Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0667580	07/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Health Medical Center-Stuttgart	1703 North Buerkle, Stuttgart, 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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Baseds upon a review of the CMS 209 form, records of testing personnel competency assessment, lack of documentation and interview with laboratory staff, the laboratory failed to assess testing personnel competency utilizing the six procedures required by CFR 493.1413(b)(8) for 2 of sixteen testing personnel included on the form CMS 209. Findings follow: A) Review of the authorizations to perform testing signed by the laboratory director, testing personnel (numbers 10 -11 on form CMS 209) are authorized to perform moderately complex testing in chemistry, hematology, coagulation, and urinalysis specialties. B) Review of the competency assessment records for testing personnel (numbers 10 and 11 on the form 209) dated January 2023, January 2024, and January 2025 revealed that the personnel were evaluated as competent to perform patient testing on the Alinity chemistry analyzer, the Sysmex 1000/XN hematology analyzer, the Sysmex CA-600 coagulation analyzer, and the Clinitek Advantus urinalysis analyzers but the competency evaluations did not indicate the procedures used to evaluate the personnel competencies. C) Upon request, the laboratory could not provide documentation that the competencies of testing personnel (numbers 10 and 11 on the form CMS 209) were evaluated using the six procdures required by CFR 493.1413(b)(8). D) In an interview on 7/22/25 at 11:05 a. m., the laboratory staff member (number 2 on the form CMS 209) confirmed that the testing personnel (numbers 10 and 11 on the form CMS 209) performed moderately complex patient testing and the competencies were not evaluated using the six required procedures.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based upon a review of the Dade application sheet for on-board stability for innovin reagent for the Sysmex CA 600 analyzer, observations made during a tour of the laboratory, and interview with a laboratory staff member, the laboratory failed to document the expiration date and time of the innovin reagent used for prothrombin time (PT) testing on the Sysmex CA-600 coagulation analyzer. Findings follow: A) Review of the application sheet for on-board stability of innovin reagent on the Sysmex CA 600 coagulation analyzer revealed an on-board stability of 24 hours. B) During a tour of the laboratory at 08:40 a.m. on 7/24/25, the container of innovin in use on-board the Sysmex CA-600 analyzer was observed, labeled with the word "innovin" on the container, and no other labeling as to date/time placed into use or expiration date/time. C) When asked when the innovin was placed into use, the laboratory staff member (number 1 on the form CMS 209) stated "at 12:00 a.m. on 7 /24/25" and explained the laboratory staff replaces the innovin at midnight with fresh innovin which is placed in a container labeled "innovin". D) When asked if it was possible that the laboratory staff on duty at 12:00 a.m. could possibly forget to change the innovin reagent the laboratory staff member (number 1 on the form CMS 209) confirmed that it was a possibility. E) When asked if there was documentation which would allow laboratory staffing during the day hours to determine if the time/date of the last innovin change, the laboratory staff member (number 1 on the form CMS 209) responded that there was not such documentation available.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based upon the review of the Individualized Quality Control Plans (IQCP) for High Sensitivity Troponin (TNI) performed on the I-Stat instrument, Naturetic Peptide Tests (BNP) on I-Stat instrument, and microbiological assays performed by Polymerase Chain Reaction (PCR) procedures on the Cepheid GeneXpert instrument the laboratory failed to specifiy the external quality control (QC) material employed in the IQCP of three of three plans reviewed. Finding follow: A) Review of the IQCP for

	TNI assays performed on the I-Stat instrument revealed that external QC will be performed monthly and when a new lot number and shipment of reagents are received. The identity of the control material used was not specified. B) Review of the IQCP for BNP assays performed on the I-Stat instrument revealed that external QC will be performed monthly and when a new lot number and shipment of reagents are received. The identity of the control material used was not specified. C) Review of the IQCP for PCR assays performed on the Cepheid GeneXpert instrumentrevealed that external QC will be performed monthly and when a new lot number and shipment of reagents are received. The identity of the control material used was not specified. D) In an interview on 7/24/25 at 11:45 a.m., the laboratory staff member (number 2 on the form CMS 209) confirmed that the IQCP's identified above did not specify the identity of the external control materials used in the QC process.
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 a review of the laboratory's policy for quality control (QC), review of QC results for prothrombin time (PT) assays, documentation of corrective acction, patient test results, lack of documentation, and interviews with laboratory staff members, the laboratory failed to evaluate patient test results performed since the last successful QC performance in one of one occasions when corrective action taken resulted in changes to the testing system. Findings follow: A) Review of the laboratory policy for "Quality Control and Corrective Action" revealed " the 1 2S Westgard rule is implemented. The rule is violated when a control result falls outside of the mean by + /= 2 standard deviations (SD). Violations of the 1 2S rule constitutes a QC failure requiring evaluation and remediation before patient resulting can occur". B) Review of QC for PT assays results in March 2025 revealed that on 3/10/25 level three for Dade Citrol coagulation control lot # 556598 failed greater than 2 SD on seven consective times at 4:22 p.m. with a corrective action of "repeat with same control", at 4:30 p.m with corrective action "repeat with new control", at 4:53 p.m. with corrective action "will perform maintenance and repeat", at 5:02 p.m. with corrective action "add reagent and repeat", at 5:46 p.m. with corrective action "change reagent", at 7:00 p.m. with corrective action "will perform mainteance and repeat", at 7:11 p.m. with corrective action "repeat with same QC", before being acceptable at 7:38 p.m.. The performance of maintenance and change of reagents represent a change in the testing system. C) Review of QC results for PT assays revealed that the last successful QC performance prior to 3/10/25 at 4:22 p.m. was performed on 3/10/25 at 8:09 a.m. D) Review of patient PT results performed on 3/10/25 revealed that patient 33662 had a PT performed and resulted on 3/10/25 at 10:51 a.m., and patient 534958 had a PT performed and resulted at 3:26 p.m. E) Upon request, the laboratory was unable to provide documentation that the PT results identified above had been evaluated. F) In an interview on 7/22/25 at 3:00 p.m., the laboratory staff member (number 2 on the form CMS 209) confirmed that the patients(33662 and 534958) PT results performed on 3/10/25 had not been evaluated.