| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 05D0617090 | 01/16/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Butte County Health Dept Laboratory | 695 Oleander Ave, Chico, CA | |

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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| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the Cepheid GeneXpert analyzer (PCR), review of manufacturer's Quality Control instructions, laboratory records, and written procedures for Norovirus I/II and Influenza A/B; the lack of quality control records, and interview with Technical Consultant-2 (Testing Person-2), it was determined that the laboratory failed to include positive and negative control materials each day that patients specimen were tested. Findings included: a. For 3 out of 3 patients test records selected at random from 2018 - 2019, the laboratory failed to provide QC records of positive and negative Virus-analyte-specifc control materials on each Date of testing, as follows: Date Lab # Analyte ---------- 12 /16/18 2018 - 1711 Norovirus I/II 1/02/19 2019 - 0006 Influenza A/B 9/27/19 2019 - 1535 Norovirus I/II b. Laboratory written procedures failed to include control materials that were positive and negative for Influenza A, Influenza B, Norovirus I, and Norovirus II with each day of testing. c. The manufacturer's instructions for Quality Control stated that inactivated virus controls for use as external negative and positive controls were not provided and could be obtained for use "in accordance with local, state, and federal accrediting organizations". d. Technical Consultant-2 (Testing Person-2) affirmed (1/16/20 @ 4pm) the aforementioned lack of external QC records; and thus the laboratory's failure to include positive and negative control materials each day of testing as required by State and CLIA. e. The reliability and quality of results reported for Influenza A/B and Norovirus I/II could not be assured when tested |

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| | without external virus controls. The laboratory stated (12/03/19) approximately 222 results were reported annually. . |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on the written procedures approved without external QC, the lack of quality control records, and deficiency cited, the Laboratory Director is herein cited for deficient practice in providing overal administration to ensure that QC is established in accordance with State and CLIA regulations. Findings included: a. The Laboratory Director approved testing and reporting results without positive and negative controls each day of testing. b. See D5449. . |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of written procedures and records for positive and negative QC each day of testing, and deficiency cited (D5449), the Technical Consultants are herein cited for deficient practice in their responsibility to provide scientific oversight at all times and establish quality control programs in accordance with State and CLIA requirements. |