

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466383	(X3) Date Survey Completed 07/23/2024
Name of Provider or Supplier Jacksonville Medical Care	Street Address, City, State 1300 Braden Street, Jacksonville, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: A review of laboratory policies and procedures for chemistry reviewed and approved by the laboratory director on 7/20/15, a review of the chemistry Quality Control (QC) records, and interviews with laboratory staff, demonstrated that the laboratory failed to follow written procedures for Chemistry QC. Survey findings include: A) Review of the "Siemens Dimension EXL Procedure revealed that the QC policy states: "2 levels of quality control material are performed on each day of patient testing "and "the following Westgard multirules for acceptance of quality control results are used: 1 3S A run is rejected when a single control measurement exceeds the mean plus or minus 3 SD" B) Review of the chemistry QC records for September 2023, revealed that three levels of Biorad Multiquel QC material lot numbers level one 56711, level two 56712, and level three 56713 were run on each day of patient testing. C) Review of the chemistry QC records for September 2023 revealed that 21 of 22 runs level one QC lot number 56711 was resulted as > 3 SD with a note "running with other two levels in range" for Calcium (CA) analysis, on 9/14/23 level one QC for for Sodium (NA) was resulted as >3 SD with a note "running with other two levels in range", and on 9/18/23 level two lot number 56712 for NA analysis was resulted as > 3 SD with a note "running with other two levels in range". D) In an interview, at 01:20 p.m. on 7 /23/24, the laboratory director confirmed that the procedure for QC performed on the Siemens Dimension EXL Procedure was not currently being followed, and the</p>

laboratory ran three levels of QC material on each day of patient testing with the rule that QC results were acceptable if two of the three levels resulted within 2 SD of the target mean. .