DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

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

Admin Info: 20-04-CLIA

DATE: **December 16, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Provider-performed Microscopy Project 2020 (Pilot)

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) is preparing the Regional Offices (RO) and State Agencies (SA) for the upcoming Provider-performed Microscopy (PPM) project and this memorandum includes information on the following:
  - **State Selection Process**: One State Agency was randomly selected from each of the 10 CMS Regions.
  - **Survey Process:** Each participating State Agency will survey 2% of the laboratories with a PPM certificate in their state during FY2020.
  - **PPM Project 2020 Surveyor Tool:** This surveyor tool will help focus the surveyor on the appropriate CLIA regulations to consider when inspecting laboratories with a PPM certificate.
  - **Surveyor training for participating State Agencies (SA):** Training for SA staff is tentatively scheduled for Wednesday, December 4th from 1-3pm EST, provided by CO staff (via Webinar).

Background

The State Agency (SA) surveys laboratories under the authority of section 1864 of the Social Security Act in accordance with CMS policies and procedures. As per 42 CFR,§493.1775 (a) and (b), while laboratories with a Certificate for Provider-performed Microscopy (PPM) Procedures are not subject to biennial inspections, the SA may conduct an inspection at any time during the laboratory's hours of operation to do the following:

- Determine if the laboratory is performing testing in a manner that does not constitute an imminent and serious risk to public health.
- Evaluate a complaint from the public.
- Determine if the laboratory is performing tests beyond the scope of its certificate.
- Collect information regarding the appropriateness of tests specified as waived tests or PPM procedures.

A pilot study initiated by CMS in 2000 focused on the quality of testing performed in both Certificate of Waiver (CoW) laboratories and PPM laboratories. Due to the exponential growth

of waived testing, CMS decided to initially focus efforts on improving compliance in laboratories with a CoW. However, during this pilot project we found that 25% of the Provider-performed Microscopy laboratories did not perform competency assessments, 38% did not verify the accuracy of the testing at least twice annually and 6% were operating under the incorrect CLIA certificate. As a result, CMS, in collaboration with the Centers for Disease Control (CDC) developed educational booklets for both types of laboratories in order to help address the quality issues found during the pilot project.

In 2017, in collaboration with 3 CMS Regional Offices, CMS initiated a pilot study and performed educational surveys in six laboratories with a PPM certificate to evaluate the testing being performed and to identify any issues associated with that testing. We found that issues similar to those identified in 2000 remain in laboratories with a PPM Certificate. As a result, CMS decided to enlarge the scope of this pilot project to continue to evaluate and identify if potential issues continue in these laboratories. CMS will provide a copy of the "Provider-performed Microscopy Procedures – A Focus on Quality Practices" booklet to each participating laboratory with a PPM certificate to educate and assist these laboratories in improving its quality of testing.

Overview of the PPM Survey Project for 2020

Selection of States

There are a total of 10 randomly selected states (one per region) participating in this project. Each state will survey 2% of laboratories with a Certificate for PPM Procedures within that state. See Table 1 for selected states and the number of laboratories to be surveyed.

Table 1: Selected States and Number of Laboratories to be Surveyed (2% Sample)

Region	State	Total PPM Labs	2% Sample
RO1	Rhode Island	96	2
RO2	New York	728	15
RO3	Delaware	118	2
RO4	Georgia	1185	24
RO5	Indiana	974	19
RO6	Oklahoma	382	8
RO7	Iowa	293	6
RO8	North Dakota	28	1
RO9	Nevada	101	2
RO10	Oregon	597	12
	Total	**4502**	**91**

Source: CMS CLIA Database 2018

Survey Process

1. Select a 2 percent sample of laboratories with a PPM certificate located in the selected state. Consider selecting a variety of laboratories with a PPM certificate by type (e.g. Physician Office, Community Clinic, and Rural Health Clinic).
2. For efficiency, cluster PPM surveys with routine surveys when possible.
3. Follow normal State agency procedures for scheduling a survey. Send a Survey Announcement letter (Attachment #1) to the PPM laboratory as a confirmation.

4. **Required**: Provide a copy of the booklet "Provider-performed Microscopy Procedures – A Focus on Quality Practices" while on-site. **Optional**: provide a copy of the "Ready, Set, Test" booklet.
5. Use the PPM Project 2020 Surveyor Tool (Attachment #2) to survey the laboratory using the Outcome-Oriented Survey Process. In the Outcome-Oriented Survey Process, emphasis is placed on the laboratory's quality system as well as the structures and processes throughout the entire testing process that contribute to quality test results.
6. Survey the laboratory for all tests performed under the PPM certificate, including PPM procedures and waived tests. Identify any testing performed beyond the certificate.
7. Cite deficiencies using form CMS-2567 and notify the laboratory using the post-survey model letters provided (Attachments #3 and #4).
8. Follow established procedures for revisit surveys, as applicable.

PPM Project 2020 Surveyor Tool

This surveyor tool will help focus the surveyor on the appropriate CLIA regulations to consider when inspecting PPM laboratories.

Surveyor Training for Participating SA

The information contained in this memorandum will be shared with all appropriate survey and certification staff, their managers, and the State/RO training coordinators assigned to work with determinations involving compliance with CLIA. It is strongly recommended that the participants in this project listen to the surveyor training from 2018 that can be accessed through the Integrated Surveyor Training Website (ISTW) - *The Fundamentals of a Laboratory with a CLIA Certificate for Provider-Performed Microscopy (PPM).* Training for SA staff is tentatively scheduled for Wednesday, December 4th from 1-3pm EST, provided by CO staff (via Webinar).

Contact: For questions or concerns relating to this memorandum, please direct them to PPMCOWProject@cms.hhs.gov.

Effective Date: Immediately. This information should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

Attachment (s) - 4
Attachment 1: PPMP Survey Announcement Letter
Attachment 2: Provider-performed Microscopy Project 2020 Surveyor Tool
Attachment 3: PPMP Standards-out Letter
Attachment 4: PPMP Conditions-out Letter

cc: Quality, Safety and Oversight Regional Office Management

Dear Laboratory Director:

Your laboratory has been selected to be surveyed as part of the Clinical Laboratory Improvement Amendment (CLIA) program's efforts to visit and gather information about the testing being performed in laboratories with a Certificate for Provider Performed Microscopy (PPM) procedures in the United States. Your survey will take place on (enter date and time).

The (XXXX) State Agency representing the CLIA program, will conduct on-site surveys of laboratories holding PPM certificates to ensure that the laboratory is providing accurate and reliable testing. These surveys will include a wide range of laboratories and will present an opportunity for your laboratory to learn more about the CLIA program.

The authority to survey your laboratory is in the CLIA regulations at 42 CFR 493.1775 as stated below:

§493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.

(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory's hours of operation to do the following:

(b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.

(b)(2) Evaluate a complaint from the public.

(b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

(b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures. (c) The laboratory must comply with the basic inspection requirements of §493.1773.

The surveys will be conducted in a manner similar to the current CLIA compliance surveys; i.e., evaluating the ability of the laboratory to ensure quality test results based on the applicable CLIA requirements. Your laboratory will not be charged for the survey. A State surveyor will contact your laboratory by telephone to confirm the date and time of this appointment approximately 10 days prior to the projected survey date. Please have available a list of the tests your laboratory currently performs. A discussion about the survey findings will be provided at the conclusion of the survey. You will subsequently receive a written CMS-2567 report containing the survey findings, instructions on how to reply to the CMS-2567 and a contact person at the State, should you require more

information. If problems identified are not corrected in a timely manner, we may have to pursue further action. If any serious risk to public health is identified, you will be given a time sensitive opportunity to correct the patient testing practices identified as potentially causing serious risk to human health. We will only revisit laboratories that have quality concerns on the initial visit to ensure that identified problems have been corrected. ***Please contact the State Agency (SA) immediately if you are currently not testing.***

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

Sincerely,

State Survey Agency

Provider-performed Microscopy Project 2020
Surveyor Tool

Laboratory Name:	**CLIA Number:**
Date of Survey:	

PPMP Testing	**Surveyor Notes and Comments**
Standard Level D8201 and Condition Level D8100 §493.1775(b)(1-4) and §493.1771(a) 1. Are all tests performed categorized as provider-performed microscopy and/or waived?	The following tests are <u>NOT</u> within the provider-performed microscopy subcategory: • *Arachnid (tick) identification* • *Mohs procedure tissue slide* • *Body fluid exam for crystals* • *Tzanck smear* • *Gram Stains*
Mandatory Citations **Standard Level D5981 and Condition Level D5980** §493.1357 and §493.1355 2. Does the laboratory have a Laboratory Director that meets the qualifications to manage and direct a PPM laboratory?	
Standard level D5985 §493.1359(a) 3. Does the Laboratory Director direct no more than 5 non-waived laboratories?	

Provider-performed Microscopy Project 2020
Surveyor Tool

PPMP Testing	Surveyor Notes and Comments
Mandatory Citations **Standard Level D5991 and Condition Level D5990** §493.1363(a),(b)(1-3) and §493.1361 4. Are the PPM testing personnel one of the following: • Physician (M.D., D.O., D.P.M) • Dentist (D.D.S.) • Midlevel practitioner (nurse midwife, nurse practitioner, physician assistant)	
Standard Level D5993 §493.1365(a) 5. Does the practitioner (PPM testing personnel) personally process, perform and report results during the patient's visit?	
Standard Level D5995 §493.1365(b) 6. Do testing personnel use microscopes limited to bright field or a phase/contrast microscope?	
Standard Level D5201 §493.1231 7. Does the laboratory ensure confidentiality of patient information throughout all phases of the total testing process?	

PPMP Testing	Surveyor Notes and Comments
Standard Level D5203 §493.1232 8. Does the laboratory have an established policy and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection to completion of testing and reporting of results?	
Standard Level D5209 §493.1235 9. Has the laboratory established and are they following written policies and procedures to assess employees and, if applicable, consultant competency?	"Employees" in these PPM facilities means testing personnel. PPMP laboratories are not required to designate technical or clinical consultants.
Standard level D5217 §493.1236(c)(1) 10. For a laboratory performing wet mount preparations for bacteria and fungi, KOH preparations, fern tests, post-coital direct exams of vaginal/cervical mucous, qualitative semen analysis and urine sediment examinations does the laboratory verify accuracy at least twice annually?	
Standard Level D5219 §493.1236(c)(2) 11. For a laboratory performing wet mounts for parasites and human cellular elements, pinworm examinations, nasal smears for granulocytes and fecal leukocyte examinations does the laboratory verify accuracy at least twice annually?	

PPMP Testing	Surveyor Notes and Comments
Condition Level D5200 §493.1230 12. Are the General Laboratory System Deficiencies noted in questions 7-11 above sufficient enough to warrant a condition-level citation?	
Standard Level D5401 §493.1251(a) 13. Does the laboratory director ensure that an approved procedure manual is available?	
Standard Level D5403 §493.1251(b)(1-4) 14. Does the laboratory follow the procedure manual?	
Standard Level D5407 §493.1251(d) 15. Are procedures and changes in procedures signed and dated by the current laboratory director?	

PPMP Testing	Surveyor Notes and Comments
Standard Level D5415 §493.1252(c)(1-2) 16. Are the laboratory's reagents, solutions or supplies labeled appropriately and stored properly?	
Standard Level D5417 §493.1252(d) 17. Does the laboratory ensure that reagents, solutions or supplies have not exceeded their expiration dates, nor have deteriorated, or are of substandard quality?	
Standard Level D5433 §493.1254(b)(1)(i & ii) 18. Has the laboratory established a maintenance protocol that ensures equipment and instruments are performing as necessary for accurate and reliable test results and can the laboratory show documentation of its established maintenance program?	
Standard Level D5435 §493.1254(b)(2)(i & ii) 19. Does the laboratory perform and document all required function checks that are necessary for accurate and reliable test results as outlined by their established protocols?	

Provider-performed Microscopy Project 2020
Surveyor Tool

PPMP Testing	Surveyor Notes and Comments
Standard Level D5449 §493.1256 (d)(3)(ii) 20. Does the laboratory use control material when performing urine microscopic procedures?	Photomicrographs or charts of all possible urine sediment components will meet the control requirement for manual microscopic urinalysis examinations. Use D5445.
Standard Level D5787 §493.1283(a)(4) 21. Is the identity of the PPM testing personnel in the test records?	
Condition Level D5400 §493.1250 22. Are the Analytic System deficiencies in questions 13-21 sufficient enough to warrant a condition level-citation?	
Standard Level D3031 §493.1105(a)(3) 23. Does the laboratory retain analytic systems records for at least 2 years?	

Provider-performed Microscopy Project 2020
Surveyor Tool

PPMP Testing	Surveyor Notes and Comments
Standard Level D5891 §493.1299 24. Does the laboratory have policies and procedures for monitoring and correcting problems with test reporting?	
Standard Level D3041 §493.1105(a)(6) 25. Is the laboratory able to retrieve a copy of the original patient report at least 2 years after the date of the reporting?	
Standard Level D2011 §493.801(b)(3) 26. Does the laboratory ensure that there is no communication about proficiency testing across sites/locations prior to the deadline for reporting results to the PT program?	
Mandatory Citations **Standard Level D2013 and Condition Level D2000** §493.801(b)(4) and §493.801 27. Does the laboratory ensure that PT samples are not sent to any other laboratories for analysis prior to the deadline for reporting results to the PT program?	Refer to S&C: 18-07-CLIA; suspected instances of PT referral are sent from the SA to the RO and then to CO for review prior to issuing a CMS-2567.

Provider-performed Microscopy Project 2020
Surveyor Tool

Waived Testing	Surveyor Notes and Comments
Does the laboratory perform clinical laboratory tests categorized as Waived? No - Conclude survey, Yes - Continue	
Standard Level D1001 §493.15(e)(1) Does the laboratory have the current manufacturer's instructions for the waived tests performed?	
Standard Level D1001 §493.15(e)(1) Does the laboratory follow the current manufacturer's instructions for all tests performed?	Specifically note which manufacturer's instructions the testing personnel are not following. Obtain a copy of the instructions.
Standard Level D8201 and Condition Level D8100 §493.1775(b)(1-4) and §493.1771(a) Is the failure to follow manufacturer's instructions sufficient enough to warrant a condition-level citation?	For condition-level citation, gather sufficient evidence that patient test results have been, or are likely to be, adversely affected by the failure to follow manufacturer's instructions.

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [**XXX XXX-XXXX**] AND FIRST CLASS MAIL.
(CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[**TODAY'S DATE**]
[**DIRECTOR NAME**], M.D., Director
[**OWNER NAME**], Owner(s)
[**LAB NAME**]
[**ADDRESS**]
[**CITY**], [**STATE**] [**ZIP**]
CLIA #[**CLIA NUMBER**]
[**OPTIONAL:** State I.D. # [**STATE ID NUMBER**]

RE: STANDARD-LEVEL DEFICIENCIES

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all applicable CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and Title 42 of the Code of Federal Regulations, Part 493 (42 C.F.R. part 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [**STATE AGENCY NAME**] (State agency) conducted a survey of your Provider-performed microscopy laboratory that was completed on [**SURVEY DATE**]. Enclosed is form CMS-2567, Statement of Deficiencies, listing the deficiencies found during the survey. The deficiency statement references the CLIA regulations at 42 C.F.R. part 493.

You are required to respond within 10 days of receipt of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

Please return the completed form CMS-2567, dated and signed by the director, within 10 days of receipt of this notice.

Regulations at 42 C.F.R. § 493.1816 state that if a laboratory has deficiencies that are not at the Condition level, the laboratory must submit a plan of correction that is acceptable to the Centers for Medicare & Medicaid Services (CMS) in content and time frames. Further, regulations at 42 C.F.R. § 493.1816 require all deficiencies to be corrected within 12 months after the last day of the survey. Please note that depending on the nature and seriousness of the deficiency, the acceptable time frame for correction may be less than 12 months.

If your laboratory does not respond timely to this request, or if your laboratory submits a Plan of Correction that is not acceptable in content and time frames, or if your laboratory does not demonstrate compliance with all CLIA requirements by the specified completion date, we will recommend to CMS imposition of principal sanctions, i.e., suspension, limitation and/or revocation of your laboratory's CLIA certificate and concurrent cancellation of your laboratory's approval for Medicare payments per 42 C.F.R. § 493.1816.

Your laboratory will also be required to provide acceptable evidence of correction for the cited deficiencies. For your information, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice or potentially affected by the deficient practice?
2) What measures have been put into place or what systemic changes you have made ensure that the deficient practice does not recur, and
3) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

Please note that the survey takes an overview of the laboratory through random sampling. By its nature, the survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all applicable CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

In addition to CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by the [**STATE AGENCY NAME**] at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a survey using random sampling, but for which the laboratory and its director will still be held responsible.

If you have questions regarding this letter, please contact me at [PHONE #].

Sincerely,

[**SURVEYOR NAME**], [**TITLE**]
[**STATE AGENCY NAME**]

Enclosure: CMS-2567, Statement of Deficiencies

(3/23/2017) – Conditions out letter for PPM surveys - AOC request letter

IMPORTANT NOTICE – ACTION NECESSARY

VIA FACSIMILE TO [**XXX XXX-XXXX**] AND FIRST CLASS MAIL.
(CONFIRMATION OF SUCCESSFUL TRANSMISSION OF FACSIMILE CONSTITUTES PROOF OF RECEIPT)

[**TODAY'S DATE**]

[**DIRECTOR NAME**], M.D., Director
[**OWNER NAME**], Owner(s)
[**LAB NAME**]
[**ADDRESS**]
[**CITY**], [**STATE**] [**ZIP**]

CLIA # [**CLIA NUMBER**]
[**OPTIONAL:** State I.D. # [**STATE ID NUMBER**]

RE: CONDITION-LEVEL DEFICIENCIES

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all applicable CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and Title 42 of the Code of Federal Regulations, Part 493 (42 C.F.R. part 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The [**STATE AGENCY NAME**] (State agency) conducted a survey of your Provider-performed microscopy laboratory that was completed on [**SURVEY DATE**]. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. Specifically, the following Conditions were not met: [**DELETE CONDITIONS THAT DO NOT APPLY**.]

D2000 - 42 C.F.R. § 493.801 Condition: Enrollment and testing of [proficiency testing] samples;
D5200 - 42 C.F.R. § 493.1230 Condition: General laboratory systems;
D5400 - 42 C.F.R. § 493.1250 Condition: Analytic systems;
D5980 - 42 C.F.R. § 493.1355 Condition: Laboratories performing PPM procedures; laboratory director;
D5990 - 42 C.F.R. § 493.1361 Condition: Laboratories performing PPM procedures; testing personnel;
D8100 - 42 C.F.R. § 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately.

You are directed to submit a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited. Please document your allegation of compliance using the enclosed CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed CMS-2567 documented with a credible allegation of compliance to our office **WITHIN 10 DAYS FROM RECEIPT** of this notice. You must also submit documented evidence that verifies that the corrections were made. We may conduct a follow-up onsite survey in approximately 30-45 days to verify the corrections if we find your allegation of compliance to be credible and the submitted evidence to be acceptable. If your laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey. (Your allegation of compliance will be included in the public record of the inspection.)

A credible allegation of compliance is a statement or documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
3) Indicates resolution of the problems.

For your information, an acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients affected by the deficient practice or potentially affected by the deficient practice,
2) What measures have been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and
3) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If you do not submit a credible allegation of compliance and acceptable evidence of correction, or if you submit an allegation of compliance that is determined to be credible, but are found to be still out of compliance with any CLIA Condition-level requirements at the time of the follow-up visit, [**STATE AGENCY NAME**] will recommend to the [**NAME OF RO**] Regional Office of the Centers for Medicare & Medicaid Services (CMS) that sanctions be taken against your laboratory's CLIA certificate. These may include alternative sanctions (Civil Money Penalty of up to $6,033 per day of noncompliance that does not pose immediate jeopardy per 42 C.F.R. § 493.1834, Directed Plan of Correction per 42 C.F.R. § 493.1832, State Onsite Monitoring per 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of your laboratory's CLIA certificate and cancellation of you laboratory's approval for Medicare payments per 42 C.F.R. § 493.1814).

It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all applicable CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assurance measures to ensure that the deficient practices do not recur.

If you have questions regarding this letter, please contact me at [PHONE #].
Sincerely,
[**SURVEYOR NAME**], [**TITLE**]
[**STATE AGENCY NAME**]
Enclosure: CMS-2567, Statement of Deficiencies