Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0920750	07/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
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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) 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 review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with Testing Personnel (CMS 209 TP #1) , the Laboratory Director (LD) failed to sign 1 of 3 API PT attestation statements for Hematology/Coagulation testing for 1 of 3 events in 2023 and 1 of 2 events in 2024. Findings Include: 1. On the day of the survey, 07/30/2024 at 11:30 am, the following API PT attestation statements reviewed were not signed by the LD in 2023 and 2024: - 2023 Hematology/Coagulation 2nd event - 2024 Hematology/Coagulation 2nd event 4. TP#1 confirmed the findings above on 07/30/2024 at 11:30 am.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and interview with testing personnel (CMS 209 TP#1), the laboratory failed to provide complete documentation for PT results of 1 of 3 API PT events in 2023. Findings Include: 1. On the day of survey, 07/30/2024, the laboratory failed to provide the following PT documentation: Hematology/Coagulation - Comparative Evaluation 2023 Hematology/Coagulation - Part 3 of 4, page 2 of 2. 2. TP #1 confirmed the findings above on 07/30/2024 at 11:35 am.
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. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records and interview with the Testing Personnel (CMS 209 TP#1), the laboratory failed to retain the quantitative QC records for Abbott Cell-Dyn Emerald analyzer for hematology test Complete Blood Count (CBC) from 11/16/2022 to 07/25/2024. Findings include: 1. TP #1 revealed in interview that CBC patient test results were resulted twice a week between 11/16 /2022 to day of survey. 2. On the day of survey, 07/30/2024, the laboratory failed to provide quantitative QC records for Abbott Cell-Dyn Emerald analyzer for hematology test CBC from 11/16/2022 to 07/25/2024. 3 The laboratory's annual test volume for CBC for 2023 was 12000. 4 TP #1 confirmed the above findings on 07/30 /2024 at 12:00 pm.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on lack of documentation, review of laboratory procedures, and interview with testing personnel (CMS 209 TP #1), the laboratory failed to establish and maintain a policy to ensure all complaints and problems reported to the laboratory are documented and investigated when needed from 11/16/2022 to the day of survey. Findings include: 1. On the day of survey, 07/30/2024 at 1:00 pm, the laboratory could not provide a policy to ensure all complaints and problems reported to the laboratory are documented and investigated as needed from 11/16/2022 to the 07/30 /2024. 2. TP #1 confirmed the finding above on 07/30/2024 at 1:00 pm.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 review of laboratory procedure manual, and interview with testing personnel (CMS 209 TP #1), the laboratory failed to provide a complete procedural manual for Abbott Cell-Dyn Emerald Hematology test Complete Blood Count (CBC) from 11/16 /2022 to the date of survey. Findings include: 1. On the day of survey, 07/30/2024 at 12:15 pm, review of the laboratory's CBC procedure revealed it did not include the following: - Corrective action to take when calibration or control results fail to meet the laboratory ' s criteria for acceptability. - Reference intervals (normal values). - Imminently life-threatening test results, or panic or alert values. - 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. 2. TP #1 confirmed the above findings on 07/30/2024 at 12:15 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of the laboratory's temperature records, and interview with testing personnel (CMS 209 TP #1), the laboratory failed to monitor and document room temperature, room humidity, and temperatures to ensure operating conditions were met for reliable test system operation and test result reporting of Abbott Cell-Dyn Emerald CBC test from 11/16/2022 to day of survey. Findings Include: 1. The manufacturer instructions for the Abbott Cell-Dyn Emerald states the following: "the following are environmental requirements: - indoor use only - altitude up to 6562 feet (2000 meter) - temperature range: 64 - 90 F (18 - 32 C) - Maximum relative humidity

	80% for temperatures up to 90 F (32 C)." 2. The laboratory's procedure manual states the following: "the following items are stored in the refrigerator, which has the temperature checked during office hours, with a range of 2 to 8 degrees C. Manufacturer has 2 to 10C, we narrowed it to 8C, in order to be proactive before the temperature should rise above the acceptable level.) a. CDS Bould Con-Diff Controls, tri level." 3. On the day of the survey, 07/30/2024 at 12:30 pm, review of the laboratory's temperature logs revealed the laboratory failed to monitor and document min/max temperature ranges for room temperatures and room humidity from 11/16 /2022 to the day of survey. 4. The laboratory failed to monitor and document min/max temperature ranges for the refrigerator used to store QC material from 11/16/2022 to day of survey: 5. TP #1 confirmed the findings above on 07/30/2024 at 12:30 pm.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interviews with testing personnel (CMS 209 TP #1), the laboratory failed to over time rotate control material testing between 1 of 2 testing personnel who performed Complete Blood Count test (CBC) on the Cell Dyn Emerald from 11/16/2022 to day of survey. Findings include: 1. Interview with TP #1 revealed that both TP #1 and TP #2 (CMS 209 TP #1 and TP #2) performed patient laboratory testing from 11/16/2022 to day of survey. 2. On the date of the survey, 07/30/2024 at 12:05 pm, review of the laboratory's QC records for the Cell Dyn Emerald revealed TP#2 (CMS 209 TP# 2) failed to perform QC for CBC testing from 11/16/2022 to 07/30/2024. It was revealed that only TP#1 performed QC. 3. TP #1 confirmed the findings above on 07/30/2024 at 12:05 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 observation of the laboratory, review of laboratory records, and interview with testing personnel (CMS 209 TP #1), the LD failed to provide overall management and direction of the laboratory in accordance with 493.1407 for a moderate complexity laboratory. Refer to D6018, D6020, and D6024.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the testing personnel (CMS-209 TP #1), the laboratory director (LD) failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and identify any problems that require corrective action for 1 of 3 PT events in 2022, 2 of 3 PT events in 2023, and 1 of 2 PT events in 2024. Findings include: 1. API states the following on the proficiency testing performance evaluation form: "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsibile for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. The laboratory's procedure On Site Assessment by Medical Director or Designee states the following "The Medical Director or the Designee (Dr. Michael Rachshtut), will sign off on all Proficiency testing being performed, reviewing the Survey results and addressing any unsatisfactory results on the surveys." 3. On the day of survey, 07 /30/2024 at 11:00 am, review of the laboratory's API PT records revealed the LD /designee failed to provide documentation of the corrective action taken when the laboratory's reported result failed to fall within the API expected result range for the following PT analytes/events: - 2022 Hematology/Coagulation - 3rd event: Hem-14 Platelet Count, reported result 57, API expected result 59-100. - 2023 Hematology /Coagulation - 1st event: Hem-04 Platelet Count, Hem-05 Red Cell Count, reported result 44, API expected result 53-89. - 2023 Hematology/Coagulation - 3rd event: Hem-15 Monocytes/Mids, reported result 1.0, expected result 4.1-6.2. 4. Review of the laboratory's API PT records revealed the LD/Designee failed to provide documentation of the corrective action taken when the laboratory received a non-graded score for the following PT analytes/events: - 2024 Hematology/Coagulation - 1st event: Hem-03 Platelet count, reported result 64, expected result 52-88. 3. The TP #1 confirmed the findings above on 07/30/2024 at 12:30 pm.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the Abbott Cell-Dyn Emerald quality records, review of the quality control procedure and interview with testing personnel (CMS 209 TP #1), the laboratory director (CMS 209 listed as LD, Clinical Consultant, and Technical Consultant) failed to ensure the performance of lot to lot quality control studies for every new lot of quality control as stated in the laboratory's quality control procedure

	from 11/16/2022 to the day of survey. Findings include: 1. The laboratory's CBC Controls - Assayed Control Hem 01 procedures states, "Verification of Control Ranges 1. When a new of QC arrives, a sticker will be placed on the QC "NEW LOT DO NOT USE." 2. The new lot and old lot are run at the same time for all three levels (low, normal, high) at least 5 times, over a 5 day period to validate the ranges, the QC runs will be printed out and put in the "New Lot evaluation" folder. 3. The new lot and old lot parallel runs for all levels will be evaluated by the Supervisor, prior to starting any new lot of QC. If the Parallel runs are acceptable, place a "Ready to use" sticker on the boxes of the new lot of QC." 2. On the date of the survey, 07/30/2024 at 12:25 pm, the laboratory failed to provide documentation of parallel lot to lot studies for each new lot of quality control for the Abbott Cell-Dyn Emerald from 11/16/2022 to 07/30/2024. 3. TP #1 confirmed the findings above on 07/30/2024 at 12:25 pm.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records and interview with testing personnel (CMS 209 TP #1), the laboratory failed to provide documentation of the corrective actions taken for QC results that failed to meet the laboratory's established acceptable criteria for 3 of 10 hematology analytes performed from 11/16 /2022 to the day of survey. Findings Included: 1. The laboratory failed to provide quantitative QC data from 11/16/2022 to 07/25/2024. 2. On the day of survey, 07/30 /2024 at 12:45 pm, review of the laboratory's QC records revealed that the following 1 of 2 days (07/25/2024 and 07/30/2024) of quantitative QC results reviewed for hematology testing performed on the Abbott Cell-Dyn Emerald failed to meet the laboratory's established acceptable criteria: - 07/25/2024: - Hemoglobin normal Level result 09:44 AM: 10.0, acceptable range: (10.1 - 11.5) - MCH low Level result 09:42 AM: 20.2, acceptable range: (21.3 - 26.3) - MCH low Level result 09:48 AM: 21.9, acceptable range: (21.3 - 26.3) - MCHC low Level result 09:42 AM: 25.7, acceptable range: (27.9 - 33.9) - MCHC low Level result 9:48 AM: 27.8, acceptable range: (27.9 - 33.9) 3. The laboratory failed to provide documentation of the corrective actions taken for QC performed on the Abbott Cell-Dyn Emerald that did not meet the laboratory's established acceptable criteria on 07/25/2024. 4. TP #1 confirmed the findings above on 07/30/2024 at 12:45 pm.