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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 04D0468598 | (X3) Date Survey Completed 03/08/2023 |
| Name of Provider or Supplier Pat Walker Health Center, University Of Ar, Fayette | Street Address, City, State Pat Walker Health Center, University Of Arkansas, Fayetteville, 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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| D5783 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: . Through review of quality control (QC) policy and procedure , QC results for May 2022 , lack of documentation and interviews with laboratory staff it was determined that the laboratory failed to evaluate patient results back to the last successful performance of QC, on one of two occasions when QC failed criteria for acceptability. Findings follow: A) Review of the laboratory policy and procedure revealed that action is to be taken when QC fails criteria for acceptability and "1 -3S a run is rejected when a single measurement exceeds the mean plus or minus 3SD" and "2- 2S a run is rejected when 2 consecutive control measurements exceed the mean plus or minus 2SD control limit". B) Review of QC records for Creatinine test revealed that on 5/9/22 at 9:56 am Wasserman UNCM Level 1 Control lot # 1501 with acceptable limits of 1.6 to 2.0 was resulted as 2.20 flagged (>3SD), and Wasserman UECM Level 2 Control lot # 1166 with acceptable limits of 7.4 to 8.4 was resulted as 9.8 flagged (>3SD). C) Review of documentation of corrective action for the event identified above revealed that the test system had been recalibrated which indicated a change in the test system operation. D) Review of QC results revealed the previous acceptable QC results for Creatinine testing was performed on 5/6/23 at 9:31 am. E) Upon request, the laboratory was unable to provide documentation that the patient</p> |

testing performed during the interval identified in the citation above (5/6/23 9:31 am through 5/9/23 9:36 am) had been evaluated. G) In an interview on 3/8/23 at 12:50 pm the laboratory staff member (#3 on the CMS 209 form) stated that the laboratory had a policy requiring results to be evaluated back to the last successful QC when a 2-2S or 1-3S QC failure required corrective action that effectively changed the testing system and confirmed that the test identified in the citation above had not been evaluated and should have been.