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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D0713330 | (X3) Date Survey Completed 12/18/2024 |
| Name of Provider or Supplier Palo Verde Hospital | Street Address, City, State 250 N First St, Blythe, 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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| D2016 | <p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from CAP, and interview with the laboratory testing person on December 17, 2024, at 2:00 pm, the laboratory failed to successfully participate in the proficiency testing program for the blood gas, pO2 test. The findings include: 1. The laboratory participated in the CAP PT testing program for the blood gas in the specialty of chemistry in year 2023. However, it received an unsatisfactory score of 60% at the 2nd event and 0% at the 3rd event in 2023 for the pO2 test which 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 testing person on December 17, 2024,</p> |

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| | <p>at 2:00 pm, affirmed that the laboratory did not receive a satisfactory score for the pO₂ test at the 2nd and 3rd event in 2023. 3. The laboratory's testing declaration form, signed by the laboratory director on 12/17/2024, stated that the laboratory performs approximately 200 tests in blood gas, annually.</p> |
| <p>D2096</p> | <p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from CAP, and interview with the laboratory testing person on December 17, 2024, at 2:00 pm, the laboratory failed to achieve satisfactory performance for the pO₂ test in two consecutive events. The findings include: 1. The laboratory participated in in the CAP PT testing program for the specialty of routine chemistry in 2023. However, it received an unsatisfactory score of 60% at the 2nd event and 0% at the 3rd event in 2023 for the pO₂ test that resulted in an unsatisfactory analyte performance. Laboratory's failure to achieve satisfactory performance for the same analyte in two 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 testing person on December 17, 2024, at 2:00 pm, affirmed that the laboratory received an unsatisfactory score of 60% at the 2nd event and 0% at the 3rd event in 2023 for the pO₂ test. 3. The laboratory's testing declaration form, signed by the laboratory director on 12/17/2024, stated that the laboratory performs approximately 200 tests in blood gas, annually.</p> |
| <p>D6000</p> | <p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) records, and interview with the laboratory testing person during an onsite survey of the laboratory on December 17, 2024, at 2:00 pm, and the severity 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 pO₂ test. (See D6023)</p> |
| <p>D6023</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)</p> |

(e)(6) 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 CAP, and interview with the laboratory testing person on December 17, 2024, at 2:00 pm, the laboratory failed to achieve satisfactory performance for pO₂ test in two consecutive PT events. The findings include: See D2096.