

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D2141062	<b>(X3) Date Survey Completed</b> 01/10/2020
<b>Name of Provider or Supplier</b> Southern Med Pediatrics Fort Mill	<b>Street Address, City, State</b> 342 Patricia Ln, Suite 105, Fort Mill, SC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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> <p>This STANDARD is not met as evidenced by: During an onsite initial survey on 1/10/2020, based on hematology quality control (QC) package insert review, laboratory refrigerator temperature record review, and staff interview, the laboratory failed to maintain acceptable refrigerator temperatures for 337 days reviewed in 2019 and 7 days in 2020. Findings include: 1. The hematology QC package insert review had a required refrigerator temperature range between 2 and 8 degrees Celsius (or 35 to 46 degrees Fahrenheit). 2. Review of the laboratory's temperature records revealed that refrigerator temperatures were recorded in Fahrenheit and recorded below 35 degrees Fahrenheit for 337 days in 2019 (January 2019 through December 2019) and 7 days in 2020 (January 2 and 3, 2020; January 6 through January 10, 2020). There was no corrective action for the out of range temperatures available for review. 3. Testing personnel confirmed during the exit interview at 12:00 pm that the laboratory had failed to maintain proper refrigerator temperatures.</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

During an onsite initial survey on 1/10/2020, based on temperature recored review and lack of documentation, the laboratory failed to establish and follow written policies and procedures to monitor, assess, and correct problems associated with unacceptable refrigerator temperatures (see D5413).