Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0398014	06/30/2022
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation of the chemistry freezer, review of the manufacturer's requirements and chemistry freezer temperature log, and interview with the general supervisor, the laboratory did not define an acceptable temperature range that was consistent with the manufacturer's acceptable range for the Bio-Rad chemistry quality control material stored in the freezer. Findings include: 1. Review of the manufacturer's package requirements for the Bio-Rad chemistry quality control showed the manufacturer's required storage at -20 to -70 Celsius (C). 2. Observation of BioRad chemistry quality control in the chemistry freezer on June 30, 2022 at 10: 13 AM showed the manufacturer required storage at -20 to -70 Celsius (C). 3. Review of the temperature logs for 2021 showed the defined acceptable temperature range for the chemistry freezer was -18 to -25 C. Forty-eight of three hundred sixty-five days showed recorded temperatures were warmer than -20 C. 4. Interview with the general supervisor on June 30, 2022 at 10:25 AM confirmed the laboratory's acceptable range for the chemistry freezer was not consistent with the manufacturer's acceptable range for the Bio-Rad chemistry quality control material stored. This is a repeat deficiency from April 30, 2014.
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: Item 1: Based on surveyor review of maintenance logs for the Hematek 3000 slide stainer and interview with the general supervisor, the laboratory did not document routine weekly maintenance for three of fifty-two weeks in 2021. Findings include: 1. Review of "Hematek 3000 Slide Stainer Maintenance" log showed weekly cleaning of the drain troughs is required. Further review showed the laboratory did not document the weekly maintenance for three of fifty-two weeks in 2021. 2. Interview with the general supervisor on Jun 29, 2022 at 1:52 PM confirmed the laboratory did not document routine weekly maintenance on the Hematek 3000 slide stainer for three of fifty-two weeks in 2021. Item 2: Based on surveyor review of maintenance logs for the BioFire Film Array stainer and interview with the general supervisor, the laboratory did not document routine weekly maintenance for three of thirty-nine weeks between April 2021 and February 2022. Findings include: 1. Review of "BioFire FilmArray Preventative Maintenance Record" showed weekly cleaning and restart of the analyzer is required. Further review showed the laboratory did not document the weekly maintenance for three of thirty-nine weeks between April 2021 and February 2022. 2. Interview with the general supervisor on Jun 29, 2022 at 2:05 PM confirmed the laboratory did not document routine weekly maintenance on the BioFire FilmArray for three of thirty-nine weeks between April 2021 and February 2022. This is a repeat deficiency from November 4, 2020.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of laboratory procedures and blood bank temperature logs and interview with the general supervisor, testing personnel did not follow the procedure to perform and document temperature checks for the Grifols gel card incubator for 635 of 635 days between October 6, 2020 and June 29, 2022. Findings include: 1. Review of the "Blood Bank Quality Assurance" procedure revealed "heating blocks must have temperature checks performed every day". Further review revealed testing personnel must "record on the temp log". 2. Review of the "Blood Bank Daily Checks" log showed a blood bank dry block range of 36-38 Celsius (C). Further review showed no documentation on the log for the blood bank dry block temperature. 3. Interview with the general supervisor on June 29, 2022 at 11: 55 AM confirmed testing personnel did not follow the procedure to perform and document temperature checks for the Grifols gel card incubator for 635 of 635 days between October 6, 2020 and June 29, 2022. Item 2 Based on surveyor review of patient records, blood bank temperature logs and laboratory procedures and interview with the general supervisor, testing personnel did not follow the procedure to perform and document temperature checks on the water bath used to thaw fresh frozen plasma

	for transfusion for one of one patients. Findings include: 1. Review of transfusion records showed patient 1 received thawed fresh frozen plasma on October 27, 2021. 2. Review of temperature logs in the laboratory showed no log in place to track the temperature of the water bath used to thaw fresh frozen plasma. 3. Review of the "Blood Bank Quality Assurance" procedure revealed "water baths must have temperature checks performed every day". Further review revealed testing personnel must "record in the temperature log". 4. Interview with the general supervisor on June 30, 2022 at 2:38 PM confirmed testing personnel did not follow the procedure to perform and document temperature checks on the water bath used to thaw fresh frozen plasma for transfusion for one of one patients. Item 3: Based on surveyor review of laboratory procedures and centrifuge logs and interview with the general supervisor, testing personnel did not follow the procedure to perform platelet-poor plasma checks on the StatSpin Express centrifuges every six months as required for one of two checks in 2021. Findings include: 1. Review of the "Platelet Poor Plasma" procedure revealed "five samples per centrifuge are required to be tested every six months". 2. Review of the "Centrifuge Checks" log showed the platelet-poor plasma checks were performed on May 15, 2021 and June 14, 2022. Further review showed no documentation of additional platelet-poor plasma checks due November 2021. 3. Interview with the general supervisor on June 30, 2022 at 1:48 PM confirmed testing personnel did not follow the procedure to perform platelet-poor plasma checks on the StatSpin Express centrifuges every six month as required for one of two checks in 2021.