

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0394540	(X3) Date Survey Completed 09/11/2024
Name of Provider or Supplier Bellin Health Oconto Falls	Street Address, City, State 107 E Highland Dr, Oconto Falls, 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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records and interview with a Technical Consultant (Staff A), the laboratory did not review Thyroid Stimulating Hormone (TSH) patient test results obtained since the last acceptable QC run on three of three days in August 2024 when QC was not acceptable and testing personnel made changes to the test system to obtain acceptable QC results. Findings include: 1. Review of TSH QC records performed from August 1 through 30 showed control level three was not initially in control on three days of testing. The acceptable range for control level three was 33.900 - 41.100 uIU/mL (micro-International Units per milliliter). Corrective action documentation showed no indication the laboratory evaluated patient results obtained since the last acceptable test run. August 2, 2024: Run / result / rule summary / corrective action Run 1: 41.231 / warn / will repeat Run 2: 41.375 / reject / repeated, maintenance, troubleshooting Run 3: 38.705 / in control / run used August 26, 2024 Run 1: 44.631 / reject / repeated with fresh aliquot Run 2: 44.576 / reject / blew well and fresh aliquot Run 3: 44.554 / reject / repeated with fresh qc and new flex Run 4: 36.411 / in control / repeated new vial of control August 28, 2024 Run 1: 43.399 / reject / will repeat Run 2: 44.371 / reject / new reagents Run 3: 43.000 / reject / repeated, recalibrated, restandardized Run 4: 37.853 / in control 2. Interview with Staff A on September 11, 2024, at 2:40 PM confirmed the laboratory</p>

had not evaluated patient test results obtained since the last acceptable QC run when QC results were unacceptable and required changes to the test system that could have affected patient test results.