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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 42D2034788 | (X3) Date Survey Completed 07/22/2021 |
| Name of Provider or Supplier Southernmed Pediatrics (Hillcrest) | Street Address, City, State 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 |
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| D2006 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 7/22/21, based on observing documentation and personnel interview, the laboratory failed to sign the attestation statement of the proficiency testing packet Findings include 1.Observation of the proficiency testing packet for hematology showed that attestation statements for events B for 2021 weren't signed by lab director. 2. During an onsite interview with staff at 12:22pm, staff stated that the lab director had failed to sign the attestation statements.</p> |
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> |

This STANDARD is not met as evidenced by:

Based on a policy and procedure manual review, lab record review and testing personnel interview, it was determined that the lab failed to document acceptable refrigerator readings for 1 of 36 months, reviewed from February 2019 through July 2021 (2020: December) Findings include: 1. A review of the laboratory policy and procedure manual on 07/22/21 revealed that the laboratory refrigerator should operate between 2 to 6 degrees Celsius. 2. A review of the lab temperature log on 07/22/21 revealed that the lab's refrigerator temperatures were below 2 degrees Celsius for the following months: a.December 2021 (1 days)