

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0673926	(X3) Date Survey Completed 04/08/2026
Name of Provider or Supplier Baptist Medical Center South Blood Gas Lab	Street Address, City, State 2105 East South Blvd, Montgomery, 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
D0000	An on-site validation survey was conducted on April 08, 2026 with the following standard level deficiencies cited.
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: Based on review of the laboratory's policies and procedures, personnel records, competency assessment documentation and interview with Testing Personnel (TP) #2, according to the Centers for Medicare and Medicaid Services Form 209, the laboratory failed to establish and follow a policy for consultant competency assessment for 3 of 3 Technical Consultants (TCs). Findings Included: 1) Review of the laboratory's policy titled 'Baptist Health Annual and Initial Competency Corrective Action and Reassessment POL3' did not contain policies and procedures regarding consultant competencies. 2) Review of the laboratory's submitted CMS Form 209 listed three TCs for the moderate complexity testing laboratory. 3) The laboratory was asked to provide consultant competencies for the TCs. No such competencies were provided. 4) In an interview at 10:40 AM in the conference room, TC#2 confirmed the laboratory did not have an established policy to perform competency assessments for the consultant roles, and did not have TC competencies on file.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for</p>

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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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:

I. Based on direct observation, manufacturer's instructions, review of laboratory's policies and procedures, temperature records and interview with Testing Personnel (TP) #2, according to the Centers for Medicare and Medicaid Services Form 209, the laboratory failed to define room temperatures in accordance with manufacturer storage requirements for 18 of 18 Radiometer ABL 90 Quality Control (QC) QUALICHECK Ampoules. Findings Included: 1) During a tour of the facility on 4/8/2026 at 3:07 PM, 18 Radiometer ABL QC QUALICHECK Ampoules, Lot Numbers RO236, RO232, RO237, RO248, RO236, RO254 were observed stored on shelves in the 2N Respiratory Room available for use. 2) Review of the manufacturer's instructions titled 'ABL 90 FLEX Operator's Manual' revealed the following on page 84, Section 5. Quality Management, "QC Ampoules must be conditioned before measurement. Store the ampoules for 5 hours at a constant temperature between 18 to 32 degrees Celsius." 3) Review of the laboratory's policy titled 'Baptist Health Respiratory Therapy Blood Gas Lab QCP-17' stated "Performing a Manual QC: 1. QC ampoules must be conditioned before measurement. Store the ampoules for 5 hours at a constant temperature between 18 to 32 degrees Celsius." 4) Review of the laboratory's policy titled 'Baptist Health Respiratory Therapy Blood Gas Lab Relative Humidity, Room, and Refrigerator Temperature & Acceptable Limits' stated the following on page 2 of 4: "B. Room Temperature ... iv. Acceptable room temperatures ranges are 18 to 25 degrees Celsius." 5) Review of the laboratory's acceptable room temperature range revealed 15 to 25 degrees Celsius, exceeding the lower limit of the manufacturer's requirement. 6) In an interview on 4/8/2026 at 3:55 PM, TC#2 confirmed the laboratory's acceptable ranges of room temperature were not defined in accordance with the lower limit of the manufacturer's instructions and their policies.

II. Based on direct observation, review of manufacturer's instructions, laboratory policies and procedures, lack of temperature records, and interview with TC#2, the laboratory failed monitor and document temperatures and humidity in 6 of 6 rooms where the Siemens epoc blood analysis readers were stored. Findings Included: 1) During a tour of the facility on 4/8/2026 at 3:07 PM, the following rooms were seen where the Siemens epoc blood analysis readers were stored, with no temperature and humidity monitoring or documentation: a. Room ED1, Host Number 21232521400476, Reader Serial Number 30474 b. Room ED2, Host Number 20154521400550, Reader Serial Number 52871 c. Room NICU, Host Number 17296521402072, Reader Serial Number 49904 d. Room 5N, Host Number 16221521400065, Reader Serial Number 27550 e. Room Respiratory Float 1, Host Number 16208521400768, Reader Serial Number 28453 f. Room Respiratory Float 2, Host Number 17324521401908, Reader Serial Number 28246 2) Review of the Siemens epoc blood analysis reader manufacturer's instructions titled 'Siemens epoc CLSI Procedure Manual' revealed the following on page 5 of 22: "epoc Test Cards should be stored at room temperature (15 to 30 degrees Celsius), but they may be transported by the distributors at lower temperatures (2 to 30 degrees Celsius), provided transportation times do not exceed eight (8) days ... If ampoules are taken from cool storage, equilibrate the ampoules at Room Temperature (20 to 25 degrees

Celsius) ... ePOC Reader - The Reader can be operated between 15 to 30 degrees Celsius. There is an internal ambient temperature monitor that will disable the Reader function if room temperature falls outside of this range ... The Reader must be used in relative humidity of less than 85% at 30C, non-condensing. The Reader's electronic QC checks leakage current within the Reader to detect compromised performance due to high humidity." 3) Review of the laboratory's policy titled 'Baptist Health Point of Care EPOC-Blood Gas Laboratory PRO 11' stated the following on page 3 of 26: "EPOC Test Cards should be stored at room temperature (15 to 30 degrees Celsius), but they may be transported by the distributors at lower temperatures (2 to 30 degrees Celsius), provided transportation times do not exceed eight (8) days ... If ampoules are taken from cool storage, equilibrate the ampoules at Room Temperature (20 to 25 degrees Celsius) ... ePOC Reader - The Reader can be operated between 15 to 30 degrees Celsius. There is an internal ambient temperature monitor that will disable the Reader function if room temperature falls outside of this range ... The Reader must be used in relative humidity of less than 85% at 30C, non-condensing. The Reader's electronic QC checks leakage current within the Reader to detect compromised performance due to high humidity." 4) Review of the laboratory's policy titled 'Baptist Health Respiratory Therapy Blood Gas Lab Relative Humidity, Room, and Refrigerator Temperature & Acceptable Limits' stated the following on page 2 of 4: B. Room Temperature: i. Once daily the room temperature will be recorded in the Blood Gas Data Management System ... C. Relative Humidity: i. Once daily the relative humidity will be recorded in the Blood Gas Data Management System." 5) The laboratory could not provide documentation of monitoring room temperatures and humidity for the aforementioned rooms where the Siemens epoc readers were stored. 6) In an interview on 4/8/2026 at 3:55 PM, TC#2 confirmed the findings that the rooms where the Siemens epoc readers were stored did not have temperatures and humidity monitored and documented.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 Based on direct observation, review of the laboratory's policies and procedures, instrument verification studies, manufacturer instructions, and interview with the Testing Personnel #2 (TP#2 according to the Centers for Medicare and Medicaid Services Form 209), the laboratory failed to verify whether the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for 11 of 11 Radiometer ABL 90 FLEX blood gas analyzers. Findings Included: 1) During a tour of the facility on 4/08/2026 at 3:07 PM, the following Radiometer ABL 90 FLEX blood gas analyzers were observed in use: a. Location - NICU, Serial Number I393-092R0600N0003 b. Location - OH1, Serial Number I393-092R0600N0013 c. Location - Cath2, Serial Number I393-092R0600N0015 d. Location - NSICU, Serial Number I393-092R0600N0016 e. Location - CVICU, Serial Number I393-092R0600N0020 f. Location - MICU, Serial Number I393-

092R0600N0021 g. Location - CICU, Serial Number I393-092R0600N0022 h. Location - SICU, Serial Number I393-092R0600N0023 i. Location - Cath 1, Serial Number I393-092R0616N0027 j. Location - OH2, Serial Number I393-092R0616N0028 2) Review of the laboratory's policy titled 'Baptist Health New Instrument Replacement Devices & Post-Service Equipment Validation QCP 8' stated all components required of the establishment and verification of instrument performance except verifying whether the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population, as per 493.1253(b)(1)(ii). 3) The laboratory was asked to provide the verification documentation of reference intervals with the laboratory's patient population, signed and approved by the laboratory director. Only documentation for the Siemens epoc could be retrieved. Documentation for the Radiometer ABL 90 FLEX was not provided. 4) Review of the Radiometer ABL 90 FLEX Instructions for Use (IFU) stated the following on Chapter 9, page 159: 5) "About reference ranges: A reference range is the range of test values expected for a healthy population of individuals or some other defined group. Patient results that lie outside the limits will be marked with the symbols ...Reference ranges are not set up by default. Laboratories must establish their own ranges. If reference ranges are set up, patient results that lie outside the limits will be marked with symbols ..." 6) In an interview at 11:30 AM in the conference room, TC#2 confirmed the laboratory did not have documentation of a component of instrument verification for the Radiometer ABL 90 FLEX blood gas analyzers, to assess the appropriateness of manufacturer reference intervals (normal ranges) to the laboratory's patient population.