

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0979114	(X3) Date Survey Completed 05/22/2019
Name of Provider or Supplier Pediatrics West, Pc	Street Address, City, State 120 Boston Road, Groton, MA	
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	A CLIA recertification survey was conducted for the Pediatrics West, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5893	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c)</p> <p>(b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview the laboratory failed to document all postanalytic systems quality assessment activities as evidenced by the following: a) The laboratory's policy for post analytic quality assessment is to perform a review of laboratory results entered into the patient's electronic medical record (EMR) on a monthly basis. b) A review of the laboratory's post analytic quality assessment activities revealed that only February 2019 review was available. c) Interview with the laboratory technologist on 5/22/19 at 11:50 AM confirmed that post analytic quality assessment record reviews were being performed but not documented. .</p>
D6049	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant failed to document a review of proficiency testing records as evidenced by the following: a) A review of proficiency testing records for calendar years 2017, 2018, and 2019 revealed that the technical consultant had not documented a review of proficiency testing results. b) The technical consultant confirmed in an interview on 5/22/19 at 9:00 AM that proficiency testing results were being reviewed by him but was not documenting the reviews.