-2 tests during the period of review.
6. The laboratory director *(add appropriate individual)* confirmed the findings on 12/20/2020 at 2:30 pm.

Example #2, Laboratory Did Not Report Negative Results

This CONDITION is not met as evidenced by;

Based on record review and interview the laboratory failed to report SARS-Co-V-2 negative test results for 15 of 45 days reviewed from October 2020 through December 2020. Findings include:

1. SARS-CoV-2 testing documentation *(identify specific documentation reviewed)* was reviewed from October 1, 2020 through December 15, 2020.
2. SARS-CoV-2 test result reporting documentation was reviewed from October 1, 2020 through December 15, 2020.
3. Documentation revealed that SARS-CoV-2 negative test results were not reported as required for 6 days in October 2020, 7 days in November 2020, and 2 days in December 2020.
4. 223 negative test results were not reported as required during the period of review.
5. The laboratory performed 2000 SARS-CoV-2 tests during the period of review.
6. The laboratory director *(add appropriate individual)* confirmed the findings on 12/20/2020 at 2:30 pm.

Example #3, Revisit

This CONDITION is not met as evidenced by;

Based on record review and interview the laboratory failed to report SARS-Co-V-2 test results as required for 10 of 30 days reviewed from December 2020 through January 2021. Findings include:

1. SARS-CoV-2 testing documentation *(identify specific documentation reviewed)* was reviewed from December 15, 2020 through January 28, 2021.
2. SARS-CoV-2 test result reporting documentation was reviewed from December 15, 2020 through January 28, 2021.
3. Documentation revealed that SARS-CoV-2 test results were not reported as required for 6 days in December 2020 and 4 days in January 2021.
4. 156 test results were not reported as required during the period of review.
5. The laboratory performed 1620 SARS-CoV-2 tests during the period of review.
6. The laboratory director *(add appropriate individual)* confirmed the findings on 1/28/2021 at 10:45 am.

APPENDIX B: Helpful Links

- QSO Memo, Performance Specification Verification of Assays Authorized Under Emergency Use (EUA): CMS QSO-18-19-CLIA
- QSO Memo, Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency: CMS QSO-20-21-CLIA
- QSO Memo, Enforcement Cases Held during the Prioritization Period and Revised Survey Prioritization: CMS QSO-20-35-ALL
- QSO Memo, IFC, SARS-CoV-2 Test Reporting: QSO-20-37-CLIA, NH
- Admin Memo, CMS SARS-CoV-2 Laboratory Testing Comparison + COVID-19 Testing Infographic: ADMIN 20-06-CLIA
- CLIA FAQs, Surveillance/Pooled Samples: CLIA Surveillance Testing FAQ
- CLIA POC Ag Test Enforcement Discretion FAQ: CLIA POC Ag Test FAQ
- CLIA University Laboratory Testing FAQs: CLIA and University Lab Testing FAQs
- FDA Emergency Use Authorization (EUA) Tests: FDA EUA COVID-19 Test List
- FDA Frequently Asked Questions (FAQs) on Testing for COVID-19: FDA COVID-19 Test FAQs

FDA Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency: FDA COVID-19 Test Guidance

APPENDIX C: CMS-3401-IFC CoW Survey Announcement Letter

Dear Laboratory Director:

For the duration of the public health emergency (PHE) the (XXXX) State Agency, representing the CLIA program, will conduct special focused surveys of laboratories with Certificates of Waiver (CoW). This special focused survey is for the purpose of determining compliance with the CLIA Condition-level regulation (42 CFR 493.41) pertaining to COVID-19 reporting requirements. This regulation is discussed further in the letter below.

Your survey will take place on (enter date and time). Failure to allow for a survey can result in enforcement action against the laboratory's CLIA certificate. [42 CFR 493.1773]

This office requests that the following documentation be available for review by the State Agency Surveyor to facilitate the survey process:

- A copy of the laboratory's policy/procedure for reporting SARS-CoV-2 test results in accordance with the regulation.
- Documentation of SARS-CoV-2 test results
- Evidence which demonstrates the reporting of all (including negative and positive) SARS-CoV-2 test results in accordance with the regulation

These documents should be made available to the State Agency Surveyor at the date and time of the survey.

CMS is committed to taking critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE). On August 25, 2020, an interim final rule with comment period (CMS-3401-IFC) went on display at the Federal Register. CLIA regulations have been updated to require all laboratories to report SARS-CoV-2 test results in a standardized format and at a frequency specified by the Secretary, §493.41. Failure to report SARS-CoV-2 test results will result in a condition level violation of the CLIA regulation and may result in the imposition of a Civil Money Penalty (CMP) as required under §§ 493.1804 and 493.1834. For more information, the link to the policy memo, QSO-20-37-CLIA, NH, is provided for your convenience.

All CLIA-certified laboratories that perform or analyze any test that is intended to detect SARS--CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) are required to report, regardless of the type of laboratory (type of CLIA certificate) performing the testing. All (including negative and positive) SARS-CoV-2 results must be reported irrespective of the method (e.g., molecular, lateral flow) used.

Please note that health care facilities using Point of Care COVID-19 testing devices under a CLIA Certificate of Waiver, including nursing homes, pharmacies, or other settings will be required to report test results under this regulation.
§ 493.41 Condition: Reporting of SARS-CoV-2 test results. (*New*): *During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter*

referred to as a "SARS-CoV-2 test") must reportSARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

A discussion about the survey findings will be provided at the conclusion of the survey. If the State Agency Surveyor identifies any concerns, you will subsequently receive a written CMS-2567 report containing the survey findings, instructions on how to reply to the CMS-2567 and a contact person at the State, should you require more information.

If you have any questions about this survey and/or the CLIA program, please contact the State Agency at State Agency Contacts. For free educational materials, please visit the CDC website and our CLIA website.

Sincerely,

State Survey Agency

APPENDIX D: CMS-3401-IFC PPM Survey Announcement Letter

Dear Laboratory Director:

For the duration of the public health emergency (PHE) the (XXXX) State Agency, representing the CLIA program, will conduct special focused surveys of laboratories with Certificates for Provider-performed Microscopy (PPM). This special focused survey is for the purpose of determining compliance with the new CLIA Condition-level regulation (42 CFR 493.1100(a)) pertaining to COVID-19 reporting requirements. This regulation is discussed further in the letter below.

Your survey will take place on (enter date and time). Failure to permit entry for inspection can result in enforcement action against the laboratory's CLIA certificate. [42 CFR 493.1773]

This office requests that the following documentation be available for review by the State Agency Surveyor to facilitate the survey process:

- A copy of the laboratory's policy/procedure for reporting SARS-CoV-2 test results in accordance with the regulation
- Documentation of SARS-CoV-2 test results
- Evidence which demonstrates the reporting of all (including negative and positive) SARS-CoV-2 test results in accordance with the regulation

These documents should be made available to the State Agency Surveyor at the date and time of the survey.

CMS is committed to taking critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE). On August 25, 2020, an interim final rule with comment period (CMS-3401-IFC) went on display at the Federal Register. CLIA regulations have been updated to require all laboratories to report SARS-CoV-2 test results in a standardized format and at a frequency specified by the Secretary, §493.1100(a). Failure to report SARS-CoV-2 test results will result in a condition level violation of the CLIA regulation and may result in the imposition of a Civil Money Penalty (CMP) as required under §§ 493.1804 and 493.1834. For more information, the link to the policy memo, QSO-20-37-CLIA, NH is provided for your convenience.

All CLIA-certified laboratories that perform or analyze any test that is intended to detect SARS--CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) are required to report, regardless of the type of laboratory (type of CLIA certificate) performing the testing. All (including negative and positive) SARS-CoV-2 results must be reported irrespective of the method (e.g., molecular, lateral flow) used.

§ 493.1100 Condition: Facility administration. (*New)*
(a) Reporting of SARS-CoV-2 test results. During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

A discussion about the survey findings will be provided at the conclusion of the survey. If the State Agency Surveyor identifies any concerns, you will subsequently receive a written CMS-2567 report containing the survey findings, instructions on how to reply to the CMS-2567 and a contact person at the State, should you require more information.

If you have any questions about this survey and/or the CLIA program, please contact the State Agency at (insert SA contact information). For free educational materials, please visit the CDC website and our CLIA website.

Sincerely,

State Survey Agency

Frequently Asked Questions (FAQs), Reporting SARS-CoV-2 Test Results
(CMS-3401-IFC[1])

1. **I am performing SARS-CoV-2 testing and am reporting patient-specific results. Do the new reporting requirements in the CMS-3401-IFC apply to me?**

   Response: Yes. All CLIA-certified laboratories that meet the definition of a "laboratory" at 42 CF R § 493.2 must report SARS-CoV-2 test results in the manner and frequency prescribed by the Secretary. See the following June 4, 2020 guidance for more information: HHS Laboratory-data-reporting-for-covid-19-testing-FAQs.pdf.

2. **What are the SARS-CoV-2 test results reporting requirements for laboratories? To whom do I report these test results?**

   Response: The new regulations require all CLIA-certified laboratories performing SARS-CoV-2 testing to report all SARS-CoV-2 test results, including positive and negative, in the manner and frequency prescribed by the Secretary. On June 4, 2020 the Secretary of HHS published guidance related to SARS-CoV-2 test result reporting. Please see question 1 for more information.

   Laboratories in Exempt States (ES) must follow the State Licensure requirements. Currently, Washington State is an ES and New York has a partial exemption.

3. **Do the SARS-CoV-2 reporting requirements also apply to laboratories that have a Certificate of Waiver (CoW) or Certificate for Provider-performed Microscopy (PPM)?**

   Response: Yes. All facilities that fall under the CLIA definition of a laboratory, including those laboratories with a CoW or PPM, are required to report SARS-CoV-2 test results.

4. **When and how often will laboratories be required to report SARS-CoV-2 test results?**

   Response: See question 1 above. However, CLIA will only be assessing whether laboratories have, or have not, reported SARS-CoV-2 test results.

   See question 2 regarding State Licensure requirements for laboratories in Exempt States.

5. **I represent a SARS-CoV-2 surveillance laboratory that performs pooled testing and does not report patient-specific results. Am I required to report SARS-CoV-2 test results under CLIA?**

   Response: During this COVID-19 Public Health Emergency, facilities performing SARS-CoV-2 surveillance testing using a pooled sampling procedure to report **non patient-specific** SARS-CoV-2 cohort results will not require CLIA certification, and therefore will not be required to report SARS-CoV-2 test results under CLIA. This testing is not considered by CMS to be diagnostic of SARS-CoV-2 infection, and participants should not rely on information received from this type of testing for decision making purposes.

[1] https://www.federalregister.gov/documents/2020/09/02/2020-19150/medicare-and-medicaid-programs-clinical-laboratory-improvement-amendments-clia-and-patient

If at any time a **patient-specific result** is to be reported by your facility, however, you **must** first obtain a CLIA certificate and meet all requirements to perform testing. Please see this link: CLIA SARS-CoV-2 Surveillance Testing.

6. **What happens if I don't report my SARS-CoV-2 test results as required by the CLIA regulations?**

   Response: CMS may impose civil money penalties (CMPs) for any laboratory with a Certificate of Waiver (CoW), Certificate for Provider-performed Microscopy (PPM), Certificate of Compliance (CoC), Certificate of Accreditation (CoA), or Certificate of Registration (CoR) that does not report SARS-CoV-2 test results in the manner and frequency prescribed by the Secretary. Such CMPs will be $1000 for the first day of noncompliance with the new reporting requirements, and $500 for each subsequent day the laboratory fails to report SARS-CoV-2 test results. For more information, please visit: QSO-20-37-CLIA, NH. Exempt States (ESs) are those states that have been approved by CMS as having a State Licensure Program equal to, or more stringent than, the CLIA conditional level requirements. CMS would expect the ESs to have an equivalent CMP structure to CMS and would expect the ES to impose CMPs under their State licensure program for failure to report SARS-CoV-2 results to whomever is required under State law.

7. **How do I document that I reported SARS-CoV-2 test results to the appropriate authority and in the timeframe required by the Secretary?**

   Response: The CLIA regulations are not prescriptive about how a laboratory documents reporting of SARS-CoV-2 results. However, the laboratory will need to have documentation that it reported the SARS-CoV-2 results, as required, when asked by a State Agency (SA), Federal, Accreditation Organization (AO), or Exempt State (ES) surveyor.

8. **Does the reporting requirement apply to serology testing as well as molecular and antigen tests?**

   Response: Yes. All CLIA-certified laboratories must report the results of any test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (***e.g.*, molecular, antigen, antibody**), regardless of the type of laboratory (or type of CLIA certificate) performing the testing.

9. **My facility has the appropriate CLIA certificate but is not testing for SARS-CoV-2, is there anything that I need to do?**

   Response: No. If your laboratory is not performing any testing for SARS-CoV-2, there is nothing that you need to do differently at this time; however, if your laboratory decides to start testing for SARS-CoV-2, you would need to follow the reporting requirements.

10. We perform SARS-CoV-2 testing daily on staff, students, employees and/or residents. Do we have to report every result, each time we test, or do we report one result per individual?

Response: The laboratory must report **each test result** for every SARS-CoV-2 test the laboratory performs that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19, regardless of the number of times that an individual is tested.

However, tests that do not report patient-specific results (that is, tests that are not intended to detect SARS-CoV-2 or diagnose COVID-19 in a particular individual) may not be subject to these requirements. Please see question 5 for more information.

11. We perform SARS-CoV-2 testing in-house but may also send specimens for SARS-CoV-2 testing to a reference laboratory for testing. Do we have to report both results to the designated authorities?

Response: Only the laboratory that performs the SARS-CoV-2 test is responsible for reporting the test result. If a laboratory sends a specimen to another laboratory for testing and does not perform the SARS-CoV-2 testing on the specimen in-house, this laboratory does not need to report test results for the specimen sent to another laboratory for testing.

Helpful links:

- CMS-3401-IFC, Updating Requirements of Reporting of SARS-CoV-2 Test Results and Data Elements for Clinical Laboratory Improvement Amendments (CLIA '88) Laboratories, published September 2, 2020: CMS-3401-IFC
- QSO Memo, Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency: CMS QSO-20-21-CLIA
- CLIA Frequently Asked Questions (FAQs) COVID-19: CLIA COVID-19 FAQs
- FDA FAQs on Testing for SARS-CoV-2: FDA COVID-19 Test FAQs
- HHS Laboratory Data Reporting for COVID-19 Testing: HHS Laboratory-data-reporting-for-covid-19-testing-FAQs.pdf
- The Secretary's Guidance (6/4/2020), COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115: HHS Guidance covid-19-laboratory-data-reporting.pdf
- HHS FAQ on Lab Data Reporting, Technical Specifications to Aid in Implementation for Labs: HHS FAQs - Data Reporting, Technical Specifications
- HHS COVID-19 Lab Data Reporting Implementation Specifications (PDF): HHS Lab Data Reporting Implementation Specifications
- Additional information, including technical specifications, was released in July and updated in September to support laboratories with implementation. See links here: HHS FAQ Lab Data Reporting and Implementation Specifications (PDF).
- CDC Reporting COVID-19 Laboratory Data: How to Report COVID-19 Laboratory Data
- CDC DLS: LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests: https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html