

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1080594	(X3) Date Survey Completed 10/01/2019
Name of Provider or Supplier Acl Kenosha 15th Place	Street Address, City, State 2707 15th Pl, Kenosha, WI	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing records from 2018 and 2019 and interview with the technical consultant, the laboratory director or testing personnel did not attest to the routine integration of proficiency testing into the patient workload for seven events. Findings include: 1. Review of proficiency testing records from 2018 and 2019 showed all testing personnel or the laboratory director did not sign attestation statements for seven events. Not all testing personnel signed the following attestation statements: Hematology 2018-1, Urinalysis 2018-1, Hematology 2018-2, Urinalysis 2018-2, Chemistry 2018-2, Hematology 2019-1 The laboratory director did not sign the attestation statement for the Hematology 2018-3 event. 2. Interview with the technical consultant, October 1, 2019, at 9:25 AM, confirmed the testing personnel or the laboratory director did not sign the attestation statements for seven proficiency testing events.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of maintenance worksheets and interview with the technical consultant, maintenance on the PocH-100i hematology analyzer was not being documented with the frequency specified by the manufacturer. Findings include: 1. Surveyor review of the PocH-100i maintenance worksheet showed bi-weekly maintenance was not documented from April 30, 2019 to June 13, 2019. 2. Surveyor review of the PocH-100i maintenance worksheet showed quarterly maintenance was not documented between August to November 2018, or January to March 2019. 3. Interview with the current technical consultant, October 1, 2019, 10:19 AM, confirmed that bi-weekly and quarterly maintenance were not documented.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on surveyor review of competency assessments, quality control, maintenance and temperature records, and interview with the technical consultant, the technical consultants did not review records and evaluate competency to maintain oversight of the laboratory from 2017 to 2019. Findings include: 1. Review of the competency assessment records revealed no records were available for 2017. Competency records for Staff A in 2018 showed a technical consultant did not sign the evaluation and evaluation did not include any competency assessment for the PocH-100i hematology analyzer. 2. Review of the quality control records from 2018 and 2019 showed no evidence of review by a technical consultant. 3. Review of the maintenance records for the PocH-100i hematology analyzer from 2018 and 2019 showed no evidence of review by a technical consultant. 4. Review of temperature records from 2019 showed no evidence of review by a technical consultant. 5. Interview with the current technical consultant, October 1, 2019, at 9:00 AM, confirmed that a technical consultant did not ensure competency assessment was complete and available. Further interview with the technical consultant, October 1, 2019, at 10:19 AM, confirmed that a technical consultant had not reviewed quality control, maintenance and temperature records to maintain oversight of the laboratory.