

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0699949	(X3) Date Survey Completed 07/16/2024
Name of Provider or Supplier Baptist Health Medical Center Nlr Resp Care Dept	Street Address, City, State 3333 Springhill Drive, North Little Rock, AR	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Review of the CMS 209 form, lack of documentation and interviews with laboratory staff, determined the laboratory failed to assess employee competency as directed in personnel requirements. Survey findings follow: A) Review of the CMS 209 form submitted by the laboratory revealed that the laboratory staff member (#2 on the CMS 209 form) was listed as the technical consultant. B) Review of personnel records for laboratory staff member (# 2 on the CMS 209 form) revealed that no competency evaluation for the position of technical consultant was present. B) Upon request, the laboratory was unable to provide documentation of competency determinations for calendar year 2023 or 2024 for the position of technical consultant for the personnel identified above. C) In an interview at 09:45 a.m. on July 16, 2024 the laboratory staff member (# 2 on the form CMS 209) confirmed that competency determinations have not been performed on the personnel designated as technical consultant and that she had served as technical consultant for the full year of 2023 and to date in 2024.</p>
D5413	<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.</p>

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of policy and procedure manuals, manufacturer's instruction, environmental condition logs, and interview with staff, the laboratory failed to follow manufacturer's instructions for operational environment relative humidity for ABL90 FLEX PLUS Radiometer blood gas instrument . Findings follow: A) Review of the ABL 90 FLEX PLUS instrument manual (996-178N, ver 201803N) revealed the operating environment for relative humidity is "20 to 85% ". B) Review of the laboratory manual showed the laboratory's policy is to measure and record humidity every day of operation. C) Review of the laboratory humidity log for the instrument labeled as NLR CCU for the months of January 2023, February 2023, and January 2024 showed 20 of 90 days with no humidity recorded. Review of the laboratory humidity log for the instrument labeled as NLR ER for the months of January 2023, February 2023, and January 2024 showed 4 of 90 days with no humidity recorded and 5 of 90 days with humidity below 20%. D) During an interview on 7/16/2024 at 10:12 am the technical consultant confirmed that there were days where the temperature was below the manufacturer's range with no corrective actions documented. At 11:11 am on 7/16/2024 the technical consultant confirmed that humidity was not always recorded.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

. A review of personnel records of ten testing personnel performing moderately complex laboratory assays, and interviews with laboratory staff, determined the laboratory director failed to give written authorization for ten of ten testing personnel to perform moderately complex procedures without direct supervision. Survey findings follow: A) A review of personnel records of ten randomly selected testing personnel, who have completed training for performing moderately complex procedures, revealed that ten (#2, #9, #11, #13, #15, #17, #19, #21, #23, #25 as listed on the form CMS-209) failed to have the laboratory director's written authorization to perform moderately complex testing without supervision. B) In an interview, at 09:52 a.m. on 7/16/24, laboratory employee (#2 as listed on the form CMS-209) confirmed the lack of written authorizations for the ten personnel identified above and that they performed moderately complex testing for Arterial Blood Gas analysis.