

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0939515	(X3) Date Survey Completed 07/08/2024
Name of Provider or Supplier Southeast Medical Group	Street Address, City, State 1612 Highway 78 East, Suite 100, Oxford, AL	
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
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 a review of the MLE (Medical Laboratory Evaluation) Proficiency Testing (PT) records and an interview with Administration Manager, the laboratory failed to ensure the Laboratory Director and Testing Personnel signed the attestation statements for four of six Hematology events reviewed in 2023 and 2024. The findings include: 1. A review of the MLE PT records revealed no signatures by the Laboratory Director or Testing Personnel on attestation statements for the following surveys: a) 2023 Hematology 1st Event. b) 2023 Hematology 2nd Event. c) 2024 Hematology 1st Event. d) 2024 Hematology 2nd Event. 2. During an interview on 7/8/2024, at 10:15 AM, the Administration Manager confirmed the above findings.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the MLE (Medical Laboratory Evaluation) PT (proficiency</p>

testing) records, corrective action documentation, and an interview with the AM (Administration Manager), the laboratory failed to submit PT results by the submission date required by the PT provider. This was noted for one of three PT events reviewed in 2023 The findings include: 1. A review of the MLE PT records revealed a score of 0% due to "Failure to participate" for 2023-Event M3 Hematology, with a submission deadline of 9/27/2023. 2. A review of the corrective action documentation revealed the Laboratory Director submitted the PT results on 11/1/2023. 3. During an interview on 7/8/2024 at 10:15 AM, the AM confirmed the PT results were submitted after the required deadline.

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 reviews of the MLE (Medical Laboratory Evaluation) PT (proficiency testing) records, corrective action documentation, and an interview with the AM (Administration Manager), the Laboratory Director failed to submit PT results by the submission date required by the PT provider. This was noted for one of three PT events reviewed in 2023 The findings include: Refer to D5215. .