

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0698130	(X3) Date Survey Completed 02/11/2019
Name of Provider or Supplier Milford Pediatric Group	Street Address, City, State 50 Commerce Park, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, proficiency testing (PT) samples were not tested in the same manner as patient samples. Findings include: 1. Record review on 2/6/19 of the laboratory's 2017 and 2018 College of American Pathologists (CAP) PT records revealed: a. 2 of 4 bacteriology TP did not perform PT testing in 2018. b. PT hematology results were submitted for evaluation in 2017 and 2018 for 1 of 10 TP. The same TP's results were submitted for all events. c. 7 of 10 hematology TP tested the same PT samples as internal blind samples prior to the CAP PT program due date for 2017. d. 4 of 10 hematology TP tested the same PT samples as internal blind samples prior to the CAP PT program due date for 2018. 2. Staff interview with the office manager on 2/6/18 at 11:15 AM confirmed the above findings. 3. The laboratory performs 36,985 hematology tests and 6,738 bacteriology cultures annually. 4. This is a repeat violation.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on record review and staff interview, the laboratory failed to attest that proficiency testing (PT) samples were performed in the same manner as patient specimens. Findings include: 1. Record review on 2/6/19 of the laboratory's 2017 College of American Pathologists (CAP) microbiology combination attestation sheets revealed the 2017-Event A PT attestation sheet was not signed by the laboratory director. 2. Staff interview on 2/6/19 at 1:00 PM with the office manager confirmed the above finding. 3. The laboratory performs 6,738 cultures annually in the subspecialty of bacteriology.</p>
<p>D2122</p>	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to achieve a score of at least an 80 on proficiency testing (PT) in the specialty of hematology. Findings include: 1. Record review on 2/6/19 of the laboratory's College of American Pathologist (CAP) PT results revealed the laboratory received an unsatisfactory score of 63 for FH1-A 2018 Hematology Auto Differentials. 2. Staff interview on 2/6/19 at 2:00 PM with the office manager confirmed the above finding. 3. The laboratory performs 36,985 tests annually in the specialty of hematology.</p>
<p>D3031</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed retain quality control (QC) records at least for two years in the specialty of hematology. Findings include: 1. Record review of the laboratory's hematology quality control records on 2/11/19 revealed the laboratory did not have daily QC records for the Sysmex XP300 (SN B3583) analyzer from 12/16/17 through 4/25/18. 2. Staff interview with the laboratory supervisor (LS) on 2/11/19 at 11:15 AM confirmed the above finding. The LS further stated QC records were inadvertently deleted and not recoverable.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>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.</p>

	<p>Review on 2/6/19 of the laboratory's competency records revealed: a. The laboratory did not have a policy in place to assess the competency of the technical consultant (TC) or clinical consultant (CC). b. Competency documentation for the TC and CC was not available. 2. Staff interview with the office manager on 2/6/19 confirmed the above findings. 3. This is a repeat violation.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to document review of proficiency test (PT) Scores. Findings include: 1. Record review on 2/6/19 of laboratory's 2017 and 2018 College of American Pathologists (CAP) hematology PT scores revealed: a. FH2-A 2017 i. Specimen FH2-05 MCV was unacceptable. ii. Specimens FH2-01 through FH2-05 had an incorrect response due to failure to provide a valid response code for MCHC and RDW. b. FH2-B 2017 i. Specimens FH2-06 through FH2-10 had an incorrect response due to failure to provide a valid response code for MCHC. c. FH1-A 2018 i. Overall score of 63. ii. Specimen FH1-05 MCV was unacceptable. iii. Specimens FH1-01 through FH1-05 had an incorrect response due to failure to provide a valid response code for RBC, hematocrit and RDW. d. The laboratory failed to investigate and/or evaluate the results obtained. e. The results were signed as reviewed by the laboratory director. 2. Staff interview with the laboratory supervisor (LS) and office manager on 2/6/19 at 1:00 PM confirmed the above findings. The LS stated he/she was unaware results could be checked against the participant summary. 3. The laboratory performs 36,985 tests annually in the specialty of hematology.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor observation, 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, D5411, D5481, D5469, D5775, D5781 and D5791.</p>
<p>D5403</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

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 2/11/19 of the hematology procedure manual's complete blood count (CBC) procedure revealed the procedure lacked the following: a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and criteria for specimen acceptability and rejection. b. Instrument maintenance requirements. c. Control procedures. d. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. e. The protocol for reporting critical, panic, or alert test result values. f. Reference (normal) values. g. Reportable ranges. h. Reporting of test results. 2. Staff interview with the laboratory supervisor on 2/11/19 at 10:00 AM confirmed the above findings. 3. The laboratory performs 36,985 tests annually in the specialty of hematology.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

A. Based on surveyor observation, record review and staff interview, the laboratory failed to follow the manufacturer's instructions when performing patient testing in the subspecialty of bacteriology. Findings include: 1. Surveyor observation on 2/6/19 at 1:00 PM of 10 patient throat cultures planted on Strep Select Agar (SSA) revealed: a. The plates were streaked in three directions, one on top of the other, all over the plate. b. The bacitracin (A) disc was placed in the center of the plate. c. On four of the 10 plates, the A disc had fallen off of the media. 2. Record review on 2/6/19 of the

'Product information and Quality Control SSA' package insert revealed: a. Section X. Procedure, #3, "Using the swab or sterile inoculating loop, streak in a zig-zag fashion over swabbed area and continue over most of the plate surface. (see diagram 1)." Diagram 1 showed an agar plate with 3 separate quadrants streaked. b. Section X. Procedure, #4, "Aseptically place a disc onto the initial inoculum area ensuring complete contact with the agar surface. (See diagram 2)." Diagram 2 showed a disc placed between the first and second quadrant of the agar surface. 3. Record review on 2/6/19 of the bacteriology patient testing log from 7/19/18 revealed the word "vag" was written in the "TC" column for patient #5 (P5). 4. Record review on 2/6/19 of P5's medical record revealed, a vaginal culture was performed and was negative. 5. Record review on 2/6/19 of the 'Product information and Quality Control SSA' package insert revealed, "A properly collected throat swab is essential." 6. Staff interview with the office manager (OM) on 2/6/19 at 1:10 PM confirmed a vaginal culture was performed on P5. 7. Staff interview with the laboratory director on 2/6/19 at 1:05 PM confirmed the findings in 1 and 2 above. 8. The laboratory performs 5,828 throat cultures annually in the subspecialty of bacteriology. B. 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 2/11/19 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 2/11/19 of the validation studies for the Sysmex XP 300 - S/N B3583 and S/N B3575 revealed documentation for correlation studies and reference range verification was not available. 3. Staff interview with the OM on 2/11/19 at 2:00 PM confirmed the findings in B1 and 2 above. The OM 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. The OM further stated he/she thought it was complete. 4. The laboratory performs 36,985 tests annually in the specialty of hematology.

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 report on 2/11/19

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. Staff interview with the laboratory supervisor (LS) on 2/11/19 at 11:30 AM confirmed the above finding. The LS stated that QC data is being assessed each day of testing.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (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 ensure remedial action(s) were taken when quality control (QC) was out of range in the specialty of hematology. Findings include: 1. Record review of the monthly QC reports for complete blood count on 2/11/19 revealed external QC was not within acceptable limits and patient samples were tested/reported on the following dates. Documentation of corrective action(s) for unacceptable QC result was not available for review. Sysmex XP300 Serial number (SN)# B3583: a. May 21, 2018: Normal QC b. November 26, 2018: Low QC Sysmex XP300 SN# B3575: a. February 20, 2018: High QC b. March 13, 2018: Low QC c. March 31, 2018: Low QC d. April 20, 2018: Low QC e. June 2, 2018: Low QC f. December 26, 2018: Normal QC Documentation for monthly QC review by the technical consultant/designee was not available. 2. Record review of the laboratory's hematology procedure manual on 2/11/19 revealed policies and procedures for QC acceptability limits were not established. 3. Staff interview with the laboratory supervisor on 2/11/19 at 11:00 AM confirmed: a. External QC was out as listed above with corrective action(s) not documented. b. All three levels (Low, Normal & High) of QC must be within acceptable limits before testing patient samples. c. The laboratory did not have a policy or procedure manual with QC acceptable criteria. 4. The laboratory performs 36,985 hematology 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 record review and staff interview the laboratory failed to perform and document correlation studies between two hematology analyzers twice annually. Findings include: 1. Record review on 2/11/19 of Sysmex XP300 instrument's (serial number: B3575 and B3583) validation documents revealed the lack of correlation studies between the two analyzers since the instruments were placed into service on 12/16/17. 2. Staff interview with the laboratory supervisor (LS) on 2/11/19 at 10:30 AM confirmed: a. Biannual correlation studies between the above two analyzers were not performed in 2018. b. The laboratory did not have a policy for correlation studies. c.

The LS was not aware of correlation study requirements. 3. The laboratory performs 36,985 hematology tests annually.

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:

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 2/6/19 of the 2017 and 2018 laboratory incubator temperature logs revealed: a. Acceptable incubator temperature range is 36 to 37 degrees Celsius. b. Corrective action when the incubator temperature was out of range was not documented for 86 of 360 days in 2017. c. Corrective action when the incubator temperature was out of range was not documented for 172 of 365 days in 2018. d. Temperatures were not recorded for 5 of 365 days in 2017. 2. The temperature charts were not reviewed by the technical consultant to ensure corrective action was carried out when the temperatures were out of range. 3. Record review on 2/6/19 of the package insert for the Strep Select Agar revealed, "Incubate the plates at 33 - 37 degrees Celsius." 4. Record review on 2/11/19 of the 'Urine Culture Procedure Uricult' revealed "Place the vial upright in incubator for 18-24 hours at temp of 35 to 36 degrees." 5. Staff interview on 2/11/19 at 10:00 AM with the office manager confirmed the above findings. 6. The laboratory performs 6,738 cultures annually in the subspecialty of bacteriology.

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 2/6/19 revealed the laboratory failed to provide evidence of any quality assessment policies to monitor, assess and if necessary correct situations involving analytical systems. 2. Staff interview with the office manager on 2/6/19 at 3:00 PM confirmed the above finding.

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 subspecialty of bacteriology and the specialty of hematology. Findings include: 1. Record review on 2/6/19 of the laboratory's procedure manual revealed a quality assurance policy was not available. 2. Record review on 2/6/19 of the laboratory's microbiology worksheet as compared to the final patient (Pt) test report (chart) revealed the following discrepancies for rapid strep (RS), throat culture (TC), urine culture (UC) and vaginal culture (VC): Pt Test Worksheet Chart P1 TC positive negative P2 UC positive negative P2 TC not listed positive P3 UC negative no result P4 UC negative no result P5 VC no result negative P8 TC positive TC negative; oropharynx culture TC positive P9 TC negative positive 3. Record review on 2/11/19 of a hematology sysmex instrument printout as compared with the patient's chart revealed the following discrepancies: Pt Analyte Printout Chart P11 WBC 9.6 8.8 P11 Platelet 327 3,278 4. Staff interview on 2/11/19 at 11:10 AM with the office manager (OM) confirmed the above discrepancies. The OM stated results are not routinely compared to the chart to ensure accuracy, instead the OM stated he/she only checks the positives written on the worksheet to be sure the patients are treated. The OM further stated negatives on the worksheet are not checked. 5. The laboratory performs 6,738 bacteriology cultures annually in the subspecialty of bacteriology and 36,985 tests annually in the specialty of hematology. 6. This is a repeat violation.

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 surveyor observation, record review and staff interview, the laboratory director (LD) failed to 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 testing 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 ensure proficiency testing (PT) samples are tested as required. Refer to D6016. 5. The LD failed to ensure that all PT reports received are reviewed by the appropriate staff to evaluate the laboratory's

performance and to identify any problems that require corrective action. Refer to D6018. 6. The LD failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. Refer to D6019. 7. 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. 8. The LD failed to ensure quality control (QC) values were in range before reporting out patient test results. Refer to D6025.

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 reappoints 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:

A. Based on record review and staff interview, the laboratory director failed to ensure testing personnel (TP) are evaluated using the 6 required elements and/or failed to evaluate TP to ensure competency to perform and report accurate test results in the subspecialty of bacteriology. Findings include: 1. Record review on 2/6/19 of laboratory's 2017 and 2018 competency records revealed competency documentation was not available for 4 of 4 bacteriology TP in 2017 or 2018. 2. Record review on 2/6/19 of the laboratory's College of American Pathologists (CAP) 2017 and 2018 proficiency testing (PT) records revealed: a. 2 of 4 bacteriology TP did not examine PT material to accurately assess their skills in 2017. b. 2 of 4 bacteriology TP did not examine PT material to accurately assess their skills in 2018. 3. Staff interview with the office manager on 2/6/19 at 11:00 AM confirmed the above findings. 4. The laboratory performs 6,738 bacteriology cultures annually B. Based on record review and staff interview, the laboratory director failed to ensure all testing personnel (TP) tested unknown samples to demonstrate competency in performing laboratory tests. Findings Include: 1. Record review on 2/6/19 of the laboratory's College of American Pathologists (CAP) 2017 and 2018 proficiency testing (PT) records revealed: a. 2 of 4 bacteriology TP did not examine PT material to accurately assess their skills in 2017. b. 2 of 4 bacteriology TP did not examine PT material to accurately assess their skills in 2018. c. 1 of 10 hematology TP's PT results were submitted to CAP in 2017 and 2018. 2. Record review on 2/6/19 of the laboratory's 2017 and 2018 employee competency records revealed: a. 3 of 10 hematology TP did not examine previously analyzed specimens, internal blind testing samples or external proficiency testing samples to accurately assess their skills in 2017. b. 6 of 10 hematology TP did not examine previously analyzed specimens, internal blind testing samples or external proficiency testing samples to accurately assess their skills in 2018. c. 10 of 10 hematology TP were checked off for completion of previously analyzed specimens, internal blind testing samples or external proficiency testing samples in 2017 and 2018. d. Competency records for bacteriology TP were not available for 2017 and 2018. 3. Staff interview on 2/6/19 at 11:27 AM with the office manager confirmed the

above findings. 4. The laboratory performs 36,985 hematology tests and 6,738 bacteriology cultures annually.

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 2/6/19 of Sysmex XP300 instruments (serial number: B3575 and B3583) validation documents revealed the LD did not: 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 were performed as part of the validation. d. Ensure that laboratory testing personnel participated in the validation studies. 2. Staff interview with the office manager (OM) on 2/6/19 at 3:00 PM confirmed the above findings. 3. The laboratory performs 36,985 tests annually in the specialty of hematology.

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 personnel are performing the test methods as required for accurate and reliable results. Refer to D5411.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	<p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure proficiency testing samples are tested as required. Refer to D2007, D2009, D2122 and D5211.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D5211.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. Refer to D5211.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure that</p>

quality assessment programs are established and maintained to assure the quality of laboratory services provided. Refer to D3031, D5791 and D5891.

D6025

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory director failed to ensure patient test results are reported only when the system is functioning properly. Refer to D5481.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to have a director qualified to direct a laboratory performing high complexity testing in the subspecialty of bacteriology. Refer to D6078.

D6078

LABORATORY DIRECTOR QUALIFICATIONS

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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) Be a doctor of medicine, a 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and

continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director does not meet the requirements to manage and direct high complexity testing. Findings include: 1. During laboratory inspection on 2/6/19 surveyor record review of the bacteriology patient testing log from 7/19/18 revealed the word "vag" was written in the "TC" column for patient #5 (P5). 2. Record review on 2/6/19 of P5's medical record revealed, a vaginal culture was performed and was negative. 3. Record review on 2/6/19 of the 'Product information and Quality Control SSA' package insert revealed, "A properly collected throat swab is essential." This improper specimen source makes this test become high complexity. 4. Record review of the laboratory director's (LD) qualifications on 2/6/19 revealed the LD failed to have at least one year of documented laboratory training during medical residency or have at least 2 years of experience directing or supervising high complexity testing. 5. Staff interview with the office manager on 2/6/19 at 1:10 PM confirmed a vaginal culture was performed on P5.