

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0915549	<b>(X3) Date Survey Completed</b>  05/18/2020
<b>Name of Provider or Supplier</b>  East Alabama Family Practice	<b>Street Address, City, State</b>  2214 Gateway Drive Suite C, Opelika, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<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 a review of the CMS (Centers for Medicare and Medicaid) CASPER reports (#153 / #155), a review of API (American Proficiency Institute) proficiency testing evaluations, and a telephone interview with the testing personnel on May 18, 2020, the surveyor determined the laboratory failed to successfully participate in Hematology testing for two consecutive testing events, Event #3, 2019 and Event #1, 2020. The laboratory scored zero percent (0 %), due to the laboratory's "Failure to Participate," as determined by API. These zero scores resulted in an initial unsuccessful proficiency testing participation for the laboratory. The findings include: 1. A review of the CASPER reports revealed the laboratory scored zero percent (0 %)</p>

for Hematology testing for Event #3, 2019 and Event #1, 2020, two consecutive testing events. API scored the laboratory "Failure to Participate" for both events. 2. A review of the API proficiency testing records revealed zero percent scores for each analyte in Hematology, due to the laboratory's failure to participate, resulting in zero percent scores for the specialty. 3. During a telephone interview with the testing personnel on May 18, 2020, the surveyor inquired of the causes of the failures. The testing personnel explained the laboratory's results for Event #3 of 2019 were postmarked a day late (mailed a day prior to submission deadline); thus were not received by API in time for grading. API scored this event as a failure to participate. The testing personnel also stated the laboratory had not performed a self-evaluation of the results. For Event #1, 2020, the laboratory attempted to submit the results online; however the results were not received by API. According to the testing personnel, API was called and stated the submissions were affected by COVID-19 and transmission failures. The surveyor inquired of the testing personnel as to when the results were submitted, specimens received in the laboratory, and downtimes due to the COVID 19 emergency. The testing personnel stated the laboratory was closed on March 25 - 27. The specimens were received in the laboratory for testing on March 10th, but the laboratory staff was not informed. The submission deadline was March 27; but the laboratory did not test the specimens until March 31, after the submission deadline. According to the testing personnel, patient testing continued during this time, except for the dates the laboratory was closed (March 25, 26 and 27).

**D2127**

**HEMATOLOGY**  
CFR(s): 493.851(d)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:  
Based on a review of the CMS (Centers for Medicare and Medicaid) CASPER reports (#153 / #155), a review of API (American Proficiency Institute) proficiency testing evaluations, and a telephone interview with the testing personnel on May 18, 2020, the surveyor determined the laboratory failed two consecutive Hematology testing events, due to the laboratory's failure to submit the testing results prior to the submission deadlines. This affected Event #3, 2019 and Event #1, 2020. These failures lead to the laboratory's initial unsuccessful proficiency testing participation. The findings include: Refer to D2016.

**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 a review of the CMS (Centers for Medicare and Medicaid) CASPER reports

(#153 / #155), a review of API (American Proficiency Institute) proficiency testing evaluations, and a telephone interview with the testing personnel on May 18, 2020, the surveyor determined the laboratory failed two consecutive Hematology testing events, due to the laboratory's failure to submit the testing results prior to the submission deadlines. The Laboratory Director failed to ensure the laboratory staff submitted the testing results within the time-frames, established by the proficiency testing provider and necessary for grading. This affected Event #3, 2019 and Event #1, 2020. These failures lead to the laboratory's initial unsuccessful proficiency testing participation. The findings include: Refer to D2016 and D2127.