Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2121334	(X3) Date Survey Completed 03/26/2019
Name of Provider or Supplier Tanner Clinic - East Layton	**Street Address, City, State** 1750 E 3100 N, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and interview with the director, the laboratory procedure for Sulfosalicylic acid (SSA) protein precipitation failed to include qualify control procedures. The laboratory performed approximately 5 to 7 SSA protein precipitation procedures per month. Findings include: 1. The laboratory procedure manual reviewed failed to include a quality control process for SSA testing. 2. The laboratory lacked documentation SSA quality control was

	performed from 11/12/2017 to 03/26/2019. 3. In an interview on 03/26/2019 at approximately 5:30 P.M. the laboratory director confirmed the procedure lacked a quality control component.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of documentation and confirmation by the director, the laboratory failed to establish a maintenance protocol for microscope maintenance used for microscopic analysis of wet preparations, potassium hydroxide preparations, and skin scrapings. The laboratory performed approximately 30 microscopic analyses per year. Findings include: 1. The laboratory lacked a procedure for microscope instrument maintenance performance and documentation. 2. The laboratory failed to document microscope maintenance was performed in 2017 and 2018. 3. In an interview conducted on 03/26/2019 at approximately 6:00 P.M. the director confirmed the laboratory lacked a microscope maintenance procedure and lacked maintenance documentation for 2017 and 2018
D5787	TEST RECORDS CFR(s): 493.1283(a) 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). This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation and confirmation by the laboratory director, the laboratory failed to have a mechanism to identify the personnel performing proficiency testing for 12 of 12 American Proficiency Institute (API) testing events reviewed for Potassium Hydroxide, Wet Preparations, Skin scrapings, microscopic urinalysis, serum pregnancy, or complete blood count testing for tests performed from January 2017 to March 2019. Findings include: 1. Proficiency testing record review for these event's attestation statements had signatures that were unidentifiable. 2. In an interview conducted on 03/26/2019 at approximately 3:30 P.M. the director confirmed the laboratory did not have a signature translation sheet for testing personnel performing proficiency testing identification. Approximately 7 testing personnel performed proficiency tests.