Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0081915	08/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Llc	531 Faunce Corner Rd, North Dartmouth, MA	

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	A CLIA recertification survey was conducted for the SMG, Hawthorn Medical Associates laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 procedure manual failed to include reference ranges for Complete Blood Count (CBC) in the specialty of Hematology. Findings include: 1. Record review on 8/19/2022 of the 'Sysmex XN-2000' Laboratory Procedure for 2 new Sysmex Towers (right side S/N 41513 and left

	side S/N 41514), placed into service on 4/6/2020 revealed the procedure did not include reference ranges for CBC. 2. Staff interview with the Technical Supervisor (TS) on 8/19/2022 at 1:00 PM confirmed the Sysmex XN-2000 Laboratory Procedure did not contain reference ranges for CBC. The laboratory performs 71,486 CBC tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on surveyor observation, record review and staff interview, the laboratory failed to label reagents with the appropriate expiration dates in the specialty of Hematology. Findings include: 1. Surveyor observation on 8/19/2022 at 2:15 PM of the laboratory refrigerator revealed the following Hematology controls open and in use without an open date and expiration date indicated: a. Sysmex XN Check level 1, lot number 21711101 b. Sysmex XN Check level 2, lot number 21711102 c. Sysmex XN Check level 3, lot number 21711103 2. Record review on 8/19/2022 of the 'Sysmex XN-2000' Laboratory Procedure for 2 new Sysmex Towers (right side S/N 41513 and left side S/N 41514), placed into service on 4/6/2020 revealed: XN Check section, e.2, "Open vial stability is 7 days when promptly refrigerated after each use." 3. Record review on 8/19/2022 of the Sysmex XN Check package insert revealed, "Open vials and vials which have been sampled by cap piercing will retain stability for 7 days if stored at 2-8 degrees Celsius after being re-capped." 4. Staff interview on 8/19/2022 at 2:20 PM with the General Supervisor (GS) confirmed the Sysmex controls listed above were open and in use and did not have an open date or expiration date indicated. The laboratory performs 71,486 CBC tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on record review and staff interview, the laboratory failed to document centrifuge function checks every 6 months to ensure platelet poor plasma (PPP) for accurate and reliable test results for the Prothrombin Time (PT) test in the specialty of Hematology. Findings include: 1. Record review on 8/19/2022 of the laboratory's centrifuge maintenance and function checks records for the centrifuge used to spin blood collection tubes for coagulation studies, revealed a lack of documentation for PPP studies in 2020, 2021 and 2022 to date. 2. Record review of the Siemens manufacturer package insert for Siemens Innovin reagent on 8/19/2022 revealed the following statement under the Specimen Collection and Preparation Section: "Please refer to CLSI document H21-A5 for detailed information on sample preparation and

	storage." 3. Record review on 8/19/2022 of the CLSI H21-A5 document, Section 6.2: Processing Suitable Specimens revealed: "The reliability of the centrifugation procedure, to ensure plasma platelet counts are within acceptable limits, should be validated every six months or after modification of the centrifuge." 4. Staff interview with the general supervisor (GS) on 8/19/2020 at 2:30 PM confirmed PPP performance checks were not performed in 2020, 2021 and 2022 to date. The GS stated, "We don't do it. However, we just talked about adding it." The laboratory performs 9,592 PT tests and 1,212 PTT tests annually.
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 interview with the General Supervisor (GS) on 8/19 /2022, the laboratory failed to perform calibration verifications every six months or, as appropriate, as evidenced by the following: Findings include: 1. The surveyor reviewed the quality control records for calendar years 2021 and 2022. The review revealed that calibration verifications of at least three points were not performed once every six months for twenty-nine (29) out of twenty-nine (29) chemistry analytes requiring calibration verification on the Beckman AU 680 analyzer. Six-month calibration verifications were performed in February/March of 2021 and February /March of 2022. The calibration verifications were not performed every six months as required in calendar year 2021. 2. Staff interview with the GS on 8/19/2022 at 12:43 PM confirmed that calibration verifications had not been performed every six months for twenty-nine (29) out of twenty-nine (29) analytes requiring calibration verification in calendar year 2021. The laboratory performs 1,339,865 chemistry tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must

	have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Based on procedure review and interview the General Supervisor (GS) on 8/19/2022, the laboratory failed to perform twice annual evaluation between two analyzers performing the same test as evidenced by the following: The laboratory performs CBC tests using two Sysmex XN-2000 analyzers (tower right side and tower left side) and PT, PTT, and D-dimer tests using two Sysmex CS 2500 analyzers. Findings include: 1. The surveyor reviewed the comparison studies on the two Sysmex XN-2000 analyzers and the two Sysmex CS 2500 analyzers for 2021 and 2022. 2. For calendar year 2021 the laboratory performed comparison studies twice annually. The comparison studies for the two Sysmex XN-2000 analyzers on 3/21/2021 and 10/26 /2021 and the two Sysmex CS 2500 analyzers on 3/09/2021 and 11/18/2021. The laboratory's SOP states that the comparison studies are to be performed every six months. 2. For calendar year 2022 to date the laboratory failed to perform twice annual comparison studies on the two Sysmex XN-2000 analyzers for CBC and on the two Sysmex CS 2500 analyzers for PT, PTT, and D-dimer. It has been more than six months since the last comparison study has been performed. 3. Staff interview with the GS on 8/18/2022 at 11:43 AM confirmed that the comparison studies have not been performed in calendar year 2022 to date. The laboratory performs 71,486 CBC tests, 9,592 PT tests, 1,212 PTT tests, and 1,210 D-dimer tests annually.