Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0394290	07/15/2026
Name of Provider or Supplier	**Street Address, City, State**	
Hudson Physicians Inc, Sc	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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing records and laboratory records and interview with the laboratory manager (Staff B), the laboratory did not verify the accuracy twice annually of three of the four tests included in the Cepheid GeneXpert SARS-CoV-2, influenza A, influenza B, RSV (SARS CoV 2, Flu, RSV) test cartridge. Findings include: 1. Review of proficiency testing records from the Wisconsin State Laboratory of Hygiene (WSLH) showed the laboratory enrolled in the WSLH SARS /Viral Molecular (CM) program which includes SARS-CoV-2, influenza A, influenza B, and RSV. Review of results from the CM program showed the laboratory reported and WSLH graded results from only the SARS-CoV-2 test. 2. Review of PT records from API showed no records of evaluation of influenza or RSV testing. 3. Review of other laboratory records showed no twice annual evaluation of accuracy for the influenza A, influenza B, or RSV testing performed with the Cepheid GeneXpert. 4. Interview with Staff A on July 15, 2026, at 12:45 PM confirmed the laboratory did not evaluate the accuracy of their Cepheid GeneXpert testing of influenza A or B and RSV tests twice annually.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials

	using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on surveyor review of a individualized quality control plan (IQCP) and interview with the laboratory director (Staff A), the laboratory did not define the number, type and frequency of external control materials in their IQCP for the Cepheid GeneXpert for six of the six cartridge types performed using the analyzer. Findings include: 1. Review of the 'IQCP for Cepheid GeneXpert Testing' showed the IQCP applied to six different test cartridges: Group A Streptococcus (Strep A), Four in One SARS, influenzae, and respiratory syncytial virus (SARS CoV2 / Flu / RSV), Multiplex Vaginal Panel (MVP), Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) (GC/Chlamydia), Clostridioides difficile & the epidemic 027 strain (C. difficile Epi), and Group B Streptococcus (GBS). Further review of the IQCP showed the IQCP did not define the number, type and frequency of testing control materials for each test cartridge. 2. Interview with Staff A on July 15, 2026, at 1:10 PM confirmed the IQCP did not identify the number, type, and frequency required for each test included in the IQCP.