

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0124673	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Arvind M Patel Md	Street Address, City, State 956 Amboy Ave, Edison, NJ	
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
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 the surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to review and evaluate PT results obtained from the American Association of Bioanalysts (AAB) for Microbiology Testing for the Second quarter in the calendar year 2017. The finding includes: 1. There was no review or evaluation documented when the laboratory received an "*" (out of grading range or incorrect response) on Urine Colony Count (UCC) specimen #1 in the 2rd Q-2017. 2. There was no review or evaluation documented when the laboratory received a score of 50 in the 2rd Q-2017. 3. The LD confirmed on 9/20/18 at 1:05 pm that the laboratory did not review and evaluate PT results.</p>
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 surveyor review of the Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of Bacteriology testing twice annually in the calendar year 2018. The findings include: 1) The facility participated in American Association of Bioanalysts (AAB)</p>

Microbiology PT program for BA. 2) The facility failed to enroll with AAB in 2018 Q1 and Q2. 3) The LD confirmed on 9/20/18 at 1:00 pm the laboratory did not perform BA in 2018.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the lack of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to check each batch of Urine Culture media for sterility, its ability to support growth and select or inhibit specific organisms at the time of the survey. The LD confirmed on 9/20/18 at 1:10 pm that the laboratory did not perform QC.