

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0394290	(X3) Date Survey Completed 11/01/2022
Name of Provider or Supplier Hudson Physicians Inc, Sc	Street Address, City, State 2651 Hillcrest Drive, Hudson, 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 survey review of laboratory procedures and interview with the technical consultant, the chemistry procedures did not include reference intervals for testing performed on the Ortho Diagnostics Vitros 350 chemistry analyzer. Findings include: 1. Review of the laboratory procedures showed no evidence the laboratory included reference intervals for testing performed on the Ortho Diagnostics Vitros 350 chemistry analyzer in their procedures. 2. Interview with the technical consultant on</p>

November 1, 2022, at 12:35 PM confirmed the chemistry procedures did not include reference intervals for testing performed on the Ortho Diagnostics Vitros 350 chemistry analyzer.