

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469031	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Clarksville Medical Group, Pa	Street Address, City, State 601 W Mckennon St, Clarksville, AR	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Through a review of the laboratory procedure manual, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to approve, sign, and date all the laboratory procedures. Survey findings include: A. During a review of the laboratory procedures it was determined the procedure manual and individual procedures lacked the director's approval signature and date of approval. B. In an interview at 9:23 11/16/23, Testing Personell #1 (as listed on the form CMS-209) confirmed the laboratory directors written approval of the laboratory procedures was not available.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Through observation, review of the instrument manufacturer's user's manual, and</p>

interview with laboratory staff it was determined that the laboratory failed to define the conditions for proper storage of reagents and supplies consistent with manufacturer ' s instructions in one of one freezer in which supply items with a storage temperature requirement were stored. Survey findings follow: A) On a tour of the facility conducted at 10:40 AM on 11/16/23, Bio-Rad Liquid Assayed Multiquant were observed in a freezer with no frost present. B) Review of the manufacturer's package insert for Bio-Rad Assayed Multiquant revealed "For optimum performance, avoid storing this product in a frost free freezer." C) In an correspondence on 11/20/20 at 9:19am, facility staff member, identified as Testing Personell #1 on the CMS 209 form, provided documentation showing the freezer used was a frost free model.