Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2214742	04/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hematology Oncology Associates Of North	3003 Hwy 95 Ste G73, Bullhead City, AZ	

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 lack of proficiency testing (PT) records from 2021, 2022 and 2023, review of patient records, and interview with the facility personnel, the laboratory failed to enroll in an approved proficiency testing program for the regulated analytes: white blood cell (WBC), red blood cell (RBC), hematocrit, hemoglobin, platelets, and WBC Differential in the speciality of hematology. Findings include: 1. The laboratory performed Complete Blood Count (CBC) testing from July 19, 2021 through November 1, 2023 on the Cell Dyn Emerald analyzer. 2. No documentation was presented for review during the survey conducted on February 21, 2024 to indicate the laboratory was enrolled in an approved PT program during 2021, 2022 and 2023 for the regulated analytes of white blood cell (WBC), red blood cell (RBC), hematocrit, hemoglobin, platelets, and WBC Differential. 3. The facility personnel interviewed on February 21, 2024 at 03:54 PM confirmed the laboratory failed to enroll in an approved PT program for the regulated analytes of white blood cell (WBC), red blood cell (RBC), hematocrit, hemoglobin, platelets, and WBC Differential in the speciality of hematology. 4. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.

D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the number and severity of deficiencies identified during the survey conducted on February 21, 2024, it was determined the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299 for patient testing performed in the specialty of Hematology. See D5203, D5209, D5291, D5311, D5391, D5401, D5403, D5413, D5415, D5421, D5425, D5431, D5439, D5445, D5791, D5801, D5805, and D5891 for findings.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of instrument printouts for the Cell Dyn Emerald analyzer, review of patient test reports and interview with the facility personnel, the laboratory failed to establish written policies and procedures to ensure positive identification of the patient's specimen from the time of collection through completion of testing and reporting of results. Findings include: 1. The laboratory performed Complete Blood Count (CBC) testing on the Cell Dyn Emerald analyzer in the specialty of hematology from July 19, 2021 through November 1, 2023. 2. The laboratory failed to provide evidence of an established written policy and procedure to ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results, for testing performed on the Cell Dyn Emerald analyzer. 3. Instrument printouts scanned into the patient's electronic health record (EHR) as the final test report for two out of two patients (ID# MO2829 and #562707663) failed to include positive patient identification of the sample. The instrument printouts contained only the name of the patient, and failed to include at least one other unique patient identifier. 4. The facility personnel interviewed on February 21, 2024 at 4:25 PM confirmed the laboratory failed to establish policies and procedures to ensure positive identification and optimum integrity of a patient's specimen throughout the entire testing process, for testing performed on the Cell Dyn Emerald analyzer. 5. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on lack of employee competency policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures to assess the competency of the Clinical Consultant (CC) and the Technical Consultant (TC). Findings include: 1. The CMS-209, Laboratory Personnel form submitted for review during the survey conducted on February 21, 2024 listed one Technical Consultant (TC-1) who provides technical oversight for testing performed in the specialty of hematology. 2. The CMS-209, Laboratory Personnel form submitted for review during the survey conducted on February 21, 2024 listed one Clinical Consultant (CC-1) who provides clinical consultation for testing performed in the specialty of hematology. 3. No documentation was presented for review to indicate the laboratory established policies and procedures to assess the competency of the Technical Consultant and Clinical Consultant. 4. The facility interviewed on February 21, 2024 at 12:35 PM confirmed the laboratory failed to establish policies and procedures to assess the competency of the TC and CC indicated above. 5. The laboratory performed 1,254 CBC tests from July 19, 2021 through November 1, 2023.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a lack of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. No QA documentation was provided for review during the survey conducted on February 21, 2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236. 2. The facility personnel interviewed on February 21, 2024 at 4:55 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on lack of written policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, specimen processing, specimen acceptability and rejection, and specimen referral. Findings include: 1. The laboratory performed Complete Blood Count (CBC) testing on the CellDyn Emerald analyzer from July 19, 2021 through November 1, 2023. 2. No documentation was presented for review during the survey conducted on February 21, 2024 to indicate the laboratory established policies and procedures for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, specimen processing, specimen acceptability and rejection, and specimen referral. 3. The facility personnel interviewed on February 21, 2024 at 4:01 PM confirmed the laboratory failed to provide evidence of the above referenced policies and procedures at the time of the survey. 4. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on a lack of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the preanalytic laboratory systems requirements specified at 493.1241 through 493.1242. Findings include: 1. No QA documentation was provided for review during the survey conducted on February 21, 2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the preanalytic laboratory system requirements specified at 493.1241 through 493.1242. 2. The facility personnel interviewed on February 21, 2024 at 4:55 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the preanalytic laboratory systems requirements.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 lack of written test procedures for review and interview with the facility personnel, the laboratory failed to have written test procedures for CBC testing

	performed on the Cell Dyn Emerald analyzer in the specialty of hematology. Findings include: 1. The laboratory performed Complete Blood Count (CBC) testing on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023. 2. No evidence of a written procedure manual for CBC tesing performed on the Cell Dyn Emerald analyzer was presented for review during the survey. 3. Facility personnel interviewed on February 21, 2024 at 04:03 PM confirmed the laboratory failed to provide evidence of a written procedure manual for CBC testing performed on the Cell Dyn Emerald analyzer. 4. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
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 lack of a written test procedure for CBC testing performed in the specialty of hematology and interview with the facility personnel, the laboratory failed to produce evidence of a procedure manual to include the information required under 493.1251. Findings include: 1. The laboratory performed Complete Blood Count (CBC) testing on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023. 2. The laboratory failed to provide evidence of a procedure manual for CBC testing performed on the Cell Dyn Emerald analyzer to include the following information: (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) Step-by-step performance of the procedure, including test calculations and interpretation of results. (3) Preparation of calibrators, controls, reagents, and other materials used in testing. (4) Calibration and calibration verification procedures. (5) The reportable range for test results for the test system as established or verified in 493.1253. (6) Control procedures. (7) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (8) Limitations in the test methodology, including interfering substances. (9) Reference intervals (normal values). (10) Imminently life-threatening test results, or panic or alert values. (11) Pertinent literature references. (12) 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. (13) Description of the course of action to take if a test system becomes inoperable. 3. The facility personnel interviewed on February 21, 2024 at 04:36 PM confirmed the laboratory failed to establish a written test procedure that includes the required information listed above for CBC testing. 4. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
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 lack of temperature and humidity documentation for review from 2021, 2022 and 2023 and interview with the facility personnel, the laboratory failed to monitor and document the room temperature, refrigerator and ambient humidity that is essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting for testing performed on the Cell Dyn Emerald analyzer. Findings include: 1. The laboratory began CBC testing on the Cell Dyn Emerald analyzer on July 19, 2021 in the specialty of Hematology. The laboratory performed testing between July 19, 2021 and November 1, 2023. The laboratory reported that 1,254 patient tests were performed during that timeframe. 2. The laboratory failed to monitor and document the humidity of the room where CBC testing occurred and testing reagents were stored from July 2021 through November 1, 2023. The manufacturer's ambient humidity requirement for the Cell Dyn Emerald analyzer is 0 - 80%. 3. The laboratory failed to monitor and document the room temperature where CBC testing occurred and testing reagents were stored from July 2021 through November 1, 2023. The manufacturer's operating room temperature requirement for the Cell Dyn Emerald analyzer is 64 - 90 F. 4. The laboratory failed to monitor and document the temperature of the refrigerator where the Cell Dyn Emerald control materials were stored from July 19, 2021 through November 1, 2023. The manufacturer's storage requirement for control materials is 2 - 10 C. 5. The facility personnel interviewed on February 21, 2024 at 04:49 PM confirmed that the laboratory failed to produce evidence of temperature and humidity documentation from July 19, 2021 through November 1, 2023 for each day of patient testing.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on direct inspection of three levels of Cell Dyn Emerald Quality Control (QC) vials during the survey conducted on February 21, 2024 and interview with the facility personnel, the laboratory failed to label the QC vials with the open expiration date. Findings include: 1. The laboratory performed Complete Blood Count (CBC) testing on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023. 2. Review of the test manufacturer's package insert indicates Cell Dyn QC material has an open expiration date of 8 days. 3. Direct inspection of the three levels of Cell Dyn QC control material (QC lot numbers: 4008) used by the laboratory at the time of the survey failed to include labeling of the open expiration date. 4. The facility personnel interviewed on February 21, 2024 at 5:06 PM confirmed the laboratory failed to document the open expiration date on the Cell Dyn QC vials that were used for patient testing. 5. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 lack of performance specification documentation for CBC testing performed on the Cell Dyn Emerald analyzer, review of patient test records and interview with facility personnel, the laboratory failed to verify the manufacturer's performance specifications for the Cell Dyn Emerald test system, including accuracy, precision, reportable range and reference range, prior to reporting patient test results. Findings include: 1. The laboratory performed Complete Blood Count (CBC) testing on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023. 2. No documentation was presented for review to indicate the laboratory obtained performance specifications comparable to those established by the manufacturer prior to reporting patient test results, including accuracy, precision, reportable range and reference range for the Cell Dyn Emerald hematology analyzer. 3. Facility personnel interviewed on February 21, 2024 at 03:50 PM confirmed the laboratory failed to provide evidence of the verification of performance specifiications for the Cell Dyn Emerald analyzer. 4. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by:

	Based on lack of documentation for review during the survey performed on February 21, 2024 and interview with the facility personnel, the laboratory failed to determine the Cell Dyn Emerald's test system's calibration procedures and control procedures. Findings include: 1. The laboratory began CBC testing on the Cell Dyn Emerald analyzer on July 19, 2021 in the specialty of hematology. 2. No evidence was presented for review to indicate the laboratory determined calibration procedures and control procedures for testing performed on the Cell Dyn Emerald analyzer. 3. The laboratory failed to verify the manufacturer's performance specifications for CBC testing performed on the Cell Dyn Emerald analyzer. See D5423 for findings. 4. The facility personnel interviewed on February 21, 2024 at 04:00 PM confirmed the laboratory failed to determine calibration procedures and control procedures for CBC testing performed on the Cell Dyn Emerald analyzer. 5. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of hematology test records and interview with the facility personnel, the laboratory failed to perform and document the background count on two out of four testing dates prior to patient testing on the Cell Dyn Emerald hematology analyzer. Findings include: 1. The laboratory performed Complete Blood Count (CBC) testing on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023. 2. The laboratory failed to provide documentation to indicate the background count was performed prior to patient testing for two out of four testing dates reviewed during the survey (2/13/23 and 5/09/22). 3. The number of patient tests performed on 2/13/23 and 5/9/22 could not be determined at the time of the survey. 4. The facility interviewed on February 21, 2024 at 4:39 PM confirmed the laboratory failed to have documentation of the background count performed each day prior to testing patients on the testing dates listed above. 5. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected

	by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration verification documentation from 2022 for the Cell Dyn Emerald hematology analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration verification procedures as required for testing performed in the specialty of hematology. Findings include: 1. The laboratory performed Complete Blood Count (CBC) testing on the CellDyn Emerald analyzer from July 19, 2021 through November 1, 2023. 2. No documentation was presented for review from 2022 to indicate the laboratory performed calibration verification on the Cell Dyn Emerald analyzer at least once every six months, including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results. 3. The facility personnel interviewed on February 21, 2024 at 5:03 PM confirmed the laboratory failed to perform and document calibration verification procedures every six months as required during 2022. 4. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation for CBC testing performed on the Cell Dyn Emerald analyzer, review of patient test reports and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialty of hematology. Findings include: 1. The laboratory performed Complete Blood Count (CBC) testing on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023. 2. The laboratory failed to determine control procedures for the Cell Dyn Emerald analyzer prior to patient testing. See D5425 for specific findings. 3. The manufacturer's quality control requirement for the analyzer indicated above instructs personnel to test 3 levels (Low, Normal, High) of control materials each day of patient testing. 4. The laboratory failed to provide evidence of QC documentation for two out of four testing dates reviewed during the survey. No QC documentation was provided for review for testing that occurred on 2/13/23 (test results for patient MO2829 were reported), and no QC documentation was provided for review for

	testing that occurred on 5/09/22 (test results for patient MO3150 were reported). 5. The number of patients tested on 2/13/23 and 5/09/22 could not be determined at the time of the survey. 6. The number of patient testing dates between July 19, 2021 through November 1, 2023 in which quality control testing was not performed, or was performed but the results were found to be unacceptable, could not be determined at the time of the survey. 7. The facility personnel interviewed on February 21, 2024 at 04:39 PM confirmed the laboratory failed to perform and document three levels of external control material each day of patient testing as indicated above. 8. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a lack of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the analytic laboratory systems requirements specified at 493.1251 through 493.1283. Findings include: 1. No QA documentation was provided for review during the survey conducted on February 21, 2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic laboratory system requirements specified at 493.1251 through 493.1283. 2. The facility personnel interviewed on February 21, 2024 at 4:55 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic laboratory systems requirements.
D5801	TEST REPORT CFR(s): 493.1291(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 lack of established policies and procedures, review of patient test reports and interview with the facility personnel, the laboratory failed to have a manual or electronic system 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. Findings include: 1. The

	laboratory performed Complete Blood Count (CBC) testing on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023. The laboratory utilizes an electronic health record (EHR) as the final report destination. 2. Two out of four patient test results (#MO8304 from 11/10/22 and MO03150 from 5/09/22) reviewed in the EHR during the survey revealed the CBC test results were manually transcribed into the patients' EHR by the facility personnel. 3. Two out of four patient test results (#562707663 from 8/01/23 and MO2829 from 2/13/23) reviewed in the EHR during the survey revealed the facility personnel scanned the instrument printouts (which contain the CBC test results) into the patients' EHR. 4. No documentation was presented for review during the survey conducted on February 21, 2024 to indicate the laboratory has an adequate manual or electronic system 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 the EHR, in a timely manner. 5. The laboratory failed to provide documentation of an established policy or procedure to indicate how the CBC test results are entered into the EHR, whether they are manually transcribed or electronically transmitted (scanned). 6. Facility personnel interviewed on February 21, 2024 at 04:08 PM confirmed the laboratory failed to have a system in place to ensure the accuracy of patient test results and other patient-specific data that are manually entered or electronically transmitted into the EHR. 7. The laboratory performed 1,254 patient tests from July 19, 2021 through November 1, 2023.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, four out of four test reports failed to include the correct facility name where the testing was performed. Findings include: 1. The laboratory began CBC testing under the specialty of hematology on 7/19/2021. 2. The facility name listed in the CLIA database for CLIA# 03D2214742 on the survey date of February 21, 2024, and listed on the CMS-116 form presented for review during the survey, was 'Hematology Oncology Associates of North Jersey'. The current certificate effective date for CLIA# 03D2214742 is 02/24/2021. The facility name has remained unchanged since the current certificate effective date. 3. Two out of four test reports reviewed during the survey failed to include the correct laboratory name where the testing was performed. The facility name listed on two of four test reports, MO2829 and #562707663, indicated 'Hamdy Mohtaseb MD' as the facility name. 4. Two out of four test reports reviewed during the survey failed to include the correct laboratory name where the testing was performed. The facility name listed on two of four test reports, MO8304 and MO3150, indicated 'Dr. Mohtaseb Cancer Center & Blood Disorders' as the

	facility name. 5. The facilty personnel interviewed on February 21, 2024 at 4:34 PM confirmed the name of the laboratory where the testing was performed was incorrect on the final test reports reviewed during the survey.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a lack of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the postanalytic laboratory systems requirements specified at 493.1291. Findings include: 1. No QA documentation was provided for review during the survey conducted on February 21, 2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the postanalytic laboratory system requirements specified at 493.1291. 2. The facility personnel interviewed on February 21, 2024 at 4:55 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the postanalytic laboratory systems requirements.
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 the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing - Laboratory Director was not met. The laboratory director failed to ensure that the laboratory was enrolled in an HHS approved proficiency testing program for the testing performed (see D6015); the laboratory director failed to ensure that quality control and quality assessment programs are established and maintained to identify failures in quality as they occur (see D6022); the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education required to qualify for moderate complexity testing personnel (see D6029); the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process (see D6031); and the laboratory director failed to specify, in writing, the duties and responsibilities of all laboratory personnel (see D6032).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program during 2021, 2022 and 2023 for testing of the regulated analytes, WBC, RBC, Hematocrit, Hemoglobin, Platelets and WBC Differential, under the specialty of hematology. See D2000 for findings.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on facility personnel interview on February 21, 2024, quality control record review and lack of quality assessment protocols, the laboratory director failed to ensure that quality control and quality assessment programs were established and maintained to identify failures in quality as they occur for testing performed in the specialty of hematology. See D5291, D5391, D5425, D5445, D5791 and D5891 for findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(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 lack of academic credentials for review for one out of one testing personnel and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education for the type and complexity of services offered. Findings include: 1. No evidence of academic credentials was presented for review for one out of one testing personnel who began patient testing on 7/19/2021. 2. The CMS-209, Laboratory Personnel Form presented for review during the survey listed only one testing personnel, as referenced above. 3. The facility personnel interviewed on February 21, 2024 at 3:52 PM

	confirmed the laboratory failed to provide a copy of the academic credentials to qualify one of one testing personnel for moderate complexity testing. 4. The laboratory performed Complete Blood Count (CBC) testing on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023. The laboratory reported that 1,254 patient tests were performed during that timeframe.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on lack of an approved procedure manual for review and interview with the facility personnel on February 21, 2024, the laboratory director failed to ensure that an approved procedure manual was available to all laboratory personnel responsible for testing in the specialty of hematology (See D5401 for findings).
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on lack of written documentation for review and interview with the facility personnel, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each person engaged in the performance of the preanalytic, analytic and postanalytic phases of testing. Findings include: 1. No written documentation was presented for review to indicate the laboratory director specified, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results 2. The facility personnel interviewed on February 21, 2024 at 04:05 PM confirmed that the laboratory failed to provide evidence of

	written documentation specifying the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing as indicated above.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY 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 the number and severity of the deficiencies cited herein, and lack of technical oversight, the Condition: Laboratories Performing Moderate Complexity Testing - Technical Consultant was not met as evidenced by: D6040 - failure to verify the laboratory's test procedures performed and failure to verify the performance characteristics, including the precision and accuracy of the Cell Dyn Emerald test system; D6041 - failure to enroll in an approved Proficiency Testing program for the testing of regulated analytes in the specialty of hematology; D6042 - failure to establish a quality control program appropriate for the testing performed and failure to establish the parameters for acceptable levels of analytic performance to ensure that these levels are maintained throughout the entire testing process; D6053 - failure to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens; and (D6054) annually thereafter.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on lack of test verification documentation for the Cell Dyn Emerald hematology analyzer put into use by the laboratory in July 2021, the technical consultant failed to perform and document the verification of test procedures performed and failed to verify the laboratory's test performance characteristics, including the precision and accuracy of each test and test system in the specialty of hematology. See D5421 for findings.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on lack of Proficiency Testing (PT) records for testing performed in the

	specialty of hematology and interview with the facility personnel on February 21, 2024, it was determined that the technical consultant failed to ensure that the laboratory was enrolled and participated in an HHS approved PT program during 2021, 2022 and 2023. See D2000 for findings.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on lack of established quality control policies and procedures, lack of quality control records from the testing dates of 5/09/2022 and 2/13/2023 in which patient testing was performed and reported, and interview with the facility personnel on February 21, 2024, the technical consultant failed to establish a quality control program appropriate for the testing performed and failed to establish the parameters for acceptable levels of analytic performance to ensure that these levels are maintained throughout the entire testing process. See D5445 for findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation for review from 2022 and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of one out of one testing personnel (TP-1) at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation from 2022 was presented for review for one out of one testing personnel (TP-1) who began testing patient specimens in July 2021. 2. The facility personnel interviewed on February 21, 2024 at 3:53 PM confirmed the technical consultant failed to perform and document a semiannual competency evaluation for the testing personnel indicated above during 2022. 3. TP-1 performed a reported 1,254 CBC tests on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation for review from 2022 and 2023 and interview with the facility personnel, the technical consultant failed to evaluate and document the performance at least annually of one out of one individual responsible for moderate complexity testing. Findings include: 1. No annual competency evaluation documentation from 2022 and 2023 was presented for review for one out of one testing personnel (TP-1). 2. The facility personnel interviewed on February 21, 2024 at 3:53 PM confirmed the technical consultant failed to perform and document an annual competency evaluation for the testing personnel indicated above during 2022 and 2023. 3. TP-1 performed a reported 1,254 CBC tests on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on lack of personnel records for review and interview with the facility personnel on February 21, 2024 at 3:52 PM, the laboratory failed to have academic credentials required to qualify one of one testing personnel for moderate complexity testing in the specialty of hematology (Refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on lack of personnel records for review and interview with the facility personnel, the laboratory failed to have documentation of academic credentials to qualify one of one testing personnel (TP-1) for moderate complexity testing. Findings: 1. The laboratory failed to have academic credentials to qualify one of one testing personnel (TP-1) for moderate compexity testing in the specialty of hematology 2. TP-1 performed a reported 1,254 patient tests on the Cell Dyn Emerald analyzer from July 19, 2021 through November 1, 2023. 3. Interview with the facility personnel on February 21, 2024 at 3:52 PM confirmed the laboratory failed to have the required documentation to qualify TP-1 for moderate complexity testing.