

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0305187	(X3) Date Survey Completed 11/18/2021
Name of Provider or Supplier North Baldwin Infirmary	Street Address, City, State 1815 Hand Avenue, Bay Minette, AL	
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the calibration and calibration verification (C/V) records for the Roche Cobas e411 Chemistry/ Endocrinology analyzers (Serial #66X211 and #66X212), and an interview with the Quality Assurance Coordinator, the laboratory failed to perform C/V's every six months in early 2021, as required by CLIA regulations. The findings include: 1. A review of the records for the two Roche Cobas e411 analyzers revealed reagents were calibrated with less than three calibrators, and</p>

required semi-annual C/V, as per CLIA regulations. 2. A review of 2020-2021 Roche Cobas e411 records revealed C/V's were performed on both analyzer in July 2020 and on 7/24/2021, however there was no documentation of C/V's on either analyzer performed in early 2021. 3. In an interview on 11/18/2021 at 1:35 PM, the Quality Assurance Coordinator explained leadership changes caused the laboratory to miss C/V's due in January 2021. .

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on reviews of personnel files and interviews with the Technical Consultant (also the Laboratory Manager) and Testing Personnel #15 (the Respiratory Therapy [RT] Supervisor), the Technical Consultant failed to perform and document the semi-annual competency evaluation due in early 2020 for one of eight new Respiratory Therapy Testing Personnel (TP) who performed patient Arterial Blood Gas (ABG) testing. The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) revealed TP #11, a moderate-complexity TP who performed ABG testing in the Respiratory Therapy Department. 2. A review of the personnel file for TP #11 revealed GEM Premier 3500 training dated 7/31/2019, and training with an examination on the GEM 5000 dated 11/12/2020. There was no documentation of a semi-annual competency assessment for the GEM Premier 3500 due around January 2020. 3. In an interview with the Technical Consultant (also the Laboratory Manager) on 11/17/2021 at approximately 4:00 PM, the Technical Consultant stated she had recently learned testing in the Respiratory Therapy Department was under the main laboratory's CLIA #; the Technical Consultant was not aware Respiratory Therapy testing personnel evaluations had not been performed as per CLIA standards. 4. During an interview on 11/18/2021 at 10:55 AM, the surveyor reviewed the personnel records with the RT Supervisor who explained the previous RT Supervisor had left in May 2019. The current RT Supervisor stated he had not realized one of his responsibilities was to ensure competency evaluations were performed on Respiratory Therapists who performed ABG testing. .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on reviews of personnel files and interviews with the Technical Consultant (also the Laboratory Manager) and Testing Personnel #15 (the Respiratory Therapy [RT] Supervisor), the Technical Consultant failed to perform and document annual competency assessments due in 2019 for three of three Respiratory Therapy Testing Personnel (TP) who had been performing patient Arterial Blood Gas (ABG) testing since the previous survey on 9/6/2018. The findings include: 1. A review of the Form

CMS-209 (Laboratory Personnel Report) revealed TP #8, #9, and #10, moderate-complexity TP who had performed ABG testing in the Respiratory Therapy Department since the previous surveyor on 9/6/2018. 2. A review of the personnel files for TP #8, #9, and #10 revealed no documentation of competency assessments performed in 2019. 3. In an interview with the Technical Consultant (also the Laboratory Manager) on 11/17/2021 at approximately 4:00 PM, the Technical Consultant stated she had recently learned testing in the Respiratory Therapy Department was under the main laboratory's CLIA #; the Technical Consultant was not aware Respiratory Therapy testing personnel competency assessments were not being performed as per CLIA standards. 4. During an interview on 11/18/2021 at 10:55 AM, the surveyor reviewed the personnel records with the RT Supervisor who explained the previous RT Supervisor had left in May 2019. The current RT Supervisor stated he had not realized one of his responsibilities was to ensure competency assessments were performed on Respiratory Therapists who performed ABG testing. .

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:
Based on reviews of personnel files and an interview with Testing Personnel #15 (the Respiratory Therapy [RT] Supervisor), the laboratory failed to ensure training for three of eleven Respiratory Therapy Testing Personnel (TP) was performed and documented before performing patient Arterial Blood Gas (ABG) testing on the new IL (Instrumentation Laboratory) Gem 5000 analyzer in 2020. The findings include: 1. A review of the validation records for the new IL Gem 5000 ABG analyzer, revealed the Laboratory Director reviewed and approved the validation procedures on 6/10/2020. 2. A review of testing personnel records revealed dates of training on the Gem 5000 ABG analyzer as follows: A) TP #9--11/6/2020 B) TP #10--11/11/2020, and C) TP #11--11/12/2020. 3. During an interview on 11/18/2021 at 10:55 AM, the surveyor reviewed the personnel records with the RT Supervisor who explained the previous RT Supervisor had left in May 2019. The current RT Supervisor stated he had not realized his responsibilities included ensuring the testing personnel had documentation of training on new instruments before performing patient testing. During the exit summation at approximately 4:00 PM on 11/18/2020, the RT Supervisor confirmed the laboratory began using the Gem 5000 for patient testing in June 2020. SURVEYOR ID #32558 Licensure and Certification Surveyor