Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	14D0427512	10/02/2018
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
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 review of laboratory records, direct observations, and interview with testing personnel (TP) #2; the laboratory failed to enroll in proficiency testing challenges gram stain testing in the sub-specialty of bacteriology. Findings Include: 1. Direct observation of testing supplies during a tour of the laboratory on 10-2-2018, at 12:00pm, identified gram stain reagents. 2. Interview with TP#2, at 1:10 pm, confirmed that gram stain testing is performed by the laboratory. 3. Review of American Association of Bioanalysts (AAB) proficiency testing (PT) documentation found no record of PT for gram stain testing. 4. Test volume data provided by TP#2 at 1:45 pm, on 10-2-2018 documented in 2017 through 10-2-2018 that 161 gram stain test had been performed by the laboratory. 5. Interview with TP#2 confirmed on 10-2-2018, at 6:00 pm, the laboratory had not performed PT for gram stain testing.
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 records, direct observations, and interview with laboratory testing personnel (TP) #2; the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 in Appendix C of the State Operations Manual. Findings Include: 1. The laboratory failed to have procedures in place for microbiology testing. See D5401. 2. The laboratory procedure for prothrombin time testing failed to include all the required components of a test procedure. See D5403. 3. The laboratory failed to accurately monitor room temperature and incubator temperatures in 2018 and failed to have preventative maintenance records for temperature monitoring in 2017. See D5413. 4. The laboratory failed to verify the performance of the Siemens Microscan 4 after the laboratory moved to the new location into a new location in May of 2018. See D5421. 5. The laboratory failed to conduct calibration verifications for electrolytes (Sodium, Potassium, and Chloride) on the Dimension EXL 200. See D5439. 6. The laboratory failed to perform quality control testing on each lot and shipment of Tryptic Soy Agar 5% / EMB Bi-plates used for urine culture testing. See D5477. 7. The laboratory failed to perform quality controls each day tests are performed for antimicrobial susceptibility. See D5507.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to have a procedure manual for all tests performed in the specialty of microbiology. Findings Include: 1. Review of laboratory's policy and procedure manual found the laboratory failed to have procedures in place for urine culture identification, susceptibility, and gram stain testing. 2. On survey date 10-2-2018, at 2:20 pm, TP#2 confirmed no microbiology procedures were available for review.
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 review of laboratory records and interview with TP#2; the laboratory failed to outline all required components of a test procedure for prothrombin time (PT) testing. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "Hemosil Routine Control 1, Routine Control 2" for PT testing. 2. Review of the procedure, "Hemosil Routine Control 1, Routine Control 2", found the procedure failed to outline the following required components of a test procedure for PT testing: 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. Control procedures. d. Limitations in the test methodology, including interfering substances. e. Reference intervals (normal values). f. Imminently life-threatening test results, or panic or alert values. g. 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. h. Description of the course of action to take if a test system becomes inoperable. 3. Interview with TP#2 on 10-2-2018, at 6:00 pm, 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 review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to monitor refrigerator/freezer, incubator and room temperatures to ensure accurate and reliable storage of bacteriology, hematology and chemistry reagents in 2017 through the date of survey (10-02-2018). Findings Include: 1. Review of the laboratory records identified temperature record logs for 2018. 2. Review of the 2018 temperature log, "Precision Scientific Incubation", indicated that the incubator temperature was between 2-5 degrees Celsius in 2018. 3. Interview with TP#2, on 10-2-2018, at 5:38 pm, confirmed that the incubator temperatures should not be 2-5 degrees Celsius and the records were inaccurate. 4. Review of 2018

	temperature log, "Room Temperature", indicated that the room temperature of the laboratory was between 2-5 degrees Celsius in May, June, July, August, September and October in 2018. Room temperature was not documented in January through April of 2018. 5. Interview with TP#2, on 10-2-2018, at 5:38 pm, confirmed that the laboratory room temperature should not be 2-5 degrees Celsius and that the records were inaccurate. 6. No temperature records were available for review for all of 2017, which includes the laboratory's refrigerators, freezers, incubator, and room temperature of the laboratory. 7. On survey date 10-02-2018, at 6:00 pm, TP#2 confirmed the laboratory failed to document accurate temperatures for the incubator and laboratory room temperature in 2018 and no preventative maintenance temperatures were retained for 2017.
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 review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to demonstrate they can obtain performance specification comparable to those established by the manufacturer for bacteria identification and sensitivity using the Siemens Microscan 4. Findings Include: 1. Interview with TP#2, at 12:00 pm, on 10-2-2018 confirmed the laboratory moved to a new location in May of 2018. 2. Review of laboratory correlation records found no documented study performed by the laboratory to demonstrate accuracy, precision, and reportable range verification on the Siemens Microscan analyzer after the instrument was moved to the new laboratory location in May of 2018. 3. On survey date 10-02-18, at 1:55 pm, TP#2 confirmed no verification of performance study was performed for urine culture identification and susceptibilities done using the Siemens Microscan 4.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or

	replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with laboratory testing personnel (TP) #2; the laboratory failed to conduct calibration verifications as required for testing on the Dimension EXL 200 chemistry analyzer. Findings include: 1. Review of the laboratory's policy and procedure manual found no calibration verification procedure for electrolyte (Sodium, Potassium, and Chloride) testing on the Dimension EXL 200 chemistry. 2. Review of electrolyte calibration records found the instrument only performs a 2 point calibration for sodium, potassium, and chloride. 3. Interview on 10-02-2018, at 6:00 pm, with laboratory TP#2 confirmed no calibration verification procedures had been completed for Sodium, Potassium, and Chloride testing on the Dimension EXL 200. 4. Review of test volume worksheet information found 1,185 tests had been performed in 2017 each analyte (Sodium, Potassium, and Chloride) on the Dimension EXL 200 analyzer.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observations, and interview with testing personnel (TP) #2; the laboratory failed to check each batch of Tryptic Soy Agar (TSA) 5% / EMB Bi-plates for sterility, growth, inhibition, and biochemical response with initial use. Findings include: 1. Direct observation of laboratory testing supplies on 10-2-2018, at 5:25 pm, identified TSA 5% / EMB Bi-plates (Lot # 1817700) used for urine culture testing. 2. Review of urine culture testing found for 4 of 4 patient test records reviewed the laboratory failed to perform quality control testing on the TSA 5% / EMB Bi-plates. Patient Identification Culture Obtained P10 04-04-2017 P11 07-29-2017 P9 08-31-2018 P8 04-02-2018 3. On survey date 10-02-2018, at 6:00 pm, TP#2 confirmed the laboratory failed to perform and document quality control testing for TSA 5% / EMB Bi-plates. 4. Review of the test volume worksheet found the laboratory performed 399 urine cultures in 2017 and no quality control testing for the TSA 5% / EMB Bi-plates was performed and documented.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of

	media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to perform quality controls each day tests are performed for antimicrobial susceptibility testing. Findings include: 1. Review of the laboratory policy and procedure manual failed to have a procedure of susceptibility testing. See D5401. 2. Review of susceptibility testing records for 4 of 4 patient test records reviewed found the laboratory failed to perform quality control testing each day tests are performed. Patient Identification Quality Control Run Date Test Date P10 04-04-2017 04-06-2017 P11 07-25-2017 07-31-2017 P9 08-28-2018 09-02-2018 P8 04-03-2018 04-04-2018 3. Interview with TP#2 on survey date 10-02-2018, at 6:00pm, confirmed that susceptibility controls are performed weekly but no individual quality control plan (IQCP) was put in place for the reduced quality control frequency. 4. Review of test volumes records found 150 susceptibility tests were performed in 2017 when daily quality control testing was not performed and documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #2; the laboratory failed to include all the required information on patient test reports for hematology, chemistry, and microbiology. Findings Include: 1. Review of 5 of 5 patient test reports (Patient Identifier: P4, P5, P6, P7 and P10) for chemistry testing failed to indicate the address of the laboratory where the testing was performed. 2. Review of 1 of 1 patient test reports for urine culture susceptibility testing after the move to the new laboratory location (11737 S W Hwy - Ste B, Palos Heights, IL 60463) in May of 2018 found the laboratory was still using the old address, 9760 S. Kedzie Ave, Evergreen Park, IL 60805-3109 on patient test reports. 3. Review of 1 of 1 patient test reports for prothrombin time testing after the move to the new laboratory location (11737 S W Hwy - Ste B, Palos Heights, IL 60463) in May of 2018 found the laboratory was still using the old address, 9760 S. Kedzie Ave, Evergreen Park, IL 60805-3109 on patient test reports. 4. Interview with TP#2 on 10-02-2018, at 6:00

	pm, confirmed the laboratory the laboratory failed to indicate the facility address on chemistry test reports and update the address on patient test reports for prothrombin time testing and susceptibility testing.