

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2119360	(X3) Date Survey Completed 08/13/2018
Name of Provider or Supplier Granger Summit Urology American Fork	Street Address, City, State 1159 E 200 N Ste #300, American Fork, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to ensure they verified the accuracy of semen analysis at least twice annually in 2017. The laboratory performed approximately 250 post vasectomy analysis per year for the presence or absence and motility of semen. Findings include: 1. The laboratory failed to document they checked post vasectomy semen analysis accuracy twice in 2017. 2. In an interview conducted on 08/13/2018 at approximately 10:00 A.M. staff stated they did not have documentation to verify sperm counts and motility testing accuracy at least twice annually in 2017.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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 and interview with staff, the procedures for microscopic urinalysis and post vasectomy semen analysis, failed to include pertinent literary references. The laboratory performed approximately 5,500 microscopic urinalysis and 225 post vasectomy semen analysis. Findings include: 1. The laboratory procedure for urinalysis stated 2 ml of urine were to be centrifuged at 3350-3400 rpm for 2 minutes, then examine microscopically at 40 hpf for the presence of red blood cells, white blood cells, crystals , casts, and epithelial cells. The procedure lacked a literary reference that included centrifuging 2 ml of urine at 3350 to 3400 rpm for 2 minutes and be able to identify the cellular components. 2. The laboratory procedure for post vasectomy semen analysis failed to include a literary reference to support the laboratory's 5 hour specimen viability from the time of collection to performing semen analysis for presence, absence, and motility. 3. In an interview conducted on 08/13/2018 at approximately 10:00 A.M. staff confirmed the laboratory procedures did not include literary references for using 2 ml of urine specimen analysis centrifuged at 3350 -3500 rpm for 2 minutes then analyzed for red blood cells, white blood cells, crystals , casts, and epithelial cells or for semen specimen viability from the time of collection to the time of analysis.