Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0427512	03/31/2021
Name of Provider or Supplier	**Street Address, City, State**	
Evergreen Sheridan Lab	11737 S W Hwy - Ste B, Palos Heights, IL	

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
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 review the laboratory's procedures manual; patients test records; quality control records; and interview with the laboratory director, the laboratory failed to retain all analytic systems activities and quality control records for at least 2 years as specified for its Prothrombin Time and International Normalized Ratio (PT INR) testing. Findings: 1. The laboratory did not have a comprehensive procedures manual that included all required information for its PT INR tests. 2. On March 31, 2021 at 3: 00 PM, the surveyor requested the following documents: a. Patients Test Reports results for 21 patients tested from January 7, 2019 through March 31, 2021. b. Corresponding Quality Control Records for the dates of patients' testing. c. Manufacturers' assay information sheets for Lots of thromboplastin used. d. Established normal patient Prothrombin time mean with for each new thromboplastin lot number. e. Documentation of each thromboplastin lot number along with the International Sensitivity Index (ISI). f. Verification of Abnormal low or abnormal high prothrombin time testing INR calculation using ISI value. 3. There was no documentation presented to the surveyor for the following requested documents: a. Manufacturers' assay information sheets for Lots of thromboplastin used from January 7, 2019 through March 31, 2021. d. Established normal patient Prothrombin time mean for each new thromboplastin lot number used from January 7, 2019 through March 31, 2021. e. Documentation of each thromboplastin lot number along with the International Sensitivity Index (ISI) from January 2019 through March 31, 2021. f. Verification of Abnormal low or abnormal high prothrombin time testing PT INR calculation using ISI value from each lot used from January 2019 through March 31,

	2021. 4. On March 31, 2021 at 3:30 PM, the surveyor asked the laboratory director where is the documentation? The laboratory director, in turn, asked the testing person. Testing personnel told both the laboratory director that she had discarded all records from 2018. The surveyor noted that one of the lots of thromboplastin was still being used in 2019. 5. Review of QC records for the labs current lot of thromboplastin reagent revealed that there was no documentation to show that the laboratory tracked the lot number and expiration date and established normal patient Prothrombin time mean for each new thromboplastin lot testing from January 7, 2019 through March 31, 2021 for 20 of 20 patients test reports reviewed for the following dates: a. 01/07/2019 b. 02/12/2019 c. 03/26/2019 d. 04/05/2019 e. 05/21/2019 f. 06/18/2019 g. 07/05/2019 h. 08/21/2019 i. 10/29/2019 j. 01/28/2020 k. 02/26/2020 l. 03/10/2020 m. 04/06/2020 n. 05/05/2020 o. 06/25/2020 p. 08/20/2020 q. 11/17/2020 r. 12/22/2020 s. 01/15/2021 t. 03/22/2021 6. On March 31, 2021 at 4:00 PM, the laboratory director confirmed the surveyor's findings.
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 laboratory's procedures manuals; Laboratory Personnel Report - CLIA (Form 209); personnel records; and interview with the laboratory director, the laboratory failed to establish and follow written policies and procedures to assess consultant competency. Findings: 1. Review of the laboratory's procedures manual revealed that there were no procedures that describes the laboratory's process for performing competency assessments on the Clinical Consultant of the laboratory. 2. Review of form 209 revealed that the laboratory listed the name of its Clinical Consultant. 3. Review of personnel records revealed that there was no competency assessment performed on the Clinical Consultant. 4. On March 31, 2021 at 10:30 AM, the laboratory director confirmed the surveyor's findings.
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 the laboratory's procedures manual; quality control (QC) records; and interview with the laboratory director, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct problems as specified for it Hematology procedures that include Complete Blood Counts (CBCs) and Coagulation (PT INR) tests. Findings include: 1. The laboratory lacked a complete comprehensive procedure manual that includes instruction for the test order, specimen

	receipt, specimen processing, specimen testing, and result reporting. See tag D5400 2. Review of quality conrod records revealed the following: a. The laboratory used expired QC reagents when it tested and reported CBC results for patients' tested specimens. See tag D5417. b. The laboratory did not show all required steps in the performance of QC for PT INR testing. And the lab did not retain all QC documentation when it performed and report patient's PT INR test results. See tag D5545. 3. On March 31, 2021 at 4:00 PM, the laboratory director confirmed the surveyor's findings.
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 observation; review of the laboratory's procedures manuals; review of patients testing; and interview with the laboratory director, the laboratory failed to have a comprehensive procedure manual that includes all required information applicable to the procedures. Findings: 1. On March 31, 2021 at 9:30 during the walk-through of the laboratory, the surveyor observed that the laboratory performs the following tests: a. Routine Chemistry b. Microscopic Urine Analysis c. Complete Blood Counts (CBC) d. Prothrombin Time and International Normalized Ration (PT /INR) 2. Review of the laboratory's procedures manual revealed that the procedures lacked the following information: a. 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. b. Step-by-step performance of the procedure, including test calculations and interpretation of results. c. Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. d. Calibration and calibration verification procedures. e. The reportable range for test results for the test system as established or verified in 493.1253. On 11/26/2019 during patients' test reviews, 1 of 30 patients CBC results was repeated. When the surveyor asked the laboratory director to show her the procedure for what criteria was established for repeat testing, none was made availble to the surveyor. 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. Pertinent literature references. k. 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. l. Description of the course of action to take if a test system becomes inoperable. 3. On March 31, 2021 at 4:00 PM, the laboratory director confirmed the surveyor's findings.
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 review of patients test records; quality control records; and interview with the laboratory director, control materials were used after they had exceeded their expiration date during testing of patients' specimens for Complete Blood Count (CBC) tests. Findings: 1. On Mach 31, 2021 at 2:00 PM, the surveyor requested a total of 8 patients' test results along with corresponding Quality Control (QC) records for the following dates: a. 04/10/2019 b. 06/28/2019 c. 10/15/2019 d. 11/21/2019 e. 02/04 /2020 f. 05/29/2020 g. 09/09/2020 h. 01/20/2020 2. Review of QC records revealed that lot numbers of QC analyzed on 04/10/2019 expired on 04/08/2019 affecting 11 of 11 patients' test results reviewed tested on 04/10/2019 for the following lot #s of QC reagents used: a. Abnormal Low; Lot 068900 b. Normal; Lot 078900 c. Abnormal High; Lot 088900 3. The surveyor expanded her review to include the following dates: a. 04/09/2019 b. 04/11/2019 4. The expanded review revealed 24 of 24 patients' test results reviewed were also reported on 04/09/2019 when expired QC materials were used. 5. On March 31, 2021 at 3:30 PM, the laboratory director confirmed the surveyor's findings.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review the laboratory's procedures manual; patients test records; quality control records; and interview with the laboratory director, the laboratory failed to document all control procedures performed for its PT INR testing. Findings: 1. The laboratory did not have a comprehensive procedures manual that included all required information for its PT INR tests. 2. On March 31, 2021 at 3:00 PM, the surveyor requested the following documents: a. Patients Test Reports results for 21 patients tested from January 7, 2019 through March 31, 2021. b. Corresponding Quality Control Records for the dates of patients' testing. c. Manufacturers' assay information sheets for Lots of thromboplastin used. d. Established normal patient Prothrombin time mean with for each new thromboplastin lot number. e. Documentation of each thromboplastin lot number along with the International Sensitivity Index (ISI). f. Verification of Abnormal low or abnormal high prothrombin time testing INR

	calculation using ISI value. 3. There was no documentation presented to the surveyor for the following requested documents: a. Manufacturers' assay information sheets for Lots of thromboplastin used from January 7, 2019 through March 31, 2021. d. Established normal patient Prothrombin time mean for each new thromboplastin lot number used from January 7, 2019 through March 31, 2021. e. Documentation of each thromboplastin lot number along with the International Sensitivity Index (ISI) from January 2019 through March 31, 2021. f. Verification of Abnormal low or abnormal high prothrombin time testing PT INR calculation using ISI value from each lot used from January 2019 through March 31, 2021. 4. Review of quality control records revealed that the laboratory did not retaing all quality control records. Records for the labs current lot of thromboplastin reagent revealed that there was no documentation to show that the laboratory tracked the lot number and expiration date and established normal patient Prothrombin time mean for each new thromboplastin lot testing from January 7, 2019 through March 31, 2021 for 20 of 20 patients test reports reviewed for the following dates: a. 01/07/2019 b. 02/12/2019 c. 03/26/2019 d. 04/05/2019 e. 05/21/2019 f. 06/18/2019 g. 07/05/2019 h. 08/21/2019 i. 10/29/2019 j. 01/28/2020 k. 02/26/2020 l. 03/10/2020 m. 04/06/2020 n. 05/05/2020 o. 06/25/2020 p. 08/20/2020 q. 11/17/2020 r. 12/22/2020 s. 01/15/2021 t. 03/22/2021 6. On March 31, 2021 at 4:00 PM, the laboratory director confirmed the surveyor's findings.
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 the laboratory's procedures manual; quality control (QC) records; and interview with the laboratory director, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings: 1. The laboratory director did not provide laboratory personnel with a complete comprehensive procedure's manual. 2. Review of QC records revealed that testing personnel did not keep documentation of all quality control procedures required for the performance of QC of PT INR tests. See tag D6020 3. There was no documentation to show that quality assessments were performed in 2019, 2020 and 2021. When the testing personnel threw out PT INR records in 2018, the laboratory director had no idea they were thrown out. However, the laboratory director still has not reviewed any QC documentation pertaining to calculated PT INR results since 2018. 4. On March 31. 2021 at 4:00 PM, the laboratory director confirmed the surveyor's findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual; Quality Control (QC) records; and interview with the laboratory director, the laboratory director failed to ensure that quality control programs are established and maintained to assure the quality of laboratory services provided. Findings: 1. Review of the laboratory procedures manual revealed that there is a page that instructs laboratory personnel on how to calculate the mean normal prothrombin time and use it the calculation of the PT INR using the ISI value. 2. Review of QC records show that there is no documentation to show that the laboratory performed the above procedures for its current lot of thromboplastin reagent . See tag D5545 3. On March 31, 2021 at 4:00 PM, the laboratory director confirmed the surveyor's findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual; patients test records; quality control (QC) records; and interview with the laboratory director, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. Findings: 1. There were no procedures that described how the laboratory assesses the quality of the laboratory's services. 2. Review of patients test records and corresponding QC records for CBC testing show that QC materials used were expired and patients test results were still reported. There was no documentation to show QC was rerun or troubleshooted after the QC failure. See tag D5417 3. Review of QC records for PT INR shows that there was no documentation to show when new lots of thromboplastin were used, and the mean normal PT recalculated using the new lot of thromboplastin. Also, all PTINR records were discarded, without the laboratory director's knowledge in December 2018. No other PTINR records, including 2019, 2020 through March 31. 2021 were made available to the surveyor. The laboratory had not kept track reagent lot numbers. see tag D5545. 4. On March 31, 2021 at 4:00 PM, the laboratory director confirmed the surveyor's findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and interview with the laboratory director, the laboratory director failed to provide an approved comprehensive procedure manual. Findings: 1. Review of the laboratory's procedures manual revealed that the procedures manual did not include preanalytical, analytic, and post analytic procedures that described the laboratory's process for requesting tests, including standing orders; specimen receipt; logging specimens; accessioning specimens; testing specimens; repeat testing; documenting QC activities; and reporting patients' test results. 2. On March 31, 2021 at 11:30 AM, an interview, the laboratory director told the surveyor that she rewrote a procedure manual based on deficiencies cited in October 2018. However, she was unable to find the procedures manual.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manuals; Laboratory Personnel Report - CLIA (FORM 209); personnel records; and interview with the laboratory director, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant. Findings: 1. Review of the laboratory's procedures manuals revealed that there was a policy that descriibed the responsibilities and duties of the following positions: a. Laboratory Director b. Clinical Consultant c. Technical Consultant d. Testing Person 2. The following personnel were listed on Form 209 as follows: a. Person #1 is listed as Laboratory Director; Technical Consultant, and Testing Person. b. Person #2 is listed as Clinical Consultant c. Person #3 is listed as Testing Person. 3. Review of personnel records revealed that the laboratory director did not assign the position of Clinical Consultant to a specified person. 4. On March 31, 2021 at 10:30 AM, the laboratory director confirmed the surveyor's findings.