Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2050717	(X3) Date Survey Completed 11/14/2022
Name of Provider or Supplier Hematology Oncology Solutions Of Tallahassee	**Street Address, City, State** 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	A recertification survey was conducted on November 4, 2022 continuing to November 14, 2022 to gather additional documentation and information. Hematology Oncology Solutions of Tallahassee, clinical laboratory was not in compliance with 42 CFR 493, Requirements for Laboratories.
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 record review and interview, the laboratory failed to test proficiency test samples the same number of times it tests patient samples for 4 of 4 testing events reviewed for 2021 and 2022. Findings include: Review of the laboratory's proficiency testing records with American Proficiency Institute on November 4, 2022 at 10:00 a. m., revealed hematology proficiency samples were tested multiple times. For the Hematology Testing Event #1 2021, samples were run on March 25, 2021 as follows: #HSY 1 - 8:22 a.m. and 3:38 p.m. #HSY 2 - 8:24 a.m. and 3:40 p.m. #HSY 3 - 8:25 a. m. and 3:42 p.m. #HSY 4 - 8:27 a.m. and 3:44 p.m. #HSY 5 - 8:30 a.m. and 3:46 p.m. For the Hematology Testing Event #3 2021, samples were run on November 18, 2021 as follows: #HSY 11 - 10:11 a.m. and 10:12 a.m. and on November 23, 2021 at 8:56 a. m. #HSY 12 - 10:05 a.m. and 10:06 a.m. #HSY 13 - 10:14 a.m. and 10:15 a.m. #HSY 14 - 10:16 a.m. and 10:17 a.m. #HSY 15 - 10:02 a.m. and 10:04 a.m. For the Hematology Testing Event #1 2022, samples were run on March 9, 2022 as follows: #HSY 1 - 1:24 p.m. and 1:42 p.m. #HSY 2 - 1:43 p.m. and 1:49 p.m. #HSY 3 - 1:27 p. m. and 1:44 p.m. #HSY 4 - 1:28 p.m. and 1:46 p.m. #HSY 5 - 1:29 p.m. and 1:47 p.m. For the Hematology Testing Event #2 2022, samples were run on July 13, 2022 as follows: #HSY 6 - 12:51 p.m. and 1:06 p.m. #HSY 7 - 12:53 p.m. and 1:08 p.m. #HSY 8 - 12:54 p.m. and 1:10 p.m. #HSY 9 - 12:55 p.m. and 1:11 p.m. #HSY 10 - 1:

	05 p.m. and 1:12 p.m. The tests performed were White Blood Cell Count, Red Blood Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean Corpuscular Volume, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Red Cell Distribution Width, Mean Platelet Volume, Neutrophils/Granulocytes, Lymphocytes, and Monocytes/Mixed. An interview on November 4, 2022, at 11:20 a. m., the Laboratory Director confirmed proficiency samples were tested multiple times and they only rerun abnormal patient samples.
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 record review and interview, the laboratory failed to have the laboratory director and testing personnel sign and date the attestation sheet for 3 of 4 proficiency testing events in 2021 and 2022. Findings include: Review of American Proficiency Institute proficiency testing records November 4, 2022 at 10:00 a.m., revealed the laboratory director and testing personnel had not signed and dated the attestation sheet for the 2nd hematology testing event of 2021, the 1st testing event of 2022, and the testing personnel had not signed and dated the attestation sheet for the 3rd testing event of 2021. Interview with the Laboratory Director November 4, 2022 at 11:20 a. m., confirmed the attestation sheets had not been signed and dated.
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 record review and interview, the laboratory failed to establish and follow a written quality assessment policy. Findings include: Record review on November 4, 2022 at 9:30 a.m., revealed no documentation of a written quality assessment policy for the laboratory. Interview with the Laboratory Director on November 4, 2022 at 9: 30 a.m., confirmed the laboratory did not have a written quality assessment policy.
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 record review and staff interview, the laboratory failed to have a procedure manual. Findings include: At the time of survey on November 4, 2022, at 11:15 a.m., the laboratory was unable to show documentation of a procedure manual reviewed and signed by the Laboratory Director. Interview with the Laboratory Director on November 4, 2022, at 11:20 a.m., confirmed no procedure manual had been written.
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 and staff interview, the laboratory failed to document acceptable reference ranges for laboratory room and refrigerator temperature and "Chemo Room" and refrigerator temperatures where quality control and patient specimens are stored. Findings include: Review of temperature logs on November 4, 2022 at 10:15 a.m., revealed acceptable temperature ranges missing from laboratory room and refrigerator log for October 2022, and "Chemo Room" and refrigerator for July 2022. Interview with the office manager on November 4, 2022 at 10:30 a.m., confirmed the acceptable temperature ranges were missing from log sheets for October and July of 2022.