Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D1086909	03/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cadia Rehabilitation Pike Creek	3540 Three Little Bakers Blvd, 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	A recertification survey was conducted on March 7, 2023 at approximately 10:00 am at Cadia Rehabilitation Pike Creek. The laboratory was surveyed according to 42 CFR part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Specific deficiencies are as follows:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: document review and interview. The laboratory failed to review Proficiency Testing (PT), provide an attestation page, or have all testing personnel participate in the PTs as required. 1. At approximately 10:38 am on March 7, 2023 during document review it was noted that the laboratory failed to include attestation pages on 6 of 6 PTs; results were not reviewed by the Laboratory Director (LD), and the same TP completed all PTs that were performed. 2. During the interview, the RD confirmed that there were no attestation pages signed by the TP or LD as required, and only one TP of 20 participated in the PTs. 3. Also during the interview the RD confirmed that the LD failed to review 6 of 6 PT results. 4.. At the end of the interview at approximately 11:25 am, no attestation pages, evidence of any otherTP performing PTs, or evidence of LD review were provided.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: documen review and interview. The laboratory failed to review temperature logs as required. 1. During document review at approximately 11:10 am on March 7, 2023 the laboratory could not provide evidence of LD review of 3 of 3 temperature logs. 2. However, during document reveiw, under "Quality Assessment and Assurance" in the "Individulized Quality Control Plan for iSTAT tesing system" the document states, "2. Inspection of refrigerator temperature records", but there was no evidence that it was performed. 2. The RD confirmed during interview that the LD did not review temperature logs for temperature excursions or to ensure temperatures were being taken where test reagents were being stored. 3. At the end of the survey at approximately 11:25 am no evidence of temperature log review was provided as required, or as stated.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: document reviewand interview. The laboratory failed to perform Competency Assessment (CA) that included the six required elements for Testing Personnel. 1. At approximately 10:05 am on March 7, 2023 during document review, it was noted that the laboratory failed to provide Competency Assessment for 20 of 20 TP. All twenty TPs received initial and annual documented training, but none of the personnel were assessed at six months as required. 2. Additionally CA included 0 of the 6 required elements. 3. During document review of the "I-Stat Testing Competency" revised form provided on March 8, 2023, by the Respiratory Director (RD) included the six required elements of CA. 4. During interview, the RD confirmed that CA was performed initially and annually, but not at six months after the initial assessment as required and the six required elements were not included. 5. At the end of the survey at approximately 11:25 am on March 7, 2023 no six month CA was provided for any of the 20 testing personnel.