Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0979623	11/03/2021
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	A recertification survey was performed on 11/3/21. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F. R. 493.1250 Condition: Analytic systems; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of the attestation statement, the manufacturer's instructions for the Beckman Coulter AcT diff 2 hematology analyzer, a review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2019, 2020, and 2021, and staff interview, it was revealed the laboratory failed to have documentation of testing proficiency samples in the same manner it tested its patient samples for 7 of 8 events in 2019, 2020, and 2021 for Hematology testing. Findings include: 1. A review of the API's attestation statement, signed by the laboratory's testing personnel for each proficiency testing event, revealed the following: "Person Performing the Test: We certify that as closely as possible, these proficiency testing samples were tested in the same manner as patient samples." 2. A review of the manufacturer's instructions for the Beckman Coulter AcT diff 2 hematology analyzer (PN 4237416D,

	June 2003) under the section titled "What Flags and Codes Mean" revealed the manufacturer provided actions to take when specific flags were identified on CBC results. For the flag of '*' the manufacturer stated: " '*'Possible sample handling problem. Possible dual RBC population. Possible interference with WBC count. Platelet distribution failure. Possible sample interference or instrument problem. See instructions for +++++, +, or -----." "---- Thoroughly mix and rerun the sample. If flag repeats then Zap the machine and do bleach bath. ++++ Zap and rerun samples. If flag is still present after the rerun Call tech support. XXXX Mix the sample with a wooden applicator and rerun. If repeats ZAP and do bleach bath. If continues call tech support. " 3. An interview with testing person #1 on 11/3/21 at 11:00 am in the conference room revealed the laboratory repeats patient samples that have a "*" flag present on the CBC results. 4. A review of the laboratory's API proficiency testing records for 2019, 2020, and 2021 revealed the following events/samples where the proficiency sample's results were flagged with a '*' by the analyzer and not repeated: a) 2019 Hematology/Coagulation 2nd Event Specimen 07: LY, MO, GR, LY#, MO#, GR# Specimen 08: LY, MO, GR, LY#, MO#, GR# Specimen 09: MO, MO# b) 2019 Hematology/Coagulation 3rd Event Specimen 11: LY, MO, GR, LY#, MO#, GR# Specimen 13: MO, MO# c) 2020 Hematology/Coagulation 1st Event Specimen 02: LY, MO, GR, LY#, MO#, GR# Specimen 03: LY, MO, GR, LY#, MO#, GR# Specimen 05: MO, MO# d) 2020 Hematology/Coagulation 2nd Event Specimen 06: LY, MO, GR, LY#, MO#, GR# Specimen 10: MO, MO# e) 2021 Hematology /Coagulation 1st Event Specimen 01: LY, MO, GR, LY#, MO#, GR# Specimen 04: LY, MO, GR, LY#, MO#, GR# f) 2021 Hematology/Coagulation 2nd Event Specimen 07: LY, MO, GR, LY#, MO#, GR# Specimen 08: MO, MO#, RDW Specimen 10: LY, MO, GR, LY#, MO#, GR# 5. An interview with testing person #1 (as indicated on the CMS 209 form) on 11/3/21 at 11:05 a.m. in the conference room, after review of the records, confirmed the above findings. Key: CBC = complete blood count GR = granulocytes MO = monocytes, eosinophils, basophils Ly = lymphocytes RDW = red cell distribution width
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 a review of manufacturer's instructions, review of laboratory records, and staff interview, it was revealed the laboratory failed to identify issues with analytic systems. Findings include: 1. The laboratory failed to make available a written procedure for the laboratory personnel to follow for complete blood count (CBC) testing on the Beckman Coulter AcT diff 2 hematology analyzer. (refer to D5403) 2. The laboratory failed to have documentation of the laboratory director signing and approving 6 of 6 procedures. (refer to D5407) 3.The laboratory failed to ensure the Quidel Triage Total Controls were stored at temperatures required by the manufacturer. (refer to D5413) 4. The laboratory failed to have documentation of performing 3 of 4 required verification studies on the Beckman Coulter AcT diff 2 hematology analyzer. (refer to D5421) 5. The laboratory failed to have documentation

	of establishing an IQCP (Individualized Quality Control Plan) for the Quidel Triage meter to support the modification in quality control testing. (refer to D5445) 6. The laboratory failed to verify new lot numbers of external quality control for complete blood count (CBC) testing on the Beckman Coulter AcT diff 2 hematology analyzer before placing them into use. (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: Based on a review of the laboratory's verification records for the Beckman Coulter AcT diff 2 hematology analyzer, a review of the laboratory's policies, and staff interview, it was revealed that the laboratory failed to make available a written procedure for the laboratory personnel to follow for complete blood count (CBC) testing on the Beckman Coulter AcT diff 2 hematology analyzer. Findings include: 1. A review of the laboratory's verification records for the Beckman Coulter AcT diff 2 hematology analyzer revealed the analyzer was installed in June 2021. 2. A review of the laboratory's policies revealed no documentation of a written procedure for CBC testing on the Beckman Coulter AcT diff 2 hematology analyzer to include: a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. b. Step-by-step performance of the procedure, including interpretation of results. c. Preparation of calibrators, controls, reagents, and other materials used in testing. d. Calibration procedures. e. The reportable range for test results for the test system as established or verified. f. Control procedures. g. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. h. Reference intervals (normal values). i. Imminently life-threatening test results, or panic or alert values. j. 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. k. Description of the course of action to take if a test system becomes inoperable. 3. An interview with testing person #1(as indicated on the CMS 209 form) on 11/3/21 at 11:30 a.m. in the conference room, after review of the records, confirmed the above findings.

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 the laboratory's policies and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing and approving 6 of 6 procedures. Findings include: 1. A review of the laboratory's policies revealed the laboratory failed to have documentation of the laboratory director signing and approving the following 6 procedures: - CBC Machine - Covid Antibody - Covid Antigen - Centrifuge - Triage Meter - Cardiac Panel 2. An interview with testing person #1 (as indicated on the CMS 209 form) on 11/3/21 at 13:50 p.m. in the conference room, after review of the records, 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: Based on a review of the manufacturer's instructions, surveyor observation, a review of the laboratory's freezer temperature logs, and staff interview, it was revealed that the laboratory failed to ensure the Quidel Triage Total Controls were stored at temperatures required by the manufacturer for 12 of 12 months from October 2020 to October 2021. Findings include: 1. A review of the Quidel Triage Total Control Product Insert (26601 Rev. A, 05/2018) revealed the following: "Store frozen at -20C or colder in a non-defrosting freezer." 2. Surveyor observation on 11/3/21 at 12:05 p. m. of the laboratory's freezer found the following boxes of controls inside: - 1 box of Triage Total Control level 1 Lot number: C3771AN exp: 4/30/22 - 1 box of Triage Total Control level 2 Lot number: C3795AN exp: 5/21/22 3. A review of the laboratory's Freezer Temperature logs from October 2020 to October 2021 revealed the acceptable temperature for the freezer was -20C + 6. The laboratory documented the freezer temperature as -14 to -19C for every day of the 12 months from October 2020 to October 2021. 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 11/3/21 at 12:10 p.m. in the conference room, after review of the records, confirmed the above findings. Key: C = degrees Celsius
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 the laboratory's installation records for the Beckman Coulter AcT diff 2 hematology analyzer, and staff interview, it was revealed the laboratory failed to have documentation of performing 3 of 4 required verification studies for Complete Blood Count (CBC) testing on the Beckman Coulter AcT diff 2 hematology analyzer in June 2021 . Findings include: 1. A review of the laboratory's installation records revealed the laboratory installed and started performing Complete Blood Count (CBC) testing on the Beckman Coulter AcT diff 2 hematology analyzer in June 2021. 2. Further review of the laboratory's installation records revealed the laboratory failed to have documentation of performing 3 verification studies to ensure accurate and reliable test results. The following studies were not performed: a) Accuracy b) Precision c) Verification of normal patient values 3. The laboratory reported performing 7121 hematology tests on the Beckman Coulter AcT diff 2 hematology analyzer annually. 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 11/3/21 at 11:22 a.m. in the conference room stated, the purchased the analyzer from a third party. There was someone who came out and calibrated the analyzer before use, but no other studies were done. This confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records, the laboratory's QC records for the Alere Triage meter from January to November 2021, and staff interview, it was revealed the laboratory failed to have documentation of establishing an IQCP (Individualized Quality Control Plan) for the Quidel Triage meter to support the modification in quality control testing for 3 of 3 tests: CK-MB (creatine kinase myocardial band) TNI (troponin) DDIM (d-dimer) Findings include: 1. A review of the laboratory's records revealed the facility used a Quidel Triage meter (Serial number 00074363) to test for the following 3 analytes: CK-MB (creatine kinase myocardial band) TNI (troponin) DDIM (d-dimer) 2. A review of the laboratory's QC records from January to November of 2021 revealed the laboratory runs 2 levels of external quality control material: - with every new lot/shipment of test materials - or every 30 days 3. Further review of the laboratory's records revealed the laboratory failed to have documentation of an IQCP for the Quidel Triage meter to support the modification in quality control testing for the above mentioned analytes. 4. An

	interview with testing person #1 (as indicated on the CMS 209 form) on 11/3/21 at 11: 55 a.m. in the conference room, revealed she was unaware an IQCP had to be developed for the Triage meter. 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 a review of the laboratory's quality control records for the Beckman Coulter AcT diff 2 hematology analyzer from April 2021 to November 2021 and staff interview, it was revealed that the laboratory failed to verify 9 of 9 new lot numbers of external quality control for complete blood count (CBC) testing on the Beckman Coulter AcT diff 2 hematology analyzer before placing them into use. Findings include: 1. A review of the laboratory's quality control records for the Beckman Coulter AcT diff 2 hematology analyzer from April 2021 to November 2021 revealed there was no documentation of the laboratory performing lot to lot verifications for the following 9 lot numbers of external QC materials: 4C Cell Controls: Low level lot number: 069400 Low level lot number: 067500 Low level lot number: 068900 Normal level lot number: 079400 Normal level lot number: 077500 Normal level lot number: 078900 High level lot number: 089400 High level lot number: 087500 High level lot number: 088900 2. An interview with testing person #1 (as indicated on the CMS 209 form) on 11/3/21 at 11:02 a.m. in the conference room, after review of the records, confirmed the above findings. Key: QC = Quality Control
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by:

	Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory director failed to ensure verification studies were performed on each test system. (Refer to D5421)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of the manufacturer's records, the laboratory's quality control records, and staff interview, it was revealed that the technical consultant failed to establish a quality control program for the testing the laboratory performs. (Refer to D5445, D5469)