Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2319761	04/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
Regimen Pediatric Healthcare	600 Vestavia Parkway Suite 251, Vestavia Hills, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a lack of Proficiency Testing (PT) records, the laboratory failed to enroll in an approved PT program for 2026 after the effective testing date of November 2025. The findings include: 1. A review of PT records revealed the laboratory had no evidence of PT enrollment for the moderate complexity testing performed in the laboratory. 2. The LD confirmed the above findings during the exit conference on 04-01-2026 at 12:30 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 lack of the Policy and Procedure Manual, Personnel Records, Abbott Cell Dyn Emerald Validation Records, Quality Control (QC) Records and interview with the Laboratory Director, the laboratory: 1. failed to ensure documentation of the laboratory's Policies and Procedures was available for all personnel. 2. failed to perform Abbott Cell Dyn Emerald's required validation studies during implementation. 3. failed to implement a mechanism to monitor for shifts and trends. 4. failed to perform and document QC prior to patient testing. Findings include: 1. Refer to D5401. 2. Refer to D5421 3. Refer to D5441. 4. Refer to D5481.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a lack of Policy and Procedure Manual and an interview with Laboratory Director, the laboratory failed to have a written and approved policy and procedure for the moderate and waived tests performed in the laboratory effective November 2025. The findings include: 1. A review of the Procedure Manual revealed a lack of written procedures for Complete Blood Count and waived tests performed in the laboratory. 2. The LD confirmed the above findings during the exit conference on 04-01-2026 at 12:30 PM.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Abbott Cell Dyn Emerald install validation process and an interview with the Laboratory Director (LD), the laboratory failed to provide documentation of the validation studies. Surveyor noted there was no evidence of documentation from the effective testing date of Novemeber 2025. Findings included: 1. A review of the Abbott Cell Dyn Emerald Hematology analyzer validation process revealed no documentation of the following required verification studies. A) Accuracy B) Precision C) Reportable Range 2. The LD confirmed the above findings during the exit conference on 04-01-2026 at 12:30 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 Emerald Cell Dyn Hematology Quality Control (QC) records and an interview with Laboratory Director, the laboratory failed to have a procedure in place that monitors the accuracy and precision of test performance over time. The findings include: 1. A review of Emerald Cell Dyn QC records revealed no evidence daily QC performance with Levy Jennings' charts or peer group data comparison was available for review at the time of survey. 2. The LD confirmed the above findings during the exit conference on 04-01-2026 at 12:30 PM.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a lack of Hematology Quality Control (QC) records for the Abbott Cell Dyn Emerald analyzer, the patient testing history records and interview with the laboratory Director (LD), the laboratory failed to ensure at least two levels of QC were performed and acceptable, prior to analyzing patient specimens and reporting the results. The surveyor noted no QC was performed effective November 2025. The findings include: 1. A review of the Abbott Cell Dyn Emerald QC records revealed no documentation of the three levels of QC performed prior to patient testing. 2. A review of the patient history records revealed the following patients were tested and results reported without performing at least two levels of QC. A) Patient 3812 performed and reported on 01-22-2026. B) Patient 3852 performed and reported on 01-26-2026. 3. The LD confirmed the above findings during the exit conference on 04-01-2026 at 12:30 PM.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: Based on reviews of the Policy and Procedure Manual, Personnel Records, Sysmex

	XN-330 validation Records, and interviews with the Laboratory Director, the LD: 1) failed to ensure Abbott Cell Dyn Emerald validation procedures demonstrated performance characteristics specified by the manufacturer prior to use for patient testing; 2) failed to enroll in an HHS approved Proficiency Testing program. 3) failed to ensure policies and procedures were established to provide training and assessment of the testing personnel competency. 4) failed to establish and approved a written policy and procedure manual for all personnel responsible in the testing process. 5) failed to ensure education documentation was available for one of two Testing Personnel (TP) performing moderate-complexity patient testing. 6) failed to establish and maintain a Quality Assessment program to assure the quality of laboratory services provided. The findings include: 1. Refer to D6013. 2. Refer to D2000. 3. Refer to D6029. 4. Refer to D6031. 5. Refer to D6066. 6. Refer to D6093.
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 Laboratory Director (LD), the LD failed to perform and document analyzer validation procedures to verify the manufacturer's performance specifications before patient testing effective November 2025. The findings include: 1. A review of the validation records for the Abbott Cell Dyn Emerald Hematology analyzer revealed no evidence of performance based on lack of documentation for the following studies. A) Precision B) Accuracy C) Linearity or Reportable Range 2. LD confirmed the above findings during the exit conference on 04-01-2026 at 12:30 PM.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the Laboratory Director, the LD failed to ensure training was provided and documented for one of two Testing Personnel (TP) performing moderate complexity testing starting November 2025. The findings include: 1. A review of the personnel records revealed TP2 had no documentation of TRAINING to perform the moderate complexity testing in the laboratory. 2. The LD confirmed the above findings during the exit conference on 04-01-2026 at 12:30 PM.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel

	responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on a lack of Policy and Procedure Manual and an interview with Laboratory Director, the LD failed to ensure a written and approved policies and procedures for the moderate and waived tests performed in the laboratory, effective November 2025 were available for all personnel responsible for in the testing process. The findings include: 1. A review of the Procedure Manual revealed a lack of written and approved procedures for Complete Blood Count and waived tests performed in the laboratory since November 2025. 2. The LD confirmed the above findings during the exit conference on 04-01-2026 at 12:30 PM.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) (b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii)(E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory; (b)(6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the Laboratory Director, the LD failed to ensure Testing Personnel 2 (TP2) provided education documentation. This was noted for one of two testing personnel. The findings include: 1. A review of the personnel records revealed no education documentation for TP2 was available for review. 2. The surveyor requested the diploma or transcript of TP2 from the LD during the exit conference on 04-01-2026 at 12:30 PM and in an email sent on 04-02-2026 but was never provided.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on a review of policy and procedure manual and an interview with the Laboratory Director, the LD failed to establish and maintain a Quality Assessment (QA) program to assure the quality of laboratory services provided and identify or

	avoid failures in quality. The findings include: 1. A review of the policy and procedure manual revealed no written documentation describing how the laboratory will monitor and correct problems and prevent the recurrence of quality failures. 2. The LD confirmed the above findings during the exit conference on 04-01-2026 at 12: 30 PM.