

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Division of Clinical Laboratory Improvement & Quality
CLIA Operations Branch C - San Francisco Office
(San Francisco, Denver, Seattle, and Kansas City)
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707



Refer to: DCLIQ - GKY

IMPORTANT NOTICE – PLEASE READ CAREFULLY

February 9, 2024

Bradley Waples, BS. MT(ASCP)
Manager – Medical Laboratory Services
Nevada Department of Health and Human Services
Division of Public and Behavioral Health, Medical Laboratories
4220 S. Maryland Pkwy, Ste 100, Bldg A
Las Vegas, NV. 89119

Re: Clinical Laboratory Improvement Amendments State Agency Performance Review
(CLIA SAPR) Summary Report—Fiscal Year 2023 (FY 2023)

Dear Mr. Waples:

Thank you for your cooperation and the courtesies extended to Gary Yamamoto during the CLIA SAPR review of the Nevada State Agency conducted remotely during the week of February 5, 2024. Enclosed is the Summary Report for the FY 2023 review.

The Section 1864 Agreement requires that the CMS Branch Location conduct a performance evaluation of each State Agency performing CLIA survey and certification activities. The CLIA SAPR is structured to accomplish an annual evaluation of the State Agency. The goal of the CLIA SAPR is optimal performance by the State Agency as our partner in ensuring quality in laboratory practices and testing. The CMS Branch Location can provide educational assistance, information, and support, whenever needed.

The following are the eight criteria included in the FY 2023 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 Workload and Outcome-Oriented Survey Process (OOSP)
- Criterion #6 – Complaints
- Criterion #7 - Quality Assessment
- Criterion #8 - Budget – Educational for FY 2023

We encourage you to communicate any feedback regarding the SAPR process to your CMS Branch Location. However, the subject areas of the other Criteria from the previous version of the SAPR 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.

The CLIA SAPR process 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 consist 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 the CMS Branch Location to request a written corrective action plan. The Performance Threshold also serves to ensure nationwide consistency among the CMS Branch Locations.

We are pleased to report that your agency’s performance met or exceeded the Performance Threshold for all Criteria, thus no written corrective action plan is requested. Your agency is to be commended for its performance. We note that your agency has sustained optimal performance outcomes for Criterion #1, #3, #4, #5, #6, and #7 for several years. With your permission, we would like to share the “best practices” employed by your SA with other states.

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.

Again, we commend you and your staff for all 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 Gary Yamamoto at (415) 744-3738.

Sincerely,

Karen Fuller/s

Karen Fuller, Manager

Division of Clinical Laboratory Improvement & Quality

CLIA Operations Branch C

(San Francisco, Denver, Seattle, and Kansas City)



Clinical Laboratory Improvement Amendments (CLIA) Program

State: NEVADA

CLIA State Agency Performance Review

SUMMARY REPORT

Review Period: Fiscal Year 2023

(October 1, 2022 to September 30, 2023)

CLIA STATE AGENCY PERFORMANCE REVIEW FISCAL YEAR 2023

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 (OOSP)
- Criterion # 6: Complaints
- Criterion # 7: Quality Assessment
- Criterion # 8: Budget – Educational Only for FY 2023

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 2023? 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

FY 2023 Quantified Performance Results: 100%

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: 100%

FY 2022 Quantified Performance Results: 100%

WRITTEN CORRECTIVE ACTION PLAN: NO

FINDINGS:

- No new surveyors were hired in FY2023.

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS:

- The Nevada State Agency has developed a good training and competency program to meet this criterion.
- We commend the Nevada State Agency for their continued efforts to meet this criterion.

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 the receipt and entry of initial applications (Form CMS-116s), certificate type changes, and demographic updates.

SA Performance Results

FY 2023 Quantified Performance Results: 100 %

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: 29%

FY 2022 Quantified Performance Results: 100%

WRITTEN CORRECTIVE ACTION PLAN: NO

FINDINGS:

- For CLIA number 29D2270553, the Nevada State Agency records show that the CMS-116 was received on 08/11/2022 and processed on 10/18/2022, which is greater than 30 days from receipt.

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS

- We commend the Nevada State Agency for their continued efforts to meet this criterion.

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

The SA conducts PT Desk Review timely and initiates appropriate action regarding 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

FY 2023 Quantified Performance Results: 100%

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: 100%

FY 2022 Quantified Performance Results: 100%

WRITTEN CORRECTIVE ACTION PLAN: NO

FINDINGS:

- The Nevada State Agency conducted proficiency testing reviews timely and initiated appropriate actions as needed.

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS:

- We commend the Nevada State Agency for their continued efforts to meet this criterion.

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

FY 2023 Quantified Performance Results: 100%

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: 100%

FY 2022 Quantified Performance Results: 100%

WRITTEN CORRECTIVE ACTION PLAN: NO

FINDINGS:

- We request that the Nevada State Agency surveyors add the date, time, and, if applicable, location when/where sources of evidence are determined to their deficiencies' "based on" statements.

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS

- We commend the Nevada State Agency for their continued efforts to meet this criterion.

Performance Review Criterion # 5: Survey Workload and Outcome-oriented Survey Process

- 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 85%.

SA Performance Results

FY 2023 Quantified Performance Results: 100%

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: 100%

FY 2022 Quantified Performance Results: 100%

WRITTEN CORRECTIVE ACTION PLAN: NO

FINDINGS:

- The Nevada State Agency met the criterion's new educational performance indicator.

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS

- We commend the Nevada State Agency for their continued efforts to meet this criterion.

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

FY 2023 Quantified Performance Results: 100%

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: 100%

FY 2022 Quantified Performance Results: 100%

WRITTEN CORRECTIVE ACTION PLAN: NO

FINDINGS:

- The Nevada State Agency appropriately conducted and followed the CLIA complaint process.

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS

- We commend the Nevada State Agency for their continued efforts to meet this criterion.

Performance Review Criterion #7: Quality Assessment

- The SA has developed specific procedures related to SAPR.
- 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).

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

FY 2023 Quantified Performance Results: 100%

PREVIOUS 2-YEAR QUANTIFIED PERFORMANCE RESULTS

FY 2021 Quantified Performance Results: 100%

FY 2022 Quantified Performance Results: 100%

WRITTEN CORRECTIVE ACTION PLAN: NO

FINDINGS:

- The Nevada State Agency was unable to meet this criterion's two new educational performance indicators.

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS:

- We commend the Nevada State Agency for their continued efforts to meet this criterion.

****Educational for FY 2023****

Performance Review Criterion #8: Budget

- The SA submits all required documents into the Survey and Certification and Clinical Laboratory Improvement Amendments System (SCCLIA) within the specified time limits.

PERFORMANCE MEASUREMENT:

Performance Threshold for Written Corrective Action Plan

A written corrective action plan is required if the Quantified Performance Results are less than 80%.

SA Performance Result

FY 2023 Quantified Performance Results: 91%

WRITTEN CORRECTIVE ACTION PLAN: Educational for FY 2023

FINDINGS:

- The Nevada State Agency's October 2022 monthly report was submitted on 11/14/2022, which was after the deadline of the 10th of each month.

SPECIAL CIRCUMSTANCES AND NOTEWORTHY ACCOMPLISHMENTS:

- Irrespective of the findings, we commend the Nevada State Agency for their efforts to meet this new criterion's budget-specific performance indicator.