Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D1023296	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics, Carla J Cole, Do, Pa	323 N Shiloh Road, Garland, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties/subspecialties surveyed for 45 CFR 493.1215 Hematology 493.1403 Moderate Complexity Laboratory Director Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on review of the submitted CMS-209 laboratory personnel report, American Proficiency Institute (API) proficiency testing (PT) records from 2016 (3rd Event), 2017 (1st, 2nd, 3rd Events), and 2018 (1st, 2nd, 3rd Events), and staff interview, the laboratory failed to include 3 of 7 testing personnel who routinely perform patient testing in proficiency testing. Findings included: 1. Review of the CMS-209 report submitted by the laboratory revealed 7 testing persons (Testing Persons 1,2,3,4,5,6, and 7) who routinely performed testing on the QBC Star hematology analyzer. 2. Review of API Hematology proficiency testing reports for 2016 (3rd Event), 2017

	(1st, 2nd, 3rd Events), 2018 (1st, 2nd, 3rd Events) revealed the following: 2016 Event 3; performed by testing person 7 2017 Event 1; performed by testing person 1 2017 Event 2; performed by testing person 7 2017 Event 3; performed by testing person 6 2018 Event 1; performed by testing person 7 2018 Event 2; performed by testing person 3 2018 Event 3; performed by testing person 7 The laboratory failed to include testing persons 2, 4, and 5 in the API proficiency testing events. 3. The above findings were confirmed by the laboratory director in an interview on 02/27/2019 at 1520 hours in the facility office. Word Key: CMS=Center for Medicare and Medicaid Service
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records 2016 (3rd Event), 2017 (1st, 2nd, 3rd Events), 2018 (1st, 2nd, 3rd Events), and staff interview, the laboratory failed to have documentation of the laboratory director signing 1 of 7 attestation statements and testing personnel signing 1 of 7 attestation statements (2018 Hematology 2nd Event). Findings included: 1. Review of API proficiency testing records from 2016 (3rd Event), 2017 (1st, 2nd, 3rd Events) and 2018 (1st, 2nd, 3rd Events) revealed the laboratory did not have documentation of the laboratory director and the testing personnel signing the attestation statement for the following 1 of 7 PT events: 2018 API Hematology -2nd Event 2. The above findings were confirmed by the laboratory director in an interview on 02/27/2019 at 1520 hours in the facility office.
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 CMS 155 reports and American Proficiency Institute (API) proficiency testing (PT) records, the laboratory failed to attain a score of at least 80 percent for the Hematology analyte White Blood Cell (WBC) for 1 of 3 proficiency testing events in 2018 (Hematology -3rd Event). Findings included: 1. Review of CMS 155 Pediatrics, Carla J Cole, DO, PA (45D1023296) report for API 2018 3rd testing event revealed the following unsatisfactory score: WBC Score 40% 2. Review of API PT "Comparative Evaluation" record for 2018 Hematology- 3rd Event included PT samples HEM-11, HEM-13, HEM-13, HEM-14 and HEM-15. The PT samples were analyzed on the QBC Star hematology analyzer for White Blood Cell. The unsatisfactory scores were as follows: WBC Score 40% The laboratory did not attain a score of at least 80% for White Blood Cell analyte for API 2018 Hematology - 3nd Event. This is a REPEAT deficiency from the survey conducted 12/19/2016.
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 of review of laboratory policy and quality control (QC) records for the QBC Star hematology instrument, patient test reports, temperature charts, and staff interview, the laboratory failed to meet the requirements of the analytic systems, as evidenced by: 1. The laboratory failed to monitor the humidity per manufacturer's specifications for the QBC Star analyzer. (Refer to D5413 I) 2. The laboratory failed to document room temperature in the designated unit of measurement and to ensure that the proper temperature range was defined for all testing materials. (Refer to D5413 II and D5413 III) 3. The laboratory failed to develop an IQCP (Individualized Quality Control Plan) to modify the frequency of control testing for the QBC Star hematology analyzer. (Refer to D5445) 4. The laboratory failed to run external liquid controls each day of patient testing to monitor the accuracy of the QBC Star analyzer. (Refer to D5447)
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: I. Based on review of manufacturer's instructions, laboratory records (2017 and 2018) and confirmed in interview, the laboratory failed to monitor and document humidity to ensure it was within manufacturer's specifications for the QBC Star hematology analyzer. 1. Review of the operator's manual for the QBC Star hematology analyzer under the section titled "Environmental Specifications" stated, "Humidity 10% - 95% non-condensing." 2. Review of the laboratory records revealed the laboratory failed to ensure that the humidity was within manufacturer's specifications for the area in which the QBC Star instrument was in operation. The laboratory was asked to provide documentation of monitoring humidity. No documentation was provided. 3. The above findings were confirmed by the laboratory director on 02/27/2019 at 1645 hours in the facility office. This is a REPEAT deficiency from the survey conducted 07/13 /2012. Review of the facility's Plan of Correction (signed by the laboratory director 08 /03/2012) stated, "Documentation of temperature and humidity in the room where patient testing is performed using the QBC Star analyzer will be completed on a daily basis by the testing personnel." The facility failed to maintain compliance. II. Based on review of laboratory temperature charts from 2017 and 2018, and staff interview, the laboratory failed to document room temperature in the designated unit of measurement for 24 of 24 months to ensure that the recorded temperature was within the defined range. Findings included. 1. Review of the laboratory temperature charts

	for 2017 and 2018 (Lab room 1 and Lab room 2) stated, "Acceptable range for the QBC Star Operation: 16 - 32 C." All temperatures recorded were in degrees Fahrenheit. The laboratory failed to define the equivalent temperature from Celsius to Fahrenheit. The following is a random list of the recorded temperatures: Lab 1; April 3, 2017; 70 Lab 1; May 19, 2017; 72 Lab 2; June 12, 2017; 74 Lab 2; October 26, 2017; 74 Lab 1; January 2, 2018; 72 Lab 1 June 19, 2018; 74 Lab 2; March 6, 2018; 70 Lab 2 July 25, 2018; 72 2. The above findings were confirmed by the laboratory director 0n 02/27/2019 at 1645 hours in the facility office. III. Based on direct observation, review of manufacturer's instructions and review of laboratory temperature charts for 2017 and 2018 (Lab room 1 and Lab room 2), the laboratory failed to ensure the proper temperature range was defined in the laboratory for testing material stored in the testing area. Findings included: 1. A tour of the laboratory area on 02/27/2019 at 1610 hours revealed the QBC Star hematology analyzer, Quidel Sofia Influenza A+B test kits and Quidel QuickVue RSV (Respiratory Syncytial Virus) test kits. 2. Review of the manufacturer's instructions for the Quidel Sofia Influenza A+B test kit (2018) stated, "Store the kit a room temperature, 59 to 86 F (15 to 30C)." Review of the manufacturer's instructions for the Quidel QuickVue RSV test kit (20193) stated, "Store the kit at room temperature, 15 to 30C." 3. Review of the laboratory temperature charts revealed the temperature range was 16 to 32C. The laboratory failed to define a room temperature range to include all testing materials. This is a REPEAT deficiency from the survey conducted 01/26/2015.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records from 2018, quality control policies, review of previous CMS-2567 survey documents (12/19/2016), staff interview, and CLIA communication records, the laboratory failed to test at least two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to modify the frequency of QC testing for the QBC Star instrument used for performing complete blood counts. 1. QC records from 2018 revealed external liquid controls were analyzed every 3 weeks from 04/11/2018 to present. 2. Review of the laboratory's quality control policy revealed the laboratory had no documentation of the establishment of an IQCP allowing controls to be run less frequently than each day of patient testing. 3. Review of the CMS-2567 from the survey performed 12/19/2016 revealed this is a REPEAT deficiency. The laboratory's Plan of Correction (signed by the laboratory director 01/30/2017) stated "The lab director has implemented running daily external liquid controls each day of patient testing to monitor the accuracy of the QBC Star analyzer." The laboratory failed to maintain compliance for this deficiency. 4. In an interview with the laboratory director on 02/27/2019 at 1520 hours, the laboratory director stated that the QBC vendor advised her that because the QBC Star analyzer performed internal electronic QC

	every day, they did not need to external liquid controls each day of patient testing. The laboratory director was asked why the laboratory went back to running external controls every 3 weeks after 04/11/2018. The laboratory director stated that after the last survey, the laboratory ran controls each day of testing. She stated that she communicated with CLIA representatives and it was her understanding that once PT issues were resolved, the laboratory could revert back to running external quality control every 3 weeks. 5. Review of email communications between state/regional CLIA offices and the laboratory director revealed no documentation that the laboratory could run external control every 3 weeks without an Individualized Quality Control Plan (IQCP). This confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control records from 04/11/2018 through 02/10/2019, and staff interview, the laboratory failed to run external quality control material each day of patient testing to monitor the accuracy of the QBC Star hematology analyzer used for performing complete blood counts. Findings included: 1. Review of the laboratory policy titled "Hematology Procedure QBC Centrifugal Hematology" stated the following: "G. Quality Control Procedure: Two levels of controls will be run and documented on each day of patient testing prior to testing patient samples. Patient samples will not be tested until acceptable QC results are obtained." 2. Review of the QBC Star hematology analyzer quality control records from 04/11/2018 through 02/10/2019 revealed that external QC material was analyzed once every 3 weeks. The laboratory failed to ensure two levels of QC were run on each day of patient testing. The following were the dates when two levels of control material were tested by the laboratory: QBC Hematology Control; Lot number Q532; Expiration 2018-05-06 04/11/2018 05/03/2018 QBC Hematology Control; Lot number Q533; Expiration 2018-05-27 05/14/2018 QBC Hematology Control; Lot number Q534; Expiration 2018-06-17 05/29/2018 QBC Hematology Control; Lot number Q535; Expiration 2018-07-08 06/21/2018 QBC Hematology Control; Lot number Q536; Expiration 2018-07-29 07/11/2018 QBC Hematology Control; Lot number Q537; Expiration 2018-08-19 08/06/2018 QBC Hematology Control; Lot number Q538; Expiration 2018-09-09 08/22/2108 QBC Hematology Control; Lot number Q539; Expiration 2018-09-30 09/11/2018 QBC Hematology Control; Lot number Q540; Expiration 2018-10-21 10/02/2018 QBC Hematology Control; Lot number Q541; Expiration 2018-11-11 10/23/2018 QBC Hematology Control; Lot number Q542; Expiration 2018-12-12 11/12/2018 QBC Hematology Control; Lot number Q543; Expiration 2018-12-23 12/7/2018 QBC Hematology Control; Lot number Q544; Expiration 2019-01-13 01/03/2019 QBC Hematology Control; Lot number Q545; Expiration 2019-02-03 02/01/2019 QBC Hematology Control; Lot number Q546; Expiration 2019-02-24 02/10/2019 The laboratory had no documentation of the establishment of an IQCP allowing controls to be run less frequently than each day of patient testing. 4. A random review of patient test records from 04/16/2018 through 11/18/2018 revealed 204 patients were tested. The following

	is a random list of patients tested on days when quality control was not performed. (See patient alias list): Test Date/Time/Patient 06/19/2018; 1135 hours; Patient 1 07/25/2018; 1540 hours; Patient 2 07/30/2018; 1614 hours; Patient 3 08/05/2018; 1056 hours; Patient 4 08/29/2019; 1240 hours; Patient 5 10/11/2018; 0945 hours; Patient 6 10/18/2018; 1609 hours; Patient 7 10/22/2018; 1704 hours; Patient 8 11/12/2018; 1319 hours; Patient 9 11/16/2018; 1052 hours; Patient 10 The laboratory has an annual volume of 2784 hematology tests. 5. In an interview with the laboratory director on 02/27/2019 at 1520 hours, the laboratory director confirmed the external liquid QC material was analyzed once every 3 weeks. She stated that the QBC vendor advised her that because the QBC Star analyzer performed internal electronic QC every day, they did not need to external liquid controls each day of patient testing. The laboratory director confirmed the laboratory did not have an IQCP plan for the QBC instrument. This is a REPEAT deficiency from the survey conducted 12/19/2016.
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 direct observation and review of laboratory's records, the laboratory failed to establish a Quality Assessment (QA) system to monitor, assess, and correct problems in the laboratory for the analytical phase of testing. Findings included: 1. Review of manufacturer's instructions, laboratory records (2017 and 2018) and confirmed in interview, the laboratory failed to monitor and document humidity to ensure it was within manufacturer's specifications for the QBC Star hematology analyzer. Refer to D5413 I. 2. Review of laboratory temperature charts from 2017 and 2018, and staff interview, the laboratory failed to document room temperature in the designated unit of measurement for 24 of 24 months to ensure that the recorded temperature was within the defined range. Refer to 5413 II. 3. Review of manufacturer's instructions, direct observation, and review of laboratory temperature charts for 2017 and 2018 (Lab room 1 and Lab room 2), the laboratory failed to ensure the proper temperature range was defined in the laboratory for testing material stored in the testing area. Refer to 5413 III. 4. Review of quality control (QC) records from 2018, quality control policies, review of previous CMS-2567 survey documents (12/19/2016), staff interview, and CLIA communication records, the laboratory failed to test at least two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to modify the frequency of QC testing for the QBC Star instrument used for performing complete blood counts. Refer to D5445. 5. Review of laboratory policy, quality control records from 04/11/2018 through 02/10/2019, and staff interview, the laboratory failed to run external quality control material each day of patient testing to monitor the accuracy of the QBC Star hematology analyzer used for performing complete blood counts. Refer to D5447. 6. Review of quality control records and staff interview, the laboratory director failed to ensure that a quality control program was established and maintained for hematology. Refer to D6020.
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 laboratory policy, laboratory records, patient test results, and manufacturer's instructions, the Laboratory Director failed to provide overall management as evidenced by: 1. The laboratory director failed to ensure PT samples were rotated among all testing personnel. Refer to D6016 2. The laboratory director failed to ensure the quality control program was established and maintained. Refer to D6020
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: The laboratory director failed to ensure Proficiency testing (PT) samples are rotated among all testing personnel. Refer to D2007
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 review of quality control records and staff interview, the laboratory director failed to ensure that the quality control program was established and maintained for hematology. Refer to D5441, D5445, D5447.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on review of laboratory competency records from 2016, 2017, and 2018, and staff interview, the technical consultant failed to ensure the competencies included the required components. Findings included: 1. Review of laboratory records for testing personnel yearly competency revealed the document in use consisted of a check off blank as follows: ___________CBC Each year, competency was documented with a single check mark. 2. Further review of the laboratory records for yearly competency for 2016, 2017, and 2018 revealed the form did NOT include the following required components: a. Direct Observation of patient testing b. Monitoring, recording and reporting test results c. Review of immediate test results, quality control, proficiency testing, preventive maintenance d. Assessment of test performance-previously analyzed specimens, blind testing, proficiency testing e. Evaluation of problem solving skills 2. The above findings were confirmed by the laboratory director on 02 /27/2019 at 1700 hours in the laboratory office. This is a REPEAT deficiency from 01 /26/2015.