

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1102253	(X3) Date Survey Completed 08/23/2023
Name of Provider or Supplier Arizona Urology, Llc	Street Address, City, State 13555 W McDowell Rd, Suite 302, Goodyear, AZ	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) reports for 2023 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the subspecialty of Bacteriology. Findings include: 1. The laboratory's PT performance was unsatisfactory for the 1st event of 2023 as indicated below: - Subspecialty of Bacteriology - 0% 2. The laboratory's PT performance was unsatisfactory for the 2nd event of 2023 as indicated below: - Subspecialty of Bacteriology - 0%</p>
D2020	BACTERIOLOGY

	<p>CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on information the Proficiency Testing (PT) provider furnished to the State Agency, the laboratory failed to to attain an overall event score of at least 80 percent for the subspecialty of Bacteriology, for the 1st and 2nd events of 2023 resulting in unsuccessful PT performance. See D2016 for findings.</p>
<p>D2026</p>	<p>BACTERIOLOGY CFR(s): 493.823(d)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the information furnished to the State Agency by the Proficiency Testing (PT) provider, it could not be determined if the laboratory underwent training and technical assistance and if remedial action was taken to correct the PT failures for the subspecialty of Bacteriology for the 1st and 2nd events of 2023. See D2016 for findings.</p>
<p>D2028</p>	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on information the Proficiency Testing (PT) provider furnished to the state agency, the laboratory failed to achieve satisfactory performance for the subspecialty of Bacteriology for the 1st and 2nd events of 2023 resulting in unsuccessful PT performance. See D2016 for findings.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p>

The Condition of Laboratory Director was found to be not met based on the failure to provide overall management and direction as evidenced by D6089 - ensuring that proficiency testing samples are tested as required under Subpart H.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, it was determined that the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a proficiency testing program for the subspecialty of Bacteriology. See D6076 for findings.