Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2247871	(X3) Date Survey Completed 02/28/2023
Name of Provider or Supplier Jackson Hospital And Clinic	**Street Address, City, State** 9521 Vaughn Road, Pike Road, AL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory test menu, a lack of proficiency testing (PT) records and interviews with the current and previous Technical Consultants, and the Quality Coordinator, the surveyor determined the laboratory failed to enroll in Hematology proficiency testing after patient CBC (Complete Blood Count) testing began on 1/3/2023. The findings include: 1. During the entrance tour on 2/28/2023 at approximately 8:45 AM, the current Technical Consultant listed CBC's performed on the Beckman Coulter DxH 520 Hematology analyzer as the only moderate-complexity test. The surveyor then asked when patient CBC testing began; the Quality Coordinator stated patient testing began on 1/3/2023. 2. At approximately 9:45 AM, the surveyor requested the Hematology PT records; the current Technical Consultant stated the laboratory had not performed any PT. The surveyor then requested confirmation of PT enrollment, however the Quality Coordinator and current Technical Consultant did not know whether the previous Technical Consultant had placed an order with a PT provider. 3. During a phone interview on 2/28/2023 at 9:50 AM, the previous Technical Consultant (who left in early January 2023) confirmed he had not enrolled the laboratory in 2023 Hematology proficiency testing. .

D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of Hematology records, and an interview with the Technical Consultant, the laboratory failed to retain the manufacturer's package inserts for one of one Linearity Kit used for the Beckman Coulter DxH 520 verification, and one of two Hematology quality control (QC) assay sheets. The findings include: 1. A review of the Beckman Coulter DxH 520 Hematology analyzer validation records revealed the laboratory had failed to retain the manufacturer's assay sheet for the Linearity kit used for the data in the Accuracy and Reportable Range studies. 2. During an interview and review of the records on 2/28/2023 at 9:50 AM, the current Technical Consultant stated "This is all I found". During a phone interview on 2/28/2023 at 9:50 AM, the previous Technical Consultant (who left in early January 2023) stated he did not know where the assay sheet or any other records were. 3. A review of Hematology records revealed only the assay sheet for the current lot number (1441) of QC. The assay sheet for the previous lot number (1431) was not available. 4. During an interview on 2/28/2023 at 12:10 PM, the Technical Consultant stated Testing Personnel #1 said she discarded the sheet when the lab began using the new lot number of QC. .
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 reviews of the Hematology records and interviews with the Quality Coordinator, and the current and previous Technical Consultants, the laboratory: I) failed to ensure the Laboratory Director reviewed, signed and dated approval of the Beckman Coulter (B-C) DxH 520 Hematology analyzer procedures before the Testing Personnel began using the instrument for patient testing; II) failed to document whether precision was comparable to the manufacturer's performance criteria during the B-C DxH 520 Hematology analyzer verification procedures, and failed to retain the raw data (instrument printouts) used to verify the manufacturer's performance criteria for accuracy and reportable range; III) failed to calibrate the B-C DxH 520 as per manufacturer's instructions. The laboratory was unable to provide any documentation the instrument had been calibrated during the eight months since installation on 6/8/2022; IV) failed to implement a mechanism to track for quality control shifts and trends over time until the day of the survey; and V) failed to ensure

	at least two levels of quality control were acceptable each day of patient testing. The findings include: 1. Refer to D5407. 2. Refer to D5421. 3. Refer to D5437. 4. Refer to D5441. 5. Refer to D5447. .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of Hematology records, a review of the User's Manual and a procedure for the new Beckman Coulter DxH 520 Hematology analyzer, and interviews with the Technical Consultant and Quality Coordinator, the surveyor determined the Laboratory Director failed to review, sign and date approval of the procedures before the Testing Personnel began using the instrument for patient testing. This affected procedures in use for one of one new instruments performing moderate-complexity tests. The findings include: 1. During the entrance tour on 2/28 /2023 at approximately 8:45 AM, the current Technical Consultant listed CBC's performed on the Beckman Coulter DxH 520 Hematology analyzer as the only moderate-complexity test. The surveyor then asked when patient CBC testing began; the Quality Coordinator stated patient testing began on 1/3/2023. 2. A review of the "Beckman Coulter Instructions for Use" Manual revealed no documentation of the Laboratory Director's review and approval (as indicated by a signature and date) of the procedures in use by the testing personnel. The surveyor further noted the Laboratory Director failed to document approval of the "Jackson Hospital and Clinic PROCEDURE: DxH 520 Series Hematology Analyzer" in the "validation binder". 3. During a review on 2/28/2023 at 10:35 AM, the current Technical Consultant confirmed the above noted 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 a review of validation records for the Beckman Coulter DxH 520 Hematology analyzer, and interviews with the Quality Coordinator, the current Technical Consultant and the previous Technical Consultant, the surveyor determined the laboratory failed to document whether precision was comparable to the manufacturer's performance criteria. The laboratory further failed to retain the raw data (instrument printouts) used to verify the manufacturer's performance criteria for accuracy and reportable range. This affected one of one new instruments in use for moderate-complexity patient testing since 1/3/2023. The findings include: 1. During the entrance tour on 2/28/2023 at approximately 8:45 AM, the current Technical

	Consultant listed CBC's performed on the Beckman Coulter DxH 520 Hematology analyzer as the only moderate-complexity test. The surveyor then asked when patient CBC testing began; the Quality Coordinator stated patient testing began on 1/3/2023. 2. A review of the validation records for the Beckman Coulter DxH 520 Hematology analyzer revealed no documentation of verification of the manufacturer's performance characteristics for precision. 3. A further review of the Beckman Coulter DxH 520 Hematology analyzer records revealed a summary sheet for the verification of Accuracy and Reportable Ranges printed "08 June 2022", and signed by the Laboratory Director on 1/5/2023, however the laboratory had no record (such as instrument printouts) of the data used for the calculations. 4. During an interview and review of the records on 2/28/2023 at 9:50 AM, the current Technical Consultant stated "This is all I found". During a phone interview on 2/28/2023 at 9:50 AM, the previous Technical Consultant (who left in early January 2023) stated he did not know when the validation was performed, or where the records were. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of Hematology records for the Beckman Coulter (B-C) DxH 520 Hematology analyzer, a review of the Instructions for Use Manual and a laboratory policy, and interviews with the current Technical Consultant, the surveyor determined the laboratory failed to calibrate the B-C DxH 520 as per manufacturer's instructions. The laboratory was unable to provide any documentation the instrument had been calibrated during the eight months since installation on 6/8/2022. The findings include: 1. A review of Hematology records for the B-C DxH 520 revealed no documentation of calibrations on the instrument. A review of a B-C Service Report documented the DxH 520 was installed on 6/8/2022, however the laboratory had no record of a calibration performed during the installation, or before patient CBC (Complete Blood Count) testing began on 1/3/2023. 2. A review of the "Instructions for Use" Manual on page 11-1 revealed, "...When to Verify Calibration You should verify the calibration of your instrument: As dictated by your laboratory procedure ... [Refer to #3 below.] When controls show evidence of unusual trends ...". [Refer to #4 below.] 3. A review of the "Jackson Hospital and Clinic PROCEDURE: DxH 520 Series Hematology Analyzer" revealed, "...V. Calibration ...A. When to perform calibration verification ... calibration is performed every six months. ...". 4. A review of January-February 2023 Levey-Jennings graphs (printed the day of the survey) revealed all three levels of Hematology quality controls showed a positive bias (+ one to two standard deviations) for WBC (White Blood Cell) counts, Hematocrit and

	Platelets. 5. During the exit summation and review of the above records on 2/28/2023 at 12:30 PM, the surveyor confirmed the above noted findings with the current Technical Consultant. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Hematology records for the Beckman Coulter (B-C) DxH 520 Hematology analyzer, a review of the Instructions for Use Manual, and an interview with the current Technical Consultant, the surveyor determined the laboratory failed to implement a mechanism to track for shifts and trends over time until the day of the survey. This affected QC performed for two of two months of patient testing, January through February 2023. The findings include: 1. A review of Hematology quality control (QC) records for the B-C DxH 520 revealed only the daily QC printouts. The laboratory had no mechanism to track for shifts and trends over time in the QC. Patient CBC testing began 1/3/2023. 2. A review of the B-C DxH 520 "Instructions for Use" Manual on page 4-7 under "Viewing Control File Graphs", revealed the instrument had the capability to generate QC files with the corresponding Levey-Jennings (L-J) charts. 3. During an interview on 2/28/2023 at 10:45 AM, the Technical Consultant confirmed she only reviewed the daily QC printouts, and did not have a method for tracking QC shifts and trends over time. 4. As the interview continued on 2/28/2023 at 11:15 AM, the surveyor and the Technical Consultant reviewed directions on page 4-7 in the "Instructions for Use" Manual. The surveyor requested the L-J charts for the January-February 2023 QC. 5. During an interview on 2/28/2023 at 12:15 PM, the surveyor and Technical Consultant reviewed the QC data which demonstrated a positive bias (+ one to two standard deviations) in all three levels of Hematology QC for WBC (White Blood Cell) counts, Hematocrit and Platelets. The surveyor explained having a mechanism to track for shifts and trends in the QC was needed to determine when the instrument needed a calibration as per the manufacturer's instructions [refer to D5437], which in turn could affect the patient testing [refer to D5447]. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter (B-C) DxH 520 Hematology quality control (QC) records and an interview with the Technical Consultant, the surveyor determined the laboratory failed to ensure at least two levels of QC were within acceptable ranges each day of patient testing. This affected one patient with a CBC (Complete Blood Count) performed on 2/9/2023. The findings include: 1. A review of Hematology QC records for the B-C DxH 520 revealed the Low and the Normal QC (two of three levels) were outside acceptable limits on 2/9/2023. 2. During an interview on 2/28/2023 at 12:15 PM the Technical Consultant confirmed the above noted findings, and stated one patient CBC was performed on 2/9/2023. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a lack of Quality Assurance procedures and reviews, and an interview with the Quality Coordinator and Technical Consultant, the laboratory failed to implement a mechanism to monitor, assess and correct problems identified during the survey in the laboratory processes and procedures. The findings include: 1. During an interview on 2/28/2023 at 12:05 PM, when the surveyor requested the Quality Assurance procedure and documentation of QA reviews, the Technical Consultant confirmed the laboratory had no documentation. The laboratory had no mechanism to review laboratory activities to ensure: A) the laboratory was enrolled in Proficiency Testing for the Specialty of Hematology; B) manufacturer's package inserts were retained for at least two years; C) the Laboratory Director documented review and approval (via his signature and date) on instrument manuals and procedures before use by the testing personnel; D) the Beckman Coulter (B-C) DxH 520 Hematology analyzer verification procedures included precision, and the raw data (instrument printouts) used to verify the manufacturer's performance criteria for accuracy and reportable range was retained for the life of the instrument; E) the B-C DxH 520 was calibrated as per manufacturer's instructions; F) a mechanism to track for quality control shifts (QC) and trends over time was implemented; G) ensure at least two levels of Hematology quality control were acceptable each day of patient testing. 2. During the exit summation with the Quality Coordinator and Technical Consultant on 2/28/20 at 12:30 PM, the surveyor reviewed and confirmed the above concerns. .
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on reviews of the Hematology records and interviews with the Quality

	Coordinator, and the current and previous Technical Consultants, the surveyor determined the Technical Consultants failed to provide technical and scientific oversight of the laboratory, and ensure the quality of the analytic systems after patient testing began on 1/3/2023 until the day of the survey on 2/28/2023. The findings include: 1. Refer to D5400 and D5791. SURVEYOR ID# 32558 Licensure and Certification Surveyor