Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2328405	07/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Health Hub, Llc	1505 E Bradford Parkway, Suite D, Springfield, MO	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the Piccolo xpress chemistry analyzer test menu, review of the Piccolo xpress chemistry analyzer manufacturer's instructions, review of Piccolo xpress chemistry quality control (QC) documentation from September 24, 2025 to date July 14, 2026, review of patient results, and interview with testing personnel (TP) #1, the laboratory failed to follow manufacturer's instructions for performing Piccolo xpress chemistry testing. Findings: 1. Review of Piccolo xpress chemistry analyzer test menu revealed the laboratory performs five chemistry panels: general chemistry 13 lipid panel plus comprehensive metabolic panel kidney check liver panel plus 2. Review of the Piccolo xpress chemistry analyzer manufacturer instructions states: "Performing external quality control: At least every 30 days. Whenever lab conditions change. When training or retraining personnel. When test results do not match patient symptoms. With each new lot number of reagent disc used." 3. Review of review of Piccolo xpress chemistry QC documentation showed no documentation of external QC every 30 days from September 2025 to date July 14, 2026. 4. The laboratory performs approximately 204 Piccolo xpress chemistry tests annually. 5. Interview with testing personnel (TP) #1 on July 14, 2026 at 11:00 AM confirmed the laboratory failed to follow manufacturer's instructions for performing Piccolo xpress chemistry testing.
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: Based on review of "CLIA Moderate Complexity Competency Assessment" policy, testing personnel (TP) training documents, patient results and interview with the testing personnel (TP) #1, the laboratory failed to follow written policies for employee competency. Findings: 1. Review of "CLIA Moderate Complexity Competency Assessment" policy states "Competency assessments shall be completed: prior to independent testing, at 6 months after hire, annually thereafter. No employee may perform independent testing without documented competency". 2. Review of TP training documents showed no competency prior to independent testing for TP #1 for the Beckman Coulter DxH 520 hematology analyzer from November 2025 to April 2026. 3. Review of TP training documents showed no 6 month competency assessment for TP #1 for the Tosoh AIA 360 chemistry analyzer in March 2026. 4. Review of patient results showed the laboratory performs approximately 2,000 hematology patient tests and 400 chemistry patient tests per year. 5. Interview with the TP #1 on July 14, 2026 at 9:30 AM confirmed the laboratory failed to follow written policies for employee competency.
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 review of hematology and chemistry procedures, Beckman Coulter DxH 520 hematology quality control (QC) manufacturer's package insert, Beckman Coulter DxH 520, Tosoh AIA-900, and Tosoh AIA-360 operator's guides, Bio-Rad Liquichek Immunoassay Plus Control package insert, laboratory temperature logs, Tosoh AIA 360 and 900 analyzers test menus, BioRad Liquichek Immunoassay Plus Control manufacturer's instructions, performance verification procedures for the Beckman Coulter DxH 520, Tosoh AIA-360, and Tosoh AIA-900 analyzers, Tosoh AIA 360 chemistry analyzer quality control (QC) from October 2025 to June 2026 , Beckman Coulter DxH520 hematology analyzer QC and patient results, lack of documentation of QC usage, observation of freezer, BioRad Immunoassay Plus Controls, and laboratory supplies during the laboratory tour and interview with the testing personnel (TP) #1, the laboratory failed to meet the condition of analytic systems. The laboratory failed to provide procedures for acceptability of hematology and chemistry QC. (Refer to D5401); the laboratory failed to follow manufacturer's instructions for hematology QC (Refer to D5411); the laboratory failed to ensure the room temperature, humidity and freezer temperature was monitored and documented as required by the manufacturer in 2025 and to date July 14, 2026. (Refer D5413); the laboratory failed to follow manufacturer's instructions and could not provide expiration dates for BioRad Liquichek Immunoassay Plus Control for 14 of 14

	analytes. (Refer D5415); the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date. (D5417); the laboratory failed to verify performance specifications prior to reporting patient test results. (Refer D5421); the laboratory failed to include two controls materials of different concentrations each day of patient testing for 17 of 18 chemistry testing days. (Refer D5447).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of hematology and chemistry procedures, and interview with the testing personnel (TP) #1, the laboratory failed to provide procedures for acceptability of hematology and chemistry quality control (QC). Findings: 1. Review of procedures revealed no procedures for acceptability of QC for the Tosoh AIA 360 analyzer, Tosoh AIA 900 analyzer and the Beckman Coulter DxH 520. 2. Interview with TP #1 on July 14, 2026 at 11:00 AM confirmed the laboratory failed to provide procedures for acceptability of hematology and chemistry QC.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 Beckman Coulter DxH 520 hematology quality control (QC) manufacturer's instructions, lack of documentation of QC usage, patient's test results, and interview with testing personnel (TP) #1, the laboratory failed to follow manufacturer's instructions for hematology QC. Findings: 1. Review of Beckman Coulter hematology QC manufacturers instructions states "Assumes that the Instructions for Use section of the Consumable IFU/Setting Sheet is performed a maximum of 16 times within 16 days, provided they are handled properly." 2. The laboratory could not provide documentation of number of times current opened lot number of Beckman Coulter QC was used and no expiration date was on the Beckman Coulter hematology QC. 3. The laboratory performs 400 complete blood counts (CBC's) annually. 4. Interview with TP #1 on July 14, 2026 at 11:00 AM confirmed the laboratory failed to follow manufacturer's instructions for hematology QC.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter DxH 520, Tosoh AIA-900, and Tosoh AIA-360 operator's guides, Bio-Rad Liquichek Immunoassay Plus Control package insert, and laboratory temperature logs, observation of freezer, review of patient results and interview with the testing personnel (TP) #1, the laboratory failed to ensure the room temperature, humidity and freezer temperature was monitored and documented as required by the manufacturer in 2025 and to date July 14, 2026. Findings: 1. Review of the Beckman Coulter DxH 520 operator's guide states "operating temperature 18 to 32 degrees Celsius (64.4 to 89.6 degrees fahrenheit) and operating environment relative humidity at a maximum of 80%". 2. Review of the Tosoh AIA -900 and Tosoh AIA-360 operator's guides states "operating temperature 15-30 degrees Celsius and operating environment relative humidity 40%-80% (non-condensing)". 3. Review of the Bio-Rad Liquichek Immunoassay Plus Control package insert states "This product will be stable until the expiration date when stored unopened at -20 to -70 degrees Celsius". 4. Review of the laboratory temperature logs showed no documentation of room temperature, humidity and freezer temperature in 2025 and to date July 14, 2026. 5. Observation of freezer showed 2 each of level 1 Bio-Rad Liquicheck Immunoassay Plus Controls Lot 1003961 exp 02/29/2029, 3 each of level 2 Lot 1003962 exp 02/29/2029 and 3 each of level 3 Bio-Rad Liquicheck Immunoassay Plus Controls Lot 1003963 exp 02/29/28 in use. 6. Review of patients results showed the laboratory performs approximately 2,400 patient tests per year. 7. Interview with the TP #1 on July 14, 2026 at 11:00 AM confirmed the laboratory failed to ensure the room temperature, humidity, and freezer temperature was monitored and documented as required by the manufacturer.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of Tosoh AIA 360 and 900 analyzers test menu, review of BioRad Liquichek Immunoassay Plus quality control manufacturer's instructions, observation of BioRad Immunoassay Plus Controls, patient test results, and interview with testing personnel (TP) #1, the laboratory failed to follow manufacturer's instructions for BioRad Liquichek Immunoassay Plus Control for 14 of 14 analytes. Findings: 1. Review of Tosoh AIA 360 and 900 analyzers showed the laboratory performs patient testing for the following analytes; IRI, PSA, TSH, FT3, FT4, LHII, E2, SHBG, vitamin D, progesterone III, cortisol, FSH, testosterone, and Beta HCG. 2. Review of Tosoh AIA 360 and 900 analyzers showed BioRad Immunoassay Plus Controls level

	1 lot # 1003961 expiration 2/29/28, level 2 lot # 1003962 expiration 2/29/28 and level 3 lot # 1003963 expiration 2/29/28 in use. 3. Review of BioRad Immunoassay Plus Controls manufacturer's instructions stated "once thawed, opened, and stored tightly capped at 2 to 8 degrees C, this product will be stable as follows: all analytes: 14 days Except: Estradiol: 5 days Folate: 4 days" 4. Observation of BioRad Immunoassay Plus Controls showed: level 1 lot # 1003961 expiration 2/29/28 open date 7/1/26 with no expiration date and still in use level 2 lot # 1003962 expiration 2/29/28 open date 7/1 /26 with no expiration date and still in use level 3 lot # 1003963 expiration 2/29/28 open date 7/1/26 with no expiration date and still in use 5. The laboratory performs 400 chemistry tests annually. 6. Interview with TP #1 on July 14, 2026 at 11:30 AM confirmed the laboratory failed to follow manufacturer's instructions for BioRad Liquichek Immunoassay Plus Control for 14 analytes.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of laboratory supplies during the laboratory tour, review of patient results and interview with the testing personnel (TP) #1, the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date. Findings: 1. Observation of laboratory supplies during the laboratory tour on July 14, 2026 showed 1 each of Greiner Bio-One Vacuette 9NC Coagulation Sodium Citrate 3.2% Blood Tube Lot B231133Y exp 10/31/2024, 1 each of Clinitest Rapid COVID-19 Antigen Self Test Lot 2202141EUA exp 12/2022 and 4 each of Henry Schein True Metrix Pro Blood Glucose Test Strips Lot ZA50795 exp 06/30/2024 still in use. 2. Review of patient results showed the laboratory performs approximately 2,400 patient tests annually. 3. Interview with the TP #1 on July 14, 2026 at 11:00 AM confirmed the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i) (A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 performance verification procedures for the Beckman Coulter DxH 520, Tosoh AIA-360, and Tosoh AIA-900 analyzers and patient results and interview with the testing personnel (TP) #1, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of performance verification procedures for the Beckman Coulter DxH 520 analyzer

	showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: white blood cell (WBC), red blood cell (RBC), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red blood cell distribution width (RDW), platelets, mean platelet volume (MPV), percent neutrophils, percent lymphocytes, percent monocytes, percent eosinophils, percent basophils, absolute neutrophils, absolute lymphocytes, absolute monocytes, absolute eosinophils and absolute basophils prior to the beginning of patient testing in November 2025. 2. Review of performance verification procedures for the Tosoh AIA-360 analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: thyroid stimulating hormone (TSH), free triiodothyronine (FT3), free thyroxine (FT4), luteinizing hormone (LH), estradiol, follicle stimulating hormone (FSH), testosterone, prostate specific antigen (PSA), and immunoreactive insulin (IRI) prior to the beginning of patient testing in November 2025. 3. Review of performance verification procedures for the Tosoh AIA-900 analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: thyroid stimulating hormone (TSH), free triiodothyronine (FT3), free thyroxine (FT4), luteinizing hormone (LH), estradiol, sex hormone binding globulin (SHBG), vitamin D, progesterone, cortisol, follicle stimulating hormone (FSH), testosterone, and beta-human chorionic gonadotropin (BHCG) prior to the beginning of patient testing in May 2026. 4. The laboratory performs approximately 2,400 patient tests annually. 5. Interview with the TP #1 on July 14, 2026 at 10:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of Tosoh AIA 360 chemistry analyzer quality control (QC) from October 2025 to June 2026, review of Beckman Coulter DxH520 hematology analyzer QC for December 2025 and April 2026, review of patient results and interview with testing personnel (TP) #1, the laboratory failed to include two controls materials of different concentrations each day of patient testing for 17 of 18 chemistry testing days. Findings: 1. Review of Tosoh AIA 360 QC showed: 10/23/2025 thyroid stimulating hormone (TSH), Estradiol, follicle-stimulating hormone(FSH) resulted on one patient and no QC performed 10/29/25 TSH resulted on one patient and no QC performed 11/17/25 TSH resulted on one patient and no QC performed 11/26/25 TSH resulted on one patient and no QC performed 12/2/25 TSH resulted on two patients and no QC performed 12/4/25 TSH resulted on two patients and no QC performed 12 /12/25 TSH resulted on one patient and no QC performed 12/17/25 TSH resulted on one patient and no QC performed 12/26/25 TSH resulted on one patient and no QC performed 12/30/25 TSH resulted on one patient and no QC performed 1/15/26 TSH resulted on one patient and no QC performed 1/20/26 TSH resulted on one patient and no QC performed 1/22/26 TSH resulted on three patients and no QC performed 1/23 /26 TSH resulted on three patients and no QC performed 2/3/26 PSA resulted on one patient and no QC performed 3/9/26 immunoreactive insulin (IRI) resulted on one

	patient and no QC performed 4/28/26 IRI resulted on one patient and no QC performed 2. Review of Beckman Coulter DxH520 showed: 12/22/25 complete blood count (CBC) resulted on one patient and no QC performed 12/30/25 CBC resulted on one patient and no QC performed 4/7/26 CBC resulted on one patient and no QC performed 3. Interview with the TP #1 on July 14, 2026 at 1:00 PM confirmed the laboratory failed to include two controls materials of different concentrations each day of patient testing.
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 "Letter of Delegation of Authority to the Clinical Director", performance verification procedures, laboratory procesdures, quality control (QC) program, quality assessment program, Beckman Coulter DxH 520 hematology QC, testing personnel (TP) training documents, and patient results and interview with the TP #1, the laboratory failed to meet the condition of laboratory director (LD). The LD failed to ensure overall operation of the laboratory. (Refer to D6004); the LD failed to ensure that verification procedures for the Beckman Coulter DxH 520, Tosoh AIA-360, and Tosoh AIA-900 analyzers were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method prior to patient testing. (Refer to D6013); the LD failed to ensure the QC program and quality assessment program was adequate to ensure the quality of laboratory services provided and to identify failures in quality as they occur. (Refer to D6020); the LD failed to ensure hematology patient test results are not reported when the system is not functioning properly. (Refer to D6024); the LD failed to ensure one of one TP received the appropriate training prior to performing patient testing in 2025. (Refer to D6029).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director 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 "Letter of Delegation of Authority to the Clinical Director", review of performance verification procedures, review of laboratory procedures, and interview with the laboratory director and the clinical consultant, the laboratory director failed to ensure overall operation of the laboratory. Findings: 1. Review of

	"Letter of Delegation of Authority to the Clinical Director" stated the laboratory director whom is also the only qualified technical consultant delegated to the Clinical Director who is not qualified as a technical consultant, the responsibilities of a technical consultant: "Oversight of clinical laboratory operations and testing activities, Review and implementation of laboratory policies and procedures, Supervision of laboratory personnel and clinical competency activities, Review and approval of quality assurance and quality control activities, Oversight of proficiency testing and corrective action processes, Ensuring compliance with applicable CLIA, CAP, state, and other regulatory requirements, Communication with regulatory agencies, clients, and healthcare providers regarding laboratory operations". 2. Review of performance verification procedures for the Beckman Coulter DxH 520, Tosoh AIA-360, and Tosoh AIA-900 analyzers showed no approved performance verification for chemistry or hematology before patient testing started. 3. Review of laboratory procedures revealed no laboratory director approved procedures for the Tosoh AIA 360 analyzer, Tosoh AIA 900 analyzer and the Beckman Coulter DxH 520. 4. Interview with the laboratory director and the clinical consultant on July 14, 2026 between 1:00 PM and 2:00 PM confirmed the laboratory director failed to ensure overall operation of the laboratory.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of verification procedures and patient reports and interview with the testing personnel (TP) #1, the laboratory director (LD) failed to ensure that verification procedures for the Beckman Coulter DxH 520, Tosoh AIA-360, and Tosoh AIA-900 analyzers were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method prior to patient testing. Findings: 1. Review of the Beckman Coulter DxH 520 analyzer verification procedures showed no documentation to show verification procedures for the Beckman Coulter DxH 520 analyzer were adequate, reviewed and approved by the laboratory director for accuracy, precision, reportable range of test results, and verification that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population for the analytes: white blood cell (WBC), red blood cell (RBC), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red blood cell distribution width (RDW), platelets, mean platelet volume (MPV), percent neutrophils, percent lymphocytes, percent monocytes, percent eosinophils, percent basophils, absolute neutrophils, absolute lymphocytes, absolute monocytes, absolute eosinophils and absolute basophils prior to the beginning of patient testing in November 2025. 2. Review of the Tosoh AIA-360 analyzer verification procedures showed no documentation to to show verification procedures for the Tosoh AIA-360 analyzer were adequate, reviewed and approved by the laboratory director for accuracy, precision, reportable range of test results, and verification that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population for the analytes: thyroid stimulating hormone (TSH), free triiodothyronine (FT3), free thyroxine (FT4), luteinizing hormone (LH), estradiol, follicle stimulating hormone (FSH), testosterone, prostate specific antigen (PSA), and immunoreactive insulin (IRI) prior to the beginning of

	patient testing in November 2025. 3. Review of the Tosoh AIA-900 analyzer verification procedures showed no documentation to show verification procedures for the Tosoh AIA-900 analyzer were adequate, reviewed and approved by the laboratory director for accuracy, precision, reportable range of test results, and verification that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population for the analytes: thyroid stimulating hormone (TSH), free triiodothyronine (FT3), free thyroxine (FT4), luteinizing hormone (LH), estradiol, sex hormone binding globulin (SHBG), vitamin D, progesterone, cortisol, follicle stimulating hormone (FSH), testosterone, and beta-human chorionic gonadotropin (BHCG) prior to the beginning of patient testing in May 2026. 4. The laboratory performs approximately 2,400 patient tests annually. 5. Interview with the TP #1 on July 14, 2026 at 10:00 AM confirmed the LD failed to ensure that verification procedures for the Beckman Coulter DxH 520, Tosoh AIA-360, and Tosoh AIA-900 analyzers were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method prior to patient testing.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of quality control (QC) program, review of quality assessment program and interview with testing personnel (TP) #1, the laboratory director failed to ensure the quality control program and quality assessment program was adequate to ensure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. Review of quality control program showed no procedures for acceptability of QC for the Tosoh AIA 360 analyzer, Tosoh AIA 900 analyzer and the Beckman Coulter DxH 520. 2. Review of the quality assessment program revealed the laboratory failed to provide a quality assessment program that will assure the quality of laboratory services provided and to identify failures in quality as they occur. 3. Interview with the TP #1 on July 14, 2026 at 11:30 AM confirmed the quality control program and quality assessment program was adequate to ensure the quality of laboratory services provided and to identify failures in quality as they occur.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on Beckman Coulter DxH 520 hematology quality control (QC), review of hematology patient results and interview with testing personnel (TP) #1, the laboratory director failed to ensure hematology patient test results are reported only when the system is functioning properly. Findings: 1. Review of Beckman Coulter DxH 520 hematology QC showed: 12/22/25 resulted on one patient and no QC

	performed 12/30/25 resulted on one patient and no QC performed 2. Review of patient hematology complete blood count (CBC) results showed: 12/22/25 patient A had dashes and missing data on the display on the analyzer. When patient A's test report was printed all the results were on the printed page (the analyzer never showed the numbers, it was all error codes). The printed lab result page had 6 flagged results and the patient was not repeated, no QC performed and this page was resulted. 12/30/25 patient B had dashes and missing data on the display on the analyzer. When patient B's test report was printed all the results were on the printed page (the analyzer never showed the numbers, it was all error codes). The printed lab result page had 1 flagged result and the patient was not repeated, no QC performed and this page was resulted. 3. Interview on July 14, 2026 at 1:00 PM with TP #1 confirmed the laboratory director failed to ensure hematology patient test results are reported only when the system is functioning properly.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 testing personnel (TP) training documents, patient results and interview with the TP #1, the laboratory director (LD) failed to ensure one of one TP received the appropriate training prior to performing patient testing in 2025. Findings: 1. Review of TP training documents showed TP #1 had no documented training for the Beckman Coulter DxH 520 hematology analyzer prior to performing patient testing in 2025. 2. Review of patient results showed the laboratory performs approximately 2,000 hematology patient tests per year. 3. Interview with the TP #1 on July 14, 2026 at 9:30 AM confirmed the LD failed to ensure TP received the appropriate training prior to performing patient testing.