Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0469031	11/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Clarksville Medical Group, Pa	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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Through the lack of written procedures and interview, it was determined that the laboratory failed to establish and follow written Quality Assessment policies and procedures to monitor, assess and correct problems identified in the laboratory. Findings Follow: A). Upon request and the laboratory failed to provide quality assessment reports or a written Quality Assessment policy and procedure for the laboratory. B) The laboratory staff member, identified as number one on the CMS 209 form, confirmed during an interview with the surveyor at 11:05 AM on 11/24/21 that the written Quality Assessment policy and procedures and Quality Assurance reports were located at another facility and were not available.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Through review of laboratory policy and procedure, observation and interview it was determined that the laboratory failed to label one of three specimen collection containers with patient name or unique patient identifier. Findings follow: A) During a tour of the laboratory on 11/23/21 at approximately 01:50 PM one of three urine specimens was observed in the testing area labeled with the patient's first and last name only. B) Review of the laboratory policy and procedure revealed that specimen containers are to be labeled with the patient's first and last names and a unique patient identifier, patient number or patient's date of birth or specimens would be rejected. C) In an interview on 11/23/21 at 01:50 PM , the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the specimen identified above lacked proper patient identification on the container as required by policy and procedure.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Through observation, review of temperature and humidity records, review of the instrument manufacturer's user's manual, a lack of documentation and interview with laboratory staff it was determined that the laboratory failed to define and monitor the conditions for proper storage of reagents and supplies consistent with manufacturer ' s instructions in one of one storage rooms in which supply items with a storage temperature requirement were stored and failed to assure that humidity levels were acceptable for operation of the chemistry analyzer Survey findings follow: A) On a tour of the facility conducted at 10:40 AM on 11/24/21, 400 BD SST blood collection tubes, lot # 1102091 with a storage temperature requirement of 4 degrees C, and 250 Vacuette EDTA blood collection tubes lot # B21093C with a storage temperature requirement of 4 degrees C to 25 degrees C. were observed in a room closed and separated from the main laboratory area. B) Temperature and humidity records reviewed for the calendar year 2021 lacked documentation of room temperature for the storage room mentioned above. C) Review of the manufacturer's users manual for the Cobas Integra 400 chemistry analyzer revealed "environmental conditions must comply with the following conditions; relative humidity of 30% to 80% non-condensing". D) Review of the laboratory's temperature and humidity records revealed that the laboratory had defined acceptable room humidity as 20% to 80% and the humidity was recorded as less than 30% on 20 of 20 days of operation in January 2021, 17 of 17 days of operation in February 2021, 18 of 23 days of operation in March 2021, 18 of 22 days of operation in April 2021, 5 of 19 days of operation in May 2021, 2 of 21 days of operation in October 2021 and 14 of 18 days of operation in November 2021. C) In an interview on 11/24/21 at 01:30 PM, facility staff member, identified as number one on the CMS 209 form, confirmed that room

	temperature was not monitored for the storage room identified above and that the manufacturer's required operational humidity level was not maintained in the instances identified above.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through review of quality control summary reports, patient result reports, lack of documentation and interview with laboratory staff it was determined that the laboraatory reported 51 patient comprehensive metabolic panel (CMP) results without confirming quality control results met the laboratory's criteria for acceptability on three of 39 days of operation reviewed. Findings follow: A) Review of quality control summary report for January 2021 revealed that no quality control results were presented for January 13, 14 or 15 2021. B) Review of patient results reports revealed that CMP analyses were performed on; 18 patients (identified as numbers 1 through 18 on a separate patient identification list) on 1/13/21, 18 patients (identified as numbers 19 through 36 on a separate patient identification list) on 1/14/21 and 15 patients (identified as numbers 37 through 51 on a separate patient identification list) on 1/15/21. C) Upon request, the laboratory was unable to provide documentatrion of the results of quality control performed on January 13, 14, 15, 2021. D) In an interview on 11/24/21 at 01:30 PM, the laboratory staff member identified as number one of the CMS 209 form, confirmed that quality control results were not available for January 13, 14, 15, 2021.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(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: Through a review of personnel records for two laboratory testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director did not give written authorization for testing personnel to perform testing without direct supervision for two of two personnel listed as testing personnel on the CMS 209 form. Survey findings include: A) Through a review of personnel records for the two laboratory testing personnel identified on the CMS 209 form it was determined that the written authorization to test was not presented in the personnel

	documentation. B) Upon request, the laboratory was unable to present authorization to perform testing signed by the laboratory director for the two personnel listed as testing personnel on the CMS 209 form. B. In an interview, at 01:30 PM on 11/24/21, the laboratory staff member, identified as number one on the CMS 209 form, confirmed that the laboratory director had not signed an authorization to perform testing for the testing personnel identified on the CMS 209 form.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Through review of personnel competency records for two testing personnel listed on the CMS 209 form, lack of documentation and interview it was determined that the laboratory did not assess the competency of one of two testing personnel semi-annually during the first year of employment. Findings follow: A) Review of personnel records of testing personnel, identified as number 2 on the CMS 209 form, indicated that the employee was hired in June 2019. B) Upon review of personnel records of testing personnel, identified as number 2 on the CMS 209 form, competency evaluations were dated as performed in April 2020 and October 2020 which do not document competencies performed semi-annually during the first year of employment which was June 2019 to June 2020 for this personnel. C) In an interview on 11/24/21 at 1:30 PM, the laboratory staff member, identified as number one on the CMS 209, verified that competency evaluations were not performed semi-annually during the first year of employment for the testing personnel identified as number two on the CMS 209 form.