

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0871926	(X3) Date Survey Completed 03/29/2018
Name of Provider or Supplier Utah Cancer Specialists	Street Address, City, State 395 West Cougar Blvd, Suite 104, Provo, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing record review, lack of corrective actions, and interview with staff, the laboratory failed to establish written policies for the procedure the laboratory is to take when the laboratory fails to participate in hematology proficiency testing (PT) events for 1 of 6 complete blood count (CBC) testing events reviewed, (the 3rd API event of 2016). Findings include: 1. PT record review included documentation the laboratory failed to participate in CBC American Proficiency Institute (API) 3rd testing event of 2016. 2. PT records review failed to include corrective actions taken to provide assurance complete blood count testing produces accurate and reliable results at the same frequency the proficiency testing rotation provides when PT is not performed. The laboratory lacked an alternative procedure to document quality assurance performance. 3. In an interview with staff on 03/29/2018 at approximately 11:30 A.M. the laboratory technical consultant confirmed the laboratory did not have an alternative quality assessment procedure to follow when PT samples are not available to test and compare with participant summary results.</p>
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p>

This STANDARD is not met as evidenced by:

Based on temperature record review, complete blood count and i-stat reagent storage package storage instructions review, and interview with staff, the laboratory failed to document corrective actions taken when the laboratory control and reagent storage refrigerator exceeded the acceptable range for 6 days recorded from 12/20/2017 to 12/30/2017. Findings include: 1. Temperature records review included documentation the control and reagent storage refrigerator temperatures were recorded as: Date Temperature (C) 12/20/2017 31 12/21/2017 31 12/27/2017 26 12/28/2017 28 12/29/2017 27 12/30/2018 26 2. Complete Blood Count control package label and PT/INR (pro thrombin time/ international normalized ratio) i- STAT reagent and control packages stated the controls and reagent cartridges storage temperature ranges were from 2 to 8 degrees C. 3. In an interview with staff on 03/29/2018 at approximately 11:30 A.M. staff confirmed the reagents and controls were outside the acceptable limits for almost a week while the laboratory researched the problem. The laboratory did not have an alternative process for staff to follow for control and reagent storage when the storage refrigerator was inoperable.