Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0960700	03/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Tanner Memorial Clinic	2121 N 1700 W, Layton, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation and confirmation by staff, the director failed to sign and date as approve the procedure manual for collecting, labeling, processing, reading and reporting histopathology tissue samples. Findings include: 1. The laboratory procedure manuals included 2 manuals for testing biopsy and Mohs micrographic surgery specimens. The director's signature was not present for the comprehensive manual as approval for the processes. The Mohs manual lacked the date the director approved the manual. 2. In an interview conducted on 03/28/2019 at approximately 11:00 A.M. staff confirmed the manuals were missing the signature for the comprehensive manual and dates of approval for both manuals.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: Based on patient test reports review, patient slide review, histpathology log book, and confirmation by staff, the laboratory failed to ensure the patient biopsy specimen slide identification correlated with the specimen results reported for biopsy specimen M18-1781. The laboratory reported approximately 5000 tests results per year. Findings include: 1. The patient test report reviewed for the specimen logged in to the laboratory on 07/25/2018 as M18-1781 included the slide reviewed was M18-1778. The slide for the specimen was labeled as M18-1781. 2. In an interview with staff on 03/28/2019 at approximately 12:00 Noon, staff confirmed the slide labeled with the patient's name and specimen log book number was not the slide number on the test report.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on patient test report review, lack of documentation and interview with staff, the laboratory failed to establish and follow an ongoing mechanism to monitor, assess and when indicated correct problems identified for patient test reports reviewed from March 2017 to March 2019. The laboratory performed approximately 5000 histopathology cases per year. Findings include: 1. The laboratory failed to establish a post analytic procedure for review of patient test reports to identify errors in the specimen identification. (See D5801) 2. In an interview conducted on 03/28/2019 at approximately 12:15 P.M. the laboratory staff stated the laboratory did not have a process to document a review of patient test reports was performed. The laboratory practice was to dictate results into a report form and electronically sign the dictated report. It could not be determined if the testing person reviewed the dictated report prior to release.