

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469307	(X3) Date Survey Completed 07/31/2023
Name of Provider or Supplier Mercy Hospital Booneville	Street Address, City, State 880 West Main Street, Booneville, 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
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based pm a review of manufacturer's instructions titled, "Lot Conversion Protocol", review of the proficiency test "Performance Review and Corrective Action Documentation" for the third hematology and coagulation proficiency event in 2022, observations made during a tour of the laboratory, a review of the Lab Results Report File for the Stago Satellite coagulation analyzer, and interviews of laboratory personnel, the laboratory failed to meet requirements specified in 493.1252(a). D5411 - The laboratory failed to follow manufacturer's instructions for conversion to new lots of Neoplastine Protime Reagent. D5791 - The laboratory failed to correct problems identified in analytic systems</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions titled, "Lot Conversion Protocol", review of the proficiency test "Performance Review and Corrective Action</p>

Documentation" for the third hematology and coagulation proficiency event in 2022, observations made during a tour of the laboratory, a review of the Lab Results Report File for the Stago Satellite coagulation analyzer, and interviews of laboratory personnel, it was determined the laboratory failed to follow manufacturer's instructions for conversion to new lots of Neoplastine Protime Reagent. Survey findings include: A. Manufacturer's instructions titled, "Lot Conversion Studies" stated, "Lot conversion studies should be performed prior to starting a new lot number of Protime and/or APTT reagent. Lot Conversion Studies are the responsibility of the customer." It further states, "4.1. Prothrombin Time...4.1.2 Enter the correct ISI for the new lot of reagent...4.2. Establishing a New Geometric Mean...4.2.1 A new Geometric mean must be established with the following sample set: Run 20 screened normal samples with the New PT reagent." B. In an interview, at 8:55 a.m. on 7/20/2023, Testing Personnel, listed as #3 on the CMS-209, confirmed that he is the primary user of the Stago Satellite coagulation analyzer. He stated that the previous lab manager would bring a form to fill out when there was a new lot of Neoplastine (used for Protime testing) but he didn't know what the information was used for. He further stated that this hasn't happened since the manager left and he doesn't know when a lot change happens since it may happen when he is not at the laboratory. C. During a review of proficiency test records the surveyor observed the following: 2022 Hematology / Coagulation 3rd Event INR scored 0%. Corrective Action documentation dated 1/11/2023 stated that it was determined that the geo-mean and ISI were both incorrect (the ISI and normal patient geometric mean are used to calculate the reported INR results) . D. During a tour of the laboratory, on 7/20/2023 at 9:47 a.m. the surveyor observed the current lot of Neoplastine in use for Protime INR was Lot #260900. The package insert stated the ISI for this Lot of reagent is 1.32. The surveyor observed an ISI of 1.29 and a geometric mean of 13.2 programmed into the Stago Satellite instrument used for Protime INR tests. E. In an interview at 10:05 a.m. on 7/20/2023, Employee #3 (as listed on the form CMS-209) confirmed the ISI in the Stago Satellite instrument was not the correct one for the lot of Neoplastine in use. No documentation of the establishment of a geometric mean or use of correct ISI with the current lot number of Neoplastine was provided. The previous lot of Neoplastine expired 9/30/2022. F. The surveyor reviewed a document titled "Lab Results", which lists all tests performed on the Stago Satellite since the previous lot of Neoplastine expired on 9/30/2022. The document revealed 635 Protime INR results were reported since the previous lot of Neoplastine expired and during the time that there is no evidence of acceptable ISI or normal geometric mean in use to calculate the INR. Included in the patients tested were the following sample results: Specimen #22BN-292O0003 Protime reported on 10/19/2022 at 1:05 p.m. INR 1.0 (flagged as normal) time 17.6 seconds (flagged as high); Specimen #22BN-307O0002 Protime reported on 11/3/2022 at 3:52 a.m. INR 1.2 (flagged as normal) time 20.9 seconds (flagged as high); Specimen #22BN-329O0004 Protime reported on 11/25/2022 at 8:54 p.m. INR 0.9 (flagged as normal) time 16.3 seconds (flagged as high); Specimen #22BN-338O0001 Protime reported on 12/4/2022 6:41 a.m. INR 1.5 (flagged as normal) time 24.6 seconds (flagged as high) and repeated on 12/5/2022 at 6:24 a.m. INR 1.8 (flagged as normal) time 27.6 (flagged as high); and Specimen #22BN-341O0001 Protime reported on 12/7/2022 at 10:17 a.m. INR 0.8 (flagged as low) time 15.3 seconds (flagged as high). As a result of the laboratory's failure to follow manufacturer's instructions for the establishment of a new geometric mean and to update the ISI, the laboratory did not provide accurate and reliable PT/INR patient results. This represented an immediate jeopardy to patients who had INR results reported during the use of the new lot (#260900) of Neoplastine from 9/30/2022 through the date of the survey (7/20/2023).

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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of chemistry quality control for December 2022, March and May of 2023, a review of quality control policies and procedures, and through interviews with laboratory staff, it revealed the laboratory set quality control acceptable ranges, for glucose and albumin, that did not detect immediate errors due to test system failures. Survey findings include: A. A review of the quality control policies for quantitative tests revealed the policy stated that the laboratory will run 20 data points and establish in-house mean and standard deviation. B. The surveyor reviewed two levels of quality control for fifteen different analytes tested using the Cobas c 311 chemistry analyzer. Two of fifteen analytes reviewed included quality control ranges that did not detect immediate errors. In three of three months reviewed (December 2022, March 2023, and May 2023), Glucose Level BR1 (lot 92941) target mean was 86 and the 2 SD (standard deviation) acceptable range was +/-48 (38 to 134). In three of three months reviewed (December 2022, March 2023, and May 2023), Albumin Level BR2 (lot 92942) target mean was 4.2 and the 2 SD acceptable range was +/- 4.7 (-0.5 to 8.9). C. In an interview on 7/19/2023 at 2:23 p.m. laboratory general supervisor/testing person listed as #2 on the form CMS-209 confirmed the quality control ranges for Glucose and Albumin were set too wide and stated that the laboratory didn't have documentation to determine the origin of the ranges.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of proficiency test documentation, observations made during a tour of the laboratory, and interviews with laboratory staff, the laboratory failed to correct problems identified in analytic systems. Surveyor findings include: A. During a review of proficiency test records the surveyor observed the following: 2022 Hematology / Coagulation 3rd Event INR scored 0%. Corrective Action documentation dated 1/11/2023 stated that it was determined that the geo-mean and ISI were both incorrect (the ISI and normal patient geometric mean are used to calculate the reported INR results). The corrective action on the form stated, "Correct

results/settings for Geo mean and ISI were put in the co-ag". B. During a tour of the laboratory, on 7/20/2023 at 9:47 a.m. the surveyor observed the current lot of Neoplastine in use for Protime INR was Lot #260900. The package insert stated the ISI for this Lot of reagent is 1.32. The surveyor observed an ISI of 1.29 and a geometric mean of 13.2 programmed into the Stago Satellite instrument used for Protime INR tests. C. In an interview at 10:05 a.m. on 7/20/2023, Testing Personnel, listed as #3 on the form CMS-209, confirmed the ISI in the Stago Satellite instrument was not the correct one for the lot of Neoplastine in use. He further confirmed there is no documentation that the correct ISI and geometric mean have been in use at any time since starting the current lot of Neoplastine. The previous lot of Neoplastine expired 9/30/2022.