Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465892	06/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Levi Hospital Clinical Laboratory	300 Prospect Ave, Hot Springs, 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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of quality control documentation for November 2021, February 2022, and April 2022, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to establish statistical parameters for acceptable quality control for Hematology. Survey findings include: A. The surveyor reviewed hematology quality control documentation for November 2021, February 2022, and April 2022, The surveyor requested data used for calculating the acceptable ranges in use for quality control evaluation. None was provided. B. In an interview, at 1:47 p.m. on 6/21/2022, laboratory employee #1 (as listed on the form CMS-209) stated that the calculation of acceptable quality control ranges was not available.
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 a review of March 2022 quality control, a review of medical staff meeting minutes, a review of patient test documentation, and interviews with laboratory staff, it was determined the laboratory failed to review patient test results when Cholesterol quality control failed to meet the laboratory's criteria for acceptability. Survey findings include: A. Through a review of quality control documentation for March 2022 it was determined the laboratory failed to perform Cholesterol testing for Level 1 Performance Verifier on 11 of 21 days of patient testing in March. Forty-one patients were tested on 3/1/22, 3/8/22, 3/9/22, 3/10/22, 3/11/22, 3/16/22, 3/18/22, 3/21 /22, 3/22/22, 3/23/22, and 3/24/22, when only one level of control was tested. B. A review of medical staff meeting minutes dated 4/19/2022 revealed, "On 12 days, affecting 41 inpatients, only one level of QC was run for Cholesterol. This action does not follow lab policy nor CLIA rules for quality control." C. In an interview, at 2:40 on 6/21/2022, the surveyor requested documentation that the 41 patient results were reviewed for the 12 days when quality control did not follow lab policy. None was provided. During the interview, laboratory employee #1 (as listed on the form CMS-209) stated that the laboratory did not have documentation of reviewing the results of the patients tested when only one level of control was run.