| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br>34D2070977 | **(X3) Date Survey Completed**<br>04/16/2024 |
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| **Name of Provider or Supplier**<br>Surf Pediatrics And Medicine Pc | **Street Address, City, State**<br>400 S Croatan Hwy, Kill Devil Hills, NC | |
| 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** |
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| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of i-STAT validation records, the absence of proficiency testing records, and interview with the practice manager 4/16/24, the laboratory failed to enroll in proficiency testing for the i-STAT testing performed. Review of i-STAT validation records revealed the laboratory performed patient testing on the i-STAT for the following analytes: sodium, potassium, chloride, ionized calcium, carbon dioxide, glucose, blood urea nitrogen, creatinine, hemoglobin, hematocrit, and anion gap. Review of i-STAT validation records revealed the laboratory validated the instrument for patient testing in April 2022. There were no records available to document that the laboratory was enrolled in proficiency testing, and there were no proficiency testing records available for review during the survey. During interview at approximately 8: 15 a.m., the practice manager confirmed the laboratory had not enrolled in proficiency testing for the i-STAT testing performed. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including |

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| | instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of 2022, 2023, and 2024 i-STAT quality control records and interview with TP (testing personnel) #1 on 4/16/24, the laboratory failed to retain the Value Assignment Sheets (VAS) for at least two years for 6/6 lot numbers of quality control material. Findings: Review of 2022, 2023, and 2024 i-STAT quality control records revealed the laboratory had not retained the VAS for the following lot numbers of quality control material: 1. lot #229H220800181 and lot #229H222640181 for CLEW A43 and CLEW A44; 2. lot #229H222640181 for CLEW A45; 3. lot #229H223492181 and lot #229H230580181 for CLEW A45 and CLEW A46; 4. lot #229H231880181 and lot #229H232760181 for CLEW A47. During interview at approximately 9:55 a.m., TP #1 confirmed that the laboratory had not saved the VAS for each lot number of control material. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's procedure manual and interview with the practice manager 4/16/24, the laboratory did not have laboratory-specific policies and procedures available for use by personnel. Findings: Review of the laboratory's procedure manual revealed it was the i-STAT Procedure Manual provided by the manufacaturer. The manual did not include: 1. instructions for specimen collection and labeling 2. quality control procedures including the control material used and the frequency 3. the system for reporting patient test results, including alert/panic values 4. instructions for specimen referral for testing not performed on-site During interview at approximately 8:55 a.m., the practice manager confirmed they did not have laboratory-specific policies and procedures. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d) |

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| | Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's procedure manual and interview with the practice manager 4/16/24, the laboratory's policies and procedures had not been approved by the laboratory director. Review of the laboratory's procedure manual revealed the laboratory director had not signed and dated to indicate review and approval of procedures. During interview at approximately 8:30 a.m., the practice manager confirmed the laboratory's procedure manual had not been approved by the laboratory director. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions, the absence of records, and interview with TP #1 on 4/16/24, the laboratory failed to monitor and document the room temperature of the laboratory as specified by the manufacturer. Findings: Review of the i-STAT Procedure Manual revealed "... SUPPLIES and STORAGE REQUIREMENTS Cartridges ... Cartridges should not be exposed to temperatures above 30 degrees C (86 degrees F). ... Cartridges must be at room temperature (18-30 degrees C or 64-86 degrees F) prior to use. ... Room Temperature Cartridges ... Remedial Action: If the measured room temperature has exceeded 30 degrees C (86 degrees F) for any period of time: ... DO NOT USE the cartridges. ..." There were no records of room temperature monitoring for 2022, 2023, or 2024 available for review during the survey. During interview at approximately 10:05 a.m., TP #1 confirmed they had not monitored room temperature. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions, review of 2022, 2023, and 2024 i-STAT records, and interview with TP #1 on 4/16/24, the laboratory failed to perform and document thermal probe checks at least every six months as required by the |

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| | manufacturer. Findings: Review of "Procedure Manual for the i-STAT 1 System" revealed "... Every 6 Months Procedures ... Update i-STAT 1 Analyzer Software Update the software as provided by Abbott Point of Care. Perform an external Electronic Simulator test after software update. Verify thermal probe reading as described below. Thermal Probe Check Procedure ... Acceptable: a value from -0.1 to +0.1, inclusive ..." Review of the laboratory's 2022, 2023, and 2024 i-STAT records revealed no documentation of thermal probe checks. During interview at approximately 9:45 a.m., TP #1 stated they did not realize they needed to document thermal probe checks. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel records, the absence of records, and interview with the laboratory director 4/16/24, the the laboratory director failed to perform and document semiannual competency evaluations for 3 of 3 testing personnel during their first year of testing patient specimens. Review of personnel records revealed there was no documentation of semiannual competency evaluations for TP #1, TP #2, and TP #3 during the first year of testing. During interview at approximately 8:40 a.m., the laboratory director confirmed he had not documented competency evaluations for the testing personnel. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel records, the absence of records, and interview with the laboratory director 4/16/24, the laboratory director failed to perform and document annual competency evaluations for 3 of 3 testing personnel in 2023. Review of personnel records revealed there was no documentation of annual competency evaluations for TP #1, TP #2, and TP #3 in 2023. During interview at approximately 8: 40 a.m., the laboratory director confirmed he had not documented competency evaluations for the testing personnel. |