

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2095593	(X3) Date Survey Completed 06/12/2018
Name of Provider or Supplier Ip Burley 1	Street Address, City, State 1021 E Main St Ste A, Burley, ID	
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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the laboratory director and technical consultant, the laboratory failed to retain instrument data from the Beckman Coulter AU 480 chemistry analyzer and the Stago prothrombin time instrument for the American Proficiency Institute (API) events in 2017 and 2018. Findings: 1. An API record review revealed the laboratory failed to retain the AU480 chemistry analyzer data printouts for the API chemistry 2017 events 2 and 3 and 2018 events 1 and 2. 2. An API record review revealed the laboratory failed to retain the Stago prothrombin time instrument data printout for the API hematology 2018 event 1. 3. An interview on June 12, 2018 at 8:00 AM, with the laboratory director and technical consultant, confirmed the instrument printouts for proficiency testing in chemistry and prothrombin time were not retained with the proficiency testing records.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p>

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the laboratory director and technical consultant, the laboratory failed to establish and document a maintenance program for scheduled and unscheduled maintenance activities for the Beckman Coulter AU 480 chemistry analyzer, Stago prothrombin time instrument, and the Beckman Coulter AcT Diff 2 since the last survey on August 8, 2016. Findings: 1. A record review of the laboratory maintenance records, revealed the laboratory failed to document corrective actions when maintenance activities are performed on the analyzers for unscheduled repairs or maintenance activities since the last survey. 2. An interview on June 12, 2018 at 9:30 AM, with the laboratory director and technical consultant, confirmed the laboratory failed to document maintenance activities for the analyzers .

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on records review and an interview with the laboratory director and technical consultant, the laboratory failed to follow written procedures for identifying and correcting problems in the analytical system to include quality control procedures, equipment maintenance activities, and calibration activities since the last survey on August 8, 2016. Findings: 1. A record review of instrument calibrations from the Beckman Coulter AU480 revealed the instrument data was not available at the time of survey or reviewed during the calibration verification review process on May 2, 2018 and October 24, 2017. 2. A record review of maintenance and troubleshooting documentation, revealed the laboratory failed to establish a procedure for documenting unscheduled maintenance activities for the Beckman Coulter AU 480, Beckman Coulter AcT Diff 2, and the Stago prothrombin time instrument since the last survey. 3. A record review of quality control performed on the BD Affirm III for June 2018 revealed the laboratory testing personnel failed to document the correct control organism used for testing on the BD Affirm III instrument. 4. An interview on June 12, 2018 at 10:30 AM, with the laboratory director and technical consultant, confirmed the laboratory failed to establish and follow quality assessment activities for the laboratory.