

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0467710	<b>(X3) Date Survey Completed</b> 07/20/2022
<b>Name of Provider or Supplier</b> Family Medicine Assoc Of Blytheville	<b>Street Address, City, State</b> 1521 N Tenth Suite C, Blytheville, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by:                      . Through a review of package instruction for Roche Coaguchek, laboratory patient logs, patient medical records, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to follow manufacturer's instructions when performing the Coaguchek test system for evaluating Prothrombin Test (PT) and International Normalized Ratio (INR). Survey Findings Follow: A. A review of Roche Coaguchek package insert revealed the purpose of the test system "The purpose of Coaguchek test system is intended for use by professional healthcare providers for quantitative Prothrombin Time (PT) Testing for monitoring Warfarin therapy." B. A review of Coaguchek patient logs from November 2021- March 2022 August 2019 (5 of 5 months) revealed patient #128297, patient #134549, patient #136025, patient #127262, patient #125638, patient #116424, patient #127535, patient #137810, patient #124531 and patient #131985 (10 of 15 patients reviewed) had PT/INR test performed on Roche Coaguchek. C. A review of medical records for the patients listed above revealed these patients had the PT/INR test performed on the Roche Coaguchek but were not on Warfarin Therapy. D. In an interview on 7/20/2022 at 1500, laboratory personnel #2 (as listed on form CMS-209) confirmed the PT/INR was performed on the patients mentioned above and they were not on Warfarin Therapy.</p>
<b>D5441</b>	<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</p>

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:

. Through a review of the laboratory's policy and procedure manual, quality control (QC) data for 2022, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to have a policy for shifts and trends to monitor the accuracy and precision of the quality control process. Survey Findings Follow: A. A review of the policy and procedure manual revealed the laboratory failed to have a policy to monitor shifts and trends for the evaluation of accuracy and precision over time to meet established quality control criteria. B. A review of Levy Jennings charts for April (one of three months reviewed) 2022 revealed: Performance Verifier (PV) Level 1 Control Lot #Y8558, Blood Urea Nitrogen (BUN) results were below the assayed mean of (20.2): Glucose results were below the assayed mean of (87.5) and Creatinine results were below the assayed mean of (1.04). C. A review of Levy Jennings Charts for March 2022 revealed: PV Level 2 Lot #F9070, Potassium results were below the assayed mean of 5.49. Creatinine, Total Bilirubin and Phosphorus results were all below the assayed mean. D. The surveyor requested a policy or procedure to monitor shifts and trends. None was provided. E. In an interview on 7/20 /2022 at 14:30 PM Laboratory testing personnel #2 (as listed on form CMS 209) confirmed the laboratory failed to have a written procedure to monitor shifts or trends.