Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2050717	12/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hematology Oncology Solutions Of Tallahassee	1309 Thomaswood Dr, Tallahassee, 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 Hematology Oncology Solutions of Tallahassee on 12/11/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2000-Enrollment of Testing Samples-493.801 D5400-Analytic Systems-493.1250 D6000-Moderate Complexity Lab Director-493.1403
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 review of American Proficiency Institute (API) proficiency testing records, attestation statements, and interview with the Laboratory Director, the laboratory failed to test proficiency samples in the same manner as patients' specimens for two of two years (2023-2024) reviewed. Findings included: 1. The laboratory failed to report proficiency testing samples in the same manner as it reports patient specimens for three (1st and 2nd event of 2023 and 3rd event of 2024) of six (1st, 2nd, and 3rd events of 2023 and 2024 hematology samples. Refer to D2006. 2. The laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples for two (1st event of 2023 and 3rd event of 2024) of six (1st, 2nd, and 3rd events of 2023 an 2024) for 2023-2024. Refer to D2010. 3. The laboratory failed to maintain a copy of the attestation statement provided by the proficiency (PT

	program), signed by the Testing Person and the Laboratory Director for a minimum of two years in two (1st and 2nd event 2024) of six (1st, 2nd, and 3rd events for 2023 & 2024) PT events. Refer to D2015.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) records and interview, the laboratory failed to report proficiency testing samples for hematology in the same manner as it reports patient specimens tests for three (1st and 2nd event of 2023 and 3rd event of 2024) of six events (1st, 2nd, and 3rd events of 2023 and 2024). The findings included: 1. Review of the 1st event of 2023 sample #HSY-1 the laboratory reported 560 for platelet (PLT) count to the proficiency program-the printouts from the hematology instrument documented PLT count of 555 and 564. Sample #HSY-2 the laboratory reported 230 for PLT count to the proficiency program-the printouts from the hematology instrument documented PLT count of 218 and 245. The laboratory reported 6.5 for White Cell Count (WBC)- the printouts from the hematology instrument documented WBC 6.4 and 6.6: and for Red Cell Count (RBC) the laboratory reported 4.36-the printouts documented RBC of 4.32 and 4.40. Sample #HSY-3 the laboratory reported 11.3 for WBC- the printouts from the hematology instrument documented WBC 11.1 and 11.5: and for RBC the laboratory reported 5.34-the printouts documented RBC of 5.30 and 5.37. Sample #HSY-4 the laboratory reported 100 for PLT count to the proficiency program-the printouts from the hematology instrument documented PLT count of 99 and 103. Sample #HSY-5 the laboratory reported 468 for PLT count to the proficiency program-the printouts from the hematology instrument documented PLT count of 477 and 459. 2. Review of the 2nd event of 2023 sample #HSY-06 the laboratory reported 11.4 for WBC- the printouts from the hematology instrument documented WBC 11.3. Sample #HSY-07 the laboratory reported 90 for PLT- the printouts from the hematology instrument documented PLT 93. 3. Review of the 3rd event of 2024 sample #HSY-12 the laboratory reported 6.8 for WBC- the printouts from the hematology instrument documented WBC 6.9 and 6.6, and for RBC the laboratory reported 4.69-the printouts documented RBC of 4.70 and 4.68, and the laboratory reported 221 for PLT count to the proficiency program-the printouts from the hematology instrument documented PLT count of 227 and 215. Sample #HSY-13 for RBC the laboratory reported 3.68-the printouts documented RBC of 4.04 and 3.93, and the laboratory reported 346 for PLT count to the proficiency program-the printouts from the hematology instrument documented PLT count of 348 and 345. Sample #HSY-14 the laboratory reported 104 for PLT count to the proficiency program-the printouts from the hematology instrument documented PLT count of 100 and 107. Sample #HSY-15 the laboratory reported 15.3 for WBC- the printouts from the hematology instrument documented WBC 15.7 and 14.9, and for RBC) the laboratory reported 5.45-the printouts

	documented RBC of 5.50 and 5.39. 4. Interview on 12/06/24 at 1:30 PM the Laboratory Director confirmed the hematology proficiency results reported and the results from the instrument printouts did not match but could not explain the discrepancies. The Laboratory Director stated patient results would be reported as documented from one run of hematology testing not in the manner as the proficiency results for the 1st, 2nd event of 2023 and 3rd event of 2024.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) records and interview, the laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples for two (1st event of 2023 and 3rd event of 2024) of six (1st, 2nd, and 3rd events of 2023 an 2024) proficiency events reviewed. This is a repeat deficiency from the recertification survey dated 11/14/2022. Finding included: 1. API proficiency records for 2023-2024 revealed hematology API samples were tested multiple times. 2. Hematology 1st event of 2023 samples were run on 3/08/2023 as follows: #HSY1-4:43 PM and 4:55 PM #HSY2-4:44 PM and 4:57 PM #HSY3- 4:46 PM and 5:01 PM #HSY4-4:47 PM and 5:02 PM #HSY5-4:41 PM and 4:49 PM 3. Hematology 3rd event of 2024 samples were run on 11/08/2024 as follows: #HSY11-9:34 AM and 9:35 AM #HSY13- 4:46 PM and 5:01 PM #HSY14-4:47 PM and 5:02 PM #HSY15-4:41 PM and 4:49 PM 4. Review of the plan of correction (signed by the Laboratory Director 12/29/2022) from the 11/14/2022 recertification survey revealed the laboratory would "no longer run API samples 2x, we will only run once unless abnormal." The Laboratory Director was named as responsible for the correction.
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 American Proficiency Institute (API) proficiency testing records and interview, the laboratory failed to maintain a copy of the attestation statement provided by the proficiency (PT program), signed by the Testing person and the Laboratory Director for a minimum of two years for two (1st and 2nd event 2024) of six (1st, 2nd, and 3rd events for 2023 & 2024) PT events reviewed. This is a repeat deficiency from the recertification survey dated 11/14/2022. Findings included: 1. The

	API records for 2023-2024 did not include attestations signed by the Laboratory Director and Testing person for 1st and 2nd event 2024. 2. The Laboratory Director confirmed on 12/6/2024 at 11:15 AM the API proficiency records did not include the attestations signed by the Laboratory Director and Testing person for 1st and 2nd event 2024. 3. Review of the plan of correction (signed by the Laboratory Director on 12/29/2022) from the 11/14/2022 recertification survey revealed that the Laboratory Director would be responsible to correct the deficiency and that "we will make sure all pages are signed and we check behind each time a test is performed."
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, observation, and interview it was determined the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems for two of two years (2023-2024) reviewed. Findings included: The laboratory failed to accurately monitor one of two refrigerators for two of two years (2023 and 2024). Refer to D5413. The laboratory failed have an analytic systems quality assessment (QA) to review of the effectiveness of corrective actions taken to resolve prevent recurrence of problems for two of two years (2023 and 2024). Refer to D5793.
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 record review, observation, and interview the laboratory failed to accurately monitor one of two refrigerators for two of two years (2023 and 2024). This is a repeat deficiency from the recertification survey dated 11/14/2022. Findings included: 1. On 12/06/2024 at 12:30 PM. The "chemo room" refrigerator thermometer, where the Boule Con-Diff Tri-Level hematology controls were stored, was observed to be broken. The manufacturer storage requirements for the Boule Con-Diff Tri-Level hematology controls (QC) was listed as 2-8 degrees Celsius (C). 2. Records for the "chemo room refrigerator" sheets documented the acceptable fridge range as 20-25 degrees Fahrenheit. 20-25 degrees Fahrenheit converts to (-6.6 to -3.8 C) which is not within acceptable range per manufacturer. 3. The Lab Director at 12:45 pm on 12/06

	/2024 confirmed the thermometer was broken and did not know how long the thermometer had been broken and could not verbalize that 2-8 degrees Celsius equals 35.6-46.4 degrees Fahrenheit. 4. Review of the plan of correction (signed by the Laboratory Director 12/29/2022) from the 11/14/2022 recertification survey revealed "We will add a temp range for the room, fridge, and humidity. Each month the daily logs will be {signed} by the medical director to ensure the forms are correctly filled out." The Laboratory Director is listed as the person responsible for the correction.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, observation, and interview the laboratory failed have an analytic systems quality assessment (QA) to review of the effectiveness of corrective actions taken to resolve and prevent recurrence of problems for two of two years (2023 and 2024) reviewed. Findings included: 1. The laboratory failed to accurately monitor two of two refrigerators for two of two years (2023 and 2024). Refer to D5413. This is a repeat deficient practice from the recertification survey dated 11/14 /2022 with an accepted of Correction on 1/04/2023. 2. The laboratory Monthly Quality Assurance Checklists for 2023 and 2024 did not indicate the laboratory's QA process had effectively reviewed corrective actions to ensure recurrence of deficient practices cited during recertification survey dated 11/14/2022. 3. The Lab Director on 12/06/2024 at 1:30 PM verified the laboratory had previously been cited for failure to monitor temperatures in the "Chemo" room refrigerator appropriately and with the thermometer broke continued to not be monitored appropriately.
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, observations, and interviews the Lab Director failed to provides overall management and direction of the laboratory for two of two years (2023-2024). Refer to D6004.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory

	director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review, observations, and interviews the Lab Director failed to provides overall management and direction of the laboratory for two of two years (2023-2024). Findings included: The Lab Director failed to ensure the laboratory failed to test proficiency samples in the same manner as patients' specimens for two of two years (2023-2024). Refer to D2000. The Lab Director failed to ensure monitoring and evaluate the overall quality of the analytic systems and correct identified problems for two of two years (2023-2024). Refer to D5400.