Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0979623	12/16/2022
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	An onsite survey conducted 12/16/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 surveyor observation, laboratory records, a review of the Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview the laboratory failed to retain patient complete blood count (CBC) instrument printouts from the ActDiff 2 hematology analyzer for 11 of 11 months reviewed in 2022. The findings include: 1. In a tour of the laboratory on 12/16/2022 at 10:10 hours surveyor noted a Beckman Coulter AcT Diff 2 hematology analyzer used for patient complete blood count's (CBC's). Surveyor queried for the patient printouts from the analyzer for January to November 2022 and the laboratory supervisor stated that the analyzer records were transcribed into the electronic medical record and then shredded. 2. Review of the CMS 116, section VII "Non-Waived Testing" listed the annual test volume for Hematology as 17,550. 3. In an interview on 12/16/2022 at 13:40 hours, in the laboratory, the laboratory supervisor confirmed that the patient records from the ActDiff 2 hematology analyzer were not kept from January to November 2022.
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 laboratory policy, a review of the Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in an interview the laboratory failed to include critical values in their Complete Blood Count (CBC) policy for the Coulter Act2 hematology analyzer. The findings include: 1. Review of the laboratory hematology policy titled "Processing CBC" stated: "7. If results are dangerously high. Please bring to provider's attention." Surveyor queried for the laboratory's critical values list and the documentation that providers were notified of dangerously critical values, and none was provided. 2. Review of the CMS 116, section VII "Non-Waived Testing" listed the annual test volume for Hematology as 17,550. 3. In an interview on 12/16/2022 at 11:40 hours, in the conference room, the laboratory supervisor confirmed that the laboratory CBC policy did not include critical values or include instructions for the notification and documentation of such values.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 direct observation and confirmed in interview the laboratory failed to ensure that expired supplies were not available for use for 39 of 39 expired supplies observed on 12/16/2022. The findings include: 1. In a tour of the laboratory on 12/16/2022 at 10:10 hours the surveyor observed the following 39 expired supplies available for patient collection and testing: EDM3 Solution Potassium Hydroxide 10%: 1 bottle Lot 0275, Expired 10/01/2022 BD Vacutainer ACD Solution A: 8 tubes Lot 0289283, Expired 10/31/2022 BD Vacutainer Sodium Heparin: 10 tubes Lot 0258292, Expired 09/30/2022 Greiner bio-one NH Trace Elements Sodium Heparin: 20 tubes Lot 456275, Expired 08/31/2022 2. In an interview on 12/16/2022 at 10:20 hours, in the laboratory, the laboratory supervisor confirmed that the above supplies were available for patient testing.
D5783	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) documents, laboratory policy, patient test records, and confirmed in interview, the laboratory failed to conduct patient remediation for 33 of 33 patients reviewed when quality control failures could not be solved with basic repeat testing for QC events reviewed in January 2022. The findings include: 1. Review of the laboratory document titled "CBC Corrective Action Log" had the following documentation of action, other than repeat testing, when QC was out of the laboratory's acceptable limits in January 2022: 1/5/2022 - Zapped and Bleached Bath 1/7/2022 - Zapped and Bleached Bath 1/9/2022 - Zapped and Bleached Bath 1/10/2022 - Zapped and Bleached Bath 1/11/2022 - Zapped and Bleached Bath 1 /12/2022 - Zapped and Bleached Bath, Called support 1/13/2022 - Zapped and Bleached Bath 1/14/2022 - Zapped and Bleached Bath 1/15/2022 - Zapped and Bleached Bath 1/17/2022 - Zapped and Bleached Bath A random review of patients from the above days had the following 33 patients that had been tested since the last acceptable QC. 1/6/2022: 7 Patients Ticket number: 404800 404819 404815 404839 404855 404867 404890 1/8/2022: 11 Patients Ticket number: 404981 404979 404982 404977 404975 404988 404987 404989 404992 404999 1/11/2022: 7 Patients Ticket number: 405124 405132 405137 405150 405171 405165 405177 1/16/2022: 8 Patients Ticket number: 405509 405508 405515 405511 405512 405523 405528 405529 2. Review of the laboratory policy titled "Quality Control Review" did not include steps for patient remedial action for QC events that could not be resolved with basic repeat testing. 3. In an interview on 12/16/2022 at 13:10 hours, in the conference room, the laboratory supervisor confirmed that patient remediation to the last acceptable QC had not been performed on the above QC events which could not be resolved with basic repeat testing.