

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466447	(X3) Date Survey Completed 04/01/2026
Name of Provider or Supplier Baptist Health Medical Center - Hot Spring County	Street Address, City, State 1001 Schneider Drive, Malvern, 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: Through review of the CMS 209 form, documentation of the authorization to perform testing, review of laboratory documentation of competency assessment, lack of documentation, and interview with laboratory staff the laboratory failed to assess testing personnel competency on an annual basis for one of nine testing personnel listed on the CMS 209 form. Findings follow: A) The surveyor reviewed the personnel records of nine of twenty-one testing personnel listed CMS 209 form. B) Review of authorization to perform testing documentation revealed that employee (# 23 on the form CMS 209) was authorized to perform moderately complex arterial blood gas (ABG) testing from January 2023 to the date of the survey. C) Review of competency assessment records revealed that the employee (# 23 on the CMS 209 form) had competency assessments documented on February 2023, September 2023, January 2025, and September 2025 but no competency assessment was documented between September 2023 and January 2025, a period of 15 months. D) Upon request, the laboratory was unable to provide competency assessments for the period of September 2023 through January 2025 for employee (# 23 on form CMS 209). E) In an interview on 3/31/26 at 11:00 a.m., the laboratory staff member (# 2 on form CMS 209) confirmed that the employee had been authorized to perform moderately complex ABG testing between February 2023 and the date of the survey and competency assessments were not performed between September 2023 and January 2025.</p>
D5783	CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based upon review of the laboratory's policy and procedure for "Coagulation Quality Control (QC) PT and PTT", Sysmex CA-600 QC report, the corrective action report for coagulation, patient results, lack of documentation, and interview, the laboratory failed to evaluate patient results back to the last successful Prothrombin Time (PT) QC results when quality control (QC) results were outside of the laboratory's acceptable range on two of three months reviewed. Findings follow: A) Review of the laboratory policy and procedure for quality control of coagulation testing revealed that "both levels of control should be within tolerance limits established for that specific lot number of control before patient testing". B) Review of the Sysmex CA-600 QC report for March 2025 revealed that QC01 lot# 564881 with a laboratory defined acceptable range of 9.7 to 10.9 seconds was reported 11.1 on 3/2/25 at 07:29 p.m., 11.1 on 3/2/25 at 07:50 p.m., before being acceptable on 3/2/25 at 08:03 p.m. hours, and, QC03 lot # 556581 with a laboratory defined acceptable range of 40.8 to 49.2 seconds was reported 49.7 on 3/2/25 at 07:31 p.m., 50.3 on 3/2/25 at 07:48 p.m., before being acceptable on 3/2/25 at 08:03 p.m. C) Review of the Sysmex CA-600 QC report for March 2025 revealed that the last successful QC results occurred on 3/2/25 at 10:00 a.m.. D) Review of the coagulation testing corrective action sheet revealed the corrective action taken to bring QC results into acceptable range was "change innovin and repeat". The replacement of innovin (the PT assay reagent) represented a change in the testing system. E) Review of patient results revealed that one PT test was performed and reported on patient, identified as number 1 on a separate patient identification list on 3/2/25 at 11:14 a.m.. F) Upon request, the laboratory was unable to provide documentation that the patient result identified above had been evaluated. G) Review of the Sysmex CA-600 QC report for November 2025 revealed that QC01 lot# 564881 with a laboratory defined acceptable range of 9.7 to 10.9 seconds was reported 11.0 on 11/15/25 at 06:41 p.m., 11.0 on 11/15/25 at 06:51 p.m., before being acceptable on 11/15/25 at 07:08 p.m. H) Review of the coagulation testing corrective action sheet revealed the corrective action taken to bring QC results into acceptable range was "perform probe rinse". The performance of the maintenance procedure of performing a probe rinse represented a change in the testing system. I) Review of the Sysmex CA-600 QC report for November 2025 revealed that the last successful QC results occurred on 11/15/25 at 10:00 a.m.. J) Review of patient results revealed that two PT tests were performed and reported on patients, identified as numbers 2 and 3 on a separate patient identification list on 11/15/25 between 10:00 a.m. and 06:41 p.m. K) Upon request, the laboratory was unable to provide documentation that the patient results identified above had been evaluated. L) In an interview on 3/31/25 at 11:30 a.m. the laboratory staff members (# 2 on the CMS form 209) confirmed that PT tests were performed and reported on patients identified above and had not been evaluated.