

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1050198	(X3) Date Survey Completed 01/24/2024
Name of Provider or Supplier Satellite Med, Llc	Street Address, City, State 1120 Sam'S Street, Cookeville, TN	
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
D6022	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's quality assurance (QA) plan, review of monthly quality control (QC) records, lack of corrective action records, and staff interview, the laboratory director failed to ensure the laboratory's QA process was effective in addressing problems identified with monthly QC performance of the hematology testing system for four of eight months reviewed in 2022 and 2023. The findings include: 1. Observation of the laboratory on 01/24/2024 at 8:15 a.m. revealed a Medonic M-Series Hematology Analyzer (SN: 27939) in use for complete blood count (CBC) patient testing. 2. A review of the laboratory's QA plan revealed the following statements in the section "Quality Control- Hematology - Medonic-M": - "At the end of each month, the quality control results are submitted to eCQAP for evaluation and comparison with other laboratories using the same instruments and controls." 3. A random review of eight eCQAP monthly reports for evaluation of Boule Con-Diff QC performance on the Medonic M-Series analyzer (SN: 27939) revealed the following: -The October 2022 Report for lot numbers 22206-31, 22206-32, and 22206-33 contained the "S1" flag for the white blood cell count (WBC) analyte on the high-level control (lot: 22206-33). -The June 2023 Report for lot numbers 22302-31, 22302-32, and 22303-33 contained the "S1" flag for the hemoglobin (HGB) analyte on all three control levels. -The August 2023 Report for lot numbers 22304-31, 22304-32, and 22304-33 contained the "S1" flag for the</p>

hemoglobin (HGB) analyte on the normal level control (lot: 22304-32). -The November 2023 Report for lot numbers 22307-31, 22307-32, and 22307-33 contained the "S1" flag for the hemoglobin (HGB) analyte on the normal level control (lot: 22307-32). -All eCQAP reports defining the "S1" flag to mean results are outside the defined reference limit. 4. There were no documented evaluations or corrective actions conducted by the laboratory for QC results flagged as outside the defined limits on the laboratory's monthly eCQAP reports in 2022 and 2023. 5. An interview with the lead testing person on 01/24/2024 at 2:15 p.m. confirmed the laboratory's quality assurance process failed to address QC issues indicated by the monthly eCQAP reports.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on the observation of the laboratory, review of the laboratory's procedures, and staff interview, the laboratory director failed to review and approve the procedure used for patient complete blood count (CBC) testing in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 01/24/2024 at 8:15 a.m. revealed a Medonic M-Series Hematology Analyzer (SN: 27939) in use for CBC testing. 2. A review of the laboratory's procedure titled "Medonic M Series Hematology Analyzer" revealed a blank space in the section listed for "Lab Director Approval" and "Date." 3. An interview with the lead testing person on 01/24/2024 at 2:15 p.m. confirmed there was no signature by the laboratory director or date indicating the review and approval of the procedure used for patient CBC testing.