Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0397909	02/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Thedacare Medical Center - New London	1405 Mill St, New London, 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 submitted Form CMS-209 (Laboratory Personnel Report) and competence evaluations and interview with the Laboratory Manager (Staff A), the laboratory did not establish and follow written policies and procedures to assess seven of seven employees performing general supervisor responsibilities, five of five employees performing technical consultant or technical supervisor responsibilities, and three of three performing clinical consultant responsibilities. Findings include: 1. Review of the Form CMS-209 submitted for the survey showed seven staff members identified as general supervisors (Staff A, B, C, D, E, F, G) and five as technical consultants or supervisors (Staff B, C, D, E, and H), and three clinical consultants (Staff H, I, and J) other than the laboratory director. 2. Review of competence evaluations showed no evidence the laboratory evaluated the competence of staff in performing their assigned general supervisor, technical supervisor, technical consultant, or clinical consultant responsibilities. 3. Interview with Staff A on February 20, 2024, at 4:00 PM confirmed the laboratory had not established procedures to evaluate employee competence in performing the general supervisor, technical supervisor, technical consultant or clinical consultant responsibilities.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and

	procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and procedures and interview with the Laboratory Manager (Staff A), the laboratory did not review the effectiveness of corrective actions taken in response to one of one unacceptable potassium hydroxide (KOH) test result on event 2022-03 and did not ensure completion of the corrective actions identified when one of two KOH test results were unacceptable for event 2023-02. Findings include: 1. Review of PT reports from API (American Proficiency Institute) showed the following unacceptable results for the KOH Glass Slide samples in events 2022-03 and 2023-02: Event 2022-03 Sample KOH-05: Laboratory reported, "No fungal elements / yeast observed", the API expected result was, "Fungal elements / yeast observed". Event 2023-02 Sample KOH-04 Laboratory reported, "No fungal elements / yeast observed", the API expected result was, "Fungal elements / yeast observed." 2. Review of the laboratory's corrective actions for the two events showed the same person performed testing on sample 2022-03 KOH-05 and 2023-02 KOH-04. Review of the 2022-03 event showed staff completed training and evaluation with unknown samples. In response to the unacceptable result in 2023-02 event, the laboratory noted the KOH test procedure did not identify how many microscopic fields personnel should evaluate prior to determining a negative result. 3. Review of the current KOH Procedure showed the laboratory had not updated the procedure after the 2023-02 event. 4. Interview with Staff A on February 19, 2024, at 1:05 PM confirmed the laboratory had not reviewed the effectiveness of corrective actions taken after the 2022-03 PT event and did not revise the procedure to prevent recurrence of problems after the 2023-02 event.
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 one of one BioFire Film Array procedure and interview with the Laboratory Manager (Staff A), the procedure did not specify which portions of the procedure applied to this laboratory and the laboratory did not maintain a copy of the procedure with the date the laboratory discontinued performing the BioFire Respiratory Pathogen Panel (RP2). Findings include: 1. Review of the "BioFire Film Array Operation Procedure" revealed the procedure included testing panels that this laboratory did not perform and did not show the discontinuation date for testing the RP2 panel. 2. Interview with Staff A on February 19, 2024, at 2:10 PM confirmed the laboratory had discontinued testing with the RP2 panel on November 14, 2023. Further interview revealed the "BioFire Film Array Operation Procedure" was a system wide procedure that included panels not performed at this laboratory and did not include laboratory specific initiation or discontinuation dates for the panels performed at this laboratory.
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 worksheets, observation in the laboratory, and interview with Testing Personnel (Staff B) and the Laboratory Manager (Staff A), 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 worksheet showed testing personnel documented the lot numbers and expiration dates of the four reagents in use. The worksheet showed the laboratory started using Remel Iodine reagent, lot 125913, on January 23, 2024. Testing personnel listed the expiration date as June 20, 2024, on the worksheet. 3. Observation of the four Gram stain reagents in the laboratory on February 19, 2024, at 3:15 PM revealed the Gram iodine reagent in use was lot 125913. Further observation showed no indication of a reduced reconstituted expiration date. 4. Interview with Staff B on February 19, 2024, at 3:15 PM revealed staff B was unaware of the three-month expiration date for reconstituted Gram iodine. 5. Interview with Staff A on February 19, 2024, at 3:30 PM confirmed the laboratory was not following the manufacturer's instructions for the reduced expiration date of the Gram iodine reagent after reconstitution.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of Gram stain worksheets and interview with the Laboratory Manager (Staff A), the laboratory had not followed procedures to monitor completion of the Gram stain worksheet for twelve of twelve months in 2023. Findings include: 1. Review of the Gram stain worksheets for the twelve months in 2023 revealed three days testing personnel performed patient testing without performing quality control (See D6177). Further review of the worksheets showed no indication the technical supervisor reviewed the worksheets to ensure testing personnel completed the worksheets and followed laboratory quality control procedures. 2. Interview with Staff A on February 19, 2024, at 3:30 PM confirmed the Gram stain worksheets showed no documented review to monitor for problems.
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: Item 1: Based on surveyor review of procedures and Gram stain worksheets and interview with the Laboratory Manager (Staff A), testing personnel did not adhere to the laboratory's quality control policies for daily Gram stain testing during three of twelve months in 2023. Findings include: 1. Review of the 'Gram Stain Procedure' showed the laboratory required quality control testing at least each day of testing for infrequent users (reading less than one Gram stain per shift). 2. Review of the Gram stain worksheets from January through December 2023 showed personnel performed patient testing without performance of quality control on March 15, May 6, and June 18, 2023. 3. Interview with Staff A on February 19, 2024, at 3:30 PM confirmed the worksheets did not show personnel performed quality control testing each day they performed patient testing. Item 2: Based on surveyor review of maintenance logs and interview with the Laboratory Manager (Staff A), testing personnel did not document all required weekly or monthly maintenance in 2023 for five of ten analyzers reviewed. Findings include: 1. Review of maintenance logs for the following five analyzers showed personnel did not document all semi-periodic maintenance as required: Access (2 analyzers). Testing personnel did not document one of four weeks of weekly maintenance on both analyzers in December 2023 and January 2024. Personnel also did not document weekly maintenance in week 2 on analyzer 2 in August 2023. ACT5: Testing personnel did not document monthly maintenance (print reagent log and daily checks from analyzer) from January through October 2023 except for August. The logs showed use of the analyzer was discontinued in October 2023. DXH690: Testing personnel did not document monthly maintenance in October or December 2023. DXH 600: Testing personnel did not document monthly maintenance in seven of twelve months in 2023. Personnel documented monthly maintenance in February, March, April, May, and October 2023. 2. Interview with Staff A on February 20, 2024, at 2:30 PM confirmed testing personnel had not documented all maintenance performed as required.