

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469307	(X3) Date Survey Completed 11/29/2018
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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Through a review of May, August, and October 2018 coagulation quality control and patient results on instrument test strips from the IL ACL 7000 coagulation instrument, and interviews with laboratory staff, it was determined that on one of three occasions when quality control was unacceptable, the laboratory reported patients before acceptable results were obtained for the control . Survey findings follow: A. During a review of Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) quality control for May, August, and October 2018, it was revealed that on 8/19/2018 at 3:24 a.m. PT level 3 was reported as 30.5 seconds with an acceptable range of 21.5 to 30.1 seconds. PT level 3 control was not documented again until 9:39 a.m. on 8/19/2018 when the result was documented as 29.1. B. Instrument test strips from 8/19/2018 on the IL ACL 7000 coagulation instrument include PT results for Patient #31082510 tested at 3:27 a.m. and Patient #31081792 tested at 8:06 a.m. before the quality control was acceptable at 9:39 on 8/19/2018. C. In an interview at 2:19 p.m. on 11/29 /2018, laboratory employee #6 (as listed on the form CMS-209) confirmed that patient PT results were reported before acceptable quality control results were obtained on 8 /19/2018.</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

. Through a review of the new instrument validation documentation dated 5/2/2018 for the Cobas e411 Chemistry Analyzer and validation documentation dated 5/2/2018 for the Cobas c311 Immunochemistry Analyzer , lack of documentation, as well as interviews with staff, it was determined the Laboratory failed to have the director approve validation procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics as evidenced by: A. A review of the validation documentation for the Cobas e411 Chemistry Analyzer and for the Cobas c311 Immunochemistry Analyzer dated 5/2/2018, revealed the validation procedures were not approved and signed by the Laboratory Director. B. In an interview on 10/29/2018 at 2:19 p.m., laboratory employee #6 (as listed on CMS form 209) confirmed the validation procedures for the for the Cobas e411 and Cobas c311 were not approved or signed by the Laboratory Director.

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 a review of personnel records for nine testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, it was determined the technical supervisor failed to evaluate high complexity testing personnel at least annually. Survey findings follow: A. Personnel records for three of nine laboratory testing personnel (#1, #2, and #3 as listed on the form CMS-209) failed to include annual competency documentation. The personnel records for employees #1, #2, and #3 failed to include documentation of annual competency assessments performed in 2017. B. In an interview at 1:18 p.m. on 11/28/2018, the laboratory general supervisor confirmed the lack of annual competency assessments in 2017 for employees #1, #2, and #3 .