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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D0901303 | (X3) Date Survey Completed 04/23/2025 |
| Name of Provider or Supplier Aberdeen Ph/Blood Gas Lab | Street Address, City, State 660 Mchenry Road, Aberdeen, MD | |
| 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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| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the "Instrument Comparison Log" for June 2023, procedure manual, and interview with the laboratory administrator (LA), the laboratory's procedure manual failed to have written and approved instructions for the instrument comparison procedure performed every six months on the two GEM 5000 blood gas analyzers. Findings: 1. The "Instrument Comparison Log" for June 2023 states "Analyze the same blood gas specimen on each instrument and record results on log." The log listed the allowable differences for each analyte and the identity of each blood</p> |

gas analyzer. 2. The procedure manual that was reviewed did not include step-by-step instructions for performing, recording, and calculating the comparison between the two blood gas analyzers. 3. According to the LA and instrument printouts attached to the log, every six months patient specimens were tested until 20 sets of results were gathered and compared. The results are entered into a spreadsheet and the differences calculated. There was no documented review of the comparison showing that the results were acceptable. 4. During the validation survey on 04/23/25 at 11:45 AM, the LA confirmed that the procedure manual did not include step-by-step instructions for how to perform, document and calculate the instrument comparison test between the two blood gas analyzers.