Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2329115	06/17/2026
Name of Provider or Supplier	**Street Address, City, State**	
Southpark Heart And Rhythm Center	445 Charles H Dimmock Pkwy, Suite 102, Colonial Heights, VA	

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 announced initial CLIA survey was conducted at Southpark Heart and Rhythm Center on June 16, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The survey concluded with an offsite interview with the Laboratory Director on 6/17/26. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Southpark Heart and Rhythm Center was not in compliance with applicable Standards and Conditions under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Conditions: D2000 - 42 CFR. 493.801 Enrollment Proficiency Testing Samples D6000 - 42 CFR 493.1403 Laboratory Director D6063 - 42 CFR 493.1421 Laboratory Testing Personnel
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 a review of the Centers for Medicare and Medicaid Services Application for Certification form (CMS 116), a tour, review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to enroll in a PT program for ten of ten Chem8+, six of six blood gas EG6+, and two of two iSTAT PT Plus regulated analytes while reporting 96 patient results during the initial survey timeframe of January 2026 to June 16, 2026. Findings include: 1. Review of the

	laboratory's CMS 116 form revealed that the laboratory director (LD) identified non waived chemistry, hematology, and blood gas patient testing by Abbott iSTAT analyzer. 2. A tour of the surgery center facility's laboratory testing areas on 6/16/26 at 1:00 PM revealed one Abbott iSTAT analyzer (serial number 448552) in use for patient point of care testing. The inspector noted the following test cartridges in use for iSTAT analysis of regulated analytes: Chem8+ - Carbon Dioxide (CO2), Chloride (Cl), Creatinine (Creat), Calcium (Ca), Glucose (Glu), Potassium (K), Sodium (Na), Urea Nitrogen (BUN), and Hematocrit (Hct); ECG+ - pH, Partial Pressure Carbon Dioxide (pCO2), Partial Pressure Oxygen (pO2), Na, K, Hct; PT Plus - Prothrombin Time (PT), International Normalized Ratio (INR). 3. Review of the laboratory's PT records revealed no documentation for calendar year 2026 year to date. The inspector requested to review 2026 hematology PT Event 1 records for the regulated analytes outlined above. The records were not available for review. The laboratory director (LD) stated on 6/16/26 at 2:30 PM, "We have not enrolled for proficiency testing yet." 4. Review of patient iSTAT test logs for timeframe of January 2026 to the date of the initial survey revealed 95 regulated analyte patient test results had been reported by the surgery center while failing to enroll in PT up to 6/16/26. 5. Interviews with the LD and facility's office manager on 6/17/26 at 4:30 PM confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: A. Based on a tour, review of manufacturer instructions, temperature and patient test logs, procedures, lack of documentation, and interviews, the laboratory failed to establish protocols and to monitor refrigerator temperatures to ensure proper storage for their iSTAT test reagents and quality control materials 67 of 112 days reviewed (timeframe: 1/12/26 to 6/16/26). Findings include: 1. A tour of the surgery center facility's laboratory testing area on 6/16/26 at 1:00 PM revealed one Abbott iSTAT analyzer, serial number (SN) 448552, in use for patient point of care testing The inspector noted the following test iSTAT test reagent cartridges stored in the "med room" Accucold reagent refrigerator: Chem8+ - 2 boxes of 25 cartridges, lot number # H26066, expiration date (exp) 9/3/26; TriControls Calibration Verification Levels 1-5 2 boxes lot # 25274, exp 1/31/27; ECG+ - 3 boxes of 25 cartridges, l box lot # N26036, exp 10/05/26, 2 boxes lot # N26061, exp 10/30/26; ACT Cartridges - 3 boxes of 25 cartridges, 1 box lot # R26072 exp 9/9/26, 1 box lot # R26107A exp 10/14 /26, 1 box lot # R26120 exp 10/27/26; ACT Controls - 3 boxes Level 1 lot # 261186 exp 6/30/26, 2 boxes Level 2 lot # 271194 exp 02/2/8/27; PT Plus - 2 boxes of 25 cartridges, 1 box lot # c25355a exp 06/19/26, 1 box lot # C26044 exp 8/12/26; PT Plus Controls - 6 boxes Level 1 lot # 501995 exp 3/31/27, 6 boxes Level 2 lot # 511195 exp 3/31/2027; 2. Review of the Abbott manufacturer's package instructions for the reagent and control materials outlined above revealed temperature storage requirements to be 2-8 C (35-46 F). 3. Review of temperature logs for the timeframe

	of 1/12/26 to 6/17/26 revealed 67 days lacked Accucold refrigerator temperature readings. The inspector noted that the laboratory had recorded temperatures on two days a week (Tuesdays and Wednesdays). The inspector inquired regarding why temperatures were not recorded on all of facility's operating days (Monday-Friday). The office manager stated on 6/17/26 at 3 PM, "The staff monitors the refrigerator temperatures every day but only record it two days a week. I am not sure why temperatures are not recorded every day of monitoring." 4. Review of patient logs (1 /12/26 - 6/16/26) revealed that 14 patients' laboratory results were reported from the Abbott iSTAT on dates that reagent/QC storage temperatures were not monitored as outlined below: 4/17 - ID 165233 ACT (3 tests assayed); 5/08 - ID 163803 ACT, ID 302306 Chem 8 and ACT (3 tests assayed); 5/15 - ID 257654 ACT (3 tests assayed); 5 /22 - ID 344365 ACT (2 tests assayed), ID 152869 (2 tests assayed); 5/28 - ID 209129 ACT (2 tests assayed); 5/29 - ID 300992 ACT (2 tests assayed), ID 167260 (2 tests assayed); 6/01 - ID 183715 ACT (2 tests assayed); 6/08 - ID 201100 ACT (2 tests assayed); 6/11 - ID 276243 ACT (2 tests assayed); 6/12 - IDs 271509 and 343307 Chem 8, ID 271509 ACT (3 tests assayed), 343307 ACT (4 tests assayed), 272939 ACT (6 tests assayed); 42 iSTAT test cartridges were utilized for patient testing on 10 of the 67 days lacking reagent and QC storage temperature monitoring (review timeframe: 112 days of laboratory operation 1/12/26 to 6/16/26). 5. Review of the procedure manual revealed no criteria for environmental monitoring of laboratory temperatures. The inspector requested to review a procedure that outlined proper storage of reagents to ensure accurate and reliable iSTAT system operation, and patient test result reporting. A protocol was not available for review. 6. Interviews with the LD and facility's office manager on 6/17/26 at 4:30 PM and a follow up interview with the LD on 6/18/26 at 3 PM confirmed the above findings. B. Based on a tour, review of manufacturer's user guide, temperature logs, procedures, lack of documentation, and interviews, the laboratory failed to establish protocols and to monitor room temperature of two of two test stations to ensure proper iSTAT operation and patient testing for 112 of 112 days reviewed (timeframe: 1/12/26 to 6/16 /26). Findings include: 1. A tour of the facility's laboratory testing area on 6/16/26 at 1: 00 PM revealed one Abbott iSTAT analyzer (SN 448552) in use for patient testing in the nursing pre/post station. During the tour of the facility, the inspector also noted a box of ACT iStat test cartridges stored at room temperature in the surgery suite. The box had 4 of 25 cartridges (lot number R26072, expiration date 9/9/26, with open expiration date modified to 7/1/26). 2. Review of the iSTAT User Guide revealed in Section 6 "Procedure for Patient Testing" precaution instructions: "Ensure test cartridges and analyzer are at room temperature prior to patient testing". 3. Review of temperature logs for the timeframe of 1/12/26 to 6/17/26 revealed no monitoring of the room temperature for the nursing pre/post iSTAT station nor the surgery room. The inspector requested to review room temperature logs for both locations. The records were not available. 4. Review of procedures revealed no criteria for environmental monitoring of laboratory temperatures. The inspector requested to review a procedure to monitor room temperature of the analyzer and reagents to ensure accurate and reliable iSTAT system operation, and patient testing. A protocol was not available for review. 5. Interviews with the LD and facility's office manager on 6/17/26 at 4:30 PM and a follow up interview with the LD on 6/18/26 at 3 PM confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 a review of the Centers for Medicare and Medicaid Services Application for Certification form (CMS 116), iSTAT patient test logs, electronic medical record test results, lack of documentation, and interviews, the laboratory failed to ensure that their test reports accurately indicated the performing laboratory name and address for three of three random patient reports reviewed on the date of the initial survey, June 16, 2026. Findings include: 1. Review of the laboratory's CMS 116 form revealed that the laboratory director (LD) identified routine chemistry, blood gas, and hematology testing by Abbott iSTAT analyzer and the name and address of the laboratory as: Southpark Heart and Rhythm Center, 445 Charles H. Dimmock Parkway Suite 102, Colonial Heights, Virginia 23834. 2. During a review of the iSTAT onboard patient test records, the inspector selected and requested the following tests to review from the laboratory's electronic medical record (EMR) system: ID *****33 Activated Clotting Time dated 4/17/26; ID *****06 Chem 8 (Carbon Dioxide, Chloride, Creatinine, Calcium, Glucose, Potassium, Sodium, Urea Nitrogen, and Hematocrit), dated 5/8/26; ID *****89 EG6+ (pH, Partial Pressure Carbon Dioxide, Partial Pressure Oxygen, Sodium, Potassium, Hematocrit) dated 4/27/26; 3. A review of the patient EMR laboratory reports outlined above, revealed that three of the three selected patient reports identified the testing laboratory as Alligned Cardio (no address). The inspector inquired as to protocols for ensuring the laboratory test reports accurately identify the name and address of the physical location where testing is performed. The LD stated on 6/16/26 at 3 PM, "This is an oversight and I will update our test report format today." 4. Interviews with the LD and facility's office manager on 6/17/26 at 4:30 PM confirmed the above 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 a review of proficiency testing records, tour, review of manufacturer instructions and user guide, temperature and patient test logs, procedures, lack of documentation, and interviews, the laboratory director failed to ensure that the: 1. proficiency testing enrollment was verified for Chemistry and Hematology regulated analytes on the Chem8+, blood gas EG6+, PT Plus by Abbott iSTAT instrument from January 2026 to June 16, 2026 - Cross Reference D6015; 2. procedure manual included protocols to monitor laboratory temperatures to ensure proper storage of reagents/quality control materials and proper iSTAT operation and patient testing for 112 of 112 days reviewed (timeframe: 1/12/26 to 6/16/26) - Cross Reference D6031
D6015	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on a review of laboratory records, lack of documentation, and interviews, the laboratory director failed to ensure proficiency testing enrollment for Chemistry and Hematology regulated analytes on the Chem8+, blood gas EG6+, PT Plus by Abbott iSTAT instrument from January 2026 to June 16, 2026. Cross Reference D2000
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer instructions and user guide, temperature and patient test logs, procedures, lack of documentation, and interviews, the laboratory director failed to ensure that the procedure manual utilized by the testing personnel included protocols to monitor laboratory temperatures to ensure proper storage of reagents/quality control materials and proper iSTAT operation and patient testing for 112 of 112 days reviewed (timeframe: 1/12/26 to 6/16/26). Cross Reference D5413
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the laboratory director failed to retain documentation of personnel qualifications for eight of eleven testing personnel performing nonwaived patient testing in the specialities of Chemistry and Hematology during the initial survey timeframe of January 2026 to June 16, 2026. Cross Reference D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory

	science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the laboratory failed to retain documentation of personnel qualifications for eight of eleven testing personnel performing nonwaived patient testing in the specialities of Chemistry and Hematology during the initial survey timeframe of January 2026 to June 16, 2026. Findings include: 1. Review of the CMS 209 form revealed that the laboratory (LD) identified eleven testing personnel (TP) qualified as performing patient Activated Clotting Time, Chem8 Panel, Prothrombin Time/International Normalized Ratio and Blood Gas patient testing on an Abbott iSTAT analyzer during the initial CLIA review timeframe. 2. Review of the laboratory's personnel records revealed no documentation of education for TP #1 - #8. The inspector requested to review the education documentation for TP #1 - #8. The records were not available for review. (See Personnel Code Sheet) 3. Interviews with the LD and facility's office manager on 6/17/26 at 4:30 PM confirmed the above findings.