

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0397838	<b>(X3) Date Survey Completed</b>  08/21/2019
<b>Name of Provider or Supplier</b>  Thedacare Physicians Neenah	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the technical consultant, the laboratory director has not signed the PT attestation statements confirming the routine integration of the proficiency testing samples into the patient workload and has not delegated the responsibility for signing the statement in writing to the technical consultant. Findings include: 1. Review of PT records showed the laboratory director had not signed four of four attestation statements for events one and two for the hematology and chemistry events in 2019. 2. Interview with the technical consultant on August 21, 2019 at 11:00 AM confirmed the laboratory director had not delegated in writing the responsibility for signing the attestation statements to the technical consultant.</p>
<b>D5403</b>	<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)</p>

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of hematology procedures and interview with the technical consultant, the procedure manual does not provide instructions to testing personnel requiring referral of abnormal white cell differentials. Findings include: 1. Review of the "Morphologic Hematology Review Guidelines SMRP Policy HEME98" showed the procedure provides instruction for differentiating abnormal cell morphologies but does not direct the testing person to refer the sample to a laboratory that is qualified to perform high complexity differentials. Further review of procedures revealed, "Review of results is not necessary if the patient's results have been previously reviewed and no significant change in results has occurred." The list of cells that testing personnel can report without additional review includes blasts, sickle cells, and parasite inclusions which are abnormal cells. 2. Interview with the technical consultant at 12:30 PM on August 21, 2019 confirmed this laboratory only reports moderate complexity white cell differentials and confirmed the procedures do not require referral of abnormal white cell differentials.

**D5409**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(e)

The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

This STANDARD is not met as evidenced by:

Based on surveyor review of procedures and interview with the technical consultant, the laboratory's procedures for the ESR STAT PLUS and the AU 680 analyzers do not include the date of initial use of these procedures in this laboratory. Findings include: 1. Review of the procedure for the ESR STAT PLUS showed no evidence of the date of initial use of this test system in this laboratory. 2. Review of the procedure for the AU 680 analyzers showed no evidence of the date of initial use of this test system in this laboratory. 3. Interview with the technical consultant on August 21, 2019 at 3:00 PM confirmed the laboratory did not maintain the date of initial use with the procedures for the ESR STAT PLUS or the AU 680 analyzers. This is a repeat deficiency previously cited on August 22, 2017.