Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2133323	05/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Greater Pittsburgh Surgery, Llc	1675 Route 51, Jefferson Hills, PA	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals, lack of documentation, and interview with the Clinical Manager (CM) and Facility Administrator (FA), the laboratory failed to establish a competency assessment procedure to assess 3 of 3 Testing personnel (TP), and 1of 1 General Supervisor for their supervisory responsibilities from 07/22/2024 to the day of survey. Findings Include: 1. On the day of survey, 5/14/2025, at 1:30 pm, the laboratory could not provide a competency assessment procedure to assess the competency for 3 of 3 TP (CMS 209 Personnel #1, #2, #3) and 1 of 1 GS (CMS 209 personnel #2) from 7/22/2024 to 5/14/2025. 2. The FA confirmed the findings above on 5/14/2025, at 1:30 pm.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Clinical Manager (CM), the laboratory failed to verify the performance specifications for hematology testing analyzed on 1 of 1 GEM Hemochron 100 prior to reporting patient test results from 7 /22/24 to the date of the survey. 1. On the day of the survey, 05/14/2025 at 1:30 am, the laboratory failed to provide documentation for the verification of performance specifications for precision, accuracy, reportable range, and reference intervals/range for the following analytes tested on 1of 1 GEM Hemochron 100 before reporting patient results from 7/22/2024 to 05/14/2025: - Activated Clotting Time (ACT) 2. The laboratory could not provide a procedure for the establishment and verification of performance of new instruments, analytes or methodology. 3. The laboratory performed 100 hematology tests in 2024 (CMS 116 estimated annual volume) 4. The CM confirmed the findings above on 05/14/2025 at 01:30 pm.