

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D0398942	<b>(X3) Date Survey Completed</b> 10/04/2024
<b>Name of Provider or Supplier</b> Minnesota Urology, Pa	<b>Street Address, City, State</b> 6025 Lake Road, Suite 200, Woodbury, MN	
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>D0000</b>	The Minnesota Urology, PA laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey which concluded on October 4, 2024 . The following standard-level deficiencies were cited: 493.1255 Calibration and calibration verification procedures 493.1413 Technical consultant responsibilities .
<b>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by:          . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document hematology analyzer calibration as required by the manufacturer on two of four occasions in 2023 and 2024. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor during a tour of the laboratory on at 9:10 a.m. on 10/03/24. 2. A Beckman Coulter DxH 500 hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory performed approximately 5,541 hematology tests annually as indicated on the Form CMS-116</p>

obtained from the laboratory on date of survey. 3. DxH calibration was required when indicated on calibration verification reports as established in the manufacturer's DxH 500 Instructions for Use manual 4. The laboratory performed calibration verification on four dates in the time period reviewed; 04/21/23, 10/16/23, 05/20/24, and 08/21/24. The laboratory failed to perform calibration on two of four occasions when calibration verification results listed on the analyzer Cal. Report indicated this activity was required. See below 10/16/23 Calibration Report Cal: WBC, HGB, PLT 05/20/24 Calibration Report Cal: WBC, HGB, MCV Fail: RBC 5. In an interview at 3:25 p.m. on 10/03/24, the Technical Consultant confirmed the above finding and stated testing personnel did not perform calibration on the two occasions when the calibration report indicated calibration was needed.. .

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure three of three tenured testing personnel were evaluated for test procedure competency in all testing areas in 2022 and 2023. Findings are as follows: 1. The laboratory performed KOH preparation (KOH), vaginal wet preparation (VWP), and quantitative sperm analysis (SA) microscopic examination testing as confirmed by the General Supervisor during a tour of the laboratory at 9:10 a.m. on 10/03//24 2. An Olympus CH30 microscope was observed as present and available for use during the tour. 3. The Competency Assessments for MLT Personnel procedure provided by the laboratory indicated testing personnel were evaluated for competency in all testing areas during training, after 6 months of work, and annually thereafter. 4. Competency assessments for KOH, VWP, and SA microscopic examination testing were not included in the Competency Assessment Worksheet (Testing Personnel) forms completed for three of three tenured testing personnel in 2022 and 2023. The laboratory was unable to provide the missing evaluations upon request. 5. In an interview at 11:10 a.m. on 10/03/24, the Technical Consultant confirmed the above finding. .