Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0481909	03/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hunt Regional Pediatric Clinic Greenville	5101 Wellington St Suite C, Greenville, 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 with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were 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 42 CFR 493.1250 Analytic Systems 493.1403 Laboratory Director, (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.
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 American Proficiency Institute testing forms, CMS (Centers for Medicare & Medicaid Services) 209 form, and staff interview, the laboratory failed to ensure patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory for 3 of 3 events in 2021 (Event 1, 2, 3). Findings Included: 1. Review of American Proficiency Institute (API) testing events, revealed Testing Person (TP-1) performed the following events: 2021

	Hematology/Coagulation 1st, 2nd and 3rd 2. Review of the laboratory's CMS 209 form submitted at the time of survey, revealed four Testing Persons (TP-1, TP-2, TP-3, TP-4) were listed as performing moderate complexity testing (hematology). TP-2, TP-3 and TP-4 performed testing of patient specimens and did NOT participate in PT events. The laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing. 3. During an interview on 03/24/2022 at 02:40 p.m. with the laboratory representatives, TP-1 confirmed no other testing persons performed proficiency testing in 2021. This confirmed the above findings.
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 the Centers for Medicare and Medicaid (CMS)-209 form, American Proficiency Institute (API) Proficiency Testing (PT) 2020 and 2021 records, and staff interview, the laboratory director and testing persons failed to attest to the routine integration of proficiency samples into the patient workload for 4 of 6 proficiency testing events. Findings Included: 1. Review of the CMS 209 form revealed 4 Testing Persons (TP-1 through TP-4) performing moderate complexity hematology testing. 2. Review of API instructions stated the following: "ATTESTATION STATEMENT SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 3. Review of the laboratory's API proficiency testing 2020 records (Hematology 1st, 2nd, and 3 Events) and 2021 records (Hematology 1st and 2nd Events, revealed the laboratory director or designee failed to sign the attestation statement for the following: 2020 API Hematology 1st Event The Laboratory Director failed to attest to the routine integration of proficiency samples into the patient workload. 2020 API Hematology 2nd Event The Laboratory Director failed to attest to the routine integration of proficiency samples into the patient workload. 2021 API Hematology 1st Event The Laboratory Director failed to attest to the routine integration of proficiency samples into the patient workload. 2021 API Hematology 3rd Event The Laboratory Director failed to attest to the routine integration of proficiency samples into the patient workload. 4. During an interview on 03/24/2022 at 02:46 p.m. in the break room, the Laboratory Director, after review of the proficiency testing records, confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	I. Based on review of the laboratory policies, submitted Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of competency assessment, based on the position responsibilities, for 2 of 2 clinical consultants in 2020 and 2021. Findings Included: 1. Review of laboratory policy titled, "Quality Assurance" revealed the following: "Personnel Assessment If the laboratory has employees, the Laboratory Director will use personal observation to perform ongoing evaluation of all employees of the laboratory to ensure competence in job performance." 2. Review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form listed two Clinical Consultants (CC-1 and CC-2) for moderate complexity testing. 3. Review of laboratory personnel records from 2020 and 2021 revealed there was no documented competency assessment for the duties performed as a clinical consultant for CC-1 and CC-2. 4. During an interview on 03/24/2022 at 10:46 a.m. in the break room, the Laboratory Director confirmed the above findings. II. Based on review of the laboratory policies, submitted Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of competency assessment, based on the position responsibilities, for 2 of 2 technical consultants in 2020 and 2021. Findings Included: 1. Review of laboratory policy titled, "Quality Assurance" revealed the following: "Personnel Assessment If the laboratory has employees, the Laboratory Director will use personal observation to perform ongoing evaluation of all employees of the laboratory to ensure competence in job performance." 2. Review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form listed two Technical Consultants (TC-1 and TC-2) for moderate complexity testing. 3. Review of laboratory personnel records from 2020 and 2021 revealed there was no documented competency assessment for the duties performed as a clinical consultant for TC-1 and TC-2. 4. During an interview on 03/24/2022 at 10:46 a.m. in the break room, the Laboratory Director confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory policy, laboratory records, and staff interview, it was revealed the laboratory failed to meet analytic systems requirements, as evidenced by: Findings Included: 1. The laboratory failed to define in their policy the quantification of the terms "occasional, TMTC" when reporting urine microscopy results for 2 of 5 patients reviewed. (January 2022-March 2022). Refer to D5403 I. 2. The laboratory failed to have a policy in place for sending patient specimens offsite for confirmatory testing. Refer to D5403 II. 3. The laboratory failed to follow manufacturer's instructions for 2 of 6 patients randomly reviewed. Refer to 5411. 4. The laboratory failed to ensure room humidity ranges were within operating specifications for 2 of 2 months reviewed in 2022. Refer to D5413 I. 5. The laboratory failed to ensure room temperature ranges were within operating specifications for 2 of 2 months reviewed in 2022. Refer to D5413 II. 6. The laboratory failed to ensure the

	reference range for hematology analytes were verified by the laboratory's studies. Refer to 5421. 7. The laboratory failed to perform monthly maintenance for 12 of 12 months in 2021 as required by the manufacturer for the Horiba ABX Micros 60 hematology analyzer. Refer to D5429. 8. The laboratory failed to have documentation of verifying 1 of 1 new lot of control prior to placing into service. Refer to D5469.
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: I. Based on review of laboratory policies, patient final reports, and confirmed in staff interview, the laboratory failed to define in their policy the quantification of the terms "occasional, TMTC" when reporting urine microscopy results for 2 of 5 patients reviewed. (January 2022-March 2022). Findings Included: 1. Review of laboratory policies revealed the laboratory used a urinalysis textbook as the policy for urinalysis. 2. Review of patient final reports revealed the following: a. Patient 03 Date Performed: 03/24/2022; Test: Urinalysis with microanalysis Result: Occasional epithelial cells b. Patient 04 Date Performed: 01/31/2022; Test: Urinalysis with microanalysis Result: TMTC WBC, occasional RBC and bact The laboratory failed to define in their policy the quantification of the terms "occasional, TMTC" when reporting urine microscopy results for 2 of 5 patients reviewed. 3. During an interview on 03/24/2022 at 02:46 p.m. in the break room, the Laboratory Director confirmed the above findings. II. Based on review of manufacturers instructions, laboratory policy, final patient reports and staff interview, the laboratory failed to have a policy in place for sending patient specimens offsite for confirmatory testing. Findings Included: 1. Review of manufacturer's instructions for the Uricult CLED+Polymyxin/MacConkey microbial identification of uropathogens revealed the following: "Limitations of the procedure: Bacterial identifications based on the biochemical reactions evidenced by Uricult and colony morphology will result only in a presumptive identification. Bacterial variation may occur and atypical strains may be isolated. In instances where a definitive bacterial identification is necessary for proper patient management, the incubated paddle may be used as a transport media to forward bacterial culture to a laboratory to further study." 2. Review of laboratory policy revealed the laboratory failed to have a policy in place for sending patient specimens offsite for confirmatory

	testing. 3. Random review of final patient revealed the following 2 of 6 patients (January 2022-March 2022) in which the laboratory stated a specific strain of bacteria for patient diagnoses without sending the patient specimen out for confirmatory testing: a. Patient: 01 (See attached patient list) Date Performed: 01/31/2022 Test- Urine Culture (No smear); Result: E. coli b. Patient: 02 (See attached patient list) Date Performed: 03/10/2022 Test- Urine Culture (No smear); Result: E. coli 4. During an interview on 03/24/2022 at 02:46 p.m. in the break room, the Laboratory Director confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, final patient reports (January 2022-March 2022) and confirmed in interview, the laboratory failed to follow manufacturer's instructions for 2 of 6 patients randomly reviewed. Findings Included: 1. Review of manufacturer's instructions for the Uricult CLED+Polymyxin /MacConkey microbial identification of uropathogens revealed the following: "Limitations of the procedure: Bacterial identifications based on the biochemical reactions evidenced by Uricult and colony morphology will result only in a presumptive identification. Bacterial variation may occur and atypical strains may be isolated. In instances where a definitive bacterial identification is necessary for proper patient management, the incubated paddle may be used as a transport media to forward bacterial culture to a laboratory to further study." 2. Random review of final patient revealed the following 2 of 6 patients (January 2022-March 2022) in which the laboratory stated a specific strain of bacteria for patient diagnoses without performing further studies: a. Patient: 01 (See attached patient list) Date Performed: 01/31/2022 Test- Urine Culture (No smear); Result: E. coli b. Patient: 02 (See attached patient list) Date Performed: 03/10/2022 Test- Urine Culture (No smear); Result: E. coli The laboratory failed to follow manufacturer's instructions for 2 of 6 patients randomly reviewed. 3. During an interview on 03/24/2022 at 02:46 p.m. in the break room, the Laboratory Director confirmed the above findings.
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 direct observation, review of Horiba Micros 60 hematology analyzer

	operating specifications, laboratory environmental records (01/2022-02/2022), and confirmed in interview, the laboratory failed to ensure room humidity ranges were within operating specifications for 2 of 2 months reviewed in 2022. 1. During a tour of the laboratory on 03/24/2022 at 11:20 a.m., the surveyor observed a Horiba Micro 60 hematology analyzer on the laboratory counter. 2. Review of Horiba Micros 60 hematology analyzer operating specifications revealed the following: "2.4 Humidity /temperature conditions: Maximum relative humidity 85% for temperatures up to 30 C (86 F)" 3. Review of laboratory environmental logs revealed the laboratory failed to document room humidity for 2 of 2 months in 2022 (01/2022-02/2022). 4. During an interview on 03/24/2022 at 02:46 p.m. in the break room, Testing Person 1, confirmed the above findings. II. Based on direct observation, review of Horiba Micros 60 hematology reagent storage specifications, laboratory environmental records (01/2022-02/2022), and confirmed in interview, the laboratory failed to ensure room temperature ranges were within operating specifications for 2 of 2 months reviewed in 2022. Findings Included: 1. 1. During a tour of the laboratory on 03/24/2022 at 11:20 a.m., the surveyor observed a Horiba Micro 60 hematology analyzer on the laboratory counter and corresponding reagents. 2. Review of Horiba Micros 60 hematology reagent storage specifications revealed the following: "Equipment: Reagents Utilized A. ABX Minidil LMG- 10 mL Part # 1210802010 3. Review of laboratory environmental logs revealed the laboratory failed to document room humidity for 2 of 2 months in 2022 (01/2022-02/2022). 4. During an interview on 03/24/2022 at 02:46 p. m. in the break room, Testing Person 1, confirmed the above 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 review of manufacturer's instructions for the Horiba Micros 60 hematology analyzer, laboratory verification studies, laboratory records, and confirmed in interview, the laboratory failed to ensure the reference range for hematology analytes were verified by the laboratory's studies. Findings Included: 1. Review of manufacturer's instructions for the Horiba Micros 60 hematology analyzer (Rev. 5 DCO-16-0022) revealed the following: "Reportable Range: It is recommended that the user confirm the reportable range and/or reference interval at time of installation. Please refer to CLIA for specific requirements when performing the method evaluation studies." 2. Review of laboratory verification studies (2019) for the Horiba Micros 60 hematology analyzer revealed the laboratory did not use patients from their population to verify hematology reference ranges. 3. Review of laboratory records revealed the laboratory was using hematology patient reference ranges provided by the Children's Hospitals and Clinics of Minnesota, not ranges provided by their own patient population. The laboratory failed to ensure the reference range for hematology analytes were verified by the laboratory's studies. 4. During an interview on 03/24 /2022 at 02:46 p.m. in the break room, the Laboratory Director confirmed the above findings.

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, Horiba Micros 60 operator's manual, laboratory maintenance logs, and confirmed in interview the laboratory failed to perform monthly maintenance for 12 of 12 months in 2021 as required by the manufacturer for the Horiba ABX Micros 60 hematology analyzer. Findings Included: 1. Review of manufacturer's instructions for the Horiba Micros 60 hematology analyzer (Rev. 5 DCO-16-0022) revealed the following: "Weekly Maintenance: Concentrated Cleaning Cycle- a concentrated cleaning cycle must be performed with Minoclair solution once weekly." 2. Review of Horiba Micros 60 operator's manual (Version 5) revealed the following: "B. Maintenance: Failure to perform any of the recommended maintenance may result in poor reliability of the system." 3. Review of laboratory maintenance logs revealed the laboratory did not document weekly maintenance on the Horiba Micros 60 hematology analyzer for 12 of 12 months in 2021. 4. During an interview on 03/24/2022 at 11:28 a.m. with Testing Person 1 (TP-1), in the laboratory, TP-1 stated she did not document weekly maintenance performance on the Horiba Micros 60. This confirmed the above findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, quality control records (March 2022) and staff interview, it was revealed the laboratory failed to have documentation of verifying 1 of 1 new lot of control prior to placing into service. Findings Included: 1. Review of Horiba Medical Hematology Reference Control manufacturer's instructions revealed the following: "Performance and characteristics Assay values on a new lot of control should be confirmed before it is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the previous lot are acceptable." 2. Review of laboratory policies revealed the laboratory failed to have a policy for new lot quality control acceptability testing. 3. Review of quality control records revealed the laboratory began a new lot of Horiba

	Medical Hematology Reference Control in March 2022. Further review of quality control records revealed the laboratory failed to have documentation of verifying the new lot of quality control before placing into service for 1 of 1 new quality control lot in March 2022. 4. During an interview on 03/24/2022 at 01:46 p.m. in the laboratory, Testing Person 1 stated the manufacturer did not inform the laboratory verifying new quality control lots was a requirement. This 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 laboratory procedures, laboratory quality control records, patient records, and confirmed in staff interview, the laboratory failed to have an effective QA (quality assessment) in place to identify and correct problems for the analytical phase of testing. Findings included: 1. Review of laboratory policy titled, "Quality Assessment" revealed the following: "The laboratory has established a Quality Assurance (QA) Program. It is the policy of the laboratory to apply principles of this QA program to all activities of this laboratory, including preanalytic, analytic and postanalytic activities. The QA program assures the accurate, reliable and prompt reporting of test results and provides methods to evaluate the effectiveness of it's policies and procedures, to identify and correct problems and assure the adequacy and competency of the staff." 2. The laboratory failed to ensure patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory for 3 of 3 events in 2021 (Event 1, 2, 3). Refer to D2007. 3. The laboratory director and testing persons failed to attest to the routine integration of proficiency samples into the patient workload for 4 of 6 proficiency testing events. Refer to D2009. 4. The laboratory failed to have documentation of competency assessment, based on the position responsibilities, for 2 of 2 clinical consultants in 2020 and 2021. Refer to D5209. 5. The laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program for 1 of 3 events in 2020. Refer to D5213 I. 6. The laboratory failed to have documentation of competency assessment, based on the position responsibilities, for 2 of 2 technical consultants in 2020 and 2021. Refer to D5213 II. 7. The laboratory failed to define in their policy the quantification of the terms "occasional, TMTC" when reporting urine microscopy results for 2 of 5 patients reviewed. (January 2022-March 2022). Refer to D5403 I. 8. The laboratory failed to have a policy in place for sending patient specimens offsite for confirmatory testing. Refer to D5403 II. 9. The laboratory failed to follow manufacturer's instructions for 2 of 6 patients randomly reviewed. Refer to 5411. 10. The laboratory failed to ensure room humidity ranges were within operating specifications for 2 of 2 months reviewed in 2022. Refer to D5413 I. 11. The laboratory failed to ensure room temperature ranges were within operating specifications for 2 of 2 months reviewed in 2022. Refer to D5413 II. 12. The laboratory failed to ensure the reference range for hematology analytes were verified by the laboratory's studies. Refer to 5421. 13. The laboratory failed to perform monthly maintenance for 12 of 12 months in 2021 as required by the manufacturer for the Horiba ABX Micros 60 hematology analyzer.

	Refer to D5429. 14. The laboratory failed to have documentation of verifying 1 of 1 new lot of control prior to placing into service. Refer to D5469.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory policies, laboratory records, and patient records, the laboratory director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The laboratory director failed to ensure testing systems provided quality laboratory services.. Refer to D6079.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy and confirmed in staff interview, the Laboratory Director failed to ensure laboratory overall operations and test systems were in compliance with regulations as evidenced by: 1. The laboratory failed to ensure patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely perform testing in the laboratory for 3 of 3 events in 2021 (Event 1, 2, 3). Refer to D2007. 2. The laboratory director and testing persons failed to attest to the routine integration of proficiency samples into the patient workload for 4 of 6 proficiency testing events. Refer to D2009. 3. The laboratory failed to have documentation of competency assessment, based on the position responsibilities, for 2 of 2 clinical consultants in 2020 and 2021. Refer to D5209. 4. The laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program for 1 of 3 events in 2020. Refer to D5213 I. 5. The laboratory failed to have documentation of competency assessment, based on the position responsibilities, for 2 of 2 technical consultants in 2020 and 2021. Refer to D5213 II. 6. The laboratory failed to define in their policy the quantification of the terms "occasional, TMTC" when reporting urine microscopy results for 2 of 5 patients reviewed. (January 2022-March 2022). Refer to D5403 I. 7. The laboratory failed to have a policy in place for sending patient specimens offsite for confirmatory testing. Refer to D5403 II. 8. The laboratory failed to follow manufacturer's instructions for 2 of 6 patients randomly reviewed. Refer to 5411. 9. The laboratory failed to ensure

	room humidity ranges were within operating specifications for 2 of 2 months reviewed in 2022. Refer to D5413 I. 10. The laboratory failed to ensure room temperature ranges were within operating specifications for 2 of 2 months reviewed in 2022. Refer to D5413 II. 11. The laboratory failed to ensure the reference range for hematology analytes were verified by the laboratory's studies. Refer to 5421. 12. The laboratory failed to perform monthly maintenance for 12 of 12 months in 2021 as required by the manufacturer for the Horiba ABX Micros 60 hematology analyzer. Refer to D5429. 13. The laboratory failed to have documentation of verifying 1 of 1 new lot of control prior to placing into service. Refer to D5469.