Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0398014	05/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Thedacare Medical Center Wild Rose	601 Grove Ave, Wild Rose, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Item One: Based on surveyor review of procedures and competence evaluation records and interview with the General Supervisor, the laboratory did not follow their policies and procedures for documentation of competence evaluations for four of six testing personnel. Findings include: 1. Review of the 'Lab Orientation, Training, and Competency Policy' showed competency "must be assessed at least annually" for non-waived testing personnel. 2. Review of testing personnel 'Competency Assessment' logs from 2023 showed four of six testing personnel did not complete competence assessment for all test systems identified on the list as current test systems in the laboratory. The form includes boxes to confirm use of each of the six elements in the evaluation and spaces for the evaluator to date and initial when the test system evaluation was completed. The forms showed the six elements for the following test systems (as identified on the forms) were not documented, and the items listed were not dated or initialed as completed. Staff A: Post Vasectomy / Wet Prep / Gram Staining - Sputum for Acceptability / Triage Staff B: ABL 80 / Post Vasectomy Staff C: Manual Cell Counts - WBC, Platelet / Fluids - General, CSF, Differentials / Gram Staining - Sputum for Acceptability Staff D: EPOC The forms for Staff D showed evaluation of the six required elements for only one of the thirty-two tests evaluated. 3. Interview with the General Supervisor on May 21, 2024, at 11:00 AM confirmed testing personnel did not ensure completion of competence evaluations for all tests and confirmed personnel evaluating competence did not complete documentation as required in 2023. Item two: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209, procedures, and records, and interview

	with the General Supervisor, the laboratory did not document competency assessment in the last year for five of five testing personnel that functioned as technical consultants and / or technical supervisors. Findings include: 1. Review of the Form CMS-209 submitted for this survey showed five testing personnel (Staff A, B, D, E, and F) who also functioned as technical consultants and / or technical supervisors. 2. The 'Competency Assessment for Leaders Fulfilling CLIA Roles (i.e., Technical Supervisors, Technical Consultants, and General Supervisors)' procedure stated, "Leaders fulfilling a CLIA defined role as technical supervisor, technical consultant, or general supervisor and performing competency assessment for testing personnel are to be competency assessed annually as part of the annual performance review process for leaders. This competency assessment for leaders performing competency assessment for testing personnel will be completed by their manager/director and documented within Workday as competent (yes/no)." 3. Review of competence records showed no evidence of evaluation of the performance of the technical consultant and technical supervisor responsibilities by the five identified testing personnel. 4. Interview with the General Supervisor on May 22, 2024, at 11:00 AM confirmed the laboratory did not evaluate the competence of the five testing personnel in meeting the additional responsibilities of technical consultant and / or technical supervisor in the past year.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the manufacturer's instructions and laboratory procedures, observation in the laboratory, and interview with the General Supervisor, the laboratory did not follow the manufacturer's instructions for one of four Gram stain reagents. Findings include: 1. Review of the manufacturer's instructions for Remel Gram Iodine reagent showed the reagent required reconstitution prior to use and the instructions directed, "Use Gram Iodine within 3 months after reconstitution." 2. Review of the "Gram Stain Procedure" showed no requirement for use of the stain within 3 months of reconstitution. The effective date of the procedure was May 6, 2022. 3. Observation of the four Gram stain reagents in the laboratory on May 22, 2024, at 2:00 PM revealed the Gram Iodine reagent in use was lot 134761, expiration date April 26, 2025. 4. Interview with the General Supervisor on May 22, 2024, at 2: 15 PM confirmed the laboratory was not following the manufacturer's instructions for the reduced expiration date of the Gram Iodine reagent after reconstitution.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on surveyor observation in the laboratory and interview with the General Supervisor, the laboratory did not label the reconstituted Gram Iodine reagent with the three-month reconstituted expiration date. Findings include: 1. Observation of the current gram stain reagents in the laboratory on May 22, 2024, at 2:00 PM revealed the Gram Iodine reagent in use was lot 134761, expiration date April 26, 2025. The three-month reconstituted expiration date was not evident on the bottle. 2. Interview with the General Supervisor on May 22, 2024, at 2:15 PM confirmed personnel had not labeled the Gram Iodine bottle with the expiration date to reflect the three-month expiration after reconstitution of the reagent.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Item One: Based on surveyor review of laboratory procedures and records, and interview with the General Supervisor, the laboratory did not perform function checks on two of two centrifuges used for coagulation sample preparation every six months to ensure the use of platelet poor plasma for coagulation testing in 2022, 2023, and 2024. Findings include: 1. The 'Platelet Poor Plasma' procedure stated, "Centrifuges used for coagulation specimens need to be validated semi-annually". The procedure section required personnel to test five samples per centrifuge every six months. 2. Review of laboratory records showed testing personnel completed the function checks for two centrifuges, StatSpin 3 and StatSpin 4, on the following dates. StatSpin 3: June 14, 2022 February 17, 2023 September 20, 2023 April 28, 2024 StatSpin 4: March 11, 2023 September 20, 2023 April 28, 2024 3. Interview with the General Supervisor on May 21, 2024, at 1:05 PM confirmed the validation was due for StatSpin 3 in December 2022, August 2023, and March 2024, and the validation was due for StatSpin 4 in March 2024. Further interview confirmed the laboratory did not complete the platelet poor plasma validation procedures as required in 2022, 2023, and 2024. This is a repeat deficiency cited at D6175 on June 30, 2022. Item Two: Based on surveyor review of maintenance records and interview with the General Supervisor, the laboratory did not document the required MAGNEHELIC Gauge Reading for the Biological Safety Cabinet for twenty-two of the last twenty-two months. Findings include: 1. Review of the 'Microbiology Quality Control and Maintenance Log' from July 2022 to April 2024 showed one of the monthly maintenance requirements was documentation of the reading of the MAGNEHELIC Gauge. Review of the logs showed testing personnel did not record the MAGNEHELIC Gauge reading on any of the logs. 2. Interview with the General Supervisor on May 22, 2024, at 11:15 AM confirmed testing personnel did not document the MAGNEHELIC Gauge function check in the last twenty two months.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) 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. This STANDARD is not met as evidenced by: Based on surveyor review of procedures and records and interview with the General Supervisor, the laboratory did not perform two of the last four calibrations of the fibrinogen test on the ACL TOP analyzer every six months as required by the laboratory procedures. Findings include: 1. Review of the calibration section of the 'Fibrinogen - ACL TOP' procedure showed the procedure required a new reference curve every six months. 2. Review of calibration records for the ACL TOP showed the laboratory performed fibrinogen calibrations on April 13, 2022, February 2, 2023, June 29, 2023, and May 13, 2024. 3. Interview with the General Supervisor on May 22, 2023, at 1:05 PM confirmed fibrinogen calibrations were due in October 2022 and December 2023. Further interview confirmed the laboratory did not meet the six-month calibration requirement for the fibrinogen test. This is a repeat deficiency previously cited on November 4, 2020.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the General Supervisor, the laboratory did not perform calibration verification on the ABL80 Flex CO-OX every six months as required. The laboratory did not perform one of two

	verifications due in 2023. Findings include: 1. Review of the calibration verification records for the ABL80 Flex CO-OX analyzer showed testing personnel performed calibration verification testing on April 17, 2023, and on April 20, 2024. No other records were available for calibration verification in 2023 or 2024. 2. Interview with the General Supervisor on May 22, 2024, at 11:36 AM confirmed the laboratory did not complete the calibration verification for the ABL80 Flex CO-OX analyzer that was due in November 2023.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of blood bank quality control records and manufacturer's product insert and interview with the General Supervisor, testing personnel did not identify that the control results for Anti-D testing did not match the manufacturer's criteria for acceptability on three of three days in May 2024. Findings include: 1. Review of Quality Control (QC) worksheets completed on May 4, 5, and 6, 2024 showed personnel recorded the Anti-D result as 4+ for QC samples 1 - 4. The worksheets showed no evidence testing personnel did not accept the results. 2. Review of the QC manufacturer's product insert showed the expected result for Anti-D with QC sample 1 was negative, the expected result for QC samples 2, 3, and 4 was positive. 3. Interview with the General Supervisor on May 22, 2024, at 12:30 PM confirmed the results for Anti-D testing with QC sample 1 did not meet the manufacturer's criteria for acceptability and confirmed testing personnel did not identify the QC was not acceptable.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the General Supervisor, the laboratory did not perform inspections or verify proper functioning of the audible alarm system on two of two blood storage units in the last two years. Findings include: 1. Review of laboratory transfusion services records showed no evidence of inspections of the alarm system for the blood bank refrigerator or freezer. 2. Interview with the General Supervisor on May 22, 2024, at 3:30 PM confirmed procedures required the alarm system inspections and verifications quarterly and confirmed testing personnel had not completed the inspections and verification of the alarms in the last two years.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the general supervisor, laboratory personnel did not document the corrective actions taken when the DG Reader Net was not working for nine of nine days in January, one of one day in February, and three of three days in May 2024. Findings include: 1. a. Review of the DG Reader Net Maintenance Log from January 2024 showed testing personnel documented the Reader was 'Down' from January 1 through January 8, 2024. The log showed testing personnel completed the daily maintenance on January 11, there is no documented evidence on the Maintenance log that the reader was not functional on January 11, 2024. Review of the Blood Bank Manual Gel QC log showed an entry on January 11, 2024, marked "DG Reader down". b. Review of the Blood Bank Manual Gel QC log from February 2024 showed testing personnel noted "DG Reader Down" during the second week of the month. Personnel did not date the entry. Review of the DG Reader Net Maintenance Log from February 2024 showed no evidence the DG Reader Net was down in February. c. Review of Ortho Confidence Quality Control logs completed on May 4, 5, and 6, 2024, showed testing personnel noted, "DG reader down" with the control results. 2. Review of the corrective action logs for the DG Reader Net showed testing personnel documented the last corrective action taken in November 2020. Review showed no evidence of corrective action documentation in January, February, or May 2024. 3. Review of instrument service reports showed a technical service representative provided the most recent report after completing repairs to the DG Reader Net on December 19, 2023. 4. Interview with the General Supervisor on May 22, 2024, at 12:30 PM confirmed personnel did not document corrective actions taken when testing personnel indicated the DG Reader Net was not functioning as expected.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory quality records and interview with the General Supervisor, the laboratory's system to ensure accurate and reliable transmittal of data did not include the evaluation of manually entered test results for two of two years. Findings include: 1. Review of laboratory quality assurance records from 2023 and 2024 showed no evaluation of the accuracy of manually entered test results. 2. Interview with the General Supervisor on May 22, 2024, at 3:30 PM confirmed the laboratory's evaluation of accurate and reliable entry of data did not include evaluation of manually entered test results during the last two years.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of Individualized Quality Control Plans (IQCP) and interview with the General Supervisor, the Laboratory Director did not ensure maintenance of two of nine IQCP to assure the quality of laboratory services provided. Findings include: 1. Review of IQCP records showed the Microbiology Media IQCP required maintaining Manufacturer Quality Control certificates for media. Review of the IQCP for the BioFire Film Array Respiratory Panel showed personnel completed the Quality Assurance review of the IQCP on January 3, 2023, the IQCP showed no evidence it was not in effect. 2. Interview with the General Supervisor on May 22, 2024, at 9:00 AM revealed the laboratory received media from the Neenah microbiology laboratory and does not receive manufacturer quality control certificates to retain. Further interview confirmed the laboratory discontinued patient testing with the BioFire Film Array Respiratory Panel on October 23, 2023, and confirmed the laboratory did not discontinue the BioFire IQCP.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records and interview with the General Supervisor, testing personnel did not follow quality control procedures for documenting quality control (QC) results for immunohematology reagent quality control in three of five months in 2024. Findings include: 1. Review of the 'Blood Bank Reagent Quality Control' procedure showed, "Quality Control of all reagents and cards used for the backup method(s), manual gel and tube, must be performed at least once a week and each day of use" and "All manual QC will be resulted onto the QC log". The procedures included instructions for using QC 01 and 02. 2. Review of

	the 'Blood Bank Manual Gel QC' logs for January and February 2024 showed testing personnel documented QC on January 4, 18, and 25, and February 1, 15, 22, and 29. The January log included an entry on January 11 "DG Reader Down". Personnel did not date the entry for the second week in February but stated "DG Reader Down". 3. Review of QC worksheets for testing performed on May 4, 5, and 6 showed testing personnel tested 4 QC samples each day and recorded the results on a QC worksheet for a different test system that was not in use. 4. Interview with the General Supervisor on May 22, 2024, at 12:30 PM confirmed testing personnel did not follow the QC procedures when they did not document the manual QC results for the second week in January or February 2024 when the DG Reader was not functioning. Further interview confirmed testing personnel did not follow procedures when personnel tested QC samples 3 and 4 in addition to samples 1 and 2 in May 2024 and when they did not enter the results on the 'Blood Bank Manual Gel QC' log.