Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0902455	03/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Milford Pediatric Group	One Golden Hill St, Milford, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to enroll in proficiency testing (PT) in the specialties of Hematology and Microbiology. Findings include: 1. Record review on 3/11/19 of the laboratory test reports revealed the laboratory was performing the following moderate complexity tests. a. Complete blood count (CBC) b. Throat culture by Strep Select Agar. c. Urine culture, uricult 2. Record review of the laboratory's inspection documentation on 3/11/18 revealed the laboratory failed to provide evidence or documentation of PT enrollment for the above tests. 3. Staff interview with the practice manager (PM) on 3/11/18 at 10:30 AM confirmed the above findings. The PM stated the laboratory has been performing bacteriology testing since opening 8 - 10 years ago and hematology testing for approximately 4 years and never enrolled in PT. 4. The laboratory performs 621 cultures annually in the specialty of microbiology and 8,225 tests annually in the specialty of hematology.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to retain quality control (QC) and instrument maintenance records at least for two years in the specialty of hematology. Findings include: 1. Record review of the laboratory's hematology QC and maintenance records on 3/11/19 revealed the laboratory did not have the daily QC and maintenance records for the Horiba hematology analyzer as indicated below: a. June 2017 b. August 2017 c. October 2017 2. Record review of the laboratory's hematology QC records on 3/11/19 revealed the laboratory did not have daily QC records for the Sysmex XP300 (SN B3577) analyzer from: a. 12/28/17 through 6/6/18. b. 11/27/18 through 2/11/19. 3. Staff interview with the laboratory supervisor (LS) on 3/11/19 at 11:15 AM confirmed the above findings. The LS further stated QC records were inadvertently deleted and not recoverable.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's procedure manual on 3/11/19 revealed the following: a. The laboratory did not have policy in place to assess the competency of the technical consultant (TC) and clinical consultant (CC) until 2019. The new policy was signed by the laboratory director but not dated. 2. Record review on 3/11/19 of the laboratory's testing personnel records revealed: a. Competency assessment documentation for the TC, CC, and laboratory moderate complexity testing personnel was not available, since the laboratory opened 8 - 10 years ago. 3. Staff interview with the practice manager (PM) on 3/11/19 at 11:10 AM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel until recently and they were not assessed. The PM stated the new policy was put into place approximately a week prior to inspection and although the policy was signed by the laboratory director, it was not dated.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. The cumulative effect of this lack of oversight resulted in the laboratory's inability to ensure accuracy and reliability of patient test results in the specialty of hematology and the subspecialty of bacteriology. Refer to D5403, D5407, D5413, D5421, D5429, D5469, D5471, D5781, and D5791.
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 which includes all three phases (pre-analytical, analytical and post-analytical) of testing in the specialty of hematology. Findings include: 1. Record review on 3/11/19 of the CMS-116 form dated 2/11/19 submitted by the laboratory for change of certificate type from certificate of waiver to certificate of compliance, revealed the application was received on 2/13/19 at the state agency. The laboratory currently has a certificate of registration. 2. Record review on 3/11/19 of the hematology procedure manual complete blood count (CBC) procedure, revealed the following: a. The procedure was updated and signed by the laboratory director on 2 /26/19. b. The following were not included in the procedure while the laboratory was testing patient samples up until 2/11/19. i. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and criteria for specimen acceptability and rejection were not included in the procedure in use while patients were being tested. ii. Instrument maintenance requirements. iii. Control procedures. iv. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. v. The protocol for reporting critical, panic, or alert test result values. vi. Reference (normal) values. vii. Reportable ranges. viii. Reporting of test results. 3. Staff interview with the practice manager (PM) on 3/11/19 at 10:00 AM confirmed the above findings. The PM stated the laboratory has been performing CBC's for approximately 4 tears. 4. The laboratory performs 8,225 tests annually in the specialty of hematology.

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to approve new laboratory procedures before they were put into use in the laboratory. Findings include: 1. Record review of the laboratory procedure manual on 3/11/19 revealed the Horiba CBC procedure was not signed by the laboratory director. 2. Record review on 3/11/19 of the Horiba validation documentation revealed the validation was performed by the manufacturer on 7/28/14. 3. Staff interview with the practice manager on 3/11 /19 at 11:00 AM confirmed the Horiba validation took place in 2014 and the procedure was never signed by the laboratory director.
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 document temperatures in the specialty of microbiology. Findings include: 1. Record review on 3 /11/19 of the 2017 laboratory incubator temperature logs revealed, temperatures were not recorded for 84 of 365 days in 2017. 2. Staff interview with the practice manager on 3/11/19 at 11:00 AM confirmed the above finding.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow the manufacturer's instructions when performing new instrument validation studies in the specialty of hematology. Findings include: 1. Record review on 3/11/19 of the Sysmex Operator's Manual, Section 3, Validation Protocols, revealed, "It is the

	customer's responsibility to perform additional studies, following the requirements of their accrediting agency. The following protocols are provided: Correlation Studies and Reference Range Verification." 2. Record review on 3/11/19 of the validation studies for the Sysmex XP 300 - S/N B3577 revealed documentation for correlation studies and reference range verification was not available. 3. Record review on 3/11 /19 of the Horiba CBC analyzer (no longer in use) validation documentation revealed the validation was performed by the manufacturer on 7/28/14. Documentation for participation by the laboratory staff was not available. 4. Staff interview with the practice manager (PM) on 3/11/19 at 1:00 PM confirmed the above findings. The PM stated he/she was told by the Sysmex representative that the validation data performed by the Sysmex representative was to be given to the CLIA inspectors and thought it was complete. The PM further confirmed the manufacturer performed the validation studies on the Horiba analyzer. 5. The laboratory performs 8,225 tests 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 routine maintenance and function checks for laboratory equipment in the specialty of hematology. Findings include: 1. Record review of the laboratory's 2017 and 2018 hematology maintenance records on 3/11/19 revealed the laboratory did not have the daily maintenance records for the Horiba hematology analyzer as indicated below: a. June 2017 b. August 2017 c. October 2017 2. Staff interview with the practice manager on 3/11/19 at 11:15 AM confirmed the above findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to perform statistical analysis on quality control (QC) data to evaluate and detect any outliers, shifts or trends in control values due to instrument malfunctions in the specialty of

	hematology. Findings include: 1. Record review of hematology QC reports on 3/11/19 for the Sysmex XP 300 analyzer, placed into service on 12/28/17 revealed the lack of evaluation of the QC data to detect any outliers, shifts or trends in control values due to instrument malfunctions or changes in the analytical system. 2. Record review on 3 /11/19 of the Horiba ABX hematology analyzer's May 2017 'All Peer Comparison report' revealed: a. Platelet and mean corpuscular volume (MCV) controls were in the unacceptable zone. b. The report was signed as reviewed by the practice manager (PM). c. Corrective action(s) were not taken to address the unacceptable data. 3. Staff interview with the laboratory supervisor and PM on 3/11/19 at 11:30 AM confirmed the above findings. 4. The laboratory performs 8,225 tests annually in the specialty of hematology.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform quality control (QC) as required in the specialty of microbiology. Findings include: 1. Review of the laboratory's quality control (QC) records from 2011 to 2019 on 3/11/19 revealed: a. The laboratory failed to document the positive and negative reactivity for each new lot number or shipment of bacitracin discs since testing patient samples started approximately 8 -10 years ago. b. The laboratory failed to check each new lot number and shipment of Strep Select Agar and Uricult media for sterility and the ability of the media to support growth, select for or inhibit specific organisms, since testing patient samples started approximately 8-10 years ago. 2. Staff interview with the practice manager (PM) on 3/11/19 at 11:00 AM confirmed above findings. The PM stated QC is performed at their sister laboratory in Milford on new lots and shipments, then the discs and/or media are brought over to the Stratford location. The PM also stated this has been the practice since this location opened approximately 10 years ago. 3. The laboratory performs 621 cultures annually in the specialty of microbiology.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: A. Based on record review and staff interview, the laboratory failed to take corrective action when the laboratory incubator temperature was out of range in the subspecialty of bacteriology. Findings include: 1. Record review on 3/11/19 of the 2017 laboratory incubator temperature logs revealed: a. Acceptable incubator temperature range is 36 degrees Celsius. b. Corrective action when the incubator temperature was out of range was not documented for 32 of 365 days in 2017. c. An arrow pointing upward was noted for 47 of 365 days when the incubator temperature was out of range in 2017. d. An arrow pointing downward was noted for 3 of 365 days when the incubator temperature was out of range in 2017. e. Temperatures were not recorded for 84 of 365 days in 2017. f. The temperature charts were not reviewed to ensure corrective action was carried out when the temperatures were out of range. 2. Record review on 3 /11/19 of the package insert for the Strep Select Agar revealed, "Incubate the plates at 33 - 37 degrees Celsius." 3. Record review on 3/11/19 of the 'Urine Culture Procedure Uricult' revealed "Place the vial upright in incubator for 18-24 hours at temp of 35 to 36 degrees." 4. Staff interview on 3/11/19 at 9:48 AM with the practice manager confirmed the above findings. 5. The laboratory performs 621 cultures annually in the subspecialty of bacteriology. B. Based on record review and staff interview, the laboratory failed to take corrective action when the laboratory refrigerator temperature was out of range in the specialty of hematology. Findings include: 1. Record review on 3/11/19 of the 2017 laboratory refrigerator temperature logs revealed: a. Acceptable refrigerator temperature range is 1.7 to 7.8 degrees Celsius. b. Corrective action when the refrigerator temperature was out of range was not documented for 22 of 365 days in 2017. 2. The temperature charts were not reviewed to ensure corrective action was carried out when the temperatures were out of range. 3. Record review on 3 /11/19 of the package insert for the hematology controls in use revealed a required storage temperature of 2 to 8 degrees Celsius. 4. Record review on 3/11/19 of the bacitracin (A) disc package insert revealed, "Once opened, After use, store vial or cartridge to protect product integrity at 2 to 8 C." 5. Record review of the package insert for the Strep Select Agar used for throat cultures revealed, "Plated media should be stored at 2 to 8 C." 6. Staff interview on 3/11/19 at 10:00 AM with the practice manager and the laboratory supervisor (LS) confirmed the findings in B above . The LS stated he/she thought the temperatures were acceptable because they fell in the range given by the state for vaccination storage and temperature recording. C. Based on record review and staff interview, the laboratory failed to take corrective action when quality control peer review results were unacceptable. Findings include: 1. Record review on 3/11/19 of the Horiba ABX hematology analyzer's May 2017 'All Peer Comparison report' revealed: a. Platelet and mean corpuscular volume (MCV) controls were in the unacceptable zone. b. The report was signed as reviewed by the practice manager (PM). c. Corrective action(s) were not taken to address the unacceptable data. 2. Staff interview with the laboratory supervisor and PM on 3/11 /19 at 11:30 AM confirmed the findings in C1. 3. The laboratory performs 8,225 tests annually in the specialty of hematology.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish and follow written quality assessment policies and procedures encompassing the subspecialty of bacteriology and the specialty of hematology. Findings include: 1. Record review of the laboratory procedure manual on 3/11/19 revealed: a. The laboratory instituted a quality assessment policy dated 3/6/19 under the title. b. The policy was signed by the laboratory director, but the LD did not put a date by his/her signature. c. The laboratory failed to provide evidence of any quality assessment policies to monitor, assess and if necessary correct situations involving analytical systems prior to 3/6/19. 2. Staff interview with the practice manager on 3/11/19 at 1: 00 PM confirmed the above findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish and follow a written policy for post analytical quality assurance and failed to confirm results are reported accurately on the final patient test report in the specialty of hematology. Findings include: 1. Record review on 3/11/19 of a hematology Sysmex instrument printout as compared with the patient's chart revealed the following discrepancies: Pt Analyte Printout Chart 837.1 MPV 9.8 9.2 2. Staff interview on 3/11 /19 at 11:10 AM with the practice manager and the laboratory supervisor (LS) confirmed the above discrepancies. The LS further stated it was a transcription error.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1407. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure accuracy and reliability of patient test results in the specialty of hematology and the subspecialty of bacteriology. 1. The LD failed to ensure the competency of all laboratory personnel. Refer to D5209 and D6004. 2. The LD failed to ensure verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. Refer to D6013. 3. The LD failed to ensure testing personnel (TP) follow the manufacturer's instructions when performing patient testing or new instrument validation studies. Refer to D6014. 4. The LD failed to enroll in proficiency testing (PT) in the specialties of hematology and microbiology. Refer to D6015 and D2000. 5. The LD failed to establish and

	actively maintain a quality control (QC) program to assure the quality of laboratory services provided. Refer to D6020. 6. The LD failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6021. 7. The LD failed to ensure employment of a qualified technical consultant and clinical consultant to oversee the laboratory. Refer to D6033, D6035, D6056, and D6057. 8. The LD failed to ensure TP were trained before performing moderate complexity testing. Refer to D6029. 9. The LD failed to establish policies and procedures to monitor moderate complexity TP to ensure accurate test results. Refer to D6030.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to evaluate testing personnel (TP) to ensure competency to perform and report accurate test results in the subspecialty of bacteriology and the specialty of hematology. Findings include: 1. Record review on 3/11/19 of the laboratory's employee records revealed competency documentation was not available for moderate complexity TP since the laboratory started testing patient samples approximately 10 years ago. 2. Staff interview with the practice manager (PM) on 3/11/19 at 11:00 AM confirmed the above findings. The PM stated all competency is performed at their sister laboratory in Milford and competency assessment is not performed at the Stratford location.
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 (LD) failed to have a policy in place or review validation and verification of new instrumentation in the specialty of hematology. Findings include: 1. Record review on 3/11/19 of Sysmex XP300 instrument (serial number: B3577) validation documents revealed the LD did

	not do the following prior to patient testing: a. Sign the validation data as reviewed and /or approved. b. Establish a written policy for acceptable criteria when performing validation studies. c. Ensure correlation studies and reference range verification were performed as part of the validation. d. Ensure that laboratory testing personnel participated in the validation studies. 2. Record review on 3/11/19 of the Horiba ABX Micros 60 Validation data and checklist dated 7/28/14 revealed the LD did not do the following prior to patient testing: a. Sign the validation data as reviewed and/or approved. b. Establish a written policy for acceptable criteria when performing validation studies. c. Ensure correlation studies and reference range verification were performed as part of the validation. d. Ensure that laboratory testing personnel participated in the validation studies. 2. Staff interview with the practice manager on 3 /11/19 at 10:00 AM confirmed the above findings.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure laboratory personnel are performing the test methods as required for accurate and reliable results. Refer to D5209, D6004 and D6030.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to enroll in proficiency testing (PT) in the specialties of Hematology and Microbiology. Refer to D2000.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to establish and actively maintain a quality control (QC) program to assure the quality of laboratory services provided. Refer to D5469 and D5471.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. Refer to D3031, D5781, D5791 and D5891.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure new testing personnel (TP) received appropriate training to perform moderate complexity testing prior to reporting patient test results. Findings include: 1. Record review of the laboratory's personnel files on 3/11/19 revealed training documentation was not available for testing personnel. 2. Staff interview with the practice manager (PM) on 3/11/19 at 10:00 AM confirmed the above findings. The PM stated testing personnel are trained at their sister laboratory in Milford and are therefore considered trained for Stratford as well. 3. The laboratory performs 621 cultures annually in the specialty of microbiology and 8,225 tests annually in the specialty of hematology.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to establish policies and procedures to evaluate the competency of moderate complexity testing personnel to ensure accurate test results are reported. Refer to D5209 and D6004.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to employ a technical consultant (TC) to oversee moderate complexity testing in the specialties of microbiology and hematology. Refer to D8100.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived

	testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to employ a technical consultant to oversee moderate complexity testing in the specialties of microbiology and hematology. Refer to D6033 and D8100.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to employ a clinical consultant (CC) to oversee moderate complexity testing in the specialties of microbiology and hematology. Refer to D8100.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to employ a clinical consultant to oversee moderate complexity testing in the specialties of microbiology and hematology. Refer to D6056 and D8100.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.

	This CONDITION is not met as evidenced by: A. Based on record review and staff interview conducted on 3/11/19, the laboratory failed to restrict testing to Certificate of Waiver tests. Refer to D9999. B. Based on record review and staff interview, the laboratory failed to employ a technical consultant (TC) and clinical consultant (CC) to oversee moderate complexity testing in the specialties of microbiology and hematology. Findings include: 1. Record review on 3/11/19 of the laboratory's procedure manual revealed the laboratory was performing moderate complexity complete blood counts and urine and throat cultures. 2. Record review on 3/11/19 of the laboratory's CLIA certification documentation revealed: a. The laboratory has had a certificate of waiver since opening in 2009. b. The laboratory has never had a TC or CC designated. 3. Staff interview with the practice manager (PM) on 3/11/19 at 11:30 AM confirmed the above findings. The PM stated moderate complexity testing has been performed since the laboratory opened approximately 8 - 10 years ago. Microbiology from opening and hematology for approximately 4 years.
D9999	493.39 Notification requirements for laboratories issued a certificate of waiver: Laboratories performing one or more tests listed in 493.15 and no others must notify HHS or its designee-- (a) Before performing and reporting results for any test or examination that is not specified under 493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and (b) Within 30 days of any change(s) in-- (1) Ownership; (2) Name; (3) Location; or (4) Director. This requirement is not met as evidenced by: Based on record review and staff interview, the laboratory failed to restrict testing to Certificate of Waiver tests. Finding include: 1. Record review on 3/11/19 of the laboratory's patient test records revealed the laboratory was performing moderate complexity testing on patient samples above its CLIA certificate type for complete blood count (CBC), throat culture and urine culture. 2. Record review on 3/11/19 of the CMS-116 form dated 2/11/19 submitted by the laboratory for change of certificate type revealed the application was received on 2/13/19 at the state agency. 3. Staff interview with the practice manager (PM) on 3/11/19 at 10:00 AM confirmed: a. The laboratory was testing the above indicated moderate complexity tests for approximately 10 years. b. The laboratory was in possession of a CLIA waiver certificate until 2/11/19 when a certificate type change was submitted. c. The PM was not aware the laboratory was testing patient samples above its certificate type level. 4. The laboratory performs 621 cultures annually in the specialty of microbiology and 8,225 tests annually in the specialty of hematology.