Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0679478	01/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Island Coast Pediatrics Pa	13650 Metropolis Ave Ste 101, Fort Myers, FL	

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	An announced CLIA recertification survey was conducted at Island Coast Pediatrics PA from 01/07/2025 to 01/14/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400-Analytic Systems-493.1250 D6000-Moderate Complexity Laboratory Director-493.1403 D6033-Technical Consultant-Moderate Complexity-493.1409
D2128	HEMATOLOGY CFR(s): 493.851(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of College of American Pathologist (CAP) evaluation reports, review of Quality Assurance policies, and interview, the laboratory failed to take and document remedial action for unacceptable analyte scores for hematology testing for three of three events (1st event of 2023, 2nd event of 2024, and 3rd event of 2024). Findings include: 1. Review of College of American Pathologist (CAP) evaluation reports for 1st event of 2023 documented an unacceptable score (80%) for Mean Corpuscular Hemoglobin Concentrate (MCHC) for sample FH1-05 and Neutrophil /Granulocyte Absolute for sample FH1-05, 2nd event of 2024 documented an unacceptable score (80%) for Hematocrit (HCT) for sample FH1-10, and 3rd event of 2024 for Lymph for sample FH1-12 (80%). The CAP records did not include any documentation of remedial actions taken for the listed unacceptable scores. 2. The Quality Assurance Program policy approved by the Lab Director on 4/22/2022 and 4

	/24/2024 showed Proficiency Testing failures were to be investigated, remedial actions were to be taken, and any corrective actions were to be documented. 3. On 1 /07/2025 at 1:20 PM, Testing Person F confirmed remedial action was not taken or documented for the unacceptable analyte scores for the 1st event of 2023, 2nd event of 2024, and 3rd event of 2024.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a process to ensure all quality control documents and patient test printouts were maintained for two of two years (2023 and 2024). Findings include: 1. The "Emerald/CBC [Complete Blood Count] control" policy, last revised 04/22/2022 and signed by the Lab Director on 05/02/2024, revealed a printout of each control ran was to be maintained for two years. 2. Quality Control Report for June 2024 and November 2024 revealed: the high control was ran: two times on 06/13, 06/15, 06/17, 06/25, 06/28, 11/11, 11/14, 11/15, and 11/26; three times on 11/20 and 11/29, and four times on 06/24 and 11/09. The normal control was ran: two times on 06/13, 06/18, 11/08, 11/13 and 11/15, three times on 11/09, 11/11, 11/25 and 11/27, and five times on 11/20 and 11/21/2024. The low control was ran two times on 06/15, 06/24, 06/25, 06/27, 11/02, 11/11, 11/20, and 11/22/2024, and three times on 11/29. 3. The quality control printouts for June 2024 and November 2024 showed only one printout for the repeated quality controls listed above. 4. No manufacturer inserts were retained for any quality controls. 5. On 01/07 /2025 at 1:35 PM and 01/08/2025 at 12:15 PM, Testing Person F reported: patient test printouts for 2023 and 2024 were shredded and not retained, the lab only retained one printout for each level of control ran each day, the CELL-DYN Emerald analyzer retained some patient tests and quality controls ran but was unsure how many days of data the analyzer stored, and no manufacturer inserts were retained.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on review of of College of American Pathologist (CAP) evaluation report and interview, the laboratory failed to verify the accuracy of an ungraded proficiency testing score for one of one event (1st event of 2023) for Hematology. Findings include: 1. Review of College of American Pathologist (CAP) evaluation report for 1st event of 2023 documented exception code 20 for Mixed/Monocytes sample FH1-03. Exception code 20 legend revealed "Response was not formally graded ...Please

	see the participant summary for additional information." 2. On 1/07/2025 at 1:20 PM, Testing Person F confirmed the laboratory had not verified the accuracy for 1st event of 2023 for Mixed/Monocytes sample FH1-03.
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 record review and interview, the laboratory failed to have a procedure approved by the Lab Director for panic or alert values of hematology results (See D5403), failed to follow the CELL-DYN Emerald hematology analyzer manufacturer instructions for patient test results (See D5411), failed to perform background testing per the manufacturer instructions prior to running patient samples (See D5435), failed to follow quality control policies and procedures (See D5441), failed to take corrective action when quality control failed and patient samples were tested and reported (See D5783), failed to maintain a system that included the identity of the personnel who performed the hematology tests (See D5787), failed to retain patient test instrument printouts for the CELL-DYN Emerald Hematology analyzer (See D5789), and failed to follow written policies and procedures for an on-going mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (See D5791).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on record review and interview, the procedure manual failed to include a procedure approved by the Lab Director for panic or alert values of hematology results for two of two years (2023-2024) reviewed. Findings include: 1. Review of a policy for reporting critical test results revealed the ordering providers were to be notified of critical results. The policy did not state what would be a critical Hematology result. The policy provided was not documented as reviewed or approved by the Lab Director. 2. On 1/08/2025 at 11:04, Testing Person F confirmed the laboratory did not have a list of critical values for Hematology testing, and no critical result policy approved by the Lab Director was present for review.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview, the lab failed to follow the CELL-DYN Emerald hematology analyzer manufacturer instructions on four (#1-#4) of 5 patients test results (#1-#5) reviewed. Findings include: 1. The Instrument Alarms, Operational Alerts, and Measure and Data Flags instructions from the manufacturer instruction manual, dated April 2012, showed the operational alert, "QC [Quality Control] ALERT" indicates quality control failed. White blood cell differential flags "L2, L3" directions include retesting the specimen. 2. Test printouts for five patients showed Patient #1, #3 and #4's white blood cell differentials flagged with L2 or L3, and Patient #2 and #3 had the operational alert "QC ALERT". There were no additional sample printouts. 3. On 01/08/2025 at 12:15 PM, Testing Person F confirmed the four patient samples were reported without addressing the "QC ALERT" and/or the retesting of the specimens for the differential flags.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform background testing per the manufacturer instructions prior to running 14 patient samples for two (06/07/2024 and 06/24/2024) out of thirty days reviewed (06/01/2024 to 06/30/2024). Findings include: 1. The CELL-DYN Emerald Hematology Operator's Manual, dated April 2012, showed background counts for white blood cells, red blood cells, hemoglobin, and platelets must be within acceptable parameters prior to testing patient samples. 2. The instrument printouts for the CELL-DYN Emerald Hematology

	analyzer for June 2024 showed no background counts were present for 06/07/2024 and 06/24/2024. 3. On 01/07/2024 at 1:35 PM, Testing Person F confirmed the above. 4. Instrument History Reports for 06/07/2024 and 06/24/2024 showed 1 patient sample was tested on 06/07/2024, and 13 patient samples were tested on 06/24/2024. 5. On 01/08/2025 at 10:53 AM, Testing Person F confirmed patient samples were ran on 06/07/2024 and 06/24/2024.
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 record review and interview. the laboratory failed to: (A) ensure 18 patient samples were not ran when two levels of control were out of range for two (11/09 /2024 and 11/15/2024) of 60 days reviewed (June 2024 and November 2024), (B) perform precision testing when changing lot numbers for the CELL-DYN Emerald Hematology analyzer for two of two years reviewed (2023 and 2024), (C) follow the policy and procedures to document remedial action when running quality control samples for two of two months reviewed (June 2024 and November 2024), and (D) monitor over time the accuracy and precision of the test performance for two of two years reviewed (2023 and 2024). Findings include: (A) 1. The policy titled Emerald /CBC (complete blood count) Controls, with a revision date of 04/22/2022, showed an "Objective: To avoid errors with patient test results." Step #9 of the procedure showed two out of three controls must be within normal limits to perform patient testing. "If you have two controls out of Range or multiple out of range on one control, repeat testing". 2. Quality Control Reports for 06/2024 and 11/2024 (60 days) were reviewed. Data for 11/09/2024 showed the high and normal levels of control were out of range, and documented in bold on the Quality Control Reports. The high control values out of range were white blood cells (WBC)/8.8, percent lymphocytes (%LYM) /26.3, percent granulocytes (%GRAN)/68.6, granulocytes (GRAN)/6.0, red blood cells (RBC)/4.39, hemoglobin (HGB)/12.4, hematocrit (HCT)/39.0, mean corpuscular volume (MCV)/88.9, mean corpuscular hemoglobin (MCH)/28.2, and platelets (PLT) /234. The normal control value out of range was HGB/4.37. Data for 11/15/2024 showed the high and normal levels of control were out of range. The high control values that were out of range were WBC/8.8, percent lymphocytes/25.7, %GRAN/69. 3, GRAN/6.1, RBC/4.45, HGB/12.4, HCT/39.5, MCV/88.8, MCH/27.9, and PLT/222. The normal control value out of range was HGB/12.5. 3. History Reports printed on 01 /08/2025 showed 6 patient samples were tested on 11/09/2024. 12 patient samples were tested on 11/15/2024. 4. On 1/8/2025 at 12:15 PM, Testing Person F confirmed patient testing was performed and reported on 11/09/2024 and 11/15/2024, when two levels of control were out of range. (B) 1. The policy and procedure titled Controls and Calibrations, revised 04/22/2022 and last reviewed/signed by the Lab Director on 04/24/2024, showed prior to using a new lot number, precision testing must be

completed. 2. The most recent lot change data was reviewed which included quality control printouts dated 01/08/2025. Control lot numbers L4288, N4288, and H4288 were put into use on 10/25/2024. New control lot numbers L4344, N4344, and H4344 were put into use 12/31/2024. No precision testing data was available. 3. On 01/08 /2025 at 12:25 PM, Testing Person F confirmed the above and stated the lab did not perform precision testing when they changed lot numbers for 2023 and 2024. (C) 1. The policy titled Emerald/CBC Controls, with a revision date of 04/22/2022 showed a procedure to run each control once, document daily on the Computer Control Log, if two controls are out of range or there are multiple values out of range for one control repeat the test, results that continue to be out of range require the Supervisor notification immediately, information will be documented on the Control Log, and remedial action will be documented. 2. The monthly Control Logs for 06/2024 and 11 /2024 showed no documentation of any remedial action. 3. Quality Control Reports for 06/2024 and 11/2024 (60 days) were reviewed. June 2024: (a) Low Control, lot L4120, put into use on 06/07/2024 with an expiration date of 08/16/2024, (1) 06/07 /2024 ran at 1:33 PM. The control was out of range, PLT/34. (2) 06/15/2024 ran twice. Once at 8:52 AM and a second time at 8:53 AM. The second run had multiple values out of range. They included: WBC/9.1, %LYM/23.6, %GRAN/70.2, lymphocytes (LYM)/2.1, mid sized white blood cells (MID)/0.6, RBC/4.26, HGB/11. 9, HCT/38.3, MCV/89.9, MCH/27.9, and PLT/194. (3) 06/17/2024 ran at 7:34 AM, out of range value, MCV/84.2. (4) 06/20/2024 ran at 7:32 AM, out of range value, MCV/84.5. (5) 06/24/2024 ran twice, at 7:28 AM and 7:36 AM. Values out of range, respectively, MCV/85.1 and MCV/84.5. (6) 06/25/2024 ran twice, at 7:35 AM and 7: 49 AM. Values out of range, respectively, MCV/84.9 and MCV/84.2. (7) 06/27/2024 ran twice, at 7:21 AM and 7:25 AM. MCV/84.9 was out of range on first run. (8) 06 /29/2024 ran at 7:56 AM. MCV/84.5 was out of range. (b) Normal Control, lot N4120, put into use 06/07/2024 with an expiration date of 08/16/2024. (1) 06/13/2024 ran twice, at 7:38 AM and 7:41 AM. PLT/237 was out of range on first run. (2) 06/18 /2024 ran twice, at 7:36 AM and 7:39 AM. All values were within acceptable range. (c) High Control, lot H4120, put into use 06/07/2024 with an expiration date of 08/16 /2024. (1) 06/13/2024 ran twice, at 7:36 AM and 7:42 AM. HCT/48.7 was out of range on the first run. (2) 06/15/2024 ran twice, at 8:56 AM and 9:00 AM. Multiple controls were out of range on the first run. WBC/9.1, %LYM/22.2, %GRAN/70.7, GRAN/6.4, RBC/4.30, HGB/11.9, HCT/38.6, and PLT/198. (3) 06/17/2024 ran twice, at 7:38 AM and 7:42 AM. Multiple controls were out of range on the first run. WBC /24.0, GRAN/20.3, RBC/6.55, HGB/19.1, and HCT/59.9. (4) 06/24/2024 ran four times, at 7:32 AM, 7:35 AM, 7:37 AM, and 7:41 AM. The first three runs the MCV values were out of range. Respectively, MCV/93.8, MCV/93.5, and MCV/93.5. (5) 06 /25/2024 ran twice, at 7:43 AM and 7:47 AM. The first run had multiple values out of range. WBC/9.1, %LYM/23.4, %GRAN/69.2, GRAN/6.3, RBC/4.25, HGB/11.9, HCT /38.6, and PLT/194. (6) 06/28/2024 ran twice, at 7:42 AM and 7:44 AM. The second run had multiple values out of range. WBC/9.0, %LYM/24.3, %GRAN/69.0, GRAN /6.2, RBC/4.26, HGB/12.0, HCT/39.0, and PLT/200. November 2024: (a) Low Control, lot L4288, put into use 10/25/2024 with an expiration date of 01/31/2025. (1) 11/02/2024 ran twice, at 8:22 AM and 8:24 AM. The first run the analyzer was unable to measure any values. (2) 11/22/2024 ran twice, at 8:51 AM and 8:53 AM. The first run had multiple values out of range. WBC/3.1, percent mid sized white blood cells (% MID)/15.4, MID/0.5, and PLT/219. (3) 11/29/2024 ran three times, at 8:37 AM, 8:49 AM, and 8:51 AM. The first run had multiple values out of range. WBC/3.0, %GRAN /33.7, and LYM/1 .8. The second run the analyzer was unable to measure any values. (b) Normal Control, lot N4288, put into use 10/25/2024 with an expiration date of 01 /31/2025. (1) 11/01/2024 ran twice, at 8:03 AM and 8:09 AM. RBC/4.42 was out of range on the first run. (2) 11/04/2024 ran at 8:40 AM. RBC/4.37 was out of range. (3)

	11/05/2024 ran at 8:30 AM. RBC/4.37 was out of range. (4) 11/06/2024 ran twice, at 8:30 AM and 8:31 AM. The first run had two values out of range. RBC/4.39 and HGB /12.6. (5) 11/09/2024 ran three times, at 9:42 AM, 9:43 AM and 9:44 AM. The first run, RBC/4.45, out of range. The second run, RBC/4.42 and HGB/12.6, out of range. The third run, HGB/4.37, out of range. (6) 11/11/2024 ran three times, at 8:56 AM, 8: 58 AM and 10:43 AM. The first run RBC/4.42 and HGB/12.5 out of range. The third run, RBC/4.38, out of range. (7) 11/12/2024 ran at 8:45 AM. The HGB/12.6 was out of range. (8) 11/15/2024 ran twice, at 8:47 AM and 8:59 AM. The first run %MID/10. 8 and MID/1.0 were out of range. The second run, HGB/12.5 was out of range. (9) 11 /16/2024 ran at 9:39 AM. The RBC/4.37 was out of range. (10) 11/18/2024 ran at 8:29 AM. The RBC/4.43 was out of range. (11) 11/20/2024 ran five times, at 8:35 AM, 8: 37 AM, 8:40 AM, 8:44 AM, and 8:50 AM. The first and second runs the RBC/4.40 and HGB/12.6 were out of range. The third and fourth runs the RBC/4.37 and HGB /12.5 were out of range. (12) 11/21/2024 ran five times, at 8:39 AM, 8:46 AM, 8:51 AM, 9:01 AM, and 9:28 AM. The first run the RBC/4.41 was out of range. The second run RBC/4.40 and HGB/12.6 were out of range. The third run RBC/4.37 and HGB/12.6 were out of range. The fourth run RBC/4.38 and HGB/12.5 were out of range. The fifth run RBC/4.41 and HGB/12.5 were out of range. (13) 11/22/2024 ran at 8:54 AM. The HGB/12.5 was out of range. (14) 11/23/2024 ran at 9:13 AM. The HGB/12.5 was out of range. (15) 11/25/2024 ran three times at 8:35 AM, 8:40 AM, and 8:42 AM. The first run RBC/4.38 and HGB/12.5 were out of range. The second run RBC/4.43 and HGB/12.5 were out of range. The third run the HGB/12.6 was out of range. (16) 11/26/2024 ran at 8:50 AM. The RBC/4.39 and HGB/12.5 were out of range. (17) 11/27/2024 ran three times, at 8:33 AM, 8:34 AM, and 8:39 AM. The first run, the RBC/4.43 and HGB/12.4 were out of range. The second run, the RBC/4.45 and HGB/12.5 were out of range. (18) 11/29/2024 ran twice, at 8:35 AM and 8:30 AM. The analyzer was unable to measure any values on the first run. The second run the RBC/4.40 was out of range. (c) High Control, lot H4288, put into use 10/25/2024 with an expiration date of 01/31/2025 (1) 11/09/2024 ran four times, at 9:35 AM, 9:37 AM, 9:39 AM, and 9:40 AM. The first run RBC/5.60 was out of range. The second run RBC/5.56 and HCT/52.8 were out of range. The fourth run had multiple values out of range, WBC/8.8, %LYM/26.3, %GRAN/68.6, GRAN/6.0, RBC/4.39, HGB/12. 4, HCT/39.0, MCV/88.9, MCH/28.2, and PLT/234. (2) 11/14/2024 ran twice, at 8:47 AM and 8:49 AM. The second run WBC/0.1, RBC/0.01, HGB/0.0 and PLT/0 were out of range and the remaining values were not measured or calculated. (3) 11/15 /2024 ran twice, at 8:50 AM and 8:51 AM. The second run had multiple values out of range, WBC/8.8, %LYM/25.7, %GRAN/69.3, GRAN/6.1, RBC/4.45, HGB/12.4, HCT /39.5, MCV/88.8, MCH/27.9, and PLT/222 were out of range. (4) 11/20/2024 ran three times, at 8:36 AM, 8:41 AM, and 8:43 AM. The first run the HCT/52.8 was out of range. (5) 11/26/2024 ran twice, at 8:49 AM and 8:53 AM. The first run RBC/5.54 was out of range. (6) 11/20/2024 ran three times, at 8:42 AM, 8:44 AM, and 8:47 AM. The first and second runs the analyzer could not measure values. 4. On 01/07/2025 at 2:10 PM and 01/08/2025 at 12:15 PM, Testing Person F confirmed the quality control data and failure to follow their policy and procedure to document remedial actions. (D) 1. Review of records failed to reveal any monitoring of shifts and trends over time. 2. On 01/07/2025 at 1:35 PM, Testing Person F confirmed the lab does not monitor the control performance over time to identify shifts, trends, or ensure ongoing accuracy and precision of the quality controls.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's

	established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to take corrective action when quality control failed for two of two days (11/09/2024 and 11/15/2024) and 18 patient samples were tested and reported. Findings include: 1. The policy "Emerald /CBC Controls" with a revision date of 04/22/2022 was reviewed. The policy objective stated, "To avoid errors with patient test results". Two out of three controls must be within normal limits to perform patient testing ."If you have two controls out of Range or multiple out of range on one control, repeat testing". 2. Quality Control Reports for the month of November 2024 were reviewed. Data for 11/09/2024 showed the high and normal levels of control were out of range based on the bold print documented on the Quality Control Reports. The high control values out of range were white blood cells/8.8, percent lymphocytes/26.3, percent granulocytes/68.6, granulocytes/6.0, red blood cells/4.39, hemoglobin/12.4, hematocrit/39.0, mean corpuscular volume/88.9, mean corpuscular hemoglobin/28.2, and platelets/234. The normal control value out of range was hemoglobin/4.37. Data for 11/15/2024 indicated the high and normal levels of control were out of range. The high control values that were out of range were white blood cells/8.8, percent lymphocytes/25.7, percent granulocytes/69.3, granulocytes/6.1, red blood cells/4.45, hemoglobin/12.4, hematocrit/39.5, mean corpuscular volume/88.8, mean corpuscular hemoglobin/27.9, and platelets/222. The normal control value out of range was hemoglobin/12.5. 3. History Reports printed on 01/08/2025 showed 6 patient samples were tested on 11/09 /2024, and 12 patient samples were tested on 11/15/2024. 4. The computer control log for November 2024 showed no documentation of corrective action. 5. On 1/8/2025 at 12:15 PM, Testing Person F confirmed patient testing was performed and reported with no corrective action was taken.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a system that included the identity of the personnel who performed the hematology test(s) for two of two years (2023-2024). Findings include: 1. Review of instrument patient reports for Patient #1, #2, #3, #4, and #5 revealed no documentation of the Testing Personnel who had performed hematology testing. 2. Review of the Laboratory Personnel Report, Form CMS-209, signed by the Lab Director on 1/6/2025 showed 7 Testing Personnel performed moderate complexity hematology testing. 3. On 1/08/2025 at 11: 04 AM, Testing Personnel F confirmed the laboratory did not have a system to

	maintain the identity of the personnel who performed the hematology testing for 2023 and 2024.
D5789	TEST RECORDS CFR(s): 493.1283(b) (b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain patient test instrument printouts for the CELL-DYN Emerald Hematology analyzer for two of two years (2023 and 2024). Findings include: 1. There were no instrument printouts for 2023 and 2024 (See D3031). 2. On 01/07/2025 at 2:10 PM, Testing Person F confirmed the laboratory does not retain the patient test result printouts. They indicated the CELL-DYN Emerald analyzer retained some patient tests, but did not know how many days of data the analyzer stored.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems for two of two years reviewed (2023-2024). Findings include: 1. Review of the Quality Assurance Program, revised 04/24/2024 and signed by the Lab Director, showed the laboratory must follow written policies and procedures to monitor and evaluate the ongoing and overall quality of the total testing process to include Quality Control (QC), Patient Test Results, and Record Retention. The Quality Assurance (QA) Checklist was to be completed monthly, signed by the Lab Director/Designee (Technical Consultant), and the checklist record would be kept for two years. 2. On 01/08/2025 at 12:20 PM, Testing Personnel F stated there were no monthly QA checklist for 2023-2024 to review as required by the laboratory policy and there was no evidence the deficient practices identified during the survey in analytic testing had been identified by the laboratory through the written Quality Assurance Program for 2023-2024. 3. The procedure manual failed to include a procedure approved by Lab Director for panic or alert values of hematology results for 2023 and 2024 (See D5403). 4. The laboratory failed to follow the CELL-DYN Emerald hematology analyzer manufacturer instructions on 4 (#1-#4) of 5 (#1-#5) patients test results (See D5411). 5. The laboratory failed to perform background testing per the manufacturer instructions prior to running 14 patient samples for two (06/07/2024 and 06/24/2024) out of thirty days reviewed in June 2024 (See D5435). 6. The laboratory failed to follow its quality control policy and procedures (See D5441). 7. The laboratory failed to take corrective action when quality control failed for two of two days (11/09/2024 and 11/15/2024) and 18 patient samples were tested and reported (See D5783). 8. The laboratory failed to maintain a system that included the identity of the personnel who performed the

	hematology testing for 2023 and 2024 (see D5787). 9. The laboratory failed to have a system to ensure manually transcribed hematology test results were accurately entered into the patients' electronic health record for 2023 and 2024 (See D5801).
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a system in place to ensure manually transcribed hematology test results were accurately entered into patients' electronic health record for two of two years reviewed (2023 and 2024). Findings include: 1. The laboratory policy and procedures revealed no policy, procedure, or system to ensure patient hematology results, complete blood counts with automated differential (CBC diff), were accurately transcribed into the patient electronic health records. 2. There were no instrument printouts for 2023 and 2024 (See D3031). 3. On 01/07/2025 at 2:10 PM and 01/08/2025 at 12:15 PM, Testing Person F confirmed the lab staff manually transcribes CBC diff into the patient electronic health record and shreds the patient test result printout after manually entering the data. Testing Person F confirmed the laboratory has no means to verify the accuracy of the results transcribed.
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 record review and interview, the Laboratory Director failed to ensure the hematology testing system was developed and provided quality laboratory services for all aspects of moderate complexity test performance (See D6007), failed to ensure personnel performed the hematology testing as required for accurate and reliable results (See D6014), failed to ensure six of six proficiency testing events were reviewed by the appropriate staff to evaluate the laboratory's performance and identify any problems that required corrective action (See D6018), failed to ensure the quality control and quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred (See D6020), and failed to ensure the establishment and maintenance of acceptable levels of analytical performance for hematology testing (See D6023).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure the hematology testing system was developed and provided quality laboratory services for all aspects of test performance for two of two years reviewed (2023-2024). Findings include: 1. The laboratory failed to have a process to ensure all quality control documents and patient test printouts were maintained for 2023 and 2024 (See D2128). 2. The laboratory failed to monitor and evaluate the overall quality of the hematology analytic systems and correct identified problems for 2023 and 2024 (See D5400). 3. The laboratory failed to have in place a means to ensure manually transcribed hematology test results were accurately entered into the patients' electronic health record for 2023 and 2024 (See D5801).
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure personnel performed the hematology testing as required for accurate and reliable results for two of two years reviewed (2023-2024). Findings include: 1. Two of two Technical Consultants (TC A and B) failed to identify training needs and ensure three Testing Personnel (TP C, D, and H) of seven TP (C, D, E, F, G, H, and I) received training for the hematology testing performed. (See D6045) 2. Two of two Technical Consultants (TC A and B) failed to evaluate the competency of one testing personnel (TP H) of seven TP (C, D, E, F, G, H, and I) (See D6046).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure six of six proficiency testing events (1st, 2nd, and 3rd for 2023 and 2024) were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings include: 1. Review of delegation of duties by the Laboratory Director dated 4/25/2024 listed Technical Consultant B as a designee to sign CAP (College of American Pathologists) proficiency testing. 2. Review of the Job description for the Laboratory Delegate listed the responsibilities

	included ensuring reports were reviewed by appropriate staff and corrective actions plans were followed when results were unacceptable or unsatisfactory. 3. On 1/8/2025 at 10:30 AM, Testing Person F confirmed the Laboratory Delegate was Technical Consultant B. 3. Review of CAP 1st, 2nd, and 3rd hematology evaluation reports for 2023 and 2024 documented Testing Personnel H (TP H) reviewed the reports and not the Technical Consultant. Review of the Job Description for TP H showed they were not listed as a delegate for this responsibility. 4. The Laboratory Director failed to ensure the lab verified the accuracy of one of one event (1st event of 2023) assigned a proficiency testing score that did not reflect laboratory test performance for hematology, (See D5215) and for unacceptable analyte score for three of three events with unacceptable scores (1st event of 2023, 2nd event of 2024, and 3rd event of 2024), remedial action failed to be taken and documented for hematology testing (See D2128). 5. On 1/07/2025 at 1:20 PM, Testing Person F confirmed the 6 proficiency testing events were reviewed by TP H, and no problems were identified that required corrective action (See D2128 and D5215).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 record review and interview, the Laboratory Director failed to ensure the quality control and quality assessment programs were established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occurred for two of two years reviewed (2023 and 2024). Findings include: The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (See D5791).
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for hematology testing for two of two years reviewed (2023 and 2024). Findings include: 1. The lab failed to follow the CELL-DYN Emerald hematology analyzer manufacturer instructions on four (#1-#4) of 5 (#1-#5) patients test results (See D5411). 2. The laboratory failed to perform background testing per the manufacturer instructions prior to running 14 patient samples for two (06/07/2024 and 06/24/2024) out of thirty days reviewed for June 2024 (See D5435).
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, two of two Technical Consultants (TC-A and B) failed to ensure that patient test results were not reported until all corrective actions had been taken and the test system was functioning properly (See D6044), failed to identify training needs and ensure three Testing Personnel (TP C, D, and H) of seven TP (C-I) received training for the hematology testing performed (See D6045), failed to evaluate the competency of one TP (H) of seven TP (C-I) (See D6046), failed to monitor the recording and reporting of test results (See D6048), and failed to review intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records (See D6049).
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and interview, two of two Technical Consultants (TC-A and B) failed to ensure that patient test results were not reported until all corrective actions were taken and the test system was functioning properly for two of two years reviewed (2023 and 2024). Findings include: 1. The laboratory failed to perform background testing per the manufacturer instructions prior to running 14 patient samples for two (06/07/2024 and 06/24/2024) out of thirty days reviewed for June 2024 (See D5435). 2. The laboratory failed to follow its quality control policy and procedures (See D5441).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on record review and interview, two of two Technical Consultants (TC-A and B) failed to identify training needs and ensure three Testing Personnel (TP C, D, and H) of seven TP (C-I) received training for the hematology testing performed. Findings include: 1. Review of the Laboratory Personnel Report (CMS 209), signed by the Laboratory Director 1/6/2025, listed two TC (TC A and B) and seven TP (C-I). 2. Job description for Laboratory Delegate listed one of the responsibilities was to ensure personnel have been appropriately trained. 3. On 1/8/2025 at 10:30 AM, Testing Person F stated the Laboratory Delegate was for the position Technical Consultant 3. Review of CELL-DYN Emerald installation, documented a new model of hematology analyzer was put into use 9/23/2024. 4. Training documentation for the new model of analyzer put into use 9/23/2024. failed to include training documentation for TP- C,

	D, and H. 5. On 1/08/2025 at 11:24 AM, Testing Person F confirmed the lack of training for TP- C, D, and H on the new model of hematology analyzer put in use 9/23 /2024 prior to testing patient samples.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on record review and interview, two of two Technical Consultants (TC-A and B) failed to evaluate the competency of one testing personnel (TP-H) of seven TP (C-I) for two of two years (2023-2024). Findings include: 1. Review of the Laboratory Personnel Report (CMS 209) signed by the Laboratory Director 1/6/2025 listed two Technical Consultants (TC-A and B) and seven TP (C-I). 2. Job description for Laboratory Delegate listed one of the responsibilities was to ensure personnel have demonstrated competency. 3. On 1/8/2025 at 10:30 AM, Testing Person F stated the Laboratory Delegate was for the position Technical Consultant. 4. The Laboratory Competency Testing Program, revised and approved by Lab Director 04/25/2024, showed annual competency was to be performed by Laboratory Director or designee (Technical Consultant) annually. 5. Review of competency records for 2023 and 2024 showed no documentation for annual competency for TP-H. 6. On 1/08/2025 at 11:24 AM, Testing Person F, confirmed the lack of competency for TP-H for 2023 and 2024.
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) (b)(8)(ii) Monitoring the recording and reporting of test results; This STANDARD is not met as evidenced by: Based on record review and interview, two of two Technical Consultants (TC- A and B) failed to monitor the recording and reporting of test results for two of two years reviewed (2023 and 2024). Findings include: 1. The laboratory failed to retain patient test instrument printouts for the CELL-DYN Emerald Hematology analyzer for 2023 and 2024 (See D5789). 2. The laboratory failed to have a system to ensure manually transcribed hematology test results were accurately entered into the patients' electronic health record for 2023 and 2024 (See D5801).
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) (b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; This STANDARD is not met as evidenced by: Based on record review and interview, two of two Technical Consultants (TC-A and

	B) failed to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records for two of two years reviewed (2023 and 2024). Findings include: 1. For unacceptable analyte score for three of three events with unacceptable scores (1st event of 2023, 2nd event of 2024, and 3rd event of 2024) remedial action failed to be taken and documented for hematology testing (See D2128). 2. The lab failed to have a process to ensure all quality control documents and patient test printouts were maintained for 2023 and 2024 (See D3031). 3. The lab failed to follow the CELL-DYN Emerald hematology analyzer manufacturer instructions on four (#1-4) of 5 (#1-5) patients test results (See D5411). 4. The laboratory failed to perform background testing per the manufacturer instructions prior to running 14 patient samples for two (06/07/2024 and 06/24/2024) out of thirty days reviewed for June 2024 (See 5435). 5. The laboratory failed to follow its quality control policy and procedures for 2023 and 2024 (See D5441). 6. On 01/08/2025 at 1:00 PM, Testing Person F confirmed TC-A (who is also the Lab Director) or TC-B had reviewed the intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records for 2023 and 2024.