

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2256543	(X3) Date Survey Completed 11/09/2022
Name of Provider or Supplier Baptist Health Floyd At Jefferson Ridge	Street Address, City, State 3516 E 10th St, Jeffersonville, IN	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to ensure one of one level 1 control (lot 223810) and one of one level 2 control (Lot 22381402) in use did not exceed the expiration date for one of one Hematology Analyzers (Sysmex XN-550) and one out of four patients (PT#4) reviewed. Findings Included: 1.) During a tour of the laboratory on 11/2/2022 at 9:56 am, revealed an American Biotech Supply (ABS) refrigerator that contained the following controls: a.) Level 1 lot 2238140 was opened on 10/16/2022 and expired on 10/31/2022 b.) level 2 lot 22381402 opened on 10/16/2022 and expired on 10/31/2022 There were no other open controls in the fridge. XN-L controls are used in Sysmex XN-550. 2.) Review of "XN-L Check Hematology Control for Sysmex XN-L Analyzer" revision 11/2018, stated, "Storage and shelf life after first opening ... Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 C after re-capped." 3.) Review of patient records indicated PT#4 was tested for complete blood count (CBC) on 11/1/2022 using the Sysmex XN-550 analyzer when level 1 and level 2 controls were expired. 4.) The annual test volume for Hematology is 8,652. 5.) During an interview on 11/2/2022 at 9:57 am, SP#2 (Clinical Administrative Manager) confirmed the controls level 1 and level 2 had expired on 10/31/2022</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p>

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 observation, record review and interview, the laboratory failed to ensure the documentation was completed for the certificate of carryover verification and certificate of reportable ranges for one of one Hematology analyzers (Sysmex XN-550) in use for patient testing since August 15, 2022, and for four of four patients (PT#1-PT#4) reviewed. Findings Included: 1.) During a laboratory tour on 11/2/2022 at 9:56 am, revealed a Sysmex XN-550 used in Hematology testing. 2.) Review of "XN-Series XN-L Method Verification Manual" revision 2, December 2016 states "Section 3 Method Verification Protocols ... The CAS is to verify that the analyzer meets manufacture's performance claims by performing the following studies: Reportable Range Carryover" 3.) Review of the "Certificate of Reportable Range Verification" revealed the wrong instrument model number "XN-450" was listed and the name on the laboratory was incorrect. The laboratory director signed the document on 7/12/2022. 4.) Review of the "Certificate of Carryover Verification" revealed the wrong instrument model number "XN-450" was listed and the name of the laboratory was incorrect. The laboratory director signed the document on 7/12/2022. 5.) Review of patient records indicated the follow patients were tested for complete blood count (CBC) using the Sysmex XN-550 analyzer: a. PT#1 was tested for CBC on 8/22/2022. b. PT#2 was tested for CBC on 9/6/2022. c. PT#3 was tested for CBC on 10/8/2022. d. PT#4 was tested for CBC on 11/1/2022. 6.) The annual test volume for Hematology is 8,652. 7.) During an interview on 11/2/2022 at 1:45 PM, SP#2 confirmed the validation paperwork was not complete for XN-550