Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0282958	12/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Westchester Pediatric Llc	10300 Sunset Dr Ste 351, Miami, FL	

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 announced CLIA recertification survey was conducted at WESTCHESTER PEDIATRIC LLC from December 10, 2025, to December 16, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to have documentation that the Laboratory Director reviewed and approve the Medonic M Series Complete Blood Counter (CBC) analyzer verification of performance study conducted on 11/18/2025. Findings included: 1-Review of the Method Validation for the Medonic M series CBC analyzer study performed on 11/18/2025 revealed that the study failed to have the acceptance signature of the Laboratory Director. The laboratory tested 130 patients from 11/18/2025 to 12/10/2025. 2-Review of the Medonic M Series Complete Blood Counter (CBC) analyzer New Instrument Validation Instructions PN 203129A stated "All validation information must be signed by the Laboratory Director and must be saved for the life of the instrument but no less than 2 years." 3-During an interview on 12/10/2025 at approximately 11:41 AM, Testing Personnel #1 confirmed that the laboratory failed to have documentation that the Laboratory Director reviewed and approved the verification performance study for the hematology analyzer.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i)

	(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Consultant (TC) or a designee failed to do direct observation of Patient testing during competency evaluation for testing personnel (TP) on four (4) out five (5) in 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 12/01 /2025, revealed the following: Laboratory Director (LD) was also the Clinical Consultant (CC) and the Technical Consultant (TC) for the Hematology specialty. The laboratory had five testing personnel (TP1, TP2, TP3, TP4, and TP5). 2- Review of Quality Assurance Plan under the section for PERSONNEL TRAINING AND QUALIFICATIONS stated that "Laboratory Director will use personal observation to perform ongoing assessment of all employees of the laboratory to ensure competence of the job performance." 3- Review of competency assessments records titled "LABORATORY PERSONNEL EVALUATION" for TP2 (04/02/2025), TP3 (04/02 /2025), TP4 (04/02/2025), and TP5 (01/06/2025) revealed that direct observations of patient testing were observed and signed by TP1, who had no delegation letter to do personnel competency. 4- During interview on 12/10/2025 at approximately 1:26 PM, the LD/TC admitted that she did not performed direct observation of patient testing in 2025 during personnel competency evaluations for TP2, TP3, TP4 and TP5
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Consultant (TC) or a designee failed to do direct observation of performance of instrument and function check of the MEDONIC Hematology analyzer during competency evaluation for testing personnel (TP) on four (4) out five (5) in 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 12/01/2025, revealed the following: Laboratory Director (LD) was also the Clinical Consultant (CC) and the Technical Consultant (TC) for the Hematology specialty. The laboratory had five testing personnel (TP1, TP2, TP3, TP4, and TP5). 2- Review of Quality Assurance Plan under the section for PERSONNEL TRAINING AND QUALIFICATIONS stated that "Laboratory Director will use personal observation to perform ongoing assessment of all employees of the laboratory to ensure competence of the job performance. 3- Review of competency assessments records titled "LABORATORY PERSONNEL EVALUATION" for TP2 (04/02/2025), TP3 (04/02/2025), TP4 (04/02 /2025), and TP5 (01/06/2025), revealed that direct observations for the performance of instrument and function check of the MEDONIC Hematology analyzer were observed and signed by TP1, who had no delegation letter to do personnel competency. 4- During interview on 12/10/2025 at approximately 1:26 PM, the LD /TC admitted that she did not perform direct observation in 2025 for the performance of instrument and function check during personnel competency evaluations for TP2, TP3, TP4 and TP5.