Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0477343	10/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mckinney Pediatrics	1872 N Lake Forest Drive, Mckinney, 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 493.1409 Technical Consultant 493.1421 Testing Personnel (moderate complexity) 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.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing records the laboratory failed to test hematology proficiency samples the same number of times it routinely tests patient samples for the third testing event in 2018 and testing event 1 for 2019. The findings were: 1) In review of 2018 and 2019 laboratory hematology proficiency testing records from API (American Proficiency Institute) the laboratory did not test PT samples the same number of times it would routinely test patients in the third testing event for 2018 and the first testing event for 2019. a) i) 2018 proficiency record showed testing personnel #11 performed testing on samples HSY-11 - HSY-15 on 11/20/2018 as indicated by

	signature and sample numbers hand written on attestation form for 2018 Hematology /Coagulation 3rd Event. ii) Testing personnel #5 performed testing on samples HSY-11 - HSY-15 on 11/20/2018 as indicated by signature and sample numbers hand written on attestation form for 2018 Hematology/Coagulation 3rd Event. b) i) 2019 proficiency record review showed testing personnel #5 performed testing on samples HSY 1-5 on 3/26/2019 as indicated by signature and sample numbers hand written on attestation form for 2019 Hematology/Coagulation 1st Event. ii) Testing personnel #11 performed testing on samples HSY 1-5 on 3/26/2019 as indicated by signature and sample numbers hand written on attestation for 2019 Hematology/Coagulation 1st Event. 2) Findings were confirmed by the Technical Consultant in an exit interview on 10/22/2019 at 1215 hours. This is a repeat deficiency for this laboratory.
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, laboratory records for the Sysmex pocH-100i hematology analyzer, 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 ensure that Complete Blood Count (CBC) results with flags were verified prior to reporting these results to the provider. Refer to D5403 2. The laboratory failed to ensure humidity levels were within manufacturer's specifications and documented prior to performing patient testing. Refer to 5413 I 3. The laboratory failed to ensure temperature ranges were documented prior to performing patient testing. Refer to D5413 II 4. The laboratory failed to ensure room temperature ranges were within manufacturer's specifications prior to performing patient testing. Refer to D5413 III 5. The laboratory failed to ensure that Sysmex Eightcheck 3WP X-TRA quality control (QC) material was labeled with new expiration dates according to the manufacturer. Refer to D5415 6. The laboratory failed to ensure that Sysmex reagents, PocH-pack D and PocH-pack L, were labeled with new expiration dates according to the manufacturer. Refer to D5415 II 7. The laboratory failed to ensure verification studies were complete prior to performing patient testing. Refer to D5421 8. The laboratory failed to have documentation of maintenance at any time during 21 of 21 months. Refer to D5429
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 manufacturer's instructions for the Sysmex pocH-100i hematology analyzer (Serial Number G4510), random review of patient test records, laboratory policy, and staff interview, it was revealed that the laboratory failed to ensure that Complete Blood Count (CBC) results with flags were verified prior to reporting these results to the provider. Findings included: 1. Review of the Sysmex pocH-100i hematology analyzer Quick Guide (Document number MKT-70-1010 Revision 7) stated the following: "Flag; Probable sample cause; Correction: WL; Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase in large platelets, platelet aggregation or agglutination, precipitation of fibrin, presence of proteins or lipids; Check smear, Warm sample and repeat analysis. RL; Presence of fragmented red blood cells, increase in large platelets, platelet aggregation or agglutination, presence of micro-erythrocyte; Check smear, Warm sample and repeat analysis, Manual count. PL; Effects of cryoglobulins, fragmented red blood cells, or cellular fragments of white blood cells; Check smear, Warm sample and repeat analysis, Manual count. WU; Incomplete lysing of red blood cells, presence of immature white blood cells, white blood cell aggregation, platelet satellite phenomenon, etc; Check smear, Warm sample and repeat analysis. RU; Effects of cold agglutinin, inclusion of white blood cells; Check smear, Warm sample and repeat analysis. PU; Increase of large platelets, inclusion of fragmented red blood cells, precipitation of cryoglobulins, platelet aggregation or agglutination, presence of micro-erythrocytes; Check smear, Warm sample and repeat analysis, Manual count. DW (RBC); Significant anisocytosis; Check smear. DW (PLT); Inclusion of fragmented red blood cells, nonuniformity in size of platelets, effects of cryoglobulins, etc; Check smear. MP (RBC); Effects of anemia treatment or blood transfusion causing the presence of cells of multiple sizes; Check smear. MP (PLT); Platelet aggregation, low platelet count; Check Smear. T1; Incomplete lysing of red blood cells, etc., causing the first two WBC populations in the WBC histogram not to be separated, presence of CML or other immature granulocytes; Check smear, Warm sample and repeat analysis. T2; Aged sample, incomplete lysing of red blood cells, etc., causing the last two WBC populations in the WBC histogram not to be separated, presence of CML or other immature granulocytes; Check smear, Warm sample and repeat analysis. F1, F2, F3; Sample with high values for monocytes, eosinophils, and basophils, incomplete lysing of red blood cells, aged sample, etc., presence of CML or other immature granulocytes. Check smear, Warm sample and repeat analysis. AG; Presence of nucleated red blood cells, increase of large platelets, platelet aggregation of agglutination, precipitation of fibrin, presence of protein or lipids, etc.; Check smear, Warm sample and repeat analysis., Wash blood cells. 2. A random review of patient test reports from the Sysmex pocH-100i hematology analyzer from 10/07/2019 through 10/21/2019 revealed the following 2 of 19 results with a CBC flag: Date 10/08 /2019; Patient 21675471; T2 Flag; NO documentation of repeat testing. Date 10/15 /2019; Patient 215864606; T2 Flag; NO documentation of repeat testing. 3. The laboratory was asked to provide a policy for flagged CBC results. No policy was provided. 4. In an interview on 10/22/2019 at 1145 hours in the breakroom, testing

	person #5 was asked to describe how flagged CBC results were addressed. She stated that she thought that testing person repeated the test. Testing person #5 was asked if the laboratory had a policy for flagged CBC specimens and did the laboratory send out specimens for a blood smear review. She stated that the laboratory did NOT have a policy for flagged CBC specimens and never sent out a specimen for a smear review. Testing person #5 was asked if the results for the flagged CBC specimen was given to the provider. She stated that the provider was given the flagged results. This confirmed the above findings. Word Key: WBC= White Blood Count RBC=Red Blood Count PLT=Platelet CML=Chronic Myeloid Leukemia
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 the manufacturer's instructions for the Sysmex pocH-100i hematology analyzer, review of the laboratory's environmental monitoring records from 01/01/2018 through 10/22/2019 and staff interview, the laboratory failed to ensure humidity levels were within manufacturer's specifications and documented prior to performing patient testing. Findings included: 1. A review of the manufacturer's instructions for the Sysmex pocH-100i hematology analyzer (AJ921414 na, December 2014) under section "1.2 Technical Information" stated, "Relative humidity: 30% to 85%" 2. A review of the laboratory's environmental monitoring records from 01/01/2018 through 10/22/2019 revealed the laboratory had an established acceptable humidity range for the laboratory of 10% - 80%. 3. Further review of laboratory's environmental monitoring records from 01/2018 through 09 /2019 revealed the laboratory failed to document humidity levels each day of patient testing for 10 of 21 months. The laboratory failed to document humidity levels 01 /2018, 02/2018, 03/2018, 04/2018, 05/2018, 06/2018, 07/2018, 08/2018, 09/2018, and 10/2018. 4. The laboratory was asked to provide documentation of establishing an acceptable humidity range for the laboratory. No documentation was provided. 5. An interview with testing person #5 (as listed on Form CMS-209), who is also the nurse manager, on 10/22/2019 at 1200 hours in the breakroom confirmed the findings. This is a REPEAT deficiency from the survey conducted 07/18/2017. Key: CMS - Centers for Medicare and Medicaid Services II. Based on review of the manufacturer's instructions for the Sysmex pocH-100i hematology analyzer, review of the laboratory's environmental monitoring records from 01/2018 through 09/2019 and staff interview, the laboratory failed to ensure temperature ranges were documented prior to performing patient testing for 10 of 21 months. Findings included: 1. A review of the manufacturer's instructions for the Sysmex pocH-100i hematology analyzer (AJ921414 na, December 2014) under section "1.2 Technical Information" stated, "Operating Temperature 59-56 F" 2. Review of laboratory's environmental monitoring records from 01/2018 through 09/2019 revealed the laboratory failed to document room temperature readings each day of patient testing for 10 of 21 months. The laboratory failed to document room temperatures for 01/2018, 02/2018, 03/2018,

	04/2018, 05/2018, 06/2018, 07/2018, 08/2018, 09/2018, and 10/2018. 3. An interview with testing person #5 (as listed on Form CMS-209), who is also the nurse manager, on 10/22/2019 at 1200 hours in the breakroom confirmed the findings. III. Based on review of Sysmex Eightcheck 3WP X-TRA hematology control material manufacturer's instructions, review of the laboratory's environmental monitoring records from 01/2018 through 10/22/2019 and staff interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications prior to performing patient testing. Findings included: 1. Sysmex Eightcheck 3WP X-TRA hematology control material manufacturer's instructions (350493-3) stated the following: "Remove vial of Eightcheck 3WP X-TRA from the refrigerator and equilibrate to room temperature (18 -30 C) for 15 minutes before use." 2. A review of the laboratory's environmental monitoring records from 01/01/2018 through 10/22 /2019 revealed the laboratory had an established an acceptable room temperature range for the laboratory of 61 -86 F (16 - 30 C). The laboratory's acceptable room temperature range did NOT ensure temperature ranges were within manufacturer's specifications (18 - 30 C) for the Sysmex Eightcheck 3WP X-TRA hematology control material. 3. An interview with testing person #5 on 10/22/2019 at 1200 hours in the breakroom confirmed the findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on direct observation, review of manufacturer's instructions and staff interview, it was revealed the laboratory failed to ensure that 6 of 6 vials of Sysmex Eightcheck 3WP X-TRA quality control (QC) material were labeled with new expiration dates according to the manufacturer. Findings included: 1. Observed in the laboratory refrigerator on 10/22/2019 at 1040 hours were the following 6 vials Sysmex Eightcheck 3WP X-TRA material in-use for the Sysmex pocH-100i hematology analyzer (Serial Number G4510) hematology analyzer: Lot number 91980710; Expiration date 2019-10-23 Lot number 91980711; Expiration date 2019-10-23 Lot number 91980712; Expiration date 2019-10-23 Lot number 92820710; Expiration date 2020-01-15 Lot number 92820711; Expiration date 2020-01-15 Lot number 92820712; Expiration date 2020-01-15 The vials were NOT labeled with an open date or a new expiration date. 2. Sysmex Eightcheck 3WP X-TRA hematology control material manufacturer's instructions (350493-3) stated the following: "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 C." The laboratory failed to ensure Sysmex Eightcheck 3WP X-TRA quality control (QC) material was labeled with new expiration dates according to the manufacturer. 3. An interview with testing person #5 on 10/22/2019 at 1040 hours in the laboratory confirmed the findings. II. Based on direct observation, review of manufacturer's instructions and staff interview, it was revealed the laboratory failed to ensure that Sysmex reagents, PocH-pack D and PocH-pack L, were labeled with new expiration dates according to the manufacturer. Findings included: 1. During a tour of the laboratory on 10/22/2019 at 1040 hours, the following Sysmex PocH reagents were observed to be in-use for the Sysmex pocH-100i hematology analyzer a. PocH-

	pack D; Lot number Y9012; Expiration date 2020-10-12 b. PocH-pack L; Lot number Y9001; Expiration date 2020-04-09 The reagents were NOT labeled a new expiration date. 2. Review of the Sysmex pocH-100i hematology analyzer Quick Guide (Document number MKT-70-1010 Revision 7) stated the following: "pocH-pack D, Diluent for hematology analyzers; Opened, reagent stability is maximum 60 days ... ... pocH-pack L, Opened, reagent stability is maximum 90 days." The laboratory failed to label Sysmex reagents, PocH-pack D and PocH-pack L, with new expiration dates according to the manufacturer. 3. An interview with testing person #5 on 10/22/2019 at 1040 hours in the laboratory confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on staff interview and review of the laboratory's verification records for the Sysmex pocH-100i hematology analyzer, it was revealed the laboratory failed to ensure verification studies were complete prior to performing patient testing. The findings were: 1. In an interview on 10/22/2019 at 1145 hours in the breakroom, testing person #5 was asked to provide CBC patient reports. She stated that the print out from the Sysmex pocH-100i hematology analyzer was given to the provider and then scanned into the patient's electronic medical record. Testing person #5 was asked if the normal references ranges were part of the patient final report. She stated, "Normal ranges are based on the provider's set knowledge." 2. A review of the laboratory's verification records revealed the laboratory failed to perform a patient normal range verification as part of the instrument verification for the Sysmex pocH-100i hematology analyzer (serial number: G4510) when it was installed in January 2016. 3. The laboratory was asked to provide documentation of performing a patient normal range verification. No documentation was provided. This is a REPEAT deficiency from the survey conducted 07/18/2017.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the Sysmex pocH-100i hematology analyzer, laboratory maintenance records (01/2018 through 09/2019) and staff interview, the laboratory failed to have documentation of maintenance at any time during 21 of 21 months. Findings included: 1. Review of the Sysmex pocH-100i hematology analyzer Quick Guide (Document number MKT-70-1010 Revision 7)

	stated the following: "Daily Maintenance-Shutdown; Every two weeks (or 150 samples)-Clean transducer; Every three months (or 1500 samples)-Clean Waste Chamber; As needed-Discard Waste Fluid." 2. In an interview on 10/22/2019 at 1145 hours in the breakroom, testing person #5 was asked to provide maintenance records for the Sysmex pocH-100i hematology analyzer. She provided a laboratory form titled "Sysmex pocH-100i Maintenance Log". The documentation failed to document daily, every two week, every three week or as needed maintenance. Testing person #5 was asked for any other maintenance records. No documentation was provided. Testing person #5 stated that she was not aware maintenance should be documented. This confirmed the above findings.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review patient test reports for complete blood count (CBC) testing performed on the Sysmex pocH-100i hematology analyzer 10/07/2019 through 10/21/2019, and staff interview, it was revealed the laboratory failed to ensure reference intervals were available for 19 of 19 CBC result evaluations. Findings included: 1. A review of patient test reports from 10/07/2019 through 10/21/2019 revealed the following 19 of 19 CBC test reports that failed to ensure reference intervals were available for test result evaluation: Patient Identification Number: 202499092 3674 21675471 177356354 243311152 53058 32316 8027 260942471 215864606 224714236 255362312 174678865 37384 41851 1735 4840 263225232 8040 2. In an interview on 10/22/2019 at 1145 hours in the breakroom, testing person #5 was asked to provide CBC patient reports. She stated that the print out from the Sysmex pocH-100i hematology analyzer was given to the provider and then scanned into the patient's electronic medical record. Testing person #5 was asked if the normal references ranges were part of the patient final report. She stated, "Normal ranges are based on the provider's set knowledge." This confirmed the above findings.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of laboratory policies and staff interview, it was revealed the laboratory failed to have a policy for defining the laboratory alert values and a procedure to follow for proper notification and documentation. The findings were: 1. A review of the laboratory's policies and procedures revealed that the laboratory did not have documentation of a policy that included the defining of the laboratory's alert values for the tests it performed, proper notification of the ordering health care

	provider of the alert value, and documentation of the notification. 2. An interview with testing person #5 on 10/22/2019 at 1145 hours in the breakroom confirmed the findings. This is a REPEAT deficiency from the survey conducted 07/18/2019.
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 manufacturer's instructions, laboratory policy, laboratory records, and laboratory proficiency testing, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure proficiency testing specimens were treated as patients. Refer to D6016 2. The laboratory director failed to ensure reports of test result included pertinent information required for interpretation. Refer to D6026 3. The laboratory director failed to ensure 2 of 10 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6029 4. The Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 6 of 10 testing persons performing moderate complexity testing. Refer to D6030
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 the laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory director failed to ensure proficiency testing materials are analyzed the same number of times as patient samples for CBC (complete blood count). Refer to D2010.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by:

	Based on review of patient test reports for hematology testing performed on the Sysmex pocH-100i hematology analyzer, the laboratory director failed to ensure reports of test results included pertinent information required for interpretation. The laboratory failed to ensure reference intervals were available for 19 of 19 complete blood count result evaluations. Refer to D5807.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records and staff interview, the laboratory director failed to ensure 2 of 10 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6065
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory's policy, and confirmed in interview, the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 6 of 10 Testing Persons performing moderate complexity testing. Refer to D6053 and D6055
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of laboratory policies, CMS 209 form, and personnel records, the technical consultant failed to provide technical oversight of the laboratory, as evidenced by: 1. The technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for 8 of 10 testing persons. Refer to D6053. 2. The technical consultant failed to have documentation of the competency assessments being performed on 6 of 10 testing persons in 2018 for the Sysmex pocH-100i hematology analyzer prior to performing patient testing. Refer to D6055
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, personnel records, and staff interview, the technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for 8 of 10 testing persons listed on Form CMS-209. Findings included: 1. Review of the CMS 209 form revealed 10 Testing Persons (TP #1 - TP#10) performing moderate complexity testing. 2. Review of laboratory personnel records revealed a form titled "Personnel Assessment" that stated the following: "CLIA guidelines require the semiannual assessment of personnel competency during the first year of test performance for moderate or high complexity testing. Thereafter, evaluation must be performed at least annually. Additionally, an individual's performance must be reevaluated with methodology or instrument changes ... .The following notations will be used to designate the assessment tool used. OBS: Direct observation of test performance; RR: Review of patient testing records including intermediate worksheets, logs, and final reports; QC; Review of quality control activities including performance and recording; RA: Assessment of problem solving skills via review of remedial action documentation; IM: Observation and/or record review of instrument maintenance and function checks; PT or SS: Assessment of test performance through analysis of proficiency (PT) or previously analyzed samples (SS) ... ..." 3. A review of laboratory personnel records revealed the laboratory began testing on the Sysmex pocH-100i hematology analyzer 01/2016. 4. Review of the "Personnel Assessment" document revealed the following for each testing person: Testing person #1 Employed: 01/2007 to present The laboratory failed to provide documentation of Sysmex PocH 100i training and competency assessments at least twice the first year of patient testing. Testing person #2 Employed: 04/2002 to present Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [No assessor documented]; Date 2016, 2017, 2018, 2019. This documentation failed to indicate what assessment tools were used and exact dates of assessments. This documentation failed to evaluate Sysmex PocH 110i training and competency assessments at least twice the first year of patient testing. Testing person #3 Employed 10/2015 to present Sysmex PocH 100i hematology analyzer "Training Checklist" 07/2016 Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [Nurse Manager]; Date 2016, 2017, 2018, 2019. This documentation failed to indicate what assessment tools were used and exact dates of assessments. This documentation

	failed to evaluate Sysmex PocH 110i competency assessments at least twice the first year of patient testing. Testing person #4 Employed 04/2017 to present Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [Nurse Manager]; Date 2017, 2018, 2019. This documentation failed to indicate what assessment tools were used and exact dates of assessments. This documentation failed to evaluate Sysmex PocH 110i training and competency assessments at least twice the first year of patient testing. Testing person #5 Employed 10/2018 to present Sysmex PocH 100i hematology analyzer "Training Checklist" 10 /15/2018 Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [Nurse Manager]; Date 2016, 2017, 2018, 2019. This documentation failed to indicate what assessment tools were used and exact dates of assessments. This documentation failed to evaluate Sysmex PocH 110i competency assessments at least twice the first year of patient testing. Testing person #8 Employed 04/2018 to present Sysmex PocH 100i hematology analyzer "Training Checklist" 06 /27/2018 Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [Nurse Manager]; Date 2016, 2017, 2018, 2019. This documentation failed to indicate what assessment tools were used and exact dates of assessments. This documentation failed to evaluate Sysmex PocH 110i training competency assessments at least twice the first year of patient testing. Testing person #9 Employed 03/2011 to 08/2019 Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [No assessor documented]; Date 2016, 2017, 2018 This documentation failed to indicate what assessment tools were used and exact dates of assessments. This documentation failed to evaluate Sysmex PocH 110i training and competency assessments at least twice the first year of patient testing. Testing person #10 Employed 06/2010 to 05/2019 Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [No assessor documented]; Date 2016, 2017, 2018 This documentation failed to indicate what assessment tools were used and exact dates of assessments. This documentation failed to evaluate Sysmex PocH 110i training and competency assessments at least twice the first year of patient testing. 6. In an interview on 10/22/2019 at 1015 hours in the breakroom, the laboratory manager was asked to how competency was assessed. She stated that she just recently took over the job of laboratory manager. She stated she did not know how semiannual competency was assessed. This confirmed the above findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS-209 form, laboratory policy, laboratory's personnel records (2016 -2018), and staff interview, it was revealed the technical consultant failed to have documentation of the competency assessments being performed on 6 of 10 testing persons in 2018 for the Sysmex pocH-100i hematology analyzer prior to performing patient testing. Findings included: 1. Review of the CMS 209 form revealed 10 Testing Persons (TP #1 - TP#10) performing moderate complexity testing. 2. Review of the laboratory policy titled "Quality

	Assurance Policies and Procedures" stated the following: "6. Personnel Assessment: The Laboratory Director will use the results of Proficiency testing and direct observation to perform an annual evaluation of all testing personnel to ensure competency in job performance." This policy did NOT address competency evaluation of monitoring, recording and reporting of test results; direct observation of instrument maintenance; review of preliminary results, quality control, proficiency testing, or preventive maintenance; or assessment of problem solving skills. 3. Review of laboratory personnel records revealed a form titled "Personnel Assessment" that stated the following: "CLIA guidelines require the semiannual assessment of personnel competency during the first year of test performance for moderate or high complexity testing. Thereafter, evaluation must be performed at least annually. Additionally, an individual's performance must be reevaluated with methodology or instrument changes ... .The following notations will be used to designate the assessment tool used. OBS: Direct observation of test performance; RR: Review of patient testing records including intermediate worksheets, logs, and final reports; QC; Review of quality control activities including performance and recording; RA: Assessment of problem solving skills via review of remedial action documentation; IM: Observation and/or record review of instrument maintenance and function checks; PT or SS: Assessment of test performance through analysis of proficiency (PT) or previously analyzed samples (SS) ... ..." 4. A review of laboratory personnel records revealed the laboratory began testing on the Sysmex pocH-100i hematology analyzer 01/2016. 5. Review of the "Personnel Assessment" document revealed the following for each testing person: Testing person #1 Employed: 01/2007 to present The laboratory failed to provide documentation for annual competency assessment for 2018. Testing person #2 Employed: 04/2002 to present Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [No assessor documented]; Date 2016, 2017, 2018, 2019. This documentation failed to document annual competency for 2018 according to laboratory policy. Testing person #3 Employed 10/2015 to present Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [Nurse Manager]; Date 2016, 2017, 2018, 2019. This documentation failed to document annual competency for 2018 according to laboratory policy. Testing person #4 Employed 04/2017 to present Indicated on the "Personnel Assessment form: Analyte /Instrument Sysmex PocHi; Via Inservice and Demo; By [Nurse Manager]; Date 2017, 2018, 2019. This documentation failed to document annual competency for 2018 according to laboratory policy. Testing person #9 Employed 03/2011 to 08/2019 Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [No assessor documented]; Date 2016, 2017, 2018 This documentation failed to document annual competency for 2018 according to laboratory policy. Testing person #10 Employed 06/2010 to 05/2019 Indicated on the "Personnel Assessment form: Analyte/Instrument Sysmex PocHi; Via Inservice and Demo; By [No assessor documented]; Date 2016, 2017, 2018 This documentation failed to document annual competency for 2018 according to laboratory policy. 6. In an interview on 10/22/2019 at 1015 hours in the breakroom, the laboratory manager was asked to how competency was assessed. She stated that she just recently took over the job of laboratory manager. She stated she did not know how competency was assessed in 2018. This confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.

	1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form and personnel records, the laboratory failed to have documentation that 2 of 10 testing persons met the qualifications required to perform moderate complexity testing. Refer to D6065 and D6066
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 2 of 10 testing persons met the qualifications required to perform moderate complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person #1 through Testing Person #10 listed to perform moderate complexity testing. 2. Review of personnel records revealed the laboratory did not have documentation to ensure the following testing persons were qualified to perform moderate complexity testing: a. Testing person #6; No education documents provided b. Testing person #7; No education documents provided 3. In an interview on 10/22/2019 at 1015 hours in the breakroom, the laboratory manager was asked to provide educational documentation for testing person #6 and testing person #7. No documentation was provided. This confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for the following 5 of 10 testing persons to qualify them to perform moderate complexity testing: The findings were: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 10 /18/2019) revealed the laboratory identified 10 testing personnel. 2. A review of laboratory personnel records revealed the laboratory began testing on the Sysmex

	pocH-100i hematology analyzer 01/2016. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for 5 of 10 testing personnel (as listed on Form CMS-209) who performed moderate complexity testing on the Sysmex pocH-100i hematology analyzer: Testing person #1 Employed: 01/2007 to present No training documentation for the Sysmex pocH-100i hematology analyzer. Testing person #2 Employed: 04/2002 to present No training documentation for the Sysmex pocH-100i hematology analyzer. Testing person #4 Employed: 04 /2017 to present No training documentation for the Sysmex pocH-100i hematology analyzer. Testing person #9 Employed: 03/2013 to 08/2019 No training documentation for the Sysmex pocH-100i hematology analyzer. Testing person #10 Employed: 06/2010 to 05/2019 No training documentation for the Sysmex pocH-100i hematology analyzer. 3. In an interview on 10/22/2019 at 1015 hours in the breakroom, the laboratory manager was asked to provide Sysmex pocH-100i training documentation for testing person #1, #2, #4, #9 and #10. No documentation was provided. This confirmed the above findings.