Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1048934	05/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Wrmc Medical Complex Laboratory	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5783	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 Quality Control (QC) policy and procedure, Chemistry QC reports for January 2022, May 2022 and September 2022, corrective Action Logs for the same time periods, patient result reports and interview with laboratory staff it was determined that in one of three months reviewed, laboratory failed to evaluate patient test results back to the last successful QC when QC failure required actions which resulted in changes to the test system . Survey findings follow: A) Review of the laboratory's policy and procedure for quality control revealed that the laboratory was obligated to review previously reported patient results to the last successful QC performance when QC failure required corrective action that changed the performance of the test system. B) Review of MAS ChemTRAK Unassayed control lot # 24801 QC reports for 9/13/22 revealed that level 1 QC for Alkaline Phosphatase (AlkPtase) failed greater than minus 2 standard deviation indices (SD) from the target value on four successive attempts at 3:01 am (with comment "will rerun with same QC fluid"), at 4:29 am (with comment "will rerun with fresh QC material"), at 5:53 am (with comment " will ask ___ to look at this for resolution", at 7:22 am (with comment "result fell below peer data range will recalibrate"), before being acceptable at 9:16 am. Recalibration reflected a change in the performance of the test system. . C) Review of the QC reports for September 2022 revealed that the last acceptable QC

	result for AlkPtase prior to the occasions identified above was performed on 9/12/22 at 0:33 am. D) Review of patient result reports revealed that AlkPtase testing was performed and reported on 33 patients (#s 1 through 33 on a separate patient identification list) on 9/12/22. E) In an interview on 5/3/23 at 5:00 p.m., the laboratory staff members (#6 and #12 on the CMS 209 form) confirmed that the AlkPtase results reported on 9/12/22 on the patients identified above had not been evaluated and should have been.