

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0720027	(X3) Date Survey Completed 01/07/2022
Name of Provider or Supplier Capitol Medical Enterprises Llc DbA Capital Med Gr	Street Address, City, State 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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the hematology laboratory did not take and document corrective actions when quality control results for testing performed on the analyzer (performing patient complete blood count) did not meet the laboratory's criteria for acceptability. Findings: 1. The laboratory written procedure states that corrective actions must be taken when two of the three quality control reagents (level 1, level 2 and level 3) tested each day of patient testing fail to fall within the expected range and patient results may not be reported; 2. On October 16, 2021 the platelet count for both level 1 and 2 of the hematology control failed to meet the laboratories criteria for acceptability and corrective actions were not taken prior to patient testing; 3. On September 1, 2021 the red blood cell count for both level 2 and 3 of the hematology control failed to meet the laboratory's criteria for acceptability and corrective actions were not taken prior to patient testing; 4. On June 2, 2021 the red blood cell count for both level 2 and 3 of the hematology control failed to meet the laboratory's criteria for acceptability and corrective actions were not taken prior to patient testing; 5. On April 1, 2021 the red blood cell count for both level 2 and 3 of the hematology control failed to meet the laboratories criteria for acceptability and corrective actions were not taken prior to patient testing; 6. On consecutive testing days 7/10/21 and 7/12/21 the red blood cell count for level 2 of the hematology</p>

control failed to meet the laboratories criteria for acceptability and corrective actions were not taken prior to patient testing. The laboratory must investigate and take corrective actions when an analyte for a control fails to fall within the expected range on consecutive days of testing; 7. This was confirmed during interview with laboratory staff on the afternoon of the day of the survey.

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 record review, the laboratory director failed to ensure the quality assurance plan identified hematology quality control failures for testing performed on the complete blood count analyzer and did not take corrective actions (such as retraining testing and technical consultant staff to recognize quality control failures and act as described in written procedures) to resolve the recurring quality control failures during year 2021. See D5783 for findings.