

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1087089	(X3) Date Survey Completed 01/03/2019
Name of Provider or Supplier Edward Condon Medical Pc	Street Address, City, State 6080 Jericho Turnpike, Suite 314, Commack, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the chemistry calibration records and an interview with the technical consultant and the testing person, the laboratory failed to discontinue the use of expired calibration materials. FINDINGS: 1) On January 3, 2019 at approximately 12:00 PM the technical consultant and the testing person confirmed surveyor findings that the laboratory used expired calibrator materials, lot number 76193U100 expired July 28, 2018 to calibrate Vitamin D 25 OH testing on August 6, 2018. 2) Approximately 100 patients were tested for VitD 25 OH testing using the expired calibrator materials during the above time frame. PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEYS CONDUCTED ON MARCH 24, 2015 AND FEBRUARY 3, 2017.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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</p>

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 review of laboratory Quality Control (QC) records and an interview with the technical consultant and the testing person, the laboratory failed to perform lot to lot verification of the Abbott Architect i2000 and the Immulite 2000 analyzers assayed controls. Findings: At approximately 1:00 PM on January 3, 2019, the technical consultant and the testing person confirmed that the laboratory had not verified chemistry, endocrinology and immunology assayed QC prior to use in calendar years 2017 and 2018.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:
Based on the surveyor's review of laboratory records, the laboratory director failed to provide overall management and direction of the laboratory. The laboratory director failed to ensure that the laboratory had: 1. Maintained the plan of correction from the surveys conducted on February 25, 2013, March 24, 2015 and February 3, 2017; 2. Effective QA review was performed to correct problems identified in the general laboratory system, refer to D6021. PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON MARCH 24, 2015 AND FEBRUARY 3, 2017.

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 a review of the laboratory Quality Assessment (QA) records, and interview with the technical consultant and the testing person, the laboratory director failed to follow the laboratory's QA procedures. Findings Include: At approximately 1:00 PM on January 3, 2019, the technical consultant and the testing person confirmed surveyor findings that although the QA reviews were performed and the problems were identified by the laboratory's technical consultant, the laboratory director failed to ensure that actions were taken to prevent recurrence of the original problem. Refer to D5417, D5469 PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE

SURVEYS CONDUCTED ON FEBRUARY 25, 2013, MARCH 24, 2015 AND
FEBRUARY 2, 2017.