

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0683066	(X3) Date Survey Completed 10/16/2020
Name of Provider or Supplier Pima County Health Department	Street Address, City, State 1493 W Commerce Court, Tucson, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) attestation statements for 2019 (kit #31824289) and 2020 (kit #33230629) and interview with the laboratory personnel, the laboratory failed to have the director (or designee) sign the attestation statements under the subspecialty of Bacteriology. Findings include: 1. The PT attestation statements noted above did not have the signature of the director or designee. 2. The laboratory personnel acknowledged that the attestation statements indicated above lacked the signature of the director or designee.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) reports from 2019 and 2020. the laboratory failed to provide evidence of a review and evaluation for PT scores received for Gram Stain evaluation. Findings include: 1. The PT review page for PT kit #31824289 from the 3rd event of 2019 and kit #33237754 from the 2nd event of 2020 failed to indicate a reviewed by signature and date. 2. The laboratory personnel acknowledged that the PT scores were reviewed, but the review was not documented.</p>

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 lack of competency evaluation documentation for review and interview with the laboratory personnel, the technical consultant failed to provide an evaluation of the performance of 1 out of 3 individuals responsible for moderate complexity testing at least annually. Findings include: 1. During the survey conducted on October 16, 2020, no 2019 annual competency evaluation documentation was presented for review for 1 out of 3 testing personnel for testing performed under the specialty of Microbiology. 2. The facility personnel acknowledged that the competency evaluation noted above was completed, but could not be located.