

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2111530	<b>(X3) Date Survey Completed</b>  10/20/2022
<b>Name of Provider or Supplier</b>  Southern Rapid Care	<b>Street Address, City, State</b>  4332 Orange Beach Blvd, Orange Beach, AL	
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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Hematology calibration records and an interview with Testing Personnel #1, the laboratory failed to ensure calibration material was utilized before the expiration date on one out of three calibrations reviewed from June 2021 to October 2022. The findings include: 1. A review of the Beckman Coulter AcT Diff 2 calibration records revealed a calibration was performed on 10/13/2022, using calibrator lot number 4757, which expired on 9/17/2022. 2. During an interview on 10/20/2022 at 11:00 AM, Testing Personnel #1 confirmed the above findings.</p>
<b>D5437</b>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p>

This STANDARD is not met as evidenced by:  
Based on a review of Hematology calibration records, a review of the Beckman Coulter AcT Diff 2 Operator's Manual, and an interview with Testing Personnel #1, the laboratory failed to follow the manufacturer's instructions to perform quality controls after calibrations, and before running patient samples. This was noted for three out of three calibrations reviewed from 2021-2022. The findings include: 1. A review of Hematology records revealed the Beckman Coulter AcT Diff 2 was calibrated on 11/22/21, 5/20/22, and 10/13/22. However, quality control records revealed no documentation of quality controls performed after the calibrations. 2. A review of the Beckman Coulter AcT Diff 2 Operator's Manual revealed under "Calibration", "...17 Verify calibration by running 4C PLUS cell control...". 3. During an interview on 10/20/2022 at 11:00 AM, Testing Personnel #1 confirmed the above findings.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on a review of the IQCP (Individualized Quality Control Plan) for the iStat, a review of quality control (QC) records, and an interview with Testing Personnel #1, the laboratory failed to ensure two levels of quality control (QC) were performed and documented every 30 days of patient testing as per the IQCP. This was noted four out of sixteen months reviewed from 2021-2022. The findings include: 1. A review of the IQCP for the iStat revealed a QC Plan which specified two levels of QC should be performed and documented for the Chem 8 + cartridge every 30 days of patient testing, and with each new lot number and shipment of reagent cartridges. 2. A review of the iStat Chem 8 + QC records revealed no QC was performed in February 2022, March 2022, August 2022, and October 2022; the patient log revealed 23 patients tests were performed during this time. 3. During an interview on 10/20/2022 at 1:00 PM, the surveyor reviewed and confirmed the above findings with Testing Personnel #1. The surveyor then asked how many patient tests were performed during the above months; Testing Personnel #1 reviewed data in the Electronic Medical Record, and determined 23 patients were performed during the four-month inquiry period.