Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0675384	04/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Capital Health Hematology/Oncology	40 Fuld Street Suite 404, Trenton, NJ	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all Testing Personnel (TP) who performed Hematology tests participated in the American Academy of Family Practioner's (AAFP) PT events in the calendar years 2019 and 2020. The finding includes: 1. A review of all PT events revealed that only one out of two TP performed PT all events in 2019 and 2020. 2. The TP #1 listed on CMS form 209 confirmed on 4/21/21 at 10:30 am that PT events were not rotated between TP.
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 surveyor review of Proficiency Testing (PT) records and interview with the

	Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Hematology testing performed with the American Academy of Family Physicians (AAFP) in the calendar year 2019, events A and C - 2020 and A 2021. The TP #1 listed on CMS form 209 confirmed on 4/21/21 at 11:00 am that the PT results were not reviewed. This was sited on previous survey completed on 1/31/19.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the surveyor review of Quality Assessment (QA) policy and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the QA program was maintained and the Plan of Correction (POC) was followed from 8/22/16 to the date of survey. The findings include: 1. Plan of Correction (POC) stated "QA is performed yearly and evaluated and signed by the LD" but there was no documented evidence POC was followed. 2. There was no documented review of the Levy Jennings Charts, Quality Control, Maintenance or Temperature records. 3. The TP #1 listed on CMS form 209 confirmed on 4/21/21 at 11:50 am that the laboratory did not maintain the QA program. Note: This deficiency was cited on two previous surveys preformed 8/22/16 and 1/31/19.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with the required elements for Hematology tests performed on the Medonic M series analyzer from 1/31/19 to the date of the survey.

	The TP #1 listed on CMS form 209 confirmed on 4/21/21 at 10:40 am that a CA procedure was not established. This was sited on previous survey completed on 1/31 /19.