

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0397838	(X3) Date Survey Completed 08/15/2023
Name of Provider or Supplier Thedacare Physicians Neenah	Street Address, City, State 333 N Green Bay Road, Neenah, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of hematology procedures and interview with a technical consultant, staff A, the laboratory procedure "HEME98 Morphologic Hematology Review Guidelines" allowed reporting of abnormal white blood cells (WBC) differential findings and red blood cell (RBC) morphologic abnormalities that are inconsistent with the limitation of moderate complexity testing personnel to report only normal WBC differentials findings and RBC morphological results. Findings include: 1. Review of the "HEME98 Morphologic Hematology Review Guidelines" revised June 13, 2022, showed the procedure included the following instructions:</p>

ThedaCare Physician Laboratories defined by CLIA as moderately complex laboratories will send all CBCs (Complete Blood Counts) to ThedaCare Regional Medical Center-Neenah (TCN) if the following criteria met: WBC Differential Abnormalities: a. An absence of neutrophils or lymphocytes. b. Absolute eosinophil great than 1.5. c. Bands greater than 30%. d. Metamyelocytes greater than 10%. e. Any left shift more immature than metamyelocytes. f. Reactive lymphocytes >5%. g. Any atypical lymphocytes. RBC Morphologic Abnormalities: a. Evidence of hemolysis or marked regenerative process. 1. Nucleated RBCs greater than 5 2. 3+ polychromasia. 3. Schistocytes b. Evidence of disordered red blood cell production. 1. 2-3+ acanthocytes or stomatocytes 2. 2-3+ hypochromia 3. MCV greater than 110 (accept for newborn babies) 2. Interview with staff A on August 15, 2023, at 9:15 AM confirmed the laboratory was considered moderate complexity and confirmed the procedure did not require referral of all abnormal WBC differentials or red cell morphology to a laboratory qualified to perform high complexity differentials. Item 2: Based on survey review of patient reports and laboratory procedures and interview with a technical consultant, staff A, the "Prothrombin Time-ACL TOP" procedure did not include a reference interval for testing performed on the Werfen ACL Top 300 analyzer for one of two results reported. Findings include: 1. Review of patient reports showed the facility reports both the prothrombin time (PT) and international normalized ratio (INR) for coagulation testing. 2. Review of the "Prothrombin Time-ACL TOP" procedure showed no evidence the laboratory included a reference interval for PT testing performed on the analyzer in their procedure. 3. Interview with staff A on August 15, 2023, at 1:45 PM confirmed the coagulation procedures did not include a reference interval for PT testing performed on the Werfen ACL Top 300 coagulation analyzer.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on surveyor review of maintenance logs on the Beckman Coulter AU680 chemistry analyzers and interview with a technical consultant, staff A, the laboratory did not document routine weekly maintenance for four of twenty-six weeks reviewed on serial number (SN) 2018026363 and two of twenty-six weeks reviewed on SN 2018026361. Findings include: 1. Review of "AU 680 Maintenance Log" showed the following: SN 2018026363: No documentation of weekly maintenance between January 16-20, 2023, February 13-17, 2023, March 27-31, 2023, and June 19-23, 2023. SN 2018026361: no documentation of weekly maintenance between February 26-March 4, 2023, and March 12-March 18, 2023, 2. Interview with the staff A on August 15, 2023, at 1:12 PM confirmed the laboratory did not document routine maintenance on the Beckman Coulter AU680 chemistry analyzers for all weekly requirements in 2023.