Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0694743	01/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Joseph M Johnson	1675 N 200 W Ste 9c, 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
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 laboratory procedure manual review and interview with staff, the laboratory procedure manual failed to include the current reference for test performance for 2 of 3 procedures reviewed (urine culture and susceptibility). Findings include: 1. The laboratory procedure for performing urine culture and susceptibility testing review failed to include the literary reference for performing pediatric urine cultures using CLED agar for growth determination followed by susceptibility testing. 2. In an interview with staff on 01/24/2018 at approximately 2:00 P.M., staff confirmed they had changed procedures for urine cultures from a manufacturer's kit to using a single

	type of differential agar (CLED) to determine growth sufficient and for the formulary used for susceptibility testing.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on media control records review, lack of documentation, and confirmation by staff, the laboratory failed to check sterility for 1 of 3 culture media reviewed, sheep's blood agar (SBA) for quality control organism culture for 2 of 2 years of testing reviewed January 2016 to January 2018. The laboratory performed approximately 2 quality control cultures per month. 1. The laboratory failed to perform sterility checks with each new lot number of SBA agar. 2. Staff confirmed on 01//24/2018 at approximately 1:50 P.M., they did not record sterility checks for each new lot number or shipment of SBA agar received.