

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D1048934	<b>(X3) Date Survey Completed</b>  04/14/2021
<b>Name of Provider or Supplier</b>  Wrmc Medical Complex Laboratory	<b>Street Address, City, State</b>  195 Hospital Drive, Suite E, Cherokee Village, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5777</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c)</p> <p>(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Through review of the laboratory's policy and procedure for quality control (QC), policy and procedure for quality assurance (QA), review of patient results for Albumin (Alb) performed on 8/10/20 and interview it was determined that the laboratory failed to have a functional system to identify patient test results that appear inconsistent with expected distribution. Finding follow: A) Upon review of the laboratory's policies for QC and QA no policy for identifying and assessing patient test results that appear inconsistent with a patients, age, sex, diagnosis or expected distribution was noted. B) Review of patient results for Alb performed on 8/10/20 revealed that 13 of 35 Alb tests performed and reported on 8/10/20 were flagged as abnormally low and 12 , identified as patients numbered 24 through 35 on a separate patient identification list, of the 13 patients flagged as low were performed consecutively between the hours of 1448 and 2231. and were the last Alb tests performed on that day. C) Review of the patient Alb results performed on 8/10/20 revealed that the 12 consecutive with abnormally low Alb results, identified as numbers 24 through 35 on the separate patient identification list, varied as to age and sex. D) In an interview on 4/14/21 at 01:15 the laboratory staff member, identified as number 2 on the CMS 209 form, confirmed that 12 consecutive abnormally low Alb results on patients varying in age and sex would not conform to an expected distribution, that they were not identified and assessed, and that these findings would be used as a inservice topic and example for laboratory testing personnel.</p>

## CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(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.

This STANDARD is not met as evidenced by:

Through review of laboratory quality control policy and procedure, laboratory quality control (QC) records, review of patient results, lack of documentation and interview it was determined that the laboratory failed to evaluate patient results back to the last successful QC performance on one of one occasions when QC for Albumin (Alb) failed to meet the laboratory's criteria for acceptability. Findings follow: A) Review of the laboratory's policy and procedure for QC revealed that QC performance fails to meet the laboratory's criteria for acceptability if results of QC deviates from the target by equal to or greater than three standard deviation interval (SDI) or deviates from the target value by two or greater SDI but less than three SDI on two or more successive trials. B) Review of the laboratory's quality control records revealed that on 8/11/20 QC for Alb, lot # 2111A target of 4.0 range of (3.7 to 4.3) was resulted as 2.42 (-10.5 SDI) at 0135 with a comment of "rerun", as 2.47 (-10.2 SDI) at 0154 with a comment of "rerun with fresh QC", as 2.67 (-8.9 SDI) at 0207 with a comment of "rerun with fresh QC and as 2.57 (-9.5 SDI) at 0221 with a comment of "rerun with new reagent at end of old lot, switching over to new lot" before being acceptable with a result of 3.88 (-0.8 SDI) at 0229. The change of reagents represents a change in the test system. C) Review of the laboratory's quality control records revealed that on 8/11/20 QC for Alb, lot # 2113A target of 2.6 range of (2.4 to 2.9) was resulted as 1.68 (-9.2 SDI) at 0151 with a comment of "rerun", as 1.84 (-7.6 SDI) at 0207 with a comment of "rerun with fresh QC", as 1.80 (-8 SDI) at 0221 with a comment of "rerun with new reagent at end of old lot, switching over to new lot" before being acceptable with a result of 2.63 (-0.3 SDI) at 0228. The change of reagents represents a change in the test system. D) Review of patient results for Alb revealed that 35 patients, identified as patients number 1 through 35 on a separate patient identification list, had Alb performed and reported on 8/10/20 between 0726 and 2231 since the last successful QC for Alb run on 8/10/20 at 0055. E) Upon request, the laboratory could not produce documentation that the Alb results for the patients identified above had been evaluated and remediated, if necessary. F) In an interview on 4/14/21 at 01:20 PM the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the Alb QC performed on 8/11/21 failed to meet the laboratory's criteria for acceptability and Alb results for patients performed since the last acceptable QC were not evaluated.