

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0703582	(X3) Date Survey Completed 09/26/2018
Name of Provider or Supplier District 4 Public Health	Street Address, City, State 301 Main Street, Lagrange, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 26, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the program coordinator, the Laboratory Director failed to attest the routine incorporation of the American Proficiency Institute (API) proficiency test samples into the patient workload using the facility's routine methods. The findings include: 1. Seven (7) out of 13 laboratories in District 4 had no records of signed attestation statements from the Laboratory Director and testing personnel for 2017 and 2018 proficiency test for Vaginal Wet Preparation and Potassium Hydroxide (KOH) Preparation. 2. An interview with the program coordinator on September 26, 2018 at approximately 7 PM in the conference room #109, confirmed these findings. **Repeat Deficiency**</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency</p>

testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on review of proficiency test (PT) records and interview with the program coordinator, the laboratory failed to retain copies of all PT events of the American Proficiency Institute (API) proficiency test samples. Findings include: 1. Review of PT records revealed two (2) counties of District 4 did not retain copies of the 2017 test event #2. 2. Review of PT records revealed thirteen (13) of the thirteen (13) counties failed to retain PT laboratory log sheets for 2017 and 2018 thus far. 2. An interview with the program coordinator on September 26, 2018 at approximately 7 PM in the conference room #109 confirmed these findings.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on review of proficiency test (PT) records and interview with the program coordinator, 13 out of 13 laboratories in District 4 failed to review and evaluate the results of the American Proficiency Institute (API) proficiency test for 2017 and 2018 to date. Finding include: 1. There was no evidence that the API proficiency test was reviewed and evaluated by the Laboratory Director for 13 of 13 laboratories in District 4 for 2017 and 2018 to date. 2. Interview with the program coordinator on September 26 at approximately 7 PM in the conference room # 109, confirmed these findings. ****Repeat Deficiency****

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on review of the laboratory records, procedure manual (SOP), and staff interview, the laboratory failed to establish and verify an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the lab. Findings include: 1. Review of the SOP revealed the lack of a written Quality Assessment (QA) program for thirteen(13) of thirteen (13) counties in District 4. 2. Review of the laboratory's records revealed no documentation of pre-analytic, analytic, or post-

	<p>analytic monitors for twelve (12) of thirteen (13) counties in District 4. 3. Interview with the program coordinator on September 26, 2018 in the conference room #109 at approximately 7 PM, confirmed the missing aforementioned QA.</p>
<p>D5293</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records, procedure manual (SOP), and staff interview, the laboratory failed to establish and verify an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the lab. Findings include: 1. Review of the laboratory's records revealed no documentation of pre-analytic, analytic, or post-analytic monitors for twelve (12) of thirteen (13) counties in District 4. 2. Review of the SOP revealed the lack of a policy to review of the effectiveness of corrective actions taken to resolve problems for thirteen (13) of thirteen (13) counties in District 4. 3. Interview with the program coordinator on September 26, 2018 in the conference room #109 at approximately 7 PM, confirmed the missing aforementioned QA.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature records and staff interview, the lab failed to monitor the room temperature (RT) and relative humidity (RH) in all testing facilities. Findings include: 1. Review of temperature records revealed four (4) of thirteen (13) counties in District 4 failed to monitor RT and RH. 2. Review of temperature records revealed acceptable ranges were not on all temperature log sheets for 2017 and 2018. 2. Interview with the program coordinator on September 26, 2018 in the conference room #109 at approximately 7 PM, confirmed not all labs monitored RT and RH and established acceptable temperature ranges for their equipment.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of maintenance records and staff interview, the lab failed to calibrate the microscope(s) per the procedure manual and perform maintenance on eyewash stations and centrifuge. Findings include: 1. Review of 2017 maintenance records revealed two (2) of thirteen (13) counties in District 4 failed to perform calibration on the microscopes (SN#123599, SN#706355, and Scientific LW /Revelation III). 2. Review of maintenance logs revealed no documents available for the eyewash stations in thirteen (13) of thirteen (13) counties in District 4 for 2017 and 2018 thus far. 3. Review of maintenance records revealed no centrifuge calibration records for one (1) of thirteen (13) counties for 2017 and 2018 thus far. 4. Interview with the program coordinator on September 26, 2018 in the conference room #109 at approximately 7 PM, confirmed the missing aforementioned maintenance.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control (QC) document review and staff interview, the laboratory failed to perform and document QC on potassium hydroxide (KOH) and saline wet preparation slides. Findings include: 1. No QC documents were available to review on KOH or saline wet preparation slides at the time of survey. 2. An interview with the program coordinator on 9/26/18 at 1:40 PM in the conference room # 109, confirmed controls were not performed on KOH or saline wet preparation slides .

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on document reviews and staff interview, the laboratory director failed to: ensure laboratory successfully submitted PT testing events of 2017, have a Quality Assessment (QA) program and performed monitors for QA/QC (quality control) failures, performed QC as required, review PT scores, ensure all PT documents are retained, ensure competency evaluations are performed annually by designated, qualified personnel; ensure room temperatures and humidity is monitored, and ensure maintenance is performed on eyewash stations and microscopes. Findings include: For details refer to: D2009, D2015, D5211, D5291, D5293, D5413, D5429, D5449, D6017, D6022

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to ensure PT results were returned within the time frame required by the PT agency. Findings include: 1. Review of PT records for 2017 revealed two (2) of thirteen (13) counties in District 4 received a score of 0% on Events #1 and #2 for "no results received". 2. Interview with the program coordinator on September 26, 2018 at approximately 7 PM in conference room #109, confirmed results were not reported to the PT agency in time to be evaluated which resulted in a score of 0%.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records, procedure manual (SOP), and staff interview, the laboratory director failed to ensure that the quality control (QC) and quality assessment(QA) programs are established and maintained to identify failures in quality. Findings include: 1. Review of the SOP revealed the lack of a written Quality Assessment (QA) program for thirteen(13) of thirteen (13) counties in District 4. 2. Review of the laboratory's records revealed no documentation of pre-analytic, analytic, or post-analytic monitors for twelve (12) of thirteen (13) counties in District 4. 3. No QC documents were available to review on KOH or saline wet preparation slides at the time of survey. 4. Interview with the program coordinator on September 26, 2018 in the conference room #109 at approximately 7 PM, confirmed the missing aforementioned QA and QC.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the "Personnel Competency Review Forms" and staff interview, the technical consultant (TC) (lab director) failed to ensure that the staff maintain competency. Findings include: 1. Review of the personnel competency forms revealed staff #11 (CMS 209 form of Coweta Co.(CCHD)) had dated the form test date as 7/16 /18 and 9/16/18, and the reviewer (not TC or designee) signed and dated the form as 4 /26/18. 2. Interview with the program coordinator on 9/26/18 in conference room #109 at approximately 7:30 PM, confirmed the difference in the dates and the reviewer was not the TC or designee.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of testing personnel (TP) documents and staff interview , the technical consultant (TC) (lab director) failed to perform annual competency on testing personnel. Findings include: 1. Review of TP documents revealed the TC (lab director) failed to perform annual competency on testing personnel in 2017 and 2018. 2. Review of TP documents revealed the annual competency was performed by unqualified personnel in twelve (12) of thirteen (13) counties in District 4. 3. Review of TP documents revealed one (1) county had a qualified staff perform the annual competencies but did not provide a letter of designee. 4. Interview with the program coordinator on September 26, 2018 in the conference room #109 at approximately 7 PM, confirmed the aforementioned competency documentation.