

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0991904	(X3) Date Survey Completed 05/26/2022
Name of Provider or Supplier Southern Medical Group	Street Address, City, State 211 East Stadium, Magnolia, 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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the laboratory Policy and Procedure Manual, observations made during a tour of the laboratory, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to follow written policies for positive identification of urine specimens. As evidenced by: A. A review of the laboratory policy section for specimen collection and handling revealed "Record patients name and one other unique identifier (e.g.- date of birth, account number, or accession number on tubes and other specimen containers)." B. During a tour of the laboratory, at 1400 on 5/26/2022, the surveyor observed five urine containers in the laboratory sink. Five of five urine containers were labeled with the patients first and last name only. C. In an interview at 1400 on 5/25/2022, the technical consultant confirmed the urine containers were not labeled according to laboratory policy.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when</p>

they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Through a review of the laboratory's policy and procedure manual, Chemistry Quality Control (QC) records for January thru April of 2022, medical records, lack of documentation as well as interview with staff it was determined the laboratory failed to document Chemistry QC on days when patients were tested. Survey Findings Follow: A. A review of the Laboratory policy manual revealed the Chemistry Quality Control policy: "All quantitative quality control values will be plotted on Levy-Jennings (LJ) graph observed daily and printed monthly. Each control will have a target (mean) and a 2SD range. If control values are in range, patient samples can be tested, and test results reported. If either control is outside its 2SD range, corrective action must be taken before patient samples can be tested and reported." B. A review of QC data for the month of March 2022 (one of three months reviewed) revealed on 03/11/2022 Level I Chemistry Control for Sodium (116.0-123.0) was reported as 127.0 outside the 2SD range of 123.05. Chemistry Control Level II (lot # G9072) was reported in range. C. A review of QC data for the month of April 2022 (one of three months reviewed) revealed on 4/8/2022 Level I Chemistry Control for Calcium (7.470-8.570) was reported as 8.59 and 8.68 on repeat. Chemistry Control Level II for Calcium was reported in range. D. The surveyor requested documentation for two levels of acceptable QC for Sodium for 3/11/2022 and Calcium on 4/8/2022. None was provided. The laboratory did not have documentation of corrective action for the days QC was out of range. E. A review of patient medical records for 3/11/2022 revealed the laboratory reported twelve patients for Sodium with one level of QC in range. A review of patient medical records for 4/08/2022 revealed the laboratory reported six patients for Calcium with one level of QC in range. F. In an interview on 05/26/2022 at 1300, the technical consultant confirmed patients were tested and reported with one level of acceptable QC for March 11, and April 8 2022.