

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2223375	(X3) Date Survey Completed 09/25/2025
Name of Provider or Supplier Quest Diagnostics - Oklahoma City Rrl	Street Address, City, State 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 09/25/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interviews with the laboratory director, the laboratory failed to follow their written policy for performing correlation studies prior to implementation for two of two coagulation reagent lot changes during the review period of August 2025 to the current date. Findings include: (1) On 09/25/2025 at 09:30 am, the laboratory director stated the following: (a) The laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing using the Sysmex CA-600 series analyzer. (2) The coagulation reagents were put into use approximately on 09/10/2025: (a) Dade Innovin lot #564678 was used for the PT reagent (b) Dade Actin FSL, lot #575043 was used for the PTT reagent (3) A review of the Electronic Document Control System titled, "Coagulation Reagent & Controls Roll-Over, Validation Protocol" on page 5, under section 5.3.2 "Validation Protocol-Correlation (Parallel Studies)" stated the following: (a) "A minimum of 40 specimens (20 normal and 20 abnormal) must be tested with the old and new lot of reagents. Test specimens within one hour of each other (old versus new lot). The 20 normal specimens can be the normal donor specimens used for the reference interval verification study." (4) A review of the PT and PTT correlation (parallel studies) records identified the</p>

laboratory failed to utilize a minimum of 40 specimens (20 normal and 20 abnormal) as follows: (a) PT - A total of 25 specimens had been tested (consisted of three abnormal specimens) ; (b) PTT - A total of 24 specimens had been tested (consisted of ten normal and 14 abnormal specimens). (5) The records were reviewed with the laboratory director who stated on 09/25/2025 at 01:00 pm, the laboratory had not followed their policy for performing correlation studies for the new lot numbers of PT and PTT reagents.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory director, the laboratory failed to ensure competency evaluations for moderate complexity testing had been performed at least two times (semiannually) during the first year of testing for one of one testing person. Findings include: (1) On 09/25/2025, a review of personnel records for one person performing moderate complexity testing identified the following: (a) Testing Person #2: (i) For the Clinitek Advantus test system, the initial training was completed on 06/27/2024 and the first competency evaluation was completed on 04/23/2025. There was no documentation that a competency evaluation had been completed until 09/23/2025; (ii) For the Sysmex XN-1000 test system, the initial training was completed on 06/25/2024 and the first competency evaluation was completed on 12/31/2024. There was no documentation that a competency evaluation had been completed until 09/23/2025; (iii) For the Beckman Coulter DxC700 test system, the initial training was completed on 07/30/2024 and the first competency evaluation was completed on 04/23/2025. There was no documentation that a competency evaluation had been completed until 09/23/2025. (2) The findings were reviewed with the laboratory director who stated on 09/25/2025 at 11:10 am, the second competency evaluation had not been completed during the first year of patient testing as stated above.