Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0721195	(X3) Date Survey Completed 07/23/2024
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
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Item 1 Based on surveyor review of laboratory procedures and records, and interview with the laboratory manager, staff A, testing personnel did not follow procedures for calibration verification for two of two Abbott I-Stat chemistry analyzers. Findings include: 1. Review of the "i-STAT CHEM 8' procedure stated the following: " Calibration verification is also performed Every 6 months On any new or replacement device before being clinically used. After major maintenance or service. As part of the troubleshooting process when controls reflect an unusual trend or are consistency of range. And as recommend by the manufacturer." 2. Review of calibration verification records showed calibration verification in July 2023 and July 2024, with no additional calibration verification performed in January 2024. 3. Interview with staff A on July 23, 2024, at 2:25 PM confirmed testing personnel did not follow the procedure for calibration verification on the Abbott I-Stat chemistry analyzer. Item 2 Based on surveyor review of laboratory procedures and records, and interview with the laboratory manager, staff A, testing personnel did not follow procedures for calibration verification for one of one Abbott I-Stat chemistry analyzers that was taken out of service for major service on the analyzer. Findings include: 1. Review of the "i-STAT CHEM 8' procedure stated the following: " Calibration verification is also performed Every 6 months On any new or replacement device before being clinically used. After major maintenance or service. As part of the troubleshooting process when controls reflect an unusual trend or are consistency of range. And as recommend by the manufacturer." 2. Review of deviation logs showed I-Stat analyzer, serial number 380580, was removed from service August 22, 2023, for failures with

	the electronic simulator, and placed back into service on October 11, 2023. 3. Review of calibration verification records showed no documentation that a calibration verification had been performed prior to putting the analyzer back into service. 4. Interview with staff A on July 23, 2024, at 2:25 PM confirmed testing personnel did not follow the procedure for calibration verification on the Abbott I-Stat chemistry analyzer.