| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 52D0397838 | 12/20/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Thedacare Physicians Neenah | 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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of hematology procedures and interview with the technical consultant, the laboratory procedure, 'HEME98 Morphologic Hematology Review Guidelines', allowed reporting of abnormal white blood cell (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 differential and morphologic results. Findings include: 1. Review of the "HEME98 Morphologic Hematology Review Guidelines" revised October 25, 2021 showed the procedure included the following instructions: ThedaCare Physician Laboratories |

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| | 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 is met: WBC Differential Abnormalities: including an absence of neutrophils or lymphocytes, absolute eosinophil greater than 1.5, bands greater than 30%, metamyelocytes greater than 10%, myelocytes greater than 5%, and any left shift more immature than myelocytes, RBC Morphologic Abnormalities: including evidence of hemolysis or marked regenerative process (nucleated RBCs greater than 5, 3+ polychromasia, schistocytes) or evidence of disordered red blood cell production (2 - 3+ acanthocytes or stomatocytes, 2 - 3+ hypochromia. MCV greater than 110 (except for newborn babies)), Miscellaneous findings including hypersegmentation. 2. Interview with the technical consultant (staff A) on December 20, 2021 at 2:15 PM confirmed this laboratory was limited to the performance of moderate complexity (normal) differentials and confirmed the procedures did not require referral of all abnormal white cell differentials or red cell morphology to a laboratory qualified to perform high complexity |
| **D5409** | PROCEDURE MANUAL<br>CFR(s): 493.1251(e)<br><br>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of one new laboratory procedure and interview with the technical consultant, the laboratory did not document the date of initial use of the D-dimer test system with the procedure. Findings include: 1. Review of the procedure for D-dimer testing signed by the laboratory director on April 15, 2020 showed no evidence of the date of initial use of the test system in the laboratory. 2. Interview with the technical consultant (staff A) on December 20, 2021 at 2:20 PM confirmed the laboratory did not maintain the date of initial use for D-dimer testing with the procedure for the test. This is a repeat deficiency previously cited on August 22, 2017 and August 21, 2019. |
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(a)(b)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor comparison of current citations with previous citations for this laboratory and interview with the technical consultant, the laboratory director has not assured continuing compliance with the applicable regulations for two of two procedure manual deficiencies identified during this survey. Findings include: 1. |

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| | Comparison of current analytic citations with previous survey results showed both procedure manual deficiencies were cited previously: D5403 was cited at the last survey on August 21, 2019 D5409 was cited both at the last survey on August 21, 2019 and the previous survey on August 22, 2017 2. Interview with the technical consultant (staff A) on December 20, 2021 at 2:30 PM confirmed the laboratory director had not ensured continued compliance with previously cited regulations. |