Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0720027	06/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Capitol Medical Enterprises Llc Dba Capital Med Gr	8401 Connecticut Ave Ste 201, Chevy Chase, MD	

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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory patient logs, interview with the laboratory manager, and the technical consultant (TC), the laboratory failed to validate procedures to perfrom high complexity bacteriology testing. Findings: 1. Patient A, one of the 8 patients that had a throat culture performed on June 12, 2019 with the Strep select agar and the BD Taxo A disc. Patient A culture result was documented as "pos+" in the "pos/neg/MD" section on the "throat culture worksheet" log. 2. The lab manager stated that patient A had a negative rapid strep on 6/12/19 and the physician ordered a throat culture on 6/12/19. The culture was read at 48 hours and the result was positive. 3. The "throat culture worksheet" log had a line with an arrow at the end drawn down the "pos/neg/MD" section with "neg" for all 8 patients including patient A tested for throat cultures on 6/12/19. 4. On June 14, 2019 patient A had a rapid strep performed and the result was "pos" on the "consult diagnostic strep" log. Patient A was not seen on 6/14/19 even though patient A appeared on the "consult diagnostic strep" log. 5. The lab manager stated that the physician ordered a rapid strep for patient A after the throat culture reading which was documented as "positive" on 6/12/19. 6. The lab

	manager stated that the physician ordered the medical assistant to use a colony from the culture plate that was ran on 6/12/19 to run the rapid strep test on 6/14/19. 7. The laboratory modified the rapid strep test to perform high complexity testing with a colony from a throat culture with the Strep Select Agar plate and the BD Taxo A disc. 8. The rapid strep procedure states to use a swab that has been rubbed in the back of the patient's throat. 9. The laboratory did not follow the written procedure for incubating throat cultures with the Strep Select Agar plate and the BD Taxo A disc for the 18-24 hours and reading. 10. The TC confirmed that the physician performed high complexity testing with the rapid strep test kit and that the physician failed to follow the written procedure for performing throat cultures.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of hematology quality controls (QC) and interview with the technical consultant (TC), the TC failed to identify the training needs of testing persons performing hematology QC. Findings: 1. On March 21, 2019, the TP ran the hematology normal QC twice and the low QC once. The high QC was not ran. 2. The hematology procedure states to run a low, normal, and high level of QC each day of patient testing. 3. The TC stated that she was not aware that TP did not run all three separate levels of hematology QC. 4. The TC did not document the error in the TC notes for March 2019 nor was the TP advised of the error.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of bacteriology quality control (QC) results, review of the written procedure manual, and interview with the technical consultant (TC), the testing personnel (TP) failed to follow the written procedures for performing throat culture QC. Findings: 1. The TP did not follow the written QC procedure for performing throat cultures with the Taxo A disc. 2. The TP were incubating the "negative" throat culture QC plated with the Taxo A Disc up to 48 hours and reading. Once the plate was read the TP did not document the date read on the QC log and the plate was discarded. 3. The Throat culture written procedure for performing the negative throat culture QC states to plate the Group B Strep just as a patient specimen, add the Taxo A disc, incubate for 18-24 hours and read. 4. The TC stated that she was not aware that the TP were not following the procedure for performing throat culture QC.