Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D1072872	05/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Utah Cancer Specialists	389 South 900 East, Suite 100, Salt Lake City, 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
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on monthly site visit quality assessment reports review, their individualized quality control plan (IQCP) review, and email interview with the technical consultant (TC), the laboraotry failed document they reviewed their individualized quality control plan for Prothrombin Time testing performed on the iSTAT instrument to determine the frequency of reduced quality control was adequate. Findings include: 1. Monthly site visit reports included a checklist for the reviewing quality control, proficiency testing, and patient test reports but failed to mention that the IQCP had been reviewed. 2. The IQCP reviewed failed to include the frequency or method the laboratory employed for IQCP review. 3. In an e-mail interview with the technical consultant on 05/28/2019 and 05/30/2019 the TC stated routine monthly site visit reports quality assessment was sufficient for monitoring the IQCP. The technical consultat failed to provide direct documentation the IQCP had been reviewed for needed changes to the plan since approval in 2016.