

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0465492	(X3) Date Survey Completed 01/03/2018
Name of Provider or Supplier Baptist Health Ouachita Valley Family Clinic	Street Address, City, State 353 Cash Road, Camden, 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
D0000	. This is the CLIA recertification survey of the Laboratory conducted on 01/02/2018. At the time of recertification survey, the Laboratory was not in compliance with the following conditions: 42 CFR 493.1215: Hematology 42 CFR 493.1403: Moderate Complexity Laboratory Director
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: . Through a review of Laboratory policy and procedure manual, patient medical records, manufacturer's instructions, Coagulation lot change studies, lack of documentation as well as interviews with staff, it was determined the Laboratory failed to meet the requirements for Hematology. As evidenced by: 5411: The laboratory failed to perform Coagulation Rollover studies when converting to new lot of Innovin reagent.</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:</p>

. Through a review of manufacturer ' s instructions (package inserts), Coagulation reagent lot change studies, lack of documentation, procedure manual and interviews with laboratory staff , it was determined the laboratory failed to follow manufacturer's instructions for changing lot numbers of coagulation reagent and establishing normal patient mean (MNPT) for the calculation of INR results. As evidenced by: A. The laboratory uses the CA-600 Coagulation instrument for performing Prothrombin Time (PT) coagulation tests and reporting INR (International Normalized Ratio). B. Through a review of the Siemens Innovin (package inserts): The manufacturer states when converting to new lots of reagents for hemostasis analyzers. These procedures should be followed before new lots of reagents are put into use: a Normal Range Study b. 20 Normal Individuals c. 10 males; 10 females d. Fresh samples preferred, frozen samples may be used if prepared and thawed per CLSI (NCCLS) guidelines for platelet poor plasma. e. Medication History: no aspirin, hormones, herbal supplements. f. 20 is minimum requirement for statistical validity. g. Assay samples on current and new lot numbers reagents simultaneously or within 10 minutes of each other. h. Calculate mean and 2 SD range. i. Mean Normal Prothrombin Time (MNPT) for INR calculation should be geometric mean. CLSI H54-A recommends using geometric mean for determining MNPT. C. The surveyor requested documentation of the lot change studies for the current lot number of Innovin (#539387 with an ISI value of 1.02) reagent which was put in use on 05/8/2017. No documentation was provided. D. A review of the laboratory procedure manual revealed: the laboratory did not have a policy or procedure for Normal Range Study or Lot Change studies, nor did the laboratory have a policy or procedure for calculating MNPT. E. A review of patient medical records revealed the following patients had PT/INR results using Innovin lot # 539387: In May 2017, (36 patients): patient #00094917; patient #00212841; patient #02065800; patient #00485723; patient #00013938; patient #02151028; patient #0284155; patient #00214949; patient #02143654; patient #00105550; patient #022205668; patient #02218724; patient #00286018; patient #00348883; patient #02139763; patient #02221195; patient #00717632; patient #00595182; patient #006929004; patient #00434121; patient # 02056779; patient #00735984; patient #00702127; patient #02223350; patient #00172339; patient #000422157; patient #00784111; patient #02065800; patient #02086435; patient #02056779; patient #00147392; patient #02206677; patient #00434299 and patient #00128162: In August 2017, (17 patients); patient #00214949; patient #00743298; patient #02071335; patient #02206677; patient #02139763; patient #00230264; patient #02288930; patient #00038485; patient #00743298; patient #02205668; 02096471; patient #02368263; patient #02218724; patient #00370273; patient #02226306; patient #00105550 and patient #02139763: In November, (15 patients): patient #00172339; patient #00973325; patient #02226306; patient #02139763; patient #02368263; patient #00212841; patient #00038485; patient # 01074854; patient #02368263; patient #00284222; patient #00964133; patient #00838511; patient #00163283; patient 302067857 and patient #02057025. F. In an Interview on 1 /3/2018 at 1030, laboratory employee #1 (as listed on form CMS 209) confirmed the laboratory had not performed Lot Change studies for the current lot of Innovin reagent.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for

example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Through a review of Streck Erythrocyte Sedimentation Rate (ESR) Chex package inserts, ESR quality control, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to establish the criteria for acceptability of ESR assay. As evidenced by: A. A review of package insert for ESR-CHEX for automated Sedimentation Rate states: "The assay values are derived from replicate analysis on both automated and manual methods. Upon receipt of a new control lot, it is recommended that an individual laboratory establish its own mean and limits. However, the control means established by the laboratory should fall within the Expected range specified for the control." B. In a review of ESR quality control, it was determined the mean and acceptable range in three of three months (July, September and December 2017) reviewed matched the expected range as listed on the ESR-Chex package insert. C. The surveyor requested documentation of established ranges for ESR quality controls. None was provided. D. In an interview on 1/03/2018 at 10:00, laboratory employee #1 (as listed on CMS-209) confirmed that the laboratory has not established their own mean and range for ESR quality controls. The laboratory uses the manufactures ranges for the ESR assay.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

. Through a review of quality assurance manual, policy and procedure, lack of documentation, as well as interviews with staff, it was determined the Laboratory Director failed to provide overall management and direction as cited at: 6014: the Laboratory Director failed to ensure that laboratory personnel are performing the test methods as require for accurate and reliable results.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

. Through review of manufacturer's reagent package inserts, lack of documented, determination of mean normal patient Prothrombin Time, as well as interview, it was determined the Laboratory Director failed to ensure Coagulation testing was performed as required for accurate and reliable results as cited at: D5411- The laboratory failed to follow manufacturer's instructions for changing lot numbers of coagulation reagent