| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 04D0469031 | 09/11/2025 |
| **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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>. Based upon a review of the Policy and Procedure Manual, lack of documentation, and interview with staff, the laboratory procedure manual failed to include a policy /procedure for rejection of samples failing to meet criteria for acceptability. As evidenced by: A) A review of the laboratory Policy and Procedure Manual revealed that it did not include a policy/procedure for rejection of improper/inadequate /mislabeled or unlabeled specimens. B) In an interview on 9/11/25 at 10:04 a.m. the laboratory staff member (number 6 as listed on form CMS-209) , confirmed the Policy |

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| | and Procedure Manual did not include a procedure for rejection of specimens not meeting criteria for acceptability. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Review of the laboratory's Policy for Quality Control (QC), quality control rresults for July 2025, "Result Listing by Patient Report" for July 2025, and interview with laboratory staff determined that the laboratory reported patient results for Blood Urea Nitrogen (BUN) tests on one of twenty-two days of testing when QC results failed to meet the laboratory's criteria for acceptability and failed to record all attempts to obtain acceptable QC results. Survey findings follow: 1. The laboratory reported patient results when QC failed to meet the criteria for acceptability. A) Review of the Laboratory's Policy for "Quality Assurance Quality Control " revealed "Criteria for acceptable quality control range and limits. QC will be accepted if two levels are within or less than 2SD range, or if one level is greater than 2SD but within 3SD, and the other level is within or less than 2SD". . B) Review of the QC report for BUN assays for July 2025 revealed that Biorad QC level 1 lot# 45961 with an acceptable range of 12 to 16 was reported as 30 with a flag of :>3SD on 7/29/25 st 10:02 a.m. C) Review of the "Result Listing by Patient Report" for July 29, 2025 revealed that BUN assays were performed and reported on fourteen patients (identified as #1 through #14 on a separate patient identification list). D) In an interview on 9 /11/25 at 10:04 a.m.., the laboratory staff member ( #6 on form CMS 209) confirmed that patient results were released for BUN assays on 7/29/25 against laboratory policy when QC result of any level of control was > 3SD of the target value. 2. The laboratory failed to record all attempts to obtain acceptable QC results. A) Review of QC results for BUN assays performed in July 2025 revealed QC results were recorded between the hours of 08:00 a.m. and 09:00 a.m. on every day except 7/29/25 when they were recorded at 10:02 a. m. and 7/30/25 when they were reecorded at 02:06 p.m. B) In an interview on 9/11/25 at 10:04 a.m., the laboratory staff member (#6 on the form CMS 209) said "we keep running QC until it comes in". When asked what happens with QC results that are not acceptable stated they are rejected and they are not documented. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based upon review of the laboratory's policy for quality assurance (QA), review of clinical chemistry Levey-Jenning Quality Control (QC) charts for November 2024, and March 2025, lack of documentation, and interview with laboratory staff, the laboratory failed to follow written policies and procedures to monitor, assess, and correct problems identified an the analytic systems. Finding follow: A) The laboratory |

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| | policy and procedure for QA under the heading of "Review" states "the laboratory will do monthly reviews and evaluations of all control data to show that test were accurate and reliable or in need of corrective action" and under the sub-heading of "Quantitative controls" states "monthly review of the Levy-Jennings charts to evaluate and assess the quality of the control runs. The laboratory will look for random error and systematic error. A systematic error is evidenced by a change in the mean of control values. The change my be gradual and demonstrated as a trend in control values or it may be abrupt and demonstrated as a shift in control values. Even when control values fall within the 2 SD, it can be a cause for concern. The source of the problem should be investigated and corrective action action and troubleshooting must be undertaken." B) Review of the Levey-Jennings QC charts for November 2024 revealed that beginning 11/18/24 and continuing for the remainder of the month three of three levels of Biorad Multiqual Lot # 4596 demonstrated a shift down for Albumin (ALB) assays with 5 of 8 assays of level 1 recording values below the mean, 8 of 8 assays of level 2 recording values of 1 standard deviation (SD) below the mean, and 8 of 8 assays of level 3 recording values of 2(SD) below the mean. C) Review of the Levey-Jennings QC charts for March 2025 revealed that beginning 3/24/25 and continuing for the remainder of the month three of three levels of Biorad Multiqual Lot # 4596 demonstrated a shift down for Cholesterol (CHOL) ) assays with 6 of 6 assays of level 1 recording values 1 SD below the mean, 6 of 6 assays of level 2 recording values of 1 (SD) below the mean, and 6 of 6 assays of level 3 recording values of 2(SD) below the mean. D) Upon request, the laboratory was unable to provide docuementation of the monthly review of the indications of shifts identified above. E) In an interview on 9/11/25 at 10:04 a.m., the laboratory staff member (# 6 on form CMS 209) said she was not aware if a monthly review was performed. |