

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0049978	(X3) Date Survey Completed 04/17/2025
Name of Provider or Supplier Baptist Health Medical Center Heber Springs	Street Address, City, State 1800 Bypass Road, Heber Springs, 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: Based on review of the CMS 209 form, personnel records, and interview conducted on 4/17/2025 it was determined that the competency of the testing personnel was not assessed by the laboratory director on an annual basis. Findings follow: A) Review of Technical Consultant (TC) personnel files on the CMS 209 form, four of four TC personnel revealed that the annual evaluation of the competency of the TC personnel was documented only once dated May 2023 and no other documentation of testing personnel competency was presented. B) Review of a "Delegation of Duties" form signed and dated by the laboratory director on 9/20/23 revealed that the laboratory TC (TC1, TC2, TC3 and TC4 on the form CMS 209) was delegated the duties of technical consultant for "all moderate complexity testing performed in the General Laboratory". C) In an interview on 4/16/2025 at 10:30 a.m. TC3 on the CMS 209 form, no other competency evaluations were present and available. D) Review of Technical Consultant (TC) personnel files on the CMS 209 form, four of four personnel revealed that the annual evaluation of the TC competency was not documented 2024. E) Upon request, the laboratory was unable to provide other competency evaluations of the TC personnel on the CMS 209 form, no 2024 competency evaluation for TC.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test</p>

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 upon a review of new instrument validation documentation for the Allinity Chemistry analyzer and interviews with staff, the laboratory failed to validate the reportable range in use for seven of ten chemistry tests reviewed. Survey findings include: A) The surveyor reviewed new instrument validation documentation for the Allinity chemistry analyzer dated 5/1/24. In a review of the validation documentation for reportable range, it was determined seven chemistry tests out of ten reviewed, failed to have the reportable range in use validated. The following test reportable ranges were not validated: Amylase (AMY) - the maximum reportable range in use is 6554 but it was only validated to 6348, Blood Urea Nitrogen (BUN) - the maximum reportable range in use is 125 but it is only validated to 120, total Cholesterol (CHOL) the maximum reportable range in use is 705 but it is only validated to 676, Carbon Dioxide (CO2) the maximum reportable range in use is 50 but it is only validated to 44, Direct Bilirubin (DBIL) - the maximum reportable range in use is 15 but it is only validated to 13, Glucose (GLU) - the maximum reportable range in use is 800 but it is only validated to 755 - Total Bilirubin (TBIL) the maximum reportable range in use is 25 but it is only validated to 22. B) In an interview at 3:30 p.m. on 4/16/25, laboratory employee #TC3 (as listed on the form CMS-209) stated that the information system manages multiple Allinity analyzers in different related facilities and is set to use the reportable ranges cited by the instrument manufacturer and confirmed the reportable ranges in use by the laboratory had not been fully validated to the maximum reportable range in use.