

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0666704	(X3) Date Survey Completed 11/21/2018
Name of Provider or Supplier Cedar Crest Emergicenter	Street Address, City, State 1101 So Cedar Crest Blvd, Allentown, PA	
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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory quality assessment (QA) policy, laboratory QA documents, and interview with Technical Consultant (TC), the laboratory failed to document QA reviews for 2017 to 11/21/2018. Findings include: 1. On the day of survey, 11/21/2018, the laboratory provided a policy describing QA procedure, but could not provide documentation of QA activities in 2017 and 2018. 2. The TC on 11/21/2018 confirmed the findings above on around 11:00 am.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless</p>

the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on calibration records and interview with the Technical Consultant (TC), the laboratory failed to perform calibration on the Roche Cobas Mira chemistry analyzer and the Medonic Hematology Analyzer at least every 6 months from 2017 and 2018. Findings include: 1. On the day of survey, 11/21/2018, review of calibration record revealed the laboratory did not perform calibration on the Roche Cobas Mira chemistry analyzer and the Medonic Hematology Analyzer at least every 6 month in 2017 and 2018. - Roche Cobas Mira was calibrated on 10/03/2017 and again on 10/10/2018. - Medonic Complete Blood Count (CBC) Analyzer was calibrated on 05/15/2017, 01/23/2018 and again 09/12/2018. 2. In 2017: 40,752 chemistry and hematology tests were performed. 3. The TC confirmed the findings above on 11/21/2018 around 11:30 am.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on, the review of testing personnel (TP) competency assessment records, proficiency testing records and interview with Technical Consultant (TC), the TC failed to evaluate the assessment of test performance through external proficiency testing samples or internal blind testing samples on 5 of 8 testing personnel from 2017 to the date of survey. Findings Include: 1. On the day of survey, 11/21/2018, the review of competency assessment records revealed that the labortaory did not evaluate the assessment of test performance through external proficiency testing samples or internal blind testing samples for 5 of 8 TP in 2017 and 2018. 2. The TC confirmed the findings above on 11/30/2018 around 10:15 am.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of competency assessment record and interview with the Technical

Consultant (TC), the TC failed to evaluate and document the performance of 2 out of 8 testing personnel (TP) responsible for the Chemistry, Hematology and Immunology tests for their semi-annually competency during the first year. Findings include: 1. On the day of survey, 11/21/2018, the laboratory was unable to produce semi annual competency assessment records performed for testing personnel #5 and #6. 2. TP#5 initial training was performed on 08/17/2017 and their 1st competency assessment was not performed until 05/02/2018. 3. TP#6 initial training was performed on 10/03/2017 and their 1st competency assessment was not performed until 05/18/2018. 4. The TC confirmed the findings above on 11/21/2018 around 9:50 am.