

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2206486	(X3) Date Survey Completed 10/25/2022
Name of Provider or Supplier Mid Coast Hospital	Street Address, City, State 123 Medical Center Drive, Brunswick, ME	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the point of care consultant (PC1), the laboratory failed to document the 6 month temperature probe calibration check on the Avox 4000 testing for CO-Oximetry. Findings include: 1. Record review of the laboratory's Avox 4000 maintenance log on 10/25/2022 revealed no probe calibration check to be performed in 2022. 2. Record review of the Avox 4000 manufacturer's instructions on 10/25/2022 revealed the statement: "The calibration of the temperature probe should be checked once every six months". 3. During interview with (PC1) on 10/25/2022 at 9:15 AM, (PC1) confirmed the above findings. 4. The laboratory performs 300 CO-Oximetry tests annually.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p>

This STANDARD is not met as evidenced by:
Based on review of the proficiency testing PT graded results from the American Proficiency Institute (API) and staff interview, the laboratory failed to ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance. Findings include: 1. Record review on 10/25/2022 of the API proficiency testing performance evaluation for 2022, Chemistry Event 1, revealed no performance review documentation. 2. Staff interview on 10/28/2022 at 10:00AM with the point of care consultant confirmed the above findings. 4. The laboratory performs approximately 800 tests annually in the specialty of Chemistry.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the point of care consultant (PC1) the laboratory director (LD) failed to specify, in writing, the responsibilities and duties of each consultant (TC1). Findings include: 1. Record review of the laboratory manual on 10/25/2022 revealed that (TC1) had not been specified in writing as a technical consultant. 2. Record review of the testing personnel competency assessments for the period 2021-2022 on 10/25/2022 revealed (TC1) to be performing testing personnel competencies. 3. Interview with the (PC1) on 10/25/2022 at 9:00am confirmed the above findings. 4. The laboratory performs 800 tests annually in the specialty of Chemistry.