Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0642313	07/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Izard Regional Hospital	61 Grasse Street, Calico Rock, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Through a review of the new instrument validation documentation for the Opti CCA TS 2 blood gas analyzer, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to verify the normal range of the new test system. Survey findings follow: A. The laboratory documented validation of a new Opti CCA TS 2 blood gas analyzer. The validation documentation was signed by the laboratory director on 3/18/2021. B. A review of the Opti CCA TS 2 new instrument validation data revealed the laboratory failed to verify the normal range for the blood gas tests. C. In an interview at 1:22 p.m. on 7/21/2021, laboratory employee #3 (as listed on the form CMS-209) confirmed the laboratory failed to validate the new instrument normal range for blood gases.
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 the HORIBA Minotrol-16 Hematology Control assay sheets and instructions for use, a review of the documented establishment of mean and range for hematology controls, and interviews with laboratory staff, it was determined the laboratory failed to establish the statistical parameters for acceptable quality control. Survey findings include: A. The HORIBA Minotrol-16 Hematology Control instructions for use state, "Upon receipt of a new lot of hematology control, each laboratory should establish its own mean value and range." B. Through a review of the HORIBA Minotrol-16 Hematology Control assay sheets for Lot # MX429 (put in use 5/5/2021) and the laboratory's established ranges for hematology controls, it was determined the established ranges were the same values as the assay sheet ranges (not established by the laboratory). Examples are as follows: Low WBC package insert range 0.4 (established lower/upper limits 2.0 +/-0.4); Low Hemoglobin package insert range 0.4 (established lower/upper limits 6 +/- 0.4); Low Platelet package insert range 20 (established lower/upper limits 69.5 +/- 20); Normal WBC package insert range 0.8 (established lower/upper limits 7.8 +/- 0.8); Normal Hemoglobin package insert range 0.6 (established lower/upper limits 13.4 +/- 0.6); Normal Platelet package insert range 40 (established lower/upper limits 250.7 +/- 40); High WBC package insert range 1.6 (established lower/upper limits 20.3 +/- 1.6); and High Hemoglobin package insert range 0.7 (established lower/upper limits 18.2 +/- 0.7). C. In an interview at 10: 06 on 7/21/2021, laboratory employee #3 confirmed the laboratory calculates a target mean for new lots of hematology controls but uses the package insert range as it's acceptable range limits instead of calculating its acceptable range based on statistical parameters.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through a review of the laboratory policy and procedure manual, a review of the operators manual for the Hemochron Signature Elite coagulation analyzer, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform quality control each 8 hours of testing for D-dimer, and the laboratory failed to document two levels of control each 8 hours for Protime and PTT testing. Survey findings include: 1. The laboratory failed to perform quality control each 8 hours of testing for D-dimer. A. A review of the laboratory policies and procedures revealed the written policy for D-dimer states that quality control will be

	performed every 30 days. B. The laboratory had no documentation of D-dimer quality control every 8 hours of testing. C. In an interview, at 1:53 p.m. on 7/20/2021, laboratory employee #3 (as listed on the form CMS-209) stated the D-dimer quality control is performed monthly and she confirmed the laboratory did not have an IQCP for D-dimer. 2. The laboratory failed to document two levels of control each 8 hours of testing for Protime and PTT. A. The IQCP for Protime and PTT, using the Hemochron Signature Elite, states that liquid controls are run once per month or whenever a new lot of cuvettes is opened. It further stated that two levels of electronic quality control will be performed every 8 hours. B. At 9:00 a.m. on 7/21/2021, the surveyor requested electronic quality control documentation. Laboratory employee #3 (as listed on the form CMS-209) stated that the electronic quality control was not printed or saved into the laboratory information system. She further stated that there may be a way to retrieve the quality control data from the instrument. C. A review of the Hemochron Signature Elite operator's manual revealed that the instrument will only hold 600 results. (The laboratory performs 2 levels of electronic quality control on two different tests every 8 hours which would add up to 600 results in 50 days) D. In the interview at 9:00 a.m. on 7/21/2021, laboratory employee #3 confirmed that the instrument would not store two years of quality control data.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . Through a review of Quality Control (QC) documentation for May 2021 and interviews with laboratory staff, it was determined the laboratory failed to document all corrective actions taken when results of control material failed to meet established criteria for acceptability. Survey findings follow: A. A review of QC documentation for May 2021 (one of three months reviewed) revealed on 05/11/2021 Level 3 BUN control was run six times before the result was acceptable (as documented on the instrument printer tapes). Although the Levey-Jennings quality control graph only shows two results (75 and 74) and a note "repeat ok", the instrument printouts included 75, 77.3, 75.9, 75.6, 75.1, and 74.2. There were no documented corrective actions taken to bring the controls into the acceptable range. B. In an interview at 14: 00 on 06/07/2021 laboratory employee #1 (as listed on the form CMS-209) confirmed there were no documented corrective actions for the quality control failures.