Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2226039	04/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics - Fort Smith Rrl	6801 Rogers Ave, 1st Floor Lab, Fort Smith, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: By review of personnel records and interview it was determined that the competency of the technical consultant was not assessed by the laboratory director on an annual basis. Findings follow: A) Upon review of personnel files the last documented annual evaluation of the competency of the technical consultant (employee #5 from the form CMS-209) was dated July 2019 and was for another laboratory. B) In an interview, at 10:03 AM on 4/13/22, the laboratory staff member, identified as numbers 3 and 4 on the CMS 209 form, confirmed the lack of competency documentation for the technical consultant.
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 the of three months of Monthly Quality Control (QC) data and Levy-Jennings Charts, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to establish the criteria for acceptability of hematology control materials using statistical parameters for each lot number of control materials on one of three months reviewed. Survey findings follow: A) Review of the Levy-Jennings charts for hematology QC XN-Check Lot numbers 20003101, 20003102, 20003103 performed in March 2022 revealed that all daily results for all three levels appeared to be indistinguishable from the mean target values and the acceptable range for all analytes in complete blood cell testing were defined as the mean target value plus/minus the mean target value resulting in an acceptable range of 0.00 to 2 times the mean target value. Review of acceptable ranges for July and December 2021 revealed that acceptable ranges for CBC analytes were determined by plus/minus two standard deviations. B) In an interview on 4/13 /22 at 11:55 AM the laboratory staff member, identified as number three on the CMS 209 form, stated that an error was made in defining the acceptable range for hematology QC in the hematology instrument for the lot numbers of QC material identified above and for March and the entire use cycle of the lot numbers of QC material testing personnel would not have a correct notification if QC results were unacceptable.
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 the laboratory policy and procedure for quality control (QC), QC results for Partial Thromboplastin Time (PTT) assays, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to document corrective action taken when quality control results were outside the laboratory's criteria for acceptability in one of one month of quality control results reviewed. Findings follow: A) Review of the laboratory's policy and procedure for quality control revealed that when QC results fail to meet criteria for acceptability all corrective action must be documented. B) Review of Citrol Level 1 Lot # 564839 QC results for PTT assays with an acceptable range of 25.1 to 28.1 was resulted as 31.0 > 4 standard deviations from target value on 3/11/22. C) Upon request the laboratory was unable to provide documentation of the corrective action taken to bring level 1 QC within acceptable limits D) In an interview on 4/13/22 at 10:15 AM the laboratory staff member, identified as number 5 on the CMS 209 form, confirmed that corrective action on the failure identified above was not documented and the laboratory policy and procedure required documentation.