

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0524878	(X3) Date Survey Completed 11/14/2019
Name of Provider or Supplier Logan Urology Clinic	Street Address, City, State 550 E 1400 N Suite J, Logan, 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 microscopic urinalysis and post vasectomy testing at least twice annually from November 2017 to November 2019. The laboratory performed approximately 2 to 5 microscopic tests per month. Findings include: 1. The laboratory failed to document they verified microscopic urinalysis and post vasectomy semen analysis testing twice annually in 2018 and up to November 14, 2019. 2. In an interview with laboratory staff on 11/14/2019 at approximately 4:15 P.M. staff stated the laboratory did not record twice annual microscopic test accuracy verification from November 2017 to November 2019.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>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).</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to</p>

maintain an information or record system that included the records and dates of all microscopic urinalysis and post vasectomy semen analysis specimen testing performed from November 2017 to November 2019. Findings include: 1. The laboratory failed to document the dates of microscopic urinalysis and post vasectomy tests performed. 2. In an interview with staff on 11/14/2019 at approximately 4:00 P. M. staff stated the laboratory performed microscopic urinalysis and post vasectomy estimated at approximately 2 to 5 times per month during the course of a patient's visit. Staff stated the laboratory did not record the dates of specimen testing or specimen identification for tests that were performed during the course of patient visits.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with staff, the laboratory director failed to ensure the laboratory personnel performed microscopic urinalysis and post vasectomy semen analysis accurately and reliably for 2 years of testing reviewed from November 2017 to November 2019. Findings include: (See D5217 and D5787).