Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0398014	06/10/2026
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: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209, procedures, and records, and interview with the laboratory manager (Staff A), the laboratory did not document competency assessment in the last year for ten out of eleven personnel that functioned as technical consultants and / or technical supervisors. Findings include: 1. Review of the Form CMS-209 submitted for this survey showed eleven personnel (Staff A, B, C, D, E, F, G, H, I, J, K) who functioned as technical consultants and / or technical supervisors. 2. The 'Lab Orientation, Training, and Competency Policy' stated in section E, "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 Staff A had a form with delegation of duties with a competency statement signed by the laboratory director in the past year. There was no evidence of evaluation of the performance of the technical consultant and technical supervisor responsibilities for the remaining ten personnel. 4. Interview with Staff A on June 9, 2026, at 12:05 PM confirmed the laboratory did not evaluate the competency of the ten personnel for delegated technical consultant and technical supervisor responsibilities in the past year. This is a repeat deficiency, previously cited on May 22, 2024.

D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) (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 laboratory manager (Staff A), two of two reviewed new procedures for the i-STAT analyzer showed date of initial use at this laboratory was different from the actual date of initial use for patient testing. Findings include: 1. a. Review of the procedure for chemistry and blood gas cartridges (CG8+, CG4+, and CHEM8+), 'CG8+, CG4+ and CHEM8+ via i-STAT', showed the procedure was in use at this laboratory as of October 1, 2025. b. Review of the procedure for high sensitivity troponin I (hsTNI), 'hsTNI via i-STAT system', showed the procedure was in use at this laboratory as of October 24, 2025. 2. Interview with Staff A on June 9, 2026, at 1:30 PM revealed this laboratory put the i-STAT analyzer with CG4+, CHEM8+, and hsTNI cartridges into use for patient testing on February 3, 2026, and confirmed the procedures did not accurately show the date of initial use for the tests at this laboratory.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on surveyor review of individualized quality control plans (IQCP) and interview with the laboratory manager (Staff A), the laboratory did not define the type of quality control (QC) material required for two of six IQCPs reviewed. Findings include: 1. a. Review of the IQCP for the laboratory's urine drug screen (UDS), 'IQCP UDS13 Medtox Profile V', showed the document stated, "External QC: Analyze 2 level(s) of QC each week of patient testing. The controls are not supplied with the reagents and must be ordered separately." Review of the IQCP showed the document did not identify what type of controls the laboratory required. b. Review of the IQCP for the qualitative human chorionic gonadotropin (hCG) test, 'Serum Pregnancy Test - Cardinal Health hCG Combo Rapid Test' showed the document stated, "External QC Samples: Analyze 2 level(s) of QC each month of patient testing. Both the positive and negative controls are purchased controls...". The IQCP did not define what positive or negative controls the laboratory required. 2. Interview with Staff A on June 9, 2026, at 2:05 PM confirmed the two IQCP documents did not specify the type of control required for external control testing for the Medtox Profile V or the Cardinal Health hCG Combo Test.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on surveyor review of procedures, proficiency testing (PT) and quality control (QC) records and interview with testing personnel and the laboratory manager, the director did not ensure personnel maintained weekly QC review requirements after a procedure revision in October 2025. Three of three analytes reviewed showed staff had not evaluated QC results weekly to identify shifts or trends in results when the laboratory information system (LIS) identified QC warnings. Findings include: 1. Review of the 'Laboratory Quality Control Policy' showed personnel are to address control results showing trends when noting violations of the 4-1 SD (Standard Deviation), S-10-T, or S-R 3S rules by using the 'QC Follow-up Worklist Review' report. The procedure later stated, "QC Follow-up Worklist Review - Unacceptable QC results are summarized and reviewed at least weekly by delegated testing personnel". 2. Review of American Proficiency Institute (API) PT records from the 2026 Chemistry Core 1st event showed the following results for Phenytoin, 60%; Vancomycin, 80%; and D-Dimer, 80%: a. Phenytoin micrograms/ milliliter (ug/mL) Sample | Reported | Expected | Standard Deviation Index (SDI) CH-01 | 21.2* | 14.8-20.1 | 2.6 CH-02 | 7.7 | 4.6 - 8.7 | 1.9 CH-03 | 7.2 | 5.1 - 9.2 | 0.1 CH-04 | 13.8 | 9.9 - 14.0 | 2.0 CH-05 | 35.6* | 24.2 - 32.9 | 2.2 * denotes unacceptable results b. Vancomycin (ug/mL) Sample | Reported | Expected | Standard Deviation Index (SDI) CH-01 | 29.6 | 24.3 - 33.0 | 0.7 CH-02 | 3.6 | 1.4 - 5.5 | 0.2 CH-03 | 3.3 | 0.5 - 4.6 | 1.5 CH-04 | 18.4* | 13.4 - 18.3 | 2.8 CH-05 | 62.9 | 48.3 - 65.5 | 1.2 * denotes an unacceptable result c. D-Dimer microgram Fibrinogen Equivalent Units/milliliter (ugFEU/mL) Sample | Reported | Expected | Standard Deviation Index (SDI) CH-01 | 6.563 | 4.838 - 7.137 | 1.5 CH-02 | 1.497* | 1.050 - 1.482 | 3.2 CH-03 | 0.760 | 0.532 - 0.868 | 1.1 CH-04 | 2.116 | 1.599 - 2.274 | 1.6 CH-05 | 3.343 | 2.553 - 4.255 | -0.2 * denotes an unacceptable result 3. Review of the "Proficiency Testing Problem Investigation Form" reports completed by Staff A on March 5 and 19, 2026, for the API 2026 Chemistry Core 1st Event showed the following testing dates and information about the controls on the dates of testing: a. Phenytoin: "CH-01 analyzed on 1/23/26", "CH-05 was analyzed on 1/18/26". "QC review for month of January showed a positive bias for level 3". b. Vancomycin: "Sample CH-04 was analyzed on 1/18/26". "Level 2 was out 2SD for 2 out of 3 runs. Level 3 flagged with a S-10x rule" c. D-Dimer: Sample CM-02 analyzed on 1/26/2026", "QC reviewed for the month of January. Positive bias observed with both levels." 4. Review of Quality Control results from January 1 - 31, 2026 in the Beaker LIS showed: a. Phenytoin: Nine days displayed a hammer icon showing a control rule warning or violation required evaluation. The LIS noted two series of 10x events, the first from January 12 - 14 and the second from January 25 - 29. The second series included all three levels of control. b. Vancomycin: Seventeen days displayed a hammer icon. Results for control level three showed a 10x warning; the results were above the mean for fourteen days from January 6 - 19, 2026. Personnel tested the Level two control three times to obtain an acceptable result on January 18, 2026. c. D-Dimer: Fourteen days displayed a hammer icon. Results for the high control were at or below the mean only twice during the month. The results were greater than two SD on six days. 5. Interview with testing personnel (Staff F) on June 10, 2026, at 9:15 AM revealed they reviewed

	control results monthly but did not review weekly unless the third shift testing personnel indicated there were issues with results. The interview also confirmed they had not completed 'QC Follow-up Worklist Review' reports for phenytoin or vancomycin QC warnings in January 2026. 6. Interview with the laboratory manager (Staff A) on June 9, 2026, at 11:00 AM confirmed the unacceptable PT results revealed potential issues with quality of test results. This interview also revealed that the laboratory revised the QC procedures in October 2025 to require review of warning flags on a weekly basis and Staff A stated they were not aware whether personnel completed any weekly 'QC Follow-up Worklist Review' reports during January 2026. Further interview on June 10, 2026, at 10:00 AM confirmed the director did not ensure testing personnel maintained quality procedures to identify failures in quality as they occurred.