

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0173708	(X3) Date Survey Completed 01/16/2018
Name of Provider or Supplier Westside Pediatric Group Llp	Street Address, City, State 497 Beahan Road, Rochester, NY	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's Quality Control (QC) waived testing records and an interview with the laboratory director, the laboratory failed to follow the Magellan manufacturer's required instructions for quality control and test performance requirements for the ESA LeadCare II. FINDINGS: The laboratory director confirmed on 01/16/2018 at 1:30 PM, that the external controls for the ESA LeadCare II was performed however, the laboratory tested and reported patient samples for lead screening on the Magellan ESA LeadCare II, when the level two control was out of range for the following lots: a. QC lot# 1609P expiration date 03/29/18 was reported as 21.4 manufacturer's range was 23.7-31.7. Approximately 45 patients were tested and results reported from 01/24/17 through 03/06/17. b. QC lot # 1610M expiration date 04/05/18 was reported as 14.9 manufacturer's range was 27.0-34.0. from 04/12/17 through 05/17/17. Approximately 42 patients were tested and results were reported from 04/12/17 through 05/17/17.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

	<p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Assessment (QA) policies /procedures and an interview with the laboratory director, the laboratory failed to follow the laboratory's written QA policy and perform an annual QA review for all phases of hematology testing for the calendar year 2017.</p>
<p>D5437</p>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the calibration records for the Emerald analyzer and confirmed in an interview with the laboratory director, the laboratory failed to calibrate the hematology analyzer at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzer. FINDINGS: 1. The laboratory director confirmed on 01/16/2018 at approximately 2:00 PM, that the Abbott Emerald hematology analyzer was out of calibration from 11/02/2017 through 01/09/2018. 2. The laboratory's calibration policy and the manufacturer of the hematology analyzer require calibration every six months. 3. The calibration documentation for the last recorded calibration on 05/02/2017 was reviewed at survey. 4. Approximately 100 patient specimens were tested and reported for CBC test from 11/02/2017 through 01/09/2018, when analyzer was out of calibration.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor's findings and interview with the laboratory director, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the: 1. QC program for hematology testing was maintained, refer to D6020; 2. QA reviews were performed annually, refer to D6021; 3. new testing person hired on 03/27/17 had the appropriate education, refer to D6029.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on surveyor's review of the hematology QC records and confirmed in an interview with the laboratory director, the laboratory director failed to ensure that the QC program for hematology testing was maintained to assure quality of laboratory services. Refer to: D5437.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on surveyor's review of the Quality Assessment (QA) policy and confirmed in an interview with the laboratory director, the laboratory director failed to ensure that the general laboratory systems QA reviews were performed annually, as required by their QA policy for the calendar year 2017. Refer to D5291.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on surveyor's review of the testing personnel education records, training and competency evaluation records and confirmed in an interview with the laboratory director, the laboratory director failed to ensure that the new testing person hired on 03/27/17 had the appropriate education, prior to patient testing.