Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0978965	09/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Grace Hematology & Oncology	3159 Hendersonville Rd, Fletcher, NC	

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
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 2018 and 2019 Temperature and humidity logs, the absence of documentation, and interview with TP (Testing Personnel) 9/11/19, the laboratory failed to monitor and document the conditions required for accurate and reliable test performance. Findings: Random review of 2018 and 2019 temperature and humdity logs revealed refrigerator temperature, room temperature, and room humidity were not documented for the following: 1. November 2018 - 5 of 19 days with no refrigerator temperature documentation (11/26-11/30); 2. March 2019 - 4 of 20 days with no room temperature documentation (3/11-3/15); 3. April 2019 - 2 of 21 days with no refrigerator, room temperature, or room humidity documentation (4/8-4 /9); 4. May 2019 - 4 of 23 days with no refrigerator temperature documentation (5/27-5/30); During interview at approximately 2:15pm, TP #1 confirmed the missing temperature documentation was overlooked.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of 2019 hematology quality control (QC) records and observation, the laboratory failed to discard control materials and supplies that had exceeded the expiration date. Findings: 1.) Random review of 2019 hematology QC revealed the Coulter 4C-ES cell control lot numbers 068800, 078800, and 088800 expired on 3/25 /19, and was in use 3/26/19, 3/27/19, 3/28/19, 3/29/19, and 4/1/19. 65 patients were tested between 3/26/19-4/1/19. During tour of laboratory at approximately 2pm, the surveyor observed the following expired supplies, that were available for use: 2.) a. Hemocue hb 201 microcuvettes, lot #1704201, expired 7/9/18. b. Royal Blue BD Vacutainer Trace Element Serum blood tube, lot #7279890, expired 10/31/18. c. Royal Blue BD Vacutainer Trace Elements K2EDTA blood tube, lot #8011601, expired 1/31/19. d. Pink BD Vacutainer K2EDTA blood tube, lot #7305676, expired 4 /30/19.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of 2017 API (American Proficiency Institute) PT (proficiency testing) records and review of the laboratory's PT policy 9/11/19, the LD(Laboratory director) failed to ensure corrective action plan was followed when the laboratory received unacceptable PT results. Findings: The Laboratory's "Proficiency Testing" Policy states, "For any unacceptable score....We will rerun the proficiencies and/or take action to identify and correct the problem. We will also fill out the PT failure form and retain the record for 2 years." Review of 2017 API 3rd event revealed the LD reviewed the graded results on 8/21/18. There was no corrective action documented for the 80% score for HCT(Hematocrit).