

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0929048	(X3) Date Survey Completed 02/11/2021
Name of Provider or Supplier St George Urology	Street Address, City, State 1490 E Foremaster Dr Ste 300, St George, 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 verify urinalysis test accuracy at least twice annually for 2 of 2 years of testing reviewed (February 2019 to February 2021). The laboratory performed approximately 3000 urinalyses per year. Findings include: 1. The laboratory lacked documentation microscopic urinalysis accuracy at least twice annually in 2019 and 2020. The laboratory lacked documentation for 1 of 2 accuracy checks in 2019 and 2020. 2. In an interview with the lead medical assistant on 02/11/2021 at approximately 1:30 P. M. the medical assistant confirmed microscopic urinalysis twice annual verification of test accuracy was not documented for 2019 and 2020.</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</p>

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, direct observation on 02/11/2021 at approximately 11:45 A.M., and interview with testing person 1 the procedure manual failed to include in the step by step process the amount of urine to be analyzed when performing a microscopic urine. The laboratory performed approximately 3000 urinalysis per year. Findings include: 1. Procedure manual review failed to include a standard amount of urine for test personnel to measure when decanting the urine specimen collected into the centrifuge tube for condensing the amount of dissolved materials microscopically. The urinalysis procedure did not include a literary reference for performing a microscopic urinalysis. 2. Direct observation of urine specimen testing on 02/11/2021 at approximately 11:45 A.M. staff poured approximately 1 to 2 milliliters (ml) of urine into a conical centrifuge tube. The tube capacity was approximately 12 ml. The remainder of the specimen was not used. This process was repeated for approximately 5 other specimens observed. 3. In an interview with the laboratory medical assistant on 02/11/2021 at approximately 1:15 P. M., the medical assistant confirmed the procedure did not include the amount of specimen preferred for a standardized method to perform microscopic urinalysis or a reference for the amount of urine to use for microscopic analysis prior to centrifugation.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on PSS 602 centrifuge operator's manual review, lack of documentation, and interview with staff, the laboratory failed to follow the manufacturer's instructions to calibrate the RPM output to the rotor speed knob at least once every six months for two years of testing reviewed (February 2019 to February 2021). The laboratory performed approximately 3000 tests per year. Findings include: 1. Operator's manual review on page 5 states that RPM calibration is to be performed at least once every 6 months. 2. The laboratory failed to document they calibrated PSS 602 centrifuge RPM with the instrument setting knob once every 6 months for 4 of 4 six month period between February 11, 2019 and February 11, 2021. 3. In an interview conducted on 02 /11/2021 at approximately 1:15 P.M. the lead Medical Assistant confirmed the lab did not calibrate the PSS 602 centrifuge between February 2019 and February 2021.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on lack of twice annual test verification, performing function checks at the frequency prescribed by the manufacturer, failure to ensure the laboratory establish and follow quality assurance programs, failure to evaluate testing personnel competency the director failed to provide overall management and direction for urinalysis and post vasectomy semen analysis testing from February 2019 to February 2021. (See D6022)

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on lack of twice annual urinalysis microscopic test accuracy documentation (See D5217), failure to calibrate the speed of the urinalysis centrifuge at least every 6 months (See D5429), lack of competency evaluations twice the first year of testing (See D6050); once per year after the first year of testing (See D6053), and failure to ensure testing personnel follow established laboratory procedures (See D6070), the laboratory director failed to monitor the overall operation and administration of the laboratory.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on personnel records review, lack of documentation, and interview with staff, the director/technical consultant failed to evaluate 3 of 3 testing personnel semi-annually their first year of testing in 2020. The number of tests each test person performed in 2019 was not determined. Findings include: 1. Personnel records review included 3 test people performing urinalysis and post vasectomy their first year of testing. 2. Personnel records review failed to include competency evaluations for test persons 2, 3, and 4 for 2020. 3. In an interview conducted on 02/11/ 2021 at approximately 1:15 P.M. the lead Medical Assistant stated. Test person 1 was the lead Medical Assistant in 2018. Since that time test person 1 had been on leave twice and as a result competency was not performed on the previous timetable.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on personnel records review, lack of documentation, and interview with staff, the director/technical consultant failed to evaluate 1 of 1 testing personnel annually in 2019. The number of tests performed in 2019 was not determined. Findings include: 1. Personnel records review included 1 test person performing urinalysis and post vasectomy after the first year of testing. 2. Personnel records review failed to include competency evaluations for test person 1 for 2019. 3. In an interview conducted on 02/11/2021 at approximately 1:15 P.M. the lead Medical Assistant stated. Test person 1 was the lead Medical Assistant in 2018. Since that time test person 1 had been on leave twice and competency was not performed on the previous timetable.

D6070

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on procedure manual review, post vasectomy test records review, lack of corrective action documentation, and interview with staff, the laboratory testing personnel failed to follow laboratory instructions to process post vasectomy specimens within 15 minutes of specimen receipt and failure to reject specimens that are received more than 2 hours after collection for 2 of approximately 50 specimens reviewed. Findings include: 1. Procedure manual review and post vasectomy work sheet review included the specimen rejection criteria of the time from collection to drop off was less than or equal to 2 hours, time from drop off to test performance was less than 15 minutes. 2. Post vasectomy test records review included documentation 2 of approximately 50 specimens reviewed from February 2019 to February 2021 were processed more than 30 minutes after being received by the laboratory (Specimen for patient number 61726 collected on 06/02/2020 at 10:15 A.M., dropped off at 10:40 AM. and tested at 11:35 A. M. and specimen for # 67054 collected on 02/10/2021 at 7:10 A.M. dropped off at 9:20 A.M. and tested at 10:45 A.M.. 3. The laboratory failed to record corrective actions taken for the deviation of hold times from the procedure and work sheet specified drop off and performance restrictions. 4. In an interview conducted on 02/11/2021 at approximately 1:30 P.M. the lead medical assistant stated the laboratory did not reject specimens performed more than 15 minutes after receipt nor were there corrective actions recorded when staff was not able to follow the laboratory director approved instructions for post vasectomy sperm presence and motility; or absence evaluation.