

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0706718	<b>(X3) Date Survey Completed</b>  01/17/2018
<b>Name of Provider or Supplier</b>  Buffalo Pediatric Associates Llp	<b>Street Address, City, State</b>  1360 North Forest Road, Suite 101, Williamsville, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<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 office manager, the laboratory failed to follow the manufacturer's requirements for quality control and test performance requirements for the Magellan ESA LeadCare II. FINDINGS: 1. The office manager confirmed on 01/17/2018 at 2:30 PM, that the external controls for the ESA LeadCare II were performed. However, the laboratory tested and reported patient samples for lead screening on the Magellan ESA LeadCare II when level 1 and 2 controls were out of range for the following lots: a. QC lot# 1507 expiration date 01/27/17 Level 1 control was reported as 14.8 and the manufacturer's range was 3.3-9.3. Approximately 43 patients were tested and lead results were reported from 06/28/16 through 09/06/16. b. QC lot # 1609 expiration date 03/06/18 Level 2 control was reported as 26.9 and the manufacturer's range was 27.8-36.0. Approximately 48 patients were tested and lead results were reported from 06/30/17 through 10/02/17. c. the laboratory did not retain the control assay sheets and did not record control results for the following lots: 1604 expiration date 10-26-17; 1603 expiration date 9-3-17; 1504 expiration date 10-23-17 and 1508 expiration date 2-12-17. Approximately 111 patients were tested and lead results were reported from 1/4/16 through 5/31/16.</p>