

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0988959	(X3) Date Survey Completed 08/05/2021
Name of Provider or Supplier A O P Pa Db a Central Georgia Cancer Care	Street Address, City, State 114 Sutherlin Drive C 1, Warner Robins, 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 August 5, 2021. Condition and Standard level Citations were found. 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:
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents the laboratory failed to received successful evaluation scores the the Specialty, Hematology, Sub-specialty White Blood Cell Differential (WBC DIFF), for event two and three in 2020. REFERENCE: D2123, D6019</p>

D2123

HEMATOLOGY

CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API), Proficiency Testing (PT), evaluation reports and staff interview, the laboratory failed to receive successful scores for 2020 event 2 and 3 for the Specialty Hematology, sub-speciality White Blood Cell Differential. Findings: 1. Review of the API PT documents for 2020, 2nd event for Hematology, the laboratory failed to achieve an acceptable score for the subspecialty of White Blood Cell Differential. The facility scored 20% for the overall White Blood Cell Differential (WBC DIFF), It was noted on the review that the specimens were not tested as instructed in the API directions for testing the hematology samples. The instructions state that the samples were to be tested in the Quality Control mode for the Sysmex 430 Hematology analyzer. 2. Review of the API PT documents for 2020, 3rd event for Hematology, the laboratory failed to participate in the 3rd event by failing to submit results. There was no evaluation report for the 3rd event. It was noted on the evaluation report review that the laboratory manager was out on medical leave and the results were not submitted to API for evaluation. There was no self evaluation documents available at the time of the survey. 3. Review of the API PT documents for 2020, event 2 and 3 for Hematology, the laboratory failed to score successfully, 2 out of 3 events for the WBC DIFF. The laboratory received an overall score of 20% for the WBC DIFF for the 2nd , and 0% for the 3rd event. 4. Review of the API PT documents for 2020, event 1 and 3 for Specialty Hematology, sub-specialty ProTime (PT) the laboratory recieved a score of 60% on event 1 for PT, and received a score of 0% on event 3 for PT for failure to submit the results for evaluation. There was no self-evaluation documentation available at the time of the survey. 4. Interview with the Laboratory Manager, on August 5, 2021, at approximately 12:30pm, in the Manager's office, confirmed the above aforementioned statements.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents and staff interview, the Laboratory Director (LD) failed to ensure that an approved action plan was followed for the proficiency testing results that were found to be unacceptable or unsatisfactory for the 2020 PT documents for event 2 and 3 for the Specialty-Hematology, Sub-specialty White Blood Cell Differential (WBC DIFF). Findings: 1. Review of the APT PT documents for 2020, event 2 for WBC DIFF, the laboratory received a score of 20%. Any score less than 80%, is an unsatisfactory score. There was no corrective action for the less than 100% score received. Any score of less than 100%, should have corrective action documented. It was documented on the evaluation report that the samples were not tested following the instructions provided from API, for testing on a Sysmex 430 Hematology Analyzer. The instructions stated that the samples should be ran in the Quality Control (QC) mode. 2. Review of the API PT documents for 2020, event 3, the results were not submitted to API for evaluation. It was stated on the evaluation report that the results were not submitted due to the Laboratory Managers leave of absence. There was no documented self evaluation performed at the time of the survey. 3. Interview with the Laboratory Manager, on August 5, 2021, at approximately 2:30pm, in the Manager's office, confirmed the aforementioned statements.