Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0093126	12/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics, Llc	3 Sterling Dr, Wallingford, CT	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide a complete ova and parasite procedure to reflect the actual procedure in place in the subspecialty of parasitology. Findings include: 1. Record review on 12/6/2022 of the laboratory 'Ova and Parasites, Concentration Method and Trichrome Stain, SOP ID: QWAQDMI823' procedure revealed in Section 18: Document History: signed by the laboratory director 7/22/2022 states "Scope of work being performed at Wallingford RRL (QWA) will only be performing section 10, reporting in QMPs, all staining and sample preparation will be taking place at the Marlborough laboratory." 2. Staff

	interview on 12/6/2022 at 11:30AM with the parasitology technical supervisor revealed the following: a. The laboratory receives Trichrome slides already stained. b. The laboratory receives previously processed centrifuged pellets for the concentrate microscopic examination. c. The laboratory begins the ova and parasite procedure from section 10 of the above procedure. 3. The laboratory performs 2,100 parasitology tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow the manufacturers recommendation and define the appropriate humidity range in the specialties of hematology and chemistry. Findings include: 1. Record review on 12/06 /2022 of the Sysmex XN-2000 hematology analyzer 'Instruction for Use' manual revealed that the relative humidity should be between 20 to 85% for proper function. 2. Record review on 12/06/2022 of the BeckMan Coulter AU DxC700 and AU680 chemistry analyzers 'Precautions, Installation, and Specification, 2.2 Installation Environment Precautions' revealed that the relative humidity should be between 40 to 80% for proper function. 3. Record review on 12/06/2022 of the 'PRL Use Only - Humidity/Temperature Chart' for the period October 1, 2022 to December 6, 2022 revealed the following: a. The chart acceptable humidity range is 10 to 80%. b. All humidity readings fell within 10 to 80%. c. 11 of 67 days the humidity fell below the XN-2000 analyzer minimum humidity of 20%. d. 57 of 67 days the humidity fell below the BeckMan Coulter analyzers minimum humidity of 40%. 4. Staff interview on 12/06/2022 at 2:45 PM with the chemistry general supervisor #2 revealed that he /she was unaware of the different humidity ranges for proper function of the hematology and chemistry instruments. 5. The laboratory performs 574,907 tests annually in the specialty of hematology and 1,006,875 tests annually in the specialty of chemistry.
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 record review and staff interview, the laboratory failed to perform the calibration verification to include the low, mid and the highest value of the reportable range for D-Dimer in the specialty of Hematology. Findings include: 1. Record review on 12/6/2022 of the laboratory's Method validation D-Dimer on CS-2500 verified the On-Board dilution check, Analytical Measurement Range (AMR): 0.19 to 4.40 mcg /mL FEU and Clinical Reference Range 0.19 to 35.00 mcg/mL FEU. 2. Record review on 12/6/2022 of the "Normal Calibration Curve" print out performed on 10/12 /2022 with DDi Reag: 568828, Calibrator/Lot No. 569428 reveals the six-point calibration with the DDI values as follows: 0.16,0.32,0.64,1.27,2.55 and 5.10. 3. Record review on 12/6/2022 of the D-Dimer-CS procedure manual revealed the following: a. Section 10.4: Analytical Measurement Range (AMR): CS series: 0.19-~4.40 mcg/mL FEU (calibrator dependent). With 1:10 dilution, AMR is extended to ~35 mcg/mL FEU (calibrator dependent). b. Section 10.6: Repeat Criteria and Resulting: If the result is "35 with > flag", Repeat. If repeat confirms, report as ">35 mcg/mL FEU". 4. Record review on 12/6/2022 of calibration verification records revealed the following: a. Six-point calibration verification is performed for each new reagent lot. b. The calibration verification material failed to include at least one value near the upper limit of the AMR with 1:10 dilution extended to 35.0 mcg/mL FEU as stated in 3a above. 5. Staff interview on 12/6/2022 at 1:00 PM with the Hematology Technical Supervisor # 2, confirmed the above findings. 6. The laboratory performs approximately 984 tests annually.
D5527	PARASITOLOGY CFR(s): 493.1264(c)(d) (c) Each month of use, the laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the Trichrome permanent stain had the required quality control (QC) performed in the subspecialty of parasitology. Findings include: 1. Record review on 12/6/2022 of the CMS 116 survey application signed by the laboratory director revealed the following: a. Section VIII: Non-waived Testing with parasitology checked off. b. Signed analyte test list included with the application listed Ova and Parasite on the test menu. 2. Record review on 12/6/2022 of laboratory 'Ova and Parasites, Concentration Method and Trichrome Stain, SOP ID:QWAQDMI823' procedure revealed the following: a. Section 6: Quality Control: Trichrome stain: Positive control slide containing protozoa

	and a negative control slide containing white blood cells and no protozoa. b. QC Frequency: Trichrome stain: i. Each new lot number or shipment of reagents must be tested with a positive and negative control prior to reporting patient results. ii. Test a positive and negative control with each day of patient testing or whenever reagents are changed. 3. Record review on 12/6/2022 of the Ova and Para QC logbook revealed the lack of documentation of QC for the Trichrome stain. 4. Staff interview on 12/6 /2022 at 11:30AM with the parasitology technical supervisor confirmed the following: a. The laboratory receives Trichrome slides from a referral laboratory already stained. b. The referral laboratory does not send a control slide(s) with each batch of slides. 5. The laboratory performs 2,100 parasitology tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review on 12/6/2022 of 2 final Complete Blood Count (CBC) test reports revealed the laboratory failed to ensure the normal ranges matched the laboratory established age specific ranges in the specialty of Hematology. Findings include: 1. Record review on 12/6/2022 of the laboratory's Procedure Manual (PM) revealed the laboratory established age specific normal ranges for CBC as follows: 2 Day(d), 3d, 2-week, 1 month(m), 2m, 3m, 6m, 1 year(y), 2y, 6y, 12y, 18y, 133y and No Age. 2. Record review on 12/6/2022 of 2 CBC patient test reports Blood Count (CBC) revealed the following: a. Reference Range attached for Patient A, age 7 month = the laboratory established reference range for age 1 year for the following analytes: Red Blood Cell (RBC), Hemaglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV) and Mean Corpuscular Hemaglobin (MCH). b. Reference Range attached for Patient B, age 14 years = the laboratory established reference range for age 18 years for the following analytes: RBC, HGB, HCT, MCV and MCH. 3. Record review on 12/6/2022 of the Laboratory CBC procedure revealed the procedure failed to establish the process to select which reference range is appropriate for patients that fall outside the laboratory established age specific reference range. 4. Staff interview on 12/6/2022 at 1:30 PM with the Hematology Technical Supervisor # 1 confirmed the above findings. 5. The laboratory performs approximately 71,856 RBCs, 72,600 HGBs, 72,331 HCTs, and 71,856 MCV tests annually.