Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D2325966	02/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
Delaware Pcr Partner	700 W Lea Blvd Ste 104, Wilmington, DE	

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
D0000	An Initial Survey was conducted on February 26, 2026 at approximately 9:00 AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation, facility document review, and interview, the facility failed to establish and verify performance specifications for a QuantStudio3 (a laboratory test system designed for speed and ease of use) test system for 1 of 2 instruments in use. Findings included: During the laboratory tour and concurrent interview on 02/26/2026 at 9:30 AM, two QuantStudio3 instruments were observed in the laboratory. Technical Supervisor (TS) #1 stated that both instruments were currently used for patient testing. A facility document titled, "[The facility's name] [a brand of test name] UTI [urinary tract infection]-Wound PCR [polymerase chain reaction; an in vitro diagnostic test developed for specific detection of urinary and wound pathogens] Panels Validation Report," signed by the Laboratory Director (LD) and TS #1 on 08

	/28/2025, revealed the laboratory performed a validation of the analytical performance specifications of the assay on a QuantSudio3 with the serial number 272312183, which included the following parameters: -Analytical Sensitivity (LOD) -Clinical Evaluation: Analytical Accuracy -Precision/Reproducibility -Stability -Interference -Specificity -Carry Over -Reportable Range -Reference Range The facility's preventive "Quantstudio 3 #2 Maintenance Log" documents revealed a QuantStudio3 testing instrument with the serial number 272312179 was used for testing of patient samples starting in September 2025. During an interview on 02/26/2026 at 1:05 PM, TS #1 stated they did not have any documentation a validation of analytical performance specifications was completed by the laboratory on the QuantStudio3 testing instrument with the serial number 272312179 when it was initially put into use. During an interview on 02/26/2026 at 1:15 PM, TS #1 stated that the validation of analytical performance specifications was only performed on the QuantStudio3 testing instrument with the serial number 272312183.