

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0870937	(X3) Date Survey Completed 11/14/2019
Name of Provider or Supplier Coppell Pediatric Associates Pa	Street Address, City, State 1705 E Beltline Road, Coppell, TX	
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	An entrance conference was held 11/14/2019 with the Office Manager. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 11/14/2019, this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1215 Hematology 493.1403 Laboratory Director Moderate Complexity Testing An exit conference was held on 11/14/2019 with the laboratory director. The exit conference attendee was advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided.
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records for American Proficiency Institute (API) 2019 Hematology/ Coagulation 2nd Event dated 7/18/2019 the laboratory did not test the proficiency testing samples in the same manner as it would a patient sample. The findings were: 1) API proficiency attestation statement showed on 7/18 /2019 testing personnel #3 performed testing on proficiency samples QBC-6, QBC-7, QBC-8, QBC-9, and QBC-10. 2) API proficiency attestation statement showed on 7/18 /2019 testing personnel #2 performed testing proficiency samples QBC- 6, QBC-7,</p>

QBC-8, QBC-9, and QBC-10. 3) In interview on 11/14/2019 @1145 hours testing personnel #3 stated "(Testing personnel #2) does all of the PT testing, if you see our two initials we did it together. She was showing me how to do it."

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) documents the laboratory failed to maintain a copy of all records for 2018 Hematology/Coagulation - 1st Event. The findings were: 1) The surveyor requested proficiency records for 2018 Hematology/ Coagulation- 1st Event on 11/14/2019 @1000 hours. 2) API internet entry records were furnished by the laboratory director @1025. The surveyor requested raw data for the proficiency event. 3) The laboratory director returned @ 1030 hours and stated "It may be up in the attic. I will have to send an employee to look for it." 4) Requested documents were not produced by the close of survey. This is a repeat deficiency from 10/24/2017

D2121

HEMATOLOGY

CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) documents of 2018 and 2 events of 2019 the laboratory failed to attain a score of at least 80 percent of each analyte in testing event of 2018 Hematology/Coagulation - 3rd Event for WBC. The findings were: 1. Proficiency testing results revealed that the laboratory attained a score of 60 percent for WBC on 2018 Hematology/Coagulation - 3rd Event. 2. Interview with the laboratory director on 11/14/2019 @1215 hours confirmed that the laboratory failed to attain an acceptable score of at least 80 percent.

D2128

HEMATOLOGY

CFR(s): 493.851(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score,

remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on review of American Proficiency Institute proficiency documents for 2018 and 2019 the laboratory failed to undertake and document remedial action, or provide training or technical assistance to correct problems for the unacceptable score of 60 percent in 2018 Hematology/Coagulation - 3rd Event for WBC. The findings were: 1. Proficiency testing results revealed that the laboratory attained a score of 60 percent for WBC on 2018 Hematology/Coagulation - 3rd Event. 2. Review of 2018 Hematology/Coagulation - 3rd Event Proficiency Testing Performance Evaluation showed no documentation of remedial action, training or technical assistance to correct problems associated with proficiency testing failure. 3. Documentation of remedial action was requested by the surveyor on 11/14/2019 @ 1215 hours. 4. In interview with the laboratory director on 11/14/2019 @ 1215 hours the laboratory director stated "I attempted to go back to rerun the samples but they had been thrown out."

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 review of the QBC logs, QBC instrument quality control (QC) daily printouts, and in interview with staff, the laboratory failed to retain QBC instrument printout for a QC failure on 06/29/2018. Findings included: 1. Review of QBC logs for QC Level 1 (Lot #Q535-1) included a documented comment on 06/29/2018 at 11:15 am that stated, "ERROR OUT OF RANGE" and "Repeat run in range." 2. Review of the QBC instrument quality control (QC) daily printouts for 06/29/2018 included 1 daily printout, which was the QC that was in range. The daily printout that was out of range was not available. The values of the out of range QC was unknown. The laboratory did not ensure all QC daily printouts, including out of range data, were retained for at least 2 years. 3. During the exit conference on 11/14/2019 at 4:30 pm, the laboratory director reviewed and confirmed the above findings.

D5024

HEMATOLOGY
CFR(s): 493.1215

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
Based on review of the laboratory's policy manual, QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, and patient QBC test results, the

laboratory failed to meet the requirements of the specialty of hematology, as evidenced by: 1. The laboratory used expired control material on the QBC analyzer and analyzed/reported 4 patient test results on 01/24/2018. Refer to D5417. 2. The laboratory reported 63 QBC hematology patient test results when results of control material did not meet the manufacturer's criteria for acceptability for 13 of 62 days from 01/04/2018 through 10/07/2019. Refer to D5481. 3. The laboratory failed to document corrective action taken when QC did not meet the laboratory's criteria for acceptability for 13 of 62 days from 01/04/2018 through 10/07/2019. Refer to D5781. 4. The laboratory failed to evaluate patient test results obtained in the unacceptable test run and since the last acceptable test run to determine if patient test results have been affected (including documentation of evaluation) for 63 QBC hematology patient test results for 13 of 62 days from 01/04/2018 through 10/07/2019. Refer to D5783.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
This STANDARD is not met by: Based on a review of American Proficiency Institute (API) for all events of 2018 and 2 events of 2019 for Hematology the laboratory failed to review and verify accuracy for the analytes not evaluated or scored by the proficiency program. Note: This is a repeat deficiency for the laboratory. The findings were: 1. API Proficiency Testing Performance Evaluation page states, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. A 'Not Graded' score was given for the following analytes: QBC-09 WBC 2018 2nd Event QBC-11 WBC 2018 3rd Event QBC-15 WBC 2018 3rd Event QBC-02 WBC 2019 1st Event QBC-04 PLT 2019 1st Event QBC-05 WBC 2019 1st Event QBC-06 WBC 2019 2nd Event 3. Interview with the laboratory director on 11/14 /2019 @ 1215 hours documentation for self- evaluation of ungraded analytes were requested. None were provided. The laboratory director stated "I just assumed that there was just no consensus so there was nothing to compare it to."

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 review of the laboratory's policy manual, QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, patient QBC test results, and in interview with staff, the laboratory failed to ensure all control procedure were included in the procedure manual. Findings included: 1. Review of the laboratory's procedure manual did not include all control procedures to ensure QC results were within criteria for acceptability prior to reporting patient test results; corrective action was taken when QC did not meet the laboratory's criteria for acceptability; and document evaluation of patient test results obtained in an unacceptable QC run. 2. The surveyors review of QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, and patient QBC test results identified the following deficient practices and lack of policies/procedures: a) The laboratory reported 63 QBC hematology patient test results when results of control material did not meet the manufacturer's criteria for acceptability for 13 of 62 days from 01/04/2018 through 10/07/2019. Refer to D5481. b) The laboratory failed to document corrective action taken when QC did not meet the laboratory's criteria for acceptability for 13 of 62 days from 01/04/2018 through 10/07/2019. Refer to D5781. c) The laboratory failed to evaluate patient test results obtained in the unacceptable test run and since the last acceptable test run to determine if patient test results have been affected (including documentation of evaluation) for 63 QBC hematology patient test results for 13 of 62 days from 01/04/2018 through 10/07/2019. Refer to D5783. 3. During the exit conference on 11/14/2019 at 4:30 pm, the laboratory director reviewed the above findings and confirmed.

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 direct observation, review of manufacturer's instructions, temperature/humidity charts, and in interview with staff, the laboratory failed to ensure their defined temperature and humidity ranges were consistent with the manufacturer's for equipment and supplies stored in the laboratory for 10 of 10 months in 2017, 2018, and 2019. Findings included: 1. During a tour of the laboratory on 11/14/2019 at 2:00 pm, the following BD Vacutainer collection tubes were observed stored in cabinets

(random sampling of observation): BD Microtainer Tubes with K2E (quantity of 50), Lot #8290928, expiration date 03/31/20 BD Vacutainer Serum blood collection tubes (10 mL, quantity of 100), Lot #9094665, expiration date 03/31/20 BD Vacutainer K2 EDTA blood collection tubes (4.0 mL, quantity of 100), Lot #9095743, expiration date 08/31/20 BD vacuainer instructions for use (manufacturer's instructions) stated, "STORAGE: Store tubes at 4-25 degrees C (39-77 degrees F), unless otherwise noted on the package label." The laboratory's defined temperature range was 16-32 degrees C (61-90 degrees F), exceeding the upper end temperature of BD Vacutainer requirements for storage. 2. Review of the QBC analyzer operator's manual (manufacturer's instructions) stated, "2.4 SPECIFICATIONS: 2.4.1 QBC Centrifuge: Operating Temperatures: For QBC Hematology: 20 to 32 degrees C (68 to 90 degrees F) ...Operating Relative Humidity: 0% to 80%" and "3.4 PLACEMENT AND OPERATING EQUIPMENT: Be sure to keep the operating area within the temperatures listed below. For QBC Centrifugal Hematology tests: operating temperature should be maintained at 20 to 32 degrees C (68 to 90 degrees F) to assure proper cell layering in QBC blood tubes." The laboratory's defined temperature range was 16-32 degrees C (61-90 degrees F), the lower end being lower than the required operating conditions of the QBC (20 degrees C). The laboratory's defined humidity was defined as not to exceed 95%, exceeding the required operating conditions of QBC (80%). 3. Review of temperature/humidity charts from 11/2017, 12/2017, 04/2018, 05/2018, 06/2018, 01/2019, 02/2019, 03/2019, 10/2019 and 11/2019 included defined temperature of 16-32 degrees C (61-90 degrees F) and "HUMIDITY SHOULD NOT EXCEED 95%." The following days included temperatures that were out of range for BD Vacutainer storage requirements (39-77 degrees F): 12/20/2017: 80 degrees F 12/30/2017: 80 degrees F 04/10/2018: 80 degrees F The laboratory's defined temperature and humidity ranges were not consistent with BD Vacutainer storage criteria and QBC analyzer operating condition criteria. 4. During the exit conference on 11/14/2019 at 4:30 pm, the laboratory director reviewed the above findings and confirmed. C - Celsius F - Fahrenheit

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
 Based on review of the QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, patient QBC test results, and in interview with staff, the laboratory used expired control material on the QBC analyzer and analyzed/reported 4 patient test results on 01/24/2018. Findings included: 1. Review of the QBC Diagnostics Hematology Control Kit manufacturer's instructions stated, "MIXING THE CONTROL: ...1. Remove controls from the refrigerator and check that the open-vial stability and lot expiration date have not been exceeded." 2. Review of QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, and patient QBC test results revealed the laboratory analyzed expired control material and reported patient test results, as follows: QC Level 1 (Lot #Q527-1) and Level 2 (Lot #527-2) lot expiration date was 01/21/2018 and was tested on 01/24/2018. Patients 63, 64, 65, and 66 were analyzed and reported on 01/24/2018. (see patient alias list) The laboratory did not ensure the control material used had not exceeded its expiration

date. 3. During the exit conference on 11/14/2019 at 4:30 pm, the laboratory director reviewed the above findings and confirmed.

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 review of the laboratory's policy manual, QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, patient QBC test results, and in interview with staff, the laboratory reported 63 QBC hematology patient test results when results of control material did not meet the manufacturer's criteria for acceptability for 13 of 62 days from 01/04/2018 through 10/07/2019. Findings included: 1. Review of the laboratory's policy manual did not include control procedures for ensuring control material (QC) meet manufacturer's criteria for acceptability before analyzing and reporting patient test results. Refer to D5403. 2. Review of QBC Diagnostics Hematology Control Kit manufacturer's instructions stated, "INTERPRETING CONTROL RESULTS: Compare control results to the ranges listed on the assay sheet to determine whether or not the results are acceptable. The lot number on the assay sheet must match the lot number on the control vials" and "TROUBLESHOOTING: ...When a result exceeds QC limits, do not begin testing patient specimens." The laboratory used the assay sheets from the control material for day-to-day QC acceptability. 3. Review of QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, and patient QBC test results revealed the laboratory reported QBC hematology patient test results when results of control material did not meet the manufacturer's criteria for acceptability, as follows: 01/04/2018 - QC Level 1 (Lot #Q527-1) Granulocyte (GRAN) result was 9.9 ($X10^9/L$); assay sheet range for GRAN: 8.1 - 9.7; and 4 patient test results were reported (that included GRAN values): Patient 1, 2, 3, and 4 (see alias list) 05/31/2018 - QC Level 2 (Lot #534-2) GRAN result was 11.9 ($X10^9/L$); assay sheet range for GRAN: 6.0 - 11.6; and 5 patient test results were reported (that included GRAN values): Patient 5, 6, 7, 8, and 9 (see alias list) 06/04/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 10.9 ($X10^9/L$); assay sheet range for LY/MO: 6.2 - 10.6; and 6 patient test results were reported (that included LY/MO values): Patient 10, 11, 12, 13, 14, and 15 (see alias list) 06/08/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 12.0 ($X10^9/L$); assay sheet range for LY/MO: 6.2 - 10.6; and 4 patient test results were reported (that included LY/MO values): Patient 16, 17, 18, and 19 (see alias list) 06/11/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 11.5 ($X10^9/L$); assay sheet range for LY/MO: 6.2 - 10.6; and 9 patient test results were reported (that included LY/MO values): Patient 20, 21, 22, 23, 24, 25, 26, 27, 28 (see alias list) 06/13/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 11.7 ($X10^9/L$); assay sheet range for LY/MO: 6.2 - 10.6; and 9 patient test results were reported (that included LY/MO values): Patient 29, 30, 31, 32, 33, 34, 35, 36 (see alias list) 06/14/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 10.8 ($X10^9/L$); assay sheet range for LY/MO: 6.2 - 10.6; and 5 patient test results were reported (that included LY/MO values): Patient 37, 38, 39, 40, 41 (see alias list) 03/14/2019 - QC Level 1 (Lot #Q547-1) Hemoglobin (Hb) result was 8.7 (g/dL); assay

sheet range for Hb: 9.2 - 10.8; and 2 patient test results were reported (that included Hb values): Patient 42 and 43 (see alias list) 03/16/2019 - QC Level 1 (Lot #Q547-1) Hemoglobin (Hb) result was 9.0 (g/dL); assay sheet range for Hb: 9.2 - 10.8; QC Level 2 (Lot #Q547-2) Hemoglobin (Hb) result was 10.5 (g/dL); assay sheet range for Hb: 10.6 - 12.2; and 1 patient test result was reported (that included Hb value): Patient 44 (see alias list) 09/25/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.2 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 1 patient test result was reported (that included Hb value): Patient 45 (see alias list) 09/26/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.2 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 6 patient test results were reported (that included Hb values): Patient 46, 47, 48, 49, 50, 51 (see alias list) 09/30/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.4 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 4 patient test results were reported (that included Hb values): Patient 52, 53, 54, 55 (see alias list) 10/07/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.3 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 7 patient test results were reported (that included Hb values): Patient 56, 57, 58, 59, 60, 61, 62(see alias list) The QBC log included a check mark in the "OK" column for QC acceptability for all QC dates /values mentioned above. 3. During the exit conference on 11/14/2019 at 4:30 pm, the laboratory director reviewed and confirmed the above findings.

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 review of the laboratory's policy manual, QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, patient QBC test results, and in interview with staff, the laboratory failed to document corrective action taken when QC did not meet the laboratory's criteria for acceptability for 13 of 62 days from 01/04/2018 through 10/07/2019. Findings included: 1. Review of the laboratory's policy manual did not include control procedures for documenting corrective action taken when QC did not meet the laboratory's criteria for acceptability. Refer to D5403. 2. Review of QBC Diagnostics Hematology Control Kit manufacturer's instructions stated, "INTERPRETING CONTROL RESULTS: Compare control results to the ranges listed on the assay sheet to determine whether or not the results are acceptable. The lot number on the assay sheet must match the lot number on the control vials" and "TROUBLESHOOTING: ...When a result exceeds QC limits, do not begin testing patient specimens." The laboratory used the assay sheets from the control material for day-to-day QC acceptability. 3. Review of QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, and patient QBC test results revealed the laboratory did not document correction taken when QC did not meet the laboratory's criteria for acceptability for the following days: 01/04/2018 - QC Level 1

(Lot #Q527-1) Granulocyte (GRAN) result was 9.9 (X10⁹/L); assay sheet range for GRAN: 8.1 - 9.7; and 4 patient test results were reported (that included GRAN values): Patient 1, 2, 3, and 4 (see alias list) 05/31/2018 - QC Level 2 (Lot #534-2) GRAN result was 11.9 (X10⁹/L); assay sheet range for GRAN: 6.0 - 11.6; and 5 patient test results were reported (that included GRAN values): Patient 5, 6, 7, 8, and 9 (see alias list) 06/04/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 10.9 (X10⁹/L); assay sheet range for LY/MO: 6.2 - 10.6; and 6 patient test results were reported (that included LY/MO values): Patient 10, 11, 12, 13, 14, and 15 (see alias list) 06/08/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 12.0 (X10⁹/L); assay sheet range for LY/MO: 6.2 - 10.6; and 4 patient test results were reported (that included LY/MO values): Patient 16, 17, 18, and 19 (see alias list) 06/11/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 11.5 (X10⁹/L); assay sheet range for LY/MO: 6.2 - 10.6; and 9 patient test results were reported (that included LY/MO values): Patient 20, 21, 22, 23, 24, 25, 26, 27, 28 (see alias list) 06/13/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 11.7 (X10⁹/L); assay sheet range for LY/MO: 6.2 - 10.6; and 9 patient test results were reported (that included LY/MO values): Patient 29, 30, 31, 32, 33, 34, 35, 36 (see alias list) 06/14/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 10.8 (X10⁹/L); assay sheet range for LY/MO: 6.2 - 10.6; and 5 patient test results were reported (that included LY/MO values): Patient 37, 38, 39, 40, 41 (see alias list) 03/14/2019 - QC Level 1 (Lot #Q547-1) Hemoglobin (Hb) result was 8.7 (g/dL); assay sheet range for Hb: 9.2 - 10.8; and 2 patient test results were reported (that included Hb values): Patient 42 and 43 (see alias list) 03/16/2019 - QC Level 1 (Lot #Q547-1) Hemoglobin (Hb) result was 9.0 (g/dL); assay sheet range for Hb: 9.2 - 10.8; QC Level 2 (Lot #Q547-2) Hemoglobin (Hb) result was 10.5 (g/dL); assay sheet range for Hb: 10.6 - 12.2; and 1 patient test result was reported (that included Hb value): Patient 44 (see alias list) 09/25/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.2 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 1 patient test result was reported (that included Hb value): Patient 45 (see alias list) 09/26/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.2 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 6 patient test results were reported (that included Hb values): Patient 46, 47, 48, 49, 50, 51 (see alias list) 09/30/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.4 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 4 patient test results were reported (that included Hb values): Patient 52, 53, 54, 55 (see alias list) 10/07/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.3 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 7 patient test results were reported (that included Hb values): Patient 56, 57, 58, 59, 60, 61, 62(see alias list) The QBC log included a check mark in the "OK" column for QC acceptability for all QC dates/values mentioned above. 3. During the exit conference on 11/14/2019 at 4:30 pm, the laboratory director reviewed the above findings and confirmed.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy manual, QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, patient QBC test results, and in interview with staff, the laboratory failed to evaluate patient test results obtained in the unacceptable test run and since the last acceptable test run to determine if patient test results have been affected (including documentation of evaluation) for 63 QBC hematology patient test results for 13 of 62 days from 01/04/2018 through 10/07/2019. Findings included: 1. Review of the laboratory's policy manual did not include control procedures for ensuring control material (QC) meet manufacturer's criteria for acceptability before analyzing/reporting patient test results and documentation of evaluating results obtained during an unacceptable test run. Refer to D5403. 2. Review of QBC Diagnostics Hematology Control Kit manufacturer's instructions stated, "INTERPRETING CONTROL RESULTS: Compare control results to the ranges listed on the assay sheet to determine whether or not the results are acceptable. The lot number on the assay sheet must match the lot number on the control vials" and "TROUBLESHOOTING: ...When a result exceeds QC limits, do not begin testing patient specimens." The laboratory used the assay sheets from the control material for day-to-day QC acceptability. 3. Review of QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, and patient QBC test results revealed the laboratory reported QBC hematology patient test results when results of control material did not meet the manufacturer's criteria for acceptability. The laboratory did not document evaluation of all patient test results obtained in the following QC test runs and since the last acceptable QC test run: 01/04/2018 - QC Level 1 (Lot #Q527-1) Granulocyte (GRAN) result was 9.9 ($\times 10^9/L$); assay sheet range for GRAN: 8.1 - 9.7; and 4 patient test results were reported (that included GRAN values): Patient 1, 2, 3, and 4 (see alias list) 05/31/2018 - QC Level 2 (Lot #534-2) GRAN result was 11.9 ($\times 10^9/L$); assay sheet range for GRAN: 6.0 - 11.6; and 5 patient test results were reported (that included GRAN values): Patient 5, 6, 7, 8, and 9 (see alias list) 06/04/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 10.9 ($\times 10^9/L$); assay sheet range for LY/MO: 6.2 - 10.6; and 6 patient test results were reported (that included LY/MO values): Patient 10, 11, 12, 13, 14, and 15 (see alias list) 06/08/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 12.0 ($\times 10^9/L$); assay sheet range for LY/MO: 6.2 - 10.6; and 4 patient test results were reported (that included LY/MO values): Patient 16, 17, 18, and 19 (see alias list) 06/11/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 11.5 ($\times 10^9/L$); assay sheet range for LY/MO: 6.2 - 10.6; and 9 patient test results were reported (that included LY/MO values): Patient 20, 21, 22, 23, 24, 25, 26, 27, 28 (see alias list) 06/13/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 11.7 ($\times 10^9/L$); assay sheet range for LY/MO: 6.2 - 10.6; and 9 patient test results were reported (that included LY/MO values): Patient 29, 30, 31, 32, 33, 34, 35, 36 (see alias list) 06/14/2018 - QC Level 2 (Lot #534-2) Lymphocyte/Monocyte (LY/MO) result was 10.8 ($\times 10^9/L$); assay sheet range for LY/MO: 6.2 - 10.6; and 5 patient test results were reported (that included LY/MO values): Patient 37, 38, 39, 40, 41 (see alias list) 03/14/2019 - QC Level 1 (Lot #Q547-1) Hemoglobin (Hb) result was 8.7 (g/dL); assay sheet range for Hb: 9.2 - 10.8; and 2 patient test results were reported (that included Hb values): Patient 42 and 43 (see alias list) 03/16/2019 - QC Level 1 (Lot #Q547-1) Hemoglobin (Hb) result was 9.0 (g/dL); assay sheet range for Hb: 9.2 - 10.8; QC Level 2 (Lot #Q547-2) Hemoglobin (Hb) result was 10.5 (g/dL); assay sheet range for Hb: 10.6 - 12.2; and 1 patient test result was reported (that included Hb value): Patient 44 (see alias list) 09/25/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.2 (g/dL); assay sheet range for Hb:

10.5 - 12.1; and 1 patient test result was reported (that included Hb value): Patient 45 (see alias list) 09/26/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.2 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 6 patient test results were reported (that included Hb values): Patient 46, 47, 48, 49, 50, 51 (see alias list) 09/30/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.4 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 4 patient test results were reported (that included Hb values): Patient 52, 53, 54, 55 (see alias list) 10/07/2019 - QC Level 2 (Lot #Q557-2) Hemoglobin (Hb) result was 10.3 (g/dL); assay sheet range for Hb: 10.5 - 12.1; and 7 patient test results were reported (that included Hb values): Patient 56, 57, 58, 59, 60, 61, 62(see alias list) The QBC log included a check mark in the "OK" column for QC acceptability for all QC dates/values mentioned above. 3. During the exit conference on 11/14/2019 at 4:30 pm, the laboratory director reviewed and confirmed the above findings.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy manual, QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, patient QBC test results, and quality assessment (QA) monthly records, the laboratory's QA system did not include a review of effectiveness in identifying problems and taking corrective actions to prevent recurrence of problems in the specialty of hematology for 3 of 12 months in 2018 and 3 of 12 months in 2019. Findings included: 1. Review of QA monthly records for 01/2018, 05/2018, and 06/2018 included the following criteria for assessment: "Our QUALITY CONTROL POLICIES were performed as specified: All reagents, controls, kits, etc. that exceeded their expiration date were discarded. Any necessary remedial action was performed and documented. All quality control /calibration were performed and accepted before patient test results were reported. Quality control results were examined for possible problems." "Yes" was documented for the above criteria. The surveyor's review of records identified the laboratory used expired control material on the QBC analyzer and analyzed/reported 4 patient test results on 01/24/2018. Refer to D5417. The surveyor's review of records identified the laboratory reported QBC hematology patient test results when results of control material did not meet the manufacturer's criteria for acceptability on 01/04/2018, 05/31/2018, 06/04/2018, 06/08/2018, 06/11/2018, 06/13/2018, and 06/14/2018. Refer to D5481. The surveyor's review of records identified the laboratory did not document correction taken when QC did not meet the laboratory's criteria for acceptability for 01/04/2018, 05/31/2018, 06/04/2018, 06/08/2018, 06/11/2018, 06/13/2018, and 06/14/2018. Refer to D5781. The surveyor's review of records identified laboratory did not document evaluation of all patient test results obtained in the unacceptable QC test runs and since the last acceptable QC test runs on 01/04/2018, 05/31/2018, 06/04/2018, 06/08/2018, 06/11/2018, 06/13/2018, and 06/14/2018. Refer to D5783. 2. Review of QA monthly records for 03/2019, 09/2019, and 10/2019 included the following criteria for assessment: "Our QUALITY CONTROL POLICIES were

performed as specified: Any necessary remedial action was performed and documented. All quality control/calibration were performed and accepted before patient test results were reported. Quality control results were examined for possible problems." "Yes" was documented for the above criteria. The surveyor's review of records identified the laboratory reported QBC hematology patient test results when results of control material did not meet the manufacturer's criteria for acceptability on 03/14/2019, 09/25/2019, 09/26/2019, 09/30/2019, and 10/07/2019. Refer to D5481. The surveyor's review of records identified the laboratory did not document correction taken when QC did not meet the laboratory's criteria for acceptability for 03/14/2019, 09/25/2019, 09/26/2019, 09/30/2019, and 10/07/2019. Refer to D5781. The surveyor's review of records identified laboratory did not document evaluation of all patient test results obtained in the unacceptable QC test runs and since the last acceptable QC test runs on 03/14/2019, 09/25/2019, 09/26/2019, 09/30/2019, and 10/07/2019. Refer to D5783. The laboratory's QA system did not include a review of effectiveness in identifying problems and taking corrective actions to prevent recurrence of problems in the specialty of hematology.

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 review of API PT records, QA monthly records, the laboratory's policy manual, QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, and patient QBC test results, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart, as evidenced by: 1. The laboratory director did not ensure PT was maintained as required under Subpart H of this part. Refer to D6016. 2. The laboratory director failed to ensure the QA program was established and maintained to assure quality of laboratory services provided. Refer to D6021. 3. The laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established criteria. Refer to D6024. 4. The laboratory director failed to ensure that patient test results were reported only when the system was functioning properly. Refer to D6025

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;

This STANDARD is not met as evidenced by:
Based on review of American Proficiency Institute (API) documents and in interview

with staff, the laboratory director did not ensure PT was maintained as required under Subpart H of this part. The laboratory failed to maintain a copy of all records for 2018 Hematology/Coagulation - 1st Event. Refer to D2015. Note: D2015 is a repeat deficiency from 10/24/2017.

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 review of the laboratory's policy manual, QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, patient QBC test results, and quality assessment (QA) monthly records, the laboratory director failed to ensure the QA program was established and maintained to assure quality of laboratory services provided. The laboratory's QA system did not include a review of effectiveness in identifying problems and taking corrective actions to prevent recurrence of problems in the specialty of hematology. Refer to D5793.

D6024

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 all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy manual, QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, and patient QBC test results, the laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established criteria, as evidenced by: 1. The laboratory failed to document corrective action taken when QC did not meet the laboratory's criteria for acceptability for 13 of 62 days from 01/04/2018 through 10/07/2019. Refer to D5781. 2. The laboratory failed to evaluate patient test results obtained in the unacceptable test run and since the last acceptable test run to determine if patient test results have been affected (including documentation of evaluation) for 63 QBC hematology patient test results for 13 of 62 days from 01/04/2018 through 10/07/2019. Refer to D5783.

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 review of the laboratory's policy manual, QBC Diagnostics Hematology Control Kit manufacturer's instructions, QBC logs, control assay sheets, QBC instrument quality control (QC) daily printouts, and patient QBC test results, the laboratory director failed to ensure that patient test results were reported only when the system was functioning properly, as evidenced by: 1. The laboratory used expired control material on the QBC analyzer and analyzed/reported 4 patient test results on 01/24/2018. Refer to D5417. 2. The laboratory reported 63 QBC hematology patient test results when results of control material did not meet the manufacturer's criteria for acceptability for 13 of 62 days from 01/04/2018 through 10/07/2019. Refer to D5481.