

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0992761	<b>(X3) Date Survey Completed</b>  04/30/2024
<b>Name of Provider or Supplier</b>  Thedacare Physicians Oshkosh	<b>Street Address, City, State</b>  600 N Westhaven Dr, Oshkosh, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, observation of hematology quality control (QC) material and interview with testing personnel, staff A, and technical consultant, testing personnel did not label three of three opened QC vials with the opened date and open expiration date. Findings include: 1. Review of the "DxH 520 Quality Control" procedure stated under the "Quality Control" header "Open stability: 16 days". 2. Observation of the hematology QC in the laboratory refrigerator on April 30, 2024, at 12:15 PM revealed three vials of hematology quality control, Lot# 362415811, 362415812, and 362415813. Further observation of the vials showed no opened date and no revised expiration date on the vials. 3. Interview with staff on April 30, 2024, at 12: 20 PM confirmed the hematology QC expiration date changes when the vials are opened. Interview with the technical consultant on April 30, 2024, at 12:20 PM confirmed testing personnel did not label the QC vials with the opened date and expiration date after they were opened.</p>