

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0690710	(X3) Date Survey Completed 03/06/2019
Name of Provider or Supplier Chatham County Health Dept Clinic	Street Address, City, State 1395 Eisenhower Drive, Savannah, 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 March 6, 2019. 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:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the laboratory failed to test PT samples in the same manner it test patient samples. NOTE: This is a repeat deficiency and was also cited at the 2/6/2017 survey. Findings include: 1. Review of 2017 & 2018 PT records revealed in-house worksheets were provided to testing personnel (TP) with instructions to perform testing on specific numbered samples and return results to the technical consultant (TC) before the deadline for submitting results to API. 2. Review PT records for 2017 event 2 gram stain testing revealed the following: A. Instructions from API revealed the deadline for submitting results is 07/07/17. B. In-house work sheets revealed instructions to return results to the TC by 07/05/17. C. Results submitted to API do not correspond with the answers recorded on the in-house work sheets for GS 6, 8 & 9. The TP who also signed the attestation statement for GS 6 recorded "gram positive & "no diplococci seen". Results submitted to API are "gram negative" & "diplococci seen". The TP who also signed the attestation statement for GS 8 recorded "gram negative" & "diplococci seen". Results submitted to API are "no gram negative & "no diplococci seen". The TP who also signed the attestation statement for GS 9 recorded "gram positive (which would have been reported as "no</p>

gram negative") & "diplococci seen". Results submitted to API are "gram negative" & "no diplococci seen". E. In-house work sheets revealed all 5 PT samples were read by the technical consultant as well as one of the TP. The answers recorded on the technical consultant's in-house worksheet are the same as those reported to API. 3. Review PT records for 2018 event 1 gram stain testing revealed the following: A. In-house work sheets revealed instructions to return results to the TC by 3/8/18. B. In-house worksheets also revealed specimens numbered GS 1 & GS 2 were read by two testing personnel and all five samples GS 1-5 were read by the technical consultant. C. Attestation statement revealed two TP signed certifying they tested sample GS 2. D. Results submitted to API do not correspond with the answers recorded on the in-house work sheets for GS 1 & 4. TP who also signed the attestation statement for GS 1 recorded " diplococci seen". The second TP who read GS 1 also recorded " diplococci seen". Results submitted to API are "no diplococci seen". The TP who also signed the attestation statement for GS 4 recorded "diplococci seen". Results submitted to API are "no diplococci seen". E. In-house work sheets revealed the answers recorded on the technical consultant's in-house worksheet are the same as those reported to API. 4. Review of PT records for 2018 event 3 gram stain testing revealed the following: A. Instructions from API revealed the deadline for submitting results is 10/12/18. B. In-house work sheets revealed instructions to return results to the TC by 10/4/18. C. In-house worksheets also revealed specimens numbered GS 14 & GS 15 were read by two testing personnel and all five samples GS 11-15 were read by the technical consultant. There is a handwritten note on the worksheet for one of the TP reading GS 15 instructing them to read and pass to another TP because they have more nurses than slides. D. Attestation statement for 2018 event 3 gram stain testing revealed two TP signed certifying they tested sample GS 14. E. Results submitted to API do not correspond with the answers recorded on the in-house work sheets for GS 12 & 15. The TP who also signed the attestation statement for GS 12 recorded "diplococci seen". Results submitted to API are "No diplococci seen". Two testing personnel read GS 15. Both recorded "diplococci seen". Results submitted to API are "No diplococci seen". The answers recorded on the technical consultant's in-house worksheets are the same as those reported to API. 5. Review of 2017 event 3 & 2018 events 1, 2 & 3 in-house work sheets of PT samples for saline wet prep slides & potassium hydroxide (KOH) slides revealed multiple testing personnel looked at the samples, recorded results and submitted their findings to the TC before the deadline for submitting results to API. Review also revealed the TC viewed all PT samples and recorded results on a worksheet. 6. Interview with the TC on March 6, 2019 in her office at 1: 30 pm confirmed gram stain PT samples were tested and reported to API as described above. The TC also confirmed wet prep PT samples were read by all available testing personnel before results were submitted to API. The TC confirmed she read all PT samples but does not routinely test patient samples and she submits results she records to API when there is a discrepancy between results recorded by TP and her results.

D2009

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) proficiency testing attestation records and staff interview, the laboratory director failed to sign the

	<p>attestation statements. Findings include: 1. Review of the attestation statement for 2018 microbiology event 3, revealed the laboratory director's signature is stamped and is not an original signature. 2. Review of the attestation statement revealed "physically sign" is underlined in the instructions printed on form. 3. Interview with the technical consultant on March 6, 2019 at 1:30 pm in her office revealed she has been given authorization to use a stamp with the lab director's signature. NOTE: This is a repeat deficiency and was also cited at the 2/6/2017 survey.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory director failed to provide overall management and direction for the laboratory. Refer to D 6016</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing attestation records and staff interview, the laboratory director failed to sign the attestation statements. Findings include: 1. Review of the attestation statement for 2018 microbiology event 3, revealed the laboratory director's signature is stamped and is not an original signature. 2. Review of the attestation statement revealed "physically sign" is underlined in the instructions printed on form. 3. Interview with the technical consultant on March 6, 2019 at 1:30 pm in her office revealed she was given authorization to use a stamp with the lab director's signature</p>