Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0687923	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier Srhp -Edgefield Medical Center	**Street Address, City, State** 155 Ridge Medical Plaza, Edgefield, SC	

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 initiated on 09/07/2023 and concluded on 09/07/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on performance summary documents from the American Proficiency Institute and interview, the laboratory failed to review and evaluate the results obtained for proficiency testing for 5 (2021 Events 1 and 3; 2022 Events 1, 2, and 3) of 9 events reviewed. Findings included: A review of the "American Proficiency Institute Performance Summary" for the "2021 Hematology / Coagulation - 3rd Event" revealed the sedimentation rate was 0%. There was no documentation or corrective action available for review to indicate the failures were reviewed and evaluated by the laboratory. A review of the "American Proficiency Institute Performance Summary" for the "2021 Hematology / Coagulation - 1st Event" revealed the sedimentation rate was 50% and the erythrocyte count was 60%. There was no documentation or corrective action available for review to indicate the failures were reviewed and evaluated by the laboratory. A review of the "American Proficiency Institute Performance Summary" for the "2022 Hematology / Coagulation - 1st Event" revealed the vaginal wet preparation and vaginal wet preparation (potassium hydroxide) were 0%. There was no documentation or corrective action available for review to indicate the failures were reviewed and evaluated by the laboratory. A review of the "American Proficiency Institute Performance Summary" for the "2022 Hematology / Coagulation - 2nd Event" revealed the granulocytes was 60%. There was no documentation or corrective action available for review to indicate the failures

	were reviewed and evaluated by the laboratory. A review of the "American Proficiency Institute Performance Summary" for the "2022 Hematology / Coagulation - 3rd Event" revealed the monocytes was 60%. There was no documentation or corrective action available for review to indicate the failures were reviewed and evaluated by the laboratory. In an interview on 09/07/2023 at 12:28 PM, the Laboratory Manager confirmed the multiple proficiency testing failures and confirmed there was no corrective actions.
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 the laboratory procedure manual review and interview, the laboratory failed to ensure laboratory procedures for laboratory downtime, venipuncture, throat culture collection, urine collection, wet prep/potassium hydroxide (KOH), urine microscopic, and critical values were established, reviewed, approved, and signed by the Laboratory Director for 3 (2021, 2022, and 2023) of 3 years reviewed. Findings included: A review of a laboratory procedure manual revealed the following procedures were not established, reviewed, or approved by the Laboratory Director - downtime, venipuncture, throat culture collection, urine collection, wet preparation/KOH test procedure, urine microscopic procedure, and critical values. In an interview on 09/07/2023 at 11:00 AM, the Laboratory Manager confirmed the laboratory did not have established or approved procedures for laboratory downtime, venipuncture, throat culture collection, urine collection, wet preparation/KOH, urine microscopic, and critical values and the laboratory currently utilized the test methodologies.
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 document review and interview, the laboratory failed to ensure laboratory humidity values were monitored and recorded for 3 (2021, 2022, 2023) of 3 years reviewed. Findings included: A review of the "CELL-DYN Emerald Operator's Manual," dated June 2010, indicated "Installation Environment The following are environmental requirements: * Indoor use only * Altitude up to 6562 feet * Temperature range: 64 [degrees] - 90 [degrees F [Fahrenheit] * Maximum relative humidity 80% for temperatures up to 90 [degrees] F." There was no documentation available for review to indicate the laboratory monitored and documented humidity values for 2021, 2022, and 2023. In an interview on 09/07/2023 at 11:53 AM, the Laboratory Manager stated the humidity values were not being monitored in the laboratory where the Cell-Dyn instrument was located and operated.