

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0644240	<b>(X3) Date Survey Completed</b> 12/04/2019
<b>Name of Provider or Supplier</b> Shasta County Public Health Lab	<b>Street Address, City, State</b> 2650 Breslauer Way, Redding, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2020</b>	<p><b>BACTERIOLOGY</b> 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 review of 2018 laboratory proficiency testing records, AAB (American Association of Bioanalysts) Bacteriology proficiency testing reports, and patients test results; and interview with Technical Supervisor-2 (Testing Person-3), it was determined that the laboratory failed to attain overall scores of at least 80%, constituting unsatisfactory performances in the culture and identification of Bacteria. Findings included: a. Event 1/ 2018: The laboratory reported incorrect responses (*) for a score of 50%, as follows: # Lab result Intended ----- 2 Gram positive * Group A Strep / Gram negative 3 Klebsiella Staph epidermidis pneumonia * 5 Neisseria sp, NOS * (no Neisseria) b. Event 3/ 2018: The laboratory reported incorrect responses (*) for a score of 40%, as follows: # Lab result ----- 1 E. coli * 4 Shigella flexneri * 5 Klebsiella pneumoniae * c. The laboratory Corrective Action Report for Event 3/ 2018 attributed the source of the error to the laboratory using the wrong set of specimen, which were perviously received and tested for the 2nd event; and that all 5 specimen received for the 3rd event had not been used for culture and identification. d. Technical Supervisor-2 (Testing Person-3) affirmed (12/04/19 @ 5pm) the aforementioned incorrect responses and unsatisfactory scores. e. The reliability and quality of bacterial identifications performed in 2018 could not be assured. Based on the laboratory tally, the laboratory performed approximately 100 bacterial identifications in 2018.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p>

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory proficiency testing records, proficiency testing reports from AAB, CAP (College of American Pathologists), and CDC (Centers for Disease Control) and patients test records, the lack of laboratory records, and interview with Technical Supervisor -2 (Testing Person-3), it was determined that the laboratory failed to evaluate incorrect responses and unacceptable results. Findings included: a. Proficiency testing reports from AAB, CAP, and CDC notified the laboratory of incorrect responses/ unacceptable results (\*) as follows: Event B / 2018.....CAP - Mycobacteriology Lab result: Smear Negative \* Intended: Smear Positive Event 2/ 2018..... CDC - Influenza PCR Lab result: positive for Influenza A \* Intended: Negative Event Q1 / 2019....AAB-Bacteriology Lab result: Pseudomonas, not aeriginosa \* Intended: Pseudomonas aeriginosa Q2 / 2019....AAB-Bacteriology Lab result: Gram positive organism \* Intended: Gram negative b. Laboratory documents titled "Proficiency Survey Summary Report" failed to evaluate each incorrect /unacceptable result to identify the source of the analytic error, provide appropriate corrective action to ensure reliable testing, and review testing performed on patients specimen to identify effect on results. c. Technical Supervisor-2 (Testing Person-3) affirmed (12/04/19) the aforementioned lack of evaluations of incorrect results and failure to determine effect on testing patients specimen. d. The reliability and quality of results reported in 2018 for Mycobacteria, Influenza, and Bacterial Cultures and Identification could not be assured. The laboratory affirmed (12/04/19 @ 5pm) test volumes reported in 2018 as follows: Mycobacteriology.....100 Influenza PCR .....360 Bacterial Culture & ID.....100

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

The laboratory director must ensure 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.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory records, the Laboratory Director is herein cited for deficient practice and involvement in ensuring the evaluation of proficiency testing incorrect/unacceptable results to determine sources of errors in test performance and provide appropriate corrective action. See D5211. .

**D6118**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(5)

The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

This STANDARD is not met as evidenced by:

Based on the deficiency cited (D5211), the Technical Supervisors are herein cited for

deficient practice in their responsibilities for resolving technical problems revealed through incorrect/unacceptable results in proficiency testing. See D5211.