

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0394290	(X3) Date Survey Completed 04/28/2021
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory director, the laboratory director did not review the performance specification verification records on the Streck Mini-Cube erythrocyte sedimentation rate (ESR) analyzer prior to reporting patient results. Findings include: 1. Review of the "Certificate of Training" for the Streck Mini-Cube ESR analyzer showed the laboratory started reporting patient results on October 7, 2020. 2. Review of the "Correlation Approval Form" for the Streck Mini-Cube ESR analyzer showed the laboratory director reviewed and accepted the performance specification records on October 16, 2020. 3. Interview with the laboratory director on April 28, 2021 at 11:35 AM confirmed the laboratory director did not review and accept the performance specification records for the Streck Mini-Cube ESR analyzer prior to reporting patient results.</p>