| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D1085817 | 08/22/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Epic Care | 6380 Clark Ave, Dublin, 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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| **D6017** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(ii)<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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory proficiency testing records from American Association of Bioanalysts (AAB), the CMS Casper records, and interview with the quality assessment manager on August 22, 2019, the laboratory director failed to ensure that proficiency testing results are returned within the timeframe's established by the proficiency testing program. The findings included: a. The laboratory is enrolled with American Association of Bioanalysts (AAB) for hematology proficiency testing (PT) for complete blood counts (CBC). b. The laboratory PT results for event 1 of 2019 revealed a failure for all CBC analytes for which the laboratory is enrolled, due to late submission of PT results after the timeframe deadline. c. The laboratory had performed a self evaluation of the results and would have passed at 100% for each CBC analyte, but the review failed to indicate what policy changes or testing personnel remedial training were included inorder to ensure that future PT results would be returned within the timeframe's established by the PT provider. d. The laboratory QA manager confirmed by interview on August 22, 2019 that the laboratory had failed to submit the PT results prior to the AAB PT deadline for submission. e. The laboratory reports performing approximately 20,814 patient CBC's annually. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES |

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| | CFR(s): 493.1407(e)(12)<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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's CMS-209 (laboratory testing personnel report), review of the laboratory's testing personnel records, and interview with the laboratory QA manger on August 22, 2019, the laboratory director failed to ensure that policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. The findings included: a. The laboratory policy (S.Lab.01) Training & Competency Assessment does not include evaluation of initial competency, biannual competency and annual competency as set forth in 42 C.F.R. 493.1413(9). b. According to the CMS-209, the laboratory listed five (5) testing personnel, of which one (1) was a new testing personnel since April 2019, who performs patient testing for complete blood counts (CBC) on the Horiba Micros60 automated hematology analyzer. c. The laboratory had initial training documentation provided by the analyzer manufacturer for the (1) new testing personnel, but did not have documentation of a competency assessment as required per 42 C.F.R. 493.1407 9(14), regarding the testing personnel's competency assessment for preanalytical, analytical and postanalytical competency, identifying which examinations and procedures the individual is authorized to perform, and weather supervision is required for specimen processing, reporting, and weather review is required prior to reporting patient test results, prior to patient testing. d. The laboratory had no documentation of competency for the the (4) testing personnel for 2018, and the competency assessment performed for 2019 did not identify which examinations and procedures each individual is authorized to perform and weather supervision is required for specimen processing, reporting and weather review is required prior to reporting patient test results. e. The laboratory QA manager confirmed by interview on August 22, 2019 at approximately 10:30 a.m., that the laboratory did not have initial competency assessment for the (1) new testing personnel, or annual competency for the other (4) testing personnel for the year 2018. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's CMS-209 (laboratory personnel report) and interview with the laboratory QA manager on August 22, 2019, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year. The findings included: a. The laboratory's CMS-209 reports five (5) testing personnel for performing automated complete blood counts on the Horiba micros60 hematology analyzer. b. Four (4) of the five (5) testing personnel had no documentation of competency assessments performed in 2018. c. The laboratory's quality assessment (QA) policy (P.Lab.01 v 1) states that review of the testing personnel will include review of personnel competency assessments. The QA report dated 08/14/2019 did not document the lack of competency assessments for the (1) new testing personnel, but rather indicated that competency assessments in the personnel binders were current. d. The laboratory QA manager confirmed by interview that the laboratory did not have documentation of initial competency assessment for the (1) new testing personnel (2019) or for the (4) testing personnel annual competency for 2018. e. The laboratory reports performing approximately 20,814 patient CBC's annually. |