

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2264430	(X3) Date Survey Completed 08/27/2024
Name of Provider or Supplier Thedacare Medical Center-Orthopedic Spine And Pain	Street Address, City, State 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, maintenance logs and instrument operator's manual and interview with a technical consultant, staff A, the maintenance listed in the procedure did not include all maintenance listed on the logs and in the manufacturer's operator's manual for one of two new analyzers reviewed. Findings include: 1. Review of the "Routine Operation and Maintenance-DxU/IRIS (Arkray and iQ)" procedure stated maintenance as follows: 1. Daily a. Clean instrument surfaces, sampler and load/unload stations i. Diluted Iris cleaner (1:10) or alcohol</p>

pads followed by Di water, then dry. b. Clean strip water box with DI, then dry. 2. Every 3 days: (Monday and Thursdays) a. Clean strip feeder and strip stopper. DO NOT use canned air. b. Clean introduction tray i. Diluted Iris cleaner (1:10) or alcohol pads followed by Di water, then dry. 3. Weekly a. Clean transport tray i. Diluted Iris cleaner (1:10) or alcohol pads followed by Di water, then dry. b. Clean S. G. cell i. Diluted Iris cleaner (1:10) or alcohol pads followed by Di water, then dry. 4. Monthly a. Clean iQ sample probe bath i. Using DI water on a cotton swab, wipe residue away from the center outward. b. Perform calibration" 2. Review of the maintenance log showed the maintenance tasks above with additional tasks to be performed to include: "Monthly: Clean nozzle and adapter (iQ), Replace Lamina (filter every other), Replace wash solution filter and Clean air filter. As needed: Replace white plate, replace drain valve, check measurement and replace printer paper." 3. Review of the DxU/Iris operator's manual showed the above tasks but did not reference Lamina replacement. 4. Interview with staff A on August 27, 2024, at 8:05 AM confirmed the maintenance listed in the "Routine Operation and Maintenance-DxU/IRIS (Arkay and iQ) procedure did not include all maintenance tasks to be performed.