

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0282958	(X3) Date Survey Completed 01/30/2020
Name of Provider or Supplier Westchester Pediatric Llc	Street Address, City, State 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 Pediatrics LLC on 01/30/2020. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6064 - Testing Personnel Qualifications - 493.1423(a)
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Lab Manager the laboratory failed to monitor quality control (QC) over time for shifts and trends for 2 (2018-2020) out of 2 years reviewed. Findings Included: Review of QC records revealed only daily QC. There was no documentation of monitoring the shifts and trends of the QC over time. Interview on 01/30/20 at 12:07 PM the Lab Manager confirmed that they did not have a system in place to monitor shifts and trends of the QC over time.</p>
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on record review and interview with the Lab Manager the laboratory failed to verify the education of 1(#E) out of 5 (#A-E) Testing Personnel (See D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on record review and interview with the Lab Manager the laboratory failed to verify the education of 1(#E) out of 5 (#A-E) Testing Personnel. Findings Included: Review of the CMS 209 signed and dated by the Laboratory Director on 01/29/2020 revealed that there were 5 Testing Personnel. Review of employee files revealed only a Medical Assistant certificate in Testing Personnel #E's file. There were no diplomas for review. Interview on 01/30/20 at 12:00 PM the Lab Manager confirmed that the certificate was all that they had for review.