Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2013239	07/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Austin Rrl	3708 Jefferson Street Suite B, Austin, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the validation records, manufacturer's instructions, laboratory's policy and procedure, observation, requisition slips, courier records, interview, and pre-survey paperwork, the laboratory failed to spin the neonatal total bilirubin and neonatal direct bilirubin using the Advanced Bilirubin Stat-Analyzer Photometer by Advanced Instruments within approximately 30 minutes to one hour after collection for five out of five specimens reviewed. Findings follow. A. Review of the validation showed the Advanced Bilirubin Stat-Analyzer Photometer was validated on 5/12 /2021. B. Review of the Advanced Instruments technical reference titled INSTRUCTION- In-Vitro Diagnostic of Neonatal Bilirubin Using the Advanced BR2 Bilirubin Stat-Analyzer, CL00357 Rev 0, under VII. SAMPLE REQUIREMENTS for Serum at Collection/Preparation stated, "Allow the blood to clot at room temperature (approximately 30-60 minutes) and separate the serum from cells by centrifugation as soon as possible after clot formation." C. Review of the laboratory's policy and procedure titled Neonatal Bilirubin by Bilirubinometer, 11/2012, under 3. SPECIMEN

	REQUIREMENTS for 3.1 Patient Preparation at Specimen Collection and/or Timing stated, "Collect using standard phlebotomy techniques for neonates. Separate from clot as soon as possible after visible clot formation, usually 30 minutes after collection." And, under 3. SPECIMEN REQUIREMENTS for 3.2 Specimen Type & Handling at Timing Considerations stated, "Sample collected in serum separator tube must be allowed to clot for at least 30 minutes, but no longer than 1 hour." D. Surveyor observed neonatal bilirubin and direct bilirubin samples received in the laboratory unspun: 1. At 1115 hours on 07/20/2022, surveyor observed sample, requisition # 311423083, from account #10764290 was in the drop-off tray in the laboratory. Review of the requisition slip showed it was collected at 9:37 AM. Review of the Route Detail Sheet STAT Calls form showed the Call Received Time as 9:56 AM, and the Pick Up Time was 10:59 AM, Delivery Time was 11:07 hours (elapsed time thus far was 1 hour 38 minutes). 2. At 1211 hours on 7/20/2022, surveyor observed sample, requisition # 38942869, from account #4902575, was dropped off in the laboratory. Review of the requestion slip showed it was collected at 10:48 AM. review of the Route Detail Sheet STAT Calls form showed the Call Received Time as 10:49 AM, and the Pick Up Time was 11:27 AM, Delivery Time was 12:06 hours. At 1211 hours surveyor observed testing personnel #2, as listed on the CMS form 209, centrifuge the sample (elapsed time was 1 hour 23 minutes). 3. At 1336 hours on 7/20/2022, surveyor observed sample, requisition # 0115582, from account #56924, was in the drop-off tray in the laboratory. Review of the requestion slip showed it was collected at 10:18 AM. review of the Route Detail Sheet STAT Calls form showed the Call Received Time as 11:20 AM, and the Pick Up Time was 12:38 PM, Delivery Time was 13:17 hours. At 1405 hours surveyor observed testing personnel #2 centrifuge the sample (elapsed time was 3 hours 47 minutes). 4. At 1336 hours on 7/20/2022, surveyor observed sample, requisition # 0008471, from account #61179, was dropped off in the laboratory. Review of the requestion slip showed it was collected at 11:18 AM. review of the Route Detail Sheet STAT Calls form showed the Call Received Time as 11:53 AM, and the Pick Up Time was 12:34 PM, Delivery Time was 13:36 hours. At 1405 hours surveyor observed testing personnel #2 centrifuge the sample (elapsed time was 2 hours 47 minutes). 5. At 1336 hours on 7/20/2022, surveyor observed sample, requisition # 0023525, from account #61178, was dropped off in the laboratory. Review of the requestion slip showed it was collected at 10:57 AM. review of the Route Detail Sheet STAT Calls form showed the Call Received Time as 12:22 PM, and the Pick Up Time was 1:11 PM, Delivery Time was 13:36 hours. At 1405 hours surveyor observed testing personnel #2 centrifuge the sample (elapsed time was 3 hours 8 minutes). E. Interview with testing personnel #1, as listed on the CMS form 209, on July 20, 2022 at 1115 hours acknowledged the lab receives samples from outpatient clients that may or may not be spun and was unaware of the processing time for neonatal bilirubins and looked it up in the SOP for the surveyor. F. Review of the Annual Test Volume & Proficiency Testing Programs Worksheet showed an annual testing volume of 2,010 for the Bilirubinometer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit

	of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the validation records, calibration verification records and interview, the laboratory failed to perform calibration verifications on Progesterone, Estradiol, Total Human Chorionic Gonadotropin (THCG) every 6 months on the Siemens Centaur CP for one of two events reviewed from March 2021 - July 2022. Findings follow. A. Review of validation records for the Centaur CP showed the validation was completed 3/22/2021. B. Review of the calibration verification records for Progesterone, Estradiol, and THCG performed on the Centaur CP analyzer showed calibration verifications were performed on 3/23/2022 (elapsed time was 12 months). C. Surveyor requested on July 20, 2022 at 1015 hours additional calibration verification records. Interview with testing personnel #1, as listed on the CMS form 209, on July 20, 2022 at 1040 hours in the laboratory verified one of two calibration verifications were not performed.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of the validation records, manufacturer's instructions, laboratory's policy and procedure, observation, requisition slips, courier records, interview, and pre-survey paperwork, the Laboratory Director failed to ensure the laboratory spun neonatal total bilirubin and neonatal direct bilirubin using the Advanced Bilirubin Stat-Analyzer Photometer by Advanced Instruments within approximately 30 minutes to one hour after collection for five out of five specimens reviewed (see D5311).