



**Center for Clinical Standards and Quality/Quality, Safety & Oversight Group**

**Admin Info: 21-09-CLIA**

**DATE:** September 30, 2021

**TO:** State Survey Agency Directors

**FROM:** Director  
Quality, Safety & Oversight Group

**SUBJECT:** Issuance of Clinical Laboratory Improvement Amendments of 1988 (CLIA)  
State Agency Performance Review (SAPR)—Fiscal Year 2021 (FY 2021)

**Memorandum Summary**

- **CLIA SAPR Review Protocol:** The FY 2021 review is continuing the restructured, more streamlined, SAPR process introduced in FY 2019.
- **Goal:** CLIA State Agency (SA) optimal performance, with support from the Centers for Medicare & Medicaid Services (CMS) Branch Locations, as necessary.
- **Summary Report for Each CLIA SA:** The aim of each report is a balanced picture of the CLIA SA's operations. **The SA "Performance Thresholds for Written Corrective Action Plan", "Quantified Performance Results" or "Written Corrective Action Plan" results will be reported on the Summary Report. The review year in FY 2021 is October 1, 2020 through September 30, 2021.**
- **Review of Other Subject Areas:** CMS Branch Locations have the overarching responsibility and authority for SA oversight, which is not superseded nor limited by the CLIA SAPR. Subject areas not specifically addressed by the FY 2021 Review Criteria may also be reviewed at the CMS Branch Location's discretion.
- **Due Date:** Draft CLIA SAPR Summary Reports, Worksheets and Cover Letters are due to the applicable Branch Manager by Friday, **March 4, 2022.**

**Background**

The CLIA SAPR is a mandated annual evaluation of each SA's performance of its survey and certification responsibilities under the CLIA program. The evaluation is performed by the CMS Branch Locations CLIA program personnel.

**Objectives and Goal**

The objectives of the SAPR are to document CLIA program oversight of SA performance and to support and facilitate SA performance improvement, as needed. The goal is optimal SA performance to further quality in patient testing.

SAs are encouraged to utilize the SAPR reports enclosed in Attachment 2 throughout the entire fiscal year to identify any areas which may need to be addressed before each annual SAPR review. SAs should contact their CMS Location if they wish to request a specific report throughout the year.

### **CMS CLIA Location Collaborative Support**

CMS CLIA Location collaborative support is an integral part of the CLIA SAPR. The collaboration includes assistance with CLIA SA internal reviews of Statements of Deficiencies (SODs), Allegations of Compliance (AOCs), and Plans of Corrections (POCs), where circumstances warrant, such as States with less than 1.0 CLIA surveyor full-time equivalent, or non-laboratorian supervisors. This activity can double as a training opportunity. Collaboration also provides further opportunities for mutual understanding of obstacles to optimal CLIA SA performance, brainstorming for solutions, and learning best practices of similar states. The SAPR process supports and enhances communication between the SA, CMS CLIA Locations, and CMS Baltimore.

In addition, the SAPR enables the SA to identify and correct issues related to their survey and certification duties in a more timely manner. The goal of the SAPR process, whether onsite or remote, is optimal CLIA SA performance and quality patient testing.

**Please Note:** The SAPR Summary report should not identify individual surveyors, laboratories, or CLIA numbers. Discussions regarding issues related to specific surveyors, laboratories, or CLIA numbers should occur at the onsite visit, or virtual visit, as applicable.

### **FY 2021 Protocol**

**The CLIA SAPR review for FY 2021 includes SA “Performance Thresholds for Written Corrective Action Plan”, “Quantified Performance Results”, or “Written Corrective Action Plan” results on the Summary Report.** CMS CLIA Locations have the option to expand the review to include additional areas of CLIA SA responsibilities which, in their judgment, merit evaluation or monitoring. The seven criteria are:

- Criterion #1—Personnel Qualifications, Training, and Competency
- Criterion #2 – Data Management
- Criterion #3—Proficiency Testing (PT) Desk Review
- Criterion #4—Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)
- Criterion #5—Survey Workload and Outcome-Oriented Survey Process (OSP)
- Criterion #6—Complaints
- Criterion #7—Quality Assessment

The CMS Locations are required to enter feedback in the “Findings”, “Special Circumstances Affecting Performance”, and “Noteworthy Activities and Accomplishments” sections to address any accomplishments (e.g., up-to-date on workload) or extenuating circumstances related to the public health emergency (PHE) and prioritization of surveys during the PHE.

It is strongly recommended that the States upload all documents into ASPEN (e.g., applications, change requests). This makes for a more efficient review process and allows for a more streamlined sharing of documents between the SA and CMS CLIA Location.

## **FY 2021 SAPR Review**

**The CMS Locations are required to enter feedback in the “Findings”, “Special Circumstances Affecting Performance”, and “Noteworthy Activities And Accomplishments” sections to address any accomplishments (e.g., up-to-date on workload) or extenuating circumstances related to the public health emergency (PHE) and prioritization of surveys during the PHE.**

### **Criterion #1: Personnel Qualifications, Training, and Competency**

Goal: The SA has an:

- Effective system is in place to ensure that all CLIA surveys are conducted by qualified and competent individuals.
- Ongoing training program to improve survey skills.
- Ongoing program to ensure that SA CLIA clerical staff and surveyors are properly trained in a timely manner.
- Ongoing mechanism to maintain and improve competency.

This criterion remains unchanged from the FY 2020 SAPR Criterion #1.

This criterion includes performance indicators (PIs) related to personnel qualifications and training. It also includes a PI related to competency to ensure all surveyors have an ongoing program to utilize feedback and focus on: interpreting regulations consistently, adhering to the State Operations Manual, and improving/maintaining surveyor skills.

### **Criterion #2: Data Management**

Goal: The SA has implemented a mechanism to ensure that data entry is done both accurately and within the appropriate timeframe and that all personnel responsible for data management have been trained.

This criterion remains unchanged from the FY 2020 SAPR Criterion #2.

The five fields included in the FY 2021 review are: Facility Name, Federal Tax Identification Number (TIN), Facility Address, Name of Director, and telephone number. The expectation is that if other demographic information is provided, this information should be accurately reflected in the database.

### **Criterion #3: Proficiency Testing (PT) Desk Review**

Goal: The SA conducts PT Desk Review timely and initiates appropriate action regarding unsuccessful participation.

This criterion remains unchanged from the FY 2020 SAPR Criterion #3.

### **Criterion #4: Principles of Documentation (POD), Plan of Correction (POC), Allegation of Compliance (AOC)**

Goal: The SA has a review system/process to ensure that all CLIA surveyors:

- Write clear, concise, and legally defensible SOD (CMS-2567) that are consistent with the CLIA POD.
- Accept only POC/AOCs that meet the criteria for acceptability.

This criterion remains unchanged from the FY 2020 SAPR Criterion #4.

This criterion combines a review of POD and POC/AOCs as well as including a PI related to the utilization and understanding of mandatory citations.

#### Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OSP)

Goal: The SA has a system to ensure that all surveyors conduct surveys using the outcome-oriented survey process, AND the SA has implemented a tracking system and ensures that the survey time frames are met.

This criterion remains unchanged from the FY 2020 SAPR Criterion #5.

This criterion includes PIs related to the OSP and timeliness of survey upload.

#### Criterion #6: Complaints

Goal: The SA accepts and processes all complaints from receipt to closeout, following CMS policies and procedures.

This criterion remains unchanged from the FY 2020 SAPR Criterion #6.

#### Criterion #7: Quality Assessment (QA)

Goal: The SA has developed specific procedures related to SAPR, and the SA has an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity (i.e., quality assessment).

This criterion remains unchanged from the FY 2020 SAPR Criterion #7.

This criterion requires the SA to have an overall QA program to identify and correct issues related to their certification and survey responsibilities throughout the year rather than annually. This criterion results in a more systemic look at processes and procedures of the SA as related to their responsibilities, thus affecting a more proactive approach rather than a reactive approach.

#### **Relationship to Other CMS Branch Location Oversight Responsibilities**

CMS CLIA Locations have the overarching responsibility and authority for CLIA SA oversight, which is neither superseded nor limited by the CLIA SAPR. Thus, the CMS CLIA Location may review a State's performance related to any aspect of CLIA SA responsibility not specifically evaluated by the standard protocol for FY 2021. Any review conducted in addition to the standard protocol should be documented in a separate section of the CLIA SAPR Summary Report and presented separately from the review outcomes of the standard Criteria designated for the FY 2021 review.

**Attachments—Listing and Descriptions**

Attachment #	Name
1	<ul style="list-style-type: none"> <li>• FY 2021 CLIA SAPR Document: Performance Review Criteria, Performance Indicators, and Worksheets, Review Tools, Examples</li> <li>• FY 2021 CLIA SAPR Criterion 2 Review Tool – Data Management (<i>required</i>)</li> <li>• FY 2021 CLIA SAPR Criterion 4, POD Principle 3, Composition of a Deficiency Citation, Review Tool (with reference sheet) (<i>required</i>)</li> <li>• FY 2021 CLIA SAPR Criteria 4 CMS Branch Location Review Tool—Principles of Documentation (POD) and Acceptable Plan of Correction /Credible Allegation of Compliance (POC/AOC) (<i>optional</i>)</li> </ul>
2	<ul style="list-style-type: none"> <li>• FY 2021 CLIA SAPR Data Reports –Description of Mandatory and Optional Reports – CMS Baltimore will provide electronic copies of these reports. Only CASPER 104 Instructions will be utilized for FY 2021 review (see pages 3-4).</li> </ul>
3	<ul style="list-style-type: none"> <li>• FY 2021 CLIA SAPR—The Summary Report Template</li> </ul>
4	<ul style="list-style-type: none"> <li>• FY 2021 CLIA SAPR Cover Letter_CAP Resp Template—for Transmitting the Summary Report to the SA</li> <li>• FY 2021 CLIA SAPR Model Letter—for Response to SA Corrective Action Plans FY 2021 CLIA SAPR Model Letter—for Response to SA Corrective Action Plans</li> </ul>

**Attachment #1:**

- **Document: Performance Review Criteria, Performance Indicators, and Worksheets**  
The Review Criteria, Performance Indicators, and instructions for completing the Worksheets are consolidated into one Excel document for ease of reference. Instructions for completion are contained in the section entitled “General & Specific Instructions”. The Worksheets must be completed electronically.
- **Criterion 2 CMS Branch Location Review Tool—Data Management**  
(*Required*) This tool is used by the CMS CLIA Location Reviewer to review the accuracy and timeliness of input into the database for initial Form CMS-116, certificate type changes, and updated demographic information. For FY 2021, the Review Tool for Criterion #2, Data Management, remains the same five (5) fields on the Form CMS-116 reviewed in FY2020. The 5 fields include: Facility Name, Federal Tax Identification Number(TIN), Facility Address, Name of Director, and telephone number. Criterion Review tool #2 has been moved next to Criterion #2 for ease of use.

- **Criterion 4, POD Principle 3, Composition of a Deficiency Citation, Review Tool**  
(*Required*) This tool is used by the CMS Branch Location Reviewer to review CMS-2567 Statements of Deficiency for adherence to POD Principle 3, Composition of a Deficiency Citation. This review tool has been moved next to Criterion #4 for ease of use. References remain at the end.
- **Criteria 4 CMS Branch Location Review Tool—Principles of Documentation (POD) and Acceptable Plan of Correction /Credible Allegation of Compliance (POC/AOC)**  
(*Optional*) This tool is used by the CMS CLIA Location Reviewer to review CMS-2567 Statements of Deficiency and Plan of Correction for adherence to POD and proper acceptance of POC/AOC. Outcomes from this review will be used for year-to-year comparisons, monitoring for improvement, and assessment for national training, as needed. This review tool has been moved next to Criterion #4 for ease of use. References remain at the end.

### **Attachment #2:**

- **FY 2020 CLIA SAPR Data Reports – Instructions and Description for both Mandatory and Optional Reports**  
CMS Baltimore will provide electronic copies of all SAS Viya mandatory and optional reports for each Branch Location Office for FY 2021.

Each CLIA Location Office will need to utilize CASPER 104 to evaluate demographic changes for Criterion #2, Data Management, PIs #6 and #7. See pages 3-4, Attachment 2.

It is recommended that the report “ACTS Complaint/Incident Investigation Log” be used to identify complaints for Criterion #6, Complaints for the FY 2021; however, details regarding the timeline should be verified either onsite or remotely at the SA as the documentation is a true indication of whether timelines have been met. In addition, tracking sheets developed and implemented at the CMS Branch Locations may be used.

CMS CLIA Locations have the overarching responsibility and authority for SA oversight; therefore, subject areas not specifically addressed by the FY 2021 Review Criteria may also be reviewed at the CMS CLIA Location’s discretion. The addendum report should indicate why the additional measure(s) are being reviewed.

### **Attachment #3:**

- **FY 2021 CLIA SAPR Summary Report Template**  
All narrative sections, “Findings”, “Special Circumstances Affecting Performance”, and “Noteworthy Activities and Accomplishments” appear on the Summary Report **and need to be completed**. It is very important to provide a narrative in these sections so that CMS has a complete picture of the SA’s performance.

**The CMS Locations are required to enter feedback in the “Findings”, “Special Circumstances Affecting Performance”, and “Noteworthy Activities And Accomplishments” sections to address any accomplishments (e.g., up-to-date on**

workload) or extenuating circumstances related to the public health emergency (PHE) and prioritization of surveys during the PHE.

**Please note: The CLIA SAPR review for FY 2021 will include reporting of SA “Performance Thresholds for Written Corrective Action Plan”, “Quantified Performance Results” or “Written Corrective Action Plan” results on the Summary Report.**

**Attachment #4:**

- **FY 2020 CLIA SAPR Cover Letter CAP Resp Template for Transmitting the Summary Report to the SA**

The language in this model letter has been updated to address the FY 2021 review. Model language is included for instances where the CMS CLIA Location has exercised the option to review additional subject areas. Instructions for the associated narrative are now more specific.

- **CLIA SAPR Model Letter for Response to SA Corrective Action Plan**

**Due-Date for Draft Summary Reports, Worksheets, and Cover Letters and CMS CLIA Location Review Tools**

Draft FY 2021 CLIA SAPR packages are due to the applicable Branch Manager by **Friday, March 4, 2022**. Please forward the Summary Report, along with the Excel Worksheets, Cover Letter, CMS Branch Locations Review Tool for Criterion 4 and POD Principle 3, Composition of a Deficiency Citation, and associated CMS-2567s to the applicable Branch Manager.

**Effective Date:** October 1, 2021. This information should be shared with all CLIA Program survey and certification staff and their managers within 30 days of this memorandum.

/s/  
David R. Wright

Attachments: See Table on page 5 for Listing and Descriptions

cc: CLIA CMS Locations

**Attachment #1**

**CLIA SAPR Documents FY2021  
Performance Review Criteria 1-7 with Performance Indicators  
General Instructions, References, Worksheets and Review Tools**

## CLIA State Agency Performance Review FY2021 General and Specific Instructions for Completing Worksheets

### General Instructions for all Worksheets

- Refer to the 1st page of each Worksheet for a list of all Performance Indicators (PI) for that Criterion.
- In general, the 2nd page of each Worksheet contains the specific PI(s) with a data field to enter the result of each finding.
- The 3rd page of each Worksheet (if needed) is where the Branch Location consultant will enter the name of the State Agency reviewed, who in the Branch Location performed that specific review of that criterion, and the date of the review.

### **Instructions for Completing Data Fields associated with Performance Indicators**

1. Complete data fields that require information (i.e. surveyor name, CLIA #, Analyte, Specialty/Subspecialty/Event, etc.) by typing the information into the space below the column header.
2. **For PI#1 in Criteria #1, #2, #3, #4 and #7, if "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.**
3. Complete data fields that require a "Yes", "No", "NA", "Y" or "N" by entering a "1" into the space, with the exception of the "Yes" and "No" data fields located after "Written Corrective Action Plan Needed?". All of these data fields are used to calculate the Quantified Performance Result. Be careful not to "clear" any of these associated data fields. Doing so will cancel the formula in that data field and the Quantified Performance Result will not calculate correctly.
4. In the box labelled "Written Corrective Action Plan Needed?", if "Yes" enter an "X" in the "Yes" box, if "No" enter an "X" in the "No" box.
5. Please see Attachment #2, "FY21 Data Rpt Info", for information related to both mandatory and optional SAS Viya reports.

### Special Instructions for each Criterion

#### **Criterion #1: Personnel Qualifications, Training & Competency**

##### Personnel Qualifications

- Ask the SA to demonstrate how each **new surveyor** meets the requirements for PI #2 & #3.
- Review surveyor personnel information (system, personnel files, etc.) to verify that the performance indicators are satisfied for each surveyor.

##### Ongoing Training & Annual Competency Programs

- Ask the SA to demonstrate how each surveyor meets PI #4. If any one of PI #4 a. → d. is not met, indicate which was not met in the "Comment" column.

**Note for PI #5** In some instances, a SA surveyor will be unable to attend mandatory training for a variety of reasons (e.g.. personal commitment or

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...in some instances, a surveyor will be unable to attend mandatory training for a variety of reasons (e.g., personal commitment or medical issue); however, the intent is that if CMS funds a mandatory training, all SA surveyors must attend unless a staff member is given an approved exception. Denial by the SA to approve CMS-funded training is not an acceptable exception.

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**Criterion #2: Data Management**

All information for PI #2- PI #7 should be collected from the Criterion #2 Review Tool.

**CMS 116: Accuracy & Timeliness**

**For FY2021**, the following 5 selected fields will be reviewed for this criterion: Facility Name, Federal Tax Identification (TIN), Facility Address, Name of Director, telephone number. No other CMS-116 fields are required to be reviewed unless the Branch Location determines an expanded review is warranted.

**Note for PI #2:** When evaluating PI #2, the Branch Location reviewer should compare the initial Form CMS-116 to the information entered into the CLIA CMS-116 database. As long as the SA has requested additional information (e.g., laboratory director qualifications) prior to the 30 days, this PI is considered met as it is beyond the SA's control if a laboratory does not provide the requested information in a timely manner.

**Review Tool Criterion #2 has been moved up next to Criterion #2 for the convenience of completing this information. References remain at the end.**

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**Criterion #3: Proficiency Testing Desk Review**

- Review the SA's PT tracking and frequency performed to determine whether Performance Indicator #1 is met.
- Select 10 laboratories and include a cross-section of initial and non-initial unsuccessful events.
- Indicate whether unsuccessful PT is either the initial unsuccessful or the non-initial unsuccessful.
- If no non-initial unsuccessful events occurred during the FY under review, select 10 initial unsuccessful events or all, whichever is fewer.

**NOTE:** If no unsuccessful events appear on CASPER #153, **interview SA personnel** to ascertain their understanding of the proper procedure in the case of initial or non-initial unsuccessful events. Treat the criterion as met and note the interview and any related comments in line #1, PI #2 chart on this worksheet.

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**Criterion #4: Principles of Documentation (POD) & Plan of Correction (PoC), Allegation of Compliance (AoC)**

- Any CMS-2567s reviewed throughout the FY by the Branch Location (e.g., for the purpose of FMS Assessments, Condition-level non-compliance) may be incorporated into the Branch Location review to meet this criterion.

**NOTE:** In States with few surveyors, particularly those with fewer than 2 FTEs, the Branch Location staff may need to be more directly involved in the review activities and should apply the performance indicators in a manner that is reasonable for the particular SA administrative and operational set-up. This may include Branch Location participation in the SA POD and PoC/AoC review process.

## CLIA State Agency Performance Review FY2021 General and Specific Instructions for Completing Worksheets

- Ask the SA for an overview of their review system and/or other review activities they may use, and documentation of their review findings during the year under review. Seek sufficient information about the review system to determine whether the performance indicators are met.

- To quantify SA results for POD & PoC/AoC, the following formula must be used by the SA in its internal review process.

**POD:** Divide the total number of D-tags that meet the Principles of Documentation by the total number of D-tags cited on the CMS-2567s reviewed during the FY under review.

**PoC/AoC:** Divide the total number of D-tags on the PoC that meet the Criteria for Acceptability by the total number of D-tags cited on the CMS-2567s reviewed during the FFY under review.

**NOTE:** The result of these calculations are used for SA's internal review only; it is not related to the performance threshold for this criterion.

### ADDITIONAL REVIEW BY THE BRANCH LOCATION REVIEWER:

- Completion of the Criterion #4, POC Principle 3, Composition of a Deficiency Citation Review Tool **is required** (see Attachment #1 of the CLIA SAPR Admin Memo).

- Select one CMS-2567 for each CLIA surveyor in the SA. Use a separate Branch Location Review Tool for each CMS-2567 reviewed, and record your findings for Criterion #4, Principle 3 on the review tool. If all D-Tags in the CMS-2567 being reviewed meet POD, enter an "X" in column C, "All D-Tags Meet POD."

Or, if one or more D-Tags do not meet POD, enter the applicable D-Tag that does not meet POD and the reason in column E, "D-Tag Not Meeting POD + Reason".

- Leave the "All D-Tags Meet POD" column blank if 1 or more D-Tags do not meet POD.

- If there are more than 5 CLIA surveyors in the SA, review other surveyors' CMS-2567s in a subsequent year. If only 1 CLIA surveyor, select a minimum of 2 CMS-2567s. Refer, as needed, to the CLIA Principles of Documentation, when you discuss the outcome of Principle 3 with the SA.

The outcomes of the Branch Location Review Tool are for year-to-year comparison and monitoring for improvement, and assessment for national training, as needed.

**Notes:** Scan or otherwise electronically save the CMS-2567 with the Criterion #4, Principle 3 review tool., The CMS-2567 can be uploaded into SharePoint. There is no need to submit the PoC/AoC for the FY2021 SAPR review. Only the CMS-2567 should accompany the review tool.

Use of the "CLIA SAPR Criterion #4 D-tag Branch Location review tool" (the previous review tool utilized for Criterion #10 & #11) is **OPTIONAL** for FY2021.

Review Tool Criterion #4, POD Pr 3 and Tool Criterion #4 have been moved up next to Criterion #4 for the convenience of completing this information. References remain at the end.

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**CLIA State Agency Performance Review FY2021  
General and Specific Instructions for Completing Worksheets**

**Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OSP)**

**Survey Workload**

**NOTE for PI #1:** If the SA can demonstrate that all expired CoR listed on these reports were due to circumstances beyond the CLIA SA's control, do not hold the SA accountable and enter a "1" in "Yes". Document the exceptions in the Comments section of this worksheet.

**NOTE for PI #2:** If all expired CoC listed on these reports were due to circumstances beyond the CLIA SA's control, do not hold the SA accountable and enter a "1" in "Yes". Document the exceptions in the Comments section of this worksheet.

**NOTE for PI #3:** If zero or one of the time intervals between AO and CLIA surveys exceeded 90 days, enter a "1" in "Yes." If two or more of the time intervals exceeded 90 days enter a "1" in "No".

**EXCEPTION:** If the SA can demonstrate that all of the intervals which exceeded 90 days were due to scheduling changes by the laboratory or accreditation organization, do not hold the SA accountable and enter a "1" in "Yes". Document the exceptions in the Comments section of this worksheet.

**NOTE:** Postponing a validation survey more than once, at the request of the laboratory, is contrary to SOM instructions, and is not considered an exception for SAPR purposes.

**NOTE for PI #4:**

- Ask the SA to demonstrate that they have generated, evaluated and acted on the CASPER 850D reports each quarter of the FY. Enter a "1" in "Yes"; if not, enter a "1" in "No."
- If the State has no expired certificates (CoR, CoC) on the CASPER 850D report, enter "1" in "Yes." If there are mitigating circumstances beyond the SA control as to why certificates expired, enter a "1" in "Yes."

**NOTE:** The SA should be able to show that they have generated the 850D reports each quarter even if the reports show that the State has no expired certificates. If the SA has generated the CASPER 850D report and has no expired certificates, enter a "1" in "Yes"; however, if the State has no expired certificates and has NOT generated the CASPER 850D report, enter a "2" in "No".

**NOTE for PI #5:**

- Ask the SA to demonstrate their system for uploading surveys. The format need not be elaborate or automated.

**EXCEPTION:** If the SA can demonstrate that survey kit uploads were due to circumstances beyond the CLIA SA's control (e.g., laboratory did not respond to a request for an AoC/PoC), do not hold the SA accountable and enter a "1" in "Yes." Document the exceptions in the Comments section of this worksheet.

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General and Specific Instructions for Completing Worksheets**

**Outcome Oriented Survey Process**

- Any CMS-2567s reviewed throughout the FY by the Branch Location (e.g., for the purpose of FMS Assessments, Condition-level non-compliance) can be incorporated into the Branch Location review to meet this criterion. For example, a sample of FMS Assessment surveys may be reviewed to ensure follow up actions and monitoring were completed as required.
- Interview surveyor and/or supervisor to ascertain how the SA utilizes FMS feedback in the FMS Cover Letter and Summary Report, if any, for improving surveyor proficiency in OSP.
- Review the SA's mechanism for communicating SOM directives and changes to surveyors.
- Select a couple of major program directives or SOM issuances on the OSP and interview surveyors to determine whether they are familiar with them.
  - If, during the year under review, no new directives or changes were issued, interview surveyors, including newly hired, to ascertain their familiarity with SOM directives in the OSP.
- If any one of PI #6 a. → d. or PI #7 a. → c. is not met, indicate which was not met in the "Comment" column.

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**Criterion #6: Complaints**

**NOTE:** All (i.e., CLIA and non-CLIA) complaints should be tracked in some way, not just CLIA-related complaints. Ask the SA to demonstrate how they track all complaints. The method of tracking non-CLIA complaints may be manual or electronic.

**NOTE:** If the SA received no complaints, interview staff to ascertain their understanding of the complaints process and complete PI #2 - #9 based upon the interview.

**NOTE PI #1:** Review the SA mechanism for logging in and tracking complaints and verify that all CLIA-related complaints are entered into ACTS.

**NOTE PI #2:** Interview staff to determine how complaints are handled.

- Verify their understanding that ALL CoA complaints must be forwarded via ACTS to the Branch Location for disposition.
- Also verify that all staff would closely coordinate with the Branch Location when the SA is delegated the complaint for action, especially when issues have attracted media attention.

**Performance Indicators #4 - #9:**

Proceed to assess Performance Indicators #2 through #9.

- Randomly select some complaints. If the total number of complaints is 1 -10, review all.
- If the total number is more than 10, review 10.
- Follow the path of the complaint through ACTS and determine if the applicable performance indicators are met. Verify that each complaint was entered into the ACTS system, all associated actions fulfilled, and ACTS data screens completed, as appropriate. If complaint was forwarded to the AO, note that action in the Comments section.

**NOTE for PI #4:** Many of the complaints that are received are anonymous and cannot be acknowledged, mark "N/A" as applicable.

**NOTE for PI #8:** If the SA has followed the SOM and has forwarded the complaint to the Branch Location for investigation and the SA is not required

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to perform the post-investigation, enter "1" in the "Yes" box.

**NOTE for PI #9:** If the SA has followed the SOM and has forwarded the complaint to the Branch Location for disposition or if the complaint is anonymous, the SA is not responsible for the resolution or close out of the complaint. Enter a "1" in "Yes."

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**Criterion # 7: Quality Assessment**

Ensure that the SA has, and is following, their five required SAPR procedures. The procedures may be either written or electronic.

**NOTE for PI #2:** If any one of the SOPs for PI #2 are missing, indicate which was missing in the "Comment" column.

**NOTE for PI #3:** If any one of PI 3 a. → h. is not met, indicate which was not met in the "Comment" column.

**CLIA State Agency Performance Review FY2021  
References for each Criterion**

**Criterion #1 Personnel Qualifications, Training & Competency**

SOM §§4003.2, 4009A-E, 4018. 6234.2, 6410, 6434

Budget Call Letter

1864 Agreement – Article IV-A, B; Article V–C

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**Criterion #2: Data Management**

SOM §6135

Budget Call Letter

1864 Agreement – Article V-C

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**Criterion #3: Proficiency Testing Desk Review**

SOM §§6052-6058

Budget Call Letter

1864 Agreement – Article II-E

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**Criterion #4: POD/POC, AOC**

SOM §6130

Appendix C

Laboratory Principles of Documentation

1864 Agreement – Article II-A, E; Article V-C

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**Criterion #5: Survey Process & Workload**

SOM §6102

1864 Agreement, Article II-A-C, E; Article V-C

Validation Survey Protocol

Appendix C, I.-A.

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**Criterion #6: Complaints**

SOM: Chapter 5, sections for CLIA;

ACTS Procedure Guide

1864 Agreement, Article II-E; Article V-C

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**Criterion #7: Quality Assessment**

1864 Agreement – Article II-A, E, I-J; Article IV-A, B; Article

**CLIA State Agency Performance Review FY2021**  
**References for each Criterion**

**CLIA State Agency Performance Review FY2021**  
**Criterion #1: Personnel Qualifications Training and Competency**

**Overall Goal:**

The SA has an:

- Effective system in place to ensure that all CLIA surveys are conducted by qualified and competent individuals.
- Ongoing training program to improve survey skills.
- Ongoing program to ensure that SA CLIA clerical staff and surveyors are properly trained in a timely manner.
- Ongoing mechanism to maintain and improve competency.

**Performance Indicators (PIs): Personnel Qualifications**

1. The staff positions (professional and clerical) listed on CMS-1465A are occupied as reported.
2. Health Professional Qualifications as set forth in the SOM at 4009B.\*
3. For new surveyors, completion of a CMS-developed Basic Surveyor Training Course within the first three (3) months of employment (4009-C) AND the individual has completed sufficient orientation for Branch Location Evaluators to evaluate their survey skills (Federal Monitoring Survey Assessment) within one year.\*

\*Please note: If no new surveyors have been hired in the FY under review, then PIs #2 and #3 are considered met. Please indicate under the "New Surveyor", " Name/ID" column "NA".

4. For all surveyors, the SA's ongoing training and annual competency program utilizes feedback or information from and focuses on:
  - a. SA orientation, FMS, Branch Location review of any CMS-2567s and PoC/AoCs to improve surveyor skills;
  - b. Consistency in interpretation of the regulations;
  - c. Ensuring surveyor adherence to the SOM;
  - d. Improving individual surveyor skills, as needed;
5. All SA surveyors attend CMS-funded mandatory training, including those budgeted for in the annual SA budget apportionment (e.g., Consortium/Division meetings).
6. All SA surveyors participate in mandatory online training, as applicable.

**\*EXCEPTION:** Performance Indicator #3 and 4 may not be applicable to an individual who was hired shortly before the time of review.

**CLIA State Agency Performance Review FY2021  
Criterion #1: Personnel Qualifications Training and Competency**

Performance Indicator 1:	Yes	No
The staff positions (professional and clerical) listed on CMS-1465A are occupied as reported.		

**Personnel Qualifications: New Surveyors Hired During FY2021**

New Surveyor		Performance Indicators					Comments
Name or ID #	Date of Hire	PI 2		PI 3			
		Y	N	Y	N	NA	

**Ongoing Training and Annual Competency Programs: All Surveyors**

	Performance Indicators								Comments
	PI 4			PI 5		PI 6			
	Y	N	NA	Y	N	Y	N		
PI 4: For all surveyors, the SA's ongoing training and annual competency program utilizes feedback and focuses on improving/maintaining surveyor skills.									
PI 5: Attend CMS-funded mandatory training									
PI 6: Participate in mandatory online training, as applicable									

State Agency:	
Date:	
Evaluator:	
Performance Threshold:	100%
Quantified Performance Result:	<b>#DIV/0!</b>
	YES NO

**Performance Measurement:**  
Performance Threshold: 100%  
A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100% or if Performance Indicator 1 is not met.

**CLIA State Agency Performance Review FY2021**  
**Criterion #1: Personnel Qualifications Training and Competency**

Written Corrective Action Plan required?			
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**CLIA State Agency Performance Review FY2021  
Criterion #2: Data Management**

**Overall Goal:**

The SA has implemented a mechanism to ensure that data entry is done both accurately and within the appropriate timeframe, and that all personnel responsible for data management have been trained.

**Performance Indicators**

1. The SA has a mechanism to track receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates.

**Performance Indicators (PIs): CMS 116: Accuracy & Timeliness**

2. The SA has entered all reviewed initial applications (Form CMS-116) information accurately into the CMS-116 database.

**(Note: The name of the laboratory only allows for 50 characters to be entered, so the SA may use abbreviations in order to meet this requirement. The abbreviations must be reflective of information on the CMS-116.)**

**Note:** See Review Tool 4 for the list of fields that are reviewed.

3. The SA has entered all reviewed initial applications (Form CMS-116) information into the CMS-116 database within 30 calendar days of receipt by the SA.

**(Note: This performance indicator is met if the SA has requested from the laboratory any additional information which is needed to approve the initial Form CMS-116 within 30 days of receipt by the SA.)**

**Performance Indicators (PIs): Certificate Changes & Timeliness**

4. The SA has entered all reviewed certificate changes accurately into the CMS-116 database.

**(Note: If, when reviewing for certificate changes, it is noted that the demographic information does not match, further investigation should be done to ensure that the demographic information is correct, e.g., check for later CMS-116 submissions with demographic changes.)**

5. The SA has entered all reviewed certificate changes into the CMS-116 database within 45 calendar days of receipt by the SA.

**Performance Indicators (PIs): Demographic Updates & Timeliness**

6. The SA has entered all reviewed demographic updates into the CMS-116 database accurately.

7. The SA has entered all reviewed demographic updates into the CMS-116 database within 45 calendar days of receipt by the SA.

8. All personnel responsible for data entry have been trained to enter the information into the CMS data systems in accordance with their responsibilities.

**CLIA State Agency Performance Review FY2021  
Criterion #2: Data Management**

Performance Indicator 1:	Yes	No
The SA has a mechanism to track receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates.		

	PI 2		PI 3		PI 4		PI 5		PI 6		PI 7		PI 8		Comments
	CMS-116		CMS-116		Cert Changes		Cert Changes		Updates		Updates		Data Entry		
	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
PI 2: CMS-116 Accuracy															
PI 3: CMS-116 Timeliness															
PI 4: Certificate Changes: Accuracy															
PI 5: Certificate Changes: Timeliness															
PI 6: Demographic Updates: Accuracy															
PI 7: Demographic Updates: Timeliness															
PI 8: Data Entry Personnel: Training and Data Entry															

State Agency:		
Date:		
Evaluator:		
Performance Threshold:	100%	
Quantified Performance Result:	#DIV/0!	
	YES	NO
Written Corrective Action Plan required?		

**Performance Measurement:**  
 Performance Threshold: 100%  
 A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100% or if Performance Indicator 1 is not met.

## FY 2021 CLIA SAPR CRITERIA 2, Data Management

Branch Location Review Date:			State:
Branch Location Reviewer:			

### Initial CLIA Applications (Form CMS-116), PI2 + PI3

CLIA Number	Selected* Fields Accurately Entered Into CMS-116 Database	All CMS-116s Entered Within 30 Days	<u>Comments</u> List All Fields Not Accurately Entered AND/OR Entered > 30 Days
			*For FY2021 only the following 5 selected fields will be reviewed for this criterion: Facility Name, Federal Tax Identification (TIN), Facility Address, Name of Director, and telephone number. No other CMS-116 fields are required to be reviewed unless the RO determines an expanded review is warranted.
1			
2			
3			
4			
5			
6			
7			
8			

### Certificate Changes, PI4 + PI5

CLIA Number	All Certificate Changes Entered Accurately	All Certificate Changes Entered Within 45 Days	<u>Comments</u> List Certificate Changes Not Accurately Entered AND/OR Entered > 45 Days
1			
2			
3			
4			

### Demographic Updates, PI 6 + PI7

CLIA Number	All Demographic Updates Entered Accurately	All Demographic Updates Entered Within 45 Days	<u>Comments</u> List All Demographic Updates Not Accurately Entered AND/OR Entered > 45 Days
1			
2			
3			
4			

**CLIA State Agency Performance Review FY2021**  
**Criterion #3: Proficiency Testing Desk Review**

**Overall Goal:**

The SA conducts PT Desk Review timely and initiates appropriate action in regard to unsuccessful participation.

**Performance Indicators (PIs)**

1. The SA has implemented a mechanism to track PT scores every 30 - 45 days.
2. **Unsuccessful Participation:**
  - a. Verifies the scores using information from the PT provider and/or the laboratory prior to recommending an action, and takes any necessary follow-up actions based on their collaboration with their Branch Location.
  - b. Prepares CMS-2567, including appropriate D-Tags.
  - c. Notifies the laboratory to seek training/technical assistance for initial unsuccessful participation, as appropriate.
  - d. Notifies the Branch Location for all non-initial unsuccessful participation.
  - e. Tracks each case to completion/resolution (SA can verify corrective actions and effectiveness evaluated).

**CLIA State Agency Performance Review FY2021  
Criterion #3: Proficiency Testing Desk Review**

<b>Performance Indicator 1:</b>	<b>Yes</b>	<b>No</b>
The SA has implemented a mechanism to track PT scores every 30 - 45 days.		

			Performance Indicators														
			Unsuccessful Participation														
PT Desk Reviews	Initial Unsuccessful	Non-Initial (Subsequent) Unsuccessful	PI 2a			PI 2b			PI 2c			PI 2d			PI 2e		
CLIA #			Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	

<b>State Agency:</b>		
<b>Date:</b>		
<b>Evaluator:</b>		
<b>Performance Threshold:</b>	85%	
<b>Quantified Performance Result:</b>	#DIV/0!	
	YES	NO
<b>Written Corrective Action Plan required?</b>		

**Performance Measurement:**  
 Performance Threshold: 85 percent  
 A Written Corrective Action Plan is required if the Quantified Performance Result is less than 85 percent or Performance Indicator 1 is not met.

## CLIA State Agency Performance Review FY2021

### Criterion 4: Principles of Documentation(PoD) and Plan of Correction(PoC)/Allegation of Compliance(AoC)

#### **Overall Goal:**

The SA has a review system/process to ensure that all CLIA surveyors:

- Write clear, concise, and legally defensible Statements of Deficiencies (SoD) (CMS-2567) that are consistent with the CLIA Principles of Documentation (POD).
- Accept only POC/AOCs that meet the criteria for acceptability.

#### **Performance Indicators (PIs):**

1. The SA utilizes and understands mandatory citations.
2. The SA reviews the Statements of Deficiencies for clarity, conciseness and consistency with the POD on an on-going basis.
3. The SA reviews the POC/AOCs for consistency with SOM 6130.
4. The SA reviews at least 10 of each surveyor's CMS-2567s prepared during the federal fiscal year (FFY) under review for both POD and acceptability of POC/AOCs.
5. The SA review process includes participation by all surveyors as an opportunity for skill improvement.
6. The review process must include at least quarterly review and must track progress of surveyor improvement or document sustained proficiency.
7. Specific area(s) of improvement identified in Branch Location feedback (FMS Assessment and other Branch Location reviews), if any, are incorporated by the SA into their review process.
8. The SA review process quantifies\* and documents the state-wide results annually so that the State can compare results across federal fiscal years (FFY) (October 1 to September 30).

\*To quantify results, the following formula **must be used by the SA in its internal review process**. POD: Divide the total number of D-tags that meet the Principles of Documentation by the total number of D-tags cited on the CMS-2567s reviewed during the FFY under review. POC/AOC: Divide the total number of D-tags on the POC that meet the Criteria for Acceptability by the total number of D-tags cited on the CMS-2567s reviewed during the FFY under review.

**NOTE: The result of this calculation is used for SA's internal review only; it is not related to the performance threshold listed below.**

## CLIA State Agency Performance Review FY2021

### Criterion 4: Principles of Documentation(PoD) and Plan of Correction(PoC)/Allegation of Compliance(AoC)

Performance Indicator #1	Yes	No
The SA utilizes and understands mandatory citations.		

**To calculate the Results of the SA Internal Review:**  
 Type the number in the data field labelled "# D-tags meeting POD". Do the same with "Total # D-tags reviewed" data filed.. The result will auto-calculate.

P.I. 9 Results of SA Internal Review:

Performance Indicators	Yes	No
2		
3		
4		
5		
6		
7		
8		

show calculation  $\frac{\text{\# D-tags meeting PoD}}{\text{Total \# D-tags reviewed}} = \text{\#VALUE!}$

P.I. 9 Results of SA Internal Review:

show calculation  $\frac{\text{\# D-tags PoC/AoC was acceptable}}{\text{Total \# D-tags reviewed}} = \text{\#VALUE!}$

	Comments

<b>State Agency:</b>		
<b>Date:</b>		
<b>Evaluator:</b>		
<b>Performance Threshold:</b>	100%	
<b>Quantified Performance Result:</b>	#DIV/0!	
	Yes	No
<b>Written Corrective Action Plan required?</b>		

**Performance Measurement:**  
 Performance Threshold: 100% (100 percent = the SA has a review process in place that includes all activities described in Performance Indicators #1-8. It does NOT refer to the % outcome of the SA's internal review specified in Performance Indicator 6.)

A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100 percent or Performance Indicator 1 is not met.

**Criterion 4, POD Principle 3, Composition of a Deficiency Citation  
Branch Location Review Tool FY2021**

CLIA Number:	Facility Name:	
State:	Br. Loc. Reviewer:	Review Date:
Total Number of D-Tags on CMS-2567:		

Principle Requirement	All D-Tags Meet POD	D-Tag Not Meeting POD + Reason
<b>Statement of Deficient Practice aka Deficient Practice Statement (DPS)</b>		
The specific violation of regulations stated clearly, e.g., Specific action(s), error(s), lack of action (i.e., deficient practice)		
The DPS does not simply restate regulation.		
<b>Extent</b>		
Extent of deficient practice is stated in DPS		
Extent is expressed in a numerical value		
<b>Sources of Evidence</b>		
DPS contains the source(s) of evidence		
At least 2 sources, if possible?		
<b>Identifiers</b>		
Identifiers are included		
Individual's names/titles are referred to by a coding system so they remain confidential		
<b>Findings/Facts</b>		
Findings support the DPS		
Findings/facts are organized in a concise, chronological and logical order		
The questions who, what, when, where, and how are answered		
<b>Sources of Evidence</b>		
All sources of evidence in the DPS are also reflected in the findings		
Observations: date, time, location		
Interviews: date, time, identifier		
Record/Document review: record name/type		
<b>Identifiers</b>		
Individual's names are referred to by a coding system so they remain confidential		
Unique patient identifiers are used so patients cannot be identified		
<b>General</b>		
The D-Tag applicable to the requirement cited		
The deficiency citation is free of extraneous remarks and advice		

## FY 2021 CLIA SAPR CRITERIA 4 D-TAG BRANCH LOCATION REVIEW TOOL

CLIA Number:		Facility Name:				State:	
Survey Date:		BL Reviewer:				BL Review Date:	
CRITERION 4, PI #4, POD			CRITERION 4, PI #4, POC/AOC			G	H
A	B	C	D	E	F	Total # D-tags cited in CMS-2567	Additional Comments, Reason why D-tag does not meet POD OR Why POC/AOC was not acceptable/credible
Identify D-tag(s) which do not meet POD	Identify principle(s) of POD not met	Total # of D-tags which meet POD	POC: Is the POC acceptable? (Y, N, N/A)	AOC: Is the AOC credible? (Y, N, N/A)	Total # of acceptable and/or credible D-tag(s)		

**CLIA State Agency Performance Review FY2021**  
**Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OSP)**

**Overall Goal:**

- The SA has a system to ensure that all surveyors conduct surveys using the outcome-oriented survey process.
- The SA has implemented a tracking system and ensures that the survey time frames are met.

**Performance Indicators: Survey Workload**

1. The SA completes all initial surveys within 3-12 months.
2. The SA completes all recertification surveys timely so that no Certificates of Compliance expire.
3. The SA completes budgeted validation surveys within 90 days of the AO survey date.
4. The SA has generated and utilized the CASPER 850D quarterly reports to address expired certificates (CoR, CoC).
5. All surveys are uploaded in a timely manner (within 45 days).

**Please note:** If the laboratory does not provide an acceptable POD/credible AOC within 45 days, the SA will not be able to upload the kit within 45 days. If the SA has documentation to show this is the case (i.e., extenuating circumstances), the SA will not be held to the 45 day upload timeframe.

**Please note:** SA can upload Condition-level noncompliant survey kits and the system will register the upload by the SA even though L32 and L33 error messages are received.

**Performance Indicators: OSP**

6. All surveyors conduct surveys using the OSP and focus on the:
  - a. overall performance of the laboratory;
  - b. laboratory's ongoing mechanisms to monitor and evaluate its practices and solve its problems
7. Each surveyor demonstrates proficiency in assessing outcome by citing those problems or potential problems which:
  - a. relate to laboratory testing;
  - b. cause or have a potential to cause a negative impact on patient test results; and
  - c. are regulatory under CLIA.
8. All surveyors have access to the SOM and the SA ensures SOM directives and/or changes related to OSP are implemented by all surveyors.
9. SA follows the SOM for enforcement and SA identifies the appropriate cases that go to the Branch Location.

**CLIA State Agency Performance Review FY2021**  
**Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OSP)**

Performance Indicators	Yes	No	Comments
PI 1: All initial surveys (CoR) completed within 3-12 months			
PI 2: All recertification of CoC laboratories are completed timely			
PI 3: All budgeted validation surveys are completed within 90 days of the AO survey date			
PI 4: The SA generated and utilized the CASPER 850D quarterly reports			
PI 5: All surveys are uploaded in a timely manner (w/i 45 days).			
PI6: All surveyors conduct surveys using the OSP			
PI 7. Each surveyor demonstrates proficiency in assessing outcome by citing those problems or potential problems.			
PI 8: All surveyors have access to the SOM and the SA ensures SOM directives and/or changes related to OSP are implemented by all surveyors			
PI 9: SA follows the SOM for enforcement and SA identifies the appropriate cases that go to the Branch Location			

State Agency:	
Date:	

**CLIA State Agency Performance Review FY2021**

**Criterion #5: Survey Workload and Outcome-Oriented Survey Process (OSP)**

Evaluator:	
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**CLIA State Agency Performance Review FY2021**  
**Criterion #6: Complaints**

**Overall Goal:**

The SA accepts and processes all complaints from receipt to closeout in accordance with CMS policies and procedures.

**Performance Indicators:**

1. The SA utilizes the Automated Complaints Tracking Systems (ACTS) in Aspen, in accordance with the current ACTS Procedure Guide.

**NOTE: The guide is kept current at the following website:** <https://qtso.cms.gov/software/aspen/reference-manuals>

2. The SA has a mechanism to track all complaints received by the SA.

3. The SA adheres to the SOM instructions for complaints as well as the current ACTS Procedure Guide for entry of data into ACTS.

4. The SA acknowledges and notifies complainant.

5. The SA triages/evaluates complaints for proper disposition.

a. SA conducts investigations for the following only when authorized by the Branch Location: CoW, PPMP, CoA, Facilities testing w/out a certificate (NOCN).

b. Forwards via ACTS all CoA complaints received in the SA to the Branch Location for disposition.

c. Forwards to another agency (OIG, FDA, OSHA, another SA as required by law, etc), as necessary.

6. Complaints are scheduled in accordance with established procedures/priorities.

7. Complaint investigations are:

a. Conducted in accordance with established time-frames.

b. Unannounced.

8. The SA adheres to the SOM instructions for post-investigation actions.

9. There is resolution and closeout of each complaint (completion of all actions required by SOM, including follow-up to complaint, if not anonymous).

**CLIA State Agency Performance Review FY2021  
Criterion #6: Complaints**

Performance Indicator	Y	N
PI1: The SA utilize ACTS for all complaints in accordance with the current ACTS Procedure Guide.		

Performance Indicator	Y	N	Comments
PI 2: The SA has a mechanism to track all complaints received by the SA.			
PI 3: The SA adheres to the SOM instructions for complaints as well as the current ACTS Procedure Guide for entry of data into ACTS.			

CLIA # or SA Complaint ID # (if no complaints, indicate here results based on interview)	Performance Indicators																								Comments			
	PI 4			PI 5a			PI 5b			PI 5c			PI 6			PI 7a			PI 7b			PI 8				PI 9		
	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA	Y	N	NA		Y	N	NA
1																												
2																												
3																												
4																												
5																												
6																												
7																												
8																												
9																												
10																												

State Agency:	
Date:	
Evaluator:	
Performance Threshold:	90%
Quantified Performance Result:	#DIV/0!

**Performance Measurement:**  
Performance Threshold: 90 percent

**CLIA State Agency Performance Review FY2021**  
**Criterion #6: Complaints**

	YES	NO
Written Corrective Action Plan Required?		

A Written Corrective Action Plan is required if the Quantified Performance Result is less than 90 percent or if Performance Indicator 1 is not met.

**CLIA State Agency Performance Review FY2021**  
**Criterion #7: Quality Assessment**

**Overall Goal:**

- The SA has developed specific procedures related to SAPR.
- The SA has an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity (i.e., quality assessment).

**Performance Indicators:**

1. The SA has documented evidence of the implementation of CAP and/or QIP.
2. The SA must establish and follow a **written** standard operating procedure (SOP) for:
  - a. Surveyor and clerical orientation, training, and annual competency;
  - b. Entry of initial application, certificate changes, and demographic information updates;
  - c. Performing PT desk review every 30-45 days;
  - d. Handling and triaging all complaints; and
  - e. Quality Assessment, including quality indicators.
3. The SA QA must include an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity, and must include:
  - a. Identification of areas needing improvement for surveyors;
  - b. Utilization of FMS Assessments and other Branch Location feedback when identifying areas for surveyor improvement;
  - c. Measuring progress in improving surveyor skills when needed (data from SoD review, PoC/AOC review or other SA internal measurement);
  - d. Tracking of errors in data management
  - e. Interval between running CASPER 153 and 155 and review of information for PT desk review;
  - f. Timeliness of sending letters and CMS 2567s for unsuccessful participation in PT;
  - g. Identification of issues in the overall process;
  - h. All activities related to QA must be documented.

**CLIA State Agency Performance Review FY2021  
Criterion #7: Quality Assessment**

**CAP and/or QIP**

Performance Indicator	Yes	No	NA	Comments
PI 1: The SA has documented evidence of the implementation of a CAP and/or QIP.				

**SA Standard Operating Procedures**

Performance Indicator	Yes	No	NA	Comments
PI 2: The SA must establish and follow a standard operating procedure (SOP).				

**SA Quality Assessment Program**

Performance Indicator	Yes	No	NA	Comments
PI 3: The SA QA must include an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity.				

State Agency:		
Date:		
Evaluator:		
Performance Threshold:	100%	
Quantified Performance Result:	#DIV/0!	
	YES	NO
Written Corrective Action Plan Required?		

**Performance Measurement:**

Performance Threshold: 100 percent

A Written Corrective Action Plan is required if the Quantified Performance Result is less than 100 percent.

## FY 2021 CLIA SAPR CRITERIA 2, Data Management

Branch Location Review Date:			State:
Branch Location Reviewer:			

### Initial CLIA Applications (Form CMS-116), PI2 + PI3

CLIA Number	All Fields Accurately Entered Into CMS-116 Database	All CMS-116s Entered Within 30 Days	<u>Comments</u> List All Fields Not Accurately Entered AND/OR Entered > 30 Days
1 21D0000000	Y	Y	
2 21D1111111	N	Y	Facility Address, LD name misspelled
3 21D2222222	Y	N	43 days - backlog for entry
4 21D3333333	N	N	48 days - no reason given
5			
6			
7			
8			SAMPLE

### Certificate Changes, PI4 + PI5

CLIA Number	All Certificate Changes Entered Accurately	All Certificate Changes Entered Within 45 Days	<u>Comments</u> List Certificate Changes Not Accurately Entered AND/OR Entered > 45 Days
1 21D4444444	N	Y	PPM entered instead of CoW
2 21D5555555	Y	N	57 days - data entry person out on medical leave, no back up
3			
4			SAMPLE

### Demographic Updates, PI 6 + PI7

CLIA Number	All Demographic Updates Entered Accurately	All Demographic Updates Entered Within 45 Days	<u>Comments</u> List All Demographic Updates Not Accurately Entered AND/OR Entered > 45 Days
1 21D6666666	N	Y	Facility address - street address #
2 21D7777777	Y	N	61 days - data entry position vacant
3			
4			SAMPLE

### **Reference Sheet, Principle #3, Composition of a Deficiency Citation**

A deficiency citation consists of (A) a regulatory reference, (B) a deficient practice statement and (C) relevant findings.

#### **A. Regulatory Reference:**

A Regulatory Reference includes the following components:

1. A survey data tag (D-Tag) number,
2. The CFR (Code of Federal Regulations),
3. The language from that regulatory reference which specifies the aspect(s) of the requirement with which the laboratory was non-compliant, and
4. An explicit statement that the requirement was "NOT MET".

#### **B. Deficient Practice Statement (DPS)**

The statement of deficient practice is one component of the evidence. It includes:

1. The specific action(s), error(s), or lack of action (deficient practice),
2. Outcome(s) relative to the deficient practice, when possible,
3. A description of the extent of the deficient practice or the number of deficient cases relative to the total number of such cases,
4. The identifier of the individuals or situations referenced in the extent of the deficient practice; and
5. The source(s) of the information through which the evidence was obtained.

#### **C. Relevant Facts and Findings**

The facts and findings relevant to the deficient practice answer the questions: who, what, where, when, and how. They illustrate the laboratory's noncompliance with the requirement or regulation.

**How** the deficiency was determined and how the evidence relates to the requirement.

**What** laboratory practice was non-compliant?

**Who** were the patients of the failed practice or the laboratory staff involved?

**Where** the deficient practice occurred, e.g., specific locations in the laboratory documents; and

**When** the problem occurred and for how long. Include the number of records or observations and the duration of the records or observations. Include the specific dates or time period for the noncompliance.

**Reference Sheet for Branch Location REVIEW TOOL, Criterion #4**  
**Required Elements for acceptable POC and credible AOC**

**Acceptable Plan of Correction**

**Evaluation**

Does it address:

1. What corrective action(s) have been taken for patients found to have been affected by the deficient practice?
2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and applicable corrective action (s)?
3. What measure has been put into place or what systemic changes will be made to ensure that the deficient practice does not recur?
4. How the corrective action(s) will be monitored to ensure the deficient practice does not recur?

**Credible Allegation of Compliance**

**Evaluation**

Lab's Statement or documentation:

- a. Is it made by a representative of a laboratory with a history of commitment to compliance and taking action when required?
- b. Is it realistic; is it possible to accomplish corrective action(s) by date of AoC?
- c. Does it indicate that the problem has been resolved?

Lab's AoC must include acceptable evidence of correction with documentation. Does the evidence show:

1. What corrective action(s) have been taken for patients found to have been affected by the deficient practice?
2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) have been taken?
3. What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur?
4. How the corrective action(s) are being monitored to ensure the deficient practice does not recur?

**Reference Sheet for Branch Location REVIEW TOOL, Criterion #4  
Principles of Documentation (POD) - Key Points**

<b>POD Principle</b>	<b>Key Points</b>
1, Lab Compliance and Noncompliance	<ul style="list-style-type: none"> <li>◇ Compliance → D0000 (only used for compliance when <u>all</u> requirements met)</li> <li>◇ Noncompliance → List of condition level deficiencies</li> <li>◇ Type of survey</li> </ul>
2, Using Plain Language	<ul style="list-style-type: none"> <li>◇ Written clearly, objectively in active voice and in layman's terms</li> <li>◇ Avoid words such as: <i>seems, appears, inadequate, unnecessary</i></li> <li>◇ No extraneous advice, comments, directions, slang</li> <li>◇ Should contain only evidence to support noncompliance</li> <li>◇ Define acronyms, abbreviations 1<sup>st</sup> time used</li> <li>◇ Ensure accuracy of cited/quoted material</li> </ul>
3, Composition of Deficiency Statement	<ul style="list-style-type: none"> <li>◇ Deficient Practice Statement:               <ul style="list-style-type: none"> <li>◦ Clearly states what lab did/did not do to cause noncompliance</li> <li>◦ Do not merely repeat the regulation</li> <li>◦ Includes: specific action(s) or lack of action(s), outcome(s) when possible, extent, sources (2)</li> <li>◦ Name of individuals/patients should never be used</li> </ul> </li> <li>◇ Findings Statement:               <ul style="list-style-type: none"> <li>◦ Supports/illustrates lab's noncompliance</li> <li>◦ Who, what, where, when, how</li> <li>◦ Citations specific to lab, in concise and chronological or logical order</li> <li>◦ Date and time for observations</li> </ul> </li> </ul>
4, Relevance of Onsite Correction Findings	<ul style="list-style-type: none"> <li>◇ Must be documented on CMS-2567 as "NOT MET"</li> </ul>
5, Interpretive Guidelines (IG)	<ul style="list-style-type: none"> <li>◇ May not be used as a basis for citation(s)</li> <li>◇ IGs do not replace/supersede statute or regs</li> </ul>
6, Citation of State/Local Code Violation	<ul style="list-style-type: none"> <li>◇ Only used for 2 reasons, see POD</li> </ul>
7, Cross References	<ul style="list-style-type: none"> <li>◇ Applicable and provides additional strength to linked citation(s)</li> <li>◇ Must support noncompliance with requirement</li> </ul>
8, Condition Deficiencies	<ul style="list-style-type: none"> <li>◇ Includes only requirements to be corrected to achieve condition-level compliance</li> <li>◇ May stand alone as single cite or include accompanying standards</li> <li>◇ Condition statement is written as a practice statement. Findings are listed or cross-referenced</li> </ul>

## FY 2021 CLIA SAPR CRITERIA 4 D-TAG CLIA LOCATION REVIEW TOOL

CLIA Number:		Facility Name:				State:	
Survey Date:		CLIA Loc. Reviewer:				CLIA Loc. Review Date:	
CRITERION 4, PI #4, POD			CRITERION 4, PI #4, PoC/AoC			G	H
A	B	C	D	E	F	Total # D-tags cited in CMS-2567	Additional Comments, Reason why D-tag does not meet POD OR Why PoC/AoC was not acceptable/credible
Identify D-tag(s) which do not meet POD	Identify principle(s) of POD not met	Total # of D-tags which meet POD	POC: Is the POC acceptable? (Y, N, N/A)	AOC: Is the AOC credible? (Y, N, N/A)	Total # of acceptable and/or credible D-tag(s)		
			Y				
D5411							missing impact on patients

## Mandatory SAPR Reports

<u>Report Name</u>	<u>Description</u>	<u>Cr</u>	<u>PIs</u>	<u>Replacement Report Name</u>
DM-A: 116 Entry	A DETAIL report, sorted by application type, identifies the labs that applied and entered into the CLIA program in the FY under review.	2	2,3	SAPR 2
DM-B: Cert Changes	A DETAIL report listing all Certificate changes made during the fiscal year under review with a run time parameter for Geography.	2	4,5	SAPR 9A→10C
CASPER 0104D CLIA 116 Activity	A DETAIL report identifying the names of labs that had specific demographic fields updated during the FY under review. The report also displays the date the change was made, the user ID of the person who made the change, and fields changed.	2	6,7	CASPER 0104D CLIA 116 Activity
PT-A: PT Desk Rvw	A DETAIL report listing all PT Desk Reviews performed during the fiscal year under review with a run time parameter for Geography	3	All	New
SVY-A: Initial Surveys	A DETAIL report identifying the labs that had early/late initial surveys in the fiscal year under review.	5	1	SAPR 17-20
SVY-B: Expired CoC	A DETAIL report identifying the labs that had Recertification Surveys after the certificate expired.	5	2	SAPR 23
SVY-C: Validation	A DETAIL report identifying the accredited labs (ap type 3) that had Validation surveys during the fiscal year under review and showing the number of days between the AO survey date and the Validation date. Note: The report displays the labs by AO, so a lab accredited by both ASHI and AABB would display (and be counted) on 2 lines.	5	3	New
SVY-D: Survey Upload	A DETAIL report showing labs surveyed during the FY under review, and first uploaded into the ACO system more than 45 days after the survey date. Note: 'Survey Transaction Date' is a date generated at the time the State first attempts to upload certification kit in ACO.	5	8	SAPR 6

## Optional SAPR Reports

<u>Report Name</u>	<u>Description</u>	<u>PIs</u>	<u>Old Report Name</u>
OPT-A: 116 Entry, Total	A SUMMARY report providing totals on the number of 116s entered in FY. Note: Used 'ap received date', a system-generated date based on date user enters CMS-116 into CLIA data base.	n/a	SAPR 1
OPT-B: 116 Entry, Outliers	A DETAIL report showing the outlier records, i.e., States entering the CMS-116 more than 30 days after receipt of the CMS-116 form in the State agency, designated by the date stamp on the form. Notes Report compares 'state agency receipt date' to 'app received date'	n/a	SAPR 3
OPT-C: Total Surveys	A SUMMARY report provides totals on the number of labs surveyed during FY.	n/a	SAPR 4
OPT-D: Surveyed Labs	A DETAIL report identifies the labs that were surveyed during FY.	n/a	SAPR 5
OPT-E: Recert	A SUMMARY report providing totals on the number of labs that had recertification surveys accepted into the data system during FY.	n/a	SAPR 11
OPT-F: Uploaded Recerts	A DETAIL report identifying the labs that had recertification surveys accepted into the data system during FY.	n/a	SAPR 12
OPT-G: Initials	A SUMMARY report providing totals on the number of labs that had initial surveys accepted into the data system during FY.	n/a	SAPR 15
OPT-H: Uploaded Initials	A DETAIL report identifies the labs that had initial surveys accepted into the data system during FY.	n/a	SAPR 16
OPT-I: Follow-ups, Total	A DETAIL report identifying the compliance labs, surveyed during FY, that had follow-up surveys (including onsite and offsite revisits). Note: The report is sorted by a counter that totals the number of onsite hours spent in the lab. So, the offsite revisits are identified with '00' in the 'Total Onsite Teamhrs' column. The report also displays 4 deficiency counters: 1) 'Curr Tot Defs' counts the total number of D tags cited on the CMS-2567; 2) 'Cur Def Nocor' counts the number of D tags that have not been corrected; 3) 'Curr std all' counts the number of D tags deficiencies at the standard level; and 4) 'Curr cop all' counts the number of D tags deficiencies at the condition level.	n/a	SAPR 25
OPT-J: Mandatory Citations	A DETAIL report listing surveys in which mandatory citations were cited during the fiscal year under review with a run time parameter for Geography. Does not include PT Desk Review.	n/a	New
CASPER 157D: PT Excused Nonparticipation	This DETAIL report identifies the laboratories that have been given a pass for failure to participate in proficiency testing for one or more analytes/events.	n/a	CASPER 157D

**Instructions for Printing CASPER 0104D CLIA 116 Activity (Criterion 2 Data Management PI 6,7)**

[Use "DM-B: Cert Changes" for Status changes] [104 is just for Demographic changes]

1. Log into CASPER Reporting and locate CASPER report 0104D CLIA 116 Activity.
2. Select the following criteria:

Geographic Breakdown: the state on which you are performing the SAPR.

Exempt Status: Non-Exempt

Provider Status: Both

User ID: CLIAUSER [Note: CLIAUSER sets the filter to Humans, not the system]

Application Type: Select All

The screenshot shows a web-based filter interface with the following options:

- Geographical Breakdown:** Radio buttons for Nation, Region, and State (selected).
- State(s):** A dropdown menu with "Alabama" selected. Other options include Alaska, American Samoa, Arizona, and Arkansas.
- Exempt Status:** Radio buttons for Exempt, Non-Exempt (selected), and Both.
- Provider Status:** Radio buttons for Active, Terminated, and Both (selected).
- User ID:** Radio buttons for CLIAUSER (selected and circled) and CLIABATCH.
- Application Type:** A dropdown menu with "Select All" selected. Other options include 1 - COMPLIANCE, 2 - WAIVER, and 3 - ACCREDITATION.

A note at the bottom reads: "To select multiple items, hold down the Ctrl key and click the desired items"

3. Note: The RO may choose to run one Report or multiple Reports based on varying time frames. Then, use the listing to ask the State agency to pull a representative sample of lab records and, as part of the review process, compare and assess the accuracy of the ASPEN data with the associated written notifications (email, letter, CMS-116).
4. Using a time period that falls within the fiscal year SAPR under review, complete the DATE CRITERIA as illustrated below using the dates for this review period:

The screenshot shows the "Date Criteria" section with the following settings:

- Date Criteria:** A dropdown menu set to "Prior Month".
- Change Date from:** A date field set to "07/01/2016".
- Change Date thru:** A date field set to "07/31/2016".

Press NEXT

5. Leave default either as NO SELECTION, or select change types that represent application\*, termination, or demographic updates, as shown below:

The screenshot shows the "Change Type" and "Federal Jurisdiction" sections with the following settings:

- Change Type:** A dropdown menu with "Application Information" selected. Other options include --no selection--, AO Information, Application Signature Date, Director Name, Federal Tax ID, Lab Class, Letter Sent To Lab, Mailing Address, Physical Address, Provider Name, Survey Dates, Telephone, and Termination Information.
- Federal Jurisdiction:** Radio buttons for Include FJ Labs, Exclude FJ Labs (selected), and Only FJ Labs.
- Sort By:** A dropdown menu set to "CCN".
- Ascending:** A checkbox that is checked.

**Important Notes**

- **This year the Regional Offices should not use CASPER 104D to find labs with certificate type changes. Instead use the new SAPR report: DM-B: Cert Changes.**
- **When searching for demographic updates, we would recommend highlighting all fields, but only selecting 4-5 separate weeks, not 4-5 continuous weeks, throughout the FY rather than the entire FY. If you choose the entire FY, the report may be very long.**

6. Once submitted, you can go into the “Folders” then to “My Inbox” to see the report. Double click on the 104D report in the inbox.
7. Below is an excerpt of CASPER Report 104 that identifies the labs that had specific fields updated during the time period selected. On the bottom left side of the report you will see some total numbers. You can use these to determine how many changes were made in the state, region and nation for the changes requested in the report.



CASPER Report 0104D  
 CLIA 116 Activity  
 Change Dates from 05/01/2018 thru 05/31/2018  
 Connecticut - Exclude FJ Labs  
 USER ID - CLIAUSER

Run Date: 06/26/2018  
 Job # 70539853  
 Last Update: 06/26/2018  
 Page 1 of 7

CCN	Provider Name	App Type Code	Term Code	Change Date	User ID	Data Changed	Cert Exp Date
07D0094140	QUEST DIAGNOSTICS	1	00	05/03/2018	1004651	Application Signature Date, Director Name, Mailing Address	02/02/2019
07D0094385	QUEST DIAGNOSTICS	1	00	05/03/2018	1004651	Application Signature Date, Director Name, Mailing Address	08/11/2018
07D0095024	HARTFORD HEALTHCARE MEDICAL	2	00	05/02/2018	1004731	Director Name, Provider Name, Mailing Address	07/22/2018
07D0098540	QUEST DIAGNOSTICS	1	00	05/03/2018	1004651	Application Signature Date, Director Name, Generate Replacement Certificate, Mailing Address	10/13/2019
07D2003930	LABORATORY - HARTFORD LIFE	2	00	05/02/2018	1004731	Generate Replacement Certificate, Mailing Address	02/21/2020
07D2092230	HARTFORD HEALTHCARE CANCER I	3	00	05/16/2018	1004651	Application Information, Application Signature Date, Mailing Address	08/11/2019

Total Selected Criteria Changes for Connecticut = 6  
 Total Selected Criteria Changes for Boston Regional Office = 31  
 Total Selected Criteria Changes for Nation = 1,289

This 104 report was for Region 1 and mailing address changes. One page of the report displays the mailing address changes in Connecticut for the time period chosen (Change Dates from 05/01/2018 thru 05/31/2018 – see the third line in the report header).

The report lists the labs with mailing address changes – and if that lab had other changes made at the same time those are listed also.

The statistics do not count the other changes, just the number of labs with mailing address changes. In this case for the month of May 2018 Connecticut had 6 labs with mailing address changes – and those 6 labs are listed. The entire Region for May had 31 mailing address changes entered and the nation had 1,289 mailing address changes for the same timeframe.

You can also see that two different people were making these changes in Connecticut – User IDs 1004651 and 1004731.



**Clinical Laboratory Improvement Amendments (CLIA) Program**

**State: [name]**

**CLIA State Agency Performance Review  
SUMMARY REPORT**

**Review Period: Fiscal Year 2021  
(October 1, 2020 to September 30, 2021)**

# **CLIA STATE AGENCY PERFORMANCE REVIEW FISCAL YEAR 2021**

## **REVIEW CRITERIA**

- Criterion # 1: Personnel Qualifications, Training and Competency**
- Criterion # 2: Data Management**
- Criterion # 3: Proficiency Testing Desk Review**
- Criterion # 4: Principles of Documentation (POD), Plans of Correction (POC), Allegations of Compliance (AOC)**
- Criterion # 5: Survey Workload and Outcome-Oriented Survey Process (OSP)**
- Criterion # 6: Complaints**
- Criterion # 7: Quality Assessment**

**CLIA STATE AGENCY PERFORMANCE REVIEW FY 2021 SA:**

**Performance Review Criterion #1: Personnel Qualifications, Training and Competency**

The SA has an:

- Effective system in place to ensure that all CLIA surveys are conducted by qualified and competent individuals.
- Ongoing training program to improve survey skills.
- Ongoing program to ensure that SA CLIA clerical staff and surveyors are properly trained in a timely manner.
- Ongoing mechanism to maintain and improve competency.

**DID THE SA HIRE ANY NEW SURVEYORS IN FY 2021?** YES NO

**PERFORMANCE MEASUREMENT:**

*Performance Thresholds for Written Corrective Action Plan*

A written corrective action plan is required if:

- Quantified performance results are less than 100%; **OR**
- The staff positions (professional and clerical) listed on CMS-1465A are not occupied as reported.

*SA Performance Results*

Quantified Performance Results: %

**WRITTEN CORRECTIVE ACTION PLAN:** YES NO

**FINDINGS:**

**SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:**

**NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:**

**CLIA STATE AGENCY PERFORMANCE REVIEW FY 2021 SA:**

**Performance Review Criterion #2: Data Management**

The SA has implemented a mechanism to ensure that data entry is done both accurately and within the appropriate timeframe, and that all personnel responsible for data management have been trained.

**PERFORMANCE MEASUREMENT:**

*Performance Thresholds for Written Corrective Action Plan*

A written corrective action plan is required if:

- Quantified performance results are less than 100%; **OR**
- The SA does not have a mechanism to track receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates.

*SA Performance Results*

Quantified Performance Results:        %

**WRITTEN CORRECTIVE ACTION PLAN:**    YES   NO

**FINDINGS:**

**SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:**

**NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:**

**CLIA STATE AGENCY PERFORMANCE REVIEW FY 2021 SA:**

**Performance Review Criterion #3: Proficiency Testing (PT) Desk Review**

The SA conducts PT Desk Review timely and initiates appropriate action in regard to unsuccessful participation.

**PERFORMANCE MEASUREMENT:**

*Performance Thresholds for Written Corrective Action Plan*

A written corrective action plan is required if:

- Quantified Performance Results are less than 85%; **OR**
- SA has not implemented a mechanism to track PT scores every 30 – 45 days.

*SA Performance Results*

SA has implemented a mechanism to track PT scores every 30 – 45 days? Yes No  
Quantified Performance Results: %

**WRITTEN CORRECTIVE ACTION PLAN: YES NO**

**FINDINGS:**

**SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:**

**NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:**

**CLIA STATE AGENCY PERFORMANCE REVIEW FY 2021 SA:**

**Performance Review Criterion # 4: Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)**

The SA has a review system/process to ensure that all CLIA surveyors:

- Write clear, concise, and legally defensible Statements of Deficiencies (SOD) (CMS-2567) that are consistent with the CLIA Principles of Documentation (POD).
- Accept only POC/AOCs that meet the criteria for acceptability.

**PERFORMANCE MEASUREMENT:**

*Performance Thresholds for Written Corrective Action Plan*

A Written Corrective Action Plan is required if:

- Quantified performance results are less than 100%; **OR**
- The SA does not utilize and understand mandatory citations.

*SA Performance Results*

Quantified Performance Results:        %

**WRITTEN CORRECTIVE ACTION PLAN:**     YES    NO

**FINDINGS:**

**SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:**

**NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:**

**CLIA STATE AGENCY PERFORMANCE REVIEW FY 2021 SA:**

**Performance Review Criterion # 5: Survey Workload and Outcome-oriented Survey Process (OSP)**

- The SA has a system to ensure that all surveyors conduct surveys using the outcome-oriented survey process.
- The SA has implemented a tracking system and ensures that the survey time frames are met.

**PERFORMANCE MEASUREMENT:**

*Performance Thresholds for Written Corrective Action Plan*

A written corrective action plan is required if quantified performance results are less than 90%.

*SA Performance Results*

Quantified Performance Results:        %

**WRITTEN CORRECTIVE ACTION PLAN:**    YES   NO

**FINDINGS:**

**SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:**

**NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:**

**CLIA STATE AGENCY PERFORMANCE REVIEW FY 2021 SA:**

**Performance Review Criterion #6: Complaints**

The SA accepts and processes all complaints from receipt to closeout in accordance with CMS policies and procedures.

**PERFORMANCE MEASUREMENT:**

*Performance Thresholds for Written Corrective Action Plan*

A written corrective action plan is required if:

- Quantified Performance Results are less than 90%; **OR**
- SA does not utilize ACTS for all complaints.

*SA Performance Results*

- SA utilizes ACTS for all complaints? Yes No
- Quantified Performance Results: %

**WRITTEN CORRECTIVE ACTION PLAN: YES NO**

**FINDINGS:**

**SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:**

**NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:**

**CLIA STATE AGENCY PERFORMANCE REVIEW FY 2021 SA:**

**Performance Review Criterion #7: Quality Assessment**

- The SA has developed specific procedures related to SAPR.
- The SA has an on-going mechanism to monitor, assess, and when indicated, correct problems identified in their survey and certification activity (i.e., quality assessment).

**PERFORMANCE MEASUREMENT:**

*Performance Threshold for Written Corrective Action Plan*

A written corrective action plan is required if the Quantified Performance Results are less than 100%.

*SA Performance Result*

Quantified Performance Results:      %

**WRITTEN CORRECTIVE ACTION PLAN:**      YES    NO

**FINDINGS:**

**SPECIAL CIRCUMSTANCES AFFECTING PERFORMANCE:**

**NOTEWORTHY ACTIVITIES AND ACCOMPLISHMENTS:**

**COVER LETTER TEMPLATE FOR  
FY 2021 CLIA SAPR SUMMARY REPORTS**

(Date )

( Name & Address of SA Official )

Dear (SA Official ):

Re: Clinical Laboratory Improvement Amendments State Agency Performance Review  
(CLIA SAPR) Summary Report—Fiscal Year 2021 (FY 2021)

Thank you for your cooperation and the courtesies extended to [*Name of Branch Location  
SAPR Reviewer*] during the CLIA SAPR visit to [*name of SA*] conducted on [*Dates*]. Enclosed is the Summary Report for the FY 2021 review.

The Section 1864 Agreement requires that the CMS Location conduct a performance evaluation of each State Agency performing CLIA survey and certification activities. The CLIA SAPR was structured to accomplish this end in a manner consistent with the performance improvement model employed throughout the CLIA Program. Thus, the goal of the CLIA SAPR is to promote optimal performance by the State Agency, as our partner in ensuring quality in laboratory practices and testing, using an efficient and effective mechanism, that recognizes State-specific circumstances and fosters a positive performance incentive. This office stands ready to provide educational assistance, information, and support, whenever needed.

The following are the seven criteria included in the FY 2021 SAPR review:

- Criterion #1—Personnel Qualifications, Training, and Competency
- Criterion #2 – Data Management
- Criterion #3—Proficiency Testing (PT) Desk Review
- Criterion #4—Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)
- Criterion #5—Survey Process and Workload
- Criterion #6—Complaints
- Criterion #7—Quality Assessment

**We encourage you to communicate any feedback regarding the SAPR process to your CMS Branch Location.**

The subject areas of the other Criteria from the previous version of the SAPR, however, could be examined separately at each CMS Branch location's discretion, under our overarching authority for SA oversight, and reported in addition to the outcomes of the standardized review.

While the CLIA SAPR addresses major CLIA survey and certification responsibilities, it is not an exhaustive evaluation, nor an exact measurement of state agency performance. Therefore, we do not issue an overall score or grade. Performance measurements consists of gathering and quantifying a snapshot of data in a standardized fashion:

- To ascertain objectively whether your agency has fulfilled the expectations of each CLIA SAPR Performance Criterion, as delineated in the Performance Indicators; and
- To determine whether your agency must submit any written corrective action plans.

The CLIA SAPR Summary Report recognizes your agency’s strengths and accomplishments in meeting your CLIA program responsibilities, as well as any areas that may need improvement. If your agency has experienced special circumstances that affected your performance, they are also indicated, in the interest of providing a balanced view of your state’s operations.

As you examine the summary report, please keep in mind that the Performance Threshold is neither a score nor a pass/fail rating. It serves as a demarcation point for this office to request a written corrective action plan. And be assured, as well, that the Performance Threshold also serves to ensure nationwide consistency among the CMS Branch Location Offices for requesting the plans.

*(Add the following paragraph if NO written CAP is needed)*

We are pleased to report that your agency’s performance exceeded the Performance Threshold for all of the Criteria, thus no written corrective action plan is requested. Your agency is to be commended for the fine performance. *(Add the following sentence to this paragraph or at other suitable placement if optimal performance outcome has been sustained over multiple years).* We note that your agency has sustained optimal performance outcomes for **(Criterion # /Criteria ##)** for several years. With your permission, we would like to share the “best practices” employed by your SA with other states.

*(Add the following paragraphs if one or more CAP’s are needed)*

A written corrective action plan is required for the following:

*(list Number and Name for each Criterion)*

The corrective action plan should be received in this office no later than 30 days from your receipt of this letter, and should contain the following information:

- Name of your State
- Name and number of the Criterion needing corrective action and the action that will be taken
- How it will be monitored and evaluated to verify that it was successful and complete
- Name of the individual responsible for completion of the corrective action
- Expected dates of institution and completion of the corrective action
- Any other information that may be necessary to show that correction can be achieved or has already been achieved.

The CLIA SAPR Summary Report recognizes your agency’s strengths and accomplishments in meeting your CLIA program responsibilities, as well as any areas that may need improvement. If your agency has experienced special circumstances that affected your performance, they are also indicated, in the interest of providing a balanced view of your state’s operations, particularly in light of the ongoing public health emergency. We appreciate your efforts to support your state, the nation, and the CLIA program during such an unprecedented time.

*(If other subject areas were reviewed, add the following language in this cover letter)*

### Other Subject Areas Reviewed

This office exercised the option to review the following subject (area ) (areas) under our overarching authority for SA oversight:

*List each subject area by Name (without Criterion # to maintain separation from the standard protocol, e.g. “Financial Management” rather than “Criterion #3”), and add the following information in a narrative:*

- *For each subject area, indicate what was reviewed, including a description of the data gathered, the specific findings, and the overall outcome.*

Again, we commend you and your staff for all of your efforts related to the CLIA Program, and we appreciate your commitment to quality improvement. If you have any questions, comments or concerns about this letter or the Summary Report, please contact *[Name of CMS Branch location Reviewer]* at *[phone #]*.

Sincerely,

Branch Location Official

**Also, see next page: use or delete optional language**

# CLIA STATE AGENCY PERFORMANCE REVIEW

## FISCAL YEAR 2021

### STANDARD REVIEW

The following are the seven criteria included in the FY 2021 SAPR review:

**Criterion #1**—Personnel Qualifications, Training, and Competency

**Criterion #2** – Data Management

**Criterion #3**—Proficiency Testing (PT) Desk Review

**Criterion #4**—Principles of Documentation (POD), Plan of Correction (POC)/Allegation of Compliance (AOC)

**Criterion #5**—Survey Process and Workload

**Criterion #6**—Complaints

**Criterion #7**—Quality Assessment

*Use or delete the following, as appropriate:*

### OTHER SUBJECT AREAS REVIEWED

*If other subject areas were reviewed, list each by name rather than Criterion#, as shown by the following example:*

- Financial Management

**CLIA SAPR LETTER TEMPLATE**  
**For**  
**RESPONSE TO SA CORRECTIVE ACTION PLAN**

*(Date)*

**Name of CLIA State Agency official**  
**CLIA State Agency name**  
**Address**  
**City, State, ZIP code**

Re: CLIA State Agency Performance Review (SAPR), fiscal year 2021 (FY 2020)—*(State)*  
Corrective Action Plan

Dear *(CLIA SA official)*:

Thank you for the corrective action plan submitted in response to the FY 2021 CLIA SAPR. We have reviewed the plan and find that it *(includes) (does not include)* all the items, as specified in our cover letter to the CLIA SAPR summary report, dated *(date)*.

*If the corrective action plan does NOT include all the specified items, add the following paragraph, individualized for each Criterion:*

Following is the information that should be *(added to)(clarified in)* your corrective action plan.

CRITERION *(number and name)*

Informational Item(s) : *(refer to bullets listed on the model cover letter of the SAPR Summary Report, for example... “How corrective action will be monitored and evaluated to verify that it was successful and complete”.)*

Comments: *(for example... “Your plan indicates how the action will be monitored. Please also indicate how the action will be evaluated to verify that it was successful”)*

Please re-submit your corrective action plan with the requested modifications no later than 30 days from your receipt of this letter.

*Finish each letter with the following paragraph:*

As always, we appreciate your efforts in the CLIA Program and your commitment to laboratory quality improvement. If you have any questions or comments about this letter, please call *(name)* at *(telephone number)*.

Sincerely,

*Add appropriate signature.*