Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0617219	**(X3) Date Survey Completed** 10/26/2023
Name of Provider or Supplier Colusa Medical Center, Llc	**Street Address, City, State** 199 E Webster St, Colusa, 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**
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from American Proficiency Institute (API), and interview with the laboratory technical supervisor on October 26, 2023, at 1:26 pm, the laboratory failed to successfully participate in the proficiency testing program for monocytes percentage in the white blood cell (WBC) differential test. The findings include: 1. The laboratory participated in the API PT testing program for the specialty of hematology in the year 2021 and 2022. However, it received an unsatisfactory score of 60% at the 2nd event in 2021 and at the 1st event in 2022 for monocytes percentage in the WBC differential test, resulted in an unsuccessful PT participation. Therefore, the accuracy of the

	patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory technical supervisor on October 26, 2023, at 1:26 pm, affirmed that the laboratory did not receive a satisfactory score for monocytes percentage in the WBC differential test at the 2nd event in 2021 and at the 1st event in 2022. 3. The laboratory's testing declaration form, signed by the laboratory director on 10/25/2023, stated that the laboratory performs approximately 50,000 tests in hematology, annually.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from American Proficiency Institute (API), and interview with the laboratory technical supervisor on October 26, 2023, at 1:26 pm, the laboratory failed to achieve satisfactory performance for monocytes percentage in the white blood cell (WBC) differential test in two consecutive testing events. The findings include: 1. The laboratory participated in in the API PT testing program for the specialty of hematology in the year 2021 and 2022. However, it received an unsatisfactory score of 60% at the 2nd event in 2021 and at the 1st event in 2022 for monocytes percentage in the WBC differential test, that resulted in an unsatisfactory analyte performance. Laboratory's failure to achieve satisfactory performance for the same analyte in two out of three consecutive events resulted in an unsuccessful PT performance. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The laboratory technical supervisor on October 26, 2023, at 1:26 pm, affirmed that the laboratory did not receive a satisfactory score for monocytes percentage in the WBC differential test at the 2nd event in 2021 and at the 1st event in 2022. 3. The laboratory's testing declaration form, signed by the laboratory director on 10/25/2023, stated that the laboratory performs approximately 50,000 tests in hematology, annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) and patient sample testing records, and interview with the laboratory technical supervisor during an onsite survey of the laboratory on October 26, 2023, at 1:26 pm, and the severity and the number of deficiencies found and cited herein, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory, hence the Condition: Laboratories performing moderate complexity testing; laboratory director was not met. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: The laboratory director failed to ensure the

	maintenance of an acceptable levels of analytical performance for the white blood cell (WBC) differential test. (See D6095)
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from American Proficiency Institute (API) and interview with the laboratory technical supervisor on October 26, 2023, at 1:26 pm, the laboratory failed to achieve satisfactory performance for monocytes percentage in the white blood cell (WBC) differential test in two out of three consecutive PT events. The findings include: See D2130.