

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1069945	(X3) Date Survey Completed 04/01/2019
Name of Provider or Supplier Intermountain Sunset Drawstation	Street Address, City, State 1739 West Sunset Blvd, St George, UT	
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
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on patient test logs review, lack of documentation and interview with staff, the laboratory failed to ensure the laboratory record system provided identification of the testing personnel for complete blood count testing. The laboratory performed approximately 3 to 5 complete blood counts per day. Findings include: 1. Patient testing logs reviewed provided a record of the tests the laboratory performed and included the hand written initials of the person performing the tests. 2. The laboratory lacked a translation to match the initials to the testing person. 3. In an interview conducted on 04/01/2019 at approximately 2:00 P.M., the technical consultant confirmed the laboratory no longer had a record to match signed initials to the person who performed complete blood count tests.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:

Based on Individualized Quality Control Plan (IQCP) procedure review, lack of documentation, and confirmation by the technical consultant, the director failed to document the laboratory followed their procedure to review the IQCP annually to verify the reduced frequency of quality control performance was sufficient and the reduced frequency did not adversely effect testing quality for 2 of 2 tests utilizing IQCP to perform quality control at a reduced frequency, ionized calcium and prothrombin time tests performed on the iSTAT instrument. The laboratory performed approximately 8 to 10 ionized calcium and 200 prothrombin time tests per year. Findings include: 1. The IQCP reviewed lacked documentation the director reviewed the IQCP against the quality assessment documentation to evaluate the plan's adequacy since approved in 2016. 2, In an interview with staff on 04/01/2019 at approximately 2:30 P.M., staff confirmed the IQCP had not been reviewed since it was implemented in 2016.