

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0110731	(X3) Date Survey Completed 07/30/2019
Name of Provider or Supplier Robert A Hands Jr Md	Street Address, City, State 331 E Saddle River Rd, Upper Saddle River, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturer's Package Insert (MPI), observation of the incubator, and interview with the Laboratory Director (LD), the laboratory failed to follow the manufacturer's instruction for incubating throat culture plates from 7/6 /17 to the date of survey. The finding includes: 1. The MPI for bacitracin discs stated to incubate the sample between 33-37 Celsius (C) but the incubator temperature log revealed the acceptable temperature was 34-38 (C). 2. The LD confirmed on 7/30/19 at 1:10 pm that the laboratory did not follow the MPI.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the LD failed to ensure all PT results obtained from the American Proficiency Institute (API) for throat culture tests were reviewed and evaluated by the appropriate staff for the 1st event in 2019. The finding includes:

1. The laboratory participated in an off cycle event for 1-2019 but there was no evidence of evaluation of PT results.
2. The LD confirmed on 7/30/19 at 1:30 pm that all PT results were not evaluated.