

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1019978	<b>(X3) Date Survey Completed</b>  05/19/2021
<b>Name of Provider or Supplier</b>  Beaver Medical Group Lp	<b>Street Address, City, State</b>  2 W Fern Ave, Redlands, 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>D5801</b>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy &amp; procedure, random patient sample, quality control (QC) and proficiency testing (PT) records for the years of 2019 and 2020, and interview with the laboratory technical consultant on May 19, 2021 at 12:05 pm, the laboratory failed to accurately report the test results for 1 patient out of 2 patients, reviewed. The findings include: 1. The laboratory uses Rapid Point 405 instrument from Bayer to test arterial blood gases. The instrument prints out the test results and the staff manually enter the results into the report which is sent to the physicians. However, on 7/22/2019 the staff incorrectly recorded the test results on the report for patient ID 6855464. The instrument print out showed the pCO2 48.2 mmHg but the report showed pCO2 78.2 mmHg. The reported result was very high and abnormal. The normal range of pCO2 is 35-45 mmHg. Therefore, reporting wrong result might had resulted wrong treatment and thus harmed patient. 2. The laboratory technical consultant on May 19, 2021 at 12:05 pm, affirmed that the laboratory staff incorrectly recorded the test result on the report. 3. The laboratory's testing declaration form, signed by the laboratory Director on 5/18/2021, stated that the laboratory performs 40 tests, annually.</p>

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, quality control & patient test records for the years of 2019 and 2020, and interview with the laboratory technical consultant on May 19, 2021 at 12:05 pm, the laboratory director failed to assure the quality of laboratory services provided in the postanalytic phase of testing. The findings include: See D5801.