

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0701941	(X3) Date Survey Completed 09/24/2024
Name of Provider or Supplier Advantage Urology	Street Address, City, State 16311 Ventura Blvd Ste 800, Encino, CA	
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
D5393	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c)</p> <p>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality assessment records, test problem logs and interview with the laboratory testing personnel on September 24, 2024, at 12:45 pm, the laboratory failed to review the effectiveness of the corrective actions taken to resolve the sample labeling and identification problems. The findings include: 1. The laboratory testing person #1 discovered discrepancies in the sample identification and labeling by the laboratory assistants. The laboratory assistants made mistakes in labeling the sample correctly on the bacterial culture plate and in the worksheet. The laboratory assistants are responsible for plating the urine sample for bacterial culture and logging it in the worksheet. Then the testing person carry out the subsequent steps until reporting the results. The testing person found 15 cases in 2023 and 3 cases in 2024 till now as of September 24 where laboratory assistants made mistakes and later corrected. The steps taken by the laboratory to identify and correct problems and prevent their recurrence must be reviewed and documented. However, the laboratory failed to review the effectiveness of its corrective actions to prevent the recurrence. Therefore, the recurring mistakes in the sample labeling and identification have potential risk of reporting the wrong results and harm patients. 2. The laboratory testing personnel on September 24, 2024, at 12:45 pm, confirmed that it had not reviewed the effectiveness of its current policy in preventing the recurrence. 3. The</p>

	<p>laboratory's testing declaration form, signed by the laboratory director on 9/23/2024 stated that the laboratory performed approximately 5,840 tests in bacteriology, annually.</p>
<p>D5781</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, test problem logs and interview with the laboratory testing personnel on September 24, 2024, at 12:45 pm, the laboratory failed to document corrective actions taken to correct the specimen identification for 3 patients out of 10 patients, reviewed. The findings include: 1. The laboratory testing person #1 found discrepancy in bacterial culture plate labeling and culture worksheet. There was no culture plate for patient #4234 but the worksheet had the patient's name; for patient #4235 the culture plate was labeled as B.M. but the worksheet had H.S. written; and for the patient #4236 there was nothing in the worksheet. The laboratory corrected the discrepancy in the worksheet and reported the test results. However, it did not have any documentation for the corrective actions taken. It was not evident how the laboratory correctly identified the patients' sample before reporting the results. Therefore, the accuracy of the laboratory's reported result cannot be assured and may have potentially harmed patients. 2. The laboratory testing personnel on September 24, 2024, at 12:45 pm, affirmed that the laboratory did not have documentation for the corrective actions taken. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/23/2024 stated that the laboratory performed approximately 5,840 tests in bacteriology, annually.</p>
<p>D6082</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, test problem logs, quality assessment records, and interview with the laboratory testing personnel on September 24, 2024, at 12:45 pm, the laboratory director failed to assure quality laboratory services. The findings include: See D5393 and D5781.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's quality assessment records, test problem logs and interview with the laboratory testing personnel on September 24, 2024, at 12:45 pm, the laboratory director failed to ensure an effective quality assessment program established to assure the quality of the laboratory services provided. The findings include: See D5781.