Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0398014	11/04/2020
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of quality assurance records and interview with the laboratory manager, the laboratory did not perform twice-annual accuracy verification in 2019 and 2020 for the Potassium Hydroxide (KOH) test for dermatology samples. Findings include: 1. Review of quality assurance records showed no evidence the laboratory performed accuracy verification for KOH testing of dermatology samples in 2019 or 2020. 2. Interview with the laboratory manager, staff A, on November 4, 2020 at 9:30 AM confirmed the laboratory did not complete twice-annual accuracy verification of the KOH test for dermatology samples in 2019 or 2020. This is a repeat deficiency previously cited on May 21, 2008 and June 28, 2012.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of maintenance logs for the Hematek 3000 stainer and interview with the laboratory manager, the laboratory did not document routine weekly cleaning and pump tubing replacement as required in 2019 and 2020. Findings include: 1. Review of the October 2019 through October 2020 Hematek 3000 stainer

	maintenance logs showed weekly cleaning of the drain troughs is required. The logs show the laboratory documented this cleaning daily from January 1 through January 9 and January 11, 2020; the laboratory did not document any other weekly cleaning. The logs also showed the following maintenance was required: After three stain packs have been used - replace pump tubing, and after ten stain packs have been used, replace underplaten tubing. Review of the logs from July 2019 through October 2020 showed the laboratory did not document replacement of the tubing. 2. Interview with the laboratory manager, staff A, on November 3, 2020 at 2:15 PM confirmed the laboratory did not document the required cleaning and maintenance for the Hematek 3000 stainer.
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 laboratory records and procedures, and interview with the laboratory manager, the laboratory did not calibrate the fibrinogen test every six months in 2019 and 2020 as required by their procedures. Findings include: 1. Review of calibration records for the ACL Top coagulation analyzer show the laboratory calibrated the fibrinogen test on January 19, 2019 and February 19, 2020. 2. Review of the laboratory procedure, "Fibrinogen - ACL Top", COAG 201, showed the calibration section of the procedure required calibration every six months. 3. Interview with the laboratory manager, staff A, on November 4, 2020 at 10:30 AM confirmed the laboratory did not calibrate the fibrinogen assay every six months in 2019 and 2020 as required.