

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0383015	(X3) Date Survey Completed 11/30/2018
Name of Provider or Supplier Newton Clinic Pc	Street Address, City, State 300 N Fourth Avenue E, Newton, IA	
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
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Ace Alera chemistry analyzer quality control (QC) records, the Ace Alera QC package inserts, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 11/29 /2018, the laboratory failed to review the effectiveness of its system for ensuring package insert data is entered correctly into the laboratory information system (LIS) program and maintained throughout the time period that the QC lot numbers are in use for 21 out of 21 analytes, two out of two lot numbers, and 71 out of 97 days of patient testing from 07/13/2018- 11/28/2018 . Refer to D5469 for findings.</p>