Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0918709	03/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Utah Cancer Specialists - Bountiful	520 E Medical Dr #100, Bountiful, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on Coulter DXH 800 instrument maintenance records review, lack of documentation, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions to perform monthly maintenance for 4 of 24 months reviewed. The laboratory performed approximately 1000 complete blood counts per month. Findings include: 1. The laboratory used the manufacturer's instructions and preventive maintenance log sheet to record weekly and monthly maintenance for the Coulter DXH 800 complete blood count instrument. 2. The laboratory failed to document they performed monthly maintenance for the months of July, and October of 2016 and February and June of 2017. Monthly maintenance includes cleaning pneumatic supply module and all system filters. 3. In an interview on 03/01/2018 at approximately 12:15 P.M. the technical consultant confirmed the staff failed to record maintenance was performed with the frequency recommended by the manufacturer.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

	This STANDARD is not met as evidenced by: Based on proficiency testing record review, corrective action documentation, Centers for Medicare and Medicaid Services (CMS) proficiency testing summary report review, and interview with staff, the technical consultant failed to ensure the laboratory participated in the American Proficiency Institute (API) proficiency testing program commensurate with the services offered for 1 of 7 non waived tests performed, Prothrombin Time(PT) testing for 2 of 6 testing events reviewed. Findings include: 1. Proficiency testing records review failed to include documentation the laboratory participated in non-waived proficiency testing for PT testing for the 2nd and 3rd events of 2017. The proficiency testing records included documentation the laboratory reported results using a waived PT method for which the laboratory's reported results were not graded with the appropriate peer group. 2. The laboratory reviewed testing agency's graded results observing the laboratory's reported results failed versus the incorrectly reported method. They self graded their results against the correct method verifying that their results were with acceptable range of their API test method peers. 3. In an interview on 03/01/2018 at approximately 11:30 A.M., the technical consultant confirmed the laboratory reported PT results for a waived instrument. The consultant also confirmed the waived results were not reported to CMS for determination of compliance.