Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2264430	05/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Thedacare Medical Center-Orthopedic Spine And Pain	2400 E Capitol Dr, Appleton, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with a technical supervisor, staff A, the laboratory director, or a qualified designee, did not attest to the routine integration of the immunohematology PT samples into the patient workload using the laboratory's routine methods for two of two immunohematology events in 2022 and 2023. Findings include: 1. Review of the API immunohematology PT records showed staff A signed the immunohematology attestation statements as the designee. Further review showed the laboratory director, who is the immunohematology technical supervisor, did not sign two of two immunohematology attestation statements in 2022 and 2023. 2. Interview with staff A on May 23, 2023, at 9:20 AM confirmed the laboratory director, or a qualified designee, did not attest to the routine integration of the immunohematology PT samples into the patient workload using the laboratory's routine methods in 2022 and 2023.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical supervisor, staff A, the laboratory did not retain the lot and expiration date for the hematology reagent stains used for manual differentials on the Hematek 3000 slide stainer for ten of ten months reviewed in 2022 and 2023. Findings include: 1. Review of the hematology maintenance log showed no documentation of hematology stain lot or expiration date information from July 22, 2023, through May 24, 2023. 2. Interview with the staff A on May 24, 2023, at 11:36 AM confirmed the laboratory did not retain the lot and expiration dates from the hematology stain used for manual differentials.