Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2223375	03/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics - Oklahoma City Rrl	4200 W Memorial Rd, Ste 110, Oklahoma City, OK	

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
D0000	The recertification survey was performed on 3/5,6/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the quality director, technical consultant, and satellite operations director at the conclusion of the survey.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the technical consultant, the laboratory failed to follow their written policy for establishing the means for new lot numbers of control materials prior to implementation for six of six lot numbers. Findings include: (1) On 03/05/2024 at 11: 15 am, the technical consultant stated the following: (a) The laboratory performed CBC (complete blood count) testing using the Sysmex XSN-1000 hematology analyzer; (b) Three levels of XN Check QC (quality control) materials were tested each morning with the start-up of the analyzer, with one level tested after four hours and one level tested after eight hours (alternating levels by following a schedule posted on the analyzer). (2) A review of the SOP (Standard Operation Procedure) version 4, Titled, "Policy for the Determination of Targets & Limits for QC Materials" under section C."Short Shelf-life Quality Control Material" required the laboratory to test new lot numbers of controls in parallel by analyzing each level of control a minimum of twice a day for 5 days prior to the expiration of the previous lot. After a minimum of 10 data points were accumulated the mean was calculated; (3) A review of records for six control lot numbers identified the laboratory did not follow

	their policy as follows: (a) Lot #33141101, Lot #33141102, and Lot #33141103 - The controls had been tested ten times over three days as follows: (i) Six times on 11/20 /2023; (ii) Three times on 11/21/2023: (iii) One time on 11/22/2023. (b) Lot #40051101, Lot #40051102, and Lot #40051103 - The controls had been tested ten times over three days as follows: (i) Five times on 01/17/2024; (ii) One time on 01/18 /2024; (iii) Four times on 01/19/2024. (4) The findings were reviewed with the technical consultant who stated on 03/06/2024 at 11:57 am, the laboratory did not follow their written policy. 48517 Based on a review of policies and procedures, observation, and interview with the technical consultant the laboratory failed to follow their written policy for urine centrifuge speed settings from January 2022 through the current date. Findings include: (1) On 03/05/2024 at 11:00 am, the technical consultant stated the laboratory performed microscopic urine exams according to laboratory policy; (2) On 03/05/2024 a review of the policy titled, "Routine Urinalysis by Clinitek Series (Status, Status + & Advantus)" required the laboratory to centrifuge specimens for 5 minutes at 400 relative centrifugal force (RCF); (3) Examination of the Dashflex centrifuge display revealed that the lab was centrifuging at 340 RCF; (4) The findings were reviewed with the technical consultant who confirmed on 03/05 /2024 at 11:00 am, the lab was centrifuging at 340 RCF.