

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0698083	<b>(X3) Date Survey Completed</b>  07/03/2018
<b>Name of Provider or Supplier</b>  Bear Valley Community Hospital	<b>Street Address, City, State</b>  41870 Garstin Dr, Big Bear Lake, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2121</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency (PT) test result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory used IL GEM 5000 blood gas instrument reporting pH, PO2, PCO2,.. plus Hemoglobin (Hgb). b. In order to ensure the accuracy of the Hgb testing system, the laboratory enrolled its PT with WSLH PT programs. c. The laboratory attained a score of 0% for Hgb in the 2nd 2017 PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory performed Hgb in approximately 20 patient samples each monthly.</p>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records, and interview with the laboratory staff, it was determined that the laboratory failed to retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all</p>

	<p>analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>a. The laboratory performed blood gases with a new IL GEM 5000. b. Review of two patient test result reports from 6/12/18 #10131696 and 6/16/18 #10132040, at the time of survey (7/3/2018 @10:45 am), no quality controls (QC) instrument print-out sheets were available on file, and unable to retrieve from the instrument. c. With the help from the IL instrument specialist by the phone, the laboratory unable to print out the QC records to support the accuracy of the patient test result reports at the time of survey (7/3/2018 @10:45 am).</p>
<p><b>D5209</b></p>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory personnel handling the blood gas instrument, and interview with the laboratory staff, it was determined that the laboratory failed to establish and follow written policies and procedures to assess employee. The findings included: See D-2121, and D-3031 b. The testing persons did not show its competencies to handling the GEM 5000 blood gas instrument and how to generate reports including quality control print-outs.</p>
<p><b>D6004</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory operations, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to be responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. The findings included: See D-3031, D-5209, D-6067</p>
<p><b>D6023</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(6)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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)(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 observation of the laboratory operations, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. See D-6067 b. By observations of and interview with the testing personnel, the testing personnel could not show competencies to perform GEM 5000 instrument and ensure an acceptable levels of analytical performance for each test system.

**D6067**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(4)(ii)

Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on observations of the laboratory personnel testing, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to provide proper training to ensure that the individual has-- (1) the skills required for implementing all standard laboratory procedures; (2) the skills required for performing each test method and for proper instrument use; (3) the skills required to implement the quality control (QC) policies and procedures of the laboratory; (4) an awareness of the factors that influence test results; and (5) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. The findings included: a. See D-3031, and D-5209 b. The laboratory testing personnel were lack of skills to understand what procedure will trigger instrument GEM 5000 to print-out appropriate information needed. c. With helps from IL instrument specialist by phone instructions still could not print out quality control result reports for the dates of 6/12 and 6/16 /2018 at the time of survey (7/3/18 @ 11:15 am). d. No evidence and no QC documents to assure two patient testing results (one on 6/12/18 # 1013696, the other on 6/16/18 #10132040) were accurate before releasing the reports. e. By observation on site, the testing personnel were not familiar with GEM 5000 instrumentation operations to complete the surveyor requested tasks.