| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 50D0705043 | 06/20/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Yakama Indian Health Center | 401 Buster Rd, Toppenish, WA | |

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 |
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| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on a records review and interviews with testing personnel and the laboratory manager, the laboratory failed to validate their reportable range for patient testing of Myoglobin on the Alere Triage analyzer. Findings: 1. A review of the procedural manual revealed that the measureable range of Myoglobin was 5-500ng/mL. 2. An interview with the lead chemistry testing personnel revealed that the laboratory was using the analytical measurement range (AMR) as their reportable range for patient test results. 3. A review of the most current linearity for Myoglobin dated December 10, 2016 revealed that the laboratory was only able to validate a range of 50-437 ng /mL. 4. An interview with the laboratory manager on June 20, 2019 at 3:10 PM confirmed that the laboratory was using the AMR as their reportable range for patient test results and that the laboratory had run 17 Myoglobin assays in 2018. |
| **D5507** | BACTERIOLOGY<br>CFR(s): 493.1261(b)(c)<br><br>(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests |

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| | are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on a record review and an interview with the laboratory manager, the laboratory failed to run the control organisms for susceptibility testing each day of patient testing since testing resumed on the Vitek analyzer in January 2019. Findings: 1. A review of the bacteriology quality control logbook and worksheets from January thru June 2019 revealed that the laboratory failed to perform and document quality control for the appropriate organisms for susceptibility on the Vitek test system each day of patient testing since January 2, 2019. 2. An interview with the laboratory manager on June 20, 2019 at approximately 3:20 PM in the Microbiology Department, confirmed that the laboratory failed to perform quality control for susceptibility on the Vitek analyzer each day of patient testing. |