Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0979623	01/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Salas Minor Emergency Center	1655 Ne Loop 286, Paris, 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	The laboratory was found to be out of compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey completed on 1/22 /2025. The following conditions were not met: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on laboratory QC records and confirmed in interview, the laboratory failed to ensure the retention of quality control records for the DxH520 hematology analyzer for 21 of 32 weeks reviewed since it was put into use May 23, 2024. The findings included: 1. Review of laboratory quality control records for the DxH520 hematology analyzer, that was put into use for patient testing on May 23, 2024, only included the following days: September 2024: 9/13/2024 - 9/30/2024 October 2024: 10/1/2024 - 10 /31/2024 December 2024: 12/6/2024 - 12/31/2024 Surveyor asked for the remaining QC documentation, and none could be provided. 2. In an interview on 1/22/2025 at 15: 00 hours, in the conference room, testing personnel (TP) 1 stated they had misplaced, or accidentally threw away, the quality control information and that there were no additional records or back up records available.
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 laboratory quality control (QC) records, manufactures instructions for use, patient test reports, and confirmed in interview, the laboratory failed to ensure the daily hematology QC on the DxH 520 hematology analyzer was acceptable prior to testing and reporting patient results for 14 of 74 days reviewed where QC had been outside of acceptability and patients tested. Refer to D5481.
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 the laboratory "DxH 520 Performance Verification Workbook", laboratory verification studies, and confirmed in interview, the laboratory failed to ensure that the manufacturer's normal patient ranges are appropriate for the laboratory's patient population before putting into use on May 23, 2024. The findings included: 1. Review of the laboratory "DxH 520 Performance verification Workbook", section "About Reference Range" included the following statement: " ... the laboratory is required to check (verify) the manufacturer's performance specifications provided in the package insert - for accuracy, precision, reportable range (Measuring Range), and reference range." 2. Review of the laboratory provided installation information for the DxH520 hematology analyzer did not include a reference range verification. Surveyor asked for documentation the study had been performed and none was provided. 3. In an interview on 1/22/2025 at 13:56, in the conference room, testing personnel (TP) 1 stated that documentation to ensure that the manufacturers normal patient reference range was appropriate for the laboratories patients was not available.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions for use, laboratory quality control (QC) records, patient test reports, and confirmed in interview, the laboratory failed to ensure QC was acceptable on the DxH 5200 hematology analyzer, prior to testing and reporting patient results for 14 of 74 days reviewed where QC had been outside of acceptability. The findings included: 1. Review of the manufacturer's "Instructions for Use: DxH 520", chapter 4 "Quality Control", subsection "If a Control is OUT" included the following information: "If a control is not within the range configured for the test, the control is considered out ... The values that are out are flagged as low (L) or high (H) on the Sample Analysis - Patient results screen." 2. Review of the laboratory quality control records for the DxH 520 hematology analyzer, and the manufactures QC "Table of Expected Results" included the following days where QC was outside of the laboratory's acceptability and patients were tested: Date Control Level, Lot, Expiration Date Analyte - Result Flag, [Expected Result] September 2024 (9/13/2024 - 9/30/2024): 5 days where QC was out of laboratory acceptability and patients were tested. 09/13/2024 Abnormal High, Lot 372416413, EXP 11/05/2024 HCT - 46.8 L, [47.1 - 53.1 %] 09/15/2024 Abnormal High, Lot 372416413, EXP 11 /05/2024 RBC - 5.71 H, [4.89 - 5.39 x10^6 /uL] HGB - 18.71 H, [16.35 - 17.96 g/dL] HCT - 53.6 H, [47.1 - 53.1 %] 09/25/2024 Abnormal High, Lot 372416413, EXP 11 /05/2024 WBC - ..... No QC result LY- [.....] No QC result LY#- [.....] No QC result MO- [.....] No QC result MO#- [.....] No QC result NE- [.....] No QC result NE#- [.....] No QC result EO- [.....] No QC result EO#- [.....] No QC result BA- [.....] No QC result BA#- [.....] No QC result 09/28/2024 Abnormal High, Lot 372416413, EXP 11/05/2024 HCT - 46.7 L, [47.1 - 53.1 %] 09/29/2024 Abnormal High, Lot 372416413, EXP 11/05/2024 HCT - 47.0 L, [47.1 - 53.1 %] October 2024 (10/01 /2024 - 10/31/2024): 7 days where QC was out of laboratory acceptability and patients were ran. 10/08/2024 Abnormal High, Lot 372416413, EXP 11/05/2024 HCT - 47.0 L, [47.1 - 53.1 %] 10/12/2024 Abnormal High, Lot 372416413, EXP 11/05/2024 RBC - 5.90 H, [4.89 - 5.39 x10^6 /uL] HGB - 19.81 H, [16.35 - 17.96 g/dL] HCT - 56.2 H, [47.1 - 53.1 %] 10/13/2024 Abnormal High, Lot 372416413, EXP 11/05/2024 RBC - 6.36 H, [4.89 - 5.39 x10^6 /uL] HGB - 21.30 H, [16.35 - 17.96 g/dL] PLT - 348.2 L, [417 - 537 x10^3/uL] HCT - 60.5 H, [47.1 - 53.1 %] Normal, Lot 362416412, Exp 11 /05/2024 RBC - 4.91 H, [4.46 - 4.86 x10^6/ uL] HGB - 15.14 H, [13.65 - 14.85 g/dL] 10/18/2024 Normal, Lot 362416412, Exp 11/05/2024 RBC - 5.44 H, [4.46 - 4.86 x10^6/ uL] HGB - 16.83 H, [13.65 - 14.85 g/dL] HCT - 47.8 H, [39 - 44%] 10/26 /2024 Abnormal High, Lot 372416413, EXP 11/05/2024 RBC - 4.86 L, [4.89 - 5.39 x10^6 /uL] HGB - 16.27 L, [16.35 - 17.96 g/dL] HCT - 46.2 L, [47.1 - 53.1 %] 10/27 /2024 Abnormal High, Lot 372416413, EXP 11/05/2024 RBC - 5.55 H, [4.89 - 5.39 x10^6 /uL] HGB - 18.93 H, [16.35 - 17.96 g/dL] PLT - 382.5 L, [417 - 537 x10^3 / uL] Normal, Lot 362416412, Exp 11/05/2024 WBC 4.58 L, [5.95 - 8.15 x10^3/uL] RBC 5.27 H, [4.46 - 4.86 x10^6/ uL] HGB 15.96 H, [13.65 - 14.85 g/dL] HCT 46.1 H, [39 - 44%] PLT 167.2 L, [203 - 283 x10^3/uL] LY 17.54 L, [22.5 - 36.5 %] NE 76.72 H, [54.5 - 74.5 %] 10/30/2024 Normal, Lot 362416412, Exp 11/05/2024 HGB [.....] No QC result MCH [.....] No QC result MCHC [.....] No QC result December 2024 (12/6/2024 - 12/31/2024): 2 days where QC was out of laboratory acceptability and patients were ran. 12/22/2024 Abnormal High, Lot number 372416713, Exp 2/5 /2025 WBC - 13.85 L, [15.6 - 21.1 x10^3/uL] RBC - 5.64 H, [4.89 - 5.39 x10^6 /uL] HGB - 19.04 H, [16.8 - 18.4g/dL] HCT - 54.8 H, [48 - 54%] PLT - 412.7 L, [439 - 556 x10^3/uL] Normal, Lot number 362416712, Exp 2/5/2025 WBC - 3.60 L, [6.25 - 8.45 x10^3/uL] RBC - 6.34 H, [4.4 - 4.8 x10^6/uL] HGB - 18.83 H, [12.95 - 14.15 g /dL] HCT - 54.7 H, [37.1 - 42.10 %] PLT - 110.3 L, [214 - 294 x10^3/uL] LY - 11.7 L, [22 - 36%] NE - 78.06 H, [55 - 75%] EO - 9.68 H, [0 - 8%] 12/27/2024 Normal,

	Lot number 362416712, Exp 2/5/2025 RBC - 6.31 H, [4.4 - 4.8 x10^6/uL] HGB - 18.68 H, [12.95 - 14.15 g/dL] HCT - 54.0 H, [37.1 - 42.10 %] PLT - 197.1 L, [214 - 294 x10^3/uL] LY - 18.72 L, [22 - 36%] Abnormal High, Lot number 372416713, Exp 2/5/2025 RBC - 5.63 H, [4.89 - 5.39 x10^6 /uL] HGB - 19.31 H, [16.8 - 18.4g/dL] HCT - 54.7 H, [48 - 54%] Abnormal Low, Lot number 352416711, exp 2/5/2025 WBC - [.....] No QC result RBC - 4.57 H, [2.19 - 2.49 x10^3/uL] HGB - 12.36 H, [5.85 - 6.65 g/dL] HCT - 35.0 H, [16.5 - 20.5 %] PLT - 20.1 L, [56 - 96 x10^3/uL] LY - [.....] No QC result MO - [.....] No QC result NE - [.....] No QC result EO - [.....] No QC result BA - [.....] No QC result 3. Review of patient test records included the following sample of 68 patients with hematology testing during the above days where QC was outside of acceptability: On 09/25/2024 the following five patients were tested when QC was out of acceptability: 453653, 453672, 453669, 453695, 453697 On 10/05/2024 the following eight patients were tested when QC was out of acceptability: 454226, 454231, 454230, 454233, 454235, 454234, 454238, 454241 On 10/12/2024 the following three patients were tested when QC was out of acceptability: 454623, 454620, 454631 On 10/13/2024 the following two patients were tested when QC was out of acceptability: 454647, 454646 On 10/18/2024 the following eight patients were tested when QC was out of acceptability: 454923, 454933, 454924, 454928, 454972, 454994, 454991, 454999 On 10/20/2024 the following five patients were tested when QC was out of acceptability: 455027, 455029, 455026, 455039, 455037 On 10/26/2024 the following four patients were tested when QC was out of acceptability: 455387, 455392, 455389, 455396 On 10/27/2024 the following five patients were tested when QC was out of acceptability: 455413, 455419, 455420, 455429, 455426 On 10/30/2024 the following seven patients were tested when QC was out of acceptability: 455579, 455581, 455601, 455602, 455599, 455619, 455623 On 12/22/2024 the following six patients were tested when QC was out of acceptability: 458286, 458288, 458291, 458283, 458290, 458304 On 12/27/2024 the following fifteen patients were tested when QC was out of acceptability: 458486, 458489, 458494, 458480, 458502, 458485, 458506, 458511, 458510, 458482, 458521, 458525, 458527, 458534, 458538 4. In an interview on 1/22/2025 at 15:30 hours, in the conference room, testing personnel (TP) 1 confirmed that QC on the DxH 520 hematology analyzer had failed acceptability, and patients were tested during those days.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory quality control records, patient records, personnel records, training records, and manufacturer's instructions for use, the laboratory director failed to ensure overall management and direction for one of one new hematology analyzer to ensure testing personnel took the necessary remedial actions necessary when instrument QC was out of specification and that patient test results were only reported when the system was operating properly (refer to D6024), and that prior to testing patients, all personnel received the appropriate training for the operation of the new DxH hematology analyzer, put into use 5/23/2024, to ensure accurate and reliable results (refer to D6029).

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 review of laboratory quality control (QC) records, laboratory patient records, and confirmed in interview the laboratory director failed to ensure that all necessary remedial actions were taken and documented when quality control failed laboratory specifications, and failed to ensure patient test results were reported only when the DxH 520 hematology analyzer was within performance specifications, acceptable daily QC, for 14 of 74 days reviewed in September, October, and December 2024. Refer to D5481.
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 the instrument installation documentation, manufacturer's instructions for use (IFU), personnel documents, and confirmed in interview, the laboratory director failed to ensure that appropriate training was provided to testing personnel performing moderate complexity testing on one of one new DxH 520 Hematology analyzer, installed on May 23, 2024. Refer to D6066.
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 the review of laboratory personnel records and confirmed in interview 3 out of 16 testing personnel failed to have education records to meet testing personnel (TP) qualifications (refer to D6065) and failed to ensure the appropriate training, as listed in 493.1423(b)(6)(ii)(A) through 493.1423(b)(6)(ii)(H), to meet the qualifications to perform moderate complexity testing on one of one new hematology analyzer installed on 5/23/2024 (refer to 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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on the review of laboratory personnel records and confirmed in interview 3 out of 16 testing personnel failed to have education records to meet testing personnel (TP) qualifications to perform moderate complexity testing. The findings included: 1. Review of laboratory personnel files did not include education (diploma or transcript) records to ensure the personnel performing moderate complexity testing, met the qualifications under 493.1423 b(1) - b(6)(ii): TP 08 - performing hematology testing on the DxH 520. TP 10 - Performing hematology testing on the DxH 520. TP 16 - Performing urine sediment examination. Surveyor asked for documentation of education for the above and none could be provided. 2. In an interview on 1/22/2025 at 13:42 hours, in the conference room, TP1 confirmed the laboratory did not have documentation of education for the above testing personnel performing moderate complexity testing.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) (b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii)(E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory; (b)(6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the instrument installation documentation, manufacturer's instructions for use (IFU), personnel documents, and confirmed in interview, the laboratory failed to ensure the appropriate training, as listed in 493.1423(b)(6)(ii)(A) through 493.1423(b)(6)(ii)(H) to meet the qualifications to perform moderate

	complexity testing on one of one new hematology analyzer installed on 5/23/2024. The findings included: 1. Review of laboratory personnel education included the following eight testing personnel (TP) performing moderate complexity hematology testing, qualified under 493.1423(b)(6)(i), having earned a high school diploma or equivalent: TP 1 TP 2 TP 3 TP 4 TP 5 TP 6 TP 7 TP 9 TP 12 2. Review of laboratory instrumentation included the following new hematology analyzer with an implementation date of 5/23/2024: Beckman Coulter DxH 520, serial number BH010046 3. Review of the Dxh 520 IFU included the following "Safety Notice": "Read all product manuals and consult with Beckman Coulter-trained personnel before attempting to operate instrument. Do no attempt to perform any procedure before carefully reading all instructions. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, contact your Beckman Coulter Representative." Review of the DxH 520 IFU contents included a "Training Checklist", in appendix C that included the statement "Go through this checklist before operating the instrument" and topics over the following with a box for personnel initials and date completed: Hardware Software System Operations Quality Control Patient Samples Maintenance Quality Assurance At the bottom of the form was a place for the operator's name and signature, as well as the operator title. And a place for the trainer's name and signature and the trainer's title. Surveyor asked for the documentation that the above personnel were trained on the new analyzer and no documentation could be provided. 4. In an interview on 1/22 /2025 at 13:25 hours, in the conference room, TP1 stated the laboratory did not have training documentation for the new hematology analyzer, to cover the requirements found at 493.1423(b)(6)(ii)(A) through 493.1423(b)(6)(ii)(H) to qualify the above testing personnel to perform moderate complexity testing.