

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0720027	(X3) Date Survey Completed 09/21/2023
Name of Provider or Supplier Capitol Medical Enterprises Llc Db a 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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review, the laboratory did not meet the Code of Maryland requirements (COMAR) for the frequency of external quality control testing for testing performed on the Cepheid analyzers that includes SARS CoV-2, respiratory pathogens (FLU and RSV) and CG/NG testing. Findings: 1. The laboratory performs patient testing for SARS CoV- 2, RSV, FLU and CG/NG using two Cepheid analyzers. 2. The laboratory tests the positive and negative external (liquid) quality control every 30 days or when a new lot of reagent is introduced. 3. The test cartridge for the tests performed on the Cepheid meet the definition under COMAR 10.10.01.B (73) for Single-use test device for nonforensic testing. 4. COMAR 10.10.06.06 (Laboratories, Single Use Test Device) states (6) Quality Control Tests. (b) Qualitative Test System. A licensee shall ensure that quality control testing for a qualitative test system is performed and documented using known positive and negative control materials before patient testing: (i) On each lot of a single-use test device received in a shipment; (ii) At least weekly for each lot of a single-use test device used for patient testing (iii) After a single-use test device is exposed to an environment or condition that could affect the accuracy or reliability of test results; and (iv) Each day of use during test system validation. 4. The laboratory does not perform weekly external quality control checks as required by COMAR.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of competency check records for testing personnel and the technical consultant, the laboratory did not have competency records for 2022. Findings: 1. The laboratory director did not perform and document the technical consultants competency in 2022. 2. The technical consultant did not perform and document the testing personnel competency in 2022. 3. 2. This was confirmed with the technical consultant during interview on the morning of the survey.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of proficiency test records and interview, the laboratory did not document evaluation of influenza B proficiency test results returned by the proficiency test provider as not evaluated due to lack of participant consensus. Findings: 1. In the third proficiency test event of 2022, the proficiency test provider reported the laboratory's response to unknown sample #12 as not evaluated due to non consensus of participants, but the laboratory did not have documentation showing that the laboratory reviewed the result reported for Sample #12 with the given data that the proficiency test provider included in its evaluation. 2. This was confirmed with the technical consultant during interview on the afternoon of the survey.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	<p>This STANDARD is not met as evidenced by: Based on review of the laboratory written procedures and interview with the technical consultant, the written hematology procedure did not include normal values for the patient test results reported from the hematology analyzer. Findings: 1. The laboratory hematology analyzer performs patient testing for the white blood cell count, red blood cell count, hemoglobin level, platelet count and differential among other tests. The laboratory's written procedure did not include normal patient values for these tests. 2. This was confirmed with the technical consultant during interview on the morning of the survey.</p>
<p>D5409</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's written procedure and interview, the laboratory did not update the written procedure to retire procedures no longer in use. Findings: 1. The laboratory written procedure included instructions for bacterial throat cultures that are no longer performed by the laboratory, for example: The procedure for performing Group A strep cultures was included with the current test procedures, bullet #7 in the opening protocols has staff remove throat culture media from the refrigerator and at the bottom of the page the procedure instructs staff to perform quality control checks on culture media, even though bacterial cultures are no longer performed. 2. This was confirmed with the technical consultant during interview on the morning of the survey.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of preventive maintenance records and interview, the laboratory did not document preventive maintenance for the Cepheid as required by the manufacturer. Findings; 1. The Cepheid with serial number 838806 did not have weekly preventive maintenance documented during the first and second week of May 2022 and the first, second and third week of January 2022. 2. The Cepheid with serial number 11003347 did not have yearly preventive maintenance documented. 3. This was confirmed during interview with the technical consultant on the afternoon of the day of survey.</p>
<p>D5441</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures</p>

that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 A. Based on review of the printout of patient test results for CT/NG tests performed using the Cepheid Gene Expert and interview, the test records were incomplete and did not include quality control test results. Findings: 1. On December 30, 2022 record number ****877 did not have quality control test results reported (SAC SPC) for the CT/NG test. 2. The respiratory panel for the Cepheid Gene Expert did not have the control test results reported (SPC) for November 25, 2022. 3. during interview with the technical consultant on the afternoon of the survey, it was reported that the manufacturer stated this was a glitch. B. Based on review of Cepeid quality control records and interview, the laboratory did not have external (liquid) controls for SARS CoV-2 and CT/NG testing. Findings: 1. On November 2, 2022 and May 25, 2022 the external positive and negative SARS CoV-2 quality control was not performed. C. IQCP?

D5783

CORRECTIVE ACTIONS
 CFR(s): 493.1282(b)(2)

(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.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory did not document corrective actions when hematology quality control checks did not meet the laboratory's criteria for acceptability. Findings: 1. On August 11, 2023, the Low platelet quality control was tested three times. The expected result was between 57-97, the laboratory obtained results of 105, 106 and 118. The laboratory did not document corrective action on the log and the written procedure states that the controls must be within range to perform patient testing. 2. On July 3, 2023, the high platelet quality control result was 564 (acceptable range is 438-558), no corrective action was documented. 2. This was confirmed during interview with the technical consultant on the afternoon of the day of survey

D5805

TEST REPORT
 CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification,

either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient reports and interview, the patient reports did not include the source of the specimen tested. Findings: 1. The laboratory uses the Cepheid printout as the patient report, but the report does not include the source of the specimen (e.g. throat swab, urine), for example patient record number ****877 reported on December 30, 2022 that did not have specimen source on the report. 2. This was confirmed during interview with the technical consultant on the afternoon of the day of survey.