

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0158623	(X3) Date Survey Completed 08/20/2019
Name of Provider or Supplier Caredem Primary And Urgent Care Pc	Street Address, City, State 1 E Roe Blvd, Patchogue, NY	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's packet inserts for Siemens Multistix and OSOM Genzyme Influenza A&B and interview with the technical consultant and the testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new kit of Influenza A&B opened and with each new vial of the Siemens Multistix opened. FINDINGS: 1. The laboratory is using the OSOM Genzyme Influenza A&B kit. The manufacturer of the OSOM Genzyme requires that external positive and negative controls (provided in the kits) be performed with each new lot number/shipment. 2. On August 20, 2019 at approximately 1:00 PM the technical consultant confirmed surveyor's findings that documentation for the required external control testing was not available at survey from January 2019 and up to survey date. 3. The packet insert for the Siemens Multistix requires that external controls be performed with each new Vial of Multistix opened. On August 20, 2019 at approximately 1:00 PM the technical consultant confirmed surveyor's findings that documentation for the required external control testing was not available from January 2019 to the survey date. 4. Approximately 25 patient specimens were tested and reported for Influenza A&B testing and approximately 50 patients specimens were tested and reported for urinalysis during the above time frames.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratory's procedure manual and interview with the technical supervisor and the general supervisor the laboratory failed to establish a comprehensive policy/procedure manual to include: 1) A written procedure for transportation of patients' specimens from the physician offices in Coram, West Babylon, Bayshore and Miller Place to the laboratory in Patchogue for testing; 2) A written procedure describing laboratory's turnaround time from sample collection to processing and to when final results are entered into the lab computer system.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of Quality Control (QC) records and an interview with the technical consultant and the testing person, the laboratory failed to program the manufacturer expected ranges, as defined on the QC assay sheets, into the Beckman Coulter AU 480 analyzer for chemistry testing from July 15, 2019 through the survey date. FINDINGS: A) On 8/20/2019 at approximately 1:00 PM, the technical consultant and the testing person confirmed the surveyor's review of QC records finding that the laboratory failed to program the established QC ranges and expected

	<p>means into the Beckman Coulter AU 480 analyzer for the chemistry tests performed. B) Without the established QC limits, the surveyor could not determine if the quality control results were within the acceptable ranges for the chemistry analytes tested on the Beckman Coulter AU 480 analyzer. C) Approximately 60 patients' specimens were tested and reported for chemistry during this time period.</p>
<p>D5481</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of hematology quality control (QC) records and an interview with the technical consultant and the testing person, the laboratory failed to ensure that hematology QC test results were within acceptable range prior to testing patient specimens. Findings Include: Based on review of QC records and confirmed by the technical consultant and the testing person on August 20, 2019 at approximately 1:00 PM, the following levels of hematology control materials were out of acceptable range and remediation was not performed: 1. On 7/16/19 two out of three controls were out of acceptable range for Hemoglobin (Hgb) and Hematocrit (HCT) 2. On 8/1, 2, 5, 6, 7, 9, 10, 13/2019 two out of three controls were out of acceptable range for Hgb and HCT.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor's findings and an interview with the technical consultant, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory maintained the laboratory's QC program for hematology and chemistry. Refer to D6020</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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 the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control records, and an interview with the technical</p>

consultant, the laboratory director failed to ensure that the QC program for hematology and chemistry was maintained to assure quality laboratory services. Refer to: D1001, D5403, D5469, D5481