

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469307	(X3) Date Survey Completed 06/18/2021
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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the policy and procedure manual, quality control(QC) data for 2020 and 2021, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to monitor the accuracy and precision of the quality control process and failed to monitor over time the accuracy and precision of test performance. As evidenced by: A. Through a review of the policy and procedure manual it was determined the laboratory failed to have a policy to monitor shifts and trends for the evaluation of accuracy and precision over time to meet the laboratory's established criteria for the Cobias E 411 Chemistry analyzer. B. A review of Levy Jennings charts for August 2020 (one of three months reviewed) revealed: Level I Control Lot #00381162, Thyroid Stimulating Hormone (TSH) results were below the assayed mean of 1.27 (22 points): Calcium (CA) results were above the assayed mean of 8.68 (35 points). Level II Control Lot #00381165, TSH results were above the assayed mean of 3.31(14 points) and below the mean (16 points): CA results were above the assayed mean of 12.41 (30 points) and Vancomycin results were below the assayed mean of 6.68 (33 points). C. A review of Levy Jennings charts for January</p>

2021 (two of three months reviewed) revealed Level I Control Lot #00381162, TSH results were below the assayed mean of 1.26 (22 points): Alanine Aminotransferase (ATL) results were below the assayed mean of 25.0 (32 points): Phosphorus results were above the assayed mean of 6.96 (31 points) and CA results were below the assayed mean of 8.62 (33 points): Glucose (GLU) results were below the assayed mean of 79.7 (30 points): A review of Level II Control Lot #56932 Alkaline Phosphatase (ALP) results were above the assayed mean of 335.2 (26 points): Valporic Acid results were below the assayed mean of 142.4 (35 points): Calcium results were above the assayed mean of 12.5 (33 points) and GLU results were below the assayed mean of 273.8 (30 points): A review of Cardiac Level I Control Lot #00482370 revealed PRO-BNP results showed a shift with 23 points above the mean: the assayed mean of 368.8 (23 points). D. A review of Levy Jennings Charts for April 2021 (three of three months reviewed) revealed: Level 1 Control Lot #56931, Amylase results were above the assayed mean of 84.4 (21 points): A review of Cardiac Control Level I revealed Troponin results were above the assayed mean of 23.4 (29 points). E. There was no documentation that the laboratory had identified the shifts or trends in test performance or any actions performed to address the shifts or trends. F. In an interview on 6/17/2021 at 10:00 a.m., laboratory personnel #8 (as listed on form CMS-209) confirmed the laboratory did not evaluate the accuracy and precision over time to meet established criteria of acceptability.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
. Through review of the CMS form 209, personnel records, lack of documentation, and interview with staff, it was determined that the technical consultant failed to document personnel competency on an annual basis for the general supervisor. Survey findings follow: A. A review of personnel records for one of eight testing personnel revealed that the technical consultant failed to evaluate the competency for the general supervisor (as listed on form CMS 209) for 2020 and 2021. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 6/16/2021 at 10:30 a.m., laboratory personnel #8 confirmed that competency evaluations had not been performed on her duties as general supervisor.