

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1019975	(X3) Date Survey Completed 03/19/2025
Name of Provider or Supplier Beaver Medical Group P C	Street Address, City, State 839 N Highland Springs Ave, Beaumont, 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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of approved policies and procedures and interview with the testing personnel (TP) on March 19, 2025, at approximately 12:00 pm, the laboratory failed to establish and follow a written policy and procedure for specimen qualifications such acceptability and rejection criteria. The findings include: 1. The laboratory did not have a written policy and procedures for specimen preparation, storage, preservation, acceptability and rejection for Blood Gas Analysis and Lactate test. Therefore, laboratory cannot ensure the reliability of the specimens' tests results. 2. TP confirmed on 03/19/2025 at approximately 12:00 p.m., that the laboratory did not have a written policy and procedures as stated in 1. 3. The laboratory's testing declaration form, signed by the laboratory director on 02/07/2025 stated that the laboratory performed 50 Blood gas Analysis and Lactate tests annually for which there were not laboratory director's approved and dated policies and procedures available.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a</p>

procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to follow an established QC policy and procedure to perform, at least once each day patient specimens were assayed, Blood Gas Analysis and Lactate quality control procedures that included external two quality control materials of different concentrations (Refer to D5441 and D5447); establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified the analytic systems. Refer to D5311, D5401, D5791, D5813, and D5815.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory written policies and procedures for Blood Gas Analysis and interviews with the laboratory staff (LS) it was determined that the laboratory failed to have available and follow by all testing personnel written procedure for Blood Gas Analysis tests performed in the laboratory. The findings included: 1. On the day of the survey on March 18, 2025, at approximately 12:15 p.m. the laboratory failed to provide written policies and procedures for Total Protein test performed daily in the laboratory. 2. The LS confirmed on 03/21/2025 at approximately 12:30 p.m. that the laboratory did not have written policies and procedures available for the Blood Gas Analysis tests performed in the laboratory. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 02/07/2025 the laboratory processes and reports 50 Blood Gas Analysis samples annually for which the laboratory did not have a written procedure approved by the laboratory director available and followed by all testing personnel.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:
 Based on the surveyor's observation, review of the laboratory quality control (QC) records, lack of QC policy and procedure, and interviews with the testing personnel (TP), the laboratory failed to provide quality control records that monitor the accuracy and precision of the complete analytic process including the number, the type, and the frequency of the QC materials when performing Blood Gas analysis tests procedures. 1. On the day of the survey March 18, 2025, at approximately 1:15 p.m. the surveyor observed that QC documentation for the Blood Gas analysis tests performed were only performed once monthly for the years 2023, and 2024. 2. The laboratory TP by interview on 3/18/2025 at approximately 12:45 p.m. stated that an Individualized Quality Control Plan was used as the basis for not running controls each time Blood Gas Analysis tests are performed. 3. No IQCP or QC policy and procedure was available at the time of the survey on 3/18/2025. 4. The TP confirmed on March 18, 2025, that the laboratory lacked an established policy and procedure for QC and that QC is performed only once monthly.

D5447

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:
 Based on the lack of the laboratory's policy and procedure manual, five (5) randomly selected patient testing records, quality control documentation, and interviews with the testing personnel (TP), the laboratory failed to include two levels of quantitative quality control (QC) for each day of testing patient specimen for Blood Gas Analysis tests. Findings included: 1. Based on the review of five (5) randomly chosen patient test reports, one (1) out of five (5) had no quality control documentation found at the time of the survey. For the other four (4) test results reviewed ranging from 1/10/2023 to 12/16/2024 two levels of quality control for were not performed once per moth. 2. TP affirmed by interview on 3/18/2025, at approximately 2:00 p.m. that the laboratory does not have an Individualized Quality Control Plan (IQCP) to support the claim of once per monthly testing only. Therefore, reliability and quality of the test results reported cannot be assured. 3. Based on the laboratory's testing declaration submitted on 2/07/2025, the laboratory performed approximately 50 Blood Gas Analysis tests annually.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:
 Based on the lack of policies and procedures manuals, review of laboratory records, and interviews with the laboratory staff on March 19, 2025, the laboratory failed to have and follow written policies and procedures for an ongoing mechanism to monitor and assess, and when indicated, correct problems identified in the analytic systems in

2023, 2024 and currently in 2025. The findings included: 1. The laboratory lacked written and approved policies and procedures for quality control and quality assurance assessment for Blood Gas Analysis tests performed in the laboratory. 2. The laboratory did not have a designated responsible person to review all Quality Control (QC) charts and logs each time the test was performed to assure that QC was performed according to manufacturing instructions. 3. The laboratory staff confirmed by interview on March 19, 2025, at approximately 12:30 pm, that the laboratory did not have available approved policies and procedures on quality control and quality assessment to indicate that QC charts and logs had been reviewed by the laboratory director or designee the years 2023, 2024, and currently 2025. 3. The laboratory's testing declaration form, signed by the laboratory director on 02/07/2025, stated that the laboratory performed approximately 50 Blood Gas Analysis tests annually for which quality control and quality assessment plans and records for the analytic phase of testing was lacking.

D5813

TEST REPORT
CFR(s): 493.1291(g)

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:
Based on the lack of a policy and a list of critical values for Blood Gas Analysis tests performed in the laboratory including Lactate test and its reporting procedure, review five (5) randomly selected patient sampling test results and interview with the testing personnel (TP); the laboratory failed to have and follow a policy for reporting of critical values. The findings included: 1. The laboratory's lacked a policy and procedure manual, did not have a critical results notification policy, neither was a list of established critical values for all tests performed in the laboratory. 2. For one (1) out of five (5) patients results reviewed there was no documentation notes on how critical values were handled and reported by the TP. 3. The TP affirmed on March 18, 2025, at approximately 1:45 p.m. that the laboratory did not have a written policy and procedure on critical values documentation for reporting.

D5815

TEST REPORT
CFR(s): 493.1291(h)

(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory's policies and procedures, patient test records review from 1/10/2023 to 12/16/2024, and interview with the testing personnel (TP); laboratory failed to have a policy for turn-around time (TAT) for all tests performed in the laboratory. 1. The laboratory failed to provide TAT of testing for five (5) out of five (5) randomly chosen patients at the time of the survey March 18, 2025. The laboratory did not provide a TAT policy which may adversely impact patient management. 2. The laboratory's TP confirmed by interview on March 18, 2025, at approximately 12:30 p.m. that the laboratory did not have a TAT policy to notify any

	<p>delay on testing to the physician. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/7/2025, stated that the laboratory performs 50 Blood Gas Analysis tests annually for which there is not a TAT policy.</p>
D6000	<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 the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that quality control, quality assessment programs are established and maintain to assure the quality of laboratory services provided and identify failures in quality as they occur. See D 5791, D5813, and D5815. The laboratory director also failed to ensure than an approved policies and procedures is available to all personnel responsible for any aspect of the testing process. Refer to D5311, D5401, D 6020, D6031, D6032, and D6107.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: The laboratory director is herein cited for deficient practice in overall administration of the laboratory to ensure that the frequency of testing of Quality Control materials for Blood Gas Analysis test and a Quality Assurance Plan, monitoring, and documentation of activities to assure accurate, reliable, and timely test results are established and followed. Refer to D5441, D5447, and D5791.</p>
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, lack of standard policies and procedures, and interviews with the laboratory staff; it was determined that the laboratory director failed to ensure that a signed, approved, and dated written policies and procedures for all aspects of Blood Gas Analysis test is always available to all personnel responsible for any aspect of the testing process. See D5401.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on the lack of the laboratory's policies and procedures, surveyor's observation during the laboratory tour, and interview with the laboratory supervisor on March 19, 2025 at approximately 12:30 p.m., the laboratory director is herein cited for the deficient practice of lacking a written delegation of responsibilities to qualified personnel involved in preanalytic, analytic, and postanalytic phases of testing process. Refer to D5791.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records of personnel training, competency evaluation, laboratory policies and procedures, five (5) randomly selected patient testing records, and interview with the laboratory 's staff, the laboratory failed to provide records showing that the laboratory director (LD) has authorized, delegated, and approved lab personnel of any responsibilities and duties in writing. The findings included: 1. The laboratory did not have any records of written delegation and authorization of responsibilities and duties by the LD for the laboratory's staff. 2. On March 19, 2025, at approximately 1:00 p.m. the staff confirmed by interview that the laboratory director (LD) did not assign, delegated, and authorized in writing duties and responsibilities to the laboratory personnel including the testing person. 3. The laboratory testing declaration form, signed by the LD on 02/07/2025 stated that the laboratory performs 50 routine chemistry tests annually.