Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0939515	06/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
Southeast Medical Group	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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 a review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records and an interview with the Practice Manager (PM), the laboratory failed to ensure the Laboratory Director (LD), or designee and the Testing Personnel (TP/Analyst) signed the attestation statements for three of the four PT Hematology events reviewed in 2025-2026. The findings include: 1. A review of the AAB-MLE PT records revealed the LD and TP/Analyst failed to sign the attestation statements for the following PT Hematology events A) 2025 M1, missing LD signature B) 2025 M2, missing LD and TP/Analyst signatures C) 2026 M1, missing LD and TP/Analyst signatures 2. PM confirmed the above findings during exit conference on 06-23-2026 at 1:45 PM.
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 a review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records and an interview with the Practice Manager (PM), the Laboratory Director (LD) failed to document review and

	evaluation of PT performance. The surveyor noted three out of three events in 2025 had no documentation of review by the LD. The findings include: 1. A review of the AAB-MLE PT records revealed no documentation of review on the returned evaluations by the LD, or designee, for the following events, 2025 Hematology, M1, M2 and M3 Events. 2. The PM confirmed the above findings during the exit conference on 06-23-2026 at 1:45 PM.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation during the lab tour, reviews of the Quality Control (QC) labels on the QC vials, the Temperature and Humidity logs, the Abbott Cell Dyn Emerald maintenance logs and QC records, the laboratory: 1. failed to record on the vials the open expiration date for the three levels of QC. 2. failed to ensure documentation of the daily room temperature during patient testing and refrigerator temperatures were within manufacturer's acceptable limits. 3. failed to perform maintenance of the analyzer as per manufacturer's requirement. 4. failed to retain documentation to monitor the accuracy and precision of test performance over time. Findings include: 1. Refer to D5415 2. Refer to D5413. 3. Refer to D5429. 4. Refer to D5441.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on reviews of the Temperatures and Humidity logs, the Abbott Cell-Dyn 18 Plus Control labels on the vials and an interview with the Practice Manager (PM), the laboratory failed to ensure the Room Temperature and Humidity where the Hematology analyzer was in operation and the Refrigerator Temperature where the Hematology Quality Control materials were stored were documented and were within manufacturer's acceptable limits on the day of patient testing. The Room Temperature and Humidity were missing documentation for 14 out of 26 testing days in December 2024 and the Refrigerator Temperature was outside the manufacturer's acceptable limits for 21 days out of 75 testing days from January-March 2026. The findings include: 1. A review of the Temperature and Humidity logs revealed no

	documentation of the Humidity, Room and Refrigerator temperatures for the following days in 2024; a) December 5-6 b) December10-11 c) December 13-14 d) December 19-21 e) December 23-27 2. A further review of the Temperature and Humidity logs revealed the Refrigerator Temperature was outside the manufacturer's acceptable limits for the following days: A) January 2026; 6 days, B) February 2026; 12 days, E) March 2026; 3 days. 3. A review of the Abbott Cell-Dyn 18 Plus Control vials revealed the manufacturer's required storage temperature of 2-10 degrees Celsius. 4. PM confirmed the above findings during exit conference on 06-23-2026 at 1:45 PM.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor's laboratory tour observation, review of manufacturer's package inserts and confirmed in an interview with the Practice Manager (PM), the laboratory failed to label Abbott Cell-Dyn 18 Plus Quality Control (QC) materials with revised expiration dates for 3 of the 3 QC vials upon opening. Findings Included: 1. During the laboratory tour of the facility with the PM on 6-23-2026 at 9:10 AM, the surveyor observed the following Abbott Cell-Dyn 18 Plus controls for the Cell-Dyn Emerald analyzer, stored in the laboratory refrigerator. Levels L, N and H Lot Number: L6089, N6089, H6089 Expiration Date: 07-17-2026 Open Expiration Date: Not written The surveyor inquired if the above QC vials were currently being used prior to patient testing. PM confirmed the QC vials were currently in use. 2. Review of manufacturer's package insert for the Abbott Cell-Dyn 18 Plus controls revealed the following instructions, "8 Consecutive-Day Open-Tube Stability. 3. PM confirmed the above findings during exit conference on 06-23-2026 at 1:45 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Abbott Cell- Dyn Emerald analyzer maintenance logs, the Abbott Cell- Dyn Emerald Operator's Manual and an interview with the Practice Manager (PM), the laboratory staff failed to document the semi-annual maintenance. The surveyor noted the first of the two semi-annual maintenances due in March 2026 was not performed and documented. The findings include: 1. A review of the Abbott Cell Dyn Emerald Maintenance logs revealed a place to document semi-annual maintenance for the analyzer. However, there was no documentation of performance in the past eight months after the analyzer was installed in September 2025. 2. A review of the Abbott Cell Dyn Emerald Operator's Manual revealed the following manufacturer's semi-annual maintenance specifications, on Section 9: Service and

	Maintenance, page 9-14, "Lubricating the Pistons, for optimal operation...". 3. PM confirmed the above findings during exit conference on 06-23-2026 at 1:45 PM.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on review of Abbott Cell Dyn Emerald Hematology Quality Control (QC) records and an interview with Practice Manager (PM), the laboratory failed to retain documentation to monitor the accuracy and precision of test performance over time. The surveyor noted three of the three Abbott Cell-Dyn 18 Plus QC levels had no Levey-Jennings charts available for review in May 2026. The findings include: 1. A review of Abbott Cell Dyn Emerald QC records revealed no evidence of the L-J charts or peer group data comparison was available for review from May 1-22, 2026. 2. PM confirmed the above findings during exit conference on 06-23-2026 at 1:45 PM.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on a review of the validation records for the Abbott Cell Dyn Emerald Hematology analyzer, the Abbott Cell Dyn Emerald operation manual and an interview with Practice Manager (PM), the Laboratory Director (LD) failed to review and approved the validation procedures to verify the manufacturer's performance specifications before patient testing effective September 2025. The findings include: 1. A review of the validation records for the Abbott Cell Dyn Emerald Hematology analyzer revealed no evidence of LD review and approval for the following studies when the analyzer went live for patient testing 09-30-2025. A) Precision B) Accuracy C) Linearity or Reportable Range D) Carry-Over E) Method Comparison 2. PM confirmed the above findings during exit conference on 06-23-2026 at 1:45 PM.