

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466447	(X3) Date Survey Completed 06/26/2024
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of policy and procedure manuals, observation, and interview showed the laboratory was not following their written policy and procedure. Findings follow: A) Review of the policy and procedure manual titled "Baptist Health-Hot Springs County Policies and Procedures, Department: Laboratory, Subject: Quality Control Program, page 2 of 10", under the heading of General Laboratory Instructions Step 1. Procedure Choice, section d. states, "All procedures will be reviewed at least annually by the Technical Supervisor and the Laboratory Directory." B) Review of the following policies: Baptist Health-Hot Springs County Policies and Procedures, Department: Laboratory, Subject: Quality Control Program, Subject: Criteria for Rejection of Specimens, Subject: Laboratory Bloodborne Pathogen Exposure Plan, Subject: Patient Identification, Subject: Procedure for Reporting Communicable Diseases to the Arkansas Department of Health, and Subject: Procedure for Labeling Specimens for the Clinical Laboratory only had review dates of 6/14/2014 and 8/12/2022. C) In an interview on 06/26/24 at 14:47 p.m. with all the technical consultants (on the CMS 209 form) confirmed that annual reviews were not reviewed at least annually in accordance with Quality Control Program Policy.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Observation made during a tour of the laboratory, review of manufacturer's user manual, review of reagent package insert, review of the "daily maintenance log", lack of documentation and interview with laboratory staff determined that the laboratory failed to document the time that Prothrombin Time (PT) reagents were placed on the coagulation analyzer as required. Findings follow: A) During a tour of the laboratory on 6/26/24 at 09:15 a.m., the surveyor observed an unlabeled bottle of reagent placed in the slot labeled as "innovin" on the CA 600 coagulation analyzer. B) In an interview on 6/26/24 at 09:15 a.m., the laboratory staff member (#10 on page 2 of CMS form 209) confirmed that the bottle contained innovin reagent (lot # 564643 expiration date 2026-01-12) used in PT testing and stated that the reagent is changed "daily". C) When asked if the date and time the reagent was changed is documented, staff member (# 10 on page 2 of CMS form 209) produced a copy of the "Daily Maintenance" log for the CA 600 coagulation analyzer. D) Review of the Daily Maintenance log revealed that no entry specifies a change of innovin reagent, one entry is labeled "check/prepare reagent" which had a check mark corresponding to the date of 6/26/24 but no time documented. E) Review of the manufacturer user's manual for the CA 600 coagulation analyzer and the package insert for innovin reagent both specified that the reagent was stable for a period of 24 hours on the CA 600 coagulation analyzer. F) In an interview on 6/26/24 at 02:45 p.m. the laboratory staff member (#2 on page 2 of CMS 209 form) confirmed that a check mark on the daily maintenance log by a task labeled "check/prepare reagents" is not adequate to document that innovin reagent has not exceeded the time of stability on the CA 600 coagulation analyzer.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Observations made during a tour of the laboratory, review of the laboratory's policy and procedure, and interview with laboratory staff demonstrated that the laboratory had three of three bottles of hematology control available for use after exceeding the date of expiration. Findings follow: A) During a tour of the laboratory on 6/26/24 at 01:20 p.m., three of three opened bottles of XN Check hematology controls, lot # 414211 expiration date 2024-08-04 were observed in the laboratory refrigerator with the date of 6/17 written on the bottles. B) Review of the laboratory's policy and procedure for quality control (QC) for the Sysmex complete blood count (CBC) analyzer stated that the XN Check controls were stable for seven days after opening. C) In an interview on 6/26/24 at 01:20 p.m., the laboratory staff member (# 2 on the CMS form 209) confirmed that the controls identified above had been opened on 6/17/24, had exceeded their date of stability, and were available for use.