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

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	42D2034788	06/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Southernmed Pediatrics (Hillcrest)	1995 St Matthews Road, Orangeburg, 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	An announced CLIA recertification survey was conducted at Southern Med Pediatrics on 06/13/2024 by the South Carolina Department of Environmental Control (SCDHEC). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the standards of the CLIA program. The following STANDARD LEVEL DEFICIENCES were found to be out of compliance:
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: During an onsite recertification survey on 06/13/2024, based on procedure manual review, proficiency testing Wisconsin State Laboratory of Hygiene (WSLH) PT 2023-HemeReg 1 record review, and testing personnel interview the laboratory failed to test proficiency testing samples in the same manner as patient samples for 5 of 5 samples in 2023. Findings included: 1. Review procedure titled "Proficiency Testing (PT)" reveal "step # 3 samples are tested in the identical manner, as patient samples would be." 2. Review of Heme Reg 1 proficiency testing records from WSLH revealed raw data for sample: a. PT23, one, sample ID AT 12023 ran at 8:31 am, 11:02 am; no panic value noted b. PT23, two, sample ID AT 22024 ran at 8:33 am, 8:36 am, 11:06 am, 11:09 am c. PT23, three, sample ID AT3205 ran at 8:38 am and 11:13 am d. PT23, four, sample ID AT 22026 ran 8:40 am and 8:43 am, 11:21 am, 11:23 am e. PT23, five, sample ID AT 22027 ran 8:45 am, 8:47am, 11:26 am, 11:28 am Samples 1 through 5 were ran multiple times and not handled like patient samples. 3. In an interview with testing personnel on 06/13/2024 at 2:00 pm the above findings were confirmed.

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 direct observation, review of manufacturer's instructions, laboratory procedures, random laboratory environmental logs (January, February, March, April, November, December) 2022, and confirmed in staff interview, the laboratory failed to establish an acceptable room temperature range for 6 out of 6 months reviewed. Findings included: 1. During a tour of the laboratory on 06/13/2024 at 1:50 pm, the surveyor observed the following in the laboratory area: a. Non calibrated thermometer b. 1 pack, Tiger, BD Vacutainer tubes, Lot #4046196, exp. 1/31/2025 c. 1 pack, Purple, BD Vacutainer tubes, Lot#3318809 d. 10 tubes, 3.5 ml, Gold, BD Vacutainer tubes, Lot#3283885, exp. 10/31/2024 e. 14 tubes, 5.0 ml, Gold, BD Vacutainer tubes, Reference# 367986, exp. 02/28/2025 2. A review of the manufacturer's instruction label revealed room temperature requirement of 4-25C(39.2-77F). 3. Review of environmental records titled "temperature log" the room temperature (temp) range exceeded the upper limit of 25C for blood collection tubes. a. January 2022, room temp range (59-86F)/15-30C b. February 2022, room temp range (59-86F)/15-30C c. March 2022, room temp range (59-86F)/15-30C d. April 2022, room temp range (59-86F)/15-30C e. November 2022, room temp range (59-86F)/15-30C f. December 2022, room temp range (59-86F)/15-30C 4. In an interview on 06/13/2024 at 1:55 pm in the laboratory with testing personnel, the above findings were confirmed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, and staff interview for an onsite initial survey at SouthernMed Pediatrics-Orangeburg, revealed laboratory failed to label urine controls with open and expiration dates. Findings included: 1. During a tour of the laboratory on 06/13/2024 at 1:50 pm with testing personnel, the surveyor directly observed the following quality controls: a. Bio-Rad Liquichek Urine Level 1, Chemistry Control, Lot#98011, exp 11/30/2025 b. Bio-Rad Liquichek Urine Level 2, Chemistry Control, Lot#98012, exp. 11/30/2025 No documentation of open and or expiration dates written on bottle. 2. In an interview on 06/13/2024 at 1:55 pm in the laboratory with testing personnel, the above findings were confirmed.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, records review and interview it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, asses correct problems identified in postanalytical systems. Findings included: 1. Review of laboratory policies and procedures titled "Proficiency Testing (PT)" under section "C. Proficiency Testing Assessment: Reference 493.1707 Proficiency testing results will be reviewed to determine the accuracy, compliance with regulations, completeness and remedial actions instituted in the event of a proficiency test failure." 2. Review of WSLH proficiency testing records for PT HemeReg, Event 2 revealed the following: a. Erythrocytes, score 40% b. Hematocrit, score 60% c. Hemoglobin, score 60% No corrective action logs were available on the day of survey 06/13/2024. 3. Review of procedure titled "Remedial Actions" revealed remedial actions will be taken and documented when: 1. Quality Control results are outside of acceptable limits. 6. Proficiency tests are unsatisfactory. "All remedial action notes will be documented either on the quality control logs, proficiency test logs, patient's chart, or on the quality assurance log. The problem and its corrective action will be noted and initialed on the appropriate log. All quality assurance logs will be reviewed annually and sooner as it is deemed necessary." 4. Review of quality control records dated from 05 /01/2023 to 05/31/2023, the Leavy Jennings (L.J.) MX441 normal control graph for erythrocytes revealed control results for 2 points were 2 standard deviations (SD). 5. Review of quality control records dated from 05/01/2023 to 05/31/2023, the Leavy Jennings (L.J.) MX441 normal control graph for hemoglobin revealed control results for 3 points were 2 SD. 6. Review of MICROS60 Startup log records reveal equipment failed during afternoon startup on 06/27/2023 at 1:04pm. 7. In an interview with testing personnel on 06/13/2023 at 2:00 pm revealed the Horiba ABX Micro 60 was taken out of use on 02/2024. No corrective action logs documenting the above findings, investigations, or corrective actions confirmed by testing personnel.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, procedure review, and staff interview, the laboratory director failed to investigate and document corrective actions for Hematology, erythrocytes (RBC), hematocrit (HCT), and hemoglobin (Hgb) that was assigned an unsatisfactory score for 1 of 3 proficiency

	testing events reviewed for 2023. Findings included: 1. Review of graded Hematology proficiency reports from WSLH at 11:00 am revealed the following scores: a. Erythrocytes, score 40% b. Hematocrit, score 60% c. Hemoglobin, score 60% 2. There was no corrective action documentation addressing these failures available for review on the day of the survey. 3. Review of procedures titled "Remedial Actions" reveal remedial actions will be taken and documented when, "6. Proficiency tests are unsatisfactory." 4. In an interview 06/13/2024 at 2:00 pm in the conference room the above findings were confirmed.
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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on records reviewed (CMS 209), lack of education documentation, and staff interview, the laboratory failed to ensure that 4 out of 4 testing personnel had documentation of their highest diploma (high school, GED, 50 weeks military training, associate's degree, bachelor's degree, or Doctorate in Biological, Chemical or Physical Science) as listed under 42 CFR Section 493.1423 to qualify as moderate complex testing personnel. Findings included: 1. The laboratory listed 4 testing personnel on the CMS 209 personnel form on the day of survey. 2. No education records were present for review on the day of the survey for 4 of 4 testing personnel (employees, LD, TC). 3. In an interview with testing personnel in the conference /exam room on 06/13/2024 at 2:00 pm the above findings were confirmed.