Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0282958	05/10/2018
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
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory manager, laboratory failed to follow manufacturer's instructions to check and record quality controls for blood glucose test using TRUEresult blood glucose monitoring system. The findings include: On 5/10/18 at 11:30 AM, surveyor observed that TRUEresult blood glucose monitoring system did not have quality control materials to perform control tests. Record review from June 2016 to May 10, 2018 showed no quality control records for blood glucose test as explained in manufacturer's instructions for TRUEresult blood glucose monitoring system. On 5/10/18 at 2:45 PM, laboratory manager confirmed that laboratory did not follow the manufacturer's instructions and did not test the quality control materials for glucose test for TRUEresult blood glucose monitoring system.

D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, laboratory had 1- Incomplete attestation statements. 2- Incomplete yearly competency evaluation forms. 3- No quality control check and no records for glucose waived test. The findings include: On 5/10/18 at 2:30PM A- Proficiency test records from 2016 to May 10, 2018 showed that proficiency test attestation statements from 2016, 1st event to 2018, 1st event were reviewed and signed by the director but it did not specify sample set(s) tested. B- Yearly competency evaluation questionnaire forms were signed and dated without answering Y for YES or N for NO for meeting the criteria of evaluations for six of six testing personnel. On 5/10/18 at 11:30 AM C- Surveyor observed that TRUEresult blood glucose monitoring system did not have quality control materials to perform control tests. Record review from June 2016 to May 10, 2018 showed no quality control records for blood glucose test as explained in manufacturer's instructions for TRUEresult blood glucose monitoring system. I- During an interview on 5/10/18 at 2:45 PM, laboratory manager confirmed findings A, B and C, and that there was no documentation to indicate any quality assurance program, and there was no corrective action taken.