Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0694171	02/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Quinnipiac Medical Of Branford, Llc	960 Main St, Branford, 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 procedure manual in the specialty of hematology. Findings include: 1. Record review of laboratory's procedure manual on 2/21/19 for complete blood count (CBC) test revealed the lack of the following procedures: a. Specimen requirements and stability. b. Specimen acceptance and rejection criteria. c. Step by step performance of the CBC procedure. d. Calibration procedures. e. Instrument maintenance procedures. f. Quality control acceptability criteria. g. Reportable ranges and normal value. h. Corrective action for calibration or control result failures. i. Procedure when the

	system becomes inoperable. 2. Staff interview with the testing personnel #1 on 2/21 /19 at 10:30 AM confirmed the SOP manual in the specialty of hematology is incomplete and needs to be updated. 3. The laboratory performs 934 CBC tests annually in the specialty of hematology.
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 appropriately label control material in the specialty of hematology. Findings include: 1. Record review of the Sysmex XP-300 control material on 2/21/19 revealed the following: a. The laboratory utilizes Eightcheck -3WP X-Tra Controls: Low, Normal and High Controls b. The current control lot# 9029 with an expiration of 5/8 /19 was placed in service on 2/7/19. 2. Record review of the Sysmex Operation manual on 2/21/19 revealed once a control vial is open, it expires in 14 days. 3. Surveyor observation of the 3 current control vials in use on 2/21/19 at 11:20 AM revealed documentation of open and expiration date was not recorded. 4. Surveyor observation on 2/21/19 at 11:20 AM of the laboratory wall calendar revealed a notation to change the hematology controls on 2/26/19. Documentation of when the controls were placed in service was not recorded. 5. Staff interview with testing personnel #1 on 2/21/19 at 11:20 AM confirmed the above findings. 6. The laboratory performs 934 Complete Blood Counts annually in the specialty of hematology.
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 daily maintenance for laboratory equipment in the specialty of hematology. Findings include: 1. Record review of the Sysmex XP-300, Serial B1473 monthly maintenance logs on 2/21/19 revealed the laboratory failed to document daily maintenance activities from 8/10/17 through 2/21/19. 2. Record review of the Sysmex operator manual, Appendix 14.8, XP-300 maintenance checklist on 2/21/19 revealed that maintenance protocols include to clean TD chambers and hydraulic system; check trap chamber level and discard daily in order to ensure accurate and reliable test results. 3. Staff interview with testing personnel #1 (TP1) on 2/21/19 at 11:46 AM confirmed the above findings. TP1 stated daily maintenance was performed but testing personnel did not document it on the maintenance logs. 4. The laboratory performs 934 Complete Blood Counts annually in the specialty of hematology.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to evaluate and approve validation studies for the Sysmex XP-300 analyzer prior to patient testing in the specialty of hematology. Findings include: 1. Record review of the Sysmex Resource and Validation Manual on 2/21/19 revealed the following: a. Method performance of accuracy, precision, reportable range, carryover and comparison studies was performed 5/4/17. b. Documentation of the laboratory director review and acceptance of the above method characteristics was not available. 2. Staff interview with the office manager (OM) on 2/21/19 at 10:20 AM confirmed the above findings. OM further stated patient testing on the XP-300 analyzer had begun on 8/9/17. 3. The laboratory performs approximately 934 Complete Blood Counts annually in the specialty of hematology.