

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0721195	(X3) Date Survey Completed 10/04/2018
Name of Provider or Supplier Lakeview Specialty Hospital & Rehab	Street Address, City, State 1701 Sharp Rd, Waterford, WI	
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with testing personnel, the laboratory did not evaluate the results for CKMB (creatine kinase-muscle/brain fraction) testing in the first two 2017 PT events. Findings include: 1. Review of proficiency testing records from events one and two in 2017 show the CKMB results were not graded by the PT provider. No documented review of these results by the laboratory is evident. 2. Interview with testing personnel, staff A, on October 4, 2018 at 10:00 AM confirmed the laboratory did not verify the accuracy of CKMB results from events one and two in 2017.</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 surveyor review of calibration verification records and interview with testing personnel, the laboratory did not perform calibration verification every six months on the i-STAT analyzers in 2017. Findings include: 1. Review of the calibration verification records for the i-STAT analyzers show the following dates of calibration verification testing for CKMB (creatine kinase-muscle/brain fraction), Troponin, BNP (B-type natriuretic peptide) and the G3+ cartridge for Blood Gas testing: Test: Dates calibration verification performed CKMB: May 2, 2017 / March 1, 2018 Troponin: May 2, 2017 / March 2, 2018 BNP: May 3, 2017 / December 5, 2017 G3+: May 3, 2017 / December 5, 2017 2. Interview with testing personnel, staff A, on October 4, 2018 at 11:45 AM confirmed calibration verification was not performed every six months in 2017 as required.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 Based on surveyor review of laboratory records and interview with testing personnel, the laboratory did not document problems identified in the analytic systems to monitor, assess and correct identified problems. Findings include: 1. Review of quality control records for CKMB (creatine kinase-muscle/brain fraction) showed no quality control testing was documented in September 2018. No documentation showing evaluation of the lack of quality control testing or resolution of the problem is available. 2. Interview with testing personnel, staff A, on October 4, 2018 at 10:55 AM revealed the laboratory ran out of CKMB reagent in September and was unable to order reagents until the end of the month. Further interview confirmed there was no documentation of when CKMB testing was not available, assessment of the issues involved, the impact to patient care, or a plan to prevent recurrence.

D6070

TESTING PERSONNEL RESPONSIBILITIES
 CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures, test records and logs, and interview with testing personnel, testing personnel did not follow the laboratory's procedures for documenting critical test results. Findings include: 1. Review of the "Reporting Critical Lab Values" procedure shows critical results are documented on the Critical Result Log. 2. Comparison of test records for patient one from September 6 and 7 with the Critical Lab Log showed two of two critical CKMB (creatine kinase-muscle/brain fraction) results were not recorded on the Critical Result Log. 3. Interview with testing personnel, staff A, on October 4, 2018 at 11:30 AM confirmed the laboratory's procedures for maintaining records of critical patient test results were not followed.